IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-A-TARA ROHE

CIV-2022-485-13

UNDER THE	Judicial Review Procedure Act 2016
IN THE MATTER OF	an application for judicial review of a decision made under the Medicines Act 1981
BETWEEN	MKD and others
	Applicants
AND	MINISTER OF HEALTH
	First Respondent
AND	GROUP MANAGER OF THE NEW ZEALAND MEDICAL DEVICES SAFETY AUTHORITY (MEDSAFE)
	Second Respondent
AND	MINISTER FOR COVID-19 RESPONSE
	Third Respondent

AFFIDAVIT OF PETER BRUCE MCINTYRE

10 June 2022

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I, Peter Bruce McIntyre, of Dunedin, Medical Practitioner, swear:

INTRODUCTION

1. My full name is Peter Bruce McIntyre. I am qualified as a Paediatrician (FRACP) and Public Health Physician (FAFPHM) and have current full registration with the Medical Council of New Zealand and the Australian Health Practitioners Regulatory Agency. I am a Professor in Paediatrics at the University of Otago (Department of Women's and Children's Health) and the University of Sydney (Discipline of Child and Adolescent Health).

Qualifications and experience

2. My qualifications are Doctor of Medical Science (DMedSc), Doctor of Philosophy (PhD), Fellow of the Royal Australasian College of Physicians (FRACP), and Fellow of the Australian Faculty of Public Health Medicine (FAFPHM). A copy of my curriculum vitae is annexed to this report (attached as exhibit **PMB -1**).

3. My specialised areas of research interest and publications in peer-reviewed journals are primarily in four areas: the epidemiology of vaccine-preventable diseases, clinical trials of vaccines and the assessment of vaccine effectiveness and safety. I am the author of more than 400 peer-reviewed papers in these areas and based on 66 of these papers, was awarded the degree of DMedSc by the University of Sydney in 2021 after endorsement by external examiners. Based on my publication record, I am ranked in the top 0.1% of experts in immunisation in the world by the independent organisation Expertscape.

4. I have predominantly worked in immunisation for 25 years - since 1997. I was Director of the National Centre for Immunisation Research and Surveillance of Vaccine-Preventable Diseases (**NCIRS**) in Australia from 2004, together with membership of the Communicable Diseases Network of Australia and the Australian Technical Advisory Group on Immunisation, before moving to New Zealand at the end of 2017. I continue to be a Senior Professorial Fellow at NCIRS and have been a Professor in the Discipline of Adolescent and Child Health of the University of Sydney since 2004. From 2019, I have been a Professor in

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the Department of Women's and Children's Health at the University of Otago.

5. I am a current member of the World Health Organisation's (**WHO**) peak global vaccine policy advisory group, the Strategic Advisory Group of Experts (**SAGE**). I was appointed to SAGE in 2019 and in 2021 to a second term 2022 to 2024. Since the end of 2020, SAGE has met in 5 ordinary and more than 10 extraordinary sessions to consider WHO endorsement of COVID-19 vaccines following multiple preparatory meetings. I was the first author, with my 14 other colleagues on SAGE, of a global commentary on COVID-19 vaccine policy published in the Lancet in December 2021.[1]

6. In 2021 I was appointed a member of the New Zealand advisory committee on COVID-19 vaccines, the COVID-19 Vaccine Technical Advisory Group (**CV-TAG**). In that capacity, I have contributed to advice that has helped to inform government decision-making regarding COVID-19 vaccines. In particular, in late 2021 I was involved in CV-TAG's advice to Dr Ashley Bloomfield regarding Pfizer's paediatric COVID-19 vaccine that is the subject of these proceedings. I understand that Dr Ian Town, the Ministry of Health's Chief Science Advisor, has given evidence regarding the content of that advice.

7. My long experience in the formulation and endorsement of policy recommendations for vaccines, and pivotal role in development and evaluation of evidence to inform these recommendations, gives me the breadth and depth of knowledge to answer the questions set out below which are of a type that has been recurrent throughout my professional career. My appointment to expert advisory groups in Australia, New Zealand and globally speaks to the endorsement and recognition of my expertise and professional standing by my peers.

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[1] McIntyre PB, Aggarwal R, Jani I COVID-19 vaccine strategies must focus on severe disease and global equity. Lancet. 2021 Dec 16: S0140-6736(21)02835-X. doi: 10.1016/S0140-6736(21)02835-X.

Expert evidence

8. Pursuant to Schedule 4(3) of the High Court Rules 2016, I acknowledge that I have read the code of conduct for expert witnesses and agree to comply with it. I confirm that the statements made in this evidence are within my area of expertise (unless I state otherwise).

Scope of evidence

9. I have been asked to provide my expert opinion on the applicants' claim that the likely therapeutic benefits of Pfizer Inc's (**Pfizer**) COVID-19 vaccine for children aged 5 to 11 years old (**paediatric vaccine**) do not outweigh the risks of the use of the paediatric vaccine injuriously affecting the health of children aged 5 to 11. I will refer both to evidence relied upon at the time CV-TAG recommended the paediatric vaccine being made available to all 5 to 11 year olds and evidence which has since become available following real world use of the vaccine in this age group.

10. In my evidence I discuss the three primary considerations for evaluating the strength of evidence to support vaccine recommendations. These considerations are:

    10.1 the burden of disease being targeted for prevention;

    10.2 the effectiveness of the vaccine in preventing this burden at various levels of severity; and

    10.3 the safety of the vaccine in the population groups being proposed for its use.

11. I also respond to some of the claims made by the applicants' witnesses.

12. My evidence refers to the document underpinning recommendations given by CV-TAG in relation to the paediatric vaccine (now available).[2] However, this is not the focus of my evidence, nor should my evidence be construed as speaking on behalf of CV-TAG or in my capacity as a member of CV-TAG. My evidence is given as an independent expert in several

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2 https://www.health.govt.nz/system/files/documents/pages/20211215 - cv tag - decision to use vaccine in 5-11-year-olds.pdf

relevant areas: the epidemiology of vaccine-preventable diseases, clinical trials of vaccines and assessment of vaccine effectiveness and safety.

CV-TAG

13. The primary tool used by expert committees (usually called National Technical Advisory Groups on Immunisation or NITAGs) making recommendations on vaccine policy to governments or peak bodies (such as the Advisory Committee on Immunisation Practice (**ACIP**) in the United States, the Joint Committee on Vaccines and Immunisation (**JCVI**) in the UK, the National Advisory Committee on Immunisation (**NACI**) in Canada, the Australian Technical Advisory Group on Immunisation (**ATAGI**) and the WHO's SAGE) is the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Evidence to Decision (**ETD**) framework.[3]

14. Although the GRADE ETD framework is not formally used by CV-TAG in New Zealand, assembly and review of evidence is similarly comprehensive and refers to documents available from relevant international bodies such as ACIP, JCVI, NACI and ATAGI as well as published and unpublished literature.

15. Prior to making a recommendation on the paediatric vaccine, the paediatric vaccine was discussed at meetings of CV-TAG between October and December of 2021, with reference to a range of evidence. These summaries included information pertaining to both the risks and benefits of the paediatric vaccine for 5 to 11 year olds in the overall New Zealand child population and in priority subgroups. On 15 December 2021, CV-TAG recommended the Pfizer paediatric vaccine be offered to all children aged 5 to 11 with an 8-week interval between doses. As noted in the CV-TAG advice, its recommendations were subject to Medsafe approval and any listed clinical conditions. In the New Zealand context, a key consideration was equity and Te Tiriti, recognising the te ao Māori

[3] Lee, Grace et al. "Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices." MMWR. Morbidity and mortality weekly report vol. 67,45 1271-1272. 16 Nov. 2018, doi:10.15585/mmwr.mm6745a4.

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view of tamariki as not only individuals, but in the context of their links to whānau and communities.

16. Equity considerations in the advice CV-TAG members considered:

> 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." and "Māori and Pacific children are more likely to live in multigenerational families housed in overcrowded conditions ....though the risk of transmission from children is lower than from adults.

17. To this must be added the well-documented and long-standing excess burden of respiratory morbidity of all kinds among Māori and Pacific children.

18. Consideration of the overall risk-benefit of vaccines of all kinds, must take into account the population for whom the vaccine is being recommended, in this case children 5 to 11 years of age, with respect to the burden of disease in this population and what is known about the effectiveness and safety of the vaccine in question, in this case the paediatric vaccine formulation. When use of a new vaccine is being considered (historically most commonly for infants and children) by both regulatory authorities and NITAGs, data on disease burden is reasonably well known but data on the proportion of this burden which is prevented by the vaccine and the safety of the vaccine is limited to what is available from clinical trials.

19. This means that important information about use of the vaccine in groups typically excluded from clinical trial participation, such as people with co-morbidities including compromised immunity, is missing despite these groups usually being at higher risk of more severe disease or poorer vaccine responses. There is nothing unusual – in fact it is routine – in relying on post-marketing surveillance of effectiveness and safety in real-world use to inform these issues. Evidence about vaccine performance in often high-risk groups excluded from trial participation and on potential vaccine-related adverse events too infrequent to be adequately evaluated

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in a Phase III randomised clinical trial accumulates from careful, specified surveillance in large numbers of vaccine recipients in this real world context - often called "Phase IV" trials. The specifics of ongoing assessment are detailed in the Risk Management Plan (**RMP**) for the paediatric vaccine. The summary RMP for the paediatric formulation of Comirnaty was first published on 27 January 2022.[4]

20. CV-TAG was mindful of the over-riding importance of data on vaccine safety in the 5 to 11 year old age group, given that this was the age group with the lowest risk of severe disease outcomes of any so far recommended for vaccination. Noting emerging data from Canada that a longer gap between first and second doses was likely to reduce the already small risk of myocarditis, and vaccinology principles of stronger immune responses with a longer gap between doses, an 8-week gap, rather than the 3-week gap used in the clinical trial, was recommended. This longer gap also meant that data from the United States was likely to be available on safety of first and second doses prior to 5 to 11 year old children in New Zealand being eligible for the second dose. An 8-week gap was also consistent with NITAG recommendations from countries other than the US (UK, Canada, Australia).

21. The initial data from the US VAERS passive surveillance system published on December 31st, 2021 concerning reports to November 19th after more than 8 million doses had been distributed, supplemented by real-time text-based reporting from parents in the US V-Safe system, suggested lower rates of adverse events than had been seen with adolescents 12 to 15 years. To this reassuring safety data was added concerns about Omicron potentially being more likely to infect 5 to 11 year old children than the previous Delta variant, resulting in larger numbers of hospitalisations due to more infections, even if the proportion of children experiencing severe disease due to Omicron was lower than for Delta. This focus on severe disease risk continued with CV-TAG on 25th March endorsing the recommendations from NITAGs in US, Canada, UK and

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4 https://www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf

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Australia for a third primary dose in immunocompromised children 5 to 11 years of age, based on data showing inferior antibody responses in immunocompromised adolescents.

Burden of SARS-CoV-2 infection and COVID-19 disease

22. The significance of COVID-19 in children less than 12 years of age and with reference to the age indication for the paediatric vaccine, particularly disease significant enough to result in hospitalisation, intensive care admission or death, has been a key consideration throughout the pandemic. In the New Zealand context, due to the success of the elimination strategy, this only became a relevant consideration with cases of the Delta variant of SARS-CoV-2 occurring in Auckland from August 2021, and subsequently Omicron community transmission from late February 2022.

23. The situation in Australia and New Zealand with very low infection prevalence due to border restrictions is different to that of otherwise comparable Northern Hemisphere countries where a substantial proportion of children in the 5–11-year age group had antibodies due to past infection prior to availability of COVID-19 vaccines. In turn, the situation in New Zealand prior to February 2022 was different to Australia because circulation of Delta was very low outside the Auckland region. Given much larger numbers of Delta cases in an otherwise similar health and societal setting, data from New South Wales on severity of Delta infection in children was the best available indicator of potentially preventable severe disease and was referred to in the Request For Advice (**RFA**) document CV-TAG members were given to assist with their consideration of the paediatric vaccine. The RFA noted that "....although children 0-11 years were 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".

24. More detailed data which specifically refer to the 5 to 11 year age group is available from a pre-print report examining hospitalisations in Sydney

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between 1 June and 31 October 2021.[5] This report examined 5076 children 5-11 years which was 42% of the 11,985 documented infections in children less than 15 years during the Delta wave. In this age group, 22 (0.4% or 1 in 230 of the 5076) were admitted for medical reasons (compared with 117 admitted for non-medical (social) reasons) of whom 10 (45%) had COVID pneumonia similar in nature to unimmunised older children and adults. Of the 22 hospitalisations, 4 (approx. 1 in 1250 of 5076) required intensive care and 2 (1 in 2500) had the Paediatric Inflammatory Multisystem Syndrome (**PIMS-Ts**). Among the 150 children under 15 years who required medical admission because of COVID-19, only 35% had a pre-existing medical condition. When adjusted for other factors, asthma and wheeze (the most common conditions) were not significantly associated with risk of hospitalisation, reducing the proportion of children with recognised risk factors who required hospitalisation even further. Among the total of 15 children who required ICU admission, 43% did not have any prior condition.

25. A UK report of hospitalisations in 115,795 children with Delta infection found a higher proportion (1.6%) of non-trauma related admissions but this was not broken down for 5–11-year-olds separately and as the study used electronic databases, was not able to identify hospitalisations not attributable to COVID-19 as rigorously. Despite this limitation, no deaths occurred amongst this sample.[6] However, the authors did find that risk of hospitalisation was increased among ethnic minorities and children living in areas of highest deprivation, similar to a pre-Delta report from England.[7] This report found that the number of COVID-19 related hospitalisations in 2020 (6968) was similar to influenza-related hospitalisations in 2019 (6338). The percentage of COVID-19 admissions with no comorbidities (47%) was also similar to influenza admissions

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5 Williams P, Koirala A, Saravanos G et al COVID-19 in children in NSW, Australia, during the 2021 Delta outbreak: Severity and Disease spectrum medRxiv preprint doi: https://doi.org/10.1101/2021.12.27.21268348; posted December 29, 2021. https://www.medrxiv.org/content/10.1101/2021.12.27.21268348v1

6 Thelwall S, Aiano F, Harman K, Dabrera G, Ladhani SN. Risk of hospitalisation and death in children with SARS-CoV-2 delta (B.1.612.2) infection. Lancet Child Adolesc Health. 2022; 6:e16-e17. doi: 10.1016/S2352-4642(22)00096-7.

7 Ward JL, Harwood R, Smith C et al Risk factors for PICU admission and death among children and young people hospitalized with COVID-19 and PIMS-TS in England during the first pandemic year. Nat Med. 2022; 28:193-200. doi: 10.1038/s41591-021-01627-9.

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(57%), but the percentage requiring ICU (4%) was higher than for influenza (2.3%). For both COVID-19 and influenza, the percentage who required ICU increased dramatically from around 0.8% with no comorbidities to 14% among children with life-threatening co-morbidities. The percentage of the much smaller number of PIMS-Ts cases (712) who required ICU was much higher (44%). There were 29 deaths within 28 days of COVID-19 hospitalisation (0.4% of hospitalisations) although after detailed clinical review only 8 were deemed directly attributable to COVID-19 and 5 resulted from PIMS-Ts (0.7%). This mortality from England is very similar to the percentage of reported deaths among hospitalisations in 0–9-year-olds in New Zealand to May 27th (4/793; 0.5%).

26. These numbers of hospitalisations and deaths, although small in numeric and percentage terms, are of the same order as those documented pre vaccine for many diseases for which vaccines are routinely recommended in children, as recently documented in a presentation to the ACIP in the United States – see below.[8]

Pediatric vaccine preventable diseases:

Hospitalizations per year in the United States prior to recommended vaccines

	Hepatitis A[1]	Varicella[2] (Chickenpox)	Influenza[3]	COVID-19
Age	5–14 years	<20 years	5–17 years	5–11 years
Time period	2005	1988–1995	2003–2007	Oct 2020–Oct 2021
Hospitalization Burden (per 100,000 population)	**<1**	**4-31**	**30-80**	**25**

[1] https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm
[2] Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. *J Infect Dis*. 2000;182(2):383-390. doi:10.1086/315714
[3] https://www.cdc.gov/flu/weekly/weeklyarchives2007-2008/07-08summary.htm

8 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/01-COVID-Daley-508.pdf

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Note: this is a rate per 100,000 whereas deaths is an absolute number

Pediatric vaccine preventable diseases:
Deaths per year in the United States prior to recommended vaccines

	Hepatitis A[1]	Meningococcal (ACWY)[2]	Varicella[3]	Rubella[4]	Rotavirus[5]	COVID-19
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	5–11 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Oct 2020–Oct 2021
Average deaths per year	3	8	16	17	20	66

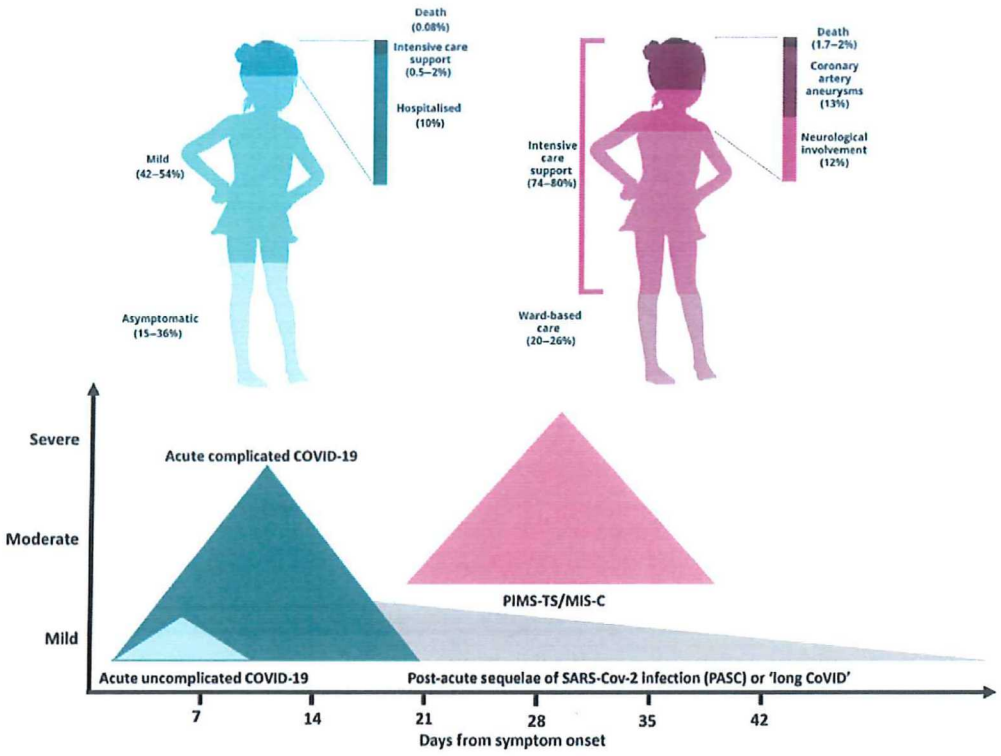
[1]Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8.
[2]National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019.
[3]Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. *J Infect Dis*. 2000;182(2):383-390. doi:10.1086/315714
[4]Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA2007; 298:2155–63.
[5]Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5-11.

Paediatric Inflammatory Multisystem Syndrome (PIMS-Ts)

27. PIMS-TS, also known as multisystem inflammatory syndrome in children (MIS-C), is a rare but serious complication of COVID-19, typically occurring approximately one month after exposure to SARS-CoV-2 infection, which causes inflammation in many parts of the body. Children and adolescents with PIMS-TS usually have a fever, rash and abdominal pain. The most severe forms of PIMS-TS are associated with inflammation of the coronary arteries which may lead to damage to heart muscle, with cases frequently requiring admission to an intensive care unit.

28. PIMS-TS caused deaths in children early in the pandemic, but earlier diagnosis and improved treatment protocols have now made deaths very rare. PIMS-TS can occur even in those where the initial SARS-CoV-2 infection was asymptomatic. With early and appropriate treatment, full recovery and good long-term outcomes, with resolution of the inflammation of the heart when it occurs is now the norm. The diagram below summarises the differences between PIMS-Ts and other manifestations of COVID-19. [9]

[9] Howard-Jones AR, Burgner DP, Crawford NW et al COVID-19 in children. II: Pathogenesis, disease spectrum and management. J Paediatr Child Health. 2022; 58:46-53. doi: 10.1111/jpc.15811.



Long COVID in children

29. Long COVID or Post COVID condition 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 WHO has recently developed a clinical case definition: "Post COVID-19 condition .....following probable or confirmed SARS-CoV-2 infection.....symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis. Common symptoms impact on everyday functioning and may be new onset following recovery from acute COVID-19, persist from the initial illness and fluctuate or relapse over time." The WHO notes that a separate definition may be applicable for children.

30. In the US, 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. A review identified 14 heterogeneous studies (4 cross-sectional, 9 prospective cohort, 1 prospective cohort) of long COVID symptoms in 19,426 children and adolescents, with prevalence from 4% to 66%. Studies which included controls clustered at the lower end of 4-7% but all

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pre-dated the Delta and Omicron variants.[10] The UK COVID Symptom Study (a citizen science project with data collected via an app, which has some associated limitations) found that of 1734 children aged 5 to 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, lower in children aged 5 to 11 years (3.1%).[11] A key question in the context of Omicron is whether these pre-Delta estimates are applicable and the impact of COVID-19 vaccines on preventing or treating them.

Summary of disease burden

31. I acknowledge the disease burden in 5 to 11 year old children is less than in 12 to 17 year olds, who in turn are less affected than even younger adults. However, when one considers the impact of the inflammatory syndrome PIMS-Ts (which does not occur in association with influenza) and the impact of much higher rates of infection with Delta and Omicron, total burden to health is considerable. Taking these factors into account, severe disease and death are present at the same or higher rates than is seen for diseases which are included in routine vaccination in New Zealand such as varicella (chicken pox), rotavirus diarrhoea and children who currently are eligible for funded influenza vaccine. Burden from COVID seems likely to be greater among Māori and Pacific children who already suffer a high burden of respiratory illness.

Effectiveness of Comirnaty mRNA vaccine in preventing this burden

32. The findings of Pfizer's efficacy trial for the paediatric vaccine are well documented and I will reiterate them. The important point to note is that when large primary efficacy trials have already been done, it is common

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10 Zimmermann, P., L.F. Pittet, and N. Curtis, How Common is Long COVID in Children and Adolescents? The Pediatric Infectious Disease Journal, 2021. 40(12).

11 Office for National Statistics UK, Prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK. 2021.

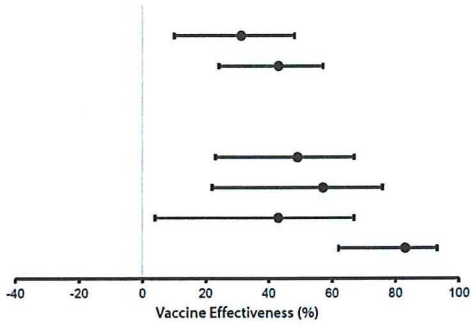
to rely on what are known as immunobridging studies for regulatory submissions pertaining to other age or population groups. These use immunological markers correlated with efficacy in the primary study to demonstrate equivalence.

33. An important variation from the original efficacy study, recommended by CV-TAG in common with NITAGs in Australia, Canada and the UK, is for there to be a gap of 8 weeks between dose 1 and 2 rather than the 3 week interval previously used in adult studies, in the paediatric study and approved in the US. This was based on routine practice in child vaccination schedules and basic immunological principles and prior experience that this results in superior immune response and effectiveness. Thus, the outcomes seen in New Zealand may not be directly comparable to those in the US but are likely to be at least as good.

34. The paediatric vaccine has had most doses given over the longest time period in the US and results from initial post-marketing assessments were presented at the May 17th meeting of the ACIP. These include both reference to recently published US studies and to some unpublished data and are pasted below:

PROTECT: VE against SARS-CoV-2 infection by age group during Omicron variant predominance, Dec 2021-Apr 2022

	Person-days	SARS-CoV-2 positive	Adjusted VE % (95% CI)
5 - 11 years			
2 doses (≥14 days)	60,290	212	31 (10-48)
2 doses (14-59 days)	26,411	156	43 (24-57)
12 - 17 years			
2 doses (≥14 days)	14,501	59	49 (23-67)
2 doses (14-59 days)	785	20	57 (22-76)
2 doses (≥60 days)	13,716	39	43 (4-67)
3 doses (≥7 days)*	8,340	8	83 (62-93)



* Median time from vaccination to test was 95 days

CDC preliminary unpublished. Based on methods in: Fowlkes AL, Yoon SK, Lutrick K, et al. Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5-11 Years and Adolescents Aged 12-15 Years — PROTECT Cohort, July 2021-February 2022. MMWR Morb Mortal Wkly Rep 2022;71:422-428. DOI: http://dx.doi.org/10.15585/mmwr.mm7111e1

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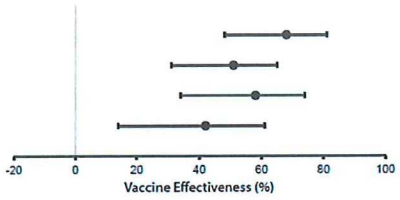
35. This figure shows that the paediatric vaccine, the only vaccine in use in the US in this age group during this period reduced any SARS-CoV-2 virus infection among 5 to 11 year olds in this study by 43% with 95% confidence that infections were reduced by at least 24%.

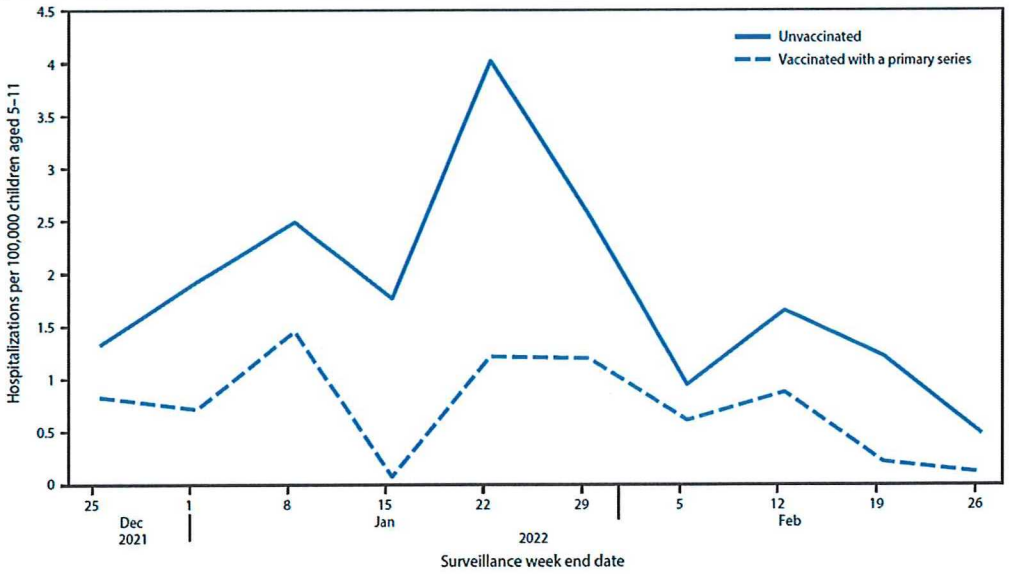
Overcoming COVID-19 platform: VE for 2 doses of Pfizer-BioNTech vaccine against hospitalization, Dec 19, 2021-Apr 27, 2022

	No. vaccinated COVID-19 patients/Total no. COVID-19 patients (%)	Adjusted VE % (95% CI)
5–11 years*	25/325 (8)	68 (48-81)
12–18 years	109/286 (38)	51 (31-65)
2–22 weeks since vaccination	42/219 (19)	58 (34-74)
23–45 weeks since vaccination	67/244 (27)	42 (14-61)



36. This figure shows that hospitalisations were reduced to a greater extent – by 68% (with 95% confidence that the reduction was at least 48% but could be as high as 81%).

FIGURE. Weekly COVID-19–associated hospitalization rates* among children aged 5–11 years, by vaccination status† during the Omicron-predominant period — COVID-NET,§ 11 states, December 25, 2021–February 26, 2022



37. This figure shows the difference in the rate of COVID-19 hospitalisation per 100,000 children 5 to 11 years old who were vaccinated with 2 doses compared with cases in unvaccinated children of the same age drawing on data from hospitals in 14 US States. During this Omicron-predominant period (December 2021 to February 2022), cumulative hospitalization rates among unvaccinated children aged 5 to 11 years were 2.1 times as

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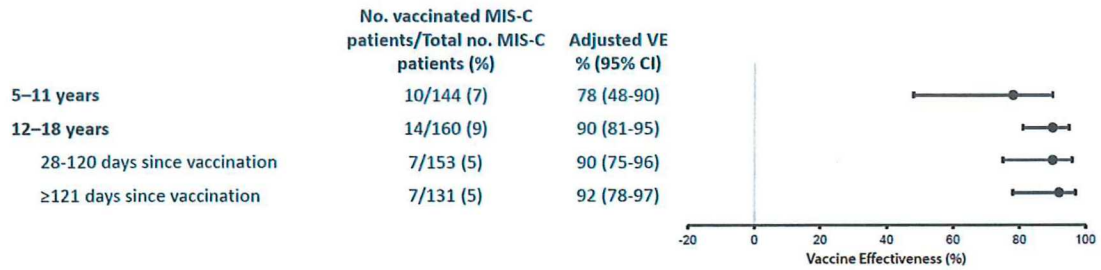
high (19.1) as those among vaccinated children (9.2). Most (87%) children aged 5–11 years hospitalized during the Omicron-predominant period were unvaccinated and no vaccinated children required oxygen support.

Overcoming COVID-19 platform: VE for 2 doses of Pfizer-BioNTech vaccine against MIS-C, Jul 1, 2021-Apr 7, 2022



38. This figure shows that the likelihood of developing the multisystem inflammatory syndrome (PIMS-Ts or here the US name MIS-C (which occurs primarily in children and adolescents some 4-6 weeks after SARS-CoV-2 infection)) was reduced by 78% in vaccinated 5 to 11 year olds compared with unvaccinated children of this age – although the reduction in 12 to 18 year olds looks higher. This may be due to smaller numbers in the 5 to 11 year olds, not a true difference.

Summary of real-life effectiveness of Pfizer paediatric vaccine in 5–11-year-olds

39. These data from the US suggest that the paediatric vaccine is effective in preventing Omicron infection in this age group after two doses given 3 weeks apart as is done in the US. It is possible that effectiveness might be higher using the longer 8-week interval in New Zealand. Although this reduction in infections is only around 40% and is likely to wane with time (noting that waning may be less among this age group than has been seen in older adults as younger children are expected to have more persistent immune responses from first principles), it is still of clinical significance and effectiveness against hospital admission is higher. There were not sufficient instances of 5 to 11 year olds requiring ICU admission or death to examine effectiveness against these most severe outcomes, but data from 12 to 17 year olds in the Omicron era in the US showed that effectiveness remained above 90% against ICU requirement.

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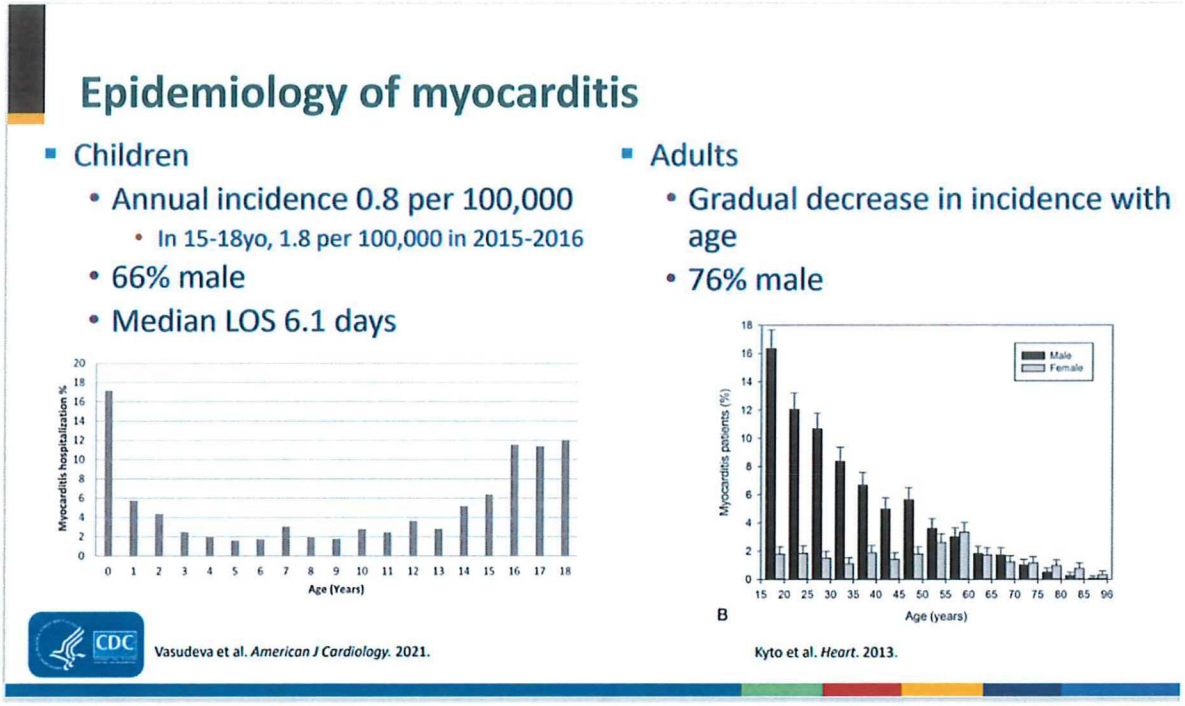
Safety of Comirnaty mRNA vaccine in 5–11-year-olds

Myocarditis and pericarditis

40. The most important safety issue with respect to the 5 to 11 year age group is myocarditis and pericarditis, as these are the only known potential adverse effects with the potential to outweigh the benefits outlined above with respect to severe COVID-19 respiratory disease or PIMS-Ts.



41. This slide shows the pattern by age of myocarditis occurring prior to use of mRNA vaccines when it was thought to most commonly be associated with a prior viral infection, although a virus was often not able to be identified and there were a number of other potential causes. Up to the age of 18 years, myocarditis had a peak in the first year of life, when it was often very severe. It was lowest in the age group from 3 years to 11 years before starting to increase from 12 years. Prior to adolescence it was equally common in boys and girls but from adolescence onwards significantly more common in males. This pattern of male predominance has also been seen with mRNA vaccine-associated myocarditis in young males.

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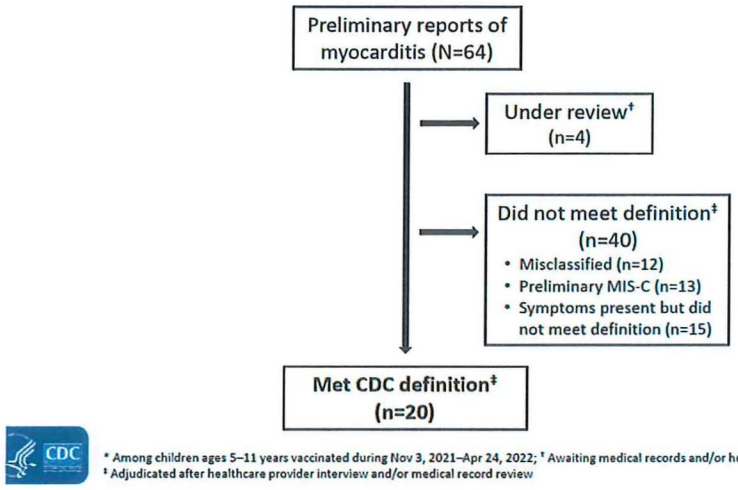
Reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–11 years* (as of April 24, 2022; ~18.1 million doses administered)



* Among children ages 5–11 years vaccinated during Nov 3, 2021–Apr 24, 2022; † Awaiting medical records and/or healthcare provider interview; some still processing; ‡ Adjudicated after healthcare provider interview and/or medical record review

From the US passive surveillance system (VAERS)

42. This slide shows that of 64 reports of possible myocarditis received by the CDC during a time when 18 million doses were administered to 5 to 11 year olds, 20 (31%) were confirmed.

VAERS reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech vaccine, days 0–7 and 8–21 after vaccination*,†

	0–7 days		8–21 days		0–7 days		8–21 days	
	Males		Males		Females		Females	
Ages (yrs)	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
⟹ 5–11	0.2	2.7	0.6	0.0	0.2	0.8	0.2	0.0
For ference 12–15	5.1	48.1	1.6	1.3	0.9	4.3	0.5	0.2
16–17	6.9	74.2	1.7	2.8	0.0	7.2	0.7	0.4
18–24	2.6	35.3	1.2	2.2	0.7	3.1	0.1	0.7
25–29	1.3	12.8	0.4	0.8	0.2	2.0	0.4	0.0
30–39	0.8	6.0	0.0	0.7	0.6	1.0	0.1	0.1
40–49	0.3	3.0	0.1	0.3	0.2	1.6	0.2	0.1
50–64	0.3	0.5	0.0	0.2	0.4	0.6	0.2	0.6
65+	0.2	0.1	0.1	0.3	0.1	0.5	0.3	0.4

43. This slide shows the rates (ie cases of myocarditis per 1 million doses administered) reported to the US passive reporting system - VAERS, similar to CARM in New Zealand. The rate in 5 to 11 year old males in the first 7 days after receiving the second dose was only 4% of the rate from VAERS reporting in 12 to 15 year olds (2.7 vs 48.1). This is likely to be a valid comparison as proportion of cases reported to VAERS for 5 to 11 year olds is likely to be at least as high as for 12 to 15 year olds, given that it is the same system and awareness of myocarditis is high amongst professionals and the public

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From the Vaccine Safety Datalink (VSD) system

44. This system actively monitors vaccination status and post vaccine events via electronic records in a large number of health maintenance organisations in the US, and so provides more robust data but from a much smaller population than VAERS. In the VSD centres, there were 786,202 doses given to around 878,000 children 5 to 11 years. Ten myocarditis cases were identified, of which 6 were verified and 3 occurred in the 7-day window post dose 2. This is a rate per million doses of 3.8, which is similar to the VAERS estimates.

Myocarditis and pericarditis due to COVID-19 compared to Pfizer vaccine

45. A recent US study reported data from 40 health care systems participating in PCORnet, the National Patient-Centered Clinical Research Network during January 1, 2021–January 31, 2022. Myocarditis risk from SARS-CoV-2 infection in 5 to 11 year old males (17.6 per 100,000) was significantly higher than following any dose of mRNA vaccine (3.2 per 100,000); a 5-fold increase.[12]

New Zealand data

46. To April 22nd 2022, 776 reports of adverse events among 5 to 11 year old children had been reported to CARM.[13]

47. As of May 27th, 2022, of an estimated 476,294 children 5 to 11 years in New Zealand, 262,705 (55%) had received the first dose (varying from 35% among Māori to 48% among Pacific and 63% among other ethnicities) and 123,151 the second, a total of 385856.[14]

48. This is a reporting rate of more than 200 per 100,000 doses.

49. No confirmed cases of myocarditis had been reported by April 29th – see below.

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12 Block JP, Boehmer TK, Forrest CB et al Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination - PCORnet, United States, January 2021-January 2022. MMWR Morb Mortal Wkly Rep. 2022; 71:517-523. doi: 10.15585/mmwr.mm7114e1.

13 https://www.medsafe.govt.nz/COVID-19/safety-report-43.asp

14 https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data

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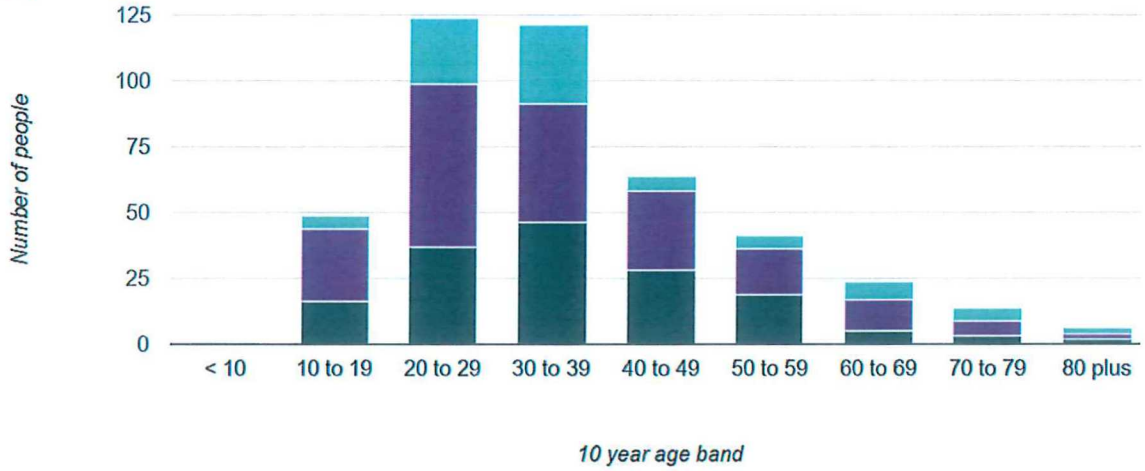
Figure 3: Ages of people reported with myocarditis/pericarditis after Comirnaty vaccination in New Zealand, by dose number, up to 29 April 2022



Australian data

50. To 22 May 2022, the TGA had received about 1,420 reports from approximately 2.2 million paediatric doses of the Pfizer vaccine administered in this age group, a reporting rate of 64 per million doses.[15] The most common reactions reported included chest pain, vomiting, fever, headache and abdominal pain. Among the total of 1420 reports were 33 reports of suspected myocarditis and/or pericarditis in this age group. Following review of information in the reports, 4 were likely to represent myocarditis and another 6 reports were likely to represent pericarditis. The table below shows myocarditis reports to TGA per 100,000 doses administered: a similar rate to the US (2.0 for second doses in males vs 2.7 in VAERS) but a somewhat higher than the US for second doses in 12 to 17 year old males (127) vs 48 for 12 to 15 year old males in VAERS.

15 https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-26-05-2022

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Table 2. Rates of likely myocarditis cases following the mRNA vaccines[‡] A. Comirnaty (Pfizer)

Age (years)	All doses		Second doses	
	Rate* per 100,000 doses		Rate* per 100,000 doses	
	Male	Female	Male	Female
5-11	0.3	0.1	0.2	0
12-17	7.7	1.5	12.7	2.4
18-29	4.3	1.2	7.9	2.1
30-39	1.9	0.7	2.5	0.8
40-49	0.7	0.6	1.0	1.1
50-59	0.4	0.2	0.2	0.3
60-69	0.1	0.3	0	0.4
70+	0.1	0.1	0	0.4
All ages*	**2.2**	**0.7**	**4.1**	**1.2**

Less severe adverse events

51. Both New Zealand (Post Vaccine Symptom Check) and Australia (AusVaxSafety) have an active text-based reporting system to maximise reporting of adverse events by sending text prompts in real time. The PVSC does not report by age. AusVax Safety provides separate reports for 5-11 year olds - these show a consistently lower rate of reporting via active text prompts of parents than has been seen for self reporting by older age groups. See detail below.

Data on this page show the responses of individuals aged 5-11 years who received the paediatric 10 microgram formulation of the Pfizer COVID-19 vaccine and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent on day 3 after vaccination. These data provide you with a profile of what to expect in the days following your child's Pfizer COVID-19 vaccination and can assist when planning for your child's COVID-19 vaccination.

Data as at 16 May 2022

Safety surveys completed

131,670 Pfizer dose 1

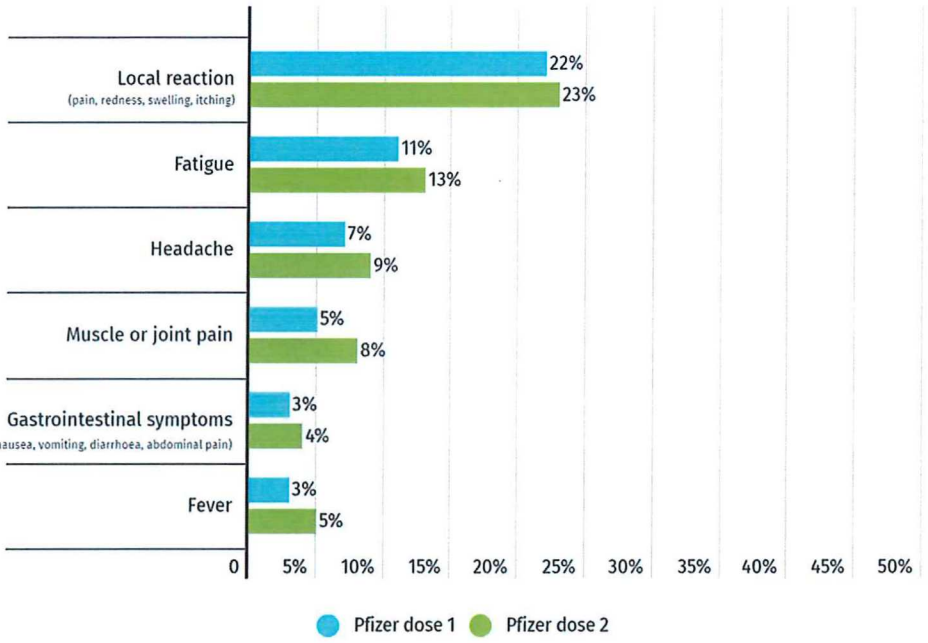
77,191 Pfizer dose 2

Reported at least one adverse event

25% Pfizer dose 1

28% Pfizer dose 2

Commonly reported adverse events

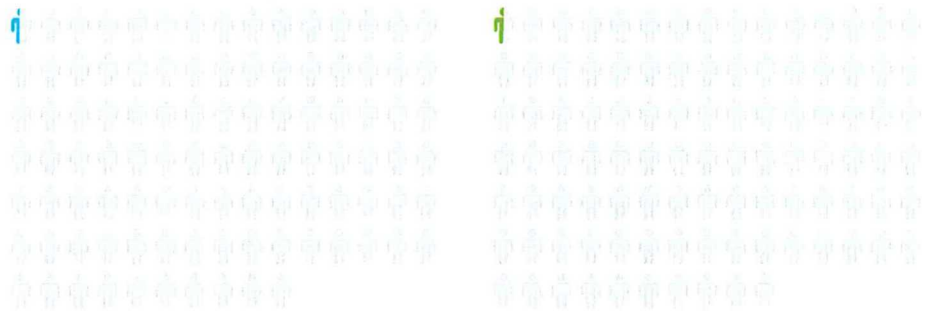


These symptoms are known to occur after vaccination. They are generally mild and short-lived. **As with any adverse event reports, not all symptoms reported may be caused by the vaccine; they may be coincidental and due to other causes.**

Medical attendance

Less than 1 in 100 people reported seeing a doctor or going to the emergency department in the days after Pfizer dose 1

Less than 1 in 100 people reported seeing a doctor or going to the emergency department in the days after Pfizer dose 2



Those who presented to GPs and emergency departments had similar adverse events to those who didn't. AusVaxSafety does not specifically ask participants the reason why they accessed medical care in the days following vaccination. Therefore medical attendance reported may or may not be related to any adverse events reported.

52. Exact % = 0.4 for dose 1 and 0.5 for dose 2

Summary of safety data

53. There are now data from passive reporting systems in the US following approximately 18 million doses of Pfizer paediatric vaccine, from Australia following approximately 2.2 million and from New Zealand following almost 380,000 doses in 5 to 11 year old children. Despite the world's highest passive reporting rates for post vaccination adverse events from New Zealand and reporting more than twice the rate of myocarditis in 12

to 17 year olds from Australia as the US, data from both countries have shown very low rates of myocarditis in 5 to 11 year old children. This has been confirmed by robust active case finding in the VSD network in the US. Less severe adverse events, even via prompted text-based active reporting, have also been substantially lower than among adolescents and adults. Given the lower risk of severe outcomes from COVID-19 this is reassuring and appropriate with respect to risk-benefit assessment.

Risk-benefit assessment

New Zealand setting

54. Risk-benefit assessment was recognised by CV-TAG as the most important consideration for recommending the use of the Pfizer vaccine in 5-11-year-old children because the direct health benefit of vaccinating children and adolescents was lower than older adults or adolescents. Assessment was in the context of the Delta outbreak, prior to Omicron.

55. With respect to risk, the most important consideration was the potential for vaccine-related myocarditis. While the relatively low background incidence of myocarditis in this age group and low overall reactogenicity in the clinical trial was reassuring, the importance of careful post marketing surveillance and early data from North America where the largest numbers of vaccine doses were being delivered was considered important. As noted above, the later start in New Zealand and longer dosing interval meant that data from 8 million doses in the US was available before commencing to offer the paediatric vaccine to 5–11-year-olds in New Zealand.

56. With respect to benefits, the lack of prior infection-derived immunity in New Zealand was thought to potentially augment the risk of more serious COVID-19 disease. The magnitude of indirect benefits was also considered potentially significant though uncertain. This included helping protect those who are immunocompromised, and vulnerable older members of multi-generational households which was an important consideration for equity, as many of New Zealand's COVID-19 cases during the Delta wave were in children in disadvantaged communities. There was also the

potential for vaccinating school-aged children reducing school disruptions and reducing cases in other age groups, particularly in the same household.

International assessments

57. The NITAGs of comparable countries – the UK, Canada and Australia – have all recommended mRNA COVID-19 vaccines for general use in 5-11-year-old children. In the UK, the recommendation was initially recommended in December 2021 for use in high-risk children only but revised advice was published on 16 February 2022 in the context of substantially increased hospitalisations in this age group and after a revised risk assessment, to include all children. Statements from NACI in Canada[16], the JCVI in the UK[17] and ATAGI in Australia[18] are all conclusive in their affirmation of positive risk-benefit for this age group. Some comparable advisory groups in Scandinavian countries have made risk group only recommendations, but none have sought to prevent or advise against use as is being suggested by the applicants. The rationale provided for a high risk only recommendation has primarily rested on uncertainty about the risk of vaccine-induced myocarditis.

Summary and opinion of overall risk-benefit

58. The primary consideration of all vaccine recommendations for routine use in healthy children is always vaccine safety. The relatively low overall risk of severe outcomes from COVID-19 disease following SARS-CoV-2 infection in the 5 to 11 year age group compared with older age groups further accentuates the priority for safety. The considerations are similar to those for influenza vaccine in this age group for whom severe outcomes are rare although well documented, including deaths in previously well children. COVID-19 adds the risk not seen with influenza or other respiratory viruses of PIMS-Ts. Although still accumulating, the available evidence suggests that two doses of the paediatric vaccine

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16 https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/updated-recommendations-use-covid-19-vaccines-children-5-11-years-age.pdf

17 https://www.gov.uk/government/publications/jcvi-update-on-advice-for-covid-19-vaccination-of-children-aged-5-to-11/jcvi-statement-on-vaccination-of-children-aged-5-to-11-years-old

18 https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/who-can-get-vaccinated/children

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prevents PIMS-Ts and respiratory COVID-19 severe enough to require oxygen or ventilatory support. The other rationale, also in common with influenza vaccine, is that vaccination will at least to a degree and for a period of time reduce transmission of SARS-CoV-2 to others in the household setting and possibly also in the school setting. Especially for children, it is almost certain that they will experience infection due to SARS-CoV-2 multiple times in their lives and doing so following vaccination is likely to result in the most robust immunity. These benefits, alongside consistent evidence of a lower rate of common adverse effects post vaccination and extremely low (compared to adolescents) though nonzero risk of myocarditis make risk-benefit favourable. Put together, it is my strong view that making the paediatric vaccine available free of charge to all children in the 5-11 age group is justified, with my only wish being that this was also the case for influenza vaccine. At the same time, it is crucial that vaccination continues to not be a requirement for school attendance or participation in out of school activities.

Applicants' evidence

59. I have read the affidavits of Byram Bridle (excluding the exhibits) (25 January and 1 May 2022), Dr Simon Brown (April 2022), Nikolai Petrovsky (14 January and 27 January 2022), Dr Robert Malone (21 January 2022), Dr Peter McCullough (25 January 2022), Dr Geert Vanden Bossche (29 April 2022), Dr Phillip Altman (2 May 2022) and Lisa Mitchell (11 May 2022). Nothing in those affidavits changes my reading of the literature or assessment of risk benefit as set out above. Time constraints do not allow me to respond to each individual statement or opinion of all these witnesses. Below I address some of the claims made in the affidavits of Dr Altman, Professor Petrovsky (14 January 2022), and Dr Brown. The absence of a response to points made by any of the applicants' witnesses should not be interpreted as agreement.

Dr Altman

60. With respect to Dr Altman's evidence, I discuss below some particular points I disagree with and which I believe it is important to discuss.

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61. Paragraphs 13 and 16: I do not agree that mRNA vaccines represent gene therapy or comply with any definition of gene therapy.

62. As stated by the genomics education program of the UK National Health Service[19] gene therapies involve making deliberate changes to a patient's DNA in order to cure or alleviate a genetic condition. This can be by adding a functional copy of a gene, disabling a gene that makes a faulty product or changing gene activation. In contrast, the mRNA contained in vaccines does not enter the cell nucleus or interact with the DNA at all and so does not constitute gene therapy.

63. This is expanded upon by Penny Riggs, Associate Professor of Functional Genomics and Associate Vice President for Research, Texas A&M University in the Conversation where she notes:[20]

> Messenger RNA instructions are timed to self-destruct, like a disappearing text or snapchat message. Structural features of the mRNA – the U in the code, its single-stranded shape, ribose sugar and its specific sequence – ensure that the mRNA has a short half-life. These features combine to enable the message to be "read," translated into proteins, and then quickly destroyed – within minutes for certain proteins that need to be tightly controlled, or up to a few hours for others.
>
> Once the instructions vanish, protein production stops until the protein factories receive a new message The vaccine provides just enough mRNA to make just enough of the spike protein for a person's immune system to generate antibodies that protect them if they are later exposed to the virus. The mRNA in the vaccine is soon destroyed by the cell – just as any other mRNA would be. The mRNA cannot get into the cell nucleus and it cannot affect a person's DNA.
>
> Although these are new vaccines, the underlying technology was initially developed many years ago and improved incrementally over time. As a result, the vaccines have been well tested for safety. The success of these mRNA vaccines against COVID-19, in terms of safety and efficacy, predicts a bright future for new vaccine therapies that can be quickly tailored to new, emerging threats. Early-stage clinical trials using mRNA vaccines have already been conducted for influenza, Zika, rabies, and

19 https://www.genomicseducation.hee.nhs.uk/blog/why-mrna-vaccines-arent-gene-therapies/

20 https://theconversation.com/what-is-mrna-the-messenger-molecule-thats-been-in-every-living-cell-for-billions-of-years-is-the-key-ingredient-in-some-covid-19-vaccines-158511

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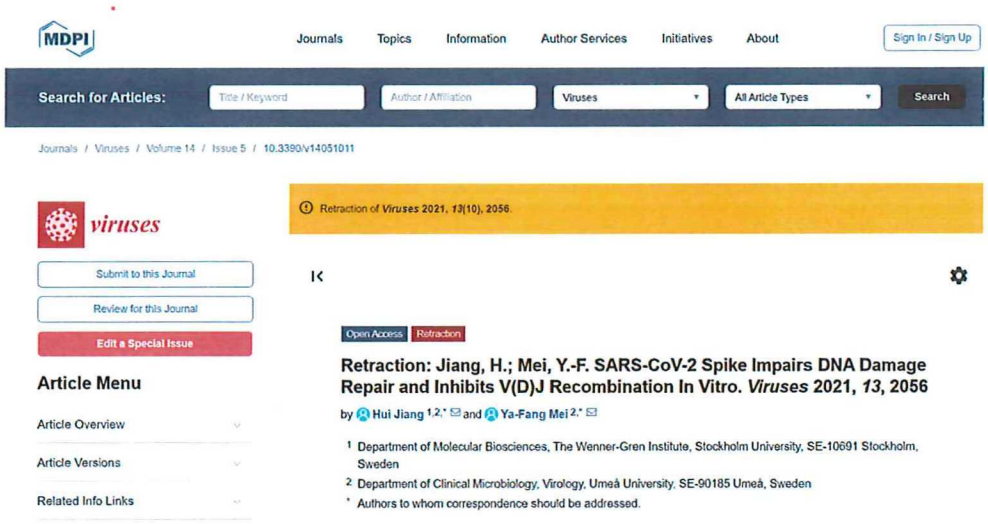
cytomegalovirus. Creative scientists are already considering and developing therapies for other diseases or disorders that might benefit from an approach similar to that used for the vaccines against COVID-19.

64. Spike protein: Dr Altmann asserts that spike protein is toxic in its own right and widely distributed in the body as are nanoparticles. He goes on to cite as a definitive reference the publication of Jiang and Mei in the journal Viruses published by MDPI. However, the Editor in Chief of the journal has retracted this paper due to improper scientific design – see below:



Retraction: Jiang, H.; Mei, Y.-F. SARS-CoV-2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro. *Viruses* 2021, *13*, 2056

by Hui Jiang [1,2,*] and Ya-Fang Mei [2,*]

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(This article belongs to the Special Issue **SARS-CoV-2 Host Cell Interactions**)

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The published article [1] has been retracted. Following publication, the first author contacted the editorial office regarding an improper experimental design with the potential to significantly affect the integrity of the resultant experimental data.

Adhering to our complaint procedure, an investigation was conducted. Both the chosen construct of the spike plasmid that contained a C-terminal fused with 6xHis tag and use of a GFP reporter system under overexpression conditions in the protocol were identified as having the potential to introduce significant ambiguity regarding the nature of the reported observations. The reliability of the results and conclusions presented have therefore been undermined. Furthermore, statements regarding the effect of the spike protein on the adaptive immunity are misleading as in this article no experiments related to the adaptive immunity were performed, and the full-length spike-based vaccine was not studied. Therefore, conclusions related to vaccine safety are not validated and lacked experimental support. This article [1] is retracted and shall be marked accordingly. This retraction was approved by the Editor-in-Chief of the journal *Viruses*.

SJT

65. I have covered other matters raised by Dr Altman in other parts of this affidavit which makes clear where I disagree. These include:

65.1 K. The statement that "survivability" of COVID-19 is 99.97% and is equivalent to influenza – while this may be true with respect to younger people vaccinated with 3 doses of COVID-19 vaccines who develop Omicron infection, it is not true for the unvaccinated or for older individuals. I discuss relative disease burden of COVID-19 and influenza in children above.

65.2 Paragraph 86a: He states that "as children largely asymptomatic" this means that there is "no evidence of contributing to transmission" or that "vaccination generates a meaningful public health benefit". I agree that the primary rationale of vaccination in this age group is the protection of the child receiving the vaccine from the risk of serious disease. However, there may be an additional benefit in reducing transmission to other household members, with transmission from children to adults well documented and likely to be higher with Omicron than Delta. Consideration of such additional benefits is well established for influenza. The UK child influenza vaccination programme which began in 2014 was deemed cost effective because in addition to direct benefit to the child, there was a large reduction in influenza transmission to older members of the community who were more at risk.

65.3 Paragraph 88: He states that "no evidence children with comorbidities are at greater risk". I cite evidence refuting this for COVID-19 and influenza above.

Professor Petrovsky (14 January 2022 affidavit)

66. With respect to Professor Petrovsky's evidence, in a similar manner to Dr Altman, I discuss below some particular points of agreement and disagreement I believe merit highlighting.

67. I agree with his statement in paragraph 64 that other vaccine platforms (ie other than mRNA) merit consideration for use in the 5 to 11 year age

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group such as inactivated viral vaccines. However, these vaccines have not been submitted for regulatory review in New Zealand (or Canada, UK, US or Australia) although widely used in children in for example Chile, Turkey and India as well as China. Not having these vaccines available as an option does not however preclude consideration of mRNA vaccines or impact on their risk benefit profile.

68. I also agree with his statement in paragraphs 60 and 61 that mRNA vaccines are not "identical to gene therapy" and in paragraph 92 that priority should be given to vaccination of children at higher risk of severe COVID-19. However, priority to this group, while important, should not deny parents of other children who may, although much more rarely, develop severe disease from choosing to vaccinate them and as healthy children are much more numerous, the total number of severe cases occurring in them is higher than among children with pre-existing illnesses.

69. I disagree with Professor Petrovsky's assertion that a study he cites demonstrates negative vaccine effectiveness (**VE**) – that is, that vaccination has increased susceptibility to Omicron infection.[21] The results presented in this study at face value show more than 95% confidence that the true VE estimate is less than zero. However, I do not believe this constitutes evidence that vaccination is causing higher disease risk. Rather, this result is almost certainly due to bias in the study methods. As the authors of the study note in the discussion of their results:

> The negative estimates in the final period arguably suggest different behaviour and/or exposure patterns in the vaccinated and unvaccinated cohorts causing underestimation of the VE. This was likely the result of Omicron spreading rapidly initially through single (super-spreading) events causing many infections among young, vaccinated individuals.

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21 Hansen CH, Scheide AB, Moustsen-Helm IR, et al. Vaccine effectiveness against SARS-Co V-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study. medRxiv 2021 doi: 10.1101/2021.12.20.21267966.

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70. Another Danish paper using similar methods but reporting on VE against hospitalisation due to Omicron rather than any Omicron infection (where such bias is much less likely) found that VE was preserved even out to more than 120 days and even in older adults but at a reduced level compared with Delta.[22]

Dr Brown

71. Dr Brown has immunology, especially innate immunity, as his major interest. As above I discuss below some points in Dr Brown's evidence merit discussing.

72. I disagree with Dr Brown's interpretation in paragraph 22 that "IFR" (infection fatality rate) should be revised down since the start of pandemic or that Omicron is now no more than flu. The Financial Times piece he refers to makes it clear that it is high levels of vaccination **and** reduced propensity to causing lower respiratory tract infection with Omicron have led to similar mortality to influenza. [23]

73. Dr Brown goes on in paragraphs 45 and 46 to quote safety data from VAERS to imply that many more deaths occur due to receiving Pfizer vaccine than from COVID – this is a basic error of misinterpretation of data from a passive surveillance system. Explanation is provided on the Medsafe website as to how deaths are assessed by them – reproduced below:

> We are monitoring people for 21 days after vaccination. This monitoring period was chosen because people can receive their second dose a minimum of 21 days after the first dose. Age-specific natural (expected) death rates were obtained for the period 2008–2019. One reason for the number of deaths in the vaccinated group appearing to be lower could be that healthcare professional of extremely frail patients give the advice not to get vaccinated.
>
> These analyses do not consider causality and instead, report on all deaths that have occurred in the monitoring period (observed deaths). This results in a much higher number than those reported to CARM where the reporter (eg, family member or health care provider) might have had a suspicion the vaccine could have played a role. The number of observed deaths also includes deaths from

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22 Gram M et al Vaccine effectiveness against SARS-CoV-2 infection 1 and COVID-19-related 2 hospitalization with the Alpha, Delta and Omicron SARS-CoV-2 variants: a nationwide Danish cohort study medRxiv preprint doi: https://doi.org/10.1101/2022.04.20.22274061; posted April 20, 2022.

23 https://www.ft.com/content/e26c93a0-90e7-4dec-a796-3e25e94bc59b

other causes, such as deaths due to accidents, medical conditions, other medicines or medical treatments.

Please note that the mortality collections operate many weeks in arrears. This means that these observed-versus-expected analyses will also be in arrears – for example, the tables below are for the period up to 28 February 2022.

Table 7: Observed-versus-expected deaths[a] by age group from any cause, up to 21 days after Comirnaty dose 1, 19 February 2021 to 28 February 2022

Age	Dose 1 – number administered	Expected deaths[b] in monitoring period	Observed deaths[c] in monitoring period	Relative risk[c] (95% confidence interval)
0 to 9	162,305	5.21	0	- [d]
10 to 19	575,985	10.65	12	1.13[e] [0.58 – 1.97]
20 to 29	647,739	22.45	24	1.07[f] [0.68 – 1.59]
30 to 39	674,239	30.98	14	0.45 [0.25 – 0.76]
40 to 49	591,484	57.35	24	0.42 [0.27 – 0.62]
50 to 59	606,975	135.39	64	0.47 [0.36 – 0.60]
60 to 69	515,770	268.86	126	0.47 [0.39 – 0.56]
70 to 79	348,951	491.52	239	0.49 [0.43 – 0.55]
80+	182,593	1,083.76	600	0.55 [0.51 – 0.60]
Total	4,306,041	2,106.16	1,103	0.52 [0.49 – 0.56]

a. Expected and observed deaths among people who have received dose 1 of the Comirnaty vaccine during the specified period, by age group. Inclusion criteria were: monitoring time of 21 days after receiving dose 1, all genders, all ethnicities, aged 5 years and older. The data was collected from the Mortality database.

b. Data for expected death rates was obtained from the AESI background rate (SAFE) study provided by the University of Auckland (however, please note that the publicly available information only shows rates of sudden death not all deaths). The age-specific background rates used are the average from 2008-2019.

c. The observed deaths column (4th column) is a raw data observation, and this is used to calculate the relative risk (5th column).

d. The relative risk has not been calculated for the 0 - 9 years age group because no deaths were observed during the monitoring period.

SJT

e. The relative risk of 1.13 does not indicate there is an increased risk of mortality in the 10 - 19 age group because the lower end of the confidence interval is 0.58 (ie, <1.0). The COVID-19 Independent Safety Monitoring Board (CV-ISMB) has reviewed AEFIs in children and found that this group was not disproportionately affected by the vaccine. Medsafe will continue to monitor this closely.

f. The relative risk of 1.07 does not indicate there is an increased risk of mortality in the 20 - 29 year age group because the lower end of the confidence interval is 0.68 (ie, <1.0).

For further reading about the methodology used to analyse death rates, see:

- Centers for Disease Control and Prevention (CDC) – Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink.
  URL: https://www.cdc.gov/vaccinesafety/pdf/VSD-1342-COVID19-RCA-Protocol_FinalV1.1_508.pdf

74. Similarly in paragraphs 59 and 60 he makes another basic error in using case data (with many inherent biases related to testing) to calculate VE by simple proportions. However, the UKHSA specifically states that this is inappropriate and should not be done:[24]

> **This data is published to help understand the implications of the pandemic to the NHS, for example understanding workloads in hospitals, and to help understand where to prioritise vaccination delivery. This raw data should not be used to estimate vaccine effectiveness.**

SWORN

at Wellington this 10th day of June 2022 before me:)

Peter Bruce McIntyre

Stacey Jade Thomson

A Solicitor of the High Court of New Zealand

[24] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1066759/Vaccine-surveillance-report-week-13.pdf

"PMB-1"

CURRICULUM VITAE

Peter Bruce McIntyre MBBS, PhD, FRACP, FAFPHM, DTM&H

Personal Details		
Full name:	**Peter Bruce McIntyre**	
Title:	**Professor**	
Gender, Country of Birth	Male, Australia	
Correspondence address:	30 Butler Street, Maori Hill, Dunedin 9010 NZ	
Phone Numbers:	Mobile (NZ) : + 64 (0) 21 281 4242	
Email addresses:	peter.mcintyre@otago.ac.nz; peter.mcintyre@sydney.edu.au	
Current Positions	**Position**	**Institution**
	Professor, Women's and Children's Health Medical Advisor and Honorary Professor Conjoint Professor	University of Otago, New Zealand Immunisation Advisory Centre, University of Auckland University of Sydney, Australia
	Senior Professorial Fellow	National Centre for Immunisation Research and Surveillance (NCIRS)

Degrees and Qualifications

DMedSc	University of Sydney	2021
PhD	University of Sydney	1995
FAFPHM	Fellow, Faculty of Public Health Medicine RACP	1992
FRACP	Fellow, Royal Australasian College of Physicians	1986
Diploma of Child Health	Royal College of Physicians, London	1982
Diploma of Tropical Medicine and Hygiene	Royal College of Physicians, London	1981
MB, BS (Hons)	University of Queensland	1977

Distinctions

(a) Officer of the Order of Australia (AO) January 2020
(b) Member Infectious Disease Academy of the NZ Ministry of Health 2019
(c) Member, World Health Organisation's Strategic Advisory Group of Experts 2019
(d) Member, World Bank's International Vaccine Task Force 2017-18
(e) National Immunisation Achievement Award – Public Health Association of Australia 2018
(f) Member, WHO Immunisation and Vaccines Implementation Research Advisory Committee 2012-17
(g) Fellow, Public Health Association of Australia 2014
(h) Ranked in top 0.1% of experts in vaccines worldwide by Expertscape

This is the exhibit marked "**PMB-1**" referred to in the annexed Affidavit of **PETER BRUCE MCINTYRE** sworn at **Wellington** this **10th** day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Stacey Jade Thomson

Previous Positions

2004-2017	Director, National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, Kids Research, Children's Hospital at Westmead and University of Sydney, NSW
1997–2004	Deputy Director, National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases
1995 - 2017	Senior Staff Specialist, Department of Immunology and Infectious Diseases, Children's Hospital, Westmead, Sydney
1994	Visiting Fellow, Harvard School of Public Health, Boston Children's Hospital and Department of Paediatrics, University of Oxford (6 months)
1989–1994	Staff Specialist in Paediatrics, Westmead Hospital, Sydney

Academic Appointments

2021	Honorary Professor, University of Auckland
2019-	Professor Department of Women's and Children's Health, University of Otago, Dunedin Medical Campus
2004-	Conjoint Professor, Discipline of Child and Adolescent Health and School of Public Health, University of Sydney

Advisory Committees – New South Wales, Australia, New Zealand and Other

New South Wales:

Advisor on immunization to Chief Health Officer 2005-2017

Member, Expert Advisory Panels on Measles and Pertussis Various 2005-2017

Member, Expert Advisory Panel on Vaccine Safety monitoring (HPV and Meningococcal C) 2003-2008

Member, Research Advisory Committee, Sydney Children's Hospitals Network

Australia:

Australian Technical Advisory Group on Immunisation 1999-2017

Communicable Disease Network of Australia 2004-2017

National Immunisation Committee 2004-2017

Chief Medical Officer's Pandemic Influenza Vaccine Advisory Group 2007-10

Chief Medical Officer's Advisory Panel on HPV vaccine safety 2008

Chief Medical Officer's Advisory Panel on vaccine safety in Australia 2011-13

New Zealand:

Member, Corona Virus Technical Advisory Group of Ministry of Health 2021

Centers of Disease Control, United States:

Invited member, Working Group on Pertussis, US Advisory Committee on Immunisation Practice 2011-2016

World Health Organisation, Geneva:

Invited Member, Working Groups on Pertussis, WHO Strategic Advisory Group of Experts 2009-10, 2014-15

Invited Member, WHO Working Group on Pneumococcal Serotype Replacement, 2010

Invited Member, WHO working group on Pertussis Surveillance Standards 2017

National and international conferences

Australia:

- Chair, organizing committee for biennial National Immunisation Conference 2006-2016
- Member, organizing committee for National Communicable Disease Conference 2007-2017

New Zealand:
Member, organizing committee, National Immunisation Conference 2018-22

International:

- Member, organizing committee for International Society for Prevention of Pneumococcal Diseases 2012 and 2018
- Initiated and subsequently member of organizing committee for international pertussis meeting through Fondation Merieux in Annecy France November 2015
- Member, organizing committee for Bill and Melinda Gates Foundation symposium on prevention of severe pertussis in low-income countries Atlanta US February 2016

Editorial Boards

Chair of Editorial Board, 2011-18; member Editorial Board 2004–2010 *Communicable Disease Intelligence*

International Editor, *Pediatric Infectious Disease Journal*, 1996-

Member, "Council of 100" for International Society for Vaccines 2013-

Invited reviewer for academic journals

1. Reviewer, *Lancet*, 2002 -
2. Reviewer, *Lancet Infectious Diseases*, 2012 -
3. Reviewer, *New England Journal of Medicine*, 2012 –
4. Reviewer, *Journal of American Medical Association*, 2007 -
5. Reviewer, *British Medical Journal*, 2001-
6. Reviewer, *Bulletin of the World Health Organisation*, 2010 –
7. Reviewer, *Canadian Medical Association Journal*, 2010 –
8. Reviewer, *American Journal of Public Health*, 2009 –
9. Reviewer, *Scandinavian Journal of Infectious Diseases*, 2008 -
10. Reviewer, *Epidemiology & Infection* 2007 –
11. Reviewer, *Pediatrics,* 2006 –
12. Reviewer, *Journal of Pediatrics*, 2006 -
13. Reviewer, *Vaccine*, 2005-
14. Reviewer, *Archives of Disease in Childhood*, 2003 –
15. Reviewer, *Clinical Infectious Diseases*, 2001-
16. Reviewer, *Emerging Infectious Diseases*, 2007-
17. Reviewer, *Medical Journal of Australia*, 1998-
18. Reviewer, *Australian and New Zealand Journal of Public Health*, 1994-
19. Reviewer, *Journal of Paediatrics and Child Health*, 1990-

Invited reviewer for grant applications:

Australia:

National Health and Medical Research Council

International:

Medical Research Council (UK), the Wellcome Trust, the Canadian Institute for Health Research, the Medical Research Council (NZ) and comparable bodies in Norway, the Netherlands, Germany and Hong Kong

Service

University:

Invited referee for promotions to Professorial level:

International: University of London, Johns Hopkins University, Yale University, University of British Columbia, University of Texas, University of Auckland, University of Oxford

Australia: Universities of Adelaide, Melbourne, Sydney, Australian National University

Postgraduate teaching:

Master of Public Health course work: Developed and subsequently took lead responsibility for the "Vaccines in Public Health" module of the Master of Public Health course, University of Sydney.

Higher degree students: successful supervision of 11 PhD students and 7 Master-level degree students to completion. Research Grants – see below

Community:

Australian Academy of Science: Invited member of the taskforce developing community monograph "Science of Immunisation" wrote several of the chapters and provided assistance with updates https://www.science.org.au/files/userfiles/learning/documents/immunisation/immunisation-2016-high-res.pdf

Public Health Association of Australia: In the role of Chair, National Immunisation Conference organizing committee for almost a decade from 2008, was responsible for several new initiatives

Australian Government Department of Health: In the role of Director of the National Centre for Immunisation Research and Surveillance, and as an expert advisor, played a pivotal role in peak advisory committees and during critical vaccine safety incidents (HPV and influenza vaccines)

New South Wales Government Ministry of Health: As an expert advisor, made critical contributions to a wide range of key initiatives in immunization. Wrote independent report on the quality of evidence on the website of the anti-immunisation advocacy group, Australian Vaccine Network

Children's Hospital at Westmead: In the role of Associate Director, Population Health Research, contributed to the development of research strategy and researcher career development

Media and community organisations: Frequent invited commentator at national and state level

Contributions to the National Centre for Immunisation and Surveillance (NCIRS)

Over a 20-year period, I was instrumental in identifying and pursuing opportunities to develop NCIRS into an organization of national and international significance, first as Deputy Director (1997-2004), then Director (2004-2017). In 2017, at the end of my Directorship, NCIRS was recognized nationally and internationally for leadership in the following research areas, all of which had been initiated and/or developed through my personal contributions:

- use of multiple data sources to describe the epidemiology of vaccine-preventable diseases in Aboriginal and non-Aboriginal children and adults
- analyses of immunization register data including development of case-control methods using the immunization register

- driving availability of individually linked register and communicable disease data
- national serosurveillance program
- PAEDS national hospital surveillance network
- AusVax national vaccine safety network
- Social research into attitudes and beliefs and interventions to improve coverage
- Clinical trials including neonatal immunization

Research Funding

Competitive Research Grants

1. Otago Medical Research Foundation: Immunity to measles in young adults: is it waning and does it matter?" commencing November 2020. $NZ 35K

2. Co-Principal Investigator: Tracking influenza and respiratory viruses in New Zealand post 2020 FluLab US University of Auckland $9.8M awarded April 2021

3. Heath Research Council: Immunity to measles in young adults: is it waning and does it matter?" $1.2M Awarded June 2021

4. Wellcome Trust: "Effectiveness of vaccines to prevent antibiotic prescribing for acute respiratory tract infections in high risk adults" based on a proposed study of vaccine and antibiotic prescribing data on a large Australian primary care database. $A449000 Chief Investigator A/Prof Bette Liu Grant awarded: commencing 2020

5. Australian Indo-Pacific Centre "Mitigating health security risks by supporting immunisation coverage and preventing outbreaks." (Universities of Sydney, Newcastle, Melbourne, New South Wales and Monash and Australian National University). A$2.4M Chief Investigator Prof Kristine Macartney Awarded for 2020

6. National Health and Medical Research Council: Invited to be a one of 9 investigators for a Centre for Research Excellence to accelerate introduction of pneumococcal conjugate vaccines in the Asia-Pacific region. $A 2.5M Lead investigator: Professor Fiona Russell (University of Melbourne) Awarded for 2021.

7. National Health and Medical Research Council Project Grant - Assessing acellular pertussis vaccine effectiveness: integrating transmission models, genetics and cohort data to inform policy (2017-2019) $429597

8. National Health and Medical Research Council Project Grant - Quantifying the effectiveness of pertussis vaccine in older adults (2016-2018) $448703

9. National Health and Medical Research Council Partnership Grant - Reducing vaccine preventable diseases in children: using national active hospital-based surveillance to evaluate and improve immunisation program performance (2016-2019) $1049915

10. National Health and Medical Research Council Project Grant - Economic evaluation of alternative pneumococcal vaccination strategies. (2015-2017) $236,941

11. National Health and Medical Research Council Project Grant - Vaccination timeliness in Aboriginal and non-Aboriginal infants: risk factors for delayed vaccination and impact on disease burden – a record linkage study. (2015-2019) $520,742.00

12. National Health and Medical Research Council Project Grant - Providing the evidence to guide adult immunisation strategies: a novel approach using a large prospective cohort study and record linkage. (2013- 2015) $492,414.49

13. National Health and Medical Research Council Project Grant - Q fever: How common is it and how can we best prevent it? Research to inform Q fever vaccine policy in Australia and - Internationally. (2013-2015). $721,150

14. Public Health Research Network Proof of Concept Grant - Linkage of the Australian Childhood Immunisation Register (ACIR) and State-based registers to evaluate and inform Australia's Immunisation Program. (Dec 2012 – March 2014) $157,457
15. National Health and Medical Research Council Project Grant - Pneumococcal conjugate vaccine (PCV) schedules for the Northern Territory (NT): randomised controlled trial of booster vaccines to broaden and strengthen protection from invasive and mucosal infections (2012-2015) $1,986,094.94
16. Australian Research Council Grant - Post-implementation economic evaluation of childhood vaccination programs (2012/13-2014) $220,000
17. Foundation for Children Grant - Optimising pertussis vaccination in infants: a new approach (2012 – 2014) $150,000
18. National Health and Medical Research Council Project Grant - Longitudinal investigation of health outcomes in urban Aboriginal children (2012-2016) $1,727,460.
19. National Health and Medical Research Council Centre of Research Excellence - Immunisation in understudied and special risk populations, (2012-2016) $2,499,969
20. National Health and Medical Research Council - Evolution of pertussis epidemics and effect of genotypes on infection outcomes and immunisation. (2011- 2013) $638,100
21. National Health and Medical Research Council Project Grant - Single versus combination pneumococcal conjugate vaccines (13PCV and PHiD-CV) for high-risk Aboriginal children (COMBO), (2010-2013) $2,870,025
22. National Health and Medical Research Council Project Grant - Characterisation of H1N1 Influenza 09 in hospitalised children using Paediatric Active Enhanced Diseases Surveillance, (2009-2010) $118,513
23. National Health and Medical Research Council Project Grant - Pertussis vaccine for newborns (2009-2011). $1,454,200
24. National Health and Medical Research Council Project Grant - Audiologic and Developmental Outcomes in urban Aboriginal Children (2008-2010) $450,750
25. National Health and Medical Research Council Capacity Building Grant in Population Health Research – Indigenous Health (2007-2010) $2,500,125
26. National Health and Medical Research Council Early Life Grant - SEARCH – Study of environment on Aboriginal resilience and child health (2005-2009) $1,950,125
27. National Health and Medical Research Council Project Grant Immunogenicity of pneumococcal conjugate vaccine in vulnerable adult populations. (2005-2007) $536, 550
28. The Financial Markets Foundation for Children A pilot study to determine the appropriate design for a trail of acellular pertussis vaccine given at birth (2004-2006) $130,000
29. National Health and Medical Research Council Public Health Research and Development Grant Childhood pneumococcal disease in Australia—epidemiology and prevention (1996-99) $160,000
30. New South Wales Department of Health (1994) Commissioned research on "Uptake of Hib vaccines in the Sydney region". $7000.
31. Commonwealth Department of Community Services and Health (1990) Research and Development Grant for "Risk factors for and costs of *Haemophilus influenzae* type b infection in Sydney children". $28,519
32. New South Wales Department of Health (1990) Research Grant for "Risk factors and costs of *Haemophilus influenzae* type b infection in Sydney children". $28,519.

Major government-contracted research

Australian Government:

1. National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, Australian Government Department of Health $16,275,000 2015-2018
2. National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, Commonwealth Department of Health and Ageing $15,610,000 2010-2014

3. National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, Commonwealth Department of Health and Ageing $5,600,000 2005-2010
4. National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases Commonwealth Department of Health and Ageing $3,000,000 2001-2005
5. Evaluation of the ACIR immunisation coverage and the impact of parental incentives Commonwealth Department of Health and Aged Care 2001 $120,000
6. Evaluation of the national MMR vaccination campaign 1998 Commonwealth Department of Health and Aged Care 1998-99 $170,000
7. Competitive Tender for National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases Commonwealth Department of Health and Aged Care 1997-2000 $2,000,000

Sponsored vaccine trials

1. Glaxo Smith Kline Follow-up of children vaccinated with MMR-varicella vaccine (MMRV003) 1999, 2000, 2001, 2002 $80,000
2. Wyeth-Lederle Vaccines and Pediatrics (Pearl River, New York) (2001) Randomised controlled trial of boosting dose of vaccine for children previously vaccinated with 9 valent conjugate pneumococccal conjugate vaccine: $184,000
3. Wyeth-Lederle Vaccines and Pediatrics (Pearl River, New York) (2000) 9 valent pneumococccal conjugate vaccine: a randomised controlled trial of 3 different lots: $400,000
4. Wyeth-Lederle Vaccines and Pediatrics (Pearl River, New York) (1998) A nasal parainfluenza vaccine for infants: a randomised controlled trial. $200,000.
5. SmithKline, Beecham (Australia and Belgium) (1998) Administration of combined hepatitis A and B vaccine to adolescents as two doses 6 or 12 months apart. $80,000.
6. SmithKline Beecham (Australia and Belguim) (1997) Immunogenicity and tolerability of MMR-varicella vaccine in infants. $90,000.
7. SmithKline Beecham (Australia and Belguim) (1996) Immunogenicity and tolerability of DTPa-Hib-HBV booster at 18 months of age. $80,000.
8. SmithKline Beecham (Australia and Belgium) (1996) Immunogenicity and tolerability of DTPa-Hib-HBV vaccine in infants. $188,000.
9. Wyeth-Lederle (Australia) (1993) Uptake of Hib vaccines in the Sydney region—a telephone-based sampling study. $16,000.
10. Merck, Sharp and Dohme (1993) Immunogenicity of PRP-OMP vaccine (PedvaxHib) in Aboriginal and non-Aboriginal children. $25,000.
11. Pasteur Merieux Serums and Vaccines (1991) Grant to support continued laboratory surveillance for invasive *Haemophilus influenzae* type b infection in the greater Sydney region. $9,200
12. Merck, Sharp and Dohme (1989) Equipment grant and seeding funding for "Risk factors and costs of *Haemophilus influenzae* type b infection in Sydney children". $7,000.

Publications

Book chapters and monographs

1. McIntyre P, Cameron A, Widmer R. Infections of the face and oral cavity. In: Isaacs D, Moxon ER, Editors. A practical approach to paediatric infections Churchill Livingstone New York 1996.
2. Burgner D, McIntyre P. Infectious diseases In: Choong R, Browne G, Wilkins B, Gaudry P, Editors. Principles and Practice of Paediatric Emergency Care. Sydney: Petty and McLennan, 1997.

3. McIntyre P. The acute management of bacterial meningitis. In: Evidence Based Pediatrics. London: British Medical Journal Publications, 2000.
4. McIntyre P. *Haemophilus influenzae* type b. In: Australian Immunisation Handbook, 7th ed. Canberra: AGPS, 2000.
5. McIntyre P. *Haemophilus influenzae* type b. In: Australian Immunisation Handbook, 7th ed. Canberra: AGPS, 2000.
6. McIntyre P. Pneumococcal disease. In: Thomson, N (ed.) Australian Indigenous Health. South Melbourne: Oxford University Press Chapter 17, 384-396 2000
7. McIntyre P. *Haemophilus influenzae* type b. In: Australian Immunisation Handbook, 8th ed. Canberra: AGPS, 2003.
8. McIntyre P. *Pertussis.* In: Australian Immunisation Handbook, 8th ed. Canberra: AGPS, 2003.
9. McIntyre P. *Pneumococcal disease* In: Australian Immunisation Handbook, 8th ed. Canberra: AGPS, 2003.
10. McIntyre P. *Meningitis.* In: Moyer VA, Elliott EJ (eds). Evidence-based pediatrics and child health. 2nd edition. London: BMJ Books; 2004. p. 285-91
11. McIntyre P. *Should dexamethasone be part of routine therapy of bacterial meningitis in industrialised countries?* In: Pollard AJ, Finn A (eds). Hot topics in infection and immunity in children II. Series in: *Advances in Experimental Medicine and Biology* 2005; 568:189-97
12. McIntyre P, Lester R. *Immunisation.* In: Yung AP, McDonald MI, Spelman DW, et al (eds). Infectious diseases: a clinical approach. 2nd ed. Melbourne: IP Communications; 2005.
13. McIntyre P. *Haemophilus influenzae* type b. In: Australian Immunisation Handbook, 9th ed. Canberra: AGPS, 2008 and 2013
14. McIntyre P. *Pertussis.* In: Australian Immunisation Handbook, 9th ed. Canberra: AGPS, 2008 and 2013.
15. McIntyre P. *Pneumococcal disease* In: Australian Immunisation Handbook, 9th ed. Canberra: AGPS, 2008 and 2013
16. McIntyre P, Gilroy N, Lester R, Macartney K. Chapter 50. *Immunisation.* In: Yung AP, Spelman DW, Street A al (eds). Infectious diseases: a clinical approach. 3rd ed. Melbourne: IP Communications; 2010
17. McIntyre P, Bolotin S, Quinn H *Global Pertussis surveillance* in Rohani P, Scarapino S (editors) The Integrative Biology of Pertussis: Epidemiology, Biology and Evolution Oxford University Press 2018
18. **McIntyre PB**, Walls T *Global impact of vaccines in children* in: Oxford Research Encyclopaedia of Public Health published on line May 2020

Articles in refereed journals

***Google Scholar Citations 2022:* H-index 66; i10 index 283; 16236 citations**

Original papers

1983-1988

1. McIntyre P, Kennedy R, Harris F. Occult pneumococcal bacteraemia and febrile convulsions. *BMJ* 1983; 286:203-6.
2. McIntyre P, Boreham PFL, Phillips RF, Shepherd RW. The chemotherapy of giardiasis: clinical responses and in vitro drug sensitivity of human isolates in axenic culture. *J Pediatr* 1986; 108:1005-10.
3. McIntyre P, Blacklock Z, McCormack JG. Cutaneous infection *Mycobacterium gordonae. J Infect* 1987; 14:71-8.
4. McIntyre P, Patel AM, Vacca A, McCormack JG. Tuberculosis in pregnancy — implications for antenatal screening in Australia. *Med J Aust* 1987; 146:42-4.

5. McCormack JG, McIntyre P, Tilse M, Ellis D. Mycetoma associated with *Acremonium falciforme* infection. *Med J Aust* 1987; 147:187-8.

6. McIntyre P, Tilse M, O'Callaghan M, McCormack J. Blood cultures in hospitalised children. *Med J Aust* 1987; 147:485-89.

7. McIntyre P, Tilse M, Lewis B, Tudehope D. Late onset neonatal sepsis due to multiple resistant coagulase negative staphylococci. *Med J Aust* 1988; 149:272-5.

1990-1999

8. McIntyre P, Gray S, Vance J. Unsuspected bacterial infections in febrile convulsions. *Med J Aust* 1990; 152:183-6.

9. McIntyre P, Gilbert GL, Burgess MA, Ziegler J. Vaccine prevention of invasive *Haemophilus influenzae* type b disease. *J Paediatr Child Health* 1990; 26:190-1.

10. McIntyre P, Lavercombe P, Kemp R, McCormack J. Epidural and subdural empyaema: diagnostic and therapeutic problems. *Med J Aust* 1991; 154:653-57.

11. McIntyre P, Leeder SR, Irwig L. Invasive *Haemophilus influenzae* type b disease in Sydney children — a population-based study. *Med J Aust* 1991; 154:832-37.

12. McIntyre P, Gilbert GL, Burgess MA, Ziegler J. Report of the immunisation subcommittee on pertussis immunisation. *J Paediatr Child Health* 1991; 27:16-21.

13. Walker J, Chen S, Packham D, McIntyre P. Five cases of neurocystericercosis diagnosed in Sydney. *Southeast Asian J Trop Med Public Health* 1991; 22:242-4.

14. Ish-Horowitz M, McIntyre P, Nade S. Bone and joint infections caused by multiply-resistant *Staphylococcus aureus* in a neonatal intensive care unit. *Pediatr Infect Dis J* 1992; 11:82-7.

15. Grattan-Smith P, O'Regan W, Ellis P, O'Flaherty S, McIntyre P, Barnes C. Rabies — a second Australian case presenting after a long incubation period. *Med J Aust* 1992;156: 651-4.

16. McIntyre P. Invasive *Haemophilus influenzae* type b disease in Australia - the beginning of the end? *Med J Aust* 1992; 156:516-8.

17. McIntyre P. Worldwide epidemiology of invasive *Haemophilus influenzae* type b disease. *JAMA* (SE Asian edition) 1993; Suppl 9:5-10.

18. McIntyre P. Invasive *Haemophilus influenzae* type b disease. *Aust Fam Physician* 1993:22:1782-9.

19. Garland S, Gilbert GL, Ferson M, Grimwood K, Hogg G, McIntyre P, Isaacs D. Investigation of congenital infection. *Med J Aust* 1993; 159: 346-348.

20. McIntyre P, Jepson R, Leeder S, Irwig L. The outcome of childhood *Haemophilus influenzae* meningitis — a population-based study. *Med J Aust* 1993; 159:772-6.

21. Sulfaro F, Fasher B, Burgess M, Isaacs D, McIntyre P. Homeopathic vaccination —what does it mean? *Med J Aust* 1994; 161:305-7.

22. McIntyre P, Leeder SR, Hall J. An economic analysis of immunisation against *Haemophilus influenzae* type b disease in Australia. *Aust J Public Health* 1994; 18:394-400.

23. Isaacs D, Ferson M, Gilbert GL, Grimwood K, McIntyre P. Chemoprophylaxis for *Haemophilus* and meningococcal infections. *J Paediatr Child Health* 1994; 30:9-11.

24. McIntyre P. An update on immunisation - 1994. *Aust Prescriber* 1994; 17:91-95.

25. McIntyre P. Vaccines against invasive *Haemophilus* influenzae type b disease. *J Pediatr Child Health* 1994; 30:14-19.

26. McIntyre P, Chey T, Smith W. The impact of immunisation against *Haemophilus influenzae* type b (Hib) disease in the Sydney region. *Med J Aust* 1995; 162:245-8.

27. Davis C, McIntyre P. Invasive pneumococcal infection in childhood: a hospital-based study 1981-92. *J Pediatr Child Health* 1995;31: 317-23.

28. McIntyre P, Isaacs D. Lumbar puncture in neonatal sepsis. *J Pediatr Child Health* 1995; 31:1-2.

29. Gilbert GL, Isaacs D, Burgess M, Garland S, Grimwood K, Hogg, McIntyre P. Prevention of neonatal group B streptococcal sepsis: is routine antenatal screening appropriate? *Aust N Z J Obstet Gynaecol* 1995; 35:120-6.

30. Kesson AM, Grimwood K, Burgess MA, Ferson MJ, Gilbert GL, Hogg G, Isaacs D, Kakakios A, McIntyre P. Guidelines for the use of acyclovir in varicella zoster infection. *J Pediatr Child Health* 1996; 32:211-8.

31. Browne GJ, Ryan JM, McIntyre P. Evaluation of a protocol for selective empiric treatment of fever without localising signs. *Arch Dis Child* 1997; 76:129-33.

32. Stormon M, McIntyre P, Morris J, Fasher B. Typhoid fever in children — diagnostic and therapeutic difficulties. *Pediatr Infect Dis J* 1997; 16:713-4.

33. McIntyre PB, Berkey CS, King SM, Schaad UB, Kilpi T, Kanra GY, Perez CM. Dexamethasone as adjunctive therapy in bacterial meningitis. A meta-analysis of randomized clinical trials since 1988. *JAMA* 1997; 278:925-31. **335 CITATIONS**

34. Liddle JL, Burgess MA, Gilbert GL, Hanson RM, McIntyre PB, Bishop RF, Ferson MJ. Rotavirus gastroenteritis: impact on young children, their families and the health care system. *Med J Aust* 1997; 167:304-7.

35. McIntyre P. Epidemiology and prevention of childhood pneumococcal disease *Curr Opin Pediatr* 1997; 9:9-13.

36. McIntyre P. Epidemiology and prevention of pneumococcal disease. *Commun Disease Intell* 1997; 21:41-6.

37. Grimwood K, Collignon PJ, Currie BJ, Ferson MJ, Gilbert GL, Hogg GG, Isaacs D, McIntyre PB. Antibiotic management of pneumococcal infections in an era of increased resistance. *J Paediatr Child Health* 1997; 33:287-95.

38. Massie RJ, Cooper PJ, Van Asperen PP, McIntyre P. *Pneumocystis carinii* pneumonia: pitfalls of prophylaxis. *J Paediatr Child Health* 1998; 34:477-9.

39. McIntyre P. Geographic differences in bacterial meningitis: less may be as interesting as more. *J Pediatr Child Health* 1998; 34:109-11.

40. McIntyre P, Craig JC. Prevention of serious bacterial infection in children with nephrotic syndrome. J Pediatr Child Health 1998; 34:477-7.

41. McIntyre P, Forrest J, Heath T, Burgess M, Harvey B. Pertussis vaccines: past, present and future in Australia. *Commun Dis Intell* 1998; 22:125-32.

42. Burgess MA, McIntyre PB, Heath TC. Pertussis re-emerging: who is responsible? *Aust N Z J Public Health* 1998; 22:9-10.

43. Burgess MA, McIntyre PB, Heath TC. Rethinking contraindications to vaccination. *Med J Aust* 1998; 168:476-7.

44. Burgess MA, Heath TC, McIntyre PB. The Measles Control Campaign and immunisation adverse events. *Commun Dis Intell* 1998; 22:136-8.

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