Record of the Immunisation Advisory Committee Meeting held online on 5 September 2024

Immunisation Advisory Committee records are published in accordance with the Terms of Reference for the Specialist Advisory Committees 2021.

Note that this document is not necessarily a complete record of the Immunisation Advisory Committee meeting; only the relevant portions of the meeting record relating to Immunisation Advisory Committee discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

The Immunisation Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

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1. Attendance

Present
Stephen Munn – Chair
Chris Pihema
David Murdoch
Erasmus Smit
Helen Evans
Lance Jennings
Nikki Turner
Osman Mansoor
Stuart Dalziel
Tony Walls

Apologies
Elizabeth Wilson
Gary (Edwin) Reynolds
James Ussher
Karen Hoare
Sean Hanna

2. Summary of recommendations

Pharmaceutical and Indication	Recommendation
• RSVPreF3 vaccine for the prevention of RSV-LTRD for people aged 60 years and over	Defer
• Influenza vaccine for children aged five years and under, within the context of vaccines and immunisation	High Priority
• Eligibility for additional doses of COVID-19 vaccine(s) be widened to health care workers currently not eligible (due to age-related eligibility)	Widened Access
• Access criteria for PCV13 and PPV23 vaccines be widened, within the context of vaccines and immunisation, to include people of any age who have had a previous episode of invasive pneumococcal disease	High Priority
• Eligibility criteria for PCV13 and PPV23 vaccines be widened, within the context of vaccines and immunisation, to include people of any age who have bronchiectasis	High Priority
• Pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine for people aged 65 years and above	Decline

3. The role of Specialist Advisory Committees and records of meetings

3.1. This meeting record of the Immunisation Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

3.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

3.3. The Immunisation Advisory Committee is a Specialist Advisory Committee of Pharmac. The Immunisation Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Immunisation Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for Immunisation that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for Immunisation that differ from the Immunisation Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Immunisation Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for vaccine-preventable communicable diseases.

4. Welcome and introduction

4.1. The Chair welcomed the Committee with a karakia followed by whakawhanaungatanga.

5. Record of Immunisation Advisory Committee meeting held Tuesday, March 26, 2024

5.1. The Committee reviewed the record of the Immunisation Advisory Committee meeting held on Tuesday 26 March 2024, and agreed that the minutes be accepted.

6. Therapeutic Group and NPPA Review

Therapeutic group distribution data and expenditure summary

6.1. The Committee considered that the quality of immunisation data currently collected in NZ is of concern. It noted that there is ongoing work to address these concerns and improve the quality of the data captured by the Aotearoa Immunisation Register (AIR). The Committee noted that the currently available data does not give certainty of reported coverage but that reported rates have continued to decline so far in 2024. The Committee noted that the proportion of children immunised is declining across all age groups and NZDep index deciles

6.2. The Committee noted the vaccine distribution summary data and expenditure summary for all vaccines. The Committee noted that the total net expenditure on vaccines had increased in the 2023 and 2024 financial years due to new funding decisions, including shingles, meningococcal B and influenza vaccines.

6.3. The Committee noted that immunisation coverage rates at milestone ages remain lower for Māori than other populations in New Zealand, and Māori children are likely to experience scheduled vaccination events later than other children. The Committee also noted data showing immunisation coverage at milestone ages by ethnicity, and immunisation coverage at milestone ages by NZDep index.

6.4. The Committee considered that the childhood immunisation programme should continue to focus on increasing coverage rates. The Committee noted that the National Public Health Service has been placing more focus on supporting Māori health services and other immunisation providers, including pharmacists to help achieve this.

Human papillomavirus vaccine (Gardasil 9)

6.5. The Committee noted that overall distribution in 2023 was higher than in 2022, but distribution up to July 2024 had been lower than the same period in 2023; in line with a decline in reported coverage.

6.6. The Committee noted that in a number of other international jurisdictions, including Australia, Canada, and in the United Kingdom there is a move to reduce the dosing schedule of HPV vaccine to a one dose schedule. The Committee noted that the Medsafe approved dose schedule is two or three doses, depending on age or risk factors.

6.7. Members considered that if a one dose schedule was implemented in New Zealand, health sector resources could be used to increase HPV coverage by the focus on administering only a single dose, enabling resourcing of other areas.

6.8. Members noted that HPV vaccine coverage had been low since the introduction of the vaccine, never meeting the low 75% target, and that some tamariki and rangatahi between the ages of 11 and 15 years have missed their first dose of the HPV vaccine and are not considered protected. Members considered that, meanwhile, those tamariki and rangatahi who had received their first dose of HPV vaccine are likely be protected with a single dose, while they may not be considered formally "fully" vaccinated, in reality they are likely protected. Members therefore considered that immunisation programme efforts should focus primarily on achieving high coverage for the first dose for those aged up to 15 years of age, ie focusing on those not receiving any HPV vaccine rather than focusing on providing a second dose.

Hepatitis B recombinant vaccine

6.9. The Committee noted that since November 2020 only 'Engerix-B' branded 10 mcg and 20 mcg have been funded.

6.10. The Committee noted that on 1 August 2024 the eligibility criteria for Hepatitis B vaccine was widened to include patients prior to planned immunosuppression of greater than 28 days.

Diphtheria, tetanus, pertussis and polio vaccine

6.11. The Committee noted the distribution of Diphtheria, tetanus, pertussis and polio vaccine to 31 July 2024 was lower than the same time point in 2023, but similar to the same time point in 2022.

6.12. The Committee noted that coverage from January to August 2024 was 93% in non Māori/non Pacific children aged 4 years, and 64% in Māori children 4 years of age.

Haemophilus influenzae type b vaccine

6.13. The Committee noted the distribution of Haemophilus influenzae type b vaccine in 2024 was tracking lower than for previous years. The Committee noted that as a result of the Vaccines RFP, there will be a change in the funded brand to Sanofi's Act-HIB from November 2024.

Measles, mumps and rubella vaccine

6.14. The Committee noted the distribution and expenditure patterns for the Measles Mumps and Rubella (MMR) vaccines. The Committee noted that distribution in 2024 is tracking lower than the same period in 2023, 2022 and 2021.

6.15. The Committee noted that Pharmac | Te Pātaka Whaioranga continues to maintain high stock levels of MMR vaccine to allow a rapid response to any emerging outbreak.

Meningococcal conjugate vaccines

6.16. The Committee noted that the distribution of Meningococcal ACWY vaccine to July 2024 was below distribution for 2023 but similar to distribution in 2022.

6.17. The Committee noted that since access to Meningococcal ACWY vaccine was widened from 1 December 2019 for people in close-living situations, increased distribution is evident in January and February each year, likely due to uptake of the vaccine by secondary or tertiary students entering halls of residence or boarding hostels at the start of the academic year.

6.18. The Committee noted that Meningococcal B vaccine (Bexsero) was funded for high-risk immunocompromised groups and close contacts of cases of any meningococcal group from July 2021. Access was further widened from March 2023 for children under 5 years of age and adolescents in close living situations.

6.19. The Committee noted that since Meningococcal B vaccine was funded, the number of cases of group B meningococcal disease in New Zealand has been declining each year.

6.20. The Committee noted its previous advice that Meningococcal B vaccine should ideally be administered as early as possible and that the infant 6 week milestone visit would be the preferred time. The Committee noted that the Meningococcal B vaccine has been included in the Childhood Immunisation Schedule at 8 weeks, with an alternative schedule starting at 6 weeks. The Committee noted that administration at 6 weeks is not an approved dose schedule in the New Zealand data sheet, which is a barrier to immunisation at 6 weeks.

6.21. The Committee requested that Health New Zealand | Te Whatu Ora work with Pharmac | Te Pātaka Whaioranga to provide more detailed information on the incidence of meningococcal B infection in infants under 4 months old stratified by Meningococcal B vaccine status, particularly those infants currently being immunised and assessing if delayed first doses may be contributing to disease burden in these young infants.

Pneumococcal conjugate vaccine

6.22. The Committee noted the distribution and expenditure patterns for pneumococcal conjugate vaccines.

6.23. The Committee noted that following an increase in invasive pneumococcal disease (IPD) notifications due to serotype 19A, PCV13 replaced PCV10 as the funded pneumococcal conjugate vaccine from 1 December 2022.

6.24. The Committee considered that the most recent available ESR surveillance data up to December 2023 showed there is still a high incidence of IPD caused by serotype 19A occurring in children under 5 years of age. The Committee noted that Māori and Pacific children were disproportionately represented in cases of IPD.

6.25. The Committee noted that a funding application for a catch-up programme for children 1 to 5 years of age has been considered by Pharmac and is ranked on the Options for Investment List, and reassessment of this funding application was completed in recent months. Members considered the need for a pneumococcal disease catchup programme is far greater than a catchup programme for meningococcal B disease due to the greater impact of indirect protection from pneumococcal disease that does not seem to apply to Meningococcal B vaccine.

6.26. The Committee reiterated its view that funding a catch-up programme for children under 5 years of age is a high priority and was urgently required to reduce the burden of IPD.

6.27. The Committee noted that herd immunity effects from immunising children under 5 years of age indirectly provide some protection for people over 65 years of age.

Pneumococcal polysaccharide vaccine

6.28. The Committee noted that the distribution of PPV23 is significantly lower than the conjugate vaccine, since PPV23 is funded for high-risk individuals only. The Committee noted that distribution to July 2024 was similar to distribution in 2023 and 2022. The Committee noted that there are also private market sales of PPV23, but data was not available on the extent of private use.

Diphtheria, tetanus and pertussis vaccine

6.29. The Committee noted the distribution and expenditure patterns for diphtheria, tetanus and pertussis vaccine. Distribution to July 2024 is tracking slightly behind the same time in 2023.

6.30. The Committee noted that from 1 July 2019 access was widened for pertussis vaccine to include pregnant women from the second trimester of pregnancy, and parents or primary care givers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than three days.

6.31. The Committee reiterated the importance of maternal pertussis vaccination in pregnancy and considered that maternal vaccination rates are very low across the country, with variation by maternal age and ethnicity.

6.32. Members considered that implementation activity should be focused on increasing maternal immunisation rates, followed by on time vaccination of the 6 week immunisation for children.

6.33. The Committee noted that there is not a funded primary care visit for pregnant people. Members supports increasing vaccinator workforce and the training of midwives as all of life vaccinators. Members considered that the maternal dose given in pregnancy should also be considered as the child's first dose and be recorded against both the mother's and child's immunisation records.

6.34. The Committee considered there is a need to have better data on maternal pertussis vaccination rates. The Committee considered that it would like to see maternal pertussis administration data during pregnancy and requested Health NZ provide this data to Pharmac.

Bacillus Calmette-Guerin vaccine

6.35. The Committee noted that uptake of the BCG vaccine is unpredictable and inconsistent.

6.36. The Committee noted that distribution was low in 2020 and 2021, possibly related to a number of factors related to public health measures to manage the COVID-19 pandemic, including reduced immigration and reallocation of regional public health services staff to other duties. However distribution rates in 2024 are consistent with previous years.

Diphtheria, tetanus, pertussis, polio, hepatitis B and Haemophilus influenzae type b vaccine

6.37. The Committee noted the distribution pattern of the hexavalent vaccine has been tracking consistently with previous years, apart from a reduction in distribution during the 2020 COVID-19 lockdown.

6.38. The Committee noted that from 1 July 2024 access was widened for re-vaccination of children under the age of 18 years old following a haematopoietic stem cell transplant.

Poliomyelitis vaccine

6.39. The Committee noted that poliomyelitis vaccine distribution had increased in 2023 compared with the last two years. The Committee considered this was possibly related to the increase in international travel, since the New Zealand border was reopened following COVID-19 public health measures, which would have included countries with endemic polio or experiencing outbreaks.

6.40. The Committee noted that the Poliomyelitis vaccine distribution in 2024 has been similar to doses distributed to the same time point in 2023.

Hepatitis A vaccines

6.41. The Committee noted the distribution for hepatitis A vaccines showed occasional peaks in distribution for both paediatric and adult vaccines, which were likely related to specific outbreaks. An outbreak in Christchurch in January 2020 and a national outbreak from September 2022 were noted to be linked to the consumption of imported frozen berries.

6.42. The Committee noted that distribution of the paediatric presentation in particular has been higher than usual to date in 2023, with a noticeable increase in distribution seen in May 2023.

6.43. From 1 January 2023 to 15 August 2024, 8,349 hepatitis A vaccinations have been administered, with highest numbers in children under the age of 4 years and in people aged 15 to 29 years recorded as being male.

6.44. The Committee considered that among those not already eligible for the hepatitis A vaccine, people with renal failure and users of illicit IV drugs are at risk of more severe disease but not at an increased risk of acquiring Hepatitis A infection. Members considered men who have sex with men (MSM) may also be at higher risk of acquiring Hepatitis A, and recalled previous discussions (PTAC February 2015, Immunisation Subcommittee February 2015) around MSM living with HIV, patients with chronic liver disease, users of illicit IV drugs, and healthcare workers. The Committee requested that additional epidemiological evidence for Hepatitis A be considered at a future meeting.

6.45. Committee members considered that half of reported cases in New Zealand are in returning travellers. The Committee considered that people who frequently travel to countries where Hepatitis A is endemic would be considered at an increased risk of acquiring Hepatitis A.

6.46. The Committee noted that people living in New Zealand who frequently travel to the Pacific or Asia could be at higher risk of acquiring Hepatitis A. The Committee considered that funding Hepatitis A vaccine for this purpose would protect their whānau and the wider New Zealand population. The Committee noted that it would like to review more data for this population.

6.47. The Committee noted that Pharmac does not fund vaccines that are considered for travel but that in this case Pharmac could re-examine what's considered travel vaccine.

Varicella vaccine

6.48. The Committee noted that varicella vaccine distribution was reduced during the 2020 COVID-19 lockdown period and had been lower than usual up to June 2021. The Committee noted that distribution returned to normal levels and started tracking higher than usual in 2023 but was starting to decrease in 2024.

6.49. The Committee noted that as a result of the 2022 Vaccines RFP, that from 1 July 2024 there has been a brand change from Merck Sharp and Dohme's Varivax to GlaxoSmithKline's Varilrix.

6.50. The Committee requested it be able to review varicella epidemiology and hospitalisation data to help assess if there is a need for a second varicella vaccine dose in the childhood immunisation schedule, at a future meeting.

6.51. The Committee noted that Australia has implemented a two-dose schedule using MMRV for both doses.

6.52. Members considered that the current eligibility criteria leave a gap in eligibility due to all infants born on or after 1 April 2016 being eligible for primary vaccination, and a

catch up for previously unvaccinated children turning 11 years of age on or after 1 July 2017. The Committee considered that this means that unvaccinated children aged between 8 and 11 years old are not currently eligible for a funded varicella vaccine. The Committee considered that this eligibility gap should be closed.

Rotavirus oral vaccine

6.53. The Committee noted that distribution of rotavirus oral vaccine remained steady from year to year. In March 2023, there was a change from oral drops to a squeezable tube presentation.

Zoster Vaccine (Shingrix)

6.54. The Committee noted the distribution and expenditure patterns for zoster vaccine.

6.55. The Committee noted that the live attenuated vaccine (Zostavax) was funded until its discontinuation in November 2022. The recombinant zoster vaccine (Shingrix) was funded from 1 December 2022. Shingrix has a two-dose schedule, and this is reflected in the steadily increasing distribution seen.

6.56. The Committee noted that from 1 July 2024 access was widened for some people with immunosuppression.

6.57. Members considered that zoster vaccines are often being administered pre-winter, along with influenza vaccine. From an implementation perspective, this is an optimal time to capture people that are eligible for their zoster vaccine.

Influenza vaccine

6.58. The Committee noted that immunisation claims for funded influenza vaccine (to 13 July) in 2024 were lower than for both 2023 and 2022, however the Committee noted that in 2022 and 2023, eligibility was temporarily widened to include Māori and Pacific peoples from 55 to 64 years of age and children under 12 years of age.

6.59. The Committee noted that funding applications for permanent widened access for these groups have been assessed and ranked on Pharmac's Options for Investment List, and a further funding application for all children under 5 year of age was considered at this meeting.

6.60. The Committee noted that, at the time of the meeting, funded influenza crude coverage rates for people age 65 years and over were: 63% for those of NZ European or Other ethnicity, 53% for Māori, 52% for Pacific peoples and 50% for individuals of Asian ethnicity (Data to 28 July 2024).

6.61. The Committee noted that the age group with the highest uptake of influenza vaccine was 75 to 84 years of age, followed by people aged 85 years and over.

6.62. The Committee noted that as result of the 2022 Vaccines RFP, Viatris has had Principal Supply Status for Influvac Tetra from 1 February 2024. Influvac Tetra is approved for use from 6 months of age, so only one vaccine is required for all eligible people. This is in contrast to previous years, where more than one vaccine has been required to cover the whole eligible population.

6.63. The Committee noted that a number of combination vaccines combining influenza with COVID-19 or Respiratory Syncytial Virus vaccine are currently in development. The Committee requested it be able to consider funding application for combination influenza vaccines at a future meeting.

6.64. Members considered that the adjuvanted and high dose influenza vaccines would likely provide more benefit for people who are considered frail elderly and people who have complex comorbidities than all people aged 65 years and over. The Committee

considered that it would like to look at the latest evidence for the use of high dose influenza vaccine and adjuvanted influenza vaccine in this demographic at a future meeting.

COVID-19 vaccine

6.65. The Committee noted that uptake for COVID-19 vaccines remains relatively low, with 427,277 vaccinations in the last 6 months (at the time of the meeting), and noticeably lower uptake than for influenza vaccine across all age and ethnic groups.

6.66. The Committee noted the high level of wastage associated with the multidose vial.

Review of outstanding funding applications

6.67. The Committee noted that following applications have been ranked on the Options For Investment list:

6.67.1. Meningococcal Conjugate vaccine - 1 - 4 years, 14 years, 5 - 21 or 13 - 21 years

6.67.2. Influenza vaccine - Open listing, Children up to 18 years of age, People over 50 years of age, Māori and Pacific Peoples 50 to 64 years of age.

6.67.3. Recombinant zoster vaccine - People over 65 years of age who require a Shingrix catch-up at least 5 years post Zostavax, Prevention of herpes zoster and post-herpetic neuralgia, people at 50 years of age and a catch-up program for people 51 to 64 years, Māori and Pacific people aged 60 years and over for the prevention of herpes zoster and post-herpetic neuralgia, Catch-up programme due to COVID-19 pandemic disruption.

6.67.4. PCV13 vaccine - An additional dose for people 12 to 59 months of age who have been fully vaccinated with PCV10.

6.68. The Committee noted that the following application has been ranked on the cost neutral list:

6.68.1. Adjuvanted quadrivalent influenza vaccine - for people 65 years of age and over.

6.69. The Committee noted that the following applications would be considered at this meeting:

6.69.1. Recombinant zoster vaccine - Prevention of herpes zoster in adults aged 65 years and older.

6.69.2. Influenza vaccine - Children aged 5 years or younger.

Update on funding decisions made since last meeting (table)

6.70. The Committee noted that since the last therapeutic group review was considered in August 2023, three vaccines funding decisions have been made.

Vaccine	Indication	Listing Date
Zoster vaccine	The recombinant zoster vaccine (Shingrix) was funded for people 18 years of age and older that are immunocompromised.	Funded July 2024

Hepatitis B recombinant vaccine	Funded for patients prior to planned immunosuppression, if for greater than 28 days.	Funded August 2024
Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine	An additional four doses are funded for (re-)immunisation for children under the age of 18 who are post haematopoietic stem cell transplantation.	Funded August 2024

Update on previous action points

6.71. The Committee noted action points made at previous meetings and the current status of these action points.

6.72. The Committee noted that although a number of these action points were in progress or completed, there were still a number that were yet to be progressed and these would be prioritised by Pharmac staff relative to other Pharmac priorities.

NPPA applications

6.73. The Committee noted that since September 2023, Pharmac had received a small number of NPPA applications relating to immunisation. These had been for Varicella Zoster vaccine and Meningococcal B and ACWY vaccines.

Looking forward

6.74. The Committee noted that Pharmac was aware of a number of new vaccines and, where applicable, was working with the relevant suppliers to seek funding applications for these products in time for the next vaccine commercial process.

6.75. The Committee noted that a number of respiratory syncytial virus (RSV) vaccines and monoclonal antibodies are approved globally. The Committee noted that one RSV vaccine (Arexvy) is currently approved by Medsafe.

6.76. The Committee noted that 20 and 21 valent pneumococcal conjugate vaccines (PCV20 and 21) are approved overseas, but there have to date been no applications submitted to Medsafe or Pharmac for these. The Committee noted that it would like to see an application for these products.

6.77. The Committee noted again that there are several combination influenza and COVID-19 or influenza and RSV vaccines in development and reiterated it would like to review combination influenza and / or RSV vaccines at future meeting.

6.78. The Committee noted that there are a number of vaccines with alternative delivery mechanisms available in other countries or in development e.g. intranasal or dermal. The Committee signalled it would be interested in reviewing applications for vaccines with alternative delivery mechanisms.

7. Correspondence: RSVpreF3 for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus A and B subtypes in adults 60 years of age and older

Application

7.1. The Committee noted that Pharmac had received correspondence and additional information from GlaxoSmithKline (GSK) on the funding application for RSVpreF3

(Arexvy) for the prevention of lower respiratory tract disease in adults aged 60 years and older.

7.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

7.3. The Committee **affirmed its previous recommendation** that the application for RSVPreF3 vaccine for the prevention of RSV-LTRD for people aged 60 years and over be **deferred**.

7.4. In affirming this recommendation, the Committee considered that the following matters remain unresolved:

7.4.1. Insufficient evidence regarding the incidence of respiratory syncytial virus (RSV) in older people in New Zealand, specifically those aged ≥60 years in the community.

7.4.2. Uncertainty of the vaccine efficacy for people aged 80 years and over, or for people aged 65 years and over who are immunosuppressed and or have unstable chronic medical conditions.

7.4.3. Uncertainty of the vaccine's duration of protection and when revaccination would be required.

Discussion

Māori impact

7.5. The Committee noted its previous considerations on the impact of funding RSVpreF3 for the prevention of lower respiratory tract disease (LRTD) in adults aged 60 years and older on Māori health areas of focus and Māori health outcomes and had no further comments at this time.

Populations with high health needs

7.6. The Committee noted its previous considerations on the health needs for RSVpreF3 for the prevention of LRTD in adults aged 60 years and older among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee discussed the impact of funding RSVpreF3 in this setting and considered that data for specific groups (eg frail elderly, those with complex comorbidities, by ethnicity and socioeconomic status) from within the observational trial populations aged ≥65 years, if available in future, would be highly valuable to suggest the potential impact of RSVPreF3 for these subgroups. The Committee otherwise had no further comments at this time.

Background

7.7. The Committee noted that, in March 2024, the Immunisation Advisory Committee reviewed the application for RSVpreF3 vaccine for prevention of LRTD, which had a focus on prevention of RSV infection in all adults over 60 years of age with revaccination after three years. At that time, the Committee recommended it be deferred due to:

- Insufficient evidence regarding the incidence of respiratory syncytial virus (RSV) in older people in New Zealand.
- Uncertainty of the vaccine efficacy for people aged 80 years or for people aged 65 years and over who are immunosuppressed and or have unstable chronic medical conditions.

- Uncertainty of the vaccine's duration of protection and when revaccination would be required.

Health need

7.8. The Committee considered that the supplier's correspondence spoke predominantly to GSK's estimate of the epidemiology locally. The Committee considered, as in March 2024, that without good local epidemiology data for the target population, the previous estimates remain uncertain.

7.9. The Committee noted a systematic review and meta-analysis by Savic et al. (Influenza Other Respir Viruses. 2023;17:e13031) which was provided by the supplier. This aimed to estimate the RSV burden in adults ≥60 years of age in high-income countries, and the authors considered the 21 included studies to be of high quality. The reported attack rate (pooled) was 1.62% (95% CI:0.84, 3.08) for RSV-associated acute respiratory infection (ARI). The Committee noted there is variability in international estimates and considered that the GSK application and estimates appeared to be based on studies with results that fell to the right of the forest plot in this publication, ie with higher attack rates, and therefore appeared to be possible statistical outliers.

7.10. The Committee noted that the supplier had also provided data and commentary on epidemiology from the Institute of Environmental Science and Research (ESR), including the number of RSV positive cases of severe acute respiratory infection (SARI) requiring hospitalisation in Auckland between 2021-2024, which were reported by age group and for those aged 50 years and over by ethnicity. The Committee considered that this did not provide data on RSV incidence in people aged ≥60 years in the community.

7.11. The Committee was made aware of:

7.11.1. International data reporting that the largest and most severe impact from RSV is in young children (US CDC Respiratory Virus Hospitalization Surveillance Network (RESP-NET) surveillance data combined for 2023-4; Staadegaard et al. Open Forum Infect Dis. 2021;8:ofab159).

7.11.2. Local data reported from the WellKiwis cohort from 2024 week 18 (cases since 29 April 2024) in which there were 11 adult cases of RSV in the community, but greater numbers in infants (75 cases) and among participating households (families) that include a large number of children (192 cases).

7.12. The Committee considered that the supplier-provided estimates for ARI incidence (58.3/1000; 30.5/1000 for upper respiratory tract infection [URTI] and 27.8/1000 for lower respiratory tract infection [LRTI]) were higher than that reported in the key clinical trial by Papi et al. (N Engl J Med. 2023;388:595-608) of 37.0/1000/year and 18.5/1000/year for URTI and LRTI respectively, and were higher than that reported (16.2/1000) in the Savic et al. systematic review and meta-analysis above.

7.13. The Committee considered that there remains insufficient evidence regarding the incidence of RSV in the target population in New Zealand, although some relevant data is emerging such as that from the WellKiwis and SHIVERS – V studies. Members noted that upcoming changes in criteria for laboratory testing for respiratory viruses (eg testing all cases in emergency departments of likely respiratory tract infection vs testing only severe cases) will impact laboratory-generated data for both virus positivity and the population tested (denominator).

7.14. The Committee considered that its March 2024 meeting record did not fully capture the Committee's consideration at the time that the burden of RSV disease in New Zealand (particularly amongst infant populations) requires immunisation against RSV to be considered as a complete strategy across the whole population. The Committee

considered that reducing the burden of RSV in young children would reduce the risk for older adults. Members considered that another part of a strategy could be a more targeted approach to vaccination of those ≥65 years of age (eg frail elderly, those with complex comorbidities).

Health benefit

7.15. The Committee noted the following international recommendations made since the last review and considered that these reinforced the appropriateness of the Committee's previous recommendation to defer this application for the target population:

- The PBAC in Australia reviewed RSVPreF3 for the same indication in July 2024 and did not recommend it, noting that the incremental cost-effectiveness ratio was unacceptably high and uncertain for adults ≥60 and ≥75 years of age.
- The US CDC released updated recommendations in August 2024 following a previous recommendation to fund RSV vaccination using shared clinical decision-making. The new recommendation was for a single dose of any FDA-approved RSV vaccine (including Arexvy) for all adults aged ≥75 years of age and for adults aged 60-74 years who are at increased risk for severe RSV disease. For adults who have previously received RSV vaccine, another dose is not recommended.

7.16. The Committee considered that there was a paucity of data relating to individuals with immunosuppression or chronic disease.

7.17. The Committee noted unpublished summary results (as a Powerpoint presentation) of RSV observational studies presented to the US CDC's Advisory Committee on Immunization Practices' (ACIP) 26- 28 June 2024 meeting).

7.17.1. The slides discussed some limitations of RSV vaccine trials, where the randomised controlled trials (RCTs) included fewer than 8% patients being aged ≥80 years, <52% had any chronic condition, and the outcome was symptomatic RSV-associated disease. The Committee considered that the observational studies included more of the relevant populations and considered that medical presentations and hospitalisations (especially severe) would be more relevant outcomes for New Zealand estimates.

7.17.2. The slides reported vaccine efficacy (from the RCTs) and effectiveness (from the observational studies) for several vaccines. The Committee considered that the observational trials reported similar results to those in the pivotal trials. However, the Committee considered there were some limitations of the observational studies:

- The data sets appear immature, noting the median duration post-vaccination was three to four months and thus insufficient to determine effectiveness beyond one season.
- Uptake was 5-10% in the study populations, likely including early adopters of new vaccines who potentially have different health-seeking behaviours.
- Methods were used to minimise bias, but bias from unmeasured confounding may remain.
- Definitions of immunocompromise varied across studies and studies were not powered to assess vaccine effectiveness for specific types of immunosuppression.

7.18. The Committee considered that relevant data will be forthcoming in future from studies such as AReSVi-023 (NCT05921903), a randomised trial investigating the

safety and immunogenicity of one or two doses of the vaccine in lung and kidney transplant recipients aged ≥50 years.

7.19. The Committee noted that the application had assumed revaccination at three years. The Committee noted previously reviewed data from the AreSVi-006 study reporting there was no difference in vaccine efficacy with revaccination for the second season compared with a single dose (Ison et al. Clin Infect Dis. 2024 :ciae010). The Committee noted that unpublished data from the same study provided by the supplier indicated that vaccine efficacy had not decreased further at the end of the second season in the single dose group. The Committee considered that this also suggests that the vaccine protection against RSV may be in the range of years, which is different to that from seasonal influenza vaccines and from COVID-19 vaccination.

7.20. The Committee noted that revaccination led to changes in humoral immune response (RSV-A and RSV-B neutralising titres) and cell-mediated immune response (RSVPreF3-specific CD4+ T-cells) in the AreSVi-004 study (unpublished data, supplied). However, the Committee noted that unpublished data from the AreSVi-006 study indicated that this does not translate to vaccine efficacy and that the supplier has stated that there are no current correlates of immunity. The Committee considered that the clinical meaning of this would not become clear until further data were available in a peer-reviewed publication.

7.21. Members noted that the updated data suggested that there was no increase in cases of Guillain-Barre syndrome, and were made aware of some international assessments of this data that have concluded that there is not a true safety signal regarding the syndrome.

7.22. The Committee considered that it is possible that a future RSV vaccination strategy might involve the use of various types of RSV immunisation (mRNA vaccines, protein subunit vaccines or monoclonal antibodies) although there is no data to inform this yet. The Committee considered that treatments such as RSVpreF3 (Arexvy) and monoclonal antibodies could be considered as parts of that strategy.

Cost and savings

7.23. The Committee considered that, similar to the supplier-provided estimates for ARI incidence, the supplier's cost utility analysis (CUA) estimates for medical visits, emergency department (ED) visits, hospitalisation and death were all higher than would be expected based on the available literature. The Committee considered that a CUA undertaken in the UK to reflect the New Zealand population (which was considered at the previous meeting in March 2024) also used much higher estimates for hospital admissions and death.

7.24. The Committee considered it reasonable to use New Zealand data where it exists, which relates to hospitalisations and death from the SHIVERS cohort in adults aged ≥65 years.

7.25. The Committee was made aware that in 2021, RSV became a notifiable disease in Australia and testing for it has increased with triple testing (for COVID-19, RSV and influenza). The Committee was made aware of country-wide data available from 2023 which reported the rate of medically notified ARI as of August 2024 was 4.4/1000 (National Notifiable Diseases Surveillance System, NNDSS). The Committee considered this represented general practitioner (GP) or ED visits with RSV in this population. The Committee noted that this is less than all other estimates of medical visits and considered this more relevant data to use for New Zealand estimates, acknowledging it will likely be an underrepresentation.

Summary

7.26. The Committee considered that the vaccine appeared effective, although the magnitude of benefit and optimal targeting for cost-effectiveness were unclear. The Committee considered at this time, the recommendation to defer the application remained reasonable and was consistent with other interpretations of the data. The Committee considered that the reasons for the original deferral were not yet resolved, and the following specific uncertainties remained:

7.26.1. A lack of robust New Zealand epidemiology, especially for older people aged ≥60 years in the community.

7.26.2. Data regarding those aged ≥80 years, with unstable chronic disease and with immunosuppression. The Committee considered that maturity of evidence regarding protection and from further RCTs in specific subgroups was required, given the short-term follow-up in the observational studies with early uptake.

7.26.3. The duration of protection was still uncertain, and maturation of data was awaited including peer-reviewed publication.

7.27. The Committee considered that further information specifically addressing these remaining areas of uncertainty would be welcome and encouraged the supplier to consider reporting data for specific groups (eg frail elderly, complex comorbidities, by ethnicity and SES status) from within the observational trial populations aged ≥65 years, if feasible.

8. Matters arising: Considerations for age-based vaccination with Recombinant Zoster Vaccine

Application

8.1. The Committee noted that Pharmac sought the Committee's advice on the most appropriate age/s (most effective, least safety concerns) to vaccinate older adults with recombinant zoster vaccine (RZV) for the prevention of the shingles and post-herpetic neuralgia.

8.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Discussion

8.3. The Committee noted the Kawai et al. BMJ Open. 2014;4:e004833 study which reported a positive non-linear relationship between incidence of herpes zoster and age, in which incidence significantly increases after the age of 50 years old.

8.4. The Committee noted that Ministry of Health data for 2018/2019 reports 483 hospitalisations were associated with herpes zoster and 60% of the cases were among adults aged 60 years and older (Health New Zealand Immunisation Handbook, accessed 2/10/2024). The Committee considered that there is also a significant number of herpes zoster associated hospitalisations among adults aged 50-59 years old.

8.5. The Committee noted the long-term durability data for recombinant varicella zoster vaccine (RVZV) from the extension study of the ZOE-50 and ZOE-70 trials.

8.5.1. The Committee noted the average age of a person at first vaccination was 67 years old, and considered that to be relevant, as through the extension phase of the study the risk of disease would be expected to be greater due to immunosenescence.

8.5.2. The Committee noted the data up to year 8 of the extension study reported by Boutry et al. Clin Infect Dis. 2022;74:1459-67:

- The vaccine efficacy was estimated from the historical disease frequency for the placebo group from the ZOE-50 and ZOE-70 studies. Eight years post-vaccination the vaccine efficacy was 84.1% (95% CI 64.4, 94; p<0.001).
- In the ZOE-50 and ZOE-70 trials the humoral immune response measured as anti-glycoprotein E antibody geometric mean concentration was 1320.5 mIU/mL (95% CI, 1253.6–1391.0) pre-vaccination and 17,296.9 mIU/mL (95% CI 16 614.7– 18 007.1) one-year post-vaccination. Five years post-vaccination the concentration was 8053.5 mIU/mL (95% CI 7239.3–8959.4) and this concentration had persisted for the duration of the study (8-years).
- In the ZOE-50 and ZOE-70 trials the cell-mediated immune response measured as the median anti-glycoprotein E CD4+ T-cell frequency (whereby those T-cells expressed 2 or more of the 4 activation markers measured) was 89.8 (interquartile range [IQR], 1.0–202.4) pre-vaccination and 799.9 (IQR 454.3–1277.3) one-year post-vaccination. Six years post-vaccination the concentration was 652.4 (IQR 314.3–1293.0) and this frequency persisted for the duration of the study (8-years).
- The Committee considered the Power Law model reported by Hastie et al. J Infect Dis. 2021;224:2025-34 was comparable to the observed humoral and cell-medicated immune response during the 8-year follow-up period and may be an appropriate model to estimate the humoral and immune response with time.

8.5.3. The Committee noted the data up to year 10 of the extension study reported by Strezova et al. Open Forum Infect Dis. 2022;9:ofac485:

- Ten years post-vaccination the vaccine efficacy was 73.2% (95% CI 46.9, 87.6; p<0.001).
- Ten-years post vaccination the anti-glycoprotein E antibody geometric mean concentration was 6391 mIU/mL (confidence intervals not reported) and whilst numerically had decreased the concentration continued to persist at levels 5-fold greater than those pre-vaccination.
- The antigen-specific CD4+ T-cell continued to persist at levels comparable to six-years post vaccination.

8.6. The Committee noted the Hastie et al. 2021 study used statistical modelling to estimate the recombinant varicella zoster vaccine efficacy with time.

8.6.1. The Committee observed that the statistical models estimating the ten-year post-vaccination humoral and cell-mediated immune responses to the recombinant varicella zoster vaccine either underestimated or reported comparable results (Boutry et al. 2022, Strezova et al. 2022, Hastie et al. 2021).

8.7. The Committee considered that there to be high-quality evidence that the recombinant zoster vaccine provides clinical protection to older adults, which is backed by evidence of serological and cell-mediated immune protection out to ten years.

8.8. The Committee considered there to be high-quality evidence supported by the subsequent extension phase studies that indicates there is a slow decline in the humoral and cell-mediated immune response that is estimated to exceed 20 years and that the Power of Law model is appropriate to estimate the vaccine waning rate.

8.9. The Committee considered that there is a clear benefit in vaccinating adults of any age, however, the optimal timing when considering the Pharmac cost-utility estimates would be between the ages of 65-74 years.

8.10. The Committee considered that currently unvaccinated older adults are at significant risk of herpes zoster infection and should be offered the vaccine. The Committee considered that the recombinant zoster vaccine is an effective vaccine protecting adults aged 80 years and over against herpes zoster infection, post-herpetic neuralgia and herpetic zoster ophthalmitis.

8.11. The Committee considered that cost-utility estimates for the 55-64-year-old age bracket was slightly lower compared to the 65-74-year-old age bracket, but that this age group would also benefit from vaccination considering the high rate of herpes zoster associated hospitalisations.

9. Influenza vaccine for children aged 5 years or younger

Application

9.1. The Committee noted that Pharmac staff sought the Committee's advice specifically regarding the health need of children aged five years and under with regard to influenza vaccination.

9.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

9.3. The Committee **recommended** that the influenza vaccine be funded for children aged five years and under with a **high** priority, within the context of vaccines and immunisation.

9.3.1. In making this recommendation, the Committee considered the following:

9.3.1.1. The high burden of disease from influenza in children aged five years and under, and the impact for those under one year of age in particular.

9.3.1.2. Evidence of vaccine effectiveness with a meaningful reduction in hospitalisations.

9.3.1.3. The cost of hospitalisations for influenza in children under one year of age.

9.3.1.4. Challenges that need to be overcome to facilitate implementation, including suitability considerations such as:

- Consideration for route of administration for influenza vaccines, as funded influenza vaccines are injected intramuscularly or deep subcutaneously.

- The impact of increasing the number of injections and visits for the Childhood Immunisation Schedule, which particularly affect younger children and their caregivers.

9.4. Members considered that children aged five to 18 years with liver disease were a high-risk group that had been inadvertently omitted from the previously recommended criteria (targeting access to the influenza vaccine to those with diseases requiring specialist care or otherwise with comorbidities placing them at risk of severe sequalae with influenza). Members considered that Pharmac should include these individuals in the current funding access criteria for influenza vaccine (ie aside from and separate to funding all children aged five years and under).

Discussion

Māori impact

9.5. The Committee discussed the impact of funding the influenza vaccine for children aged five years and under on Māori health areas of focus and Māori health outcomes. The Committee noted that Māori are among those who experience the highest burden from influenza and generally experience a range of barriers to accessing healthcare. Young Māori children are amongst those at highest risk of severe illness (Immunisation Advisory Centre (IMAC). Role of vaccination in influenza control strategies. 2022). Members considered that, due to these barriers, some Māori caregivers/whānau would not have a full awareness of vaccines that are funded for their pēpi/younger tamariki.

9.6. The Committee considered there is a need to better work with Māori in the community with vaccines and support families/whānau to access vaccines where barriers may exist, both of which would require cross-agency efforts. The Committee considered that targeting access to influenza vaccination with a mechanism such as family-based funding would be a useful strategy to convey benefits to Māori.

Populations with high health needs

9.7. The Committee discussed the health needs, in relation to funding the influenza vaccine, of children aged five years and under among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs.

9.7.1. The Committee noted that Pacific people are severely impacted by influenza and experience the highest hospitalisation and intensive care unit (ICU) rates associated with severe acute respiratory infection (SARI), and that young children of Māori or Pacific ethnicity and those living in poverty are at highest risk of severe illness. The Committee noted this meant young Pacific children are amongst those at highest risk of severe illness.

9.7.2. The Committee noted that, among infants living in South Auckland, those of Māori ethnicity were nine times more likely to present at a hospital emergency department (ED) with influenza than children of NZ European/Other ethnicity, and ten times more likely if they were of Pacific ethnicity. Both Māori and Pacific ethnicities were nine times more likely to be hospitalised with influenza. Infants domiciled in the most socioeconomically deprived areas were four times more likely to present at ED with influenza than those in the least deprived areas. Infants aged six to 11 months had a six times higher rate of influenza-related ED presentation than infants aged under two months (IMAC. 2022)

9.7.3. The Committee considered that population groups who are underserved by the health system would experience a range of barriers to accessing healthcare including vaccinations and would experience a high impact of influenza.

Background

9.8. The Committee noted that in February 2013, the Immunisation Subcommittee (now Advisory Committee) had recommended the influenza vaccine be funded for children up to 18 years of age and adults 50 years of age and over, with a high priority, noting the high-strength evidence that influenza vaccination improves health outcomes by reducing transmission, hospitalisation and death.

9.9. The Committee noted that in May 2022, the Immunisation Advisory Committee made the same recommendation upon review of the evidence including a review from the Immunisation Advisory Centre (IMAC). The Committee noted that the review had

provided insights into potential immunisation strategies across all age groups and particularly in children.

9.10. The Committee noted that Pharmac has ranked a proposal to fund the influenza vaccine for children up to 18 years of age on the Options For Investment list.

9.11. The Committee considered there was value in exploring other strategies to better reach those who could benefit from influenza vaccination and to overcome barriers related to funding constraints (eg funding for family-based or community-based administration to enable whole groups to be vaccinated at one time; targeting preschool and school-aged children who are predominantly transmitting influenza; seeking to fund other formulations; and considering a broader vaccination strategy for respiratory viruses expected to circulate annually). However, the Committee noted that Pharmac staff sought advice from the Committee specifically regarding children aged five years and under at this time.

Health need

9.12. The Committee noted that children have a greater likelihood of acquiring influenza infection and developing influenza illness. Those aged under five years, and particularly under two years, are most susceptible to being hospitalised with severe acute respiratory illness (SARI) associated with respiratory viruses, including influenza.

9.12.1. The Committee further noted that the greatest burden from influenza in New Zealand is seen in children aged five years and under in Pacific and Māori populations, based on good local epidemiological evidence.

9.13. The Committee noted recent data from the Institute of Environmental Science and Research (ESR) reporting hospitalisation and ICU rates for people with SARI by age group and by ethnicity (ESR respiratory illness dashboard, accessed 31 July 2024). These data reported the following:

9.13.1. Children aged zero to four years have the highest rates of hospitalisation due to SARI and the highest ICU rates for hospitalised influenza-positive SARI cases compared with other age groups.

9.13.2. The highest hospitalisation rates in the overall population (not reported by age group) with SARI were in Pacific people followed by Māori, and the highest ICU SARI rates were in Pacific people.

9.14. The Committee considered that children aged five years and under have different health needs to children of school or preschool age, and infants (those under one year of age). Infants are especially vulnerable to severe illness from influenza that requires hospitalisation. The Committee further noted that for the purposes of this discussion, those of preschool age were being described as one group (ie children five years of age and under) but considered that this did not capture significant differences in the impact of influenza among children within this age range. The Committee was made aware of ESR surveillance data on laboratory-confirmed influenza in hospital and community SARI (ESR 2024) that reported the following:

9.14.1. Children under one year of age are predominantly reported to have influenza-positive SARI requiring hospitalisation compared with community illness, with higher rates of positive illness in hospital than those aged between one and four years.

9.14.2. In those under one year of age, the rate of hospital SARI is higher than the rate of community illness. Whereas in children aged one to four years whose immune systems have likely encountered influenza before and are therefore less likely to have severe disease, the rate of those with illness in the

community far outweighs the rate of those hospitalised and this gap widens further in those aged five to 19 years.

9.15. The Committee considered that these data on hospitalisation and ICU rates provided evidence that children aged five years and under, with the greatest impact in children under one and those of Pacific and Māori ethnicity, experience the highest burden of disease from influenza. The Committee considered that influenza also affects families substantially, including parental absence from work to care for a sick child.

9.16. The Committee considered that there is suboptimal protection offered to infants under six months of age due to low rates of maternal influenza vaccination and that the current approach to target young children at high risk for influenza vaccination is also suboptimal.

Health benefit

9.17. The Committee noted that the evidence had not changed significantly since the IMAC evidence review, as reviewed by the Committee in May 2022.

9.18. The Committee noted the 2018 Cochrane review of influenza vaccination included data for children aged three to 16 years, and considered that younger children were most likely omitted due to a paucity of data as opposed to a lack of effect (Jefferson et al. Cochrane Database Syst Rev. 2018;2:CD004879). The Committee considered vaccination to be effective at preventing individual disease in younger children also.

9.19. The Committee noted that Jefferson et al. reported effectiveness of 50% against hospitalisation for influenza in those aged between six months and 16 years. The Committee considered this very meaningful in terms of the broader impact and cost of influenza given the large number of people affected each year.

9.20. The Committee noted that the IMAC summary of this Cochrane review indicated the number needed to treat (NNT) with an inactivated influenza vaccine to prevent one case of influenza in very young children aged two to 16 years was five; this was the smallest NNT (ie greatest gain per treatment) among the reported age groups for influenza, and members considered this NNT small (ie the gain large) in general compared with other diseases.

9.21. The Committee considered that the evidence overall was very generalisable to the New Zealand context, noting that:

9.21.1. There is good epidemiological data in New Zealand.

9.21.2. Influenza vaccine coverage in New Zealand children is suboptimal.

9.21.3. There are similarities between our health system and those where the studies were conducted.

9.21.4. Studies including older children of school age may dilute the relevance of this evidence for the group of children aged five years and under given the impact and risks associated with influenza in the younger group is different.

9.22. The Committee was made aware of evidence from the UK of high rates of transmission to children under one year of age from older siblings attending preschool or school (Hardelid et al. Eur Respir J. 2017;50:1700489). The authors reported that:

9.22.1. The study included a large cohort of children under two years of age of which 85% did not have a comorbidity or other factors putting them at increased risk of morbidity from respiratory tract infections.

9.22.2. Having one older sibling doubled the risk of hospitalisation with lab-confirmed influenza, and the risk incrementally increases for the infant under one year of age with each additional sibling.

9.22.3. Members considered this was relevant indirect evidence that suggests a higher risk for children under one year of age in larger families, and that targeting those with underlying illness may not be an effective strategy alone.

9.23. The Committee noted additional evidence identified by a Pharmac staff literature search: Esposito et al. Pediatr Infect Dis J. 2020;39:e185-91; Patel et al. Vaccine. 2020;38:608-19; Kalappanavar et al. Hum Vaccin Immunother. 2022;18:2104527.

Suitability

9.24. The Committee noted that the initial immunisation for this group consists of two intramuscular injections within the first year, then subsequent years require one injection.

9.25. The Committee considered that Pharmac could proactively look for other delivery formulations such as an intranasal formulation (especially if it were to utilise cell-based technology) for this population, as a non-injectable formulation may help to facilitate better suitability for this population.

Implementation

9.26. The Committee considered that there are challenges that would take considerable effort to overcome in order to deliver influenza vaccines to children five years and under, including:

9.26.1. The need for annual seasonal vaccination, which is not required for vaccination against most other diseases.

9.26.2. How this could complement the childhood immunisation schedule in terms of timing and avoiding an adverse impact on other childhood immunisations.

9.26.3. Fit with the overall Influenza Control Strategy and management of respiratory syncytial virus (RSV).

9.26.4. The public perception that influenza is not a severe disease.

9.26.5. That the vaccine cannot be administered in the first six months of life (at an age affected by the highest hospitalisation rates).

9.27. The Committee considered successful vaccination of children 5 years of age and younger to reach target immunisation rates would require a substantial clinical and public health services' effort including; clear messaging around annual vaccination, health promotion, vaccinator confidence and relationships with parents/caregivers/whānau, effective pre-call and recall, public education and community partnership around influenza and its severity for young children.

9.28. The Committee considered that implementation may be best achieved over the longer term and that funding for children five years of age and younger would target those at high risk.

9.29. The Committee considered there is a need to better reach Māori in the community with vaccines and support families/whānau to access vaccines where barriers may exist, both of which would require cross-agency effort.

9.30. The Committee considered that the actual implementation of funded access for children aged five years and under would present a barrier to sound group vaccination from a clinical perspective (eg funded for young children but not older siblings who may attend as a family group, which would be additionally difficult for

families the health sector fails to reach with funded vaccines) and considered additional funding mechanisms should be explored.

Cost and savings

9.31. The Committee considered that the Australian PBAC estimates of influenza vaccine uptake in children aged six months to four years (Public Summary Document. PBAC, 2022), which increased from 30% at year one to 50% at year five, would not be appropriate to use as proxies for likely uptake of influenza vaccine in this target group for New Zealand. The Committee noted that 10-15% is currently the highest uptake regionally in this young population (many regions have much lower coverage) and that, while the vaccination rates would have an upper limit, a baseline of 10% increasing to 30% uptake would be a more realistic target to aim for in the short term.

Summary for assessment

9.32. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for the influenza vaccine if it were to be funded in New Zealand for children aged five years and under. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	Individuals aged 5 years and younger who are not already eligible for funded influenza vaccination under the current access criteria (i.e., aged 5 years or younger with at least one of the specified conditions for those under 65 years of age, or aged 4 years or younger and previously hospitalised for respiratory infection or with history of significant respiratory infection).
Intervention	Influenza vaccine, administered annually (once per influenza season) as an intramuscular injection, and in a dosing, schedule as follows: • Two doses, not less than one month apart, if the vaccine is being administered for the first time. One dose for all other individuals
Comparator(s)	No vaccination
Outcome(s)	Reduction in the risk of influenza infection Reduction in the risk of severe influenza and hospitalisation • A Cochrane meta-analysis reported that inactivated influenza vaccines reduced the risk of influenza infection in children aged 3 to 16 years (RR 0.36 [95% CI 0.28 to 0.48]) (Jefferson et al. Cochrane Database Syst Rev. 2018;2:CD004879). • The effective level of protection from influenza vaccination in any given year is dependent on the match of vaccine antigens to circulating strains. • 50% efficacy against hospitalisation in those 6 months to 16 years of age.
Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.	

10. COVID-19 vaccine eligibility consideration for healthcare workers

Application

10.1. The Committee considered COVID-19 eligibility for health care workers.

10.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

10.3. The Committee **recommended** that eligibility for additional doses of COVID-19 vaccine(s) be **widened** to health care workers currently not eligible (due to age-related eligibility).

10.4. In making this recommendation, the Advisory Committee considered:

10.4.1. the health need of health care workers caused by the risk of occupational exposure to SARS-CoV-2 and the absence of a private market for COVID-19 vaccines.

10.4.2. the additional health benefit of COVID-19 vaccination, especially with reduced use of other preventative measures, including reducing the risk of acute illness and Long Covid for health care workers.

10.4.3. there is insufficient evidence that COVID-19 vaccination reduces transmission, it is plausible that vaccinating all health care workers (regardless of age-related eligibility) may reduce the risk of healthcare-acquired SARS-CoV-2 infection.

10.4.4. that publicly funded COVID-19 vaccination for health care workers may promote equitable uptake and access to COVID-19 vaccination, compared to employer-dependent access through the private market.

Discussion

Māori impact

10.5. The Committee discussed the impact of funding additional doses of COVID-19 vaccine(s) for health care workers on Māori health outcomes. The Committee was not aware of any particular group of health care workers who were experiencing inequitable health outcomes associated with COVID-19, but noted that the lack of available evidence did not exclude the possible presence of health inequity in this setting. The Committee noted that communicable disease and vaccination is not a part of Pharmac | Te Pātaka Whaioranga's Hauora Arotahi (Māori health areas of focus).

Populations with high health needs

10.6. The Committee discussed health needs of health care workers not meeting current COVID-19 vaccine eligibility criteria including those who are Māori, Pacific peoples, disabled including tāngata whaikaha Māori, and in other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee was not aware of any particular group of health care workers who were experiencing inequitable health outcomes associated with COVID-19, but noted that the lack of available evidence did not exclude the possible presence of health inequity in this setting.

Background

10.7. The Committee noted it previously considered the health need of groups eligible for COVID-19 vaccination at its November 2023 meeting, and at that time considered that front-line health care workers were more likely to catch COVID-19 from community exposure than in an occupational setting, due to the protection from their use of personal protective equipment (PPE) and other infection control measures.

10.7.1. At the same meeting, the Committee considered that if front-line health care workers were using PPE correctly, routinely and consistently, then this was not a group at an elevated risk of occupational exposure to SARS-CoV-2.

10.7.2. Members noted now, however, that currently the use of PPE is limited and therefore the risk of transmission likely higher than during the peak of the pandemic when PPE usage was greater.

10.8. The Committee noted that currently, the lower age of eligibility for a funded additional dose (booster) of COVID-19 vaccine is 30 years, with exceptions for people younger who are considered at high risk of severe disease. The Committee noted at its November 2023 meeting, it recommended that that the lower age of eligibility for COVID-19 vaccination be lifted to 65 years for people not at higher risk of severe disease; to 50 years for Māori and Pacific peoples; and that outside of these age-based criteria, people would be eligible if they had health conditions that put them at higher risk of severe disease, were disabled, or had serious mental health conditions, or were pregnant.

10.9. The Committee noted that in May 2024, Pharmac received a letter from the Immunisation Advisory Centre (IMAC) requesting that all health care workers be given funded access to COVID-19 vaccination. IMAC noted that most people aged under 30 years were not currently eligible for publicly funded COVID-19 vaccination and there was currently no option to receive access through the private market. IMAC noted that while the use of PPE had decreased the risk of occupational exposure earlier in the pandemic, many health care workplaces no longer require the uniform use of PPE, therefore increasing the risk of occupational exposure. IMAC considered that the short-term protection (3-4 months) provided by COVID-19 vaccines against symptomatic disease and the reduced risk of severe disease would be beneficial for health care workers, and any reduction in illness-related absenteeism in that group would be of benefit to the health system. The Committee noted that the COVID-19 vaccination was previously mandatory for healthcare workers.

10.10. The Committee was made aware of provisional 2023 data from the US Centers for Disease Control which showed higher rates of death due to COVID-19 than to influenza (source unconfirmed). The Committee noted that in contrast to the mortality data, there is a higher uptake of funded influenza vaccine dispensed than COVID-19 vaccine dispensed in New Zealand. The Committee considered that unlike influenza, COVID-19 so far appeared to have both summer and winter peaks, and limited seasonality (Te Whatu Ora. 2024).

10.11. Members noted that internationally:

10.11.1. The Australian Technical Advisory Group on Immunisation (ATAGI) has stated (March 2022) that it does not consider there to be sufficient evidence of benefit to recommend additional boosters in occupational groups, such as workers in aged care, residential care or health care. ATAGI based this on evidence suggesting that: protection from booster doses against transmission of the Omicron variant may be short-lived; exposure of health care workers occurs more frequently in the community than in the workplace with appropriate PPE; direct protection by boosters for [hospital] patients and [aged care] residents was more beneficial [than indirectly by vaccinating health care workers to reduce transmission]; and maintaining infection control procedures is important to minimise transmission.

10.11.2. The United Kingdom Joint Committee on Vaccination and Immunisation (JCVI) in August 2024 changed its previous recommendations on health care workers living and/or working with vulnerable people, and now did not recommend they be vaccinated in the UK Autumn 2024 rollout. The JCVI considered: additional doses of available COVID-19 vaccines provide moderate protection against severe COVID-19 for a few months but only short term (weeks') duration of protection and peak protection against symptomatic infection; an absence of good scientific data on the added protection against transmission of infection

in the era of Omicron sub-variants, with JCVI anticipating that any such protection would be extremely limited; and therefore the indirect benefit of vaccinating an individual in order to reduce the risk of severe disease in other people is less evident now compared with previous years.

10.11.2.1. The JCVI also commented it does not consider aspects of occupational health programmes in its cost effectiveness methodology, and that health and social care service providers may wish to consider whether COVID-19 vaccination provided as an occupational health programme is appropriate.

10.12. Members noted that Health New Zealand | Te Whatu Ora hospitals and private providers had obligations under the Health and Safety at Work Act 2015 (HSWA) for the safety of workplaces (including health care facilities). This extends to vaccination and other infection control measures for staff (eg face masks, PPE). Obligations include the protection of other persons (eg hospital patients) against harm arising from work and/or workplaces, including serious infection attributable to work treating or caring for a person (HSWA sections 3, 5, 17, 20, 23(1)(d)).

Health need

10.13. The Committee considered that previously the uptake of an additional dose (booster) of COVID-19 vaccine(s) had declined and this had been observed across all eligible demographic groups (Te Whatu Ora. COVID-19 vaccine data. 2024. [Accessed 2 September 2024]). No data were available on the current uptake of COVID-19 vaccine boosters in eligible health care workers.

10.13.1. Members noted Ministry of Health estimates of 213,100 people employed in hospitals, medical and other health care services, and residential care services, and other estimates of 48% of nurses being aged less than 50 years, with 14% aged under 30 years.

10.13.2. Members considered that, within health care occupational groups, exposure to SARS-CoV-2 at work would vary according to how much air was shared, the number of contacts with other people, and room ventilation.

10.14. The Committee considered that health care workers have the potential to spread COVID-19 to people who are vulnerable to severe outcomes of COVID-19.

10.14.1. Members noted that people who are hospitalised or in aged residential care are particularly vulnerable to severe outcomes from COVID-19 disease. Members noted Australian data reporting 11% of cases hospitalised with COVID-19 in most of 2020 were hospital-acquired (i.e. one hospital-acquired case of COVID-19 out of every nine patients hospitalised with COVID-19), where hospital-acquired COVID-19 in hospitalised people has likely has poorer outcomes than community-acquired COVID-19 (Veale et al. Victorian Department of Health, 2021).

10.15. The Committee considered that there is currently a shortage of health care workers in New Zealand, and COVID-19 occurring in these workers disrupts the provision of health services. The Committee noted that the health need among health care workers not currently eligible for additional doses of COVID-19 vaccine may have increased in recent times, due to reduced requirements for and use of PPE and the subsequent increased risk of occupational exposure to SARS-CoV-2.

10.16. The Committee considered that due to the short duration of protection against symptomatic infection and the ongoing emergence of new variants, health care workers may need three- or six- monthly boosters.

10.17. The Committee considered that, given the current access criteria, there is an unmet health need for individual health care workers, their patients, and for the health system. The Committee considered that this health need is hard to measure, but would be higher if the lower age limit of eligibility for COVID-19 was raised in line with the Committee's November 2023 recommendations. The Committee considered that people working in hospitals and aged residential care facilities are more likely to spread COVID-19 to more vulnerable populations, as are people who have extended contact time with or have contact with high numbers of vulnerable people, in addition to spread to vulnerable people when cared for in poorly ventilated spaces. Vulnerable people included the elderly (both hospital patients and aged care residents), oncology patients and hospital patients with cardiometabolic disorders.

10.17.1. The USA and Canada recommend all adults stay up-to-date with COVID vaccine, so do not have special recommendations for health care workers

10.18. Members noted a 2020 report by the Ministry of Health on COVID-19 in health care and support workers in New Zealand, which described how most cases in health care workers were in those in aged residential care settings and very few were in community health care settings (Ministry of Health. 2020).

10.19. The Committee considered the ethical implications of narrowing access to funded COVID-19 vaccines and noted that in the absence of a private market, people ineligible for publicly funded COVID-19 vaccination currently do not have an alternative. The Committee considered this was a distinct situation from influenza vaccination, where employer-dependent access through the private market (via occupational health services) meant that people ineligible for publicly funded influenza vaccination still had the option of receiving the vaccine either from their employer or self-funded.

10.20. The Committee considered that the introduction of a private market for COVID-19 vaccination for health care workers may lead to inequitable access to vaccination, related to costs borne by workers and dependent on the worker's particular employer's approach to providing or reimbursing the costs of occupational COVID-19 vaccinations. The Committee noted that annual influenza vaccinations for health care workers are funded by individual employers (public or private health providers) using stock from the private market. (Committee also questioned whether this approach was more cost-effective for taxpayers than Pharmac funding, while noting the issue of separate budgets would also need to be addressed)

10.21. The Committee considered that COVID-19 disease was causing a larger burden to the health system and was likely to be resulting in a higher unmet health need among health care workers and their patients than influenza (based on higher disease burden reported from USA).

Health benefit

10.22. The Committee noted that vaccine effectiveness has progressively decreased with the emergence of new variants, and this decrease has been faster since the advent of Omicron variants (Lin et al. N Engl J Med. 2024;390:2124-7, Althaus et al. BMC Med. 2024;22:227, Braeye et al. Vaccine. 2023;41:3292-300, Oord-Speets et al. COVID. 2023;3:1516-27). The Committee considered that vaccine effectiveness against infection wanes within approximately 3 months, dependant on the vaccine and virus 'match' (Link-Gelles et al. MMWR. 2024;73:77-83; Lin et al. 2024; Bloomfield et al. Emerg Infect Dis. 2023;29:1162-72). However, the Committee noted that observational data on the duration of vaccine effectiveness varies, there is limited data on the XBB vaccine, and little to no data regarding effectiveness against the latest COVID-19 variants. The Committee noted that vaccine effectiveness is higher for severe outcomes than for reducing infection/spread (Lin et al. 2024).

10.23. The Committee noted that bivalent boosters have demonstrated higher effectiveness against COVID-19 infection when combined across all ages with an absolute vaccine effectiveness (VE) of 53.5 % (95 % CI: 22.2–82.3 %) when compared with no vaccination, and relative VE of 30.8 % (95 % CI: 22.5–38.2 %) and 28.4 % (95 % CI: 10.2–42.9 %) when compared with ≥2 and ≥3 primary monovalent doses, respectively (Song et al. Vaccine. 2024;42:3389-96).

10.24. The Committee noted results of a cohort study conducted in China assessing VE of the inactivated vaccine against the BA.5 COVID-19 variant (Wang et al. JAMA Netw Open. 2023;6:e235755). The Committee noted the vaccine exhibited a VE of 48.5% (95% CI, 23.9%-61.4%) for 15-90 days after the booster dose but no protective outcome was detected beyond 90 days after the booster dose.

10.25. The Committee noted the most common adverse effects associated with COVID-19 vaccines are short-term vaccine reactions associated with an immune response to the vaccine (Medsafe. 2022, Faksova et al. Vaccine. 2024;42:2200-11). The Committee considered myocarditis is the serious if rare adverse effect associated with COVID-19 vaccination, noting incidence of COVID-19 vaccine-associated myocarditis is highest for teenagers (Faksova et al. 2024), but higher still with SARS-CoV-2 infection by wild SARS-CoV-2.

10.26. The Committee considered there is insufficient data to conclude if there are populations of health care workers that may benefit more from vaccination than others. However, the Committee considered that the population effect of vaccinating health care workers should be considered in addition to considerations surrounding individual protection.

10.27. The Committee considered the available evidence that COVD-19 may provide a health benefit to health care workers, compared with other protective measures, by reducing the risk of acute illness and Long Covid. The Committee considered that, although the evidence that COVID-19 vaccination reduces COVID-19 transmission is of very low strength and quality, it is plausible that COVID-19 vaccination for health care workers may reduce the risk of hospital-acquired SARS-CoV-2 infections.

10.28. The Committee considered that funded COVID-19 vaccination for all health care workers may help to increase the number of health care workers and may help to limit the impact of staff illness on health care service capacity and health outcomes (from both absences and presenteeism – where workers are physically in the workplace but not functioning fully because of illness etc, likelier to make mistakes on the job, etc.).

10.29. The Committee considered that health care workers are in a position to promote the vaccine to people who are at increased risk from COVID-19. The Committee considered that keeping all health care workers ‘up-to-date’ with boosters may help to promote the vaccine to these at-risk populations.

11. COVID-19 vaccines correspondence and data updates

Application

11.1. The Committee considered correspondence from CSL regarding ARCT-154 vaccine and updated evidence on Nuvaxovid COVID-19 vaccine

11.2. The Committee took into account, where applicable, Pharmac’s relevant decision-making framework when considering this agenda item.

Discussion

Background

11.3. The Committee noted that at the its March 2024 meeting the Committee considered applications for four COVID-19 vaccines. These applications were for:

11.3.1. elasomeran, elasomeran and davesomeran, andusomeran vaccine (Spikevax – Moderna)

11.3.2. SARS-CoV-2 rS XBB.1.5 vaccine (Nuvaxovid – Novavax)

11.3.3. tozinameran, riltozinameran, famtozinameran, raxtozinameran (BNT162b2) vaccine (Comirnaty – Pfizer)

11.3.4. ARCT-154 vaccine (CSL – Seqirus)

11.4. The Committee noted that at its March 2024 meeting, it was considered that the four COVID-19 vaccines were likely to be comparable in efficacy and safety, and that any of the proposed vaccines technology platforms would be suitable to be included in the procurement process for COVID-19 vaccines. However the Committee requested that it see more mature safety and efficacy data for self-amplifying mRNA vaccines.

ARCT-154 Considerations

11.5. The Committee noted that at the March 2024 meeting, three trials assessing the efficacy and safety of the ARCT-154 vaccine were considered:

- Hồ et al. Preprint
- Oda et al. Lancet Infect Dis. 2024;24:351-60
- Oda et al. Lancet Infect Dis. 2024;24:341-3.

11.6. The Committee noted that the ARCT-154 clinical and post-marketing evidence was less mature when compared with the other vaccines considered at this meeting.

11.7. The Committee noted correspondence from CSL Seqirus notifying of the publication of two pivotal phase III trials (Hồ et al. 2024 and Oda et al. 2024;24:351-60). The Committee noted that the studies did not report results by age or co-morbidity, which the Committee considered limited the studies' usefulness. The Committee noted that further study reports are expected to be available in the first half of 2025 regarding the vaccine's persistence of immunogenicity and neutralisation activity against ancestral and Omicron variants.

11.8. The Committee noted that ARCT-154 is approved in Japan but is not FDA or EMA approved.

11.9. The Committee requested that the supplier provide immunogenicity data and observational evidence on the KP.2 variant vaccine when this is available.

Nuvaxovid Considerations

11.10. The Committee noted that further evidence had been supplied by Novavax on Nuvaxovid XBB.1.5 variant vaccine.

Health benefit

11.11. The Committee noted the following observational studies reporting the vaccine's efficacy and safety:

- Link-Gelles et al. 2024. MMWR. Morbidity and Mortality Weekly Report, 73
- Kim et al. Vaccine. 2024; 42: 1440-4
- Vadivale et al. 2024 (conference abstract)

11.12. The Committee noted that two Korean matched cohort studies (Kim et al. 2024, Vadivale et al. 2024 showed similar rates of infections between Nuvaxovid and Comirnaty vaccine at day 30 and day 60 post vaccination.

11.13. The Committee noted the following studies reporting the breadth of protection provided by Nuvaxovid against different SARS-CoV-2 variants:

- Bennett et al. Lancet Infect Dis. 2024;24:581-93
- Alves et al. Vaccine. 2023; 41: 4280–86
- Bennett et al. J Infect Dis. 2024;230:e4-e162024
- Walker et al. 2024 (presentation only).

11.14. The Committee noted that the BA.5/ancestral bivalent Nuvaxovid booster showed superior neutralising antibody response to BA.5 Omicron subvariant compared to ancestral-variant vaccines (Bennett et al. 2024).The Committee noted that the Nuvaxovid XBB vaccine demonstrated a superior neutralising antibody response against Omicron XBB.1.5 compared with the Nuvaxovid ancestral monovalent vaccine (Bennett et al. 2024). Non-clinical vaccines studies showed neutralising antibody responses similar between all JN.1 subvariants after the Nuvaxovid XBB.1.5 boost (Walker et al. 2024).

11.15. The Committee noted the following studies when considering the reactogenicity of Nuvaxovid:

11.15.1. Rousculp et al. Vaccines (Basel). 2024;12:83

11.15.2. Rousculp et al. 2024 Preprint

11.15.3. Wu et al. BMC Infect Dis. 2024;24:234

11.15.4. San Francisco Ramos et al. Expert Rev Vaccines. 2024;23:266-82.

11.16. The Committee noted that the two studies (Rousculp et al. 2024, Rousculp et al. 2024 Preprint) reported nominally but non-statistically significant lower reactogenicity for Nuvaxovid compared to mRNA vaccines. The Committee noted that the systematic review and meta-analysis (San Francisco Ramos et al. 2024) reported lower risk ratios with Novavax compared with BNT for systemic symptoms (fever RR 0.41, fatigue RR 0.86, headache RR 0.86) and local reactions (injection site pain RR 0.61, redness 0.94, swelling 0.19). The Committee noted the Rousculp et al. 2024 study that reported that 38.8% administered Nuvaxovid experienced work impairment (defined as at least 50% having at least 1 day work impairment during the 6-day post vaccination) compared with 41.6% who received the mRNA vaccine. It was noted that this nominal difference was not statistically significant.

11.17. The Committee noted the Kuriyama et al. Vaccine. 2024;42:1319-25 study, a phase I/II randomised, placebo-controlled trial that reported the immunogenicity and safety data one-year post vaccination. The Committee considered that trial demonstrated that Nuvaxovid provides durable protection for up to 11 months after receiving the primary vaccination doses and up to 6 months after homologous boosting.

11.18. The Committee noted that there limited clinical evidence directly comparing the vaccine efficacy and safety of Nuvaxovid with Comirnaty or Spikevax vaccines. The Committee also considered the evidence regarding the risk of myocarditis with Nuvaxovid is unclear.

11.19. The Committee requested that the supplier provide immunogenicity data and real-world evidence on the KP.2 booster when it is available.

Covid-19 Vaccine Considerations

11.20. The Committee noted that the JN.1 variant had already started circulating during the 2024 XBB.1.5 vaccine rollout. The Committee considered that by the time a JN.1 variant-adapted vaccine is rolled out in New Zealand, that there is likely to already be further antigenic drift.

11.21. The Committee noted the June 2024 FDA advice to manufacturers of Covid-19 vaccines that recommended a monovalent JN.1-lineage vaccine composition. The Committee considered that the JN.1 variant vaccine is likely to be more effective against JN.1 subvariants than a XBB.1.5 variant vaccine.

11.22. The Committee noted recent evidence published on the durability of XBB.1.5 vaccines against Omicron subvariants. The Committee noted that the vaccine effectiveness in preventing infection decreased markedly after 20 weeks.

11.23. The Committee noted the Liu B et al. 2024 Preprint study that reported a reduction in vaccine effectiveness in individuals considered high-risk, after 90 days. The Committee considered that this evidence further supported six monthly vaccination for those at higher risk of COVID-19 mortality.

11.24. The Committee noted that post-vaccination data is only available for people vaccinated with a XBB.1.5 vaccine. The Committee requested that data be provided on immunogenicity and vaccine effectiveness of the JN.1 or KP.2 booster, depending on which one is used, when available.

12. Pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine eligibility for other groups

Application

12.1. The Committee reviewed widening the access criteria for PCV13 and PPV23 to include people of any age who have had a previous episode of invasive pneumococcal disease (IPD) and people aged 18 years and older with bronchiectasis.

12.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

12.3. The Committee **recommended** that the access criteria for PCV13 and PPV23 vaccines be widened with a **high priority**, within the context of vaccines and immunisation, to include people of any age who have had a previous episode of invasive pneumococcal disease.

12.4. The Committee **recommended** that the eligibility criteria for PCV13 and PPV23 vaccines be widened with a **high priority**, within the context of vaccines and immunisation, to include people of any age who have bronchiectasis.

12.5. In making these recommendations the Committee considered the following:

12.5.1. The high health need of individuals who have had a previous episode of invasive pneumococcal disease (IPD) and people with bronchiectasis.

12.5.2. The health need of these individuals is equivalent to the high-risk groups currently funded.

Discussion

Māori impact

12.6. The Committee discussed the impact of widening the access criteria for PCV13 and PPV23 to include people of any age who have had a previous episode of IPD and people aged 18 years and older with bronchiectasis on Māori health areas of focus and Māori health outcomes. The Committee noted that Māori and Pacific peoples experience higher rates of IPD compared to Asian and NZ European/Other/MELAA groups (Invasive Pneumococcal Disease Biannual Report January 2023- December

2023. ESR, 2024). The Committee also noted that Māori have the highest incidence rates of bronchiectasis, following adjustment for age (The Impact of Respiratory Disease in New Zealand: 2020 Updates).

Populations with high health needs

12.7. The Committee discussed the health need(s) of people of any age who have had a previous episode of IPD and people aged 18 years and older with bronchiectasis among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee discussed the impact of widening the access criteria for PCV13 and PPV23 and noted there was an increasing trend in IPD incidence with increasing socioeconomic deprivation (7.6 per 100,000 among quintile 1; 23.8 per 100,000 among quintile 5). 58.4% of cases (419/718) were living in the most deprived quintiles 4 and 5. Pacific peoples residing in areas of highest deprivation (quintile 5) had the highest rate of IPD (125.9 per 100,000), followed by Māori residing in areas of highest deprivation (114.6 per 100,000) (ESR, 2024). The Committee noted that Māori and Pacific peoples experience higher rates of IPD compared to Asian and NZ European/Other/MELAA groups (ESR, 2024).

Background

12.8. The Committee noted a pneumococcal vaccine has been part of the New Zealand childhood immunisation schedule since 2008. PCV13 is the currently funded vaccine for pneumococcal disease on the childhood immunisation schedule. Two doses of PCV13 are given as the primary course, at 6 weeks and 5 months, with a booster at age 12 months. Children who started their immunisation course with PCV10 prior to December 2022 can complete it with PCV13. PCV13 is not funded for those who have previously been fully vaccinated with PCV10.

12.9. In addition, PCV13 and PPV23 are available for vaccination and re-vaccination for people of any age with eligible conditions that affect the immune system.

12.10. The Committee noted the current application looked at widening the access criteria or PCV13 and PPV23 to include people of any age who have had a previous episode of IPD, and people aged 18 years and older with bronchiectasis.

Health Need

12.11. The Committee noted that IPD must be microbiologically confirmed as being *Streptococcus pneumoniae*, and therefore the true burden is likely underestimated. The Committee noted that there was an increase in incidence of IPD in the extremes of age, with the highest rates in older adults and young children.

12.12. The Committee noted that since 30 June 2024 there has been 264 cases of IPD, of these 50% of cases being among people aged 5-64 years (Invasive Pneumococcal Disease Dashboard, ESR, accessed 30/07/2024).

12.13. The Committee noted that in 2023, there were 757 cases of IPD notified overall (14.5 cases per 100,000 total population). The incidence of IPD has been increasing steadily since 2020, and in 2023 the IPD incidence rate was the highest observed in the past 10 years (ESR, 2024).

12.14. The Committee noted that Māori and Pacific peoples experience higher rates of IPD compared to Asian and NZ European/Other/MELAA groups (ESR, 2024).

12.15. The Committee noted there was an increasing trend in IPD incidence with increasing socioeconomic deprivation (7.6 per 100,000 among quintile 1; 23.8 per 100,000 among quintile 5). 58.4% of cases (419/718) were living in the most deprived quintiles 4 and 5. Pacific peoples residing in areas of highest deprivation (quintile 5) had the

highest rate of IPD (125.9 per 100,000), followed by Māori residing in areas of highest deprivation (114.6 per 100,000) (ESR, 2024).

12.16. The Committee considered the increase in incidence rate was due to the increase in serotype 19A in children, as well as an increase since the reduction in pandemic restrictions.

12.17. The Committee noted evidence from one surveillance series reporting that individuals who had survived an initial episode of IPD being 50 times more likely than those without a prior history of IPD to suffer a further episode of IPD (King et al. Clin Infect Dis. 2003;37:1029-36). The Committee noted there was a 2-3% prevalence of recurrence (376 recurrences in 13,924 survivors of initial IPD), with an incidence equivalent to 1.29 recurrences per 100 person-years.

12.17.1. Similar recurrence rates were noted for residents of Australia experiencing at least one initial episode of IPD between 1991 and 2016 (with recurrent episodes measured from 2001 onwards), with a 1.8% prevalence of recurrence (591 recurrences in 512 individuals, out of 28,809 primary IPD episodes in 20,218 individuals, incidence equivalent to 2.16 recurrences per 100 person-years, being 27 times that of the general population) (Malo et al. Vaccine. 2021;39:5748-56).

12.18. The Committee considered that there was a higher risk of IPD in those living with HIV and in children <5 years with chronic illness.

12.19. The Committee considered overall there was sparse data on people with IPD and bronchiectasis, which was commonly simply grouped within chronic respiratory diseases.

12.20. The Committee noted that the incidence of IPD was approximately 18 times greater in people aged 16-64 years with chronic respiratory disease than those without a risk condition, with a fatal outcome from IPD approximately four times greater (van Hoek et al. J Infect. 2012;65:17-24).

12.21. The Committee noted the Moberley et al. Cochrane Database Syst Rev. 2013;2013:CD000422. meta-analysis which reported a reduction in all cause pneumonia when vaccinated with the PPV23 vaccine, including in people with chronic conditions, although with marked heterogeneity in the data.

12.22. The Committee considered that individuals who have had a previous episode of IPD or who have bronchiectasis would experience higher hospitalisation and mortality rates from pneumococcal related conditions than would the general population.

12.23. The Committee considered the health need of people of any age who have had a previous episode of IPD or who have bronchiectasis was similar or increased compared to the currently funded high-risk groups.

12.24. The Committee noted international guidelines including the Australian Immunisation Handbook that have recommended pneumococcal vaccination for people who had experienced a previous episode of IPD (any age) and people with bronchiectasis. The Committee noted the UK guidelines recommended only for people with bronchiectasis.

Health benefit

12.25. The Committee considered that vaccinating people who have had a previous episode of IPD or who have bronchiectasis would result in lower incidence rates and fewer hospitalisations for pneumococcal disease, as well as reduced mortality, and improved health equity.

12.26. The Committee considered individuals who have had a previous episode of IPD or who have bronchiectasis would receive the same health benefit from the vaccine. The Committee considered there would be similar barriers to access as currently funded high-risk groups.

Suitability

12.27. The Committee considered issues of suitability, as part of consideration all of Pharmac's Factors for Consideration.

Cost and savings

12.28. The Committee noted the NZ bronchiectasis registry for bronchiectasis and ESR notification data for IPD are available for assessing the rates of IPD and bronchiectasis in New Zealand and it would be appropriate to use these to estimate the number of people who may benefit from vaccination. The Committee considered that the IPD notifications will underestimate true burden of disease in New Zealand.

12.29. The Committee considered uptake of the vaccine would likely be between <50% and 50-80% over a 5-year period.

Funding criteria

12.30. The Committee considered that it would be appropriate for people who are considered high risk to receive up to four (PCV13) or two (PPV23) doses as needed over their lifetime. The Committee considered overall the evidence was uncertain and that the landscape may change with new vaccine developments and better data about longer term protection.

12.31. The Committee noted that some of the high-risk groups that would not be eligible for further vaccination on and after their 18th birthday have an unmet health need including people with HIV, and nephrotic syndrome. The Committee considered access to pneumococcal vaccines for these groups should be considered.

12.32. The Committee considered there was a higher risk of IPD or non-bacteraemic pneumococcal pneumonia throughout all age groups for people who have had a previous episode of IPD or who have bronchiectasis, and age should not be restricted for these groups.

Summary for assessment

12.33. The Advisory Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for the PCV13 and PPV23 vaccines if they were to be funded in New Zealand for IPD. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Advisory Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	People who have had a previous episode of IPD	People with non-cystic fibrosis bronchiectasis
Intervention	1 dose PCV13, 2 doses PPV23	1 dose PCV13, 2 doses PPV23
Comparator(s)	No intervention	No intervention
Outcome(s)	Lower rates of invasive pneumococcal disease (IPD) and non-bacteraemic pneumococcal pneumonia (NBPP), resulting in reduced acute morbidity/loss of quality of life, hospitalisation and mortality.	Lower rates of invasive pneumococcal disease (IPD) and non-bacteraemic pneumococcal pneumonia (NBPP), resulting in reduced acute morbidity/loss of quality of life, hospitalisation and mortality.

Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.

13. Pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine for people aged ≥65 year

Application

13.1. The Committee reviewed the application for the pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine for people aged 65 years and above

13.2. The Committee took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

13.3. The Committee **recommended** that the current PCV13 pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine for people aged 65 years and above be **declined** for funding.

13.4. In making this recommendation the Committee considered the following:

- There is an increased health need for people aged 65 years and over in comparison to the general population, however the evidence of efficacy is relatively limited
- There is no evidence of mortality benefit in individuals aged 65 years and over
- There may be a greater need in people aged under 65 years but in an at-risk group.

13.5. The Committee recommended this proposal be reviewed at a later data, if evidence becomes available that conjugate vaccines, or later versions of vaccines indicate they cause a reduction in morbidity and mortality.

Discussion

Māori impact

13.6. The Committee discussed the impact of funding the pneumococcal conjugate vaccine (PCV13) and pneumococcal polysaccharide vaccine (PPV23) for people aged 65 years and above on Māori health areas of focus and Māori health outcomes. The Committee considered that incidence of pneumococcal disease is different in Māori, with a higher incidence occurring 10 years earlier in Māori than NZ Europeans. The Committee noted Māori experience higher rates of IPD across most age groups. The incidence for people aged ≥65 years was among Māori was 2.7 times that NZ European/Other/MELAA, with Māori aged ≥65 years having a rate of 75 per 100,000 compared with 27.6 per 100,000 in non-Māori non Pacific non Asian people of that age (ESR, 2024).

Background

13.7. The Committee noted applications for the PCV13 and PPV23 vaccines has previously been reviewed. PCV13 was recommended for decline in August 2015 by PTAC, whilst the PPV23 vaccine was recommended for decline by the Immunisation Subcommittee in August 2021.

Health need

13.8. The Committee noted since 30 June 2024 there have been 264 cases of invasive pneumococcal disease (IPD), 44% among people aged ≥65 years (Invasive Pneumococcal Disease Dashboard, ESR, accessed 30/07/2024).

13.9. The Committee noted since 2020, there has been an increasing trend in the incidence of IPD in all age groups. Prior to 2020 the incidence of IPD was greatest in people ≥65 years, with their incidence in 2023 being 33.7 per 100,000 (ESR, 2024). In 2023, adults ≥80 and infants/young toddlers <2 years had incidences of IPD of 56.2 per 100,000 and 35.6 per 100,000 respectively (ESR, 2024).

13.10. The Committee noted the re-introduction of the PCV13 vaccine had been associated with a marked reduction in the incidence of disease caused by 19A, with cases due to 19A reducing from 37 in 2022 to 15 in 2023 in those aged across all age groups. Despite this, the incidence of 19A IPD remains higher in the <2 years old cohort (ESR, 2024). IPD incidence in those aged ≥65 years increased further in 2023 (ESR, 2024), but the Committee considered that due to vaccinating those <2 years old it is expected that in 3-4 years' time there will be a 50% decrease in the incidence of disease caused by PCV13 serotypes among older age groups (from improved herd immunity) (Shiri et al. Lancet Glob Health. 2017;5:e51-e59).

13.11. The Committee noted in 2023, hospitalisation status was reported for 98.8% of cases, and 96.7% (n=723) of these cases were hospitalised. 291 people were aged ≥65 years and hospitalised, of whom 3.1% had pneumococcal meningitis, 3.1% empyema, 75.6% pneumonia, 13.7% bacteraemia, 4.6% other (includes septic arthritis). There were 25 deaths due to IPD, 44% of deaths being among people aged ≥65 years (ESR, 2024).

13.12. The Committee noted the ESR data reported that for all age groups, the COVID-19 pandemic decreased levels of IPD. The Committee considered that whilst there was an increase in incidence of IPD across age groups in 2023, this was a return to pre-pandemic levels after the cessation of prevention and control methods such as community-wide lockdowns.

13.13. The Committee considered that the risk of invasive pneumococcal disease (IPD) among adults aged 65 years or older was comparable to that of the currently eligible groups.

Health benefit

PCV13 evidence in adults aged 65 years and above

13.14. The Committee noted PTAC in 2015 had reviewed the CAPiTA study, a Phase 4 parallel parallel-group, randomised, placebo-controlled, double-blind, single centre trial (Bonten et al. N Engl J Med. 2015. 372:1114-25).

13.15. The Committee noted the following studies:

- Bonten et al. N Engl J Med. 2015. 372:1114-25
- van Werkhoven et al. Clin Infect Dis. 2015;6:1835-8
- van Deursen et al. Clin Infect Dis. 2017;65:787-95
- Webber et al. Vaccine. 2017;35:1266-72
- van Deursen et al. Clin Infect Dis.2018;67:42-9
- Gessner et al. Vaccine. 2019;37:5777-87
- van Werkhoven et al. Clin Microbiol Infect. 2021;27:995-9.

13.16. The Committee noted the 2015 CAPiTA study was a large placebo controlled study with over 84,000 people included, that evaluated the effect of PCV13 in over 65 year

olds in The Netherlands. The Committee considered it was unlikely such a large study would be possible again. The Committee considered that the trial included bespoke urinary antigen testing to look at non-bacteraemic forms of IPD. which is not widely available.

13.17. The Committee considered the evidence to be high quality, with many post-hoc analyses performed since the CAPiTA study was concluded.

PPV23 evidence in adults aged 65 years and above

13.18. The Committee noted the following studies with evidence for PPV23 for people aged 65 years and above were reviewed by PTAC and/or the Immunisation Subcommittee in 2014-2015:

- Moberley et al, 2013 Cochrane Database Syst Rev 2013:CD000422
- Menzies et al. Med J Aust 2014;200:112-115
- Leventer-Roberts et al. Clin Infect Dis. 2015;60:1472-80
- Vila-Corcoles et al. BMC Infect Dis. 2010,10;23
- Domínguez et al. Eur Respir J 2010;36:608-614
- Maruyama et al. BMJ 2010;340:c1004.

13.19. The Committee noted the following further studies:

- Kim et al. Vaccine. 2019;37:2797-804
- Suzuki et al. Lancet Infect Dis. 2017;17:313-21
- Vila-Corcoles et al. Clin Infect Dis. 2006;43:860-8
- Maruyama et al. BMJ. 2010;340:c1004
- Wiemken et al. Vaccine. 2014;32:2198-203
- Ochpa-Gondar et al. Clin Infect Dis. 2014;58:909-17.

13.20. The Committee considered there was no significant changes in data since PPV23 was last reviewed by the Immunisation Subcommittee in 2021. The Committee considered from the above studies there was some evidence of reduced vaccine efficacy with increasing age.

13.21. The Committee considered that the PCV13 vaccines did reduce hospitalisation rates, however the evidence was not yet compelling.

13.22. The Committee considered it would be necessary to observe the continued indirect effect on people aged 65 and over through the vaccinating of children <2 years. The Committee considered more health benefit may be possible by increasing the vaccine valency in that programme. The Committee considered there was no evidence that vaccinating people aged 65 and above would provide health benefits to younger children in reverse.

13.23. The Committee considered it was reasonable to assume that the PCV vaccines had similar efficacy in preventing non-bacteraemic pneumococcal pneumonia as they had in preventing IPD, given the lack of comprehensive data available for non-bacteraemic pneumococcal pneumonia, which is challenging to diagnose.

Cost and savings

13.24. The Committee considered that estimates for the number of people who would be vaccinated are available for the New Zealand population. The Committee considered

it was uncertain if the uptake of influenza vaccine in those aged ≥65 years would be a valid predictor of pneumococcal vaccine uptake in that age group.

13.25. The Committee was uncertain on the proportion of older people who would receive the pneumococcal vaccine alongside the influenza vaccine, however suggested that there is some improvement in uptake when there are multiple vaccines administered together.