Record of the Immunisation Advisory Committee Meeting held on 10 April 2025

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
David Murdoch
Edwin Reynolds
Elizabeth Wilson
Erasmus Smit
Helen Evans
James Ussher
Karen Hoare
Lance Jennings
Nikki Turner
Osman Mansoor
Sarah McLean-Osborn
Tony Walls

Apologies
Stuart Dalziel

2. Summary of recommendations

Pharmaceutical and Indication	Recommendation
• Fluad adjuvanted inactivated trivalent influenza vaccine (aTIV) for people aged 65 years and over, within the context of vaccines and immunisation	High priority
• Flucelvax trivalent influenza vaccine prepared in cell cultures (TIVc) for eligible people six months to under 65 years of age, within the context of vaccines and immunisation.	High Priority
• Additional dose of pertussis-containing vaccine (eg. Infanrix-hexa) in the second year of life, within the context of vaccines and immunisation.	Medium Priority

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 Immunisation.

4. Welcome and introduction

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

5. Pharmac Update

5.1. The Committee noted the Pharmac Update.

6. Record of previous immunisation Advisory Committee meeting held Thursday, September 5, 2024

6.1. The Committee reviewed and accepted the record of the Immunisation Advisory Committee meeting held 5 September 2024.

6.1.1. Members noted the HPV vaccine discussion in paragraph 6.6 (web version), that many international jurisdictions have already moved to a single dose HPV vaccine schedule.

6.2. The Committee noted the RSV Application (item 7 in web version of the record) would be discussed as matters arising in this meeting.

7. Correspondence and Matters Arising

7.1. 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 regarding the adult respiratory syncytial virus

7.1.1. The Committee noted the recent correspondence in March 2025 that Pharmac received from the supplier, GSK, regarding the Immunisation Advisory Committee's considerations of its funding application for the adult respiratory syncytial virus (RSV) vaccine RSVpreF3 (Arexvy) in March 2024 and September 2024.

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

7.1.3. The Committee acknowledged the supplier's concerns regarding the Committee continuing to defer making a recommendation for this application.

7.1.4. The Committee noted its previous deferring to recommend the application for RSVPreF3 vaccine for the prevention of RSV-LTRD for people aged 60 years. Members reiterated the rationale for deferring to make a recommendation included concerns about the evidence available in the older age group.

7.1.5. The Committee noted the recent JAMA article about the estimated vaccine effectiveness for RSV-related lower respiratory tract disease in a retrospective case-control study (Tartof et al. JAMA network open. 2024;7(12):e2450832). Members noted 57.4 % of the population studied were over 75 years of age.

7.1.6. The Committee reaffirmed its intention to review the application when more information became available. Noting that new data is now accessible, the Committee considered it would be timely and appropriate to review the latest evidence. Consequently, the Committee agreed that it should formally reconsider the application at a future meeting.

7.1.7. The Committee considered that that following further information would be required to support a further discussion about this application:

7.1.7.1. Data supporting the New Zealand disease burden for RSV in different age groups, specifically those aged 60 years and older in the community.

7.1.8. The Committee also considered there were other priority areas for the health system to consider regarding RSV disease burden and prevention. The Committee reaffirmed its previous strong support for reviewing any applications for maternal RSV vaccine and new treatments for infants to prevent RSV disease (nirsevimab).

7.2. Update on recombinant zoster vaccine in high-risk populations

7.2.1. The Committee noted this placeholder item on the agenda for Pharmac staff to share an update on work underway to consider wider access for immunocompromised groups who would benefit from the recombinant zoster vaccine by specifying particular immune-modulating agents and high-dose corticosteroids with daily doses, durations and any age aspects (signalled in criteria 2.f-g in paragraph 8.1 of the Committee's March 2024 record).

7.2.2. The Committee noted that new information from Australia, which may well materially inform the Committee's consideration of this issue, was progressing later than scheduled and is expected soon. As the expected guidance had not yet been published, Pharmac staff said they would revisit this item for discussion at a future meeting once the information has been made available.

7.3. Fluad adjuvanted inactivated trivalent influenza vaccine (aTIV) for people 65 years of age and over

Application

8.3.1. The Committee reviewed a resubmission application (data update) from Seqirus for the listing of the Fluad adjuvanted inactivated trivalent influenza vaccine (aTIV) in the Pharmaceutical Schedule as the seasonal influenza vaccination for people aged 65 years and over.

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

Recommendation

8.3.3. The Committee recommended Fluad aTIV (as aligned with current Medsafe recommendations) be included in Pharmac's next vaccines commercial procurement process for people aged 65 years and over with a **high priority,** within the context of vaccines and immunisation.

8.3.4. In making this recommendation, the Committee considered:

8.3.5.1. The health needs of people aged 65 years and over in relation to influenza is well demonstrated to be high.

8.3.5.2. There is a consistent body of evidence indicating an improvement in overall vaccine effectiveness (VE) of about 10% over non-adjuvanted vaccine in this population, acknowledging the limitations of the influenza vaccine evidence base.

8.3.5.3. Prevention of hospitalisations leading to health sector savings would be beneficial.

Discussion

Māori impact

8.3.5. The Committee discussed the impact of funding Fluad aTIV on Māori health areas of focus and Māori health outcomes.

Populations with high health needs

8.3.6. The Committee discussed the health need(s) of 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 in relation to influenza. The Committee noted that influenza and related complications (eg leading to hospitalisation) in New Zealand disproportionately affect Māori and Pacific populations. Members considered that this impact on priority populations was reflected in a recent publication reporting health outcomes from the SHIVERS study (Huang et al. J Infect Dis. 2025:jiaf097).

Background

8.3.7. The Committee noted that PTAC and the Immunisation Advisory Committee (previously Subcommittee) had considered applications for three different influenza vaccines for people 65 years and over on several occasions (refer to application tracker links for detail and current status):

- Fluad - trivalent adjuvanted inactivated influenza vaccine (aTIV) (MF59-adjuvanted)
- FLUAD QUAD – adjuvanted inactivated quadrivalent influenza vaccine (aQIV)
- Fluzone (HD-QIV) - Inactivated quadrivalent influenza vaccine, split virion (high dose)

8.3.8. The Committee noted that a key concern in PTAC's previous consideration of FLUAD QUAD was the limited evidence for a reduction on mortality rates from influenza complications (PTAC, August 2020). The Committee also noted it had previously considered that any significant mortality benefit with aQIV was not demonstrated in the supplier's resubmission, and had at that time reiterated it considered that extrapolating a mortality benefit from any time period in the study by Mannino et al. (Am J Epidemiol. 2012;176:527-33), as proposed by the supplier, was inappropriate (Immunisation Advisory Committee, May 2022).

8.3.9. The Committee noted that Pharmac has not received a funding application for a high-dose trivalent influenza vaccine (HD-TIV) to date. However, the Committee noted that Seqirus' data update included outcomes for high-dose TIV versus aTIV, and that in September 2018 the Immunisation Subcommittee had signalled that such data were of interest.

Health need

8.3.10. The Committee noted recent evidence of NZ influenza epidemiology reporting the highest rates of hospitalisation for severe acute respiratory illness (SARI) in those aged 65 years and over and in children under five (Institute of Environmental Science and Research Ltd [ESR] Recommendation for Seasonal Influenza Vaccine Composition for New Zealand for 2025. ESR, 2024; ESR Respiratory illness dashboard. Accessed 14 March 2025). The Committee considered that the health needs of people aged 65 years and over in relation to influenza were well known, however, that it was also important to recognise the effects of ageing such as frailty (and thus risk of severe influenza) have increasing significance as this population ages. Members considered that stratified age groups were a useful way to consider this difference across subgroups, despite generally not being reported in the evidence base.

8.3.11. The Committee noted estimated overall mortality rates with influenza range up to 214 per 100,000 in the very elderly (Khieu et al. J infect. 2017;75:225-33) and that globally those aged 70 years and older had the highest lower respiratory infection mortality rate (224.6 deaths [197.8–243.7] per 100,000) (GBD 2021 Lower Respiratory Infections and Antimicrobial Resistance Collaborators. Lancet Infect Dis. 2024 ;24:974–1002).

8.3.12. Members considered that deaths due to influenza are often not coded as such among frail older adults, as they are not usually necessarily directly due to influenza but often from cardiovascular events or secondary pneumonia. Members considered that data on mortality from influenza in people aged 65 years and over was therefore of poor quality and that it would be more appropriate to assess hospitalisation as the key outcome. The Committee noted that the supplier's assessment assumed no deaths occurred outside the hospital setting, however members considered that influenza-related deaths were common outside of hospital, particularly for frail elderly and/or in residential care and other long-term care settings.

8.3.13. The Committee noted vaccine coverage as of February 2024 was 63.9% with vaccine effectiveness of 88.8% on general practitioner surveillance and 60.5% from hospital SARI surveillance (2023 Acute Respiratory Illness Surveillance Report. ESR, 2024). The Committee considered this was higher than published estimates seen elsewhere and probably also would vary according to the season.

Health benefit

8.3.14. The Committee noted the World Health Organization (WHO) recommendation to the exclude the B/Yamagata lineage from quadrivalent influenza vaccines, based on the absence of this lineage virus since March 2020, most recently issued in February 2025 (WHO, 2025. Accessed 21 March 2025), resulting in a global intention to move from quadrivalent (QIV) to trivalent (TIV) influenza vaccines. The Committee noted that Medsafe has reflected this in its November 2024 guidance on influenza vaccine composition (Medsafe, 2024. Accessed 21 March 2025).

8.3.15. The Committee noted the evidence in the updated data summary, including the following:

8.3.16.1. McGovern et al Int J Infect Dis. 2024;146:107160

8.3.16.2. Three retrospective studies from the same overall cohort in the 2019-2020 Northern hemisphere season (all censored prior to COVID-19 pandemic) who received aTIV versus other comparators including HD TIV or non-adjuvanted QIV:

- Imran et al Influenza Other Respir Viruses. 2024;18:13288: Relative vaccine effectiveness (rVE) of aTIV vs QIV against influenza hospitalisation was 25.3% (95%CI: 17.7 to 32.2). The Committee considered this to be a relevant and meaningful benefit over current standard QIV, noting that precision was relatively high with the confidence intervals being reasonably narrow.

- Imran et al Open Forum Infect Dis. 2024;11:ofae459

- Imran et al. Vaccine. 2024;42:126316: The Committee noted that the rVE against influenza- or pneumonia-related hospitalisations (aTIV vs QIVe): was 19.0% (95% CI 16.3, 21.6).

8.3.16.3. Ferdinands et al. J Am Geriatr Soc. 2024;72:3875-89

8.3.16.4. Ku et al Clin Infect Dis. 2024;79:1283-92: The Committee noted that the rVE against polymerase chain reaction (PCR)-confirmed influenza-related hospitalisation (adjuvanted vs standard egg vaccine) was 61.6% (95% CI 18.1, 82.0).

8.3.16.5. Levin et al. Expert Rev Vaccines. 2024;23:124-36

8.3.16.6. Pott et al. Vaccine. 2023;41:6359-65.

8.3.16. The Committee was made aware of Emborg et al. Euro Surveill. 2025;30:pii-25-00174 and also noted Murchu et al. Rev Med Virol. 2023;33:e2329, Amicizia et al. Hum Vaccin Immunother. 2023;19:2190279 and Didion et al. medRxiv [Preprint]. 2024:2024.10.14.24315459.

8.3.17. The Committee noted that the evidence indicated that reactogenicity occurs at a higher rate with aTIV compared with QIV (or TIV). The Committee noted that this was not previously deemed to be a concern, and considered that older people are generally more tolerant of the effects of increased vaccine immunogenicity.

8.3.18. Overall, the Committee considered the evidence was generalisable and that there was a consistent body of evidence supporting a benefit of about 10% rVE with aTIV vs QIV, and a potential smaller benefit with aTIV vs HD-TIV that may be greater in those with more risk factors for influenza, although a similar efficacy cannot be excluded. The Committee considered that the occasionally wide confidence intervals in some publications did not exclude a benefit, and that the magnitudes of benefit appeared similar across the evidence.

8.3.19. The Committee considered that high-quality randomised controlled trials are not often feasible for influenza vaccines. The Committee noted that the evidence to support use of aTIV was mostly observational and that the results of most of the observational studies were adjusted for potential bias and confounding. The Committee considered that observational studies had limitations, including residual bias and confounding, which would need to be considered when interpreting meta-analyses and individual rVE point estimates.

8.3.20. Members considered that the benefit from aTIV would likely be greater in those aged 75 and over, although results were not stratified by age.

8.3.21. The Committee considered that no additional data had been provided by the supplier to justify the inclusion of a mortality benefit from aTIV in their economic

modelling. The Committee considered it remained inappropriate to extrapolate a reduction in hospitalisation to assume a 12% mortality risk reduction. The Committee considered that such an assumption was not supported by the available evidence, and a mortality reduction due to aTIV should be excluded from all modelled scenarios in a Pharmac economic assessment.

8.3.22. The Committee further considered it was not reasonable to assume an even distribution of rVE across all people aged 65 years and over in hospital, noting its earlier consideration of age stratification, frailty, and issues with coding of deaths.

8.3.23. The Committee requested it review a comprehensive package of evidence comparing traditional, HD and adjuvanted TIV vaccines.

Cost and savings

8.3.24. The Committee considered that the key outcome for economic assessment of aTIV and other improved influenza vaccines should be a reduction in hospitalisation. The Committee considered that the magnitude of this reduction, and therefore the health sector savings that might be achieved, were uncertain.

8.3.25. The Committee considered there was significant uncertainty in the supplier's estimates of the number of averted hospitalisations which were based on 12% rVE compared with QIV (Mannino et al. 2012). However, Members considered that estimates of rVE varied widely across a range of studies and appeared to be somewhat higher in the more recent test-positive and cohort studies. The Committee considered that these higher point estimates in the more recent observational studies needed to be interpreted alongside the known limitations of observational study designs.

8.3.26. The Committee considered that using an 'intermediate' time window (ie. those weeks adjacent to peak influenza occurrence with > 0.5 cases per 1000 person-weeks) to model the benefit of influenza vaccination was appropriate for use in the base case of economic modelling, and it was also appropriate to test narrower and broader time windows in sensitivity analysis.

8.3.27. The Committee considered that funding a more reactogenic and/or more effective influenza vaccine such as aTIV was unlikely to have any significant impact on the likely uptake of influenza vaccination in the age group ≥65 years. The Committee noted there was little evidence to support an assumption that influenza vaccine uptake would increase over time in this age group, especially given recent declines in immunisation coverage in New Zealand.

8.3.28. The Committee considered that there would not be incremental administration costs associated with aTIV compared to non-adjuvanted QIV. The Committee further considered that there was unlikely to be a change in the proportion of people receiving coadministration of influenza vaccine with adjuvanted recombinant zoster vaccine (Shingrix) at 65 years of age.

General

8.3.29. Members considered that it would be highly valuable if cold chain stability data were requested within a funding agreement for influenza vaccine (and any other vaccine purchased for the National Immunisation Schedule), noting issues for minor breaches can lead to days of delay and provision of cold chain stability data would be a practical improvement.

Summary for assessment

8.3.30. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for Fluad aTIV if it were to be funded in New Zealand as the seasonal influenza

vaccine for people aged 65 years and over. 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	All persons ≥ 65 years of age
Intervention	Adjuvanted trivalent influenza vaccine (aTIV)
Comparator(s)	Non-adjuvanted QIV
Outcome(s)	Annual vaccine administration, and therefore key outcomes are expected to occur within the year following administration: • Reduced hospitalisations related to influenza • Reduced health related quality of life losses from infection.
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.	

7.4. Flucelvax inactivated trivalent influenza vaccine prepared in cell cultures (TIVc) for people six months to under 65 years of age

Application

7.4.1. The Committee reviewed the resubmission application (data update) from Seqirus for Flucelvax, an inactivated trivalent influenza vaccine prepared in cell cultures (TIVc), as the seasonal influenza vaccination for eligible people six months to under 65 years of age.

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

Recommendation

7.4.3. The Committee recommended that Flucelvax trivalent influenza vaccine prepared in cell cultures (TIVc) be included in Pharmac's next vaccines commercial procurement process for the seasonal influenza vaccine for eligible people six months to under 65 years of age with a **high priority**, within the context of vaccines and immunisation.

8.4.5.1. In making this recommendation, the Committee considered the evidence of slightly greater benefit of TIVc compared to the inactivated egg-based trivalent influenza vaccine (TIVe) due to a modest improvement in vaccine effectiveness and reduced risk of egg adaptation, and the reduced impact of TIVc on the environment.

Discussion

Māori impact

7.4.4. The Committee discussed the impact of funding Flucelvax on Māori health areas of focus and Māori health outcomes.

Populations with high health needs

7.4.5. The Committee discussed the health need(s) of influenza vaccination 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 noted that influenza and related complications in New Zealand disproportionately affect Māori and Pacific populations.

Background

7.4.6. The Committee noted that it had previously considered an application for Flucelvax (QIVc) for the prevention of influenza caused by Influenza Virus Types A and B in September 2022. At that time, the Committee had recommended Flucelvax QIVc be listed with a medium priority and made several other recommendations for population subgroups.

8.4.8.1. The Committee noted that when making the previous recommendations that it had noted the evidence of non-inferiority of QIVc compared to QIVe, the reduced impact of QIVc on the environment, and the supply chain improvements with QIVc.

7.4.7. The Committee noted that, since last review, there are expected to be future differences in vaccine composition in transitioning from a quadrivalent to trivalent formulation through the omission of B/Phuket/3073/2013 (B/Yamagata lineage)-like virus strain, based on World Health Organization (WHO) 2025 guidelines.

Health need

7.4.8. The Committee noted that the health need of those aged from six months to under 65 years in relation to influenza is well established. The Committee noted the increased risk of influenza-related complications for children under five years of age and people with underlying health conditions.

Health benefit

7.4.9. The Committee considered that the most relevant evidence for effectiveness to be a systematic review meta-analysis by Coleman et al. 2023. This meta-analysis included 18 observational studies over three influenza seasons from 2017–2020.

8.4.11.1. The Committee noted a consistent trend favouring cell-based influenza vaccines in comparison to standard egg-based vaccines in terms of relative vaccine efficacy (rVE).

8.4.11.2. The Committee noted the pooled rVE for prevention of emergency department (ED) visits and hospitalisations was 9.3% (95% CI 6.1% to 16.2% across three seasons) for QIVc compared to QIVe. The Committee considered it reasonable to infer that TIVc was likely equivalent to QIVc in effectiveness.

8.4.11.3. The Committee noted the meta-analysis excluded data for children under the age of four years due to vaccination licencing in earlier seasons. However, the Committee considered that the rVE estimate was likely applicable to children under four years of age. The Committee also considered that the rVE estimate was applicable to other groups Pharmac is currently considering widening access to influenza vaccine for (people aged 6 months to 18 years [P-001784], people aged 50 to 64 years [P-001783], all people aged 6 months to 64 years [P-001779]).

8.4.11.4. The Committee noted considerable variability in vaccine effectiveness between the H3 and H1 influenza seasons reported in the meta-analysis. Members noted the paper had suggested that egg adaptation occurs with H1, but Members commented that egg adaptation is generally more associated with H3 dominant seasons.

8.4.11.5. Members noted the authors' comments that egg adaptation was generally associated with H3 strains but can also occur with H1 strains.

8.4.11.6. The Committee noted that this review, along with much of the available efficacy evidence, had been both funded and authored by the supplier and its representatives.

7.4.10. The Committee noted that the most clinically meaningful outcomes related to influenza vaccination were reductions in emergency department visits and influenza-related hospitalisations.

7.4.11. The Committee considered that there was a lack of evidence to support a reduction in mortality with TIVc compared to QIV, and a mortality reduction related to TIVc should be excluded from all modelled scenarios in a Pharmac economic assessment where QIV is the comparator.

7.4.12. The Committee noted unpublished data from Seqirus for the 2023/2024 season, preliminary results demonstrated QIVc was more effective than QIVe in preventing test-confirmed influenza with an estimated rVE of 19.8% (95% CI: 15.7–23.8).

7.4.13. The Committee also noted the following publications that provided additional evidence regarding the immunogenicity and vaccine effectiveness of TIVc:

- Stein et al. Open Forum Infect Dis. 2024;11:ofae175
- Fisman et al. (Hum Vaccin Immunother. 2024;20:2351675
- McGovern et al. Expert Rev Vaccines. 2024;23:371-9
- Gavazzi et al. (Expert Rev Vaccines. 2024;23:1020-8

7.4.14. The Committee considered that high-quality randomised controlled trials are not often feasible for influenza vaccines. The Committee noted that the evidence to support cell-based influenza vaccines compared to standard egg-based influenza vaccines was of moderate quality, primarily based on observational studies. The Committee acknowledged that observational studies had limitations, including residual bias and confounding, which would need to be considered when interpreting meta-analyses and individual rVE point estimates.

7.4.15. The Committee considered it was reasonable to generalise the available evidence to the New Zealand context, noting that SHIVERS data supports local burden of influenza disease.

7.4.16. The Committee considered that while the updated evidence did not substantially differ from that reviewed previously, it indicates that Flucelvax TIVc likely has a modest increase in vaccine effectiveness and reduced mismatch risk (egg adaptation) compared to egg-based influenza vaccine.

Suitability

7.4.17. The Committee noted its previous discussion in September 2022 regarding QIVc versus QIVe suitability, where the following reduced environmental impacts and supply chain improvements were considered:

8.4.19.1. Negative environmental impact associated with egg-based vaccine manufacture.

8.4.19.2. Using a cell-culture propagated vaccine would allow production of QIVc to increase rapidly in response to high demand or a pandemic.

8.4.19.3. Reducing the reliance on chickens and eggs reduces supply chain risk.

8.4.19.4. Significantly lowered environmental supplier impact with QIVc compared to QIVe.

8.4.19.5. Reduced need for antibiotic usage for animal welfare during manufacturing.

Cost and savings

7.4.18. The Committee considered that modelled savings related to reduced ED visits and hospitalisations with TIVc compared to QIVe could reasonably be based on the rVE estimates reported by Coleman et al (2023). The Committee considered that while Coleman et al (2023) compared QIVc to QIVe, the rVE estimate was likely to be applicable to TIVc as TIVc was probably likely equivalent to QIVc in effectiveness.

7.4.19. The Committee noted the supplier's estimate that Flucelvax would be expected to avert approximately 70 hospital admissions per year due to influenza nationally, compared with standard egg-based vaccines. The Committee noted their estimates were based on higher rVE estimates than those described in Coleman et al (2023).

7.4.20. The Committee noted that a proportion of children aged nine years and younger may require a second dose because they have not previously received an influenza vaccine or had proven influenza disease.

Summary for assessment

7.4.21. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for Flucelvax if it were to be funded in New Zealand for currently eligible people aged under 65 years. 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	People aged ≤64 years who are currently eligible for funded influenza vaccination as at the 2025 influenza season: • people aged 6 months and over who have a long-term medical condition like diabetes, asthma, or a heart condition • pregnant people • tamariki (children) aged 4 years and under who have been hospitalised for respiratory illness, or have a history of significant respiratory illness • people with mental health conditions, including schizophrenia, major depressive disorder, bipolar disorder, or schizoaffective disorder • people who are currently accessing secondary or tertiary mental health and addiction services. For detailed eligibility criteria, refer to Pharmaceutical Schedule (web version as at May 2025)
Intervention	Annual dose of TIV cell-based vaccine (Flucelvax trivalent)
Comparator(s) (NZ context)	Annual dose of egg-based vaccine
Outcome(s)	Improved vaccine effectiveness • Prevention of influenza ED visits or hospital admissions with a pooled rVE estimate of 9.3% (95% CI, 6.4% to 12.3%) (Coleman et al. Vaccines. 2023;11:1607) compared to QIVe.
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup) **I**ntervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).	

Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).

Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

8. Additional dose of pertussis-containing vaccine in the second year of life: Widening access

Application

8.1. The Committee noted that Pharmac had received a request from the National Public Health Service (NPHS) of Health New Zealand | Te Whatu Ora (Health NZ) to consider several options for widening access to a pertussis (whooping cough)-containing vaccine in the context of the current outbreak.

8.2. The Committee reviewed a proposal to widen access to pertussis vaccine by replacing Haemophilus influenzae type b (Act-HIB; Hib) vaccine with a hexavalent vaccine (DTaP-IPV-HepB/Hib; Infanrix-hexa) booster dose at the 15-month childhood immunisation visit.

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

Recommendation

8.4. The Committee recommended that an additional dose of pertussis-containing vaccine (eg. Infanrix-hexa) be funded in the second year of life with a **medium priority**, within the context of vaccines and immunisation.

8.5. In making this recommendation, the Committee considered that:

9.6.1. There may be a benefit in reduction of severe disease and hospitalisation from moving to a 3+1 primary dosing schedule compared with 3+0, although the benefit is small and supported by evidence that is not strong

9.6.2. The theoretical benefit of reduced pertussis transmission from boosted toddlers to high-risk young infants is not supported by current evidence

9.6.3. Improving antenatal maternal vaccination uptake remains the key means to provide increased protection against pertussis for infants, as even timely infant vaccination at 6 weeks of age is too late to provide protection to infants without maternal vaccination in pregnancy

9.6.4. Hexavalent vaccine boosting at age 15 months (replacing the monoantigen Haemophilus influenzae type b vaccine [Hib] immunisation scheduled at that age) would simplify the childhood vaccination schedule, with improvements to the corresponding cold chain management, reductions in the risk of Hib dosing errors, and would provide an additional hepatitis B vaccine dose. The additional dose of pertussis-containing vaccine would therefore include programme reasons (ie. supply chain and delivery simplification), but would also provide added protection against pertussis for the toddler until the four-year dose; and may have some effects on circulation of pertussis.

8.6. The Committee signalled that it would like to review hospitalisation data (including vaccination status) from the past two pertussis epidemics, to review mid-epidemic hospitalisation rates for infants and those aged under five years (disaggregated by each year of age).

Discussion

Māori impact

8.7. The Committee discussed the impact of funding an additional dose of pertussis-containing vaccine in the second year of life on the Māori health areas of focus and Māori health outcomes. The Committee noted that Māori have lower rates of maternal (Howe et al. Vaccine. 2020;38:6766-76) and infant pertussis vaccination than NZ Europeans or others, which contribute to higher transmission and more severe infection in Māori one year olds.

8.8. The Committee considered that Māori children, especially those within large families and/or living in crowded homes, would benefit from any additional protection offered by an additional dose of pertussis-containing vaccine in the second year of life. However, the Committee considered antenatal maternal vaccination to be far more likely to prevent severe pertussis disease in infants than any other intervention, and that public health strategies should prioritise higher maternal coverage before adding another dose for older children.

Populations with high health needs

8.9. The Committee discussed the health needs in relation to pertussis disease 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.

9.10.1. As with Māori, the Committee considered that Pacific children, especially those within large families and/or living in crowded homes, would benefit from any additional protection offered by an additional dose of pertussis-containing vaccine in the second year of life, along with additional protection within hexavalent vaccine against hepatitis B. However, the Committee considered maternal vaccination far more likely to prevent severe pertussis disease in Pacific infants than other interventions, and much higher antenatal maternal vaccination coverage should take priority. The Committee noted that Pacific people, like Māori, have lower rates of antenatal maternal pertussis vaccination than NZ Europeans or others (Howe et al. 2020), which contributes to higher transmission and more severe infection in Pacific one year olds.

Background

8.10. The Committee noted that pertussis vaccination is currently funded on the National Immunisation Schedule (NIS) for childhood immunisation at the following age visits:

9.11.1. Primary doses (3+0 schedule): diphtheria, tetanus, pertussis, polio, hep B, and hib vaccine (DTaP-IPV-HepB/Hib; Infanrix-hexa) at ages six weeks, three months and five months.

9.11.2. Booster doses: at age four years (diphtheria, tetanus, whooping cough, and polio vaccine (DTaP-IPV; Infanrix IPV) and another at age 11 years (tetanus, diphtheria, and pertussis (Tdap) vaccine [Boostrix]).

8.11. The Committee noted that there has been extensive consideration of pertussis vaccination approaches at Immunisation Advisory Committee (previously Subcommittee) meetings in previous years, including in March 2013, October 2015, May 2016, August 2017 and October 2019. In October 2019, the Immunisation Subcommittee considered a Ministry of Health (MoH) review of the evidence regarding the addition of a pertussis-containing vaccine in the second year of life to the Pharmaceutical Schedule, and at that time, the Committee had considered that:

9.12.1. There was no evidence for a clear health benefit from introduction of a pertussis booster in the second year of life

9.12.2. There was a clear priority to improve antenatal maternal pertussis coverage to protect infants under three months of age.

8.12. The Committee noted that in late 2024-early 2025, Pharmac staff sought additional advice from Immunisation Advisory Committee members regarding pertussis immunisation in response to the current pertussis outbreak. At that time, members:

9.13.1. Reiterated that the single most important action that can be taken to reduce infant pertussis morbidity and mortality is to achieve good antenatal maternal vaccination cover in New Zealand

9.13.2. Suggested alternative changes to the eligibility criteria could better protect the infants who are at risk of contracting pertussis, while still emphasising the importance of antenatal vaccination. This included considering an additional dose for the infant at 15 months of age, as this would better align with international recommendations and offers additional benefits.

Health need

8.13. The Committee noted that the group of children targeted by this request had been signalled by the NPHS as what they considered the highest priority group (of several) for consideration at this time. Members considered this request therefore sought to reduce the impact of severe disease for a very young subgroup, as opposed to being part of a broader programme looking at reducing the population burden of pertussis overall.

8.14. The Committee noted that the impact of pertussis on children under five years of age has been described previously, albeit those data had been aggregated and Members had not seen age group breakdowns through the epidemic periods particularly children aged one to four years, and that this is a known area of suboptimal vaccination coverage. Members considered that one pertussis case generally affects a whole family (or a bubble of close contacts), with data considered previously suggesting (but not able to confirm) that adults in a household may be more likely than young children to transmit it to infants. The Committee noted additionally that data does not suggest the main source of transmission is from toddlers and young children (aged 15 months to four years) to infants.

8.15. The Committee noted updated data from the Institute of Environmental and Science Research (ESR) pertussis dashboard (accessed 5 March 2025) and the ESR pertussis report 25 January-21 February 2025 (ESR digital library. Published 27 February 2025) in relation to the current impact of the national pertussis outbreak declared on 22 November 2024. The Committee noted that most hospitalisations were in those aged less than three months, and thus this specific very young age group has a very high health need. However, the Committee considered it reasonable to focus on the health need of those in their first six months of life in relation to hospitalisations, as these infants are considered the most likely to experience severe disease, while some hospitalisations occur in those aged from six to 11 months.

8.16. The Committee noted that those aged from one to four years would be targeted directly by this proposal, but considered that, as few were hospitalised in that age group in the present interepidemic setting, the current data did not suggest a substantial burden of severe disease in this age group outside of epidemic cycles. However, members considered that children aged from one to four years were perhaps less likely to be tested for pertussis in the community, thus potentially missing cases with appreciable illness but not needing hospitalisation.

8.17. The Committee noted that Māori and Pacific infants were among the most affected by high rates of hospitalisation with pertussis, with the greatest impact in Pacific infants, and therefore considered these groups have a particularly high health need. The

Committee noted that non-hospitalised case numbers in Māori and Pacific infants (where identified) were also high, and that hospitalisations across all ages indicated very high and high rates of non-severe disease in Māori and Pacific people, respectively. The Committee also noted that Howe et al. 2020 reported that Māori or Pacific people who gave birth between 2013 and 2018 had lower odds of receiving maternal pertussis vaccination compared with NZ Europeans or others, and that lower infant and antenatal maternal vaccination rates contributed to higher transmission and more severe infection in these groups (among other factors such as household size and socio-economic factors).

8.18. The Committee noted that the greatest number of severe pertussis cases were among those who were not fully vaccinated for their age. Further, members noted there was an absence of data on the number or proportion of these cases whose mothers were vaccinated in pregnancy. The Committee considered that even timely infant vaccination according to the childhood immunisation schedule (starting at six weeks of age) is too late to provide protection to infants without maternal vaccination in pregnancy, given that the infant's protection develops over two weeks' post their six-week vaccination and a single dose only offers limited protection. However, members considered that two-month-olds with maternal vaccination in pregnancy would be considered protected.

8.19. The Committee noted that Pharmac staff estimated maternal TdaP vaccination coverage in 2024 could have been about 60%, increased from previous years, and members considered that the lowest uptake by ethnicity would be in Māori. The Committee reiterated its previous view that antenatal maternal vaccination against pertussis is the best intervention for preventing hospital admission in high-risk groups. Members considered that this provides more than 90% protection against risk of hospital admission in the first three months of the child's life, and that it would be reasonable to put 90% of pertussis vaccination efforts into maternal vaccination, with the remaining efforts into continuing to improve timely infant vaccinations where they are not being taken up.

8.20. The Committee considered that its appraisal of health need could have been more complete if not for issues with data (on maternal vaccination in pertussis cases in infants aged under 3 months, and for pertussis notifications, which hospitalisation data are based upon) and if data were provided for pertussis cases and maternal vaccination status according to infant age and socioeconomic status. The Committee considered it would like to review hospitalisation data (including vaccination status) from the past two pertussis epidemics at a future meeting, to review hospitalisation rates in the middle of an epidemic for infants and those aged under five years.

Health benefit

8.21. The Committee noted that the key evidence for consideration was a recent report published by the Immunisation Advisory Committee (IMAC) (Nowlan et al. Review of evidence to inform the New Zealand National Immunisation Programme, 2024: Pertussis. IMAC, December 2024), which members considered to be high quality. Members considered that the evidence was generalisable to the New Zealand population, but with the caveat that many other countries have higher maternal pertussis vaccination rates.

8.22. The Committee noted an absence of evidence provided for reductions in primary care presentations (symptomatic pertussis cases and sequelae of infection) following introduction of an additional dose at 15 months.

8.23. The Committee considered that there was evidence of improved immunity from vaccination of children at 15 months in terms of increased antibodies, however, there are no established correlates of protection between antibody levels and protection

against pertussis (ie vaccine efficacy or clinically relevant outcomes such as hospitalisation and mortality) and therefore the magnitude of benefit from a 15-month booster dose on hospitalisation was uncertain. Members were made aware of evidence on relative vaccine effectiveness in preventing pertussis hospitalisation (difference of 1.8% between the 3+0 regimen and the 3+1 regimen; Mack et al. Vaccine. 2020;38:1444-9) and prevention of PCR-positive pertussis disease (3% difference between 3+0 and 3+1 regimens; Zerbo et al. Pediatrics. 2019;144:e20183466). Members considered that, while relatively small, this difference could translate into numerically many hospitalisations avoided in an epidemic.

8.24. The Committee noted that the above IMAC Review of evidence for pertussis in 2024 concluded that "… although effective in providing direct protection, there was little evidence that booster doses in preschool children or adolescents provided indirect protection for other age groups….". The Committee considered there was a lack of evidence for a transmission-reducing effect within a family/household and that the case for reduced transmission to high-risk infants was not supported. The Committee considered that pertussis vaccination does not provide sterilising immunity and so is not particularly effective in terms of preventing transmission.

8.25. The Committee considered that evidence previously reviewed by the Committee in relation to influenza transmission between young siblings was not relevant to the discussion due to the difference in disease biology (bacterial vs viral) and vaccination effect (eg acellular pertussis vaccine does not prevent pertussis bacteria from infecting the upper airways).

8.26. The Committee considered that, depending on its extent, arm swelling with repeated doses of tetanus/diphtheria toxoid-containing vaccines occurs in perhaps about 10% of cases. Members considered that while this was not harmful to the individual, parental perceptions about this would likely impact subsequent vaccination levels at a population level.

8.27. The Committee noted that maternal antibody interference from maternal vaccination in pregnancy continued to be of uncertain clinical significance regarding infant vaccination and protection against pertussis. The Committee considered that there can be a measurable difference in antibody levels in fully vaccinated infants depending on whether maternal vaccination occurred or not, with slightly lower antibody levels after the third primary dose where maternal vaccination occurred. However, members considered it remained unclear whether this correlates to any difference in the risk of pertussis infection.

8.28. The Committee noted the IMAC review included pertussis cases and vaccine effectiveness (VE) of the primary course in infants with or without maternal vaccination (adapted from data published by Regan et al. Pediatrics. 2023;152:e2023062664), and considered that while this indicated a difference in VE after three infant doses if no maternal vaccination had been received, it did not show higher rates of pertussis infection. The Committee considered that the clinical significance of the finding of reduced VE of maternal vaccination after the third infant dose was unclear as it was not associated with more pertussis cases.

8.29. Members considered that while a second-year booster dose may help mitigate any maternal antibody interference in terms of the infant's vaccine antibody response, it is unclear whether such blunting makes an impact on clinical outcomes (not immunogenicity). Members considered that New Zealand data would be required to confirm this, given that primary dosing for infants starts at the age six-week visit and correlates with a six-week health check in primary care (which therefore differs from most other countries), and that if research were to investigate outcomes of the current epidemic, case numbers could provide this data.

Suitability

8.30. The Committee considered a hexavalent vaccine appropriate to use at 15 months to provide an additional dose of pertussis and identified no other vaccines to consider for this age visit. The Committee considered that if this change were made, monovalent Hib vaccination (alone) would no longer be required at 15 months, given the hexavalent vaccine contains HiB antigen.

8.31. The Committee considered both Hib and hepatitis B immunisation were highly relevant at this age visit; that replacing Hib (alone) with a hexavalent vaccine at the 15-month visit has the potential to reduce the risk of errors with Hib; and that using a hexavalent vaccine may also improve hepatitis B immunisation schedule protection.

8.32. Members considered that a fully liquid vaccine preparation could also potentially reduce the risk of errors with Hib (as otherwise needing to be added), if such a vaccine were funded in future.

Summary for assessment

8.33. The Committee considered that the key outcomes of interest would be reductions in severe disease as measured by hospital admissions in the very young infant siblings of the vaccinated toddlers, rather than in the vaccinated toddlers themselves (where, at least outside of epidemic cycles, children aged 15+ months would seldom acquire pertussis sufficiently severe to require hospitalisation). The Committee considered that hospitalisation was likely the most useful 'hard' endpoint across the age groups including younger children, and that hospital data would be necessary given the low rate of community testing.

8.34. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for a hexavalent vaccine if it were to be funded in New Zealand for an additional dose of pertussis-containing vaccine at the 15-month visit. 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	Young children who have received the three scheduled doses of DTaP-IPV-HepB/Hib (does not include maternal vaccination, where received by mother during pregnancy) and are eligible for vaccinations delivered at the 15-month visit. Note: This proposal intends to benefit infants aged less than 6 months against severe disease via indirect protection (where young infants are otherwise infected by other household members including older siblings).
Intervention	A dose of DTaP-IPV-HepB/Hib vaccine, administered intramuscularly, at the 15-month visit The next pertussis-containing vaccine is typically delivered at the four-year assessment visit.
Comparator(s)	No pertussis-containing vaccine at the 15-month visit. The next pertussis-containing vaccine is typically delivered at the four-year aged visit.

Outcome(s)	Reduction in pertussis disease and pertussis-related hospital admissions directly in the vaccinated population (aged 15+ months) (seldom). Reduction in severe disease and pertussis-related hospital admissions in unimmunised younger siblings (aged <6 months), secondarily and indirectly. However there is a lack of evidence of such indirect protection to others, including to infants in the same household.
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.	