From: Sarah Fitt
Sent: Friday, 4 March 2022 8:45 AM
To: Lisa Williams; Andrew Oliver
Cc: Adrienne Martin; Caroline De Luca; Peter Alsop; Allanah Andrews; Jane Wright
Subject: RE: 2022-03-02 Memo to proceed: Influenza vaccine widened access consultation (A1573477)

All fine with me and agree with the plan

Ngā mihi,

Sarah

Sarah Fitt | Chief Executive
_____
PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
9 (2) (b) (ii)

-----Original Message-----
From: Lisa Williams <lisa.williams@pharmac.govt.nz>
Sent: Friday, 4 March 2022 8:38 AM
To: Andrew Oliver <andrew.oliver@pharmac.govt.nz>
Cc: Adrienne Martin <adrienne.martin@pharmac.govt.nz>; Caroline De Luca <caroline.deluca@pharmac.govt.nz>; Sarah Fitt <sarah.fitt@pharmac.govt.nz>; Peter Alsop <peter.alsop@pharmac.govt.nz>; Allanah Andrews <allanah.andrews@pharmac.govt.nz>; Jane Wright <jane.wright@pharmac.govt.nz>
Subject: 2022-03-02 Memo to proceed: Influenza vaccine widened access consultation (A1573477)

Hi Andrew, thanks for the comprehensive memo.

I'm happy to endorse going ahead with consultation on this proposal (subject to any comment from SF), however I'm not comfortable with the timing.

Rachel M from the MOH called me last night to say that the draft briefing to Vaccine ministers was going in the DG's overnight reading bag and it would go across to Ministers to go in their weekend bags. Rach was going to confirm to me today the planned timing for any meeting of Ministers to discuss the briefing, but she thought it would likely be discussed on Monday at some stage.

On that basis, I would prefer that we send a 'no surprises' to Minister Little today about our intention to issue a truncated consultation early next week (and make mention of the briefing that we are aware Ministers will be receiving today). Then we issue our consultation on Monday or Tuesday next week. I am comfortable, that given the urgency caused by Covid and the impending start of the flu vaccination programme that our consultation period is less than 10 days.

Lisa

Lisa Williams has sent you a link to "2022-03-02 Memo to proceed: Influenza vaccine widened access consultation" (A1573477) from Objective.

Open in Navigator

Double click on the attachment

Open in Supported Application
url:objective://id:A1573477@objective.pharmac.govt.nz:8643

Open in Your Browser
Latest: https://objective.pharmac.govt.nz:8643/id:A1573477/document/versions/latest
Published: https://objective.pharmac.govt.nz:8643/id:A1573477/document/versions/published

From: Allanah Andrews
Sent: Friday, 4 March 2022 3:09 PM
To: Senior Leadership Team; Engagement & Implementation Managers
Cc: Stephen Tat; Adrienne Martin; Caroline De Luca; Jane Wright; Andrew Oliver
Subject: FW: No surprises update - public consultation for influenza vaccination

FYI

From: Allanah Andrews
Sent: Friday, 4 March 2022 3:05 pm
To: Haley Ataera <haley.ataera@parliament.govt.nz>; Adelia Hallett <Adelia.Hallett@parliament.govt.nz>
Cc: Carol Morris <carol.morris@pharmac.govt.nz>; Lisa Williams <lisa.williams@pharmac.govt.nz>; Peter.Jane@health.govt.nz
Subject: No surprises update - public consultation for influenza vaccination

Kia ora Haley

This is a no surprises update for the Minister relating to Pharmac's intention to publicly consult on widening the access criteria for funded influenza vaccinations in 2022. Consultation is planned for early in the week beginning 7 March 2022.

Pharmac intends to consult on a proposal to widen access to the influenza vaccine for Māori and Pacific peoples from 55 to 64 years for the 2022 season. Continued funding for future seasons will be considered as a separate funding decision.

The consultation period will likely be shorter than our normal practice. Given the urgency caused by the current COVID-19 situation and impending start to the influenza vaccination season we consider this to be reasonable.

A decision on whether to expand access will be made in time for the commencement of the influenza vaccination season, 1 April 2022.

Pharmac has been working closely with the Ministry of Health on the 2022 influenza vaccination programme and are aware the Minister is likely to receive advice on the approach to the 2022 programme today (Friday 4 March).

We intend to put out a media release, to accompany the consultation, with a link to our website for more information. Pharmac's director of operations Lisa Williams will be Pharmac's spokesperson and available for interviews.

Please let me know if you would like any further information.

Ngā mihi / Warm Regards,

Allanah Andrews (she/her) | Manager, Policy and Government Services
Te Pātaka Whaioranga | Pharmac
PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 6011
9 (2) (b) (ii) [redacted] www.pharmac.govt.nz

PHARMAC
TE PĀTAKA WHAIORANGA

MINUTE OF THE DIRECTOR OF OPERATIONS DECISION UNDER DELEGATED AUTHORITY

JUNE 2022

The Director of Operations, exercising the authority delegated by the Chief Executive under the Financial Delegations Policy has made the following decision to:

resolve to amend the eligibility criteria for Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad) in Section I of the Pharmaceutical Schedule from 1 July 2022 (additions in bold):

A. INFLUENZA VACCINE – people 3 years and over

is available each year for patients aged 3 years and over who meet the following criteria, as set by Pharmac:

a. all people 65 years of age and over; or
b. people 55 to 64 years of age (inclusive) who are Māori or any Pacific ethnicity; or
c. people under 65 years of age who:
    i. have any of the following cardiovascular diseases:
        a. ischaemic heart disease, or
        b. congestive heart failure, or
        c. rheumatic heart disease, or
        d. congenital heart disease, or
        e. cerebrovascular disease; or
    ii. have either of the following chronic respiratory diseases:
        a. asthma, if on a regular preventative therapy, or
        b. other chronic respiratory disease with impaired lung function; or
    iii. have diabetes; or
    iv. have chronic renal disease; or
    v. have any cancer, excluding basal and squamous skin cancers if not invasive; or
    vi. have any of the following other conditions:
        a. autoimmune disease, or
        b. immune suppression or immune deficiency, or
        c. HIV, or
        d. transplant recipients, or
        e. neuromuscular and CNS diseases/disorders, or
        f. haemoglobinopathies, or
        g. are children on long term aspirin, or
        h. have a cochlear implant, or
        i. errors of metabolism at risk of major metabolic decompensation, or
        j. pre and post splenectomy, or
        k. down syndrome, or
    vii. are pregnant; or
d. children 3 and 4 years of age (inclusive) who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
e. people under 65 years of age who:
    i) have any of the following serious mental health conditions:
        a. schizophrenia; or
        b. major depressive disorder; or
        c. bipolar disorder; or
        d. schizoaffective disorder; or
    ii) are currently accessing secondary or tertiary mental health and addiction services; or

f. **children 3 to 12 years of age (inclusive), from 1 July 2022 to 31 December 2022;**

Unless meeting the criteria set out above, the following conditions are excluded from funding:

a asthma not requiring regular preventative therapy,

b hypertension and/or dyslipidaemia without evidence of end-organ disease.

B. Contractors will be entitled to claim payment for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with Heath NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C. Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

resolve to amend the restriction criteria for Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad) in Part II of Section H of the Pharmaceutical Schedule from 1 July 2022 (new criteria shown only):

Restricted
Initiation – Serious mental health conditions or addiction
Any of the following:

1. schizophrenia; or
2. major depressive disorder; or
3. bipolar disorder; or
4. schizoaffective disorder; or
5. person is currently accessing secondary or tertiary mental health and addiction services.

Initiation – children from 3 to 12 years of age (inclusive)
Children 3 to 12 years of age (inclusive) from 1 July 2022 to 31 December 2022.

resolve that no consultation on this proposal is required.

note that we recently consulted on a proposal to fund influenza vaccine for Māori and Pacific peoples from 55 to 64 years of age in March 2022 and received consultation feedback supporting funding for school aged children and people with serious mental health conditions.

note that the widened access for children 3 to 12 years age is only for the 2022 influenza season, while widened access for serious mental health or addiction is for 2022 and future seasons.

PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR CONSIDERATION BY DIRECTOR OF OPERATIONS UNDER DELEGATED AUTHORITY

To: Director of Operations

From: Manager Pharmaceutical Funding

Date: 21 June 2022

Influenza vaccine widened access for children 3-12 years of age and people with serious mental health conditions or addiction

Recommendations

It is recommended that having regard to the decision-making framework set out in PHARMAC's Operating Policies and Procedures you exercise your delegated authority and:

resolve to amend the eligibility criteria for Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad) in Section I of the Pharmaceutical Schedule from 1 July 2022 (additions in bold):

A. INFLUENZA VACCINE – people 3 years and over
is available each year for patients aged 3 years and over who meet the following criteria, as set by Pharmac:
- a. all people 65 years of age and over; or
- b. people 55 to 64 years of age (inclusive) who are Māori or any Pacific ethnicity; or
- c. people under 65 years of age who:
  - i. have any of the following cardiovascular diseases:
    - a. ischaemic heart disease, or
    - b. congestive heart failure, or
    - c. rheumatic heart disease, or
    - d. congenital heart disease, or
    - e. cerebrovascular disease; or
  - ii. have either of the following chronic respiratory diseases:
    - a. asthma, if on a regular preventative therapy, or
    - b. other chronic respiratory disease with impaired lung function; or
  - iii. have diabetes; or
  - iv. have chronic renal disease; or
  - v. have any cancer, excluding basal and squamous skin cancers if not invasive; or
  - vi. have any of the following other conditions:
    - a. autoimmune disease, or
    - b. immune suppression or immune deficiency, or
    - c. HIV, or
    - d. transplant recipients, or
    - e. neuromuscular and CNS diseases/disorders, or
    - f. haemoglobinopathies, or
    - g. are children on long term aspirin, or
    - h. have a cochlear implant, or
    - i. errors of metabolism at risk of major metabolic decompensation, or

j. pre and post splenectomy, or
k. down syndrome, or

vii. are pregnant; or

d. children 3 and 4 years of age (inclusive) who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or

e. people under 65 years of age who:

i) have any of the following serious mental health conditions:

a. schizophrenia; or

b. major depressive disorder; or

c. bipolar disorder; or

d. schizoaffective disorder; or

ii) are currently accessing secondary or tertiary mental health and addiction services; or

f. **children 3 to 12 years of age (inclusive), from 1 July 2022 to 31 December 2022;**

Unless meeting the criteria set out above, the following conditions are excluded from funding:

a asthma not requiring regular preventative therapy,

b hypertension and/or dyslipidaemia without evidence of end-organ disease.

B. Contractors will be entitled to claim payment for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with Heath NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C. Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

resolve to amend the restriction criteria for Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad) in Part II of Section H of the Pharmaceutical Schedule from 1 July 2022 (new criteria shown only):

Restricted
Initiation – Serious mental health conditions or addiction
Any of the following:

1. schizophrenia; or
2. major depressive disorder; or
3. bipolar disorder; or
4. schizoaffective disorder; or
5. person is currently accessing secondary or tertiary mental health and addiction services.

Initiation – children from 3 to 12 years of age (inclusive)
Children 3 to 12 years of age (inclusive) from 1 July 2022 to 31 December 2022.

resolve that no consultation on this proposal is required.

note that we recently consulted on a proposal to fund influenza vaccine for Māori and Pacific peoples from 55 to 64 years of age in March 2022 and received consultation feedback supporting funding for school aged children and people with serious mental health conditions.

note that the widened access for children 3 to 12 years age is only for the 2022 influenza season, while widened access for serious mental health or addiction is for 2022 and future seasons.

SUMMARY OF PHARMACEUTICAL – INFLUENZA VACCINE – CHILDREN 3-12 YEARS OF AGE						
Brand name	Afluria Quad		**Chemical name**	Influenza vaccine		
Therapeutic Group	Vaccines		**Presentation**	Inj 60 mcg in 0.5 ml syringe		
Supplier	Sanofi Pasteur		**Pharmaceutical type**	Restriction change		
MoH Restriction	Prescription medicine		**Application date**	March 2022		
Market data		**YE 30 June 2023**	**YE 30 June 2024**	**YE 30 June 2025**	**YE 30 June 2026**	**YE 30 June 2027**
Number of patients		650,510				
Number of Māori / Pacific peoples		272,590				
Community Pharmaceutical Expenditure	Subsidy (gross)	9 (2) (b) (ii)				
	Net cost of community pharmaceuticals					
	Net present value (NPV)					
TOTAL – Combined Pharmaceutical Budget	Net cost to CPB					
	Net present value					
Other DHB costs	Distribution costs	$0	$0	$0	$0	$0
	Other costs to DHBs	$7,670,000	$0	$0	$0	$0
	Net other costs to DHBs	$7,670,000	$0	$0	$0	$0
	Net present value (NPV)	$7,670,000				
TOTAL	Total cost to DHBs	9 (2) (b) (ii)				
	Net present value (NPV)					

Notes:

1. Number of patients = number of new patients in each financial year.
2. Subsidy (gross) = forecast of all spending at the current subsidy.
3. Net cost of community pharmaceuticals = forecast of change in total spending on pharmaceuticals listed in the Schedule compared with status quo. Costs would be recovered from the COVID-19 Response and Recovery Fund (CRRF) 9 (2) (b) (ii)
4. Other costs to DHBs = Cost of the Immunisation Benefit paid to vaccinators by MoH (Health NZ) for administering vaccines less savings from reduced hospitalisations and outpatient admissions.
5. Total cost to DHBs = net cost to the Schedule plus net cost to DHBs.
6. All costs are expressed ex-manufacturer, ex-GST.
7. NPV is calculated over 5 years using an annual discount rate of 8%.
8. Calculations are in A1596684.

SUMMARY OF PHARMACEUTICAL – INFLUENZA VACCINE – SERIOUS MENTAL HEALTH OR ADDICTION						
Brand name		Afluria Quad		**Chemical name**		Influenza vaccine
Therapeutic Group		Vaccines		**Presentation**		Inj 60 mcg in 0.5 ml syringe
Supplier		Sanofi Pasteur		**Pharmaceutical type**		Restriction change
MoH Restriction		Prescription medicine		**Application date**		March 2022
Market data		**YE 30 June 2023**	**YE 30 June 2024**	**YE 30 June 2025**	**YE 30 June 2026**	**YE 30 June 2027**
Number of patients		174,000	177,000	180,000	182,000	185,000
Number of Māori / Pacific peoples		19,281	20,888	22,495	24,101	25,708
Community Pharmaceutical Expenditure	Subsidy (gross)	9 (2) (b) (ii)				
	Net cost of community pharmaceuticals					
	Net present value (NPV)					
TOTAL – Combined Pharmaceutical Budget	Net cost to CPB					
	Net present value					
Other DHB costs	Distribution costs	$0	$0	$0	$0	$0
	Other costs to DHBs	$880,000	$970,000	$1,050,000	$1,150,000	$1,240,000
	Net other costs to DHBs	$880,000	$970,000	$1,050,000	$1,150,000	$1,240,000
	Net present value (NPV)	$4,500,000				
TOTAL	Total cost to DHBs	9 (2) (b) (ii)				
	Net present value (NPV)					

Notes:
1. Number of patients = number of new patients in each financial year.
2. Subsidy (gross) = forecast of all spending at the current subsidy.
3. Net cost of community pharmaceuticals = forecast of change in total spending on pharmaceuticals listed in the Schedule compared with status quo. 9 (2) (b) (ii) 9 (2) (b)
4. Other costs to DHBs = Cost of the Immunisation Benefit paid to vaccinators by MoH (Health NZ) for administering vaccines less savings from reduced hospitalisations and outpatient admissions.
5. Total cost to DHBs = net cost to the Schedule plus net cost to DHBs.
6. All costs are expressed ex-manufacturer, ex-GST.
7. NPV is calculated over 5 years using an annual discount rate of 8%.
8. Calculations are in A1596684.

Why proposal should be considered by the Director of Operations under Delegated Authority

The proposal involves a Schedule change that has an estimated Financial Impact (NPV) of less than $10,000,000 and:

- will not result in the Pharmaceutical budget or its future funding path being exceeded;
- is not inconsistent with previous Board decisions; and
- is not considered contentious by Pharmac staff.

Background and Analysis

Background

- Border restrictions and other COVID-19 related public health measures have resulted in very little influenza virus circulating in the community for the last two years. Our clinical advisors have told us that the lack of community exposure to the influenza virus is likely to have reduced the natural level immunity in the New Zealand population. We are aware that the opening of New Zealand's international border is likely to increase the risk of severe illness from influenza for people at high risk.

- We widened access to influenza vaccine for the 2022 season (beginning 1 April 2022) for Māori and Pacific peoples from the earlier age of 55 to 64 years, recognising that Māori and Pacific populations have a younger age distribution than other population groups and a high incidence of comorbidities.

- The Ministry has been engaging with us to scope possible options for further widened access to flu vaccine for the 2022 season, in the context of current uptake figures indicating likely surplus stock the end of the 2022 season, and recent widening of access by several states in Australia due to the heightened risk.

- Pharmac worked with the contracted vaccine supplier to ensure that two million doses would be available for the 2022 season, to allow for high uptake due to the heightened risk of severe illness from influenza, and to reduce hospitalisations during a period when the sector is under strain managing COVID-19 cases. As of 16 June 2022, 1.4 million doses of vaccine have been distributed, approximately the same as the same time in 2021. Staff note that the distribution rate has slowed considerably in early June and forecast that the final distribution total is likely to be 1.5 to 1.6 million doses. This would result in unused stock of 400,000 to 500,000 doses.

- To ensure the availability of two million doses, 9 (2) (b) (ii) 9 (2) (b) (ii) 9 (2) (b) (ii) 9 (2) (b) (ii) 9 (2) (b) (ii) At current usage rates, staff estimate the likely cost of unsold stock at the end of the season would be 9 (2) (b) (ii) to the COVID-19 Response and Recovery Fund (CRRF).

Proposal

- This proposal is to widen access to influenza vaccine from 1 July 2022 for two

groups:

- Children 3-12 years of age (inclusive), only for the 2022 influenza season; and
- People with serious mental health conditions or addiction, for the 2022 and future influenza seasons.

Children 3-12 years of age (inclusive)

- If approved, this widened access is expected to reduce the impact of influenza not only on the children themselves, but on the whole population, particularly older high-risk populations during the COVID-19 pandemic (with consequent pressure on the health system through epidemic influenza with ICU and hospital admissions, affecting COVID-19 hospital care). This would be by reducing the transmission of influenza in 3 to 12 year olds (who have a high incidence of influenza infection), and thus reducing wider community transmission. The Afluria Quad influenza vaccine is approved by Medsafe for people aged 3 years and over.
- Widened access for children aged 3-12 years would only be available for the 2022 influenza season, and continued funding for future seasons would be assessed as a separate proposal.
- We did not receive clinical advice directly supporting the age range from 3-12 years, but it is a combination of two of the recommended age groups (all school aged children and children under 5 years), and is in line with the quantity of vaccine that is expected to be surplus at the end of the season with the current distribution pattern. Staff note that Afluria Quad is approved by Medsafe for use in children from 3 years of age, so the proposal includes children from 3 years as well as primary school-aged children. Staff note that there is insufficient stock of Afluria Quad Junior to widen access to children under 3 years.
- Staff note that our clinical advisors considered that changes requiring a targeted recall programme to reach the right people would be challenging for vaccination providers to implement. We have raised this with the Ministry who are responsible for the implementation of immunisation programmes. The Ministry remains supportive of the proposal and has advised that pharmacists can now administer influenza vaccine to children from 3 years of age and will be a key provider for supporting the proposed widened access.
- This proposal addresses health needs related to reduced population immunity, secondary to public health measures taken to reduce community transmission of COVID-19 which have reduced population immunity to influenza and other respiratory disease. Therefore staff consider the costs would be recovered from the COVID-19 Response and Recovery Fund (CRRF), and it would be appropriate to progress this proposal, despite it not being ranked on the OFI.

People with serious mental health conditions or addiction

- This proposal is currently ranked at 9 (2) (b) on the Options for Investment list. A smaller sub-group of this proposal is currently ranked at 9 (2) (b) (ii) on the Options for Investment list. We note that at this time it is estimated that there are sufficient funds in the Combined Pharmaceutical Budget for FYR 2022/23 to progress this proposal 9 (2) (b) (ii) 9 (2) (b) (ii)
- As this proposal has been ranked on the OFI and we consider it good value for money, it would be funded from the CPB for the 2022/23 FY and future years.

Agreement (if applicable)

- There is an existing agreement with Seqirus for the supply of influenza vaccine, dated 9 May 2019. The agreement resulted from a Request for Proposals (RFP) dated 20 November 2018. No changes to this contract are included as part of this proposal.

Health Need

- Influenza can be a serious illness that is sometimes fatal. Infection with the influenza virus may need treatment in hospital for people of any age, but particularly for people who are elderly or have an ongoing medical condition. Influenza can worsen existing medical conditions such as asthma or diabetes.

- Influenza infection rates are highest in children. For example, in the SHIVERS (Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance) study (covering Auckland/Counties Manukau DHBs 2012-13) 26% of influenza infections reported were in children under 5 years of age, and 31% were in school aged children 5-19 years (Huang et al. Influenza Other Respir Viruses. 2015; 9:179-90).

- Influenza vaccine is currently funded for all people 65 years of age and older as well as other high-risk groups, however, vaccination rates are much lower for Māori and Pacific peoples compared to the wider non-Māori, non-Pacific population. Māori and Pacific peoples have a younger age distribution than other population groups and a high incidence of comorbidities. The relative risk of hospitalisation for influenza infection (and its complications) is higher for Māori and Pacific peoples than the wider population, across all age groups.

- The significant health need of people with serious mental health conditions or addiction have been noted, in the context of influenza immunisation, by both the Immunisation Subcommittee (August 2021) and PTAC (February 2022). Māori experience higher rates of mental illness, higher rates of suicide and greater prevalence of addictions than the wider population (Mental Health and Addiction Inquiry 2018).

- These funding applications align with the following Government health priorities:
    - Child wellbeing: To improve child wellbeing and support children to have a healthy start in life, noting the impact of influenza in children
    - Prevention: To improve wellbeing by preventing health conditions, which includes immunisation against infectious diseases.
    - Health equity: To better population outcomes, noting the disproportionate representation of influenza infection in Māori, Pacific peoples, and those living in high socioeconomic deprivation.
    - Infectious disease is also listed as a priority condition, which includes immunisation to prevent infectious diseases.
    - Mental health and respiratory or listed among Pharmac's Māori health areas of focus.

Health Benefit

- Influenza vaccine is funded each year for a range of people, including those 65 years and older, in pregnancy, and for people with medical conditions such as

heart disease, respiratory conditions, diabetes, renal disease, and autoimmune diseases. It is also funded for Māori and Pacific peoples from 55 years of age. Over 1.4 million people are usually vaccinated annually (funded and privately purchased).

- The Afluria Quad and Afluria Quad Junior are the only funded influenza vaccines for the 2022 season and this proposal relates to only the Afluria Quad vaccine. It is a quadrivalent vaccine, protecting against four strains of influenza virus. For the 2022 season, the strains included are: A/Victoria, A/Darwin, B/Austria and B/Phuket.

- The Immunisation Subcommittee (May 2018) has commented that vaccination of primary school age children contributes to herd immunity, protecting high risk individuals who may respond less well to vaccines.

- Both the Immunisation Subcommittee (August 2021) and PTAC (February 2022) have considered that although there is not strong empirical evidence for health benefit from influenza vaccine in people with serious mental health conditions or addiction, there is good biological and psychosocial plausibility for benefit.

Immunisation Advisory Committee View

Children 3-12 years of age (inclusive)

- In March 2022, members of the Immunisation Advisory Committee provided clinical advice by email about options for widened access to influenza vaccine. Members considered that there is likely to be low immunity to influenza in the community due to border restrictions and other public health measures to manage COVID-19. With the opening of international borders we are aware that this is likely to increase the risk of severe illness from influenza for people at high risk.

- Members considered that open access for the highest risk age groups, such as children under 5 years of age and people over 55 years of age would be their preferred approach. Members highlighted that there are also other high needs groups that were not included in the options under discussion, such as people with serious mental health or addiction issues. Members also noted that funding for a range of additional groups would be desirable, such as: all children under 5 years of age, school aged children, all people from 55-64 years of age, Māori and Pacific peoples aged 50-64 years, and Community Services Card holders.

- Members considered that COVID-19 has had a major impact on the workload of General Practitioners, pharmacists and other organisations that are involved in providing vaccination services. Members considered that this proposed change would be challenging for vaccination providers to implement a targeted recall programme to reach the right people.

- Full details of the advice provided is available from fA312477.

- The Immunisation Advisory Committee provided further clinical advice at its May 2022 meeting. The Committee noted that most members' preferred option for widened access was open access for all ages, or some priority groups such as school aged children, or those from 6 months to 5 years of age.

- The draft record of this advice is available from A1585874.

People with serious mental health conditions or addiction

- The Immunisation Subcommittee (August 2021) recommended influenza vaccine for people with serious mental health conditions or addiction be listed with a medium priority (within the context of vaccines and immunisation). Such listing was recommended subject to eligibility criteria, in effect to include:
  1. people with a serious mental health condition (schizophrenia, major depressive disorder, bipolar disorder, or schizoaffective disorder); and
  2. people currently accessing secondary and tertiary mental health and addiction service.

- Both the Immunisation Subcommittee, in August 2021, and later PTAC (February 2022) noted the significant health need of people with serious mental health conditions or addiction, and considered that although there was not strong empirical evidence for health benefit [from influenza vaccine] in this group, there was good biological and psychosocial plausibility for benefit.

- PTAC noted and agreed with the Subcommittee's recommendation that influenza vaccine for people with serious mental health conditions or addiction be listed with a medium priority.

Advisor Conflicts of Interest

All declared conflicts of interest for any clinical advisors who contributed to the above advice, and actions taken to manage the conflicts, are recorded in the relevant minutes.

Consequences for the health system

- The Ministry's National Immunisation Programme team (NIP) has advised that it is supportive of the proposed widened access for both children 3-12 and for people with serious mental health conditions or addiction, and can support an implementation date of 1 July 2022. The NIP provided the following details of how it intends to support the implementation of widened access, which address the Immunisation Advisory Committee concerns about implementing targeted immunisation programmes late in the influenza season:
  - The National Immunisation Programme (NIP) supports Pharmac further extending the influenza eligibility criteria for the 2022 season. The NIP will work with the sector including pharmacy, who are instrumental in the delivery of the 2022 influenza programme, to communicate the eligibility change. With the recent amendments to the Medicine Regulations 1984, pharmacists can now vaccinate people aged 3+ years and will be a key provider for vaccinating people who meet the expanded criteria. The NIP will also engage with the Mental Health and Addiction directorate to provide support and ensure eligible people can access the funded influenza vaccine.
  - NIP has advised that it is urgently seeking approval of funding for the Immunisation Benefit costs associated with widened access.

Suitability

- Influenza vaccine (Afluria Quad) has been approved by Medsafe for the prevention of influenza caused by Influenza Virus, Types A and B contained in the vaccine. It is approved for use in people 3 years of age and older.

- Each 0.5 ml dose of the vaccine is supplied in a prefilled syringe with needle included.

Costs and Savings

Children 3-12 years of age (for 2022 only)

- This proposal would not result in any additional expenditure to the CPB or CRRF as the stock that would be used for the widened access 9 (2) (b) (ii) 9 (2) (b) (ii) rom the CRRF.

- The proposal to fund this group would benefit up to 650,000 children, although staff estimate that uptake would be unlikely to exceed 55% as it is late in the influenza season and parents would need to take the children to their GP or local pharmacy for vaccination.

- The financial impact assumes 55% uptake of the proposed group. While this uptake is likely higher than might be achieved, it is difficult to estimate accurately as it is dependent on the implementation plans put in place by the Ministry of Health. The Ministry has advised us that it intends to leverage mechanisms established to target populations for COVID-19 vaccinations, so staff do not consider it unreasonable to assume a greater uptake (ie 55%) than might otherwise be achieved.

- This proposal would incur costs to the Ministry of Health (Health NZ from 1 July 2021) of $8,300,000 for the Immunisation Benefit paid to vaccinators for administering influenza vaccine. The would be offset by savings of $630,000 from reduced hospitalisations and outpatient admissions. The total net impact to DHBs (soon to be Health NZ), would therefore be $7,600,000. The Ministry is supportive of the widened access and has advised it is seeking approval of funding to support widened access.

- There are no costs or savings to the person or their whānau as part of this proposal.

People with serious mental health conditions or addiction

- The proposal to fund this group would benefit up to 174,000 people in the first year, and up to 185,000 people in year five. There would be a cost to the CPB in the 2022/23 FYR of 9 (2) (b) (ii) with a 5-year NPV (8%) of 9 (2) (b) (ii)

- This proposal would incur costs to the Ministry of Health (Health NZ from 1 July 2021) of $1,200,000 for the Immunisation Benefit paid to vaccinators for administering influenza vaccine in the first year, rising to $1,700,000 in year five. This would be offset by savings of $330,000 in year 1, from reduced hospitalisations and outpatient admissions, rising to $480,000 in year five. The total net impact to DHBs (soon to be Health NZ), would therefore be $4,500,000 5yr NPV (8%). The Ministry is strongly supportive of the widened access and has advised it is seeking approval of funding to support widened access.

Comments from Interested Parties

Section 49(a) of the New Zealand Public Health and Disability Act 2000 (the Act) requires Pharmac to consult, when it considers appropriate to do so.

Pharmac staff consider consultation on the recommendations contained in this paper is not necessary as we recently received consultation feedback supporting the funding of school aged children and people with serious mental health conditions when we consulted on the proposal to fund influenza vaccine for Māori and Pacific peoples from 55 to 64 years of age in March 2022. Staff note that the proposal for children from 3-12 years of age is to only fund for the remainder of the 2022 influenza season. Any future proposal for the ongoing funding of this group would be subject to public consultation. The decision paper with the March 2022 consultation response summary is available at A1576521.

Legal advisors' view

Legal advice has not been sought on this proposal because Pharmac staff do not consider it to be contentious or to raise any issues of legal concern.

Implementation

Section 49(b) requires Pharmac to take measures to inform the public, groups and individuals of Pharmac's decisions concerning the pharmaceutical schedule. Accordingly, if the Director of Operations adopts the recommendations contained in this paper Pharmac staff will notify all suppliers, and implement the listing of these products via the usual Schedule processes. The Ministry of Health (Health New Zealand from 1 July 2022) is responsible for implementation for vaccines. It has advised that it is supportive of the widened access and activities it intends to use to support the widened access are outlined above in the 'Consequences for the health system' section.

Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the Operating Policies and Procedures. Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The Decision Maker is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.

Footnotes

[1] The person receiving the medicine or medical device must be an eligible person, as set out in the Health and Disability Services Eligibility Direction 2011 under Section 32 of the New Zealand Public Health and Disability Services Act 2000.

[2] The current Māori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy.

[3] Government health priorities are currently communicated to PHARMAC by the Minister of Health's Letter of Expectations.

[4] Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

[5] Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this Factor should be considered alongside those depicted in the schematic.

PHARMACEUTICAL SCHEDULE APPLICATION

To: Immunisation Advisory Committee

From: Funding Application Advisor

Date: May 2022

Influenza vaccine widened access options [P- 001779]

QUESTIONS TO IMMUNISATION ADVISORY COMMITTEE

Note to Committee members: These questions have been identified by Pharmac staff as being particularly relevant to the application. Please feel free to provide additional information as appropriate.

Need

1. Considering the currently available vaccines for influenza, is there an unmet health need? If so, why?

   1.1. What is the strength and quality of evidence for these needs?

2. Does influenza disproportionally affect:

   - Māori?
   - Pacific people?
   - Other groups already experiencing health disparities relative to the wider New Zealand population (eg NZ Dep 9-10 deprivation, refugees/asylum seekers)?

   2.1. What is the strength and quality of evidence for populations disproportionally affected by influenza?

Health benefit

3. Do high dose quadrivalent influenza vaccines (hdQIV), adjuvanted quadrivalent influenza vaccines (aQIV) or live attenuated influenza vaccines (LAIV) provide any additional health benefit or create any additional risks compared with other funded treatment options? If so, what benefits or risks are different from alternative vaccines?

4. Does reduction of community spread through widened access to any of the following groups provide any additional health benefit of create any additional risks compared with currently funded treatments?

   - universal vaccination of the whole population
   - universal vaccination of school-aged children
   - direct and indirect protection within households

5. What is the strength and quality of evidence, including its relevance to NZ, for health benefits that may be gained from influenza vaccine for the reduction of community spread by vaccination of each of these groups?

6. Does individual protection of any of the following groups provide additional health benefit of create any additional risks compared with currently funded treatments?

- universal vaccination of children under 5 years of age
- Māori and Pacific peoples from an earlier age than 65 years

7. What is the strength and quality of evidence, including its relevance to NZ, for health benefits that may be gained from influenza vaccine for individual protection by vaccination of children under five years of age or Māori and Pacific peoples from an earlier age than 65 years?
8. Which patient population would benefit most from each of the following types of influenza vaccines?
    - QIV
    - aQIV
    - hdQIV
    - LAIV
9. Which direct or indirect protection strategies does the Committee consider would be most effective in the New Zealand setting? Please describe the patient population that would benefit from each preferred strategy.
10. What is the strength and quality of evidence, including its relevance to NZ, for health benefits that may be gained from influenza vaccine for the preferred direct or indirect protection strategies?

Suitability

11. Are there any non-clinical features of the different influenza vaccines that may impact on use, either by the patient, by family, or by healthcare workers, that have not been considered in this paper?
12. Are there any features of QIV that may impact on its use in school-age children?

    12.1. Are there any age groups where an intranasal vaccine (such as LAIV) would be preferred over an injectable vaccine (such as QIV).

General

13. Is there any data or information missing from the application, in particular clinical trial data and commentary?

Recommendations

14. Which of the following influenza vaccine types should be considered for a future listing in the Pharmaceutical Schedule (subject to product availability) and be included in the next commercial process for influenza vaccine in addition to QIV?
    - aQIV
    - hdQIV
    - LAIV
15. Should widened access to include any of the following groups be listed in the Pharmaceutical Schedule?
    - Universal vaccination of the whole population

- Universal vaccination of school-aged children (please specify age ranges)
- Universal vaccination of all children younger than 5 years of age
- Māori and Pacific peoples from an earlier age than 65 years (please specify age ranges)
- Healthcare workers
- Family or whānau of high-risk groups
- Any other groups not described above

16. If widened access is recommended, what priority rating would you give to each patient group within the context of vaccines and immunisation? [low / medium / high / only if cost-neutral]?
17. Does the Committee have any further comments or recommendations additional to the application?

PURPOSE OF THIS PAPER

The purpose of this paper is to stimulate discussion about possible influenza vaccination strategies and seek advice from the Committee regarding alternative approaches to seasonal influenza vaccination. It introduces a Pharmac initiated application to widen access criteria for influenza vaccine.

This paper summarises the evidence for vaccinating the following groups:

- Universal vaccination of the whole population
- Universal vaccination of school aged children
- Universal vaccination of children younger than 5 years of age
- Māori and Pacific peoples from an earlier age than 65 years
- Healthcare workers
- Family or whānau of high-risk groups

DISCUSSION

BACKGROUND

Previous consideration of influenza vaccine

The Pharmaceutical Schedule currently lists two influenza vaccines (Afluria Quad Junior and Afluria Quad), each with specific funding criteria, which is further discussed below under *The availability and suitability of existing medicines, medical devices and treatments*.

Previously considered applications for the funding of influenza vaccines in different population groups and the recommendations made are shown in Table 1:

Table 1: Funding recommendations for influenza vaccines

Population	Recommendation	Status
Inactivated influenza vaccine		
Influenza in patients with serious mental health conditions and addiction	Immunisation Subcommittee Oct 2019: Decline Immunisation Subcommittee Aug 2021: Medium	Options compared
Ring protection for high-risk group, Māori people from an earlier age than 65 years, Pacific people from an earlier age than 65 years	Immunisation Subcommittee May 2018: Decline	Options compared
Adjuvanted quadrivalent influenza vaccine		
Influenza vaccination for people aged 65 years and over	PTAC Aug 2020: Decline Immunisation Subcommittee Sep 2020: Cost Neutral	Options compared
Adjuvanted trivalent influenza vaccine		
Influenza vaccination for people aged 65 years and over	Immunisation Subcommittee Sep 2018: Decline PTAC Feb 2019: Decline	Declined

Additional advice sought from the Committee about widened access options

Pharmac staff sought email clinical advice from the members of the Immunisation Advisory Committee in late February 2022. Advice was sought on a number of options for widened access that had been discussed with the Ministry of Health for widened access during the 2022 influenza season:

- Māori and Pacific peoples aged 55 to 64 years
- Children aged six months to five years
- Eligible people and their whānau who live in the same dwelling (also known as "whānau approach" or "ring protection")

Most members' preferred option was open access ("universal coverage") of all ages, or some priority groups such as school age children or those from six months to five years of age.

While open access was a preferred option, most members were supportive of widened access for Māori and Pacific peoples from an earlier age. It was also suggested by members that Pharmac consider extending this down to 50 years age as this is when immune response starts to wane due to ageing.

Members noted that currently Māori and Pacific rates for influenza vaccination are much lower in those aged 65 years and over, compared to non-Māori, non-Pacific peoples. Members also noted that Māori and Pacific peoples are at increased risk from seasonal influenza. Māori and Pacific populations have a younger age distribution than other population groups and high incidence of comorbidities. Widening access from an earlier age would increase coverage in Māori and Pacific Peoples as a greater proportion of the population would be able access funded vaccination.

The eligibility criteria for influenza vaccine were widened from 1 April 2022 to include Māori and Pacific people who are 55-64 years of age, for the duration of the 2022 calendar year. This widened access was intended to reduce the impact of influenza to at-risk populations during the COVID-19 pandemic. Many Māori and Pacific people in this age range may already have been eligible for funded influenza vaccine if they had comorbidities, however, additional criteria including age and ethnicity was considered to reduce health system barriers to accessing funded influenza vaccine, as these eligible people would not have to have already accessed health services to receive a diagnosis of a qualifying condition. Other options for widened access considered by Committee members in February 2022 were also evaluated, but this option was progressed taking into account the planned vaccine supply, particularly in relation to constrained paediatric vaccine supply.

Commercial strategy and future funding applications

The last influenza vaccine RFP in 2018 resulted in the award of sole supply to Seqirus for Afluria Quad / Afluria Quad Junior. At its May 2018 meeting, the Committee recommended that hdTIV, aTIV and LAIV be included in the RFP that was issued at the end of 2018. In recent years there have been advances in vaccine technology and there are now a number of different vaccine technologies that may have advantages or disadvantages compared to standard inactivated influenza vaccine (IIV) in different patient subgroups. The newer technologies include high dose vaccines (hdQIV), adjuvanted vaccines (aQIV) and live attenuated influenza vaccines (LAIV). As Pharmac plans for the next RFP later in 2022, we seek the Committee's advice on which types of influenza vaccines could be included in the RFP. If suppliers of preferred types of vaccines do not yet have Medsafe approval in NZ,

they will need to submit their Medsafe application and make a funding application to Pharmac. Such applications would most likely be considered by the Committee and PTAC at a meeting in early 2023, once RFP bids have been received and analysed.

The Subcommittee should consider whether it is appropriate to continue the current model where there is one subsidised vaccine brand for all people, which allows for sole supply commercial arrangements, or if it would be preferred to fund different vaccines for different patient groups, taking into account the added implementation complexities.

The following table summarises the availability of other vaccines that Pharmac is aware of. Some of the vaccine types discussed at this meeting are not yet available in New Zealand, so suppliers will need to submit registration applications for these vaccines if they intend to participate in the influenza RFP to be issued in late 2022.

Table 2: Availability of influenza vaccines

Vaccine	Brand	Supplier	Medsafe Registration	Funding application
Cell based QIV	Flucelvax Quad	Seqirus	Approved	Expected July 2022
Adjuvanted QIV	Fluad Quad	Seqirus	Approved	Updated application to be considered at this meeting
High Dose QIV	Fluzone	Sanofi	Not yet submitted	Expected July 2022
LAIV	FluMist	AstraZeneca	Not yet submitted	Unknown

Need

Description of the disease

Influenza is a common viral infection that attacks the lungs, nose and throat and is spread through the air from people coughing or sneezing. It characteristically begins with the onset of fever, malaise, muscle aches, and headache, followed by the development of a cough, congestion, and a sore throat.

People suffering from influenza usually recover within one to four weeks, but there is a risk that some will develop complications, such as secondary infections, inflammation of the heart, brain, or muscle, and sometimes organ failure. Population groups most at risk of complications from influenza include very young children, pregnant women, and the elderly. Overall mortality rates with seasonal influenza in New Zealand are estimated around 13.5 per 100,000 population, but with wide variation according to gender, ethnicity and socioeconomic status and ranging up to 214 per 100,000 in the very elderly (Khieu et al. J infect. 2017;75:225-33).

The strains that most commonly affect humans are Type A, Type B and Type C.

Epidemiology

The influenza season in NZ usually occurs from May to August. The Southern Hemisphere Influenza Vaccine Effectiveness Research Study (SHIVERS) started in 2012 and collected data on influenza vaccines and hospitalisations associated with severe acute respiratory illness (SARI) and general practice presentations for influenza-like illness (ILI) in the Auckland and Counties Manukau District Health Boards.

During the 2015 influenza season the SHIVERS study collected serology samples to measure the immune response to influenza infection. The serosurvey provided data on mild influenza that did not require GP consultation and information about the level of symptomatic and asymptomatic infection within the community.

The preliminary serological data suggested that around a quarter of the population would have been infected with influenza, and of these, 80% of children and adults with influenza did not have symptoms of influenza when infected. Of those with symptomatic infections, 77% did not seek medical attention.

During the 2020 and 2021 influenza seasons, ESR had reported that there had been very little, if any, influenza circulating, due to COVID-19 pandemic public health measures such as closed borders and mask wearing. For this reason, this section focuses on the 2019 season, albeit also a season with lower than usual influenza circulation.

Rates of weekly GP visits for ILI (influenza like illness) were lower than previous years in 2019 and did not exceed 60 cases per 100,000 people in any given week (Figure 1).

Figure 1: Weekly general practice ILI rates to 29 September 2019

Note: The black line denotes the 2019 rates of ILI. Grey line denotes historical rates for previous years.
Source: ESR 2019 Influenza Surveillance intelligence dashboard

Hospitalisations

The highest proportion of influenza infections resulting in hospitalisation and death is seen in adults aged over 65 years, who have decreased immune function due to their age and may have other conditions (including diabetes, heart disease, and respiratory conditions), which increase the risk of complications from influenza.

Khieu et al. Vaccine 2015;33:4087-92 (Appendix 1) used negative binomial regression models with weekly counts of hospitalisations and isolates of influenza A, B and respiratory syncytial virus for the period 1994-2008. The modelled hospitalisation rates per 100,000 are Table 3 below. Research by Khieu et al. highlights the highest disease burden in those under 65 years of age from influenza hospitalisation is in the <1 year, 1 to 4 year, 20 to 34 year and 50- to 64-year-old age groups. Noting the relative risk of hospitalisation for Māori (1.38) and Pacific peoples (1.43) across all age groups, the hospitalisation rate in each of these age groups is likely to be amplified for Māori and Pacific relative to non-Māori.

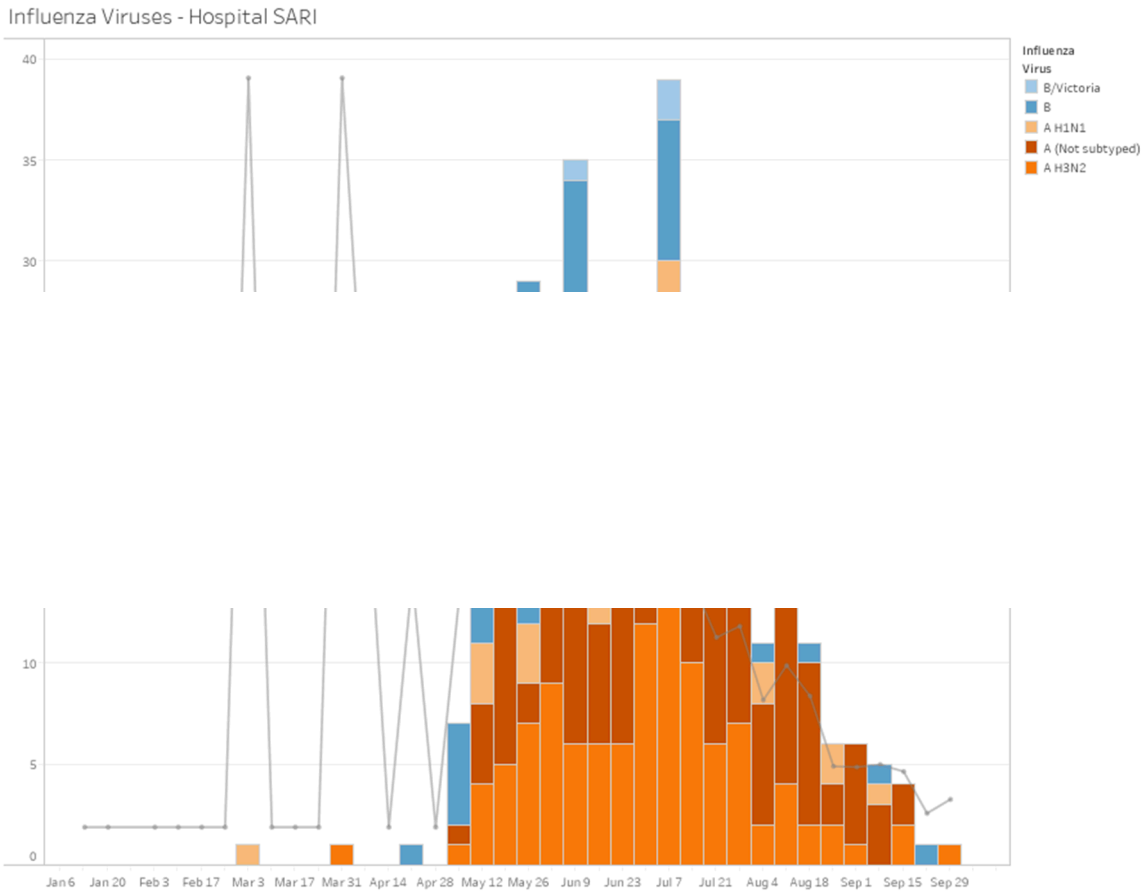
Table 3: Hospitalisation rates attributable to influenza (1994-2008), per 100,000

Description	Rate per 100,000
Hospitalisations attributable to influenza (1994-2008) – all ages, all causes*	62.4
Hospitalisations attributable to influenza (1994-2008) – <1 years, all causes*	244.5
Hospitalisations attributable to influenza (1994-2008) – 1-4 years, all causes*	161.1
Hospitalisations attributable to influenza (1994-2008) – 5-19 years, all causes*	15.8
Hospitalisations attributable to influenza (1994-2008) – 20-34 years, all causes*	52.3
Hospitalisations attributable to influenza (1994-2008) – 35-49 years, all causes*	15.7
Hospitalisations attributable to influenza (1994-2008) – 50-64 years, all causes*	53.2
Hospitalisations attributable to influenza (1994-2008) – 65-79 years, all causes*	149.9
Hospitalisations attributable to influenza (1994-2008) – >80 years, all causes*	327.8
Hospitalisations attributable to influenza (1994-2008) – Māori population all ages, all causes*	80.0 (RR vs non-Māori 1.38)
Hospitalisations attributable to influenza (1994-2008) – Pacific population all ages, all causes*	83.3 (RR vs non-Māori 1.43)
Hospitalisations attributable to influenza (1994-2008) – European/other population all ages, all causes*	58.1

*Causes included in the analysis: pneumonia and influenza, respiratory illness, circulatory illness, all medical illness, all causes

Weekly ESR surveillance data for 2019 shows that hospitalisations from influenza confirmed SARI were mostly caused by influenza A virus strains and did not exceed 40 cases per 100,000 in any given week (Figure 2).

Figure 2: 2019 rates of hospitalisation due to SARI, by influenza strain, per 100,000



Note: The grey line denotes the percentage of tested samples for that week which were influenza positive.
Source: ESR 2019 Influenza Surveillance intelligence dashboard

Mortality

Khieu et al. J Infect 2017;75:225-33 (Appendix 1) modelled seasonal influenza mortality in New Zealand, estimating the average mortality rate and identifying differences in risk by age, sex, ethnicity and socioeconomic position. Data was drawn from the New Zealand mortality dataset for the period 1994 to 2008. Mortality rates per 100,000 are shown in the Table 4 below:

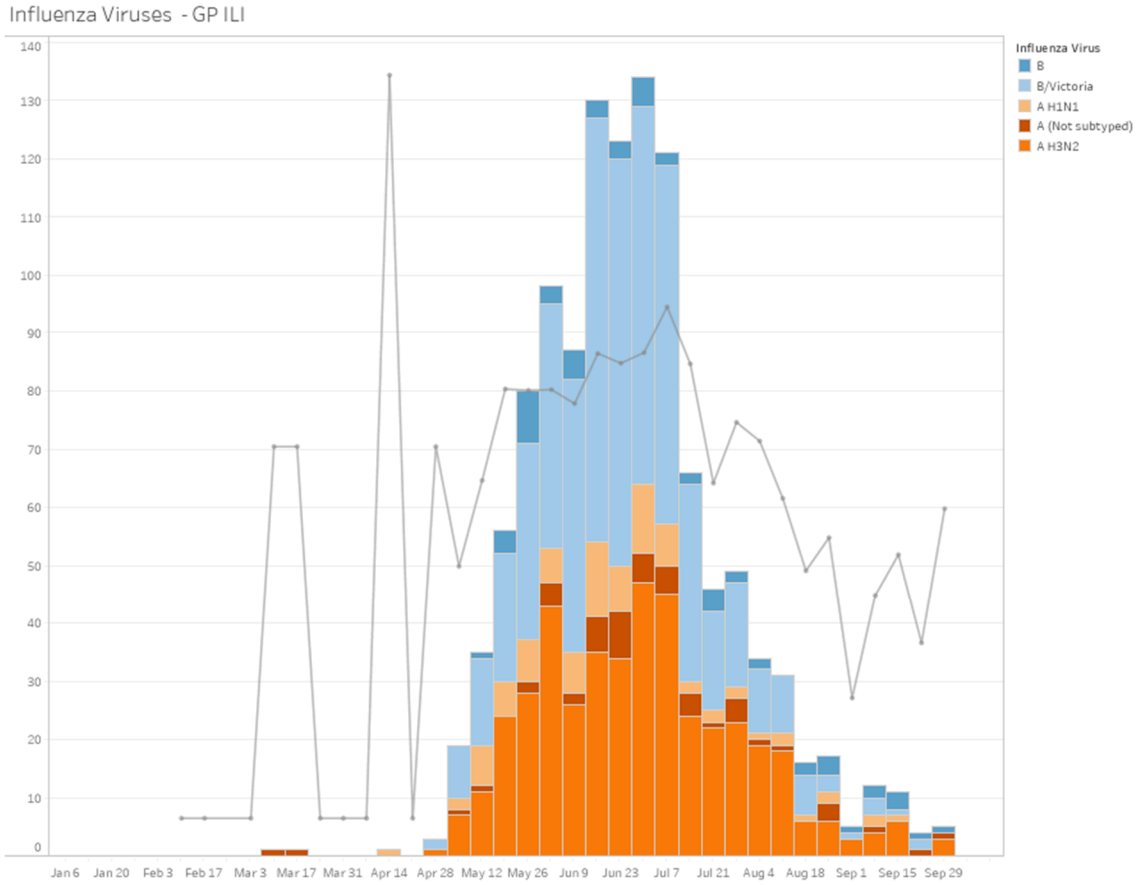
Table 4: Estimated rate of influenza-associated deaths (1994 to 2008) per 100,000

Description	Value
Estimated rate of influenza-associated deaths per 100,000 people (95% CI), all causes	13.5 (13.4, 13.6)
Estimated rate of influenza-associated deaths per 100,000 people, 20-64 years old (95% CI), all causes	2.5
Estimated rate of influenza-associated deaths per 100,000 people, 65+ years old (95% CI), all causes	90.3
Estimated rate of influenza-associated deaths per 100,000 people, 65-79 years old (95% CI), all causes	49.7
Estimated rate of influenza-associated deaths per 100,000 people, 80+ years old (95% CI), all causes	214
Estimated proportion of total deaths caused by influenza (%), all causes	1.8%

General practice community sentinel surveillance

According to ESR Influenza Surveillance data, 2019 GP visits for influenza confirmed ILI were predominantly caused by influenza B virus strains, mainly B/Victoria (Figure 3).

Figure 3: 2019 rates of GP visits due to ILI, by influenza strain, per 100,000



Note: the grey line denotes the percentage of tested samples for that week which were influenza positive.
Source: ESR 2019 Influenza Surveillance intelligence dashboard

Influenza immunisation coverage

Influenza vaccination claims data show that the coverage rate for adults aged 65 years and over was 65% in 2019. The coverage for pregnant women is 30% and for children aged 0-4 years was 3%.

Influenza vaccination claims data for 2021 show that the overall coverage rate for adults aged 65 years and over was 63.8%. Coverage data for people over 65 years of age overall and by ethnicity, provided by the Ministry of Health (MoH) Immunisation Team is provided in Table 5 below (both funded and unfunded). 2020 data is not presented due to the influence of the public health measures from the COVID-19 pandemic response, which affected this data.

Table 5: Influenza vaccination coverage uptake for adults aged over 65 years, by ethnicity, for the 2019 and 2021 influenza season

Group	Coverage
2019 influenza season	
Adults aged 65 and over (excludes unfunded)	66%
Māori people aged 65 and over	57%
Pacific people aged 65 and over	70%
2021 influenza season	
Adults aged 65 and over (excludes unfunded)	63.8%
Māori people aged 65 and over	50%
Pacific people aged 65 and over	62.4%

Source: MoH Immunisation Team

The health need of the person

Influenza is a viral infection that is associated with high morbidity and mortality due to the effects and complications of acute respiratory illness in young children, the elderly, pregnant women and those with a range of underlying medical conditions. However, healthy children and adults can also be at risk of serious illness following influenza infection.

The availability and suitability of existing medicines, medical devices and treatments

The funded influenza vaccine for 2022 for the adult population is AFLURIA QUAD (Seqirus), a non-adjuvanted QIV. The vaccine offers protection against strains A/Victoria/2570/2019 (H1N1) pdm09-like virus, A/Darwin/9/2021 (H3N2)-like virus, B/Austria/1359417/2021-like virus, B/Phuket/3073/2013-like virus.

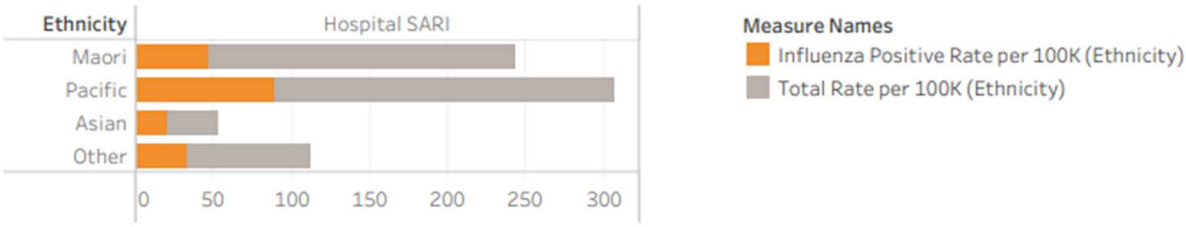
The health need of family, whānau, and wider society

Pharmac acknowledges that there may be a health need for other people as a result for caring for patients with influenza. The impact on whānau primarily comes from the risk of transmission to those living with and caring for patients with influenza.

The impact on the Māori health areas of focus and Māori health outcomes

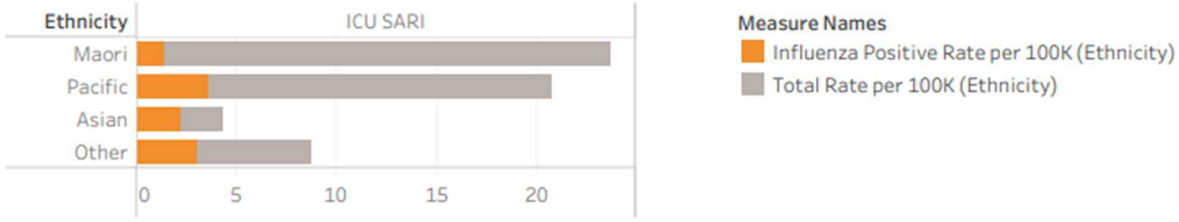
Influenza disproportionately affects Māori health outcomes, which may be in part due to lower rates of immunisation in the Māori population. Māori and Pacific peoples are more likely to be hospitalised from SARI compared with non-Māori and non-Pacific populations (Figure 4) and are also more likely to have to be treated in ICU due to SARI, though Māori rates of ICU admission from confirmed influenza are lower than for non-Māori (Figure 5).

Figure 4: Cumulative rate of hospitalisations due to SARI, by ethnicity, per 100,000



Source: ESR 2019 Influenza Surveillance intelligence dashboard.

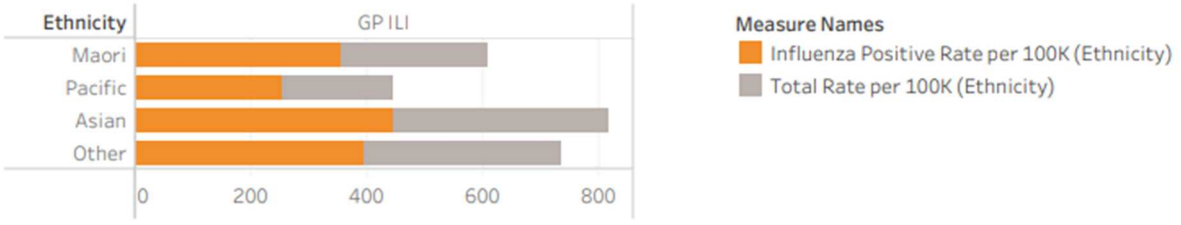
Figure 5: Cumulative rate of ICU admissions due to SARI, by ethnicity, per 100,000



Source: ESR 2019 Influenza Surveillance intelligence dashboard.

In addition, Māori and Pacific people are less likely to visit a GP than Asian, non-Māori and non-Pacific people with ILI symptoms (Figure 6) which may contribute to the increased severity of complications from influenza seen in the Māori and Pacific population.

Figure 6: Cumulative rate of GP visits for ILI, by ethnicity, per 100,000



Source: ESR 2019 Influenza Surveillance intelligence dashboard

Khieu et al (2015) estimated that influenza hospitalisation rates were 58.1 per 100,000 for the European population compared with 80.0 and 83.0 per 100,000 for Māori and Pacific people, respectively (Khieu et al. Vaccine 2015;33:4087-92). In 2017, the same authors reported that when standardising for age, the mortality rate attributable to influenza in the

Māori population was statistically significantly higher than Other/European populations with 21.1 per 100,000 compared with 4.5 per 100,000 for European/Other. The Pacific population also experienced a statistically significantly higher rate of influenza attributable mortality compared with European/Other with a rate of 6.8 per 100,000 (Khieu et al. 2017).

Currently Māori aged 65 years and over are less likely to receive their annual vaccination. Coverage measured through claims data submitted to the Ministry of Health suggests that only 50.0% of this group were able to access vaccination in 2021; uptake in this age group for the overall population was 63.8%. By contrast, Pacific people aged 65 years and over are more likely to receive their annual vaccination; claims data submitted to the Ministry of Health suggests that 62.4% of this group were vaccinated in 2021.

The impact on the health outcomes of population groups experiencing health disparities

Baker et al. conducted a national epidemiological study of hospital admissions for infectious and non-infectious diseases in New Zealand from 1989 to 2008 to investigate trends in incidence across various socioeconomic and ethnic landscapes. They found that those living in the most deprived areas (NZDep 9&10) have a higher rate of infectious disease related hospitalisations than the least deprived areas (NZDep 1&2) (Baker et al. Lancet. 2012;379(9821):1112-9)

Khieu et al. reported the influenza-attributable death rate per 100,000 was higher for more deprived areas (NZDep 9&10) compared with least deprived areas (RR 1.8, 95% CI 1.3-2.4) (Khieu et al. 2017).

The impact on Government health priorities

This funding application aligns with the following Government health priorities:

- Child wellbeing: To improve child wellbeing and support children to have a healthy start in life, noting the impact of influenza in children
- Prevention: To improve wellbeing by preventing health conditions, which includes immunisation against infectious diseases.
- Health equity: To better population outcomes, noting the disproportionate representation of influenza infection in Māori, Pacific peoples, and those living in high socioeconomic deprivation.

Infectious disease is also listed as a priority condition, which includes immunisation to prevent infectious diseases.

Health Benefit

The health benefits to the person, family, whānau and wider society

Evidence Summary

The Immunisation Advisory Centre (IMAC) has provided a brief review of the evidence to provide insight into potential further immunisation strategies that could be implemented to reduce the spread of influenza and reduce the impact of severe influenza in New Zealand. The full text version of the references in this section are available in Appendix 1, and the review (*Role of vaccination in influenza control strategies*, IMAC 2022) is provided in Appendix 2.

The IMAC 2022 review proposes a range of vaccination strategies that address the reduction community spread or the protection of high-risk individuals. The approaches are outlined in Table 6 below:

Table 6: IMAC 2022 proposed vaccination strategies

Protection of high-risk individuals (direct protection)	• Individual protection • Broadening eligible risk groups • Age groups for Māori and Pacific peoples • Consideration of additional groups funded in other jurisdictions • Ring-fencing high-risk groups to reinforce protection
Reduction of community spread (indirect protection)	• Full universal vaccination • Universal vaccination of school aged children • Direct and indirect protection within households

Direct protection

Vaccination of children

The Ministry of Health recommends vaccination of children from six months of age, but influenza vaccine is only funded from this age for people with underlying health conditions and children under five years of age who have been hospitalised for respiratory illness or have a history of significant respiratory illness. The full eligibility criteria are available on the Pharmac website.

Immunisation coverage

A study from the US (Bleser et al. PLoS ONE 2020;15(6): e0234466) examined data from the 2011 National Immunization Survey and reported that although children six months and older are recommended to receive annual influenza vaccination, uptake was substantially lower than other schedule vaccines. The study reported that about 71% of children aged 6-23 months were up to date on routinely recommended vaccines but only 33% had the

recommended influenza vaccine by their second birthday and 44% had hidden vulnerability to influenza.

Improving vaccine uptake through universal childhood vaccination

A study in Australia (De Oliveira Bernardo et al. Hum Vaccin Immunother. 2020;16(3):630-5) reported that overall influenza vaccination coverage in general practice for children aged under 5 years increased by more than five times from 2015 (3.9%) to 2018 (19.6%). Prior to universal funding, children under five years of age in the wealthiest areas were most likely to receive the influenza vaccine. After the vaccine was funded, all children in these wealthier areas (irrespective of their individual household socioeconomic levels) benefited more than those in less advantaged areas. This was because although the vaccine was accessible to all children (under five years), there was a greater increase in coverage from 2017-2018 in the wealthier areas than the disadvantaged areas.

Reduction in influenza in children following vaccination with IIV or LAIV

A 2018 systematic review reported that vaccination of healthy children with inactivated influenza vaccines (IIV) reduced influenza infection from 30% to 11% (risk ratio 0.36, 95% CI 0.25-0.48; n=1,628) and may reduce influenza-like illness (ILI) (from 28% to 20%; risk ratio 0.72, 0.65-0.79; n=19,044) in children aged between two and 16 years. Based on this, five children would need to be vaccinated with inactivated vaccine to prevent one case of confirmed influenza and 12 vaccinated to prevent one cases of ILI. The confidence of evidence for live attenuated influenza vaccine (LAIV) was less certain but demonstrated protection against influenza (from 18% to 4%; risk ratio 0.2, 0.11-0.41; n=7,718) and a reduction in ILI in children (from 17% to 12%; risk ratio 0.69; 0.6-0.8, n=124,606). Seven children would need to be vaccinated with LAIV to prevent one case of influenza and 20 children vaccinated to prevent one case of ILI in children. (Jefferson et al. Cochrane Database Syst Rev. 2018;(2):CD004879)

Vaccination in pregnancy to protect infants

A meta-analysis (Jarvis et al. Vaccine. 2020;38(7):1601-13) that pooled two randomised controlled trials reported that maternal influenza vaccination was associated with a 34% (95% CI 15% to 50%) overall reduction in laboratory confirmed influenza, but not ILI in infants up to six months of age. Two studies that were excluded from the meta-analysis for the outcome of laboratory confirmed influenza due to different controls, reported vaccine efficacy of over 70% against influenza in maternally vaccinated infants.

Vaccination of other high-risk groups: Māori and Pacific peoples

In 2013 the Ministry of Health reported that Māori people aged five to 34 years were almost twice as likely than non-Māori to be hospitalised for asthma than non-Māori people (risk ratio [RR] 1.96, 95% CI 1.87 to 2.07) and 25% more likely to be diagnosed with chronic respiratory disease at age 15-45 years (RR 1.27, 95% CI 1.06 to 1.52). Mortality rate due to COPD was almost three times that of non-Māori from the age of 35 years in 2010-12. In 2012-14, life expectancy from birth was around seven years lower for Māori than non-Māori (Ministry of Health; Health status indicators; updated 02 August 2018).

In 2010, more than half of the Māori population were aged under 25 years, and Māori had a higher prevalence of acute and chronic respiratory tract infections than non-Māori. The factors contributing to this increased risk appear to be environmental (overcrowding, poor housing, socioeconomic status, smoke exposure, nutrition), and reduced access to health

promotion programmes, such as immunisation programmes, and health care, rather than underlying genetic or medical disorders (Byrnes et al. J Paediatr Child Health. 2010;46(9):521-6).

A study investigating emergency department (ED) presentation of infants age <1 year for acute respiratory infection (ARI) at Kidz First Childrens' Hospital in South Auckland (as part of the SHIVERS project) reported that the influenza hospitalisations incidence ratio per 1,000 infants was 6.2 (95% CI 3.4 to 9.0) for Māori, 6.1 (95% CI 3.5 to 8.8) for Pacific, 0.5 (95% CI -0.01 to 1.0) for Asian, and 0.7 (95% CI 0.1 to 1.3) for European/Other (Prasad et al. Pediatr Infect Dis J. 2020;39:e176-85), in effect rates nine times higher in Māori and Pacific children compared with European/Other children.

Vaccination of other high-risk groups: Elderly

A review of literature concluded that, overall, standard influenza vaccination can attenuate the course of disease in those with breakthrough infection compared with those who are unvaccinated among community-dwelling adults ≥65 years with laboratory-confirmed influenza. A meta-analysis reported the odds of influenza-associated ICU admission was reduced by 26% (pooled odds ratio [OR] 0.74, 95% CI 0.58 to 0.93) by vaccination. The risk of death in adults hospitalised with influenza was reduced by 31% (OR 0.69, 95% CI 0.52 to0.82) compared with unvaccinated patients. Vaccination was not significantly associated with a reduction in pneumonia among adults hospitalised with influenza (OR 0.92, 95% CI 0.82 to 1.04) nor risk of hospitalisation with influenza illness seeking outpatient care (OR 0.60, 95% CI 0.28 to 1.28) (Ferdinands et al. Vaccine. 2021;39:3678-95).

Indirect protection - community (herd) immunity

Vaccination of children

A systematic review investigating vaccination of children aged six months to 17 years against influenza reported that indirect protection was conferred in some but not all settings. Across 20 out of 30 studies, the point-estimate indirect protection effectiveness (IPE) ranged from 4% to 66%. When looking at randomised controlled trials, an IPE of 60% (95% CI 41% to 72%) was shown against laboratory-confirmed influenza in members of closely connected communities when school-aged children were vaccinated, and IPE of 22% (95% CI 1% to 38%) against acute respiratory tract infection/ILI in household members of vaccinated preschool-aged children. Indirect protection against influenza mortality of the elderly was also seen by vaccinating school children who play a key role in transmission. Despite this, the review concluded that most effective way to prevent influenza at an individual level was through annual vaccination (Yin et al. Clin Infect Dis. 2017;65:719-28).

A study based in Japan observed the role of mass vaccination in schoolchildren in providing protection to the elderly and young children. During a mass vaccination campaign of school children (aged 6-15 years) from the mid-1970s to late 1980s, adjusted mortality reduced by 36% (17-51%) in Japanese seniors, which corresponded to 1,000 (400-1,800) deaths averted by annual vaccination of children. This was compared with the US, in which influenza-related mortality remained unchanged despite vaccination of the elderly population. Younger children were also reported to be indirectly protected against influenza complications during the period of mass schoolchild vaccination (Sugaya. Expert Rev Vaccines. 2014;13:1536-70).

A Dutch epidemiologic study modelled infections and argued that vaccinating young children would likely lead to an age shift in infection dynamics, which would result in limited indirect impact on the elderly from vaccinating children (Backer et al. Epidemics. 2019;26:95-103). Using a dynamic transmission model, it predicted a smaller impact and more variability in the infection attack rate. Reasons were firstly that while modelled influenza infections in young children were reduced, after years of vaccination they increased in young adults with limited natural immunity, which could drive an epidemic. Secondly, after a mild influenza season, the modelled proportion of susceptible individuals increased to result in a peak of cases the following year. The authors observed that targeting the group that plays the largest role in transmission potential requires a secure vaccine supply.

A school-based influenza vaccination programme in Autumn 2005 using LAIV were associated with directly reduced school absenteeism in elementary schools (children aged 5 to 11 years) during an influenza outbreak in Carroll County, Maryland US. With a 44% vaccination coverage, school absenteeism was observed to decline from 1.8% in the 2001-05 seasons to 0.6% in the 2005/6 season. An indirect effect was also seen in high schools (children aged 14 to 18 years) (0.3% from 1.8%); a similar trend was seen in middle schools (children aged 10 to 14 years) (Davis et al. Paediatrics. 2008;122(1):e260-e65).

A study in Israel reported that when influenza vaccine was administered in a school setting, a reduction in ILI was observed among the those vaccinated (by 60.5%) and their household members (by 27.5%). (Roseman et al. Isr J Health Policy Res. 2021;10:38). The retrospective cohort study across nine schools in Tel Aviv compared self-reported ILI within children and their households for those who were vaccinated at school in the second grade (age ~8 years) with those in the third grade (~age 9 years) who were not vaccinated a part of the school-based vaccination. In the second-grade cohort, 133/168 (79.2%) had been vaccinated. In this cohort, unvaccinated children had a higher rate of reported ILI than those who had been vaccinated (19.5% vs 7.7%, rate reduction of 60.5%, $P<0.001$); the unvaccinated children had a greater number of doctors' visits and missed school days (35.7% vs 14.9% and 42.9% vs 25.6%, respectively); and the rate of ILI among household members was also higher for unvaccinated children (35.4% vs 25.0%; rate reduction 27.3%; p = 0.03). When the second-grade cohort (52.8% vaccinated) were compared with the third-grade cohort not vaccinated as part of the programme (12.7% vaccinated), those who had been vaccinated had a 44.6% rate reduction of ILI and their household had a 22.9% rate reduction in ILI.

Ring protection

Close contacts of high-risk individuals (family members or carers)

A study in the UK reported that higher rates of vaccination rates within NHS trusts were associated with reduced sickness absence, reporting that a 10% increase in influenza vaccination rate would be associated with a 10% fall in sickness absence. (Pereira et al. Clin Med (Lond). 2017;17:484-9).

An Italian study reported that around 20% of healthcare workers were infected with influenza each year, resulting in nosocomial outbreaks and staff shortages, and that influenza vaccine coverage remained low. Over the study period, influenza vaccine coverage decreased significantly from 13.2% to 3.1% ($P<0.001$), and an associated increase in frequency of nosocomial ILI in hospitalised patients from 0.11% to 0.57% ($P<0.001$) was observed (adjusted OR of 0.97; 95% CI 0.94 to 0.99) (Amodio et al. J Hosp Infect. 2014;86:182-7).

International recommendations

International Recommendations

Table 7: International recommendations regarding the funding of influenza vaccine in different populations

Country	**QIV** **Age group**	**Comments**	**LAIV** **Age group**	**Adjuvanted or high dose** **Age group**	Comments
Australia 2022 season	All aged 6 months to 5 years	Funded	Not available		
	All ATSI people aged from 6 months	Funded		≥60 years	HD QIV
				≥65 years	aQIV
	All aged ≥65 years	Funded		≥65 years	aQIV
	Ages 5 to <65 years	Funded for: • Certain medical conditions • In pregnancy			
Canada	All aged 6 months to 23 months				
	Children ages 2 to 17 years with immunocompromise or severe asthma	Unless LAIV is not contraindicated	Children aged 2 to 17 years		
	18 to 64 years		18 to 59 years	≥65 years	HD QIV, aQIV, or QIVc
	Pregnant				
	HCW	QIV not LAIV			
Ireland	From 6 months		24 months to <18 years	≥65 years	aQIV
UK	All infants aged 6 months to <2 years	QIVe funded	All children aged ≥2 years	All adults aged ≥65 years	aQIV
	All aged ≥2 years	QIVc, if LAIV contraindicated			QIVr or QIVc
	At risk adults 18 to 64 years	QIVc or QIVr (or QIVe, if other options unavailable)			
	All adults aged 50 to 64 years				

Abbreviations: ATSI, Aboriginal Torres Strait Islander peoples; LAIV, live attenuated influenza vaccine; QIV, Quadrivalent inactivated influenza vaccine; QIVc, cell-based; QIVe, egg-based; QIVr, recombinant.

Consequences for the health system

If the funding criteria for the influenza vaccine were to be widened, this would be expected to reduce the number of and complications of influenza infection, thereby reducing the pressure on and costs to the healthcare system.

Suitability

The features of the medicine or medical device that impact on use

Standard dose inactivated influenza vaccines are an injectable presentation. These are suitable to be given to most individuals, including young children, the elderly, pregnant women, and immunocompromised people.

Adjuvanted and high dose inactivated influenza vaccines are injectable presentations. Both are indicated for people 65 years of age or older. Adjuvanted vaccine is associated with injection site reactions. An adjuvanted influenza vaccine funding application is to be reviewed as a separate agenda item at this meeting. It is anticipated that a funding application for high dose inactivated influenza vaccine will be reviewed the upcoming September 2022 Committee meeting.

Live attenuated influenza vaccines (LAIV) are nasal spray presentations. They are indicated for children and adolescents from two years of age and adults up to 49 years of age. There is insufficient data around the use of LAIV in adults aged 50-64 years of age.

The intranasal presentation is more acceptable to parents / caregivers, possibly leading to increased uptake of vaccination in children compared to injectable vaccines. However, the introduction of a school or pre-school-based programme would have significant resource implications for DHBs to implement each year, and significant financial implications for the Ministry of Health funding vaccination claims.

Since live virus is administered intranasally, there is the possibility of spreading virus through viral shedding. Shedding is inversely correlated with age, with the youngest children most likely to shed virus over the longest time.

LAIV are contraindicated for immunosuppressed individuals.

LAIV are not Medsafe approved for use in New Zealand and Pharmac has not received any funding applications to date.

Costs and Savings

Costs and savings to pharmaceutical expenditure

No cost analysis has been undertaken at this time, as this paper discusses possible strategic options for widening access to influenza vaccine in New Zealand, rather than listing any

particular vaccine. Once clinical advice is obtained on the most appropriate options for widening access, cost analysis can be undertaken on those options.

The annual gross subsidy on influenza vaccine is approximately 9 (2) (b) (ii) million for 730,000 doses.

APPENDICES

Appendix 1: Key evidence

- Amodio et al. 2014
- Backer et al. 2019
- Bleser et al. 2020
- Byrnes et al. 2010
- Davis et al. 2008
- De Oliveira Bernado et al. 2020
- Ferdinands et al. 2021
- Jarvis et al. 2020
- Jefferson et al. 2018
- Khieu et al. 2015
- Khieu et al. 2017
- Pereira et al. 2017
- Prasad et al. 2020
- Roseman et al. 2021
- Sugaya. 2014
- Yin et al. 2017

Appendix 2: Role of vaccination in influenza control strategies, IMAC 2022

THE FACTORS FOR CONSIDERATION

Factors are presented here in the order they appear in the paper, without implying any ranking or relative importance.

NEED

- The health need of the person
- The availability and suitability of existing medicines, medical devices and treatments
- The health need of family, whānau, and wider society
- The impact on the Māori health areas of focus and Māori health outcomes
- The impact on the health outcomes of population groups experiencing health disparities
- The impact on Government health priorities

HEALTH BENEFITS

- The health benefit to the person
- The health benefit to family, whānau and wider society
- Consequences for the health system

SUITABILITY

- The features of the medicine or medical device that impact on use by the person
- The features of the medicine or medical device that impact on use by family, whānau and wider society
- The features of the medicine or medical device that impact on use by the health workforce

COSTS AND SAVINGS

- Health-related costs and savings to the person
- Health-related costs and savings to the family, whānau and wider society
- Costs and savings to pharmaceutical expenditure
- Costs and savings to the rest of the health system