National Health Emergency Plan

H5N1 Pre-Pandemic Vaccine Usage Policy (Revised 2013)

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Contents

PLEASE NOTE

This policy aligns with current expectations of developments in the early stages of an H5N1 influenza pandemic.

Actual developments may require this policy to be revised at any time.

Key points

- The NZ Government holds 150,000 vaccination courses of H5N1 pre-pandemic vaccine made from a currently circulating avian influenza virus.
- The vaccine is stored in New Zealand. It is a Crown Asset managed by the Ministry of Health.
- The vaccine may only be released for use by the Director General of Health after considering all relevant available information and the advice of the Director of Public Health.
- The vaccination course requires two doses of vaccine given at least 3 weeks apart; with 3 week timing, it takes about six weeks from the first dose to the development of immunity to the seed virus.
- Development of immunity to the seed avian H5N1 influenza virus may provide cross-protection against a human H5N1 virus, but the effectiveness of any protection cannot be known ahead of time.
- Offers of vaccine will be prioritised between and within agencies and services in the national interest.
- The vaccine will be offered to people in specifically identified agencies and/or occupational groups who provide essential pandemic response services *AND* who, by the nature of their duties, may be closely and continually exposed to people who have, or may have, human H5N1 influenza, *AND* who cannot reasonably modify their work practices to further reduce the risks of exposure.
- Current target groups are approximately 150,000 front-line workers in:
    - Health
    - Defence
    - Police
    - Border management agencies
    - Social support agencies
    - Corrections
    - Fire Services
    - New Zealand-based international aircrew.
- People wishing to have the vaccine must sign an informed consent form.
- The vaccine will be free of charge to qualifying people who sign the informed consent form. It will not be available for sale or purchase.
- DHBs will be responsible for administering vaccine to all qualifying people other than Defence staff, who will be vaccinated by Defence Medical Services.
- The Cook Islands, Niue and Tokelau will be supplied with population-based pro-rata volumes.

1 Background

The New Zealand Government holds a supply of 150,000 vaccination courses (300,000 doses) of an H5N1 pre-pandemic vaccine (H5N1 vaccine), made by Baxter Healthcare. from a currently circulating strain of the H5N1 avian influenza virus. The vaccine is a Crown Asset managed by the Ministry of Health.

2 Vaccine characteristics

The vaccine is a monovalent, non-adjuvanted influenza virus vaccine for active immunization against the H5N1/Indonesia/05/2005 wild type virus (a Clade 2 avian H5N1 virus). It contains Vero cell-derived, double-inactivated, sucrose gradient-purified whole virions of influenza type A based on the requirements of the current edition of the European Pharmacopoeia for interpandemic vaccine. The vaccine does not contain egg or chicken protein, or any other serum-derived protein. It is packed without preservative in multi-dose vials each containing 10 doses.

Each 0.5ml dose contains 7.5µg haemagglutinin antigen of the avian influenza virus strain in saline. Effective vaccination requires two doses of vaccine given intramuscularly at least three weeks apart. When both doses are given as directed the vaccine produces a level of immunity to the seed virus that meets standards for seasonal influenza vaccine by about six weeks after the first vaccination. A single vaccination will not provide any significant level of protection. Testing has shown a similar risk profile as a normal seasonal influenza vaccine.

The vaccine can reasonably be expected to provide some level of cross-protection against a human H5N1 virus, but it is not possible to predict how much. This will depend on how close (in the evolutionary sense) the human virus is to the avian seed virus, and cannot be known ahead of time. The vaccine may provide protection ranging from good to negligible. It will probably provide a priming dose for any eventual pandemic vaccination, which in turn can be expected to enhance the response to a pandemic-specific vaccination.

The vaccine will be offered to approximately 150,000 key workforce people who are likely to be most exposed to a human strain of an H5N1 virus in the early stages of a pandemic. This is expected to enhance New Zealand's pandemic responses by ensuring the availability of vaccinated staff for duty. This, in turn, will help to minimise pandemic impacts on the general population.

3 General policy

The agencies and occupational groups to be offered the vaccine will be identified and prioritised in the national interest. The overall aim of the policy is to maximise the effectiveness of New Zealand's pandemic response and maintain essential Government and health services.

Accordingly the vaccine will be offered to people in specifically identified agencies and/or occupational groups who provide essential pandemic response services *AND* who, by the nature of their duties, may be closely and continually exposed to people who have, or may have, human H5N1 influenza, *AND* who cannot reasonably modify their work practices to further reduce the risks of exposure.

4 Cook Islands, Niue and Tokelau (PICTs)

New Zealand's constitutional arrangements with the Pacific Island Countries and Territories (PICTs) of the Cook Islands, Niue and Tokelau provide for support from New Zealand in health emergencies. Accordingly H5N1 vaccine will be provided to the PICTs on a pro-rata basis equivalent to the volumes available for the New Zealand home islands (see appendix 1). Internal prioritisation of supply to the Island populations will be local decisions, but New Zealand's prioritisation policy will be made available for guidance.

5 Vaccine registration

The vaccine is expected to be registered in New Zealand before it is released for use.

As an alternative to registration the declaration of a special emergency under Section 49(b) of the Hazardous Substances and New Organisms Act 1996 could enable the use of the vaccine under Section 24D of the Medicines Act 1981.

Section 49(b) of the Hazardous Substances and New Organisms Act 1996 states 'A responsible Minister may declare an adverse event to be a special emergency if the adverse event is a matter that comes within the Minister's portfolio'. The Minister of Health is included in the list of responsible Ministers. Section 135(a) of the Hazardous Substances and New Organisms Act 1996 includes 'actual or imminent danger to human health or safety' as an Emergency for the purposes of the Act.

Declaration of a special Emergency could enable the use of Section 24D of the Medicines Act 1981 (Approval of medicines required for use in special emergency). This provides for 'An application [to be made] to the Minister [of Health] for approval to distribute, sell, or advertise in a special emergency a medicine that is or contains a hazardous substance or new organism'. The Minister may 'approve an application with or without conditions, as long as the Minister is satisfied that:

(a) the special emergency has been declared and has not come to an end; and
(b) the medicine is required for the special emergency

The status of the vaccine at the time, and the statutes and regulations under which the vaccine will be supplied and used will be advised either on release of the vaccine or in later versions of this document.

6 Release for use

The Director-General of Health will decide if and when to release the vaccine for use. The decision will take into account the situation overseas and in New Zealand, and the advice of the Director of Public Health.

Once released the vaccine supply will be managed by the Ministry of Health Emergency Management Team in conjunction with the Immunisations Team and the Director of Public Health.

7 Advice of release

DHB Chief Executives and Emergency Managers will be advised of the release through the established emergency communications channels (the alert code

communications). Further communications inside DHBs will be the responsibility of the Chief Executives and their teams.

The Ministry will advise Chief Executives of the relevant non-health agencies of the release for use. Further communications inside non-health agencies will be the responsibility of the agency Chief Executives and their teams.

The Ministry will provide as much advance notice of a release as practical, but all agencies should note that any warning time may be very short, possibly measured in days rather than weeks.

8 Distribution on release

The vaccine is currently stored in central locations. On release it will be distributed to DHBs, Defence Medical Services, and the PICTs. DHBs can expect to receive deliveries from the day after release is notified.

9 Administration responsibilities

Defence Medical Services will be responsible for vaccinating NZDF personnel; DHBs will be responsible for vaccinating all other groups in New Zealand. All aspects of PICT supply administration will be the responsibility of the Island Authorities once the vaccine is landed.

See appendix 2 for more details of responsibilities.

10 Supply volumes

Uptake of the vaccine among the qualifying staff groups cannot be known ahead of time. Seasonal influenza vaccine uptake in DHB clinical staff varies from 20% to 70% between DHBs, but this may not be a good guide to the H5N1 vaccine uptake. Uptake in other organisations is not known. The identified qualifying groups will be encouraged to take up the offer of vaccine, and if pandemic disease overseas is causing deaths it is likely uptake will be high.

As actual uptake cannot be predicted, and to avoid storage volume issues in DHBs, enough vaccine to provide a first vaccination for 70% of the estimated qualifying people will be distributed to DHBs as a first tranche (see appendix 3). Further shipments will be sized to support second doses and variations in actual demand.

Defence will receive a separate supply for its estimated 6,000 qualifying staff.

11 Qualifying staff groups

The staff groups, specific criteria for inclusion or exclusion, and the estimated numbers of people involved are shown in appendix 4. In essence, the vaccine will be offered to people who work in ‘front-line’ or ‘contact’ positions in their agencies.

Estimates of the number of qualifying health staff are derived principally from Census 2006 data and from DHB Full Time Equivalent (FTE) returns. Estimates of qualifying people in other agencies have been provided by those agencies.

Note that employment in any particular agency or sector does not automatically qualify a person for the vaccine. Only those who provide essential response services *AND* are required or expected to have close and direct contact with people who have

or may have pandemic influenza *AND* who cannot reasonably modify their work practices to further reduce the risks of exposure qualify for the offer of vaccine.

12 Prioritisation of staff groups

DHBs with relatively small numbers of people to vaccinate may not need to prioritise vaccination delivery between the various identified staff groups.

Where prioritisation of delivery to staff groups is necessary, border management agency staff (including associated public health staff and quarantine facility staff) and New Zealand-based international aircrew should be vaccinated before other staff groups. See Appendix 5.

13 Identification and certification of individuals who qualify for H5N1 vaccine

The relevant employers must identify and certify employees who meet the published qualifying criteria. This must be done on the form in appendix 6, or on one containing the same information.

Self-employed people who qualify (relatively few, and mostly in health services) must make a statutory declaration that they meet the published criteria. See appendix 7.

14 Informed consent form

Everybody who wishes to receive the vaccine must sign an informed consent form for each dose. Vaccination will not be provided unless the form is signed. See appendix 8 for patient information forms, FAQs, and the current draft informed consent form.

15 Record keeping

DHBs[1] will be responsible for collecting and maintaining informed consent forms, vaccination records, and other relevant records. DHBs will need to forward consolidated usage information and demand information to the Ministry. This data will inform MoH resupply and/or any prioritisation of supply that may become necessary.

The Ministry is investigating the use of the National Immunisation Register for H5N1 vaccine data entry. DHBs will be informed of any developments.

16 Charges and payment

The vaccine will be free of charge to people who meet criteria, and who sign the informed consent form. It will not be available for sale or purchase.

The Ministry of Health will fund DHBs to provide the vaccinations to qualifying people in their districts. The funding mechanism will be advised. DHBs should anticipate a bulk funding arrangement rather than a 'per vaccination' payment.

17 Animal disease scenario

It is possible, although unlikely, that H5N1 Highly Pathogenic Avian Influenza H5N1 (HPAI H5N1) may be found in New Zealand in wild or domestic bird flocks, or other animals. In this case New Zealand's response will be led and managed by the

[1] Defence Medical Services for NZDF personnel

Ministry of Agriculture and Forestry (MAF), with the Ministry of Health in a supporting role.

If HPAI H5N1 is found in birds or animals in New Zealand, H5N1 vaccination will be offered to all MAF staff, contractors, or other people who, as part of their duties, may come into contact with birds or animals known or suspected to be infected, or which are being culled as a precautionary measure.

A detailed vaccination programme for this situation has not been developed because of the low probability of HPAI H5N1 occurring in New Zealand, and the relatively small numbers of people who would be involved. In general the approach taken in the human disease case will be followed. People to be offered the vaccine must be identified by their employers, the informed consent form signed, and all other requirements met. The vaccine will be free to people who meet criteria. Funding methods and other operational details will be advised.

Appendix 1: Pacific Island supplies

Pro-rata supplies, rounded up: -

	Courses
Niue	**100**
Tokelau	**100**
Cook Islands	**700**
Total	**900**

Appendix 2: Responsibilities

Item	Responsibility	Notes
Policy development	Ministry, with sector and other relevant agency input	H5N1 vaccine is a national asset that must be used to enhance the effectiveness of the national pandemic response.
Implementation of policy	1) DHB CEOs 2) Defence DGDMS	
Maintenance of vaccine supplies in storage, and ongoing stability testing	Ministry	
Release of vaccine for use	Director-General of Health	Director-General must consider the advice of the Director of Public Health.
Release information from Ministry to DHB CEOs, DHB Emergency Managers, Medical Officers of Health, and CEOs of relevant agencies	Ministry	The Ministry will provide as much warning as possible, but all organisations should note that any warning time may be measured in days rather than weeks.
Release information internally within relevant agencies	DHB CEOs, other agency CEOs	

Item	Responsibility	Notes
All aspects of vaccine transport (including payment) to DHBs, Defence Medical Store, and/or Pacific Islands	Ministry	Pre-arranged volumes will be transported to DHBs, Defence Medical Store, Trentham, and to the Pacific Islands. Sufficient vaccine to provide the first vaccination for 70% of the estimated qualifying people will be distributed to DHBs and Defence. Pro-rata supplies will be provided to the Pacific Islands Further deliveries will be adjusted according to actual uptake and demand.
All aspects of vaccine storage and transport within DHBs once vaccine is delivered to DHBs	DHBs	DHBs should plan for sufficient cold chain storage and transport capacities.
All aspects of vaccine administration for Defence Force personnel, including transport of vaccine once delivered to Defence Medical Store, Trentham	Defence Forces Medical Services	Pre-arranged volumes will be delivered to Defence Medical Store, Trentham, for onward distribution and administration.
All aspects of vaccinations for Pacific Islands residents, including internal Island transport	Relevant Pacific Island Health Authority	New Zealand's prioritisation framework will be available for reference.
Identification, selection, and publicity of DHB administration sites	DHBs	Employers with large numbers of qualifying people may offer facilities for administration sites.
Identification, training and management of vaccinators	DHBs	

Item	Responsibility	Notes
Identification and certification of qualifying people	Employers, using the published criteria in the policy document. Self-employed people must make a statutory declaration.	There may be very little warning time, so employers should pre-identify employees who meet criteria. Forms for employers to certify qualifying people will be available from the Ministry website for printing off locally.
Obtaining of informed consent and provision of vaccinations to qualifying people	DHBs	Patient information, FAQs, and informed consent forms will be available from the Ministry website, to be printed off locally.
Recalls for and provision of second vaccinations	DHBs	Self-recall at the appropriate time may be the most practical option for some qualifying people. Qualifying people will need to sign a second informed consent form.
Maintenance of records, provision of usage data to Ministry	DHBs	DHBs will need to store patient qualification forms, informed consent forms and all other relevant records. The Ministry will need accurate uptake information to ensure provision of appropriate volumes in the second or subsequent tranches, and to assess total usage. Until NIR changes are advised DHBs should prepare to manage paper records.
Funding of DHBs for all aspects of vaccination programme	Ministry	Bulk funding (as in the MenzB programme) may be most appropriate method.
FAQs, queries, policy helpline	Ministry	Contact number/s and/or URLs will be advised.
Revision of policy, variation or expansion of qualifying criteria, use of strategic reserve	Ministry, after sector consultation wherever practical	Policy and/or prioritisation of supply may be varied according to epidemiology, actual uptake and/or demand. Time pressure may preclude wide consultation.

Appendix 3: DHB qualifying estimates and first tranche volumes

Estimates of the qualifying people at DHB level provide first tranche volumes for planning purposes. First tranche volumes assume a 70% takeup of the offer of vaccine among the qualifying people to be vaccinated by DHBs. Further delivery volumes will be adjusted according to actual demand.

If all qualifying people were spread evenly across the country a DHB population pro-rata distribution would be all that was necessary to develop first tranche volumes. As this is clearly not the situation, the first tranche estimates take into account the known non-random distributions of DHB, Defence, Corrections and Border agency staff.

The process used to develop DHB-level first tranche volumes is:

- Assume 150,000 people nationally qualify for the offer of vaccine (actual estimate 142,700)
- Develop DHB-level estimates of known qualifying people in DHBs, Border Agencies, Defence and Corrections
- Subtract these people (total approximately 66,000) from the DHB Census populations to provide 'corrected' population figures at both DHB and national levels
- Distribute the 84,000 remaining qualifying people evenly on a pro-rata DHB 'corrected' population basis to develop DHB 'corrected qualifying populations'
- Add the known qualifying populations EXCEPT Defence to the corrected qualifying populations to derive total DHB qualifying person estimates. Defence is not added back at DHB level because Defence will be receiving its own supply of vaccine for its qualifying people – DHBs will not need supplies to vaccinate Defence staff.
- Multiply the total qualifying person estimates by 70% (the assumed takeup rate)
- Round the resulting figure up to the nearest hundred, and add another hundred.

DHB	Estimated qualifying	First tranche volumes
Auckland	17,125	12,100
Bay of Plenty	6,357	4,600
Canterbury	17,419	12,300
Capital and Coast	9,676	6,900
Counties Manukau	14,615	10,400
Hawkes Bay	5,467	4,000
Hutt Valley	4,899	3,600
Lakes	3,388	2,500
MidCentral	5,984	4,300
Nelson Marlborough	4,642	3,400
Northland	4,947	3,600
Otago	6,673	4,800
South Canterbury	1,759	1,400
Southland	3,294	2,500
Tairawhiti	1,532	1,200
Taranaki	3,436	2,600
Waikato	12,256	8,700
Wairarapa	1,268	1,000

DHB	Estimated qualifying	First tranche volumes
Waitemata	15,415	10,900
West Coast	1,327	1,100
Whanganui	2,520	1,900
Totals	**144,000**	**103,800**

Appendix 4: Qualifying staff groups: detail

Sector or service	Rationale for selection	Qualifying for offer	Not qualifying	Est. total numbers
Health and associated services	Maintenance of the health sector's ability to provide acute services during a pandemic will alleviate morbidity and reduce mortality among the general population. WHO advice is that 'To reduce the morbidity and mortality caused by a pandemic, it is crucial that health services are kept functioning as long as possible'.	Clinical and clinical support staff who are providing essential health services, and who are required by the nature of their duties to have close and direct contact with people who have or may have pandemic influenza. 'Close and direct contact' means unavoidable physical contact with, or unavoidable maintenance of proximity within 1 metre of, a person who has or may have pandemic influenza. These will include: primary and secondary sector clinical nurses, doctors, and radiographers; hospital physiotherapists; supporting secondary service patient contact staff such as orderlies, security, clinical management, Ambulance (St John, Wellington Free Ambulance and DHB services), patient transport staff; Public Health Unit staff required to have direct contact with possible cases; Mental Health patient contact staff (inpatient and community); rest home, home care or rehabilitation service staff; private hospital contact staff; other health staff who are required as an *essential* aspect of their job to have close and direct patient contact, *AND* who cannot reasonably modify their work practices or settings to further reduce the risks of exposure. Laboratory staff including hospital, community, ESR and MAF laboratory staff who will handle specimens from patients who may have pandemic influenza. Note that epidemiology from overseas developments may modify the current prioritisation.	Nurses and doctors in solely administrative positions. Management staff and administration staff who are not required to have contact with patients to do their jobs, such as general management, payroll, call centre, catering, laundry, and other non-contact support staff, any other staff who can eliminate close and direct contacts by the modification of work practices.	105,000

Sector or service	Rationale for selection	Qualifying for offer	Not qualifying	Est. total numbers
Police	Police personnel are likely to be required to support of health services by assisting with Public Health measures, provision of direct assistance to health services and the public, and maintaining public order.	Contact staff required to deal directly with members of the public.	Sworn and non-sworn staff in positions that do not require direct contact with members of the public for the performance of duties, such as Management, administration, call centre, catering or general office support staff.	7,000
Defence	Defence forces are likely to be required to provide assistance during a pandemic either by providing direct medical assistance and support, and/or by assisting with the implementation of Public Health measures.	Defence contact staff who may be required to deal directly with members of the public if Defence Forces are deployed in support of pandemic responses.	Non-operational uniformed and civilian staff in positions that do not require direct contact with members of the public for the performance of duties, such as Management, administration, call centre, catering or general office support staff.	6,000
Border management agencies	Border management and protection functions will need to be maintained at all times.	Border management contact staff who are required to deal directly with members of the travelling public. This includes Customs officers, Immigration officers, MAF and Security officers; quarantine facility staff who must have direct contact with quarantined people to carry out their duties.	Management, administration and support staff who are not required to have close and direct contact with members of the travelling public to carry out their duties.	3,500

Sector or service	Rationale for selection	Qualifying for offer	Not qualifying	Est. total numbers
Social support	Social support organisations will have an essential role to play in delivering a range of social support measures to people directly affected by the pandemic.	Social support workers who must have close and direct personal contact with members of the public or social support organisation clients. These include specifically identified CYFS social workers, CYFS residence workers, and MSD case managers who are required to have direct contact with clients.	Management, administration and support staff who are not required to have direct contact with members of the public to perform their jobs.	3,500
Corrections	Corrections facilities and community staff provide essential services that cannot be interrupted, but which by the nature of their operations place expect staff to accept an increased level of risk.	Corrections front-line Prison Services staff (custodial and health) in prisons, and Community Probation and Psychological Services staff operating Community Residential Centres and undertaking person-to-person monitoring of high-risk offenders.	Management, administration and support staff who are not required to have direct contact with prison residents, people on probation, or people in residential centres to perform their jobs.	4,500
Fire Service	Fire Services may be involved in first medical responses, and must be maintained at the highest practical level.	Fire Service emergency response contact staff who may provide direct pandemic responses.	Management, administration and support staff who are not required to have direct contact with members of the public to perform their jobs.	10,000
New Zealand-based international aircrew; identified MFAT officials	Aircrew may be required to staff flights to/from areas affected by pandemic influenza. MFAT officials may be required to accompany evacuation flights. Vaccination will reduce the chance of infection and subsequent importation of the disease into New Zealand.	Any aircrew, engineering or ground support staff who may be required to fly into or out of a country affected, or potentially affected, by pandemic influenza. Ministry of Foreign Affairs & Trade (MFAT) officials who may be required to accompany evacuation flights.	Domestic ground staff or domestic aircrew. MFAT staff not required to accompany flights.	2,300

Sector or service	Rationale for selection	Qualifying for offer	Not qualifying	Est. total numbers
Cooks, Niue and Tokelau	See entry in main text.			900
Total				**142,700**

Appendix 5: Prioritisation between groups

DHBs with relatively small numbers of people to vaccinate may not need to prioritise vaccinations between staff groups or agencies. Where volumes require prioritisation of vaccine delivery, it is logical to prioritise the delivery of vaccine according to the anticipated sequence of events.

Accordingly, the current prioritisation of vaccination delivery to the identified groups is as below[2].

	Identified staff groups	Rationale
Group 1	• Border management agency staff (including associated public health staff and quarantine facility staff) • New Zealand-based international aircrew; identified MFAT officials	Border management staff could potentially be most exposed early in any pandemic. Vaccination of New Zealand-based international aircrew and accompanying MFAT officials will help to reduce the risk of importing influenza. Group 1 staff should be vaccinated before Group 2 if it is necessary to prioritise delivery.
Group 2	• Wider health sector • Police • Social support agencies • Fire Services • Corrections	Group 2 agencies will be involved in a landside pandemic response. Border management can be expected to delay the arrival of influenza in New Zealand even if it does not succeed in keeping it out, so Group 2 agencies/staff should be vaccinated after Group 1.

DHBs should plan to prioritise their vaccination delivery campaigns as above if total numbers to be vaccinated make prioritisation necessary. It is possible the actual epidemiology of any eventual disease, and/or actual events may change priorities. The Ministry will advise as soon as possible of any revisions to the above priorities.

[2] Defence receives its own supply and organises its own internal prioritisation

Appendix 6: Employee certification form

Employee qualification for H5N1 vaccine

[*company / organisation letterhead, name, or identification*]

This confirms that:

[full name] ……..

of [*address*] ……..

……..

……..

is currently employed by this organisation in the capacity of

[*position*] ……..

and therefore qualifies under current policy to be offered H5N1 pre-pandemic vaccine as his/her duties require that he/she may be closely exposed to people who have, or could have pandemic influenza *AND* he/she cannot reasonably modify their work practices to further reduce the risks of exposure.

[*signature*]

……..[*date*]……

[*print name*]

……

CEO / HR manager / Other [*state position*]…….

Appendix 7: Statutory declaration form

Statutory Declaration

Self-employed person qualifying for H5N1 vaccine

I, [*full name*] ……..

Of [*address*] ……..

……..

……..

solemnly and sincerely declare that

1. I am self-employed as [*occupation*]……..

2. I work in one of the occupational groups identified in the current H5N1 vaccine policy, ***AND*** as part of my normal professional duties I may be closely exposed to people who have, or could have pandemic influenza ***AND*** I cannot reasonably modify my work practices to further reduce the risks of exposure.

3. I therefore qualify to be offered H5N1 vaccine.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

……
[*signature*]

Declared at [*locality*]……..,…….. [*date*]……

Before me [*signature*] …….

Justice of the Peace / Solicitor / Other person authorised to take a statutory

declaration [*state position*]……..

Appendix 8: Draft patient information form, FAQs, and informed consent form.

H5N1 INFLUENZA VACCINE PATIENT INFORMATION FORM

READ THIS BEFORE SIGNING THE INFORMED CONSENT FORM

This vaccine is offered to you as it is believed to provide the best currently available vaccine-mediated protection against emerging or pandemic H5N1 influenza strains.

Vaccination is entirely voluntary. You are not required to accept the vaccination, or to complete the two-dose course once you have had the first dose.

Vaccine characteristics

The vaccine is a monovalent, non-adjuvanted influenza virus vaccine for active immunisation against the H5N1/Indonesia/05/2005 wild type virus.

It contains Vero cell-derived, double-inactivated, sucrose gradient-purified whole virions of influenza type A based on the requirements of the current edition of the European Pharmacopoeia for interpandemic vaccine.

The vaccine does not contain egg or chicken protein, any other serum-derived protein, any mercury, aluminium or other adjuvants (substances to make the vaccine more effective), or preservative.

Effective vaccination requires two doses of vaccine given intramuscularly at least 21 days apart. Each dose contains 7.5µg haemagglutinin antigen of the avian influenza virus strain in 0.5mL tris-buffered saline.

When both doses are given as directed, the vaccine produces an immune system reaction that meets international standards for seasonal influenza vaccine in about six weeks from the first vaccination.

Possible side effects

Influenza vaccination is usually well tolerated. The H5N1 pre-pandemic vaccine has a similar safety profile as a seasonal influenza vaccine. Possible responses include redness, tenderness or hardness at the injection site for a day or two; a mild fever, muscle aches or headaches within the first two days.

Rarely, with some vaccinations, an allergic reaction can occur almost immediately. This is very unlikely with the H5N1 vaccine as it does not contain any serum-derived proteins. However, as a precaution, you should remain under observation for 20 minutes after a vaccination.

Protection from emerging or pandemic influenza viruses

It is not possible to predict or guarantee the level of protection the vaccine may offer against any human H5N1 influenza virus, as this will depend on how close (in the evolutionary sense) a human virus is to the original avian (seed) virus used to make the vaccine.

It is likewise not possible to predict the level of protection the H5N1 vaccine may provide against an emerging pandemic virus.

By signing the informed consent form you acknowledge that you will not be able to make any claim against the Ministry of Health or the New Zealand Government relating to the effectiveness or lack of effectiveness of the vaccination.

FREQUENTLY ASKED QUESTIONS

I am allergic to eggs / chickens / horse serum. Can I take this vaccine?	The vaccine does not contain any egg, chicken or other serum-derived protein, so it should not cause a problem if you have allergies to eggs, chickens or horse serum.
I usually have a 'flu jab every year. How is this different?	The regular 'flu jabs are intended to provide protection against seasonal influenza that comes around every year. This vaccination is intended to provide protection against a new virus that has the potential to cause an influenza pandemic, but otherwise it is like any other 'flu jab.
Can I get influenza from this vaccine?	The vaccine does not contain any live influenza virus, so it cannot give you influenza. It is possible you may feel a little feverish, headachy or fatigued for a day or two after the injection. This is a relatively common reaction to vaccination, and is not influenza.
Is this vaccine made from a pandemic influenza virus?	No. The vaccine is made from a strain of H5N1 avian influenza virus. It may provide protection against an H5N1 pandemic virus. The level of protection it may provide is not known at this time.
Will this vaccine protect me against pandemic influenza?	It is not possible to say if this vaccine will protect you against pandemic influenza. However, it is believed to provide the best available vaccine-mediated protection at this time.
Do I have to have this vaccination?	No. It is entirely your decision whether to accept or decline the vaccination.
What happens if I decline? Will this be recorded anywhere?	Nothing will happen, and no record will be kept.
How much will the vaccination cost me?	It is free of charge for people who qualify to be offered the vaccine.
Does this vaccine have mercury or any preservatives in it?	The vaccine does not contain any mercury, aluminium, any other adjuvants (substances that make the vaccine more effective), or any preservatives.
If anything goes wrong with the vaccination could I make an ACC claim?	Yes, as with any other vaccination – but only if there was a problem or injury related directly to receiving the vaccine, or to the actual injection. You would not be able to make a claim if you later contracted influenza.
I want the vaccination but I'm not prepared to sign a form acknowledging I cannot make a claim if I get influenza after the vaccination. How can I get the vaccination?	You can't. You must sign the informed consent form if you want to have the vaccination.
I've had the first dose but I don't want the second dose. What will happen?	Nothing. You don't have to have the second dose if you don't want to. However the first dose on its own will not provide any level of protection at all. It is strongly recommended that you have both doses.

H5N1 VACCINE INFORMED PATIENT CONSENT FORM

PATIENT IDENTIFICATION

Family name*..... Given name*..... Middle name*.....

Address*.....

Date of birth*..... Male* □ Female* □ Phone ..... Other phone .....

Ethnicity* ..... GP ..... NHI* (if known) .....

* indicates compulsory fields

Please answer the following. If you answer YES to any of the questions, consult your healthcare professional before consenting to the vaccination.

	Yes	No
Are you pregnant or trying to become pregnant?	☐	☐
Do you have a bleeding disorder?	☐	☐
Do you have cardiovascular disease?	☐	☐
Do you have diabetes?	☐	☐
Do you have chronic renal disease?	☐	☐
Have you, or have you had Guillain-Barré syndrome (a paralysis problem)?	☐	☐
Do you have an acute respiratory illness or high fever?	☐	☐
Have you ever had an allergic reaction to any component of the vaccine?	☐	☐

INFORMED CONSENT FOR H5N1 INFLUENZA VACCINATION

I have read or had explained to me the information leaflet about the H5N1 influenza vaccine, and I have had a chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of the H5N1 influenza vaccination.

I understand and confirm that I agree to receive the H5N1 influenza vaccine by my own choice. I understand that the level of protection the vaccine may confer against a human H5N1 influenza virus or an emerging pandemic influenza virus is not known. I acknowledge that I will not be able to make any claim against the Ministry of Health or the New Zealand Government relating to the effectiveness or lack of effectiveness of the vaccination or any aspects of the vaccination other than those covered by the Accident Compensation Commission provisions.

I agree to remain under observation for 20 minutes after receiving the vaccination. I consent to the information on this form being recorded on the National Immunisation Register, and given to my healthcare provider to update applicable records.

Signed: Date:

Immunisation record (Clinic use only)	
Vaccine batch number:	
Expiry date:	
Administered:	Left arm / Right arm
Dose:	First / Second
Vaccinator:	