

Manitoba's Human Vaccination against Avian Influenza (HVAI)
Immunization Program for High-Risk Occupational Groups

Frequently Asked Questions & Answers for Health Care Providers

1. What is the Avian Influenza A(H5N1) vaccine and why is it being offered now?

Highly pathogenic avian influenza (HPAI A(H5N1)) is widespread in wild bird populations across the globe. It remains a significant concern in Manitoba as birds migrate each spring and fall. Since 2020, there has been a global increase in the number of HPAI A(H5N1) outbreaks reported in wild birds and poultry, along with sporadic detections in mammals.

While the overall public risk remains low, direct exposure to H5N1-infected animals and contaminated environments pose the greatest risk for human infection. As a preparedness measure given the current global situation, the Government of Canada has secured doses of AREPANRIX™ H5N1, a vaccine licensed for use in humans to prevent against H5N1 (also referred to generally as Human Vaccination against Avian Influenza (HVAI)). The National Advisory Committee on Immunization (NACI) has published preliminary guidance on HVAI in a non-pandemic context and a small allocation has been made available to support deployment within provinces and territories.

AREPANRIX™ H5N1 is a monovalent AS03-adjuvanted inactivated human vaccination against avian influenza. It is approved by Health Canada for use in individuals aged 6 months and older. It has not previously been used amongst the Canadian public. Like seasonal influenza vaccines, AREPANRIX™ H5N1 protects against a specific strain of the influenza virus. The current product protects against the A/American wigeon clade, which is believed to be genetically similar to the clade detected in human cases in the US. It was authorized as a strain change to the AREPANRIX™ H1N1 vaccine from the 2009 H1N1 pandemic.

2. What are the eligibility criteria for HVAI?

The goal of the HVAI program in Manitoba at this time is to prevent severe disease from H5N1 viruses among those at the highest risk of ongoing exposure. Given the very low H5N1 activity in poultry and no cattle or human cases in Manitoba, HVAI <u>may be offered</u> to the following individuals:

- People routinely involved in poultry and/or livestock culling and related operations (e.g. cleaning, disinfection) in the context of suspected/confirmed avian influenza A (H5N1).
- Personnel working with live avian influenza A (H5N1) virus (culture, isolation, manipulation) in laboratory settings.
- People who are routinely involved in the response to sick or dead birds or mammals with suspected or confirmed avian influenza A (H5N1) infections, or their environments, including those performing necropsies (e.g. conservation and wildlife staff, veterinarians or veterinary technicians)

3. When can eligible individuals receive HVAI?

For individuals choosing to be immunized in this time-limited campaign, HVAI should ideally be administered over the summer months but can be offered at any point before Manitoba's vaccine supply expires in February 2026. Summer timing allows the recommended 6-week interval between HVAI and other vaccines to pass before the fall respiratory vaccine program begins. This timing also allows protection to build before the fall bird migration, which may be a time of increased HPAI activity.

4. Can AREPANRIX™ H5N1 be given at the same time as other vaccines?

NACI recommends that it is preferable to have an interval of at least 6 weeks separating HVAI and any other vaccine, unless HVAI or another vaccine is needed urgently. This recommendation is precautionary to prevent erroneous attribution of an adverse event following immunization to one vaccine or the other. Additionally, there are no data on the coadministration of AREPANRIX™ H5N1 with other vaccines. Concurrent administration or a shortened interval between HVAI and other vaccines may be warranted in some circumstances and at the clinical discretion of the healthcare provider. In this case, vaccines should be administered in different limbs.

5. Should individuals who receive HVAI still receive the seasonal influenza vaccine?

Yes. Seasonal influenza vaccines target different influenza strains than HVAI. Immunization with the seasonal influenza vaccine is needed to protect against the strains that regularly circulate in humans. Furthermore, individuals eligible to receive HVAI are particularly recommended to receive the seasonal influenza vaccine to reduce the risk of seasonal human and H5N1 virus co-infection. This co-infection could lead to viral reassortment of a human-transmissible avian influenza virus.

6. What information on AREPANRIX™ H5N1 immunogenicity and efficacy is available?

There are no direct clinical trials supporting the immunogenicity of AREPANRIX™ H5N1 with the A/American wigeon clade. There is also no efficacy or effectiveness data for this vaccine against HPAI disease.

Based on clinical trials for similar H5N1 vaccines, two doses of AREPANRIX™ H5N1 are expected to be immunogenic. Persistence of immune responses was observed at 6 months in clinical trials; however, the duration of immune response is unknown. Correlations of protection for H5N1 have not been established, so there is uncertainty as to how immune responses observed in clinical trials translate to real-world protection. Clinical trials demonstrated that a single dose does not result in adequate immune responses.

7. What information on AREPANRIX™ H5N1 safety, contraindications, and precautions is available?

Clinical trials of similar H5N1 vaccines show they are generally well-tolerated, with short-lived mild to moderate adverse events typical of active vaccines (injection site reactions, muscle

aches, headache, fatigue, joint pain). No safety signals were observed but the clinical trials are relatively small and not powered to detect rare adverse events. There is no post-market safety data available as HVAI has not been deployed broadly. Based on the AREPANRIX™ H1N1 vaccine from the 2009 H1N1 pandemic, there may be an increased risk of developing:

- Guillain Barré syndrome (GBS) of approximately one additional case per 500,000 doses of vaccine, and
- Narcolepsy of approximately one additional case per 1,000,000 doses of vaccine.

AREPANRIX™ H5N1 is contraindicated in individuals with a history of an anaphylactic reaction to any of the vaccine components. Similar to seasonal influenza vaccines, careful consideration is needed when deciding to vaccinate an individual with a history of Guillain-Barré syndrome within 6 weeks of a prior influenza vaccine. For complete details, consult the <u>product monograph</u>.

8. What information is available regarding the use of this vaccine in pregnant, breastfeeding/chestfeeding, or immunocompromised individuals?

There is no available clinical data for the use of this vaccine in pregnant or breastfeeding/chestfeeding individuals, though seasonal influenza vaccine is considered safe in these populations. Individuals who are immunocompromised may have a diminished or insufficient immune response. See the product monograph and populations for more information. Provider discretion is advised and informed consent should include any special considerations for these populations.

9. Why are certain groups, such as farmers and hunters, excluded from eligibility?

Those living or working on poultry farms (regardless of outbreak status) and hunters are not broadly recommended for vaccination at this time. Eligibility decisions are based on expert advice which may be updated as local epidemiology and evidence evolves.

10. How should adverse events following immunization (AEFIs) with HVAI be reported?

Visit Vaccine Safety | Province of Manitoba for guidance on reporting AEFIs in Manitoba.

11. Manitoba Health, Seniors and Long-Term Care Resources

- H5N1 Avian Influenza Vaccine Quick Reference Guide for Immunizers: <u>H5N1 Avian Influenza Vaccine Quick Reference Guide for Immunizers</u>
- Adult Immunization Consent form: English: Letter size | Legal size Français: Taille des lettres | Format légal
- Avian Influenza Website: Avian Influenza | Health | Province of Manitoba
- Agriculture, Animal Health HPAI Website: Province of Manitoba | agriculture Update Avian Influenza in North America

Adapted from: Nova Scotia Human Vaccination against Avian Influenza (HVAI) Immunization Program