Avian Influenza A (H5N1) Immunization Program
Questions and Answers for Immunization Providers – July 2025

1. What is avian influenza?

Avian influenza is a viral infection caused by Type A influenza viruses. It primarily affects birds but can infect humans and other mammals. Influenza viruses, including avian, are classified into subtypes based on the two proteins on their surface, haemagglutinin (HA) and neuraminidase (NA), with 19 HA and 11 NA subtypes that can occur in numerous combinations (e.g., H1N1, H3N2, H5N1).[1]

There is currently an ongoing, global, panzootic (i.e., affecting many different animals) outbreak of highly pathogenic avian influenza (HPAI) caused by the H5N1 virus.[2] The current global outbreak of HPAI A(H5N1) is unprecedented, with widespread infections in wild birds, poultry, and numerous mammals across Canada, the United States (US), and other regions. Since March 2024, the US has reported ongoing transmission among dairy cattle.[1]

Avian influenza is not new. Prior to the relatively recent emergence of H5N1, large scale poultry outbreaks of virulent H7 subtype avian flu, known early on as "fowl plague", were documented from the turn of the 19th century, and H7 continues to circulate globally. Furthermore, panzootic H5N1 has spread widely among wild birds around the globe since 2020-21 with unprecedented numbers of deaths in wild birds and domestic poultry.[2]

The risk of exposure and transmission to humans through contact with birds, other animals, or their environments has also increased. In the US, 61 human cases of avian influenza A(H5N1) were confirmed in 2024, mainly among dairy and poultry workers, with 1 severe case. In Canada, a single, severe human case was reported in 2024. Two human cases in the US and one in Canada have had unknown exposure sources.[1]

2. What is the difference between seasonal and H5N1 avian influenza?

Both seasonal and avian influenza are respiratory illnesses that have many of the same initial symptoms such as high fever and achy muscles. Seasonal influenza is typically caused by certain Type A influenza viruses (subtype H1N1 and H3N2 viruses) and by Type B viruses. It occurs yearly, mainly in the late fall and winter, and is spread easily from person-to-person. Seasonal influenza can be a serious disease, particularly in children, pregnant women and the elderly, and can lead to hospitalization and sometimes even death.[3]

H5N1 avian influenza is caused only by Type A influenza viruses belonging to the H5N1 subtype. H5N1 viruses commonly circulate in birds but can be passed from birds and other mammals to humans. H5N1 viruses rarely infect people, but when they do, they can cause very serious illness.[3]

Historically, the human case fatality rate of H5N1 was reported to be approximately 50%, but the majority of cases seen in the United States have been mild, suggesting potential under-recognition of milder cases in previous fatality estimates. **Person-to-person transmission is extremely rare (with no evidence of this occurring during the more recent North American outbreak)**, which significantly curtails the ability of the virus to spread efficiently among human populations.[1]

3. What is influenza A (H5N1) clade 2.3.4.4?

A clade naming system was introduced to further classify the viruses into related groups based on this gene due to genetic diversity in the H5 gene. Avian influenza A(H5N1) clade 2.3.4.4 viruses emerged in China in 2008 and have been circulating widely since 2014. In the following years, the A(H5) clade 2.3.4.4 further diversified into clades 2.3.4.4a to 2.3.4.4h, including clade 2.3.4.4b.[1]

In 2020, clade 2.3.4.4b became dominant and circulated in wild birds in Asia, Africa, Europe and the Middle East. This strain was first identified in North America in December 2021 in Newfoundland and Labrador and thereafter spread within North America, as well as to Central and South America.[1]

Avian influenza A(H5N1) clade 2.3.4.4b viruses have continued to circulate widely, resulting in a large-scale epizootic (i.e., spreading rapidly among large number of animals) outbreak in wild birds, poultry, and a variety of mammals in many parts of the world. They have also caused rare human infections in some areas, including Canada and the US. A few other clades of avian influenza A(H5N1) continue to circulate in limited geographic areas.[1]

4. What is the current global, national and local epidemiology of highly pathogenic avian influenza (HPAI)?

Panzootic H5N1 virus clade 2.3.4.4b is different from previous circulating avian flu prior to 2020. It is increasingly spreading beyond wild birds to a wide variety of land and marine mammals, including more recently to dairy cattle in the U.S.[2]

There is currently no evidence that avian influenza A(H5N1) clade 2.3.4.4b viruses can be transmitted from person-to-person.[1] Avian influenza could become more serious if the virus develops the ability to spread from person-to-person. Direct exposure to H5N1 infected animals, as well as contaminated environments, pose the greatest risk for human H5N1 infection.[2]

5. What is the risk of HPAI infection for the general public?

The risk to the general public is extremely low.[1]

Avian influenza viruses usually do not infect humans and to date, has not spread from person-to-person. Cases have generally been reported in people who have had close unprotected contact with infected poultry, cattle, or environments heavily contaminated with the virus. The virus can enter the body through their mouth, eyes, or nose.[4]

From 2003 – January 2025, 964 human H5N1 cases, including 466 deaths, were reported to the World Health Organization.[4]

While the risk to the general public is extremely low, the following measures can help prevent infection:

- Avoid touching sick or dead birds and animals or their droppings.
- Do not bring sick wild animals into your home.
- Keep your pets away from sick or dead animals and their feces.[5]

For more resources on HPAI for the public, visit:

- BCCDC: Avian Influenza page
- BCCDC: Avian influenza (bird flu) in BC: How can I protect myself? resource
- FNHA: Avian Influenza page
- FNHA: Hunters, gatherers, harvesters: What you need to know about bird flu in BC resource

6. Why are we offering human vaccines against avian influenza (HVAI) in a non-pandemic context and who is eligible for HVAI in BC?

The objective for the use of currently authorized HVAI in a non-pandemic context in BC is to prevent human infection and severe human infection from avian influenza A(H5N1) viruses in select high risk groups with **repeated AND prolonged contact** with infected or potentially infected animals.

The following populations are eligible for HVAI:

- Lab workers who routinely handle samples that likely contain live avian influenza virus or who culture avian influenza virus.
- Veterinary staff performing necropsies on potentially infected animals.
- People working in diagnostic laboratories in contact with a large volume of potentially infected carcasses.
- People who repeatedly contribute to the management of infected animals including animal destruction, disposal, or building cleaning and disinfection.
- People **working in close contact with wild birds*** or in/around waterfowl habitats (e.g., wildlife/animal control officers, wildlife rehabilitation workers, wildlife researchers, hunters and trappers, people working on environmental impact assessment and surveys, people and contractors working on waterborne pathogens, etc.)

*See Question 7 for the definition of 'working in close contact with wild birds'.

7. What is meant by 'working in close contact with wild birds' in the eligibility criteria?

In the eligibility criteria listed in Question 6 above, 'working in close contact with wild birds' may include any of the following:

- Repeated exposure to wild birds potentially or known to be infected with avian influenza
    - This could include exposure during handling or processing of carcasses, uncooked meat or eggs, or other parts of animals
- Repeated exposure to environments of wild birds, including:

    - Droppings from wild birds (can contain a high concentration of viruses)
    - Surfaces contaminated by wild bird dander/body fluids including body parts (e.g., carcasses, internal organs) including contaminated vehicles, equipment, clothing and footwear
    - Contaminated air space (e.g., an enclosure when movement of wild birds and their litter may have resulted in aerosolization of the virus)
- Repeated exposure to biological material (e.g., primary clinical specimens, virus culture isolates) known to contain avian influenza virus in a laboratory setting

Note: The definition of 'working in close contact with wild birds' is intended to support immunization providers in assessing an individual's risk in a timely manner and is neither intended to be prescriptive nor to broaden eligibility beyond the groups listed in Question 6 (and currently indicated in Part 4 – Biological Products, Avian Influenza).

8. Would seasonal hunting, trapping, and harvesting be included in the definition of 'working in close contact with wild birds'?

Yes. Seasonal hunting, trapping, and harvesting is included in the definition of 'working in close contact with wild birds'. In order for an individual to be considered eligible, the exposure must be repeated during the season, as the overall risk for non-repeated exposures is very low.

Note: While for the purposes of defining eligibility, hunting, trapping, and harvesting is described as 'work', it is important for immunization providers to note that hunting, trapping and harvesting are part of traditional cultural practices for many individuals, including Indigenous Peoples. We acknowledge that not everyone who engages in these cultural practices identifies them as 'work', and we encourage immunization providers to approach these conversations with cultural sensitivity and respect for diverse ways of life.

9. Why is HVAI not being offered more broadly in BC?

HVAI is not being offered more broadly in BC for several reasons:

- For most people, the overall risk of infection is extremely low.[1]
- Most cases of clade 2.3.4.4b in North America have been mild, with only one death out of over 70 cases.[6]
- There are many outstanding questions about the AREPANRIX™ H5N1 A/American wigeon clade 2.3.4.4b vaccine, including its clinical effectiveness (current data is only available on immunogenicity), its duration of protection, the risk of viral mutations that could decrease vaccine effectiveness, vaccine safety; and uncertainty around adverse events following immunization.[1]

As such, the vaccine is only being offered to the high-risk groups listed in Question 6.

10. Why aren't health care workers eligible for this vaccine?

Health care workers are currently not eligible for this vaccine as the risk of infection is considered extremely low.[1] It is unlikely for a health care worker to encounter a patient with avian influenza given the rarity of cases. Additionally, personal protective equipment (PPE) is highly effective at preventing the transmission of avian influenza.

11. What type of vaccine is AREPANRIX™ H5N1 A/American wigeon clade 2.3.4.4b (AREPANRIX™ H5N1)?

AREPANRIX™ H5N1 is an AS03-adjuvanted inactivated, split-virion, egg based HVAI manufactured by GlaxoSmithKline Canada (GSK Canada).[1]

12. How is AREPANRIX™ H5N1 supplied?

Each carton of AREPANRIX™ H5N1 contains 10 vials of Haemagglutinin Antigen and 10 vials of AS03 Adjuvant Emulsion (10 adult doses per vial).

The antigen suspension is a translucent to whitish opalescent suspension that may sediment slightly. The emulsion is a whitish to yellowish homogeneous milky liquid.[7]

13. For which ages is AREPANRIX™ H5N1 authorized for use?

AREPANRIX™ H5N1 is authorized for use in individuals 6 months of age and older.

14. What are the doses and schedule for AREPANRIX™ H5N1?

The following doses and schedule apply to AREPANRIX™ H5N1:

- Children and adolescents 6 months-17 years of age (inclusive): 2 doses given as 0.25 mL **IM**, at least 3 weeks apart.
- Adults 18 years of age and older: 2 doses given as 0.5 mL **IM**, at least 3 weeks apart.

Note: The approved schedule from Health Canada is at least 3 weeks between doses; however, based on expert opinion an 8 week interval between doses may provide better protection. There are a number of considerations related to spacing. As part of the informed consent discussion, considerations regarding a longer interval between doses may include: the recommendation to allow at least a six week interval between H5N1 and any other vaccine, which may affect the timing of seasonal influenza and COVID-19 vaccines (see question 15); the likelihood that an individual will return for their second dose if the interval is extended; and the potential impact on how quickly protection is achieved.

See Part 4 – Biological Products, Avian Influenza Vaccine for details.

15. Why should there be an interval of at least 6 weeks between the administration of AREPANRIX™ H5N1 and any other vaccine?

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.[1] Given the limited evidence currently available, this suggested waiting period between vaccines is **precautionary** to facilitate the investigation of any **adverse events** that may arise.

However, in general, concurrent administration of inactivated vaccines with other inactivated or live vaccines is supported. As per NACI:

- There were no safety signals from studies on concurrent administration of FOCLIVIA® H5N1 (A/Vietnam) or AREPANRIX™ H1N1 with unadjuvanted seasonal influenza vaccines.
- The 6-week interval between vaccines should not delay another vaccine (e.g., seasonal influenza, post-exposure prophylaxis, etc.) that is needed urgently.
- Concurrent administration or a shortened interval between HVAI and other vaccines may be warranted in some individual circumstances at the clinical discretion of the health care provider.[1]

16. What is meant by immunogenicity, efficacy, and effectiveness?

Table 1. Definitions of immunogenicity, efficacy and effectiveness*	
Immunogenicity	The ability of an antigen (i.e., vaccine) to provoke an immune response in an individual.
Efficacy	The extent to which a vaccine provides a beneficial result under ideal conditions. The efficacy of a new vaccine is measured in phase III clinical trials by giving one group of people a vaccine and comparing the incidence of disease in that group to another group of people who do not receive the vaccine.
Effectiveness	The extent to which a vaccine provides a beneficial result under real-life conditions.

*Information drawn from the BC Immunization Manual[8]

17. What is the evidence for the efficacy/effectiveness of AREPANRIX™ H5N1?

There is no clinical effectiveness data on AREPARNIX™ H5N1 (A/American wigeon clade 2.3.4.4b) vaccine as this vaccine has not been used. Immunogenicity of a very similar vaccine, **AREPARNIX™ H5N1 (A/Indonesia clade 2.1.3.2)**, was assessed in a number of randomized controlled trials.[1]

To measure immunogenicity against the vaccine strain (i.e., homologous strain) and non-vaccine strains (i.e., heterologous strains), tests called hemagglutinin inhibition (HI) and virus neutralization assays were used:

- **Immunogenicity against the *homologous strain*:** Seroprotection rates (i.e., the proportion of people whose antibody levels reach or exceed the threshold considered protective) against

AREPANRIX™ H5N1 (A/Indonesia clade 2.1.3.2) in adults 18 and older was 76.8% to 91.0% 21 days after the second dose (depending on recipient age) and 62.2% to 63.5% six months from the start of series. In children 6 months to 17 years of age, this was 99% to 100% 21 days after the second dose and 72.4% to 95.2% six months from the start of series.

- **Immunogenicity against *heterologous strains*:** Immune responses against non AREPANRIX™ H5N1 (A/Indonesia clade 2.1.3.2) vaccine strains showed some cross-protection. However, overall immunogenicity was substantially lower.[1]

18. What is the evidence for the safety of AREPANRIX™ H5N1?

The following vaccine products provide ***indirect*** evidence relevant to the safety of AREPANRIX™ H5N1 (A/American wigeon clade 2.3.4.4b) vaccine:

- AREPARNIX™ H5N1 (A/Indonesia clade 2.1.3.2)
- FOCLIVIA® H5N1 (A/Vietnam clade 1), and
- Two monovalent GSK-produced AS03-adjuvanted vaccines licensed for use during the 2009-2010 influenza A(H1N1) pandemic:
    - AREPANRIX™ H1N1 pdm09, and
    - PANDEMRIX™ H1N1 pdm09

Safety data from previous clinical trials conducted by the manufacturer showed that AREPANRIX™ H5N1 (A/Indonesia) was generally safe. Adverse events reported following immunization (AEFIs) were predominantly mild to moderate injection site reactions that resolved within a few days without lasting problems or complications, as well as muscle aches, headache, fatigue, and joint pain. As the use of AREPANRIX™ H5N1 (A/Indonesia) was limited to clinical trials, post-marketing safety data are unavailable.[1]

Table 2. Indirect evidence relevant to the safety of AREPANRIX™ H5N1*	
Anaphylaxis	Based on the safety surveillance data from Quebec, there was increased risk of anaphylaxis noted following AREPANRIX™ H1N1 vaccination compared to **seasonal influenza vaccination**. Nevertheless, anaphylaxis and allergic reactions were still rarely observed following AREPANRIX™ H1N1 vaccine.
Guillain-Barré syndrome (GBS)	One study in Quebec and one study in Germany found a small increased risk of Guillain-Barré syndrome (GBS) following AREPANRIX™ H1N1 and Pandemrix™ H1N1, but several other studies did not show an association with AS03-adjuvanted H1N1 vaccines and GBS.
Narcolepsy	A notable safety signal (i.e., narcolepsy) was identified with PANDEMRIX™ H1N1. Narcolepsy is a neurological disorder that affects sleep-wake cycles and causes excessive daytime sleepiness. Following the 2009-2010 influenza A(H1N1) pandemic immunization campaigns, PANDEMRIX™ H1N1 was found to be associated with an increase in the incidence of narcolepsy cases among children and adolescents in Sweden and Finland compared to pre-pandemic rates, as well as in several other European countries. In Canada, a Quebec-based study showed a possible but inconclusive link between AREPANRIX™ H1N1 and narcolepsy, while other Canadian studies found no association. Overall, evidence suggested a strong link between PANDEMRIX™ H1N1 and narcolepsy in younger populations in some countries, whereas AREPANRIX™ H1N1 showed minimal to no such association. Mechanisms to explain the connection between PANDEMRIX™ H1N1 and narcolepsy are unclear, but hypotheses have suggested the role of "molecular mimicry," where a vaccine antigen triggers a CD4 T-cell mediated immune response that impacts the narcolepsy-related protein hypocretin. Some studies have assessed differences in the manufacturing process and proteins contained in the influenza A(H1N1) pdm09 vaccines to attempt to explain why narcolepsy appeared to be related to PANDEMRIX™ H1N1 and not AREPANRIX™ H1N1. No link between AS03 and narcolepsy has been found with any other AS03-adjuvanted vaccines. This includes an AS03-adjuvanted COVID-19 vaccine, Vidprevtyn Beta, given to over 2 million adults in Europe (mainly in England), as well as several other AS03-adjuvanted vaccines evaluated in early to late phase clinical trials.

*Information drawn from NACI and GSK Canada[1,7]

19. In addition to routine passive vaccine safety surveillance conducted in Canada, how will the safety of AREPANRIX™ H5N1 be monitored?

The Canadian National Vaccine Safety (CANVAS) Network is a national platform that monitors vaccine safety after vaccines are approved for use.[9] The CANVAS Network will conduct active safety surveillance in BC and several other provinces to evaluate the safety of AREPANRIX™ H5N1. Vaccine recipients may be contacted directly by CANVAS for participation.

20. Given that this is a new vaccine, how should I communicate with eligible individuals about it?

Candidly communicating information about the safety of vaccines and their benefit-risk ratios is essential. Through direct dialogue and using language that is appropriate to and understandable by the client, immunization providers should contrast the known and theoretical risks of the vaccine with the known risks associated with the vaccine preventable disease.[10]

Potential risks of any vaccine should not be considered in isolation but in comparison with risks to the individual and community, should an individual remain unimmunized.[10] See Question 21 for considerations regarding the use of HVAI vaccine in a non-pandemic context.

21. What are some considerations regarding the use of HVAI vaccine in a non-pandemic context?

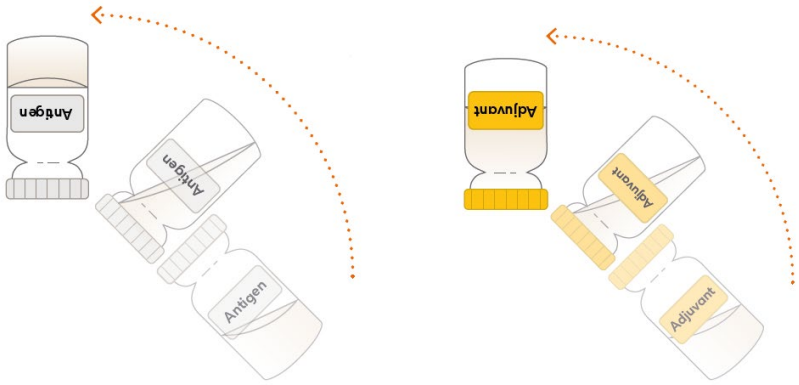
See Table 3 below for some considerations regarding the use of HVAI in a non-pandemic context.

Table 3. Considerations regarding the use of HVAI in a non-pandemic context*	
Preventing human infection	**Most people have no immunity to H5 viruses:** Most individuals are expected to have little immunity to avian influenza A(H5) viruses because they have not previously circulated in humans. **Seasonal influenza vaccine will not protect against H5N1:** The limited available evidence suggests that seasonal influenza vaccines and past influenza infections **will not** protect against infection from the avian influenza A(H5N1) clade 2.3.4.4b strains that are currently circulating in birds and mammals. However, seasonal influenza vaccine is also recommended for this population to prevent co-infection and potential viral evolution. **Efficacy/effectiveness of A(H5N1) vaccine is uncertain:** Adjuvanted A(H5N1) HVAI have met immunogenicity criteria established for authorization of influenza vaccines. Seasonal influenza vaccines and the adjuvanted H1N1 pdm09 vaccine are authorized based on these criteria, with moderate but variable vaccine effectiveness against seasonal influenza infection reported with seasonal influenza vaccines and very good effectiveness reported with adjuvanted H1N1 pmd09 vaccines during the 2009 H1N1 pandemic. Therefore, it is *plausible* that HVAI that meet authorization immunogenicity criteria will prevent human infection with avian influenza A(H5N1) viruses. However, the lack of clinical effectiveness correlation of established immunogenicity criteria to HVAI effectiveness is unknown, and there are currently no data on the efficacy or effectiveness of HVAI against infection, clinical disease, or transmission of avian influenza A(H5N1). **For people at increased risk, influenza A (H5N1) vaccine and personal protective equipment (PPE) may provide protection:** For people at increased risk of exposure to avian influenza A(H5N1) through handling live virus or contact with wild or domestic birds or animals and/or their environments, vaccination against avian influenza virus may provide another protective measure in addition to PPE and other measures.
Preventing severe disease	The spectrum of clinical disease caused by the currently circulating avian influenza A(H5N1) clade 2.3.4.4b viruses across different ages and population groups is currently uncertain: • There have been over 70 cases in Canada and the United States, most of which have occurred in farm workers and almost all of which have been mild. • The first (and only) severe human case of avian influenza A(H5N1) clade 2.3.4.4b in Canada occurred in a teenager in BC with unknown exposure. • Globally, previous avian influenza A(H5N1) strains have resulted in severe disease in humans with a case fatality rate (CFR) of approximately 50%. However, based on experience from North American cases, this may be an overestimate. • Based on the effectiveness against severe disease of seasonal influenza vaccines and adjuvanted A(H1N1) pdm09 vaccines assessed against immunogenicity criteria for authorization, it is plausible that authorized HVAI could provide protection against severe disease.

*Information drawn from NACI[1]

22. What are some additional considerations surrounding the preparation of AREPANRIX™ H5N1?

Table 4. Additional considerations for the preparation of AREPANRIX™ H5N1*	
Consideration	**Rationale**
Why do I need a 5 mL syringe to draw up the adjuvant for mixing with the antigen?	The vaccine products requiring mixing include: 1. 3mL vial containing 2.5 mL adjuvant and 2. 10mL vial containing 2.5 mL antigen Given the larger volume of adjuvant compared to the standard syringe volume, a **5 mL syringe** is recommended to draw up the adjuvant for mixing with the antigen.
Why is a 23-gauge needle preferentially recommended to withdraw the contents of the AREPANRIX™ H5N1 vial for the purposes of mixing?	A 23-gauge needle is preferentially recommended, as it reduces the risk of **coring**. Coring is when a needle pierces a vial stopper and causes small rubber particles to detach and enter the vial. The risk of coring increases with multiple vial punctures. While a 23-gauge needle is preferentially recommended, if it is not available, a 21-gauge needle may be used. **Note:** With needle gauges, a *larger* gauge number indicates a *smaller* diameter needle.
Why should the vaccine vials be allowed to reach room temperature prior to mixing (and after storage of the mixed vaccine in the fridge)?	According to the manufacturer, the recommendation to bring the vial to room temperature for a minimum of 15 minutes before use is related to potential vial stopper **coring** due to repeated needle insertion for the mixing and administration of the multidose vaccine. The vial stopper rubber has better elasticity when at room temperature which minimizes the risk of **coring**.
How and when should vaccine vials be mixed by inversion?	**Prior to adding the adjuvant to the antigen**, both the vials of adjuvant and antigen should be mixed by inversion. See image below:

	 (image from unpublished infographic provided by GSK Canada) **<u>After</u> the addition of the adjuvant to the antigen**, the vaccine should be mixed thoroughly by inversion. See image below:  (image from unpublished infographic provided by GSK Canada) As depicted in the image above, the vial should also be thoroughly mixed by inversion **<u>prior</u> to each administration**.
After the antigen and adjuvant are mixed together, by when should the vaccine be used?	In addition to the product expiry indicated on the vaccine vial, **the vaccine must be used within 24 hours after the antigen and adjuvant are mixed together.** **Note:** Label the mixed vaccine vial with the date and time the vaccine was mixed. This serves as a signal for the timeframe within which the vaccine must be used/discarded.
Can the vaccine be pre-drawn into a syringe for administration at a later time?	There is no data on mixed H5N1 vaccine stability in a syringe. According to the manufacturer, the available vaccine stability data is for 24 hours at room temperature **in the vial only**. Once mixed (as per product monograph), the vaccine must be used within 24 hours.
Which lot # should I use for documentation purposes, and where can it be found?	There are three lot numbers:

	1. One overall (combination) lot number on the grouping carton box 2. One antigen lot # indicated on the vial label and box 3. One AS03 adjuvant lot # indicated on the vial label and box The overall (combination) lot number on the grouping carton box encompasses information for both the antigen and the AS03 adjuvant components. **Note:** For the purposes of documentation, immunization providers should record the combination lot number on the **carton box**.

*Information drawn from personal communication from GSK Canada

See Part 4 – Biological Products, Avian Influenza for more information on vaccine administration.

23. What does it mean that AREPANRIX™ H5N1 is adjuvanted?

An adjuvant is a substance added to a vaccine to enhance the immune response of vaccinated individuals.[3] Many other vaccines (e.g., shingles vaccine, some influenza vaccines) are also adjuvanted to enhance immune response.

24. Which adjuvant is used in AREPANRIX™ H5N1?

AREPANRIX™ H5N1 contains the adjuvant AS03, an oil-in-water emulsion. The AS03 adjuvant is made up of the oily compounds, D,L-alpha-tocopherol (vitamin E) and squalene; an emulsifier known as polysorbate 80; and water containing small amounts of salts. This adjuvant has been widely used in influenza vaccines that were administered in other countries during the 2009 influenza pandemic.[3]

Table 5. Description of AS03 adjuvant product components*	
Product component	**What is it?**
D,L-alpha-tocopherol	D,L-alpha-tocopherol is the scientific, chemical name for vitamin E.
Squalene	Squalene is a substance naturally found in the human body, as well as in animals and plants. Squalene is manufactured in our livers and circulates in our bloodstream reaching various tissues, muscles and organs, with the highest amount found in our skin. Squalene is an essential building block to make certain hormones and other substances in our bodies. Squalene is also found in a variety of foods such as eggs and vegetable oils. In addition, cosmetics, over-the-counter medicines and dietary health supplements contain squalene derived from the liver of sharks, which is a large source of squalene.
Polysorbate 80	Polysorbate 80 is a substance that is used primarily as an emulsifier in food products, cosmetics, vitamins, medicines, and vaccines. Emulsifiers help ingredients mix together and keep them from separating, most commonly oil and water. In medicines, such as vaccines, it also functions as a stabilizer of the formulation. The substance is a derivative of sorbitol, a type of sugar, and oleic acid, a naturally occurring fatty acid.

***Information drawn from US Food and Drug Administration Influenza A (H5N1) Q&A[3]

25. Should individuals who are vaccinated with AREPANRIX™ H5N1 continue to wear Personal Protective Equipment (PPE)?

It is very important that people continue to use PPE, even if they are vaccinated. For people at increased risk of exposure to avian influenza A(H5N1) through handling live virus or contact with wild or domestic birds or animals and/or their environments, vaccination against avian influenza virus may provide another protective measure **in addition to** PPE and other biosecurity measures.[1]

Individuals involved in the clean-up and/or culling of infected animals and others involved in the outbreak control efforts must follow the PPE requirements as established by Canadian Food Inspection Agency, Public Health Agency of Canada, Environment and Climate Change Canada, and Public Service Occupational Health Program, regardless of immunization.[11]

Wearing PPE is important to minimize an individual's risk of infection and is strongly recommended for persons who may be exposed to an avian/animal source of avian influenza virus during an animal outbreak response.[11]

Appropriate PPE depends on existing hazards and site-specific risk assessments. See Guidance on human health issues related to avian influenza in Canada (HHAI) for more information on PPE.[11]

26. Where can eligible individuals obtain AREPANRIX™ H5N1?

Availability of AREPANRIX™ H5N1 may vary by region and will be available in different public health units, community health centres, or pharmacies depending on the health authority. Eligible individuals should be instructed to call their public health unit or community health centre to learn more about vaccine availability in their region.

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