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OIAC Ontario Immunization Advisory Committee
CCOI Comité consultatif ontarien de l'immunisation

Meeting Summary: Human Vaccination Against Avian Influenza in a Non-Pandemic Context in Ontario

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Overview

The avian influenza A(H5N1) virus was first identified in 1996 in Southern China.[1-3] By 2005, the virus had spread to parts of Asia, Africa, the Middle East and Europe primarily through migration of wild birds. In 2008, a new clade (2.3.4.4) emerged in China, which has diversified and circulated widely since 2014. In 2020, an influenza A(H5N1) variant belonging to clade 2.3.4.4b spread among wild birds, poultry and mammals in many regions of the world, causing zoonotic infections in humans, including in North America. In March 2024, the variant was first detected in dairy cattle in the United States, with multiple human cases identified among individuals in close contact with infected animals.[4] While the current risk to the public remains low, individuals involved in occupations or activities resulting in exposure to infected animals or live A(H5N1) avian influenza virus are at increased risk and should take appropriate precautions.[5] In addition to control measures such as personal protective equipment (PPE) and biosecurity measures, human vaccines against avian influenza (HVAI) may provide an additional layer of protection.[3]

In February 2025, the National Advisory Committee on Immunization (NACI) released preliminary guidance on HVAI in a non-pandemic context following Health Canada's authorization of the updated GlaxoSmithKline (GSK) avian influenza A(H5N1) clade 2.3.4.4b human vaccine.[3] In response to NACI's guidance, the Ontario Ministry of Health requested input from the Ontario Immunization Advisory Committee (OIAC) on considerations for HVAI deployment in the current context in Ontario, including potential triggers and high-risk groups for vaccination. Program implementation and delivery strategies were considered out of scope.

OIAC members, along with 13 invited subject matter experts in zoonotic infections, animal health, occupational health, and laboratory medicine met on March 20, 2025, to discuss considerations on whether to deploy HVAI in the current Ontario context (i.e., sporadic poultry outbreaks, no dairy cattle involvement, and no human cases). The topic was brought to the Committee for discussion only, and the OIAC will not be issuing formal recommendations regarding non-pandemic HVAI deployment in Ontario at this time.

Background

Avian influenza A(H5N1) clade 2.3.4.4b was first detected in North America in late 2021.[6] The spread of the virus has accelerated since 2024, with the United States reporting ongoing transmission in dairy cattle beginning in March 2024.[4] As of February 2025, a total of 531 bird flocks (infected premises) had been affected by avian influenza subtype A(H5) in Canada, with the largest proportion (45%, n=239)

located in British Columbia. As of March 2025, there have been outbreaks in 61 premises in Ontario, and no evidence of dairy cattle involvement anywhere in Canada.[7]

Since 2022, 102 human cases of avian influenza A(H5N1) or influenza A(H5) presumed to be avian influenza A(H5N1), have been reported worldwide, attributed to clades 2.3.4.4b and 2.3.2.1x, with 14 known fatalities.[8,9] In the United States, where there has been extensive spread of A(H5N1) among domestic poultry and livestock, 70 human cases have been reported as of March 20, 2025 (including 1 death), most following exposure to dairy cattle (59%) or poultry (34%).[10] The first and only domestically-acquired Canadian case of human avian influenza A(H5N1) was reported in British Columbia in November 2024 in a 13-year-old girl with an unknown exposure source who developed severe illness.[11]

In February 2025, the Public Health Agency of Canada (PHAC) secured an initial supply of 500,000 doses of GlaxoSmithKline's (GSK) vaccine, AS03-adjuvanted Arepanrix™ H5N1 (A/American wigeon clade 2.3.4.4b), with 60% of the supply allocated to provinces and territories (PTs) based on an equitable and risk-based approach, and 40% kept in a federal stockpile for national emergency preparedness.[5] Individual PTs are responsible for decisions on their respective vaccination programs in the context of local risk conditions.

To aid in decision-making, the National Advisory Committee on Immunization (NACI) released preliminary guidance on HVAI in a non-pandemic context.[3] NACI proposed that the objective for the use of HVAI in a non-pandemic context is to prevent human infections with avian influenza A(H5N1), as preventing animal-to-human transmission could help prevent severe disease in humans and limit opportunities for viral adaptations and reassortment events that could facilitate human-to-human transmission. NACI guidelines do not currently recommend broad deployment of HVAI but point to several factors that should be considered when deciding whether and when to use HVAI including the number, source and severity of human cases, zoonotic risk, and various virologic factors. NACI guidance also identifies key populations for HVAI, as well as scenarios that may trigger vaccine deployment.

Summary of Considerations

The OIAC reviewed and discussed the spread of avian influenza among wildlife, poultry and dairy cattle in North America; surveillance measures, incidence and characteristics of human cases; protective measures against avian influenza; safety and immunogenicity profile of Arepanrix™ H5N1 vaccine; post-marketing and safety data for AS03-adjuvanted H1N1 pandemic vaccines; NACI guidance on HVAI use in a non-pandemic context; and experiences with HVAI deployment in other jurisdictions.

Influenza A(H5N1) in Humans

- There is currently no evidence of sustained human-to-human transmission of avian influenza and human infections are rare even among individuals with extended periods of close contact with infected animals.[12]

- Influenza A(H5N1) infection had a historically high (48%) fatality rate.[8] From 2022 to January 2025, the fatality rate has been 13.7% (14/102 cases of avian influenza A[H5N1] or A[H5] presumed to be A[H5N1]). In the United States, where the majority of human cases were due to exposure to infected cattle, the case fatality rate was 1.4% (1/70 cases) from April 2024 to March 2025.[10] The lower case-fatality rates observed in recent years may be due to several factors including differences in circulating avian influenza A(H5N1) clades, improved active surveillance and testing allowing for detection of milder cases, differences in viral exposure routes (e.g.,

inhalation vs. ocular droplet), and better access to antiviral medications and PPE in affected regions.

- A study of recent human cases of avian influenza in the United States reported generally mild illness with 93% presenting with conjunctivitis, 49% with fever and 36% with respiratory symptoms.[13] However, two reports of human infection with influenza A(H5N1) belonging to the D1.1 genotype have described severe disease, with one of the two cases resulting in death.[11,14]

HVAI Safety and Immunogenicity

- In 2013, Arepanrix™ H5N1 (containing avian influenza A/Indonesia clade 2.1.3.2) was authorized by Health Canada as a pandemic vaccine.[3] In February 2025, a vaccine strain change to avian influenza A/American wigeon clade 2.3.4.4b was approved based on safety and immunogenicity data of the original formulation, as per standard practice for strain changes to seasonal influenza vaccines. There are no clinical trial data available specifically for the A/American wigeon clade 2.3.4.4b strain.

- Safety and immunogenicity studies of Arepanrix™ H5N1 (A/Indonesia clade 2.1.3.2) showed that the vaccine elicited strong humoral immune responses in adults and children aged 6 months to <18 years, with seroprotection rates being 76.8 – 91% and 99 – 100%, respectively, 21 days after the second dose of vaccine.[3,15] Effectiveness data is currently unavailable for avian influenza A(H5N1) vaccines.

- Two doses of Arepanrix™ H5N1 (A/Indonesia clade 2.1.3.2) induced cross-reactive humoral responses to heterologous strains (e.g., avian influenza A(H5N1)/Vietnam/1194/2004); however, immunogenicity was lower compared to the vaccine (homologous) strain or other strains belonging to the same clade as the vaccine strain.[3,15]

- Data regarding the duration of protection conferred by AS03-adjuvanted influenza A(H5N1) vaccines are limited and inconclusive. Clinical trials suggest that seroprotection is maintained up to 6 months in the majority of adults and children who receive the 2-dose vaccine series.[15] In contrast, one study demonstrated a sharp decline in hemagglutinin inhibition antibody titres following vaccination with loss of seroprotection within 6 months. There was, however, a persistence of microneutralization antibody titres ≥1:40 up to 1 year post vaccination. The clinical significance of these findings is unknown.[16]

- There is limited evidence on the ability to boost the immune response to AS03-adjuvanted influenza A (H5N1) vaccines. However, some studies identified anamnestic immune responses following booster vaccination with AS03-adjuvanted vaccine formulations containing homologous or heterologous influenza A(H5N1) strains.[17-19]

- Immunization was well tolerated with adverse events following immunization (AEFIs) generally being localized, transient and mild-to-moderate in severity.[3,15] There is currently no post-marketing safety data for the AS03-adjuvanted Arepanrix™ H5N1 vaccine; however, there are relevant data for AS03-adjuvanted pandemic influenza A(H1N1) vaccines (e.g., Arepanrix™ H1N1 pdm09 [GSK] and Pandemrix™ H1N1 pdm09 [GSK]) that were widely used during the 2009 – 2010 influenza A(H1N1) pandemic. A safety review of Arepanrix H1N1™ and Pandemrix™ H1N1 vaccines showed that they were generally well tolerated with an acceptable safety profile, even in special populations (e.g., pregnant, immunocompromised);[3,20] however, some safety signals were noted:

- An increased rate of anaphylaxis events following Arepanrix™ H1N1 pdm09 vaccination, as compared to seasonal influenza vaccination was observed in Quebec (incidence of 13 events per million doses vs. <1 per million doses, respectively).[21]

- In Quebec, a temporal increase in the risk of Guillain-Barré syndrome (GBS) was observed in the first 4 weeks following Arepanrix™ H1N1 vaccination among adults aged ≥50 years. The number of cases attributable to vaccination was approximately 2 per 1 million doses.[22] In Germany, a temporal increase in GBS risk was observed within 5 to 42 days of vaccination with Pandemrix™ H1N1 versus days 43 to 150 of vaccination (relative incidence of 4.65 [95% CI: 2.17, 9.98]).[23]

- A link between GSK's Pandemrix™ H1N1 and narcolepsy in children and adolescents aged 5 to 19 years of age was observed in some European countries (e.g., Sweden and Finland observed a relative risk of 7.5 [95% CI: 5.2 to 10.7] and 6.4 [95% CI: 4.2 to 9.7], respectively, compared to pre-pandemic rates).[3,24,25] Of note, GSK's Arepanrix™ H1N1, which was produced in a different manufacturing facility and widely used in North America, showed minimal to no such association.[26-28]

HVAI Guidance and Deployment in Other Jurisdictions

- As of March 2025, the U.S. Centers for Disease Control and Prevention (CDC) and the United Kingdom Health Security Agency have not provided guidance on the use of HVAI.[29,30] The Communicable Diseases Network in Australia did not recommend the use of HVAI as there have been no reported cases of avian influenza A(H5N1) in birds or other animals in Australia as of March 2025.[31,32]

- Finland is the first and only country that has deployed an HVAI program. It was initiated in June 2024 in response to multiple A(H5N1) outbreaks in fur farms, and targeted high-risk groups including those in contact with fur animals at fur farms, poultry workers, veterinarians, bird ringers, laboratory workers handling the live virus, individuals participating the handling of sick or dead animals, and close contacts of confirmed/suspected cases of avian influenza in humans.[33,34] Vaccine was only available months after a complete cull of farmed fur animals (mostly foxes and minks) at all affected fur farms in Finland, which terminated the outbreaks. Vaccine uptake among the eligible populations remains low, with approximately 5% having received the 2-dose series as of December 2024.[3]

Challenges and Data Gaps

- The use of PPE is recommended to reduce the risk of infection with avian influenza among those involved in the handling of sick or dead poultry, wild birds or other animals and their environments;[35] however, there are ongoing challenges with adherence to appropriate PPE use among high-risk occupational groups.[13,36] A study of human cases of avian influenza in the United States revealed that out of the 45 cases with animal exposure, only 36% reported use of both eye protection and respirators or face masks, as recommended by the CDC, despite handling infected poultry (e.g., during depopulation activities) or dairy cattle.[13,37] This finding likely reflects challenges with implementation including limited access to PPE in some settings, and need for prolonged use among workers exposed to infected dairy cattle.

- There are gaps in influenza A(H5N1) surveillance in Ontario such as limited geographic distribution of wildlife sampling (i.e., samples are primarily from southern Ontario, with limited

data from northern Ontario), and barriers to accessing laboratory diagnostics for individuals in key populations potentially exposed to avian influenza.

- There is insufficient evidence around population-level susceptibility to A(H5N1) viruses and there are no seroprevalence studies for Canadian subpopulations at risk of exposure to A(H5N1).
- There are currently no data on perceived risk of influenza A(H5N1) or the acceptability of HVAI use in a non-pandemic context among key populations identified in the NACI guidance.[3]

Outcome

- Given several unknowns related to vaccine safety and effectiveness, the acceptability of a non-pandemic HVAI program and the current epidemiological context in Ontario, OIAC members and invited subject matter experts were not supportive of a broad deployment of HVAI among key populations at this time.
- However, attendees were supportive of offering vaccination to select high-risk occupational groups with ongoing and significant exposure to infected animals or live virus (e.g., people who handle live avian influenza A(H5N1) virus in laboratory settings, individuals conducting animal necropsies) to prevent human infection using a shared clinical decision-making approach.
- Attendees noted that there are occupational groups or settings resulting in elevated risk of exposure to avian influenza that were missing from the NACI guidance including individuals involved in animal control, in close contact with wild birds (e.g., bird banders) or working/volunteering in wildlife rehabilitation centres, zoos or humane societies.
- The attendees also emphasized the need to address gaps in surveillance and diagnostics in Ontario for avian influenza and to engage with key populations to assess vaccine acceptability during the non-pandemic period.

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About the Ontario Immunization Advisory Committee

The Ontario Immunization Advisory Committee (OIAC) was established in August 2021 at the request of the Chief Medical Officer of Health. The Committee provides scientific and technical advice to Public Health Ontario on vaccines and immunization matters, including program implementation in Ontario, priority populations, clinical guidance, and vaccine safety and effectiveness.

OIAC's work focuses 'on publicly funded vaccines and immunization programs in Ontario, and those under consideration for new programming. The OIAC provides advice by applying scientific knowledge and the best available evidence, in addition to feasibility, acceptability and other implementation considerations.

For more information about the OIAC and its members contact secretariat@oahpp.ca.

About Public Health Ontario

Public Health Ontario is an agency of the Government of Ontario dedicated to protecting and promoting the health of all Ontarians and reducing inequities in health. Public Health Ontario links public health practitioners, front-line health workers and researchers to the best scientific intelligence and knowledge from around the world. For more information about PHO, visit publichealthontario.ca.

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