Use of zoonotic influenza vaccines in humans

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SARInet plus Severe Acute Respiratory Infections Network

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SARINET PLUS REVELAC-i REGIONAL MEETING PANAMA - MARCH 2026

Outline

- Context for human A(H5) vaccination
- WHO guidance on use of human influenza A(H5) vaccines
- Emerging real-world data and lessons from the use of A(H5) vaccines
- Looking ahead: evidence gaps and research priorities

Context for human A(H5) vaccination

- **Global public health risk of influenza** A(H5) is **low.** While, the risk of infection for occupationally or frequently exposed is **low to moderate** depending on the risk mitigation and hygiene measures in place and the local epidemiology[1].
- **Transmission between animals** continues to **occur.**
- **Over 900 detections of A(H5N1) in humans** reported **>20 countries** since 2003.
  - Sporadic cases with direct or indirect exposure to infected animals or contaminated environments.
  - Infections can be severe and even fatal.
  - Available genetic sequences of the virus from the human cases similar to those from local animals.
  - No sustained human-to-human transmission reported.
- A(H5N1) viruses, including **clade 2.3.4.4b**, continue to diversify genetically and spread geographically.
- Other **subtypes of influenza viruses**, including swine influenza viruses, continue to circulate in animals and occasionally infect humans at the interface.

1. Updated joint FAO/WHO/WOAH public health assessment of recent influenza A(H5) virus events in animals and people, July 2025
2. Influenza at the human-animal interface. WHO Summary and risk assessment, from 20 December 2025 to 22 January 2026, January 2026

WHO guidance on the use of human influenza A(H5) vaccines

Published in December 2025, following SAGE guidance in September 2025

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WHO guidance on the use of licensed human influenza A(H5) vaccines for the interpandemic and emergence periods

Background

In accordance with its mandate to provide normative guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and combination vaccines against diseases of international public health importance. The position papers are concerned primarily with the use of vaccines in large-scale immunization programmes; they are intended for use by managers of such programmes and national public health officials. They may also be of interest to international funding agencies, immunization advisory groups, vaccine manufacturers, health professionals, researchers, the scientific media and the general public.

Influenza virus infections in humans are classified into seasonal (epidemic), zoonotic, and pandemic.[1] In 2022, WHO published a position paper with guidance specifically for seasonal (epidemic) influenza vaccines.[2] This current guidance focuses on zoonotic influenza vaccines, specifically influenza A(H5) for the interpandemic[3] and emergence[4] periods. If there is an influenza pandemic emergency, WHO will provide guidance.

Orientations de l'OMS concernant l'utilisation des vaccins homologués contre la grippe humaine A(H5) pendant les périodes interpandémique et d'emergence

Généralités

Conformément à son mandat, qui prévoit qu'elle fournisse aux États Membres des orientations à caractère normatif en matière de politique sanitaire, l'OMS publie une série de notes de synthèse régulièrement mises à jour sur les vaccins et les associations vaccinales contre les maladies d'importance internationale pour la santé publique. Ces notes portent essentiellement sur l'utilisation des vaccins dans le cadre des programmes de vaccination à grande échelle et sont destinées aux administrateurs de ces programmes et aux responsables nationaux de la santé publique. Elles peuvent également présenter un intérêt pour les organismes internationaux de financement, les groupes consultatifs sur la vaccination, les fabricants de vaccins, les professionnels de la santé, les chercheurs, les médias scientifiques et le grand public.

Les infections humaines par les virus grippaux sont classées en 3 catégories: saisonnières (épidémiques), zoonotiques et pandémiques.[1] En 2022, l'OMS a publié une note de synthèse contenant des orientations spécifiques aux vaccins contre la grippe saisonnière (épidémique).[2] Les présentes orientations portent sur l'utilisation des vaccins contre la grippe zoonotique, en particulier la grippe A(H5), pendant les périodes interpandémique[3] et d'émergence.[4] En cas d'urgence due à une pandémie de grippe, l'OMS publiera des orientations spécifiques.

[1] Influenza virus infections in humans. Geneva: World Health Organization; 2018 (https://cdn.who.int/media/docs/default-source/influenza/influenza_virus_infections_humans_oct_18.pdf).

[2] See No. 19, 2022, pp. 185–208.

[3] Defined as no human cases of influenza A(H5) virus being reported, although infections in animals may occur.

[4] Defined as detection of sporadic human cases or clusters of human cases of influenza A(H5) virus, but with no sustained human-to-human transmission.

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[1] Influenza virus infections in humans. Geneva: Organization mondiale de la Santé; 2018 (https://cdn.who.int/media/docs/default-source/influenza/influenza_virus_infections_humans_oct_18.pdf).

[2] Voir N° 19, 2022, pp. 185–208.

[3] Définie comme une période au cours de laquelle aucun cas humain de grippe A(H5) n'est signalé, bien que des infections chez les animaux puissent survenir.

[4] Définie comme une période au cours de laquelle des cas humains sporadiques ou des grappes de cas humains de grippe A(H5) sont détectés, mais sans transmission interhumaine soutenue.

[WHO guidance on the use of licensed human influenza A(H5) vaccines for the interpandemic and emergence periods](), ENG/FR. December 2025

Countries should consider issuing recommendations on the use of available licensed human influenza A(H5) vaccine(s) for the interpandemic and emergence periods* based on their public health priorities.

- **Interpandemic period:** No human cases are reported, but animals may be infected.
- **Emergence period**: Sporadic human cases or clusters of human cases of are detected, but no sustained human-to-human transmission.

*As per: Preparedness and resilience for emerging threats (PRET): module 1: planning for respiratory pathogen pandemics

Factors to consider when deciding whether to use human A(H5) vaccines

These factors should be considered in combination, rather than individually

Animal

- **Proportion of affected animals in a geographic area**
- Increase in the number of **animal species infected**
- The **extent of detection** in these animals
- The **use of response measures** to prevent the spread of the virus
- **Zoonotic risk** from, for example, poultry, dairy cattle, swine, or other animals that **might increase the risk of exposure to humans at the animal/human interface**

Human

- **Number of detected human cases** and the **epidemiological trends** (e.g. increasing case counts, demographics) of infections
- **Source(s) of infection among the human cases** (e.g. zoonotic, unknown, or possible human-to-human transmission) and conditions of suspected infection (e.g. during handling of infected animals, culling, disinfection procedures)
- **Demographic characteristics and severity** of human cases

Virological

- **Circulating clade and matching** with available A(H5) vaccine(s)
- **Detection and characterization of mutations** that could increase the risk of human infection, transmission, and/or severe disease

Why use human A(H5) Vaccines between pandemics? And who to target?

Primary objective: prevention of severe disease and death in individuals at higher risk of infection with influenza A(H5) viruses

Laboratory workers who handle H5 viruses

First responders to A(H5) animal outbreaks

People with ongoing contact with animals or their environments* in geographical areas where animal/human A(H5) infections have been reported

Health workers of suspected/confirmed human A(H5) cases in designated facilities and potential vaccinators of humans

Given the current low risk of infection among the general population, A(H5) vaccination is currently not recommended for the general public.

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WHO guidance on the use of licensed human influenza A(H5) vaccines for the interpandemic and emergence periods, ENG/FR. December 2025

*This could include individuals routinely, occupationally or otherwise exposed to animals, their secretions or contaminated environments, such as poultry/ farm workers, veterinarians, zookeepers, backyard bird flock owners, live bird market vendors, and people with recreational exposure to animals (e.g. hunters, wild bird watchers).

Decision-aid matrix for determining the use of A(H5) vaccines at country level across four scenarios

Scenarios	Laboratory workers who handle H5 viruses	First responders to A(H5) outbreaks in animals	People with ongoing contact with animals or their environments in geographical areas where animal/human A(H5) infections have been reported*	Health workers involved in evaluating and managing suspected or confirmed human A(H5) cases in designated facilities and potential vaccinators of humans
Interpandemic period: no human cases, although infections in animals may occur				
Scenario 1 • No human cases; and • No animal cases	●	–	–	–
Scenario 2: • No human cases; but • Animal cases are occurring	●	●	●	–
Emergence period: sporadic human cases or clusters of human cases				
Scenario 3: • Increasing number of sporadic human cases and/or severity of sporadic human cases; with/without • Animal cases are occurring	●	●	●	●
Scenario 4: • Increasing number of clusters of human cases; with/without • Animal cases are occurring	●	●	●	●

• = Consider use based on local context and if available A(H5) vaccine supply allows – = Not recommended.

*This could include individuals routinely, occupationally or otherwise exposed to animals, their secretions or contaminated environments, such as poultry/ farm workers, veterinarians, zookeepers, backyard bird flock owners, live bird market vendors, and people with recreational exposure to animals (e.g. hunters, wild bird watchers).

Safety, immunogenicity, duration & cross-reactivity of human A(H5) influenza vaccines

- **Landscape of A(H5) vaccines**: at least 21 A(H5) vaccine products* holding active licensure (of which 13 vaccines licensed for use during the interpandemic and/or emergence periods). Most of them inactivated vaccines.
- **Commercially available**: A(H5) vaccines (H5N1 & H5N8) from 2 manufacturers.
- **Safety profile:** similar to seasonal influenza vaccines.
- **Immunogenicity:** following 2 doses of vaccine indicate potential for moderate to strong seroconversion or seroprotection based on A(H5) antibodies. Variability between vaccines and across age groups, adjuvants MF59 and AS03 enhancing immune responses.
- **Duration:** waning of antibody titres may occur from ~6 months post-primary series.
- **Cross-reactivity:** A(H5) vaccines have demonstrated varying cross-reactive immune responses to antigenically distinct viruses from different clades or sub-clades. Cross-reactive immunity is expected from the H5 component of the vaccine, irrespective of the neuraminidase type. Emerging evidence also shows detectable T-cell responses post-vaccination.

* As of September 2025. WHO guidance on the use of licensed human influenza A(H5) vaccines for the interpandemic and emergence periods, ENG/FR. December 2025

Since 2023, increasing number of countries with human A(H5) vaccination recommendations

- Finland (2023)
- Austria (2024)
- Ireland* (2024)
- Canada (2025)
- Chile* (2025)
- France (2025)
- Portugal (2025)
- ECDC (2025)
- New Zealand (2026)

*Recommendation to not vaccinate. Note: this list is illustrative and might not exhaustive.

Emerging real-world data and lessons from the use of A(H5) vaccines

Finland

2023 to date:

- Clade 2.3.4.4b led to outbreaks on 71 Finnish fur farms, **exposing humans.**
- **In 2023, Policy recommendations were issued**
- June 2024: Vaccination campaign **started with Zoonotic Influenza Vaccine Seqirus (H5N8):** 2 doses. Coverage <10%[1]
- **Key results[2,3] of THL's Competence Center for Behavior and Communication (CUBE) study**
    - Risk group perceptions of avian influenza must be taken into account
    - Different actors must cooperate
    - Use of research on vaccine behavior for planning of campaigns
- Study to evaluate humoral and cell-mediated immune responses by ZIVS against H5N1 2.3.4.4b clade in vaccine target groups[4]
- September 2024: **stop H5 vaccination**, due to end of shelf life (max 2 years as per EMA's decision). Discussion ongoing to **get more doses** through EU Joint procurement

Canada

2024 to date:

- **Unprecedented outbreaks** with widespread infections in wild birds, poultry, and numerous mammals. A severe human case reported in Canada.
- Issued **'Preliminary guidance on human vaccination against avian influenza in a non-pandemic context'**
- **Guidance and communications** from 9 provinces and territories was developed*
- July 2025: **vaccination started with GSK Arepanrix (H5N1)**, 2 doses.
- **Assessing uptake, impact and feasibility.** Less than 1000 doses administered.
- February 2026: **vaccination ended** due to expiration of doses and programme suspended until further notice.
- No decisions have been made about the **future of the programme in the context of pandemic preparedness**

Source: 1. [1] Finnish Institute for Health and Welfare. (2025). *Vaccinations recorded in the Finnish Vaccination Register*. Retrieved September 15, 2025. Available at: https://sampo.thl.fi/pivot/prod/en/vaccreg/uptake/fact_uptake 2. Selvitys lintuinfluenssarokotuksiin liittyvistä asenteista rokotuskampanjan tueksi: laadullinen tutkimus lintuinfluenssan riskiryhmään kuuluvien rokotushalukkuudesta 3. https://blogi.thl.fi/toimiva-rokotuskampanja-edellyttaa-yhteistyota-ja-vuorovaikutusta-kohderyhmien-kanssa/ 4. https://www.researchsquare.com/article/rs-6804016/v1 *Nova Scotia (Link), New Brunswick (Link), Alberta (Link), Newfoundland and Labrador (Link), Yukon (Link); British Columbia (Link), Nunavut (Link), Quebec (Link), Manitoba (Link)

Looking ahead: evidence gaps and research priorities

Vaccine safety

- Post-marketing pharmacovigilance in large populations.
- Safety profile in subgroups not included in clinical trials (e.g. pregnant women).

Vaccine immunogenicity, efficacy/effectiveness, and cross-reactivity

- Correlates of protection
- Data of cellular immunity
- Role of pre-existing immunity in protection due to previous infection and/or vaccination.
- Post-authorization data on effectiveness (reduction of transmission and severity), where possible, including duration of protection and need for revaccination.
- The need for and optimal timing of a second dose.
- Effectiveness of homologous and heterologous prime-boost vaccination strategies.
- Effectiveness of A(H5) vaccination compared with the timely administration of influenza antivirals for close contacts of suspected or confirmed human A(H5) cases.
- Determination of the breadth of cross-reactivity and cross-protection of A(H5) vaccines to different clades and subclades of viruses and from seasonal influenza vaccines.
- Coadministration with other vaccines.
- The value of mRNA influenza vaccines and other new technologies to offer broader strain protection and/or longer duration of protection.

Feasibility and acceptability

- Feasibility - including vaccine and operational costs as well as the potential opportunity costs of A(H5) vaccine introduction- and acceptability

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For every generation, vaccines work.

Your decision makes a difference.

Get vaccinated.

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