

Questions and Answers

Recommended composition of influenza virus vaccines for use in the southern hemisphere 2026 influenza season and development of candidate vaccine viruses for pandemic preparedness

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1. What is the purpose of WHO recommendations on the composition of influenza virus vaccines?

These WHO recommendations provide a guide to national public health and regulatory authorities, and vaccine manufacturers for the development and production of influenza virus vaccines for the next influenza season and for pandemic preparedness. In contrast to many other vaccines, the viruses in seasonal influenza vaccines need to be evaluated and updated regularly because circulating influenza viruses evolve continuously and may need to be updated to remain effective. Recommendations are usually made in February for the following influenza season in the northern hemisphere and in September for the following influenza season in the southern hemisphere. The recommendation dates are chosen to provide approximately 6-8 months for the production, regulatory approval and distribution of the manufactured vaccines.

For pandemic preparedness, zoonotic influenza CVV selection and development are considered at least twice a year. The decisions are based on continuous surveillance for zoonotic events (human infection with an influenza virus normally restricted to a non-human host) and influenza virus activity in animals, and virus characterization by Global Influenza Surveillance and Response System (GISRS) and its collaborators e.g., the World Organisation for Animal Health, founded as OIE (WOAH), Food and Agriculture Organization of the United Nations (FAO), and the WOAH/FAO Network of Expertise on Animal Influenza (OFFLU).

2. What is the Global Influenza Surveillance and Response System (GISRS)?

GISRS is a global system of public health institutions coordinated by WHO, currently consisting of 160 institutions, including National Influenza Centres (NICs), WHO Collaborating Centres for Influenza (CCs), WHO Essential Regulatory Laboratories (ERLs) and WHO H5 Reference Laboratories, in 130 WHO Member States. The GISRS functions year-round under WHO Terms of Reference, together with partner laboratories and its collaborators, sharing surveillance findings and virus materials from human and animal health sectors in a timely fashion to inform risk assessment and mitigation measures including the updates of seasonal influenza virus vaccines and candidate vaccine viruses (CVVs) for zoonotic influenza.

GISRS monitors the evolution of influenza viruses of public health importance, including seasonal, zoonotic and potential pandemic viruses, and recommends and implements risk assessment and response measures. Virus characterizations, combined with other available epidemiologic and disease information, form the evidence base for public health decisions on epidemic response and pandemic preparedness including selection and development of CVVs for seasonal and zoonotic influenza. GISRS also provides guidance to countries and support for activities such as training, risk assessment, outbreak response, development of diagnostic tests, testing for antiviral drug resistance and scientific interpretation of important findings.

GISRS has been expanding its scope to include other respiratory viruses. Respiratory syncytial virus (RSV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been included in the GISRS surveillance platform since 2015 and 2020, respectively. The broader application and value of GISRS have been increasingly acknowledged by the world.

Further information about GISRS is available on the WHO website.

3. How are influenza virus vaccine recommendations made?

Data and information from the GISRS network, which includes NICs, WHO CCs, WHO ERLs and WHO H5 Reference Laboratories, its collaborators, and other sources are used to make vaccine virus recommendations. This includes:

• Surveillance data:

Virus surveillance data from the GISRS network, complemented with epidemiologic and clinical findings, inform the vaccine virus selection process.

• Antigenic characterization of viruses:

GISRS laboratories, in particular WHO CCs, use post-infection ferret antisera and pooled post-vaccination human sera to evaluate antibody reactivity with the surface proteins (antigens) of circulating and vaccine influenza viruses. Antigenic cartography is used to visualize relatedness of viruses based on the data provided by WHO CCs.

• Human serology studies with influenza virus vaccines:

WHO CCs and WHO ERLs test how well antibodies from vaccinated people react with recently circulating influenza viruses.

• Genetic characterization of viruses:

GISRS laboratories conduct gene sequencing to compare the sequences of circulating influenza viruses with those of vaccine viruses to identify genetic changes that might influence protection conferred by a given vaccine.

• Virus fitness forecasting:

Virus fitness relates to the likelihood of any emerging groups of viruses becoming more prevalent. Information from modelling studies, based on genetic sequences available in databases and antigenic information provided by the WHO CCs is considered.

• Antiviral susceptibility:

GISRS laboratories analyse influenza viruses to determine if they remain susceptible to the antiviral drugs approved for treatment of influenza infections. This information is taken into consideration when specific viruses are selected as CVVs.

• Vaccine effectiveness:

The Global Influenza Vaccine Effectiveness (GIVE) Collaboration, made up of many different studies conducted in countries in both the northern and southern hemispheres, provides information on vaccine performance in previous influenza seasons and interim reports on the current season.

• Availability of CVVs:

CVVs are essential for production of vaccines in a timely manner for the next influenza season. Most vaccines produced globally use egg-based manufacturing processes which require CVVs that replicate well in eggs while cell-based vaccines require CVVs that replicate well in cell culture. Separate recommendations are made for egg- and cell-based

CVVs because of the differing replication and manufacturing processes. Influenza virus vaccines comprised of recombinant protein influenza virus antigens do not require CVVs for manufacturing.

These data, and other findings made available by GISRS, are evaluated during WHO consultations held in February and September of each year. The consultations include experts from WHO CCs, WHO ERLs, WHO H5 Reference Laboratories, NICs, OFFLU, academic institutions, and other national and regional institutions.

4. What are candidate vaccine viruses (CVVs)?

Haemagglutinin (HA) is the primary antigen in seasonal influenza vaccines. A CVV is a virus prepared for potential use in vaccine manufacturing that possesses an HA which WHO CCs have determined to be antigenically similar to the virus that has been recommended for use in vaccines.

5. Which viruses are recommended by WHO to be included in influenza virus vaccines for use in the 2026 southern hemisphere influenza season?

WHO recommends that vaccines for use in the 2026 southern hemisphere influenza season contain the following:

Egg-based vaccines

- an A/Missouri/11/2025 (H1N1)pdm09-like virus;
- an A/Singapore/GP20238/2024 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

Cell culture-, recombinant protein- or nucleic acid-based vaccines

- an A/Missouri/11/2025 (H1N1)pdm09-like virus;
- an A/Sydney/1359/2024 (H3N2)-like virus; and
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

The continued absence of confirmed detection of naturally occurring B/Yamagata lineage viruses after March 2020 is indicative of a very low risk of infection by B/Yamagata lineage viruses. Consistent with previous four WHO recommendations since September 2023, it remains the opinion of the WHO influenza vaccine composition advisory committee that the inclusion of a B/Yamagata lineage antigen is no longer warranted.

There will no longer be updated recommendations for the B/Yamagata lineage component.

6. Are the vaccine viruses in this recommendation different from those in the previous northern and southern hemisphere recommendations?

The recommended composition of influenza vaccines for the 2026 southern hemisphere is different from those viruses recommended for the 2025 southern hemisphere vaccines and the 2025-26 northern hemisphere.

The A(H1N1)pdm09 vaccine component differs from the previous 2025-26 northern hemisphere and 2025 southern hemisphere vaccine composition with the replacement of the A/Victoria/4897/2022-like virus with A/Missouri/11/2025-like virus for egg-based vaccines; and A/Wisconsin/67/2022-like virus with A/Missouri/11/2025-like virus for cell culture, recombinant protein-, or nucleic acid-based vaccines.

The A(H3N2) vaccine component differs from the previous 2025-26 northern hemisphere and 2025 southern hemisphere vaccine composition with the replacement of the A/Croatia/10136RV/2023-like virus with A/Singapore/GP20238/2024-like virus for egg-based vaccines; and A/District of Columbia/27/2023-like virus with A/Sydney/1359/2024-like virus for cell culture-, recombinant protein-, and nucleic acid-based vaccines.

The updates of the A(H1N1)pdm09 and A(H3N2) vaccine components are based on information from multiple sources of data (see question 3) and are expected to improve immune protection against A(H1N1)pdm09 and A(H3N2) viruses in the southern hemisphere 2026 influenza season.

The B/Victoria lineage vaccine component remains unchanged from the previous recommendations for the northern and southern hemispheres. Previous and present WHO influenza virus vaccine composition recommendations can be found on the WHO Global Influenza Programme website.

7. What is the position of WHO on the B/Yamagata lineage vaccine component?

The continued absence of confirmed detection of naturally occurring B/Yamagata lineage viruses after March 2020 is indicative of a very low risk of infection by B/Yamagata lineage viruses. Consistent with previous four recommendations since September 2023, it remains the opinion of the WHO influenza vaccine composition advisory committee that inclusion of a B/Yamagata lineage antigen in quadrivalent influenza vaccines is no longer warranted, and every effort should be made to exclude this component as soon as possible. National or regional authorities should make decisions regarding the transition to trivalent influenza vaccines in their jurisdictions.

8. How is GISRS monitoring for B/Yamagata-lineage viruses?

The GISRS conducts year-round surveillance for influenza viruses. Clinical specimens are submitted to NICs of GISRS and are tested for influenza and potentially other respiratory viruses of public health importance. NICs perform lineage determination on a subset or all B viruses detected. All B/Yamagata lineage viruses, if any, are shipped to a WHO CC of GISRS for confirmation and characterization. In recent years, each <u>FluNet</u> report of a B/Yamagata lineage virus detection has been followed up. After March 2020, there have been no naturally circulating B/Yamagata lineage viruses confirmed by a WHO CC or a NIC.

9. What does the term "-like virus" mean in the vaccine composition recommendation?

Recommended vaccine viruses are representative of the antigenic group(s) of viruses anticipated to circulate widely in the forthcoming influenza season. Often multiple CVVs are available which possess HA antigens from other viruses that are antigenically similar to the recommended vaccine viruses. The term "-like virus" is included to allow for the use of these other CVVs for vaccine manufacturing.

10. Why are different viruses sometimes recommended for egg- and cell-based vaccines?

Influenza viruses may not replicate equally well in the egg- and cell-based vaccine production systems. Therefore, different viruses with similar antigenic properties are sometimes recommended for the two production systems.

The use of cell-based vaccine virus sequences is recommended for recombinant protein or other relevant platforms of influenza virus vaccine production.

11. What is the difference between trivalent and quadrivalent influenza virus vaccines?

Trivalent influenza virus vaccines contain the two subtypes of influenza A virus (an A(H1N1)pdm09 and an A(H3N2) virus) and the influenza B/Victoria lineage virus.

Quadrivalent influenza virus vaccines contain the same components as trivalent vaccines, two influenza A subtypes (A(H1N1)pdm09 and A(H3N2)) and the B/Victoria lineage virus, with the addition of the B/Yamagata lineage virus. These quadrivalent vaccines are still in use in some regions where the transition to trivalent vaccines is not yet complete.

12. Who recommends, approves, and advises on influenza virus vaccine composition and use?

The WHO influenza vaccine composition advisory committee recommends which viruses should be used to make influenza virus vaccines. It is the responsibility of the vaccine manufacturers to source the appropriate CVVs or protein sequences and to obtain approval for their use from the relevant regulatory agencies. WHO publishes and updates a <u>list</u> of recommended CVVs and sequence accession numbers.

Following the global vaccine composition recommendation by WHO, national or regional authorities approve the composition and formulation of vaccines (including trivalent or quadrivalent) and develop policy for the use of influenza virus vaccines in their jurisdictions.

13. What vaccine formulation (i.e., recommendation for northern or southern hemisphere influenza season) should countries in tropical and subtropical regions consider for use in vaccination programmes?

WHO has developed <u>guidance</u> to support countries in tropical and subtropical regions in choosing between the northern and southern hemisphere formulations. These countries should consider their epidemiologic and virologic surveillance data in selecting which vaccine formulation to use and deciding when to start vaccination.

14. Which CVVs are available for use in influenza virus vaccines?

The WHO recommended CVVs for vaccine development and production for the 2026 southern hemisphere influenza season are listed on the WHO website.

The available CVVs, including those for pandemic preparedness purposes (<u>zoonotic viruses</u>), and corresponding potency test reagents are posted by type/subtype and updated on the <u>WHO</u> <u>website</u>.

15. Why and how does GISRS continue to update CVVs for pandemic preparedness purposes?

Animal influenza viruses circulate widely in some animals and transmit sporadically to humans, resulting in zoonotic infections. Human infections with influenza viruses from birds, pigs and other mammals including dairy cattle continue to be detected, and these viruses remain a public health threat. As such, GISRS and its collaborators continue to conduct surveillance and risk assessments¹ of zoonotic influenza and update CVVs for pandemic preparedness purposes.

GISRS, in collaboration with animal health partners, continuously analyses a range of zoonotic and potentially pandemic influenza viruses as they emerge and evolve. Sharing of virus materials and analysis strengthens pandemic preparedness and highlights the importance of the One Health approach through cross sectoral cooperation. Data are reviewed at least twice a year. Influenza viruses with potential public health significance and not well covered by existing CVVs are considered as a priority for new CVV development.

CVVs are developed by classical reassortment or by recombinant DNA technology, and undergo extensive quality and safety testing to ensure the CVVs are phenotypically attenuated and antigenically similar to the selected wild-type virus. An inventory of CVVs and associated potency reagents is maintained and updated for various pandemic preparedness purposes, e.g., vaccine development to conduct clinical trials, and other pandemic preparedness activities. The use of these CVVs for vaccine development and production should be based on the assessment of the public health risk and the needs in consultation with national and/or regional regulatory and public health authorities.

A list of available pre-pandemic CVVs can be found at: <u>Zoonotic influenza: candidate vaccine viruses and potency testing reagents</u>.

¹ Monthly and ad-hoc risk assessment of zoonotic influenza can be found on the WHO Global Influenza Programme website at: https://www.who.int/teams/global-influenza-programme/avian-influenza/monthly-risk-assessment-summary.

16. What is WHO's guidance on the use of influenza A(H5) virus vaccines?

In 2008, WHO published its guidance on the "Options for the use of human H5N1 influenza vaccines and the WHO H5N1 vaccine stockpile", which was updated and replaced in 2025 with the guidance, "Considerations for use of avian influenza A(H5) vaccines during the interpandemic and emergence periods"

The WHO Scientific Advisory Group of Experts (SAGE) made its recommendations on the "use of licensed human H5N1 influenza vaccines in the interpandemic period" in 2009, and reconfirmed its recommendations in 2013. In 2025, SAGE are reviewing the recommendations.

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