衞生防護中心
Centre for Health Protection

Scientific Committee on Vaccine Preventable Diseases

Interim Consensus on the Use of Respiratory Syncytial Virus Vaccines in Hong Kong (As of 17 January 2025)

On 16 January 2025, the Scientific Committee on Vaccine Preventable Diseases (SCVPD) under the Centre for Health Protection (CHP) of the Department of Health discussed and reached interim consensus on the use of respiratory syncytial virus (RSV) vaccines in Hong Kong.

Local epidemiology of RSV disease

2. The CHP monitors local RSV activity through laboratory and hospital discharge surveillance. In some years, a seasonal pattern with higher activity between June and October was observed, while in other years, no distinct seasonality was evident. Overall, RSV-associated hospital admissions in public hospitals have been concentrated among children aged under five years, followed by elderly persons aged 65 years and above. In terms of RSV-associated mortality, over 90% of hospitalised cases with fatal outcomes from any cause during the same hospitalisation episode have occurred among elderly persons aged 65 years and above.

3. In the paediatric population, excluding the spike of RSV cases observed in 2023, which was likely due to the immunity gap resulting from strict infection control and social distancing measures implemented during COVID-19 pandemic, the annual cumulative RSV-associated hospitalisation rates for children aged under five years ranged from about 900 to 1,300 per 100,000 population, comparable to reported rates in some overseas countries. Notably, no fatal cases were recorded for this age group from 2023 to 2024.

4. In the elderly population, excluding the spike of RSV cases observed in 2023, the annual cumulative RSV-associated hospitalisation rates for elderly persons aged 75 years and above ranged from about 60 to 160 per 100,000 population, which was lower than reported rates of about 250 per 100,000 population in some overseas countries. Based on hospital data, the annual cumulative mortality rate of RSV infection is about 5 per 100,000 population among elderly persons aged 65 years and above, whereas that for seasonal influenza is about 40 per 100,000 population.

RSV vaccines and efficacy

5. Currently, two protein-based RSV vaccines, including an adjuvanted recombinant protein-based RSV prefusion F vaccine (adjuvanted protein-based RSV vaccine) and a non-adjuvanted bivalent recombinant protein-based RSV prefusion F vaccine (bivalent protein-based RSV vaccine), have been registered in Hong Kong. Both vaccines are administered as a single dose and indicated for adults aged 60 years and above. Additionally, the bivalent protein-based RSV vaccine is indicated for use in pregnant women at 32 to 36 weeks of gestation to prevent severe lower respiratory tract disease caused by RSV in infants from birth through six months of age.

6. For elderly persons, clinical trials have demonstrated the efficacy of both protein-based RSV vaccines in preventing RSV-associated lower respiratory tract disease, with sustained effects of a single dose lasting for at least two years. Early real world data from post-marketing studies have shown that both vaccines were effective in preventing serious illness and hospitalisation among elderly persons. For example, a test-negative case-control analysis conducted in the United States (US) involving around 3,000 adults aged 60 years and above, who were hospitalised with acute respiratory illness, showed that protein-based RSV vaccines were 75% effective against RSV-associated hospitalisations.[1]

[1] Surie D, Self WH, Zhu Y, *et al.* RSV Vaccine Effectiveness Against Hospitalisation Among US Adults 60 Years and Older. *JAMA.* 2024 Oct 1;332(13):1105-1107.

7. For pregnant women, a phase 3 clinical trial involving approximately 7,200 participants across 18 countries evaluated the efficacy of the bivalent protein-based RSV vaccine administered between 24 and 36 weeks of gestation.[2] Interim results demonstrated that the vaccine was 81.8% effective in preventing severe medically attended RSV-associated lower respiratory tract illness in infants within 90 days after birth, and 69.4% effective within 180 days after birth.

Vaccine safety and adverse effects

8. Clinical trial results showed that both protein-based RSV vaccines are generally well tolerated with acceptable safety profiles. However, a few serious adverse events warrant attention. In elderly persons, a small number of inflammatory neurological events, including Guillain-Barré Syndrome (GBS) and acute disseminated encephalomyelitis, have been reported among vaccine recipients. Post-licensure data revealed a statistically significant increase in the risk of GBS in individuals aged 65 years and above following vaccination with the adjuvanted protein-based RSV vaccine (Incidence Rate Ratio [IRR]: 2.46), whereas the risk was elevated but not statistically significant following vaccination with the bivalent protein-based RSV vaccine (IRR: 2.02).[3] Post-licensure safety data on the two RSV vaccines in the US showed that GBS was more common than the expected background rate, with an estimated rate of less than 10 cases per one million vaccinations. On 7 January 2025, the US Food and Drug Administration (FDA) approved safety labelling changes to the prescribing information for the two protein-based RSV vaccines by requiring manufacturers to include a new warning stating that results of a post-marketing observational study suggested an increased risk of GBS during the 42 days following vaccination with the RSV vaccine.[4]

9. Regarding maternal RSV vaccination, clinical trial data showed a higher percentage of preterm births (gestational age less than 37 weeks at delivery) in the vaccine group receiving the bivalent protein-based RSV vaccine

[2] Kampmann B, Madhi SA, Munjal I, *et al.* Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. *New England Journal of Medicine.* 2023 Apr 20;388(16):1451-64.
[3] Patricia Lloyd. Evaluation of Guillain-Barré Syndrome (GBS) following Respiratory Syncytial Virus (RSV) Vaccination Among Adults 65 Years and Older. ACIP 2024. Available at: https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/05-RSV-Adult-Lloyd-508.pdf [Accessed 16 Jan 2025]
[4] USFDA. FDA Requires Guillain-Barré Syndrome (GBS) Warning in the Prescribing Information for RSV Vaccines Abrysvo and Arexvy: FDA Safety Communication. Available at: https://www.fda.gov/safety/medical-product-safety-information/fda-requires-guillain-barre-syndrome-gbs-warning-prescribing-information-rsv-vaccines-abrysvo-and [Accessed 16 Jan 2025]

compared to the placebo group (5.7% versus 4.7%), although this difference was not statistically significant.[5] In a post-marketing retrospective cohort study involving about 3,000 pregnant individuals in the US where 34.5% received the vaccine, RSV vaccination did not show an increased risk for preterm birth but there was an observed increased risk of hypertensive disorders of pregnancy in a time-dependent model.[6] Post-marketing safety analysis is actively ongoing to further address safety concerns regarding the use of RSV vaccines in pregnant women.

World Health Organization (WHO) and overseas recommendations

10. Given the global burden of RSV disease in infants, the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommended that all countries consider introducing maternal vaccination for the prevention of severe RSV disease in infants. SAGE observed that post-marketing pharmacovigilance would be important to better understand safety signals on the potential risk of preterm births associated with maternal vaccination. SAGE also noted that safety and effectiveness data from countries in South Asia, which have the highest rates of preterm births, would be important to inform local policy decisions. Of note, SAGE emphasised that decisions to include maternal vaccination in an immunisation programme should consider factors such as cost, financing, supply, anticipated coverage and feasibility of implementation within the existing health system.[7] On the other hand, SAGE noted the paucity of data for the RSV disease burden in adults in many regions of the world and the use of RSV vaccines in older adults could be considered following that for protecting infants.[8] It is expected that SAGE will advise WHO on the use of RSV vaccines for older adults during 2025 to 2026.[9]

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[5] Fleming-Dutra KE, Jones JM, Roper LE, *et al.* Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committe on Immunization Practices - United States, 2023. *MMWR Morb Mortal Wkly Rep.* 2023 Oct 13;72(41):1115-1122.

[6] Son M, Riley LE, Staniczenko AP, *et al.* Nonadjuvanted Bivalent Respiratory Syncytial Virus Vaccination and Perinatal Outcomes. *JAMA Netw Open.* 2024;7(7):e2419268

[7] WHO. Meeting of the Strategic Advisory Group of Experts on Immunization, September 2024: conclusions and recommendations. Available at: https://iris.who.int/bitstream/handle/10665/379717/WER9949-eng-fre.pdf?sequence=1 [Accessed 16 Jan 2025]

[8] WHO. Meeting of the Strategic Advisory Group of Experts on Immunization, March 2024: conclusions and recommendations. Available at: https://iris.who.int/bitstream/handle/10665/376936/WER9922-285-306.pdf?sequence=1 [Accessed 16 Jan 2025]

[9] WHO. WHO Global Market Study on RSV Immunization Products. Working document – November 2024. Available at: https://cdn.who.int/media/docs/default-source/immunization/mi4a/who-global-market-study-on-rsv-immunization-products_november-2024.pdf?sfvrsn=e6ff42a9_3&download=true [Accessed 16 Jan 2025]

11. The US[10], United Kingdom (UK)[11], Australia[12] and Canada[13] have recommended the use of RSV vaccines for elderly persons, particularly those aged 75 years and above. The US and Canada have also recommended RSV vaccination for elderly persons residing in nursing homes. Currently, there are no recommendations from these overseas jurisdictions on revaccination or regular RSV vaccination for elderly persons. The use of RSV vaccines in pregnant women is also recommended by the US, UK and Australia. While the UK recommended RSV vaccination for each pregnancy, the US and Australia would evaluate whether there is sufficient benefit of revaccination in subsequent pregnancies when more data are available. In Canada[14], RSV vaccination may be considered by pregnant individuals as a personal decision in consultation with their pregnancy care provider.

The interim consensus on the use of RSV vaccine

12. After reviewing the scientific evidence, local epidemiology, recommendations of the WHO and international health authorities, and balancing the risks and benefits of RSV vaccination, the SCVPD has reached the following consensus on the use of RSV vaccines for elderly persons and pregnant women in Hong Kong from a public health perspective.

Vaccination for elderly persons

(a) The protein-based RSV vaccines are effective in preventing RSV-associated lower respiratory tract disease among elderly persons.

(b) Pending specific recommendations from the WHO and local data from the cost-benefit perspective, the SCVPD does not currently recommend universal RSV vaccination for elderly persons.

[10] US CDC. Respiratory Syncytial Virus (RSV) Immunizations. Available at: https://www.cdc.gov/vaccines/vpd/rsv/index.html [Accessed 16 Jan 2025]
[11] UK Health Security Agency. Respiratory syncytial virus (RSV) vaccination programme. Available at: https://www.gov.uk/government/collections/respiratory-syncytial-virus-rsv-vaccination-programme [Accessed 16 Jan 2025]
[12] Australian Government Department of Health and Aged Care. Respiratory syncytial virus (RSV). Available at: https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/respiratory-syncytial-virus-rsv [Accessed 16 Jan 2025]
[13] Government of Canada. Statement on the prevention of respiratory syncytial virus disease in older adults. Available at: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisor-committee-immunization-summary-statement-prevention-rsv-disease-older-adults.html [Accessed 16 Jan 2025]
[14] Government of Canada. Statement on the prevention of respiratory syncytial virus (RSV) disease in infants. Available at: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants/naci-statement-2024-05-17.pdf [Accessed 16 Jan 2025]

(c) The SCVPD is of the view that elderly persons (especially those aged 75 years and above or living in residential care homes) may receive RSV vaccination for personal protection, as an individual decision under informed consent in consultation with their doctor.

Vaccination for pregnant women

(d) The bivalent protein-based RSV vaccine is effective in preventing severe RSV-associated lower respiratory tract disease among infants born to vaccinated mothers for up to six months after birth.

(e) Pending additional safety data for using the bivalent protein-based RSV vaccine, the SCVPD does not currently recommend universal RSV vaccination for pregnant women.

(f) The SCVPD is of the view that pregnant women may receive RSV vaccination to protect their newborn infants against RSV disease, as an individual decision under informed consent in consultation with their family doctor or doctor providing antenatal care.

13. The SCVPD will continue to monitor the scientific evidence of vaccine efficacy and safety, local epidemiology and cost-benefit data, and recommendations from the WHO and overseas authorities, and will review the use of RSV vaccine for elderly persons and pregnant women as appropriate.

January 2025