

Recommendations: Clinical Considerations for the Co-administration of RSV, COVID-19 and Influenza Vaccines Among Older Adults in Long-term Care Facilities

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Overview

In anticipation of the Health Canada authorization of the GSK RSV vaccine (RSVpreF3-AS01E) for respiratory syncytial virus (RSV), the Ontario Immunization Advisory Committee (OIAC) met on July 12, 2023 to review the Canadian RSV vaccine landscape and the clinical data for the GSK RSV vaccine candidate.

The GSK RSV vaccine received a Notice of Compliance from Health Canada on August 4, 2023, and the Ontario Ministry of Health (MOH) will be offering a targeted and limited RSV immunization program to residents in long-term care (LTC) for the fall of 2023. However, there is some uncertainty regarding when the RSV vaccine supply will become available, and how it will align with the influenza and COVID-19 booster programs. To inform the implementation of the immunization program, the MOH requested advice from the OIAC on co-administration or sequential administration of the RSV vaccine with the COVID-19 and seasonal influenza vaccines in older adults.

The committee reconvened on August 9, 2023 to review available data, and discuss clinical and implementation considerations relating to the co-administration of the RSV vaccine with other vaccines. This document provides a summary of the evidence and considerations discussed by the OIAC, and outlines the committee's recommendations.

Recommendations

1. For the 2023-24 targeted RSV immunization program for residents of long-term care facilities, the OIAC recommends that the GSK RSV vaccine be only offered to those who meet eligibility requirements as per Health Canada authorized age indications for the specific vaccine product.
2. The OIAC recommends that the GSK RSV vaccine not be routinely co-administered with COVID-19 or influenza vaccines. As a precaution, it is recommended that the RSV vaccine be administered at least 14 days before or after the administration of COVID-19 or influenza vaccines. The OIAC recommends that COVID-19 vaccines continue to be co-administered with the seasonal influenza vaccines.

3. Co-administration of the GSK RSV vaccine with COVID-19 and influenza vaccines, or a shortened interval (i.e., <14 days) between the administration of the GSK RSV vaccine and COVID-19 and/or influenza vaccine should be considered in situations where, in the recommender/provider's best judgement, the benefits outweigh the risks, including:
 - when there is an outbreak of RSV, COVID-19 or influenza within the facility or other facilities in the same geographic region
 - If community activity of COVID-19, influenza and/or RSV is high and increasing
 - when there is a risk that the individual otherwise will not receive the recommended vaccine doses
 4. Given the paucity of data on the GSK RSV vaccine in vulnerable populations (e.g., residents of long-term care facilities, ≥ 80 years old), the OIAC recommends that an evaluation of the targeted RSV immunization program be conducted in order to assess the safety and effectiveness of the GSK RSV vaccine among older adults at high risk of severe disease due to RSV.
 5. The OIAC strongly recommends the development of a centralized immunization registry to capture individual-level immunization data. This would offer clinical benefits and, through linkage to other data sources, inform future evidence-based decisions at a population health level. It will be important to have a registry or robust tracking system in place to support the evaluation of the targeted RSV immunization program among older adults, including assessment of vaccine effectiveness and safety surveillance. Until such a registry is developed, the OIAC recommends that individual-level vaccine information and resident vaccination rates be recorded at the facility level, and reported to the local public health units (PHU), similar to documentation practices for influenza vaccines.
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Background

While RSV typically manifests as an upper respiratory or asymptomatic infection in healthy individuals, older adults, particularly those with existing comorbid conditions (e.g., congenital heart disease, chronic lung disease) are more susceptible to severe disease, and have an increased risk of RSV-related hospitalization and mortality.¹⁻³ During the 2018-19 season, RSV accounted for 12.2% of all institutional respiratory infection outbreaks in Ontario, with the majority of non-influenza respiratory virus outbreaks occurring in long-term care homes.⁴

For decades, the only RSV product available in Canada was palivizumab (approved in 2002), a monoclonal antibody used as a passive immunizing agent for infants at risk of severe RSV-associated outcomes.^{5,6} More recently, another passive immunizing agent, nirsevimab, also received Health Canada authorization for pediatric use.⁷

In November 2022, GSK submitted a New Drug Submission to Health Canada for its candidate RSV vaccine for older adults, RSVpref3-AS01e.⁸ This product received a Notice of Compliance on August 4, 2023, and will be used for a targeted RSV vaccination program for residents in LTC during the 2023-24 respiratory season. An RSV vaccine candidate for older adults by Pfizer (RSVpref) is also under review by

Health Canada, while another by Moderna (mRNA-1345) has been submitted to regulatory bodies outside of Canada, including the United States, Europe and Australia.⁹⁻¹²

Evidence Summary and Considerations

In order to address questions regarding the implementation of the targeted Ontario RSV vaccination program for 2023-24, the OIAC reviewed evidence regarding the safety, efficacy and immunogenicity of RSV vaccines, including data from studies investigating co-administration with seasonal influenza or other routine vaccinations. Furthermore, anticipated timelines for RSV vaccine authorization and availability, and guidance from immunization advisory committees were examined.

Efficacy and Safety of RSV Vaccines

- The safety and efficacy of the GSK RSV vaccine in preventing RSV-related lower respiratory tract disease (LRTD, defined as at ≥ 2 lower respiratory symptoms or signs including ≥ 1 lower respiratory sign, or ≥ 3 lower respiratory symptoms lasting for at least 24 hours) was examined in a total of 24,966 participants aged ≥ 60 years (12,467 vaccine, 12,499 placebo). The study group included those with pre-existing medical conditions (39.2%), those considered high-risk according to the Charlson Comorbidity Index (33.5%), and individuals classified as pre-frail (38.3%) and frail (1.5%).¹³ The overall vaccine efficacy in preventing RSV-LRTD was 82.6% during the first season, with high vaccine efficacy observed across various age groups and those with pre-existing medical conditions.¹³ Low vaccine efficacy was observed among those who were ≥ 80 years (33.8%) or frail (14.9%); however, there were relatively low sample numbers in these populations.¹³ One vaccine dose conferred protection for up to 2 RSV seasons, with a 2nd season vaccine efficacy in preventing LRTD of 56.1%.¹⁴
- The GSK RSV vaccine was generally safe and well-tolerated among adults aged ≥ 60 years. Local and systemic reactions to the vaccine were generally mild to moderate and self-limiting, and the incidence of adverse events (AEs) were generally balanced between the vaccine and placebo groups.¹³ However, a numerical imbalance in the occurrence of atrial fibrillation was noted, with a higher incidence in the group receiving the RSV vaccine compared to placebo (10 events (0.1%) in the vaccine group vs. 4 events ($< 0.1\%$) in the placebo).¹⁵ A case of Guillain-Barré syndrome (GBS) was also deemed related to the GSK RSV vaccine in an open-label phase 3 trial.¹⁵
- The imbalance in atrial fibrillation and cases of inflammatory neurologic conditions seen with the GSK RSV vaccine were also observed with the Pfizer RSV vaccine candidate for older adults.^{16,17} In the phase 3 trial, 10 events of atrial fibrillation ($< 0.1\%$) occurred in the vaccine group vs. 4 events ($< 0.1\%$) in the placebo group.¹⁶ Three serious adverse events (SAEs) were deemed related to the Pfizer RSV vaccine candidate, which included 2 cases of inflammatory neurologic conditions: 1 case of Miller-Fisher syndrome and 1 GBS.¹⁷

Co-administration Data for RSV Vaccines

- Co-administration of the GSK RSV vaccine with the quadrivalent influenza vaccine (FLU-QIV) in adults ≥ 60 years resulted in robust immune responses to all RSV and influenza vaccine antigens.¹⁸ Similarly, in adults ≥ 65 years, co-administration of the GSK RSV vaccine with the high-dose influenza vaccine (FLU-hdQIV) typically used in LTC settings resulted in non-inferior immune responses to all vaccine antigens.¹⁴ However, there was a non-statistically significant

trend towards lower antibody titres against both vaccines with co-administration in both studies.^{14,18}

- Co-administration of the GSK RSV vaccine with the adjuvanted quadrivalent influenza vaccine in adults ≥65 years resulted in comparable immune responses to RSV, and 3 out of 4 influenza vaccine antigens. A significantly lower antibody response was observed for influenza A/Darwin H3N2; however, the clinical significance of these findings is unknown.¹⁴
- The safety profile of co-administering the GSK RSV vaccine with seasonal influenza vaccines in older adults was generally consistent with those identified for the GSK RSV vaccine alone. However, two cases of acute disseminated encephalomyelitis (ADEM), one of which was fatal, occurred in the co-administration group receiving the GSK RSV vaccine with FLU-QIV.¹⁵
- Co-administration studies have also been done with the Pfizer candidate RSV vaccine, RSVpreF. Similar to those observed for the GSK RSV vaccine, concomitant administration of RSVpreF with the seasonal influenza vaccine in adults ≥65 years resulted in non-inferior immune responses to all vaccine antigens, though a trend towards lower antibody titres was observed.^{19,20} Co-administration of RSVpreF with the tetanus, diphtheria, acellular pertussis (Tdap) vaccine was also assessed in adult, non-pregnant women aged 18 – 49 years. Non-inferior immune responses to RSV, tetanus and diphtheria were observed with co-administration; however, the response to the pertussis component of Tdap was significantly lower than when Tdap was administered alone. RSVpreF was generally safe and well-tolerated when co-administered with other vaccines, but a case of lymphadenopathy occurred in one individual who was co-administered the Tdap and RSV vaccines.¹⁹⁻²¹
- There are currently no data available regarding the co-administration of the RSV vaccine with COVID-19 vaccines or for the co-administration of the RSV, COVID-19 and influenza vaccines. Therefore, the potential for immune impacts and AEs attributable to co-administration in these circumstances is unknown.

Co-administration of COVID-19 and Influenza Vaccines

- No safety concerns have been reported to date with the co-administration of COVID-19 and influenza vaccines. A systematic review of published data found that while higher reactogenicity was observed following co-administration of COVID-19 mRNA and influenza vaccines compared to influenza vaccination alone, reactogenicity was comparable to COVID-19 vaccination alone. AEs observed were generally mild to moderate and self-limiting.²² Similarly, a recent study that examined reports from the American Vaccine Adverse Event Reporting System (VAERS) database found no unexpected AEs following co-administration of COVID-19 mRNA and influenza vaccines but noted more frequent systemic reactions with co-administration of a booster dose of COVID-19 vaccine with the influenza vaccine.²³
- There have been mixed reports regarding the impact of co-administration on the immunogenicity of COVID-19 and influenza vaccines, with some noting no significant negative impact in the immune response to vaccine antigens, and others noting decreased antibody titres with co-administration.^{22,24-26} The clinical implications of these findings are currently unknown.
- Canada's National Advisory Committee on Immunization (NACI) states that for individuals 6 months of age and older, COVID-19 vaccines may be given concurrently (i.e., same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines).²⁷

Clinical Considerations for RSV Vaccines

- Guidance from NACI on RSV vaccines for older adults and post-marketing data following co-administration of RSV vaccines with COVID-19 and influenza vaccines are both forthcoming. In the intervening period, it may be prudent to take a precautionary approach and allow for an interval of at least 14 days before or after the administration of the GSK RSV vaccine and immunization with COVID-19 and/or influenza vaccines. Sequential administration of the vaccines may prevent erroneous attribution of adverse events following immunization (AEFIs) to a particular vaccine, and also minimize the risk of vaccine administration errors and possible immune impacts due to co-administration.
- While RSV typically peaked between December and February in previous years, there has been a recent shift towards an earlier start to the RSV season following the COVID-19 pandemic.^{28, 29} During the 2022-23 respiratory season, RSV hospitalizations in the United States among adults ≥50 years peaked in November rather than January, as typically observed in prior seasons.²⁹ Due to the uncertainty of the start of the RSV season, it would be prudent not to delay the administration of the RSV vaccine, and provide the vaccine to eligible individuals as early as possible.

Additional Considerations

- Co-administration or a shortened interval (i.e., <14 days) between the administration of the RSV vaccine and influenza and/or COVID-19 vaccines may offer important opportunities to improve timely vaccine coverage in cases of respiratory virus outbreaks within long-term care facilities or others in the same geographic region, or in situations where RSV, COVID-19 and/or influenza community activity is high and increasing. In such instances, health care providers must use judgement to carefully assess the benefits and potential risks, and obtain informed consent. The informed consent process should include a discussion of risks and benefits of co-administration of the RSV vaccine with other vaccines considering the limited data.
- Given the differences in vaccine delivery models among LTC facilities across Ontario, the feasibility of administering the RSV vaccine separately from the COVID-19 and/or influenza vaccine must be considered. In cases where logistical challenges exist that preclude multiple visits by health care providers to administer vaccines in a timely manner (e.g., remote areas, availability of trained vaccinators), and residents are at high risk of missing vaccine doses, co-administration or a shortened interval (i.e., <14 days) between the administration of the RSV vaccine and influenza and/or COVID-19 vaccines may help mitigate risk and promote vaccine coverage.
- There is a paucity of data regarding the efficacy and safety of the GSK RSV vaccine among vulnerable populations, including those who are living in LTC facilities, immunocompromised or ≥ 80 years old. As such, it is essential to have a robust documentation system in place to support the monitoring and evaluation of the program, including the assessment of vaccine uptake, effectiveness, and safety, upon initiation of the targeted immunization program with the GSK RSV vaccine among residents of long-term care and high-risk facilities. Unfortunately, a mechanism for monitoring vaccination coverage for adults other than through COVaxON for COVID-19 vaccines is currently unavailable in Ontario. Development of a provincial immunization registry would offer several benefits including comprehensive data collection that would facilitate more accurate vaccine coverage and effectiveness estimates and safety

surveillance, and evidence-based decision-making regarding the implementation of RSV and other vaccination programs in the future.

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About the Ontario Immunization Advisory Committee

The OIAC is a multidisciplinary scientific advisory body that provides evidence-based advice to Public Health Ontario (PHO) on vaccines and immunization matters including vaccine program implementation in Ontario, priority populations and clinical guidance. The focus of the OIAC's work is on publicly-funded vaccines and immunization programs in Ontario, including COVID-19 and those under consideration for new programming. For more information about the OIAC and its members contact secretariat@oahpp.ca

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