

(ARCHIVED) Recommendations: Co-Administration of COVID-19 Vaccines in Children 5-11 Years

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Overview

Recommendations on the co-administration of COVID-19 vaccine with other vaccines have evolved over time with accumulating clinical experience and evidence on vaccine efficacy/effectiveness, immunogenicity, and safety. Nine months after the first COVID-19 vaccine was authorized by Health Canada, the National Advisory Committee on Immunization (NACI) modified its advice to recommend that adolescents and adults may be given a COVID-19 vaccine simultaneously with, or at any time before or after, other vaccines. In contrast, for children ages 5 to 11 years, NACI currently recommends a waiting period of at least 14 days before or after the administration of another vaccine before administering a COVID-19 vaccine.¹

To support the planning of catch-up activities for routine childhood vaccination programs that were disrupted by the pandemic, the Ministry of Health (MOH) requested the Ontario Advisory Committee on Immunization (OIAAC) review NACI's precautionary recommendation against routine co-administration of vaccines in children ages 5 to 11 years. The OIAAC met on March 23, 2022 to review relevant evidence and additional considerations to inform recommendations on co-administration of pediatric COVID-19 vaccines with other vaccines in this age group. This document provides a summary of the evidence, considerations, and the OIAAC's recommendations.

Recommendations

1. For children ages 5 to 11 years, a waiting period of at least 14 days between the administration of COVID-19 vaccine and other vaccines is generally recommended. Note that influenza vaccine is an exception (see recommendation #3).
2. Simultaneous administration (same day) or a shortened interval between COVID-19 vaccines and other live and non-live vaccines may be warranted in individual situations, including:
 - when there is a risk that the individual will not receive the recommended/due/overdue dose due to limited access to health services or being unlikely to return at a later date;
 - when individuals require accelerated vaccination schedules when planning travel or prior to immunosuppressive therapy or transplant;
 - when another vaccine is required for post-exposure prophylaxis; or
 - at the clinical discretion of the healthcare provider.
3. The pediatric formulation of the Pfizer-BioNTech (10 mcg per dose) COVID-19 vaccine may be administered simultaneously with, or at any time before or after, seasonal influenza vaccines. Influenza vaccine planning for the 2022/23 season should assume co-administration of pediatric COVID-19 vaccines and influenza vaccines.

Background

In its first statement on COVID-19 vaccines in December 2020, the National Advisory Committee on Immunization recommended that persons 18 years and older should have a 14-day waiting period after administration of another vaccine before giving COVID-19 vaccine, and have a 28-day waiting period after completion of the two-dose mRNA vaccine series before giving another vaccine.² In September 2021, NACI revised this recommendation, stating that persons 12 years and older may be given COVID-19 vaccine simultaneously, or at any time before or after, other live or non-live vaccines. This discretionary recommendation was made in consideration of accumulating evidence on efficacy/effectiveness, immunogenicity, and safety of COVID-19 vaccines to date; extensive data and clinical experience with the co-administration of non-COVID-19 vaccines that do not indicate important safety concerns or impact on immune response; and to facilitate seasonal influenza vaccine programs and other routine immunization programs that were disrupted due to the pandemic.³

Following Health Canada authorization of Pfizer-BioNTech pediatric (10 mcg) COVID-19 vaccine in November 2021, NACI recommended that COVID-19 vaccines should not routinely be given concomitantly with other live or non-live vaccines to children ages 5 to 11 years. The rationale was the need for more post-market safety surveillance data to facilitate the identification of rare and very rare adverse events, and to prevent erroneous attribution of adverse events following immunization (AEFIs) to one particular vaccine or the other.⁴

In a jurisdictional scan, clinical guidance from most provinces and territories were found to be in alignment with NACI's recommendation against routine co-administration in children ages 5 to 11 years, with some limited exceptions at the discretion of the health care provider. For example, Quebec permits the co-administration of mRNA COVID-19 vaccines with influenza or pneumococcal vaccines in persons 5 years and older, but otherwise recommends a 14-day waiting period between mRNA vaccines and other (live attenuated or inactivated) vaccines.⁵ The World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE) recommends co-administration of COVID-19 vaccines with influenza vaccines

for all eligible age groups, based on clinical trial data; a waiting period of 14 days is recommended for all other vaccines, due to lack of data for other inactivated or live vaccines co-administered with COVID-19 vaccines.⁶⁻⁸ In contrast, co-administration for all COVID-19 vaccine-eligible age groups has been recommended in the United States since May 2021, based on substantial safety data on COVID-19 vaccines collected to date and extensive experience with the co-administration of routine vaccines.⁹ The Canadian Paediatric Society and American Academy of Pediatrics both support offering COVID-19 vaccine at the same time as other required vaccines when timely co-administration can help bring routine vaccination status up-to-date.¹⁰⁻¹²

Evidence Summary and Considerations

The following summary provides an overview of the evidence reviewed and considerations discussed by the OIAC.

ROUTINE VACCINATION COVERAGE

- Current immunization coverage for routine childhood vaccines¹³ in Ontario is difficult to estimate due to the limited capacity of public health units to perform assessment activities under the *Immunization of School Pupils Act* during the pandemic response.¹⁴
- Based on a survey of Ontario physicians¹⁵ and analyses of data from children in various age groups in Ontario^{16,17} and other jurisdictions,^{18,19} it is expected that routine vaccine coverage for children in Ontario ages 5 to 11 years may have been negatively impacted by the pandemic.
- Co-administration of COVID-19 vaccine with routine childhood vaccines may offer opportunities for catch-up through primary care providers and mass immunization clinics.

IMMUNOLOGIC PRINCIPLES AND CLINICAL TRIAL DATA

- Co-administration generally refers to the simultaneous administration of more than one vaccine on the same clinic day, at different anatomic sites, and not combined in the same syringe; this may also be referred to concomitant or concurrent administration. For the purposes of AEFI surveillance, two vaccines that are administered close in time but on different days where both could be temporally associated with the same adverse event may be considered as co-administered in vaccine safety analyses.^{20,21}
- No studies of co-administration of COVID-19 mRNA vaccine with routine vaccines in children were identified in a search of the peer-reviewed and pre-print literature.
- Although it is not direct evidence, data on co-administration of COVID-19 mRNA vaccines with seasonal influenza vaccines in adults may be extrapolated to children. In two randomized trials, adults who received COVID-19 mRNA vaccine administered at the same time as age-appropriate inactivated influenza vaccine had similar rates of local and systemic adverse events and antibody responses against SARS-CoV-2 compared to adults receiving COVID-19 vaccine alone or with placebo.^{22,23}

- Experimental evidence and extensive clinical experience have demonstrated that co-administration of routine live and non-live vaccines produce seroconversion rates and rates for AEFIs similar to those observed when the vaccines are administered separately, with some exceptions. Interference between non-live vaccines with different antigenic content is likely to be limited. Therefore, non-live vaccines can generally be administered simultaneously with, or at any time before or after, live or other non-live vaccines. These general principles have informed existing guidance on co-administration of non-COVID-19 vaccines^{21,24} as well as guidance from other expert advisory groups on co-administration with COVID-19 vaccine.⁹
- General immunological principles can serve as the basis for clinical scenarios in which co-administration with COVID-19 vaccines may be considered despite a lack of direct data.

VACCINE SAFETY AND CONFIDENCE

- Extensive global experience with Pfizer-BioNTech pediatric COVID-19 vaccine has accrued since becoming available for use in children ages 5 to 11 years.
 - As of March 20, 2022, 198 reports of adverse events following immunization (AEFIs) with Pfizer-BioNTech pediatric (10 mcg) vaccine were reported to Ontario's passive vaccine safety surveillance, representing 0.02% of 1,002,970 doses administered. Allergic skin reaction was the most frequently reported adverse event for this vaccine (8.9 per 100,000 doses administered). There were four AEFIs that were classified as serious (i.e., requiring hospitalization; 2.0% of 198), one confirmed case of myocarditis, and one report of multisystem inflammatory syndrome (MIS-C).²⁵
 - In the United States, 8.7 million doses of Pfizer-BioNTech pediatric (10 mcg) COVID-19 vaccine were administered between November 3 and December 19, 2021. Of 4,240 reports received by the Vaccine Adverse Event Reporting System, 98% were non-serious and 2% were serious. Most frequently reported events were previously well-characterized (e.g., vomiting, fever), administration issues unrelated to an actual health outcome (e.g., incorrect dose), or associated with work-up for myocarditis (e.g., elevated troponin).^{26,27}
- Moderna Spikevax (50 mcg) for children ages 6 to 11 years was authorized by Health Canada on March 17, 2022. Given its recent authorization, vaccine safety data for this product is only from the clinical trial, with more extensive post-marketing safety surveillance data still yet to accumulate.²⁸
- There is limited experience of co-administration of COVID-19 vaccines with other vaccines, and co-administration may make AEFI assessments more complex. As of March 27, 2022, there have been ten AEFI reports in Ontario temporally associated with co-administration of vaccine among individuals of all ages (range, 9 to 93 years), including one event requiring hospitalization occurring in an older adult. AEFI reports occurred following co-administration of COVID-19 vaccine with the influenza vaccine (n=9) or pneumococcal vaccine (n=1).²⁵
- The parental informed consent process should include a discussion of the benefits and risks of co-administration with COVID-19 vaccines, given the limited clinical trial data available. The potential impact on vaccine hesitancy for both COVID-19 vaccines and routine vaccines if they are offered together is unclear.

The OIAC will continue to monitor the evidence on the use of Pfizer-BioNTech pediatric (10 mcg) vaccine in children ages 5 to 11 years and Moderna Spikevax (50 mcg) vaccine in children ages 6 to 11 years to inform future updates to these recommendations.

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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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