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OIAC Ontario Immunization Advisory Committee
CCOI Comité consultatif ontarien de l'immunisation

Recommendations: Management of Age-Related COVID-19 Vaccine Administration Errors

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Overview

The source of guidance to support Ontario immunizers in the management of COVID-19 immunization errors has evolved over time. In June 2021, the Ministry of Health published guidance to support the management of COVID-19 vaccine administration errors or deviations. The provincial guidance was removed in March 2022, with Ontario immunizers directed to a similar resource developed by the Public Health Agency of Canada (PHAC).[1,2] PHAC's guidance addresses several types of COVID-19 vaccine administration errors or deviations. However, Ontario's provincial COVID-19 program guidance retains advice on managing errors related to age transitions (i.e., for children aged 11 years turning 12 years before completion of the primary series) as an exception to PHAC's guidance. Furthermore, the inadvertent administration of Moderna as a booster dose for children aged 5 to 11 years is a scenario that is not specifically addressed in the provincial guidance.

The Ministry of Health sought expert opinion from the Ontario Immunization Advisory Committee (OIAC) to address two COVID-19 vaccine administration error scenarios:

1. Age indication transitions during the course of a COVID-19 primary immunization series, and
2. The inadvertent administration of Moderna (monovalent or bivalent product) as a booster dose to children aged 5 to 11 years.

The OIAC met on November 8, 2022 to review considerations for informing recommendations on the management of these specific COVID-19 vaccine administration errors. This document provides a summary of the considerations and OIAC's recommendations.

Recommendations

1. If a child transitions from one age indication to the next while receiving their COVID-19 primary immunization series, they should receive the appropriate dose for their current age at the time of immunization. However, in the context of age transitions, completion of the primary series with the same product used for series initiation should be considered valid and the primary series considered complete.

2. Though not authorized by Health Canada for use as a booster dose for ages 5 to 11 years, a dose of Moderna 25 mcg or 50 mcg inadvertently administered to a child aged 5 to 11 years as a booster dose should be considered valid and the dose does not need to be repeated with the age-authorized product (Pfizer-BioNTech 10 mcg). This advice applies regardless of whether the Moderna vaccine is a monovalent or bivalent product.

Background

The following mRNA COVID-19 vaccines have been authorized for use in Canada for the indicated age groups:

	Pfizer-BioNTech Comirnaty			Moderna Spikevax			
AGE	6 mos. to 4 years	5-11 years	≥ 12 years	6 mos. to 5 years	6-11 years	12-17 years	≥ 18 years
PRIMARY SERIES	3 mcg	10 mcg	30 mcg	25 mcg	50 mcg	100 mcg	100 mcg
BOOSTER DOSE	n/a	10 mcg	30 mcg	n/a	n/a[a]	n/a[b]	50 mcg

[a] In the United States (U.S.), Moderna COVID-19 Vaccine, Bivalent 25 mcg is authorized for use as a booster dose for children aged 6 to 11 years.

[b] Moderna Spikevax (50 mcg) (monovalent original and bivalent products) are authorized for use by Health Canada as a booster dose for individuals 18 years of age and older. The National Advisory Committee on Immunization (NACI) has provided an off-label recommendation, informed by expert opinion, for the use of Moderna Spikevax Bivalent in moderately to severely immunocompromised adolescents aged 12 to 17 years.

Vaccines that are administered in a manner that differs from the recommendations of the manufacturer (as authorized by Health Canada) and/or recommendations of NACI or the provincial program are referred to as vaccine administration errors or deviations.[1,2] There is limited evidence to guide the management of these situations. Guidance on whether to assess a dose given in error as valid, and therefore not requiring a repeat dose, or invalid, and therefore recommended to be repeated, is typically informed by vaccinology principles and expert opinion, with caveats on the need for clinical judgment in decision-making.

Many jurisdictions have issued guidance on COVID-19 vaccine administration errors and there is some variability in this guidance, which is likely a reflection of differences among expert opinion. The following are guiding principles adopted by PHAC in the management of specific vaccine administration errors resulting in too high a dose or lower than authorized dose being administered, which align with guidance from the United States (U.S.) Centers for Disease Control (CDC). [1-3]

- A higher than authorized dose administered is considered valid,
- A lower than authorized dose is generally considered invalid and will usually need to be repeated

Clinical judgment may also be necessary on a case-by-case basis regarding vaccine administration errors and deviations which may result in management decisions that differ from these guiding principles.[1,2] Moreover, pediatric age transitions are a distinct area that many expert groups have considered separately.[4,5] This includes OIAC, who recommended in November 2021 that adolescents who turn 12 years of age before completing their primary series should be regarded to have completed a valid series if the series is completed with a 10 mcg dose of Pfizer-BioNTech administered at age 12.[4]

The inadvertent administration of Moderna 25 mcg or 50 mcg as a booster dose for children aged 5 to 11 years is addressed in the latest PHAC guidance. However, this update had not yet been released at the time the Ministry posed the question to OIAC. PHAC's guidance notes that if Moderna vaccine (monovalent original or bivalent) is administered to this age group as a booster, the dose should be considered valid assuming a valid dosage amount was administered.[1] However, the guidance does not indicate the valid dosage amount for this age group.

Summary and Considerations

Age Transitions

Age indication transitions have been recognized as a distinct error category requiring explicit recommendations. OIAC's recommendation to recognize as valid a lower than authorized dose if it is the same dose used to initiate the vaccine series is consistent with guidance from NACI and other international immunization advisory groups in the U.S., United Kingdom and Australia.[5-7] The U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and the CDC allow for different dosing for certain age transitions from a younger to older age group, which are not considered by the FDA and CDC to be vaccine administration errors.[5] It is helpful to consider the benefits of accepting a lower dose as valid against the practicalities of informing clients and recalling for repeat doses, particularly for younger age groups and given that to date there are no or limited direct data on the magnitude of difference in immune response to vaccine and immune susceptibility to SARS-CoV-2 in the context of age indication transitions.

Inadvertent Administration of Moderna as a Booster Dose

For the inadvertent administration of Moderna (monovalent or bivalent product) as a booster for children aged 5-11 years, the OIAC noted that the US FDA has authorized the Moderna COVID-19 Vaccine, Bivalent 25 mcg product as a booster dose to children aged 6 to 11 years.[5] In Canada, the authorized dose of Moderna Spikevax monovalent original and bivalent formulations is 50 mcg with an age indication of 18 years of age and older. Thus, the administration of 50 mcg in children aged 5 to 11 years would be considered valid according to the guiding principles outlined above if inadvertently administered in younger age groups given it is higher than what would be the authorized dose for this age group.[8]

Additional Considerations

Recommendations for these specific scenarios around errors related to age transitions and the inadvertent administration of Moderna as a booster dose were achieved following a principle-based discussion that included the following considerations for immunizers when faced with a vaccine administration error or deviation:

- Immunologic: a lower-than-authorized dose administered is generally considered invalid as the dose the patient received may result in a suboptimal immune response.
- Implementation: communication to client/parent and the provision of counseling when an error is noted; reliability and feasibility of recalling clients; documentation and ensuring the return of clients for a repeat dose at an appropriate interval following the invalid dose.
- Maintaining parent/client confidence: revaccination or repeat doses to manage vaccination errors when there is a low likelihood of a suboptimal immune response may reduce public confidence in the immunization programme and provider services.
- Clinical judgment: these recommendations are a guide and clinical discretion maybe warranted on a case-case basis.

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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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