

Recommendations: Fourth COVID-19 Vaccine Dose for Long-Term Care Home Residents and Older Adults in Other Congregate Settings

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Overview

Residents of long-term care homes and retirement homes, and older adults living in other congregate settings are at increased risk for both COVID-19 infection and severe disease, such as hospitalization and death.¹ On December 15, 2021, the Ontario Immunization Advisory Committee (OIAC) met to review and discuss unpublished Ontario data on immunogenicity after third doses in older adults living in congregate settings and to review emerging literature on vaccine performance against the Omicron variant of concern to provide recommendations regarding fourth doses for this population.

This document provides a summary of the OIAC's recommendations and outlines their rationale.

Recommendations

1. A fourth dose of an mRNA vaccine is recommended for residents of long-term care homes (LTCH), retirement homes (RH), Elder Care Lodges and older adults living in other congregate settings providing assisted-living and health services* who received their third dose at least three months (84 days) prior.
 - Any mRNA vaccine product is acceptable as a fourth dose, although data suggest that Moderna Spikevax COVID-19 vaccine may provide a more robust humoral and cellular immune response.
 - If Moderna Spikevax COVID-19 vaccine is used, the 100 mcg product can be considered for use.

*This includes assistance with: bathing, hygiene, ambulation, feeding, dressing, continence care, skin care, dementia care, provision of meals, administration of medications, nursing, or medical services. Other congregate settings may include chronic care hospitals, or older adults living in congregate settings for people with developmental disabilities, or older adults living in congregate settings focussed on mental health and addictions.²

Background

While representing approximately 1.1% of the Canadian population, LTCH residents accounted for approximately two-thirds of all reported deaths associated with COVID-19 during the first and second waves of the pandemic, and half of all reported deaths to date.¹ Older adults may generate a less robust immune response to vaccination due to changes in the immune system associated with aging, and underlying immunocompromising conditions or medications.^{1,3,4} Due to waning immunity and declining vaccine effectiveness against COVID-19, the National Advisory Committee on Immunization (NACI) strongly recommends that a third dose of an authorized mRNA COVID-19 vaccine be offered to all long-term care residents and seniors living in other congregate settings at least six months after completion of a primary COVID-19 vaccine series.^{1,3}

In August 2021, Ontario began offering third doses to residents living in LTCH, RH and other congregate living settings for older adults. Many of these individuals are now up to five months from their third dose and are likely becoming increasingly susceptible to COVID-19 infection due to waning immunity.² As of December 8, 2021, approximately 86% of eligible LTCH residents in Ontario had received a third dose of vaccine (Ontario Ministry of Health, personal communication, 2021 Dec 15). Since becoming eligible on November 6, 2021⁵, approximately one-third of health care workers (HCW) in LTCH have received a third dose (Ontario Ministry of Health, personal communication, 2021 Dec 15). The low third dose coverage among LTCH HCW may increase the risk of exposure and infection among residents.

On November 26, 2021, the World Health Organization (WHO) classified B.1.1.529 (Omicron) as a new variant of concern (VOC).⁶ The severity of disease caused by the Omicron variant is not yet fully understood. However, Omicron's increased transmissibility and potential for immune evasion given its spike protein mutations will result in significantly increased cases counts which will have significant impacts on health care system utilisation and capacity.⁷

Rationale

The Omicron variant is highly infectious

- The Omicron variant is highly transmissible and is now the dominant circulating strain of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Ontario.
- As of December 22, 2021, the effective reproductive (Rt) number for the Omicron variant in Ontario is 2.28. All previous variants of the COVID-19 virus combined have a Rt value of 2.08.⁸
- Data from the United Kingdom have demonstrated that the odds of household transmission is 3.2 (95%CI 2.0-5.0, p <0.001) for the Omicron variant compared to the Delta variant⁷ and the Omicron variant has a significant growth advantage with a 5.4 (95% CI: 4.87-6.00) fold higher risk of reinfection compared with Delta.⁹

Two dose vaccine effectiveness wanes over time for all variants

- Vaccine effectiveness (VE) against symptomatic infection with the Delta variant for two doses of Pfizer-BioNTech Comirnaty has been demonstrated to wane over time in the United States,¹⁰ in Ontario (Dr. Jeff Kwong, ICES, personal communication, ICES, 15 Dec 2021), and in the United Kingdom¹¹ and Israel.¹²⁻¹³ VE decreases over time and is evident at four to five months after the

second dose. A third dose administered at five months appears to restore antibody titres¹¹ and VE protection against symptomatic infection and severe illness¹¹⁻¹⁴ to levels similar to pre-waned immunity. The duration of protection against Delta following a two-dose primary series with Pfizer-BioNTech Comirnaty mRNA vaccine remains high at 10 weeks and at least nine weeks with a third dose of Pfizer-BioNTech Comirnaty or Moderna Spikevax respectively.¹⁵

Vaccine performance and the Omicron variant

- Although VE wanes over time following a second dose of a COVID-19 vaccine (Pfizer-BioNTech Comirnaty), there is a greater reduction in VE against symptomatic infection for the Omicron variant compared to the Delta variant.¹⁶ In a study by Andrews et al. from the United Kingdom, among those who had received two doses of Pfizer-BioNTech Comirnaty, vaccine effectiveness against symptomatic infection with the Omicron variant was 88.0% (95% CI: 65.9 to 95.8%) at two to nine weeks, decreasing to 48.5% (95% CI: 24.3 to 65.0%) at 10 to 14 weeks and further decreasing to approximately 34-37% from 15 weeks following dose two.¹⁶
 - After nine weeks following the second dose of Pfizer-BioNTech Comirnaty, VE was lower for the Omicron variant compared to Delta for all time intervals investigated.¹⁶
 - Among those who had received a two dose primary series of Pfizer-BioNTech Comirnaty, VE was 75.5% (95%CI: 56.1 to 86.3%) against the Omicron variant 14 days after a Pfizer-BioNTech Comirnaty third dose compared to 92.6% (95% CI: 92.0-93.1%) against the Delta variant.¹⁶ Numbers were too small to estimate VE with Moderna Spikevax as either a primary series or as a third dose.
- Two additional studies from England estimated VE against symptomatic infection with the Omicron variant at least two weeks after a third dose to be 54% and 77%, respectively.^{9,16}
- VE is higher for two doses of Moderna Spikevax compared to two doses of Pfizer-BioNTech Comirnaty against non-Omicron variants for all infection, symptomatic infection and transmission for all age groups.¹⁷ There is also emerging evidence that that Moderna Spikevax provides higher antibody levels than Pfizer-BioNTech Comirnaty after a third dose.¹⁷⁻¹⁹ A full booster dose of Moderna Spikevax (100mcg) is more immunogenic than a half-dose booster of this mRNA vaccine (50mcg), and produces higher neutralizing antibody levels against the Omicron variant compared to pre-boost levels.²⁰ VE against Omicron does not appear to wane five to nine weeks after a third dose of Moderna Spikevax (50 mcg dose) when given following a two-dose series of Pfizer-BioNTech Comirnaty.¹⁵

Immune responses to COVID-19 vaccines among LTCH and RH residents

- Ontario investigators have been studying the immune response to second and third doses of COVID-19 vaccines among LTCH and RH residents.
 - In a study of LTCH residents in Ontario, neutralizing antibody levels increased following a third dose to levels similar to antibody levels observed in HCW after only two doses of COVID-19 vaccine. (Dr. Allison McGeer, personal communication, 2021 Dec 15).
 - For the equivalent period, another Ontario LTCH study suggests that residents post-third dose had substantially higher neutralization titers compared to a two-dose series, including

neutralization of the Beta variant of concern (B.1.351) (Dr. Andrew Costa, personal communication, 2021 Dec 15).²¹

- Vaccination with Moderna Spikevax as a third dose produced higher antibody levels against the Beta variant in some individuals than those who were vaccinated with Pfizer-BioNTech Comirnaty (Dr. Allison McGeer, personal communication, 2021 Dec 15; Dr. Andrew Costa, Dr. Dawn Bowdish, personal communication, 2021 Dec 15).
- Ontario data support equivalent policies for nursing homes and retirement home/assisted living settings based on equivalent neutralization antibody levels after the third dose.²¹
- It is thought that similar VE waning is likely to occur after a third dose in LTCH and RH residents, and that this waning will be compounded in the context of the Omicron variant. Preliminary data demonstrates small waning humoral (antibody) immunity at 90 days is observed following a third dose in older adults living in Ontario LTCH (Dr. Andrew Costa, Dr. Dawn Bowdish, personal communication, 2021 Dec 15).

Vaccine safety considerations

- It appears that there is much more potential benefit than harm from a fourth vaccine dose. Preliminary real-world data suggests that a third dose has a safety profile similar to the second dose of a COVID-19 vaccine.²² In a small case study in France, there were no reported serious side effects following a fourth dose of Pfizer-BioNTech Comirnaty vaccine administered to solid organ transplant recipients, although this study was not sufficiently powered to detect rare vaccine safety events.²³

Approaches in other jurisdictions

- On December 21, 2021, Israel announced that it will start offering a fourth dose of a COVID-19 vaccine to people older than 60 years of age, those who are immunocompromised and to health workers, to prevent the spread of the Omicron variant.²⁴ The Joint Committee on Vaccination and Immunisation (JCVI) of the United Kingdom indicated at the end of October 2021 (pre-Omicron) that should there be evidence of substantial waning protection from a third dose administered to “older persons and other vulnerable groups” over the next six months, and should this coincide with a further wave of infection, an additional booster (fourth) dose in the first half of 2022 might be considered.²⁵

Other Considerations

- Adults living in LTCH, RH and older adults living in other congregate living settings have a high risk of exposure, severe outcomes if infected, and changes in the immune system associated with aging. These risks are compounded by the increased time since third dose, relative to other members of the Ontario population. In addition, older adults living in congregate settings received a shorter interval between the doses in the primary series, and shorter intervals have been shown to be associated with a less robust and less durable immune response to the primary series. When taken together, these factors could exacerbate waning vaccine protection against infection and severe outcomes in this population, especially in the context of the highly transmissible Omicron variant.^{1,3} Very limited treatment options for those infected with COVID-19, limited ability for residents to physically distance, and routine regular contact with HCW for

whom third dose vaccination coverage in Ontario is currently low, provide additional support for a recommendation to provide a fourth dose to this vulnerable population in the setting of the emergence of the Omicron variant.¹

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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 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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