Ministry of Health

COVID-19 Vaccine Third Dose Recommendations

Version 7.0 January 13, 2022

Highlights of changes

- Immunocompromised individuals who are eligible for a three-dose primary series may receive a booster dose ≥ 3 months (84 days) after completion of the primary series (page 5)
- Fourth doses for specific populations ≥ 3 months (84 days) after a booster dose (page 11)

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document, mental health resources, and other information.
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Background

The Ministry of Health is closely monitoring the prevalence of the Delta and Omicron variants of concern globally and within Ontario, specifically with respect to the level of transmissibility and disease severity.

Achieving high first and second dose coverage remains the focus and main priority of the Ontario's COVID-19 vaccination program. In response to the changing risk posed by the Omicron variant, accelerated deployment of COVID-19 boosters may provide increased protection across the population. To date, a primary series of the COVID-19 vaccines have been shown to maintain high vaccine effectiveness with no evidence of waning against serious illness, hospitalization, and death from COVID-19 in most populations. Despite some evidence of increasing risk of breakthrough infection over time, those vaccinated against COVID-19 with a two-dose series continue to demonstrate significantly lower odds of SARS-CoV-2 infection compared to unvaccinated individuals and, when infections occur, symptoms tend to be milder in vaccinated cases (NACI, 2021). However, evidence is emerging that vaccine effectiveness against infection and COVID-19 disease decreases with time, and the effectiveness of currently authorized COVID-19 vaccines against the Omicron variant is uncertain. Therefore, for certain populations, an additional dose may be needed to obtain more durable protection.

The Pfizer-BioNTech and Moderna COVID-19 vaccines have been authorized for use by Health Canada as a booster dose after completion of the primary series in individuals 18 years of age and older. A risk/benefit analysis for individual patients is at the center of the collaborative clinician/patient decision-making process. Informed consent for additional doses of COVID-19 vaccine should clearly communicate what is known and unknown about the risks and benefits of an additional dose. Evidence from clinical trials suggests that booster doses of mRNA vaccines given six months after the primary series elicited a robust immune response. Real world data suggests that a booster dose provides good short-term vaccine effectiveness and has a safety profile similar to the second dose of the vaccine. There is no evidence on the long-term effectiveness of booster doses so it remains unknown at this time how long this protective benefit might last. The evidence on the risk of myocarditis/pericarditis after a booster dose of an mRNA vaccine is limited, but appears to be lower than the already rare risk after the second dose of the primary series but higher than after the first dose (NACI, 2021). See NACI guidance for more information on the evidence, safety and
immunogenicity of COVID-19 booster doses. As a precautionary measure, the additional dose of mRNA vaccine should be deferred in individuals who have experienced myocarditis or pericarditis following any preceding dose of an mRNA COVID-19 vaccine until more information is available (NACI, 2021).

Individuals that received AstraZeneca/COVISHIELD COVID-19 vaccine for their first and second dose are recommended to receive an mRNA vaccine for their third or booster dose. People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine can safely receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician. See NACI's recommendations on the use of COVID-19 vaccines for more information. If an individual needs to or chooses to receive for a booster dose of a viral vector vaccine, informed consent should include discussion about the lack of evidence on the use and effectiveness of an additional dose of viral vector COVID-19 vaccine and the increased risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), and Guillain-Barre syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2021).

The Ministry of Health, Public Health Ontario (PHO) and NACI are closely following the research on the safety and effectiveness of additional doses. Recommendations will be re-examined on an ongoing basis as new data emerges. Recommendations will be issued as part of Ontario’s ongoing COVID-19 vaccination program as further evidence becomes available. Serological testing is not recommended before or after COVID-19 vaccination (NACI, 2021).

For additional doses related to out of province vaccination, see the MOH COVID-19 Guidance for Individuals Vaccinated outside of Ontario/Canada.

**Third Dose: 3-Dose Primary Series vs. Booster Dose**

Historically in other vaccine programs, it takes years of post-marketing surveillance to determine the optimal interval between doses and dose number to complete a primary series to sustain long-term protection. Per NACI’s guidance on booster COVID-19 vaccine doses in Canada, the intent of a booster dose is to restore protection that may have decreased over time to a level that is no longer deemed sufficient in individuals who initially responded adequately to a complete primary vaccine series. This is distinguished from the intent of a third dose which might be
added to the standard primary vaccine series with the aim of enhancing the immune response and establishing an adequate level of protection for individuals who developed no or a sub-optimal immune response to a 2-dose primary series. While the term “booster dose” is used in this guidance, NACI continues to monitor the emerging scientific data on whether this dose is indeed a booster dose (to stimulate the memory response once protection has truly waned), or should be considered part of the primary series (to establish strong immune response and memory). NACI will adjust the terminology as required. See NACI interim guidance for more information.

3-Dose Primary Series for Moderately to Severely Immunocompromised

Rationale:

- Certain populations are at increased risk of severe outcomes from COVID-19, and have demonstrated a sub-optimal immune response to a complete two-dose COVID-19 vaccine series due to their underlying condition. See NACI’s Rapid Response Statement: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series for more information.

- There is emerging evidence on the safety and immunogenicity following a third dose of a COVID-19 vaccine for those that have not seroconverted following their second dose in select immunocompromised populations. Certain moderately and severely immunocompromised populations may benefit from a third dose to complete a primary COVID-19 vaccines series.

Recommendations:

- At this time a third dose of the mRNA COVID-19 vaccine will be offered for the following populations eligible for vaccination with the vaccine product authorized for their age group (these recommendations also apply to children aged 5-11 who fall within any of the categories below), to complete the primary COVID-19 vaccine series:
  - Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
Individuals receiving active treatment1 (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies

- Recipients of solid-organ transplant and taking immunosuppressive therapy

- Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)

- Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)

- Individuals with stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome

- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies2 (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the Canadian Immunization Guide for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive (See Table 1).

- For individuals with one of the above immune compromising conditions who have not initiated a COVID-19 vaccine series, individuals in the authorized age group should be immunized with a primary series of three doses of an authorized mRNA vaccine. (NACI, 2021).

- Either Moderna or Pfizer vaccines may be used as a third dose (regardless of which COVID-19 vaccine was used in the primary series). Immunocompromised individuals should be offered the full dose of either Moderna (100 mcg) or Pfizer-BioNTech (30 mcg) as a third dose. For children ages 5-11, the pediatric Pfizer-BioNTech (10mcg) vaccine should be given.

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1 Active treatment includes patients who have completed treatment within 3 months. Active treatment is defined as chemotherapy, targeted therapies, immunotherapy, and excludes individuals receiving therapy that does not suppress the immune system (e.g., solely hormonal therapy or radiation therapy). See Ontario Health/Cancer Care Ontario’s Frequently Asked Questions for more information.

2 Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months.
• The Ontario recommended interval between the second dose of the initial primary series and the third dose is at least two months (56 days). As per NACI, the minimum interval is 28 days; however, an interval longer than the minimum of 28 days between doses is likely to result in a better immune response. Exact timing should be decided with the treating provider in order to optimize the immune response from the vaccine series and minimize delays in management of the individual’s underlying condition. Additionally, the interval should consider risk factors for exposure (including local epidemiology and circulation of variants of concern) and risk of severe disease from SARS-CoV-2 infection. Some immunocompromised individuals may still be susceptible after the 1 or 2-dose primary series, so their period of susceptibility until receipt of the additional dose will also increase if the interval between doses is increased.

• Moderately to severely immunocompromised individuals who are eligible for a three-dose primary series are recommended to receive a booster dose (i.e. 4th dose) ≥3 months (84 days) after completion of the extended primary series. See section on booster doses for more information.

• For guidance on the timing of vaccination for transplant recipients and those requiring immunosuppressive therapies, for a more fulsome list of conditions leading to primary immunodeficiency, and for further information on immunosuppressive therapies, refer to Immunization of Immunocompromised Persons in the Canadian Immunization Guide (CIG), Part 3 – Vaccination of Specific Populations.

• To protect those who are immunocompromised, it also is strongly recommended that all people that come into close contact (e.g., healthcare workers and other support staff, family, friends, caregivers) with these individuals complete a full two-dose vaccine series (i.e., "ring vaccination"). Immunocompromised individuals and those that come into close contact with them should also continue to follow recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission.
Table 1: List of Significantly Immunosuppressive Medications

*This list may not be comprehensive; health care providers may identify patients on other medications that are significantly immunosuppressive. Prescriptions for the below immunosuppressant medications can be presented for additional doses as needed. If an individual presents a prescription of a medication that is not listed in Table 1, they should be directed to their health care provider to receive a referral form/letter for a third dose of a COVID-19 vaccine.

<table>
<thead>
<tr>
<th>Class</th>
<th>Generic Name(s)</th>
<th>Brand Name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steroids (&gt;20 mg per day of prednisone or equivalent for at least 2 weeks)(^3)</td>
<td>• prednisone</td>
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<tr>
<td></td>
<td>• dexamethasone</td>
<td>• Decadron</td>
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<tr>
<td></td>
<td>• methylprednisolone</td>
<td>• DepoMedrol</td>
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<td></td>
<td></td>
<td>• SoluMedrol</td>
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<tr>
<td></td>
<td></td>
<td>• Medrol</td>
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<tr>
<td>Antimetabolites</td>
<td>• cyclophosphamide</td>
<td>• Procytox</td>
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<td></td>
<td>• leflunomide</td>
<td>• Arava</td>
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<td></td>
<td>• methotrexate</td>
<td>• Trexall</td>
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<td></td>
<td></td>
<td>• Metoject</td>
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<td></td>
<td></td>
<td>• Otrexup</td>
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<td></td>
<td></td>
<td>• Rasuvo</td>
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<td></td>
<td></td>
<td>• Rheumatrex</td>
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<td></td>
<td>• azathioprine</td>
<td>• Imuran</td>
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<td></td>
<td>• 6-mercaptopurine (6-MP)</td>
<td>• Purinethol</td>
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<td></td>
<td>• mycophenolic acid</td>
<td>• Myfortic</td>
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<td></td>
<td>• mycophenolate mofetil</td>
<td>• Cellcept</td>
</tr>
</tbody>
</table>

\(^3\) As the dosing information may not be included on the patient’s prescription, confirmation of the dosage from the individual presenting their prescription is sufficient.
<table>
<thead>
<tr>
<th>Class</th>
<th>Generic Name(s)</th>
<th>Brand Name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcineurin inhibitors/mTOR kinase inhibitor</td>
<td>• tacrolimus</td>
<td>• Prograf</td>
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<td></td>
<td>• cyclosporine</td>
<td>• Advagraf</td>
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<td></td>
<td>• sirolimus</td>
<td>• Envarsus PA</td>
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<tr>
<td>JAK (Janus kinase) inhibitors</td>
<td>• baricitinib</td>
<td>• Olumiant</td>
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<tr>
<td></td>
<td>• tofacitinib</td>
<td>• Xeljanz</td>
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<tr>
<td></td>
<td>• upadacitinib</td>
<td>• Rinvoq</td>
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<tr>
<td>Anti-TNF (tumor necrosis factor)</td>
<td>• adalimumab</td>
<td>• Humira</td>
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<tr>
<td></td>
<td>• golimumab</td>
<td>• Amgevita</td>
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<td></td>
<td>• certolizumab pegol</td>
<td>• Hadlima</td>
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<td></td>
<td>• etanercept</td>
<td>• Hulio</td>
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<td></td>
<td>• infliximab</td>
<td>• Hyrimoz</td>
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<td></td>
<td></td>
<td>• Idacio</td>
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<tr>
<td>Anti-Inflammatory</td>
<td>• Sulfasalazine</td>
<td>• Remicade</td>
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<td></td>
<td>• 5-Aminosalicylic Acid (ASA)/mesalamine</td>
<td>• Avsola</td>
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<td></td>
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<td>• Inflectra</td>
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<td>• Remsima</td>
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<td>• Renflexis</td>
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<td>• Salazopyrin</td>
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<td></td>
<td>• Azulfidine</td>
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<td></td>
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<td>• Pentasa</td>
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<tr>
<td>Class</td>
<td>Generic Name(s)</td>
<td>Brand Name(s)</td>
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<tr>
<td>Anti-CD20</td>
<td>• Rituximab</td>
<td>• Rituxan</td>
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<tr>
<td></td>
<td>• ocrelizumab</td>
<td>• Ocrevus</td>
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<td></td>
<td>• ofatumumab</td>
<td>• Kesimpta</td>
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<tr>
<td>IL-1 RA (interleukin-1 receptor antagonist)</td>
<td>• anakinra</td>
<td>• Kineret</td>
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<tr>
<td></td>
<td>• canakinumab</td>
<td>• Ilaris</td>
</tr>
<tr>
<td>Anti-IL6</td>
<td>• tocilizumab</td>
<td>• Actemra</td>
</tr>
<tr>
<td></td>
<td>• sarilumab</td>
<td>• Kevzara</td>
</tr>
<tr>
<td>Anti-IL12/IL23</td>
<td>• ustekinumab</td>
<td>• Stelara</td>
</tr>
<tr>
<td>Anti-IL17</td>
<td>• secukinumab</td>
<td>• Cosentyx</td>
</tr>
<tr>
<td></td>
<td>• ixekizumab</td>
<td>• Taltz</td>
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<tr>
<td>Anti-IL17R</td>
<td>• brodalumab</td>
<td>• Siliq</td>
</tr>
<tr>
<td>Anti-BLYs</td>
<td>• belimumab</td>
<td>• Benlysta</td>
</tr>
<tr>
<td>Anti-IL23</td>
<td>• guselkumab</td>
<td>• Tremfya</td>
</tr>
<tr>
<td>Selective T-cell costimulation blocker</td>
<td>• abatacept</td>
<td>• Orencia</td>
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<tr>
<td>S1PR (sphingosine 1-phosphate receptor) agonist</td>
<td>• fingolimod</td>
<td>• Gilenya</td>
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<td></td>
<td>• siponimod</td>
<td>• Mayzent</td>
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<tr>
<td></td>
<td>• ozanimod</td>
<td>• Zeposia</td>
</tr>
<tr>
<td>Phosphodiesterase inhibitors</td>
<td>• Apremilast</td>
<td>• Otezla</td>
</tr>
<tr>
<td>Anti-integrin</td>
<td>• vedolizumab</td>
<td>• Entyvio</td>
</tr>
</tbody>
</table>

**Booster Doses for Specific Populations**

On December 3rd, 2021, NACI released updated recommendations for booster doses, based upon emerging evidence on vaccine effectiveness, the risks of exposure to SARS-CoV-2 in Canada at this time, the revised objectives of Canada’s
COVID-19 immunization program, the ongoing risk of severe illness from COVID-19, the societal disruption that results from transmission of infections, and the adverse impacts on health system capacity of the COVID-19 pandemic.

Ontario strongly recommends that a booster dose of an mRNA vaccine be offered to individuals ≥50 years of age following ≥3 months (84 days) after completion of a primary COVID-19 vaccine series. This ≥3 month (84 days) recommended interval also now applies to all populations prioritized earlier in the booster dose roll out (as listed on page 12-17).

All individuals in Ontario aged ≥18 are eligible to receive a boosters dose of an mRNA vaccine ≥3 months (84 days) after completion of a primary COVID-19 vaccine series.

**Fourth Doses for Specific Populations**

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. 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. 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.

*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.
**Booster/4th Dose Observation Period:**

Given the urgency to provide booster doses, the **15-minute observation period** for booster doses of mRNA vaccines could be waived on a temporary basis during the emergency response to the Omicron variant. A reduced post-vaccination observation period, between 5 -15 minutes could be considered for the administration of third booster doses of COVID-19 vaccine during the pandemic, if specific conditions are met such as past experience with the two previous COVID-19 vaccine doses and other relevant **conditions** as outlined in the NACI 2020-2021 influenza vaccine advice. This would be an exception to usual immunization guidance and this approach could be used in these settings (i.e., mass immunization clinic, primary care clinics, pharmacies) at this time on a temporary basis during the emergency response to the Omicron variant, weighed the risks of a reduction in observation period (e.g., small increased risk of delayed identification of an adverse event that may require immediate medical attention) reducing risk of SARS-CoV-2 transmission where physical distancing cannot be maintained and allowing more individuals to be immunised in a given time period.

NACI has outlined certain populations for which a specific products and/or doses may be preferred for a booster/additional dose, as outlined in Table 2. See NACI’s guidance on booster COVID-19 vaccine doses for additional rationale and considerations.

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^4 However, if any of Pfizer (30 mcg), Moderna (50mcg) or Moderna (100mcg) are administered as a booster/additional dose, the dose should be considered valid and would not need to be repeated. See the MOH’s COVID-19 Vaccine Administration Errors and Deviations Guidance for more details.
Table 2: Rationale and Options for Vaccine Type and Dose offered for COVID-19 Vaccine Booster Doses in Certain Populations

<table>
<thead>
<tr>
<th>Population</th>
<th>Vaccine type (and dose) for booster doses which may be preferred</th>
<th>Rationale or additional considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 18 to 29 year olds</td>
<td>Pfizer-BioNTech (30 mcg).</td>
<td>Lower reported rates of myocarditis/pericarditis following vaccination with Pfizer-BioNTech (30 mcg) compared to Moderna (100 mcg) (based on second dose data).</td>
</tr>
<tr>
<td>• ≥70 year olds</td>
<td>Either Moderna or Pfizer-BioNTech (30 mcg) may be considered. Data suggest that Moderna COVID-19 vaccine may provide a more robust humoral and cellular immune response. If Moderna vaccine is being used as the booster product, a 100 mcg dose may be preferred, based on clinical discretion.</td>
<td>Moderna (100 mcg) induces somewhat higher antibody levels compared to Pfizer-BioNTech (30 mcg). Protection (against infection and severe disease) from a primary series with Moderna (100 mcg) may be more durable than Pfizer (30 mcg). These populations may have less robust immune function (elderly) or a diminished immune response to the vaccine (some immunocompromised individuals). It is possible that Moderna (100 mcg) may induce a better immune response than Moderna (50 mcg).</td>
</tr>
<tr>
<td>• Residents of long-term care homes, retirement homes or seniors in other congregate settings</td>
<td>Either Moderna or Pfizer-BioNTech (30 mcg) may be considered. Data suggest that Moderna COVID-19 vaccine may provide a more robust humoral and cellular immune response. If Moderna vaccine is being used as the booster product, a 100 mcg dose may be preferred, based on clinical discretion.</td>
<td>Moderna (100 mcg) induces somewhat higher antibody levels compared to Pfizer-BioNTech (30 mcg). Protection (against infection and severe disease) from a primary series with Moderna (100 mcg) may be more durable than Pfizer (30 mcg). These populations may have less robust immune function (elderly) or a diminished immune response to the vaccine (some immunocompromised individuals). It is possible that Moderna (100 mcg) may induce a better immune response than Moderna (50 mcg).</td>
</tr>
<tr>
<td>• Moderately to severely immunocompromised adults (for 3rd dose as part of the primary series and for the booster dose)</td>
<td>Either Moderna (50 mcg) or Pfizer-BioNTech (30 mcg) are suitable products as a booster dose.</td>
<td>Authorized as booster doses by Health Canada</td>
</tr>
<tr>
<td>• For all other populations in whom booster doses are recommended that have not been specified above.</td>
<td>Either Moderna (50 mcg) or Pfizer-BioNTech (30 mcg) are suitable products as a booster dose.</td>
<td>Authorized as booster doses by Health Canada</td>
</tr>
</tbody>
</table>

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5 Moderately or severely immunocompromised adults receiving a booster dose after a primary series of three doses, are eligible to receive a total of four doses.
1. Residents of Long-Term Care Homes (LTCH), Retirement Homes (RH), Elder Care Lodges, and older adults living in other congregate settings

Rationale:

- The potential impact of the risk of transmission of the Delta and Omicron variants of concern in vulnerable older adult populations who live in high risk settings (i.e., congregate living with other vulnerable, high-risk adults) has been assessed, particularly in the context of emerging literature on the reduced immune response and the more rapid waning of antibody responses in this population. Some studies are showing decreases in protection against serious infection, and more notably in older adults (NACI, 2021). These individuals are at increased risk for severe disease because of their age and underlying medical conditions and are at a higher risk of exposure due to their daily interactions with staff and residents in a congregate living environment (NACI, 2021).

- Older Ontarians residing in congregate living settings were prioritized for the COVID-19 vaccine when the vaccines were first authorized; therefore, many completed their COVID-19 vaccination series early in the vaccine roll-out, leaving more time for waning should it occur. As well, many received their vaccines using the manufacturers’ recommended interval. Evidence to date suggests that, compared to longer intervals, shorter intervals between first and second doses result in lower immune responses and therefore may also result in more rapid waning of protection, including against variants of concern (NACI, 2021).

- Vaccines have been effective against COVID-19 in Long Term Care Homes in the 3-4 months after vaccination, but outbreaks are still occurring. In these outbreaks, fully vaccinated residents are being infected, and in some instances leading to severe illness and death. Offering a booster/4th dose of COVID-19 vaccine to this population is intended to help increase protection and prevent outbreaks among this vulnerable population. See NACI’s Guidance on booster COVID-19 doses in Canada for more information.

- Other congregate settings may include assisted-living facilities, chronic care hospitals, naturally occurring congregate retirement settings/congregate senior’s apartment buildings, or older adults living in congregate settings for
people with developmental disabilities, mental health and addictions issues, etc.  

- Practically, some residents may receive shorter intervals than the recommended ≥3 months (84 days) due to operational considerations when boosting entire facilities.

2. Adults ≥50 years of age

Rationale:

- Older adults are more likely to experience severe illness, hospitalization, and death from COVID-19 infection, due to their age and underlying medical conditions. Among the fully vaccinated, older age groups (80 years of age and over with the highest, followed by those aged 70 to 79) have the highest hospitalization and mortality rates from COVID-19 compared to younger age groups who are fully vaccinated (NACI, 2021).

- There is evidence that demonstrates waning immunity and decreased vaccine effectiveness against infection over time after a primary COVID-19 vaccine series in the older adult population. Although protection against severe COVID-19 outcomes appears to be more durable over time than protection against asymptomatic or mildly asymptomatic infection, some studies are showing decreases in protection against serious infection, and more notably in older adults. See NACI’s guidance on booster COVID-19 vaccine doses in Canada for more details.

- Older adults were prioritized for the COVID-19 vaccine when the vaccines were first authorized; therefore, many completed their COVID-19 vaccination series early in the vaccine roll-out, leaving more time for waning should it occur. As well, many received their vaccines using the manufacturers’ recommended interval. Evidence to date suggests that, compared to longer intervals, shorter intervals between first and second doses result in lower immune responses and therefore, may also result in more rapid waning of protection, including against variants of concern (NACI, 2021).

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6 Public Health Units can use their discretion, in collaboration with partner Ministries as needed, to determine eligible congregate settings.
3. Health Care Workers

Rationale:

- Health care workers are at an increased risk of COVID-19 infection due to their ongoing interactions and potential exposures to patients that are or may be infected with COVID-19 and can pose increased risk of transmission to vulnerable populations they care for if infected.

- Health care workers are essential for maintaining health system capacity to minimize serious illness and overall deaths in Ontario while minimizing societal disruption as a result of the COVID-19 pandemic.

- Health care workers were prioritized early in Ontario’s COVID-19 immunization program, leaving more time for waning should it occur, and many received their second doses at the product monograph interval. Evidence to date suggests that shorter intervals between doses results in lower antibody titres which may wane to below protective levels over time. While individuals who received their second dose in the primary COVID-19 vaccine series at a shorter interval from the first dose were well protected in the short-term, they may have produced lower antibody levels, which may decrease over time compared with those who had a longer interval between doses (NACI, 2021).

- Optimizing the protection of healthcare workers can help to balance any disproportionate burden of those taking on additional risks to protect the public, thereby upholding the ethical principle of reciprocity (NACI, 2021).

- Health Care Workers include:
  
  o Any regulated health professionals and any staff member, contract worker, student/trainee, registered volunteer, or other designated essential caregiver currently working in-person in a health care organization, including workers that are not providing direct patient care and are frequently in the patient environment (i.e., cleaning staff, research staff, other administrative staff).

  o Workers providing healthcare service or direct patient service in a congregate, residential or community setting outside of a health care organization.

  o See Appendix B for specific examples of health care workers.
A reduced post-vaccination observation period of at least 5 minutes up to 15 minutes may be considered for the administration of booster doses of COVID-19 vaccine to healthcare workers who are being vaccinated in healthcare settings, if past experience with the two previous COVID-19 vaccine doses was uneventful and other relevant conditions are met, as outlined in the NACI 2020-2021 influenza vaccine advice (as appropriate to the healthcare setting).

4. First Nations, Inuit and Métis Adults

Rationale:

- First Nations, Inuit and Métis populations have been disproportionately affected by COVID-19 in Canada and have experienced higher rates of COVID-19 infection due to a number of intersecting inequities and factors related to the social determinants of health. Immunization of individuals in this population has the potential to reduce or prevent the exacerbation of intersecting health and social inequities (NACI, 2021).

- Remote or isolated communities may not have ready access to sufficient health care infrastructure; therefore, their risk for severe outcomes, including death, and societal disruption is proportionally greater than in other communities (NACI, 2021).

- First Nations, Inuit and Métis populations were eligible to receive their first and second doses early in the vaccination roll out, leaving more time for waning to occur. This population was also eligible for the shortened product monograph interval and evidence to date suggests that, compared to longer intervals, shorter intervals between first and second doses result in lower immune responses and therefore may also result in more rapid waning of protection, including against variants of concern.

- As per NACI, whether or not booster dose vaccine programs are needed in distinct Indigenous communities should be determined by Indigenous leaders and communities, and with the support of public health partners in accordance with the United Nations Declaration on the Rights of Indigenous Peoples.
5. Recipients of a Viral Vector Vaccine Primary Series that was completed with only viral vector vaccines (AstraZeneca/COVISHIELD or Janssen COVID-19 vaccine)

Rationale:

- Vaccine effectiveness against severe COVID-19 outcomes with all vaccine types (including viral vector) remains high, but it is currently unclear to what extent the duration of protection may vary by vaccine product.

- In general, vaccine effectiveness against symptomatic SARS-CoV-2 infection and severe COVID-19 outcomes has consistently been lower for individuals receiving viral vector vaccines compared to mRNA vaccines. Emerging data on effectiveness suggests that vaccine protection against infection and symptomatic disease decreases more quickly with viral vector vaccines in comparison to mRNA vaccines, whereas the difference is less pronounced for severe disease. These individuals may become susceptible to infection sooner than people who received a primary series that included at least one dose of an mRNA vaccine (NACI, 2021).

- While there is limited evidence on duration of protection following a mixed viral vector and mRNA COVID-19 vaccination schedule, to date data from two studies indicate that vaccine effectiveness for those who received a mixed schedule of AstraZeneca/COVISHIELD followed by an mRNA vaccine is similar compared to those who received a complete series of mRNA vaccines (NACI, 2021).
Appendix A: List of Immunosuppressive Medications in Alphabetical Order

#
5- Aminosalicylic Acid (ASA)/mesalamine
6- mercaptopurine (6-MP)

A
Abatacept
Actemra
adalimumab
Advagraf
Amgevita
anakinra
apremilast
Arava
Avsola
azathioprine
Azulfidine

B
baricitinib
belimumab
Benlysta
Brenzys
Brodalumab

C
canakinumab
Cellcept
certolizumab
Cimzia
Cosentyx
cyclophosphamide
cyclosporine

D
Decadron (>3mg/day)
DepoMedrol (>16mg/d)
dexamethasone (>3mg/d)

E
Enbrel
Envyvio
Envarsus
Erelzi
etanercept

F
fingolimod

G
Gengraf
Gilenya
golimumab
guselkumab

H
Hadlima
Hulio
Humira
Hyrimoz

I
Idacio
Ilaris
Imuran

Inflectra
infliximab
ixekizumab

K
Kesimpta
Kevzara
Kineret

L
Leflunomide

M
Mayzent
Medrol (>16mg/d)
methotrexate
methylprednisolone (>16mg/d)
Metoject
mycophenolate
mofetil
mycophenolic acid
Myfortic

N
Neoral

O
Ocrelizumab
Ocrevus
ofatumumab
Olumiant
Orencia
Otezla
Otrexup
ozanimod

P
Pentasa
prednison ( >20mg/d)
Procytox
Prograf
Purinethol

R
Rapamune
Rasuvo
Remicade
Remsima
Renflexis
Rheumatrex
Riabni
Rinvoq
risankizumab
Rituxan
Rituximab
Riximyo
Ruxience

S
Salazopyrin
Sandimmune
Sarilumab
Secukinumab
Siliq
Simponi
Siponimod
sirolimus
Skyrizi
Solumedrol (>16mg/d)
Stelara
sulfasalazine

tacrolimus
Taltz
tocilizumab
tofacitinib
Tremfya
Trexall
Truxima

U
upadacitinib
ustekinumab

V
vedolizumab

X
Xeljanz

Z
Zeposia
Appendix B: List of Health Care Workers Eligible for Booster Doses

Regulated health professionals and any staff member, contract worker, student/trainee, registered volunteer, or other designated essential caregivers currently working in-person in a health care organization, including workers that are not providing direct patient care and are frequently in the patient environment (i.e., cleaning staff, research staff, other administrative staff) are included in the below:

- **All hospital and acute care staff including:**
  - Critical Care Units, Emergency Departments and Urgent Care Departments, COVID-19 Medical Units, Code Blue Teams, rapid response teams
  - General internal medicine and other specialists, Surgical care, Obstetrics

- **All patient-facing health care workers/staff involved in the COVID-19 response:**
  - COVID-19 Specimen Collection Centers, COVID-19 Isolation Centers
  - Mobile Testing Teams, COVID-19 Laboratory Services, Teams supporting outbreak response (e.g., IPAC teams supporting outbreak management, inspectors in the patient environment)
  - COVID-19 vaccine clinics and mobile immunization teams
  - Current members of Ontario’s Emergency Medical Assistance Team (EMAT)

- **Medical First Responders** (ORNGE, paramedics, firefighters providing medical first response, police and special constables providing medical first response as part of their regular duties)

- **Health care workers and designated essential caregivers in congregate settings** (assisted living, correctional settings, shelters, LTCHs/RHs, supportive housing, hospices and palliative care settings, etc.)

- **Home and community health care workers, providing in-person care, including:**
- Needle exchange/syringe programs & supervised consumption and treatment services
- Indigenous health care service providers including but not limited to: Aboriginal Health Access Centers, Indigenous Community Health Centers, Indigenous Inter-professional Primary Care Teams, and Indigenous Nurse Practitioner-Led Clinics
- Community health centres, chronic homecare, birth centres, dentistry and dental hygiene, Pharmacies, Primary care, Walk-in clinics, gynecology/obstetrics, Midwifery, Nurse practitioner-led clinics/Contract nursing agencies, Otolaryngology (ENT), medical and surgical specialities, medical transport, laboratory services, independent health facilities, health care providers in developmental services, mental health and addictions services
- Health care workers in schools/daycare/campus, sexual health clinics, community diagnostic imaging, dietary/nutrition, audiology, naturopathy, holistic care, chiropractic, chronic pain clinics, kinesiology/physiotherapy, occupational therapy, psychiatry, acupuncture, registered massage therapy, psychotherapy, social work, public health