An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Updated recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age

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PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

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Canada

PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

INTRODUCTION

On December 3, 2021, NACI published updated guidance on booster COVID-19 vaccine doses in Canada and reaffirmed previous NACI guidance on the recommended use of COVID-19 vaccines in children 5 to 11 years of age. Since this guidance:

- Additional evidence on the transmissibility and disease severity of the Omicron variant has emerged;
- Additional safety surveillance data on the 2-dose primary series of Pfizer-BioNTech Comirnaty (10 mcg) in children 5 to 11 years of age has been released, providing preliminary estimates on the risk of myocarditis/pericarditis in children 5 to 11 years of age;
- Many children aged 5 to 11 years who are moderately to severely immunocompromised will have completed their 2-dose series and will be seeking guidance on whether additional doses are required.

The Pfizer-BioNTech Comirnaty mRNA COVID-19 vaccine is currently the only COVID-19 vaccine authorized in Canada for use in pediatric populations under 12 years of age. Pfizer-BioNTech [10 microgram (mcg) dose] was approved for children 5 to 11 years of age on November 19, 2021 as a two-dose primary series. The Pfizer-BioNTech Comirnaty COVID-19 vaccine previously has been authorized by Health Canada for individuals 12 years of age and older, using a 30 mcg dose (December 9, 2020, individuals 16 years of age and older; May 18 2021, individuals 12 to 15 years of age).

The Pfizer-BioNTech Comirnaty COVID-19 vaccine in Canada is approved for use as a 3-dose primary series in individuals who are immunocompromised. As per the product monograph (for both 10 mcg and 30 mcg doses), persons who are immunocompromised, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine and in these individuals, a third dose may be considered as part of the primary series.

NACI has reviewed the evolving situation and evidence and has updated evidence-informed recommendations on the use of COVID-19 vaccines in pediatric populations.

METHODS

On January 11, 2022, NACI reviewed the recent evidence on COVID-19 vaccines for pediatric populations including real-world safety surveillance data from the United States (US) and Canada on the Pfizer-BioNTech Comirnaty (10 mcg) vaccine in children 5 to 11 years of age. NACI approved their updated recommendations on the use of COVID-19 vaccines in pediatric populations 5 to 11 years of age on January 19, 2022.

For further information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the COVID-19 vaccine chapter in the Canadian Immunization Guide (CIG).

NACI's recommendations are aligned with the goals of the Canadian COVID-19 Immunization Program, updated in October 2021:

- To enable as many Canadians as possible to be immunized as quickly as possible against COVID-19, while ensuring that high risk populations be prioritized;

- Minimize serious illness and overall deaths while preserving health system capacity;
- Reduce transmission to protect high risk populations.

Refer to NACI's methods for further information on NACI's recommendation development process.

Defining pediatric populations who are immunocompromised

To operationalize guidance for this population, NACI has reviewed several sources to identify which pediatric populations who are immunocompromised would likely benefit most from an additional dose of COVID-19 vaccine at this time. These sources have included evidence available in published and grey literature, the CIG chapter on Immunization of Immunocompromised Persons, and eligibility criteria for additional doses of COVID-19 vaccine in pediatric populations who are immunocompromised currently being used by other jurisdictions. In addition, the clinical expertise of committee members informed the definition of pediatric populations who are immunocompromised for the recommendations outlined in this statement.

SUMMARY OF EVIDENCE

COVID-19 Burden of Disease in Pediatric Populations

Recent epidemiological trends

Canada is currently facing an Omicron wave of the pandemic, and this variant is partially evasive to previous immunity conferred by COVID-19 vaccine or a previous SARS-CoV-2 infection. Numerous reports have shown that mRNA COVID-19 vaccines offer reduced protection against infection with the Omicron variant, and modeling estimates anticipate a fast trajectory to the peak of the Omicron wave, with substantial breakthrough cases in individuals who have received 2 or 3 doses of mRNA and other COVID-19 vaccines[1].

Canadian children 5 to 11 years of age are facing record-high incidence rates of COVID-19[1]. While additional data are required to fully determine the disease severity caused by the Omicron variant in specific populations including unvaccinated individuals, young children (<5 years of age) and the elderly, several reports and emerging studies are reporting reduced frequencies of severe outcomes from COVID-19 for the Omicron variant compared to the Delta variant[2-4].

For the most up to date information on the epidemiology of COVID-19 in Canada, please refer to the COVID-19 daily epidemiology update.

Risk of severe outcomes

Consistent with previous SARS-CoV-2 variants of concern (VOC), children 5 to 11 years of age remain at low risk of severe outcomes from the Omicron variant. While COVID-19 associated hospitalizations among children 5 to 11 years of age have increased, which is consistent with all

other age groups in Canada during the Omicron wave[1], the proportion of COVID-19 cases among children 5 to 11 years of age that have been hospitalized or admitted to ICU remains low[5]. Indirect evidence from adolescent populations in the US suggests risk of severe outcomes may be further decreased by COVID-19 vaccination. In a recent study from the CDC conducted before the arrival of the Omicron variant, among hospitalized patients 12 to 18 years of age, two doses of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) were highly effective at preventing COVID-19–related hospitalization and ICU admission or the need for life support[6].

There is limited evidence on clinical risk factors for severe COVID-19 disease in pediatric populations[7]. Children 5 to 11 years of age at increased risk for severe outcomes may include children who are obese, children who are medically fragile/have medical complexities, children with more than one comorbidity[8], children with neurological disorders[9, 10], and children with immune dysregulation associated with Down Syndrome[8] and other immunocompromising conditions.

For additional information, please refer to the Recommendation on the use of Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5 to 11 years of age.

MIS-C, post-COVID condition and myocarditis following COVID-19

Children and adolescents infected with SARS-CoV-2 are at risk of multiple inflammatory syndrome in children (MIS-C), a rare but serious condition that can occur in the weeks following infection[11]. Recent surveillance data from the US has reported high vaccine effectiveness (VE) against MIS-C (91%; 95% CI 78 to 97%)[12] for the Pfizer-BioNTech COVID-19 vaccine (30 mcg, 2-dose series) in adolescents 12 to 18 years of age.

While evidence is limited in children 5 to 11 years of age, SARS-CoV-2 infection may lead to post-COVID condition/post acute COVID syndrome (i.e., long COVID or post acute COVID-19 syndrome)[13]. Current evidence suggests the risk is lower in children compared to older age groups[14, 15].

Myocarditis can also occur as a complication of SARS-CoV-2 infection, including, very rarely, in children[16].

Overall evidence is limited on the long-term consequences of Omicron infection in children 5 to 11 years of age.

Additional information on MIS-C, post-COVID condition and myocarditis following COVID-19 in children 5 to 11 years of age can be found in NACI's Recommendation on the use of Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5 to 11 years of age.

Additional harms to children during the pandemic

Children and adolescents are also at risk of collateral harms of the COVID-19 pandemic. Prolonged schooling disruptions, social isolation, and reduced access to academic and extra-

curricular resources have profoundly impacted the mental and physical well-being of children and their families[17-22].

COVID-19 Burden of Disease in Pediatric Populations Who Are Immunocompromised

Currently, evidence is limited with respect to the relationship between immunocompromising conditions and COVID-19 disease severity in pediatric populations, given the relatively low frequency of severe outcomes from COVID-19 in children overall. In Canadian jurisdictions nationally reporting age and presence or absence of underlying comorbidity (AB, YT, and PEI), children 5 to 11 years of age with confirmed COVID-19 are more frequently hospitalized if malignancy or immunodeficiency is listed as an underlying condition than children 5 to 11 years of age with COVID-19 who do not identify malignancy or primary immunodeficiency (4.4% vs <0.5%; data as of January 5, 2022[23]). Precautionary admission due to comorbidity may contribute to the increased frequency; however, it is unclear to what extent. Regardless of comorbidity, frequency of ICU admission remained low (<0.1%)[23] in children 5 to 11 years of age.

To assess the current evidence on the risk of severe outcomes of COVID-19 in pediatric populations who are immunocompromised, all relevant studies published before December 8, 2021, which investigated the severity of SARS-CoV-2 infection in children under the age of 18 with immunocompromising conditions compared to children without immunocompromising conditions in the same age group were systematically identified (n=21 observational studies)[9, 10, 24-42]. These observational studies included approximately 380,000 children from 32 different countries. Seven of the included studies reported on the association between immunocompromising conditions and hospitalization due to COVID-19[24, 27, 28, 32, 33, 36, 38], five of which provided a statistical estimate of the relationship between immunocompromising conditions and COVID-19 associated hospitalization[24, 28, 33, 36, 38]. Additionally, 11 studies reported on risk of ICU admission due to COVID-19[25, 28-31, 36-40, 42], 8 studies reported on risk of severe disease from COVID-19[9, 10, 24, 26, 32, 34, 39, 41], and 7 studies reported on risk of death from COVID-19[25, 26, 30, 34, 35, 39, 41].

Four out of five studies reporting on risk of hospitalization indicated that children with an immunocompromising condition may be at an increased risk of hospitalization due to COVID-19, compared to children without immunocompromising conditions[24, 28, 33, 36, 38]. Interpretation of this outcome is limited by wide confidence intervals for some of the estimates of risk and the potential for risk of bias in study design and conduct that led to uncertainty in the confidence of those estimates. In particular, the higher likelihood of precautionary hospital admission triggered by the presence of an immunocompromising condition may contribute to the elevated hospitalization rates. The majority of studies reporting on risk of ICU admission indicated that children with an immunocompromising condition may not be at increased risk of ICU admission due to COVID-19, compared to children without immunocompromising conditions[25, 28-31, 36-40, 42]; however, these findings were limited in interpretation by wide confidence intervals for some of the risk estimates. Overall, current evidence is insufficient to inform on whether children who are considered moderately to severely immunocompromised are at higher risk of severe outcomes from COVID-19.

Summary of Evidence on a 2-Dose Pfizer-BioNTech Comirnaty Series in Pediatric Populations Who Are Immunocompromised

Effectiveness of a 2-dose COVID-19 vaccine series in pediatric populations who are immunocompromised

Evidence on the effectiveness of a 2-dose COVID-19 vaccine series in persons who are immunocompromised is currently limited to adult populations, where observational studies show a reduction in VE against SARS-CoV-2 infection and COVID-19 disease in adults who are immunocompromised when compared to adults who are not immunocompromised (based on use of the vaccines as per the manufacturers' schedules). The criteria for being considered immunocompromised were not consistent across the included studies, and these analyses do not provide sufficient data to determine VE for specific immunocompromising conditions or treatments.

For further information, please refer to the NACI rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series.

Immunogenicity and safety of a 2-dose COVID-19 vaccine series in pediatric populations who are immunocompromised

A rapid review of the evidence was undertaken to study the effectiveness, immunogenicity and safety of a two- or three-dose primary series of a COVID-19 mRNA vaccine in pediatric populations who are moderately to severely immunocompromised (≤18 years of age). This review identified five observational studies from four countries (Canada, France, United Kingdom, US [n=2])[43-47]. A total of 179 persons who were moderately to severely immunocompromised were included (solid tumor [n=13], solid organ transplant [n=45], inflammatory bowel disease (IBD) patients receiving anti-TNF [n=68], heart transplant [n=26], and children with severe neurodisabilities [n=27]). There were no children under the age of 12 years included in any of the identified studies. All studies used the Pfizer-BioNTech mRNA COVID-19 vaccine; however, none of the studies reported VE.

Immunogenicity: Four studies (n=105 persons) reported on the immunogenicity after the 2nd dose in pediatric populations[43, 45-47] who were immunocompromised. Overall, the seroconversion rate after the second dose of the Pfizer-BioNTech vaccine was moderately reduced compared to pediatric populations who were not immunocompromised. Specific adolescent populations had reduced seroconversion rates (patients with solid tumours, solid organ transplant recipients[45-47]) and these conditions were also associated with a lower risk of seroconversion in an analogous review in the adult population[48].

Safety: Only two studies (n=38 persons) reported safety outcomes[44, 46]. The safety profile was similar to that observed in adult populations[48] who were immunocompromised; overall the vaccine was well tolerated. There were no cases of myocarditis observed in any study, although sample sizes were small.

Overall, the current evidence is insufficient to inform on the safety and/or effectiveness of COVID-19 vaccines in children 5 to 11 years of age who are moderately to severely immunocompromised. However, limited data from adolescent populations who are immunocompromised indicates a

similar seroconversion rate after a second dose to adult populations who are immunocompromised, as well as a similar safety profile, although data are very limited.

For further information, please refer to NACI rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series.

Summary of evidence on an additional dose of COVID-19 vaccines following a 2-dose series in populations who are immunocompromised

There are currently no data on the safety, immunogenicity, or efficacy of an additional dose of a COVID-19 vaccine following a 2-dose series in children or adolescents who are immunocompromised. Current data in adults demonstrates that a third dose of an mRNA COVID-19 vaccine leads to a modest increase in antibody levels in adults who are moderately to severely immunocompromised and a modest increase in the overall proportion of adults who seroconvert/respond to vaccination.

For further information, please refer to NACI rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series

Preliminary post-market surveillance data on the safety of a third dose of Pfizer-BioNTech Comirnaty among adolescents

Additional evidence to inform on the potential safety of a third dose of Pfizer-BioNTech Comirnaty (10 mcg) for children 5 to 11 years of age who are immunocompromised can be extrapolated from indirect evidence on third doses among adolescents 12 to 15 years of age who are not immunocompromised (30 mcg formulation).

Preliminary post-market data from Israel presented at the Advisory Committee on Immunization Practices (ACIP) meeting on January 5, 2022 indicate that a third dose of Pfizer-BioNTech 30mcg vaccine is well tolerated among individuals aged 12 to 15 years[49]. Among 41,610 booster doses administered to individuals aged 12 to 15 years, 2 cases of myocarditis have been reported (a 13 year-old male with a history of pericarditis in 2019 and myocarditis 3 days after the COVID-19 booster dose and a 15 year-old male with myocarditis 4 days after the COVID-19 booster dose). Both cases were discharged from hospital in good condition.

Real World Safety Surveillance Data on Pfizer-BioNTech Comirnaty in Children 5 to 11 Years of Age

As of January 7, 2022, preliminary Canadian passive surveillance data show that among over 1,400,000 Pfizer-BioNTech COVID-19 vaccine doses administered in individuals aged 5 to 11 years (including the Pfizer 30 mcg doses administered to 11-year-old individuals before the 10 mcg pediatric dose was authorized), a total of 116 adverse events (AEs) (56 males, 50 females and 10 with unidentified sex) were reported. Vaccine safety monitoring is ongoing.

In the US, about 8.7 million doses of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) have been administered to individuals aged 5 to 11 years as of December 19, 2021; the US uses the manufacturer's recommended 21-day interval between doses. Reactogenicity data from the v-

safe surveillance system are consistent with the clinical trial results; overall the Pfizer-BioNTech 10mcg vaccine is well tolerated, where individuals aged 5 to 11 years report adverse reactions less frequently than individuals aged 12 to 15 years who received the Pfizer-BioNTech 30mcg vaccine. Overall, 12 confirmed cases of myocarditis (including 8/12 reports among males and 9/12 reports after dose 2) in individuals aged 5 to 11 years have been reported to the Vaccine Adverse Event Reporting System (VAERS)[50]. The cases of myocarditis among the 5 to 11 year-old population appear to have similar characteristics to those reported in older age groups (onset usually within a week after vaccination, more often after dose 2, more often in males than females, and the majority of individuals tend to recover quickly). However, after dose 2, the reported rate of myocarditis in males aged 5 to 11 years (4.3 cases per million doses administered) is substantially lower than in males aged 12 to 15 years (45.7 cases per million doses administered) and males aged 16 to 17 years (70.2 cases per million doses administered).

While the preliminary safety data available to date are reassuring, more information will assist in further assessment of the risk of myocarditis/pericarditis among individuals aged 5 to 11 years. At this time, the risk of myocarditis/pericarditis after dose 2 when using an extended interval (at least 8 weeks) among children ages 5 to 11 years and the safety of a third dose of COVID-19 vaccine in individuals aged 5 to 11 years are unknown. NACI continues to review the evidence as it emerges and will update its recommendations as needed.

Additional Information and Considerations

Ethics and equity considerations

Evidence has shown that some individuals who are immunocompromised have a reduced immune response to the use of the COVID-19 vaccines as per the manufacturers' schedules. Although some reduction in VE has been identified in adults who are immunocompromised when compared to the general population, the extent of the loss is unclear due to the limited evidence in this population and heterogeneous nature of immunocompromising conditions and treatments. Vaccination strategies aimed at protecting these populations have also varied across studies and jurisdictions. While VE data for children who are immunocompromised are limited, and waiting for more evidence would increase the certainty of this recommendation, it is still possible to extrapolate based on adolescent data. Available evidence on immunogenicity and safety in adolescent populations supports offering an additional vaccine dose to children 5 to 11 years of age who are moderately to severely immunocompromised, to optimize direct protection conferred by vaccine. The additional dose provides an opportunity to obtain protective immunity against COVID-19.

Timing of the additional dose and considerations for vaccine providers

There are currently limited data to determine the optimal interval between doses for individuals who are immunocompromised. Dosing intervals between the second and third doses in adults who are immunocompromised varied across studies, ranging from 28 days to 127 days, with most studies having assessed an interval of 2 to 3 months between doses[48]. A longer interval between doses in this three-dose series is likely to result in better immune responses. However, delaying the interval between doses increases the period during which the individual who is immunocompromised may be sub-optimally protected and could leave the individual who is immunocompromised susceptible to SARS-CoV-2 infection while waiting to be vaccinated with the additional dose.

In general, NACI recommends that individuals who are immunocompromised be immunized at the time when maximum immune response can be anticipated; if possible, weighing the risk of exposure and severe disease while waiting for vaccination:

- Complete a vaccine series at least 2 weeks before initiation of immunosuppressive therapies where possible.

- Delay immunization if the immunodeficiency is transient (consider if this can be done safely because exposure is unlikely in the individual's setting and circumstance[51]).

- Stop or reduce immunosuppression to permit better vaccine response, if appropriate. For more details on the timing of vaccination in relation to immunosuppressive therapy, please consult the chapter on Immunization of Immunocompromised Persons in the Canadian Immunization Guide.

In individuals who are immunocompromised, providers should aim to provide each dose of the 3-dose series with an interval of 4 to 8 weeks between doses. An interval longer than 4 weeks between each dose is likely to result in a better immune response and duration of protection. However, if a longer interval is being considered, then risk factors for exposure (including local epidemiology and circulation of VOC) and risk of severe disease (including pre-existing medical conditions, social factors, and varying access to health care services) should also be considered. Some individuals who are immunocompromised may still be susceptible after 2 doses with the Pfizer-BioNTech COVID-19 vaccine, so their period of susceptibility until receipt of the additional dose will also increase if the interval between doses is increased. Some individuals who are immunocompromised will also remain susceptible after a third dose of Pfizer-BioNTech COVID-19 vaccine.

RECOMMENDATIONS

Please see Table 1 for an explanation of strong versus discretionary NACI recommendations.

Recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age:

In careful consideration of additional safety data that has emerged since NACI first issued guidance on the use of COVID-19 vaccines in children 5 to 11 years of age, and considering benefits of vaccination in adolescents to prevent severe outcomes including MIS-C, NACI has now **strengthened its previous discretionary recommendation:**

1. **NACI recommends that a complete series with the Pfizer-BioNTech COVID-19 vaccine (10 mcg) should be offered to children 5 to 11 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between first and second dose. (Strong NACI Recommendation)**

It is essential that children aged 5 to 11 years and their parents are supported and respected in their decisions regarding COVID-19 vaccinations for their children, whatever decisions they make, and are not stigmatised for accepting, or not accepting, the vaccination offer.

NACI continues to recommend a longer dosing interval for most children despite the Omicron variant wave that is currently dominant in Canada. It is important that children are given the

opportunity to establish optimal long-term immunity against COVID-19 that will persist while the Omicron variant circulates and beyond. Longer intervals between vaccine doses allow for more robust strength and breadth of immune responses, which may be important to establish durable protection against new or resurgent VOC that may be more severe. Based on current epidemiological data, the risk of severe outcomes from the Omicron variant in children 5 to 11 years of age is expected to remain low during the interval between vaccine doses. Furthermore, based on vaccine safety monitoring in adolescents and adults, it is expected that longer intervals between doses of the Pfizer-BioNTech Comirnaty vaccine will further reduce the very rare risk of myocarditis or pericarditis following vaccination in children.

Additional considerations and rationale:

- Real-world safety data from the US (v-safe) suggests the Pfizer-BioNTech COVID-19 vaccine (10 mcg) is well tolerated in children 5 to 11 years of age, where the majority of AEs reported are non-severe, and AEs are less frequently reported than in adolescents 12 to 15 years of age.
- Currently, there are limited data on the risk of myocarditis/pericarditis in children following immunization with the 10 mcg dose of the Pfizer-BioNTech vaccine. Safety surveillance data from the US suggests that the risk of myocarditis/pericarditis may be lower in children aged 5 to 11 years following Pfizer-BioNTech (10 mcg) vaccination compared to adolescents and young adults (who receive a 30 mcg Pfizer-BioNTech dose). Among children 5 to 11 years of age, very rare cases were most often reported following dose 2 and among males.

Recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age who are moderately to severely immunocompromised*:

1. **NACI recommends that children 5 to 11 years of age who are moderately to severely immunocompromised* should be immunized with a primary series of three doses of the Pfizer-BioNTech COVID-19 vaccine (10 mcg), using an interval of 4 to 8 weeks between each dose. (Strong NACI Recommendation)**
2. **For children 5 to 11 years of age who are moderately to severely immunocompromised* who have previously received a 2-dose primary series with the Pfizer-BioNTech COVID-19 vaccine, NACI recommends that a third dose should be offered 4 to 8 weeks after the second dose. (Strong NACI Recommendation)**

Children considered moderately to severely immunocompromised* should receive a 3-dose primary series where the interval between each dose is between 4 and 8 weeks. A longer interval between doses is likely to result in a better immune response and duration of protection. However, if a longer interval is being considered, then risk factors for exposure (including local epidemiology and circulation of VOC) and risk of severe disease should also be taken into account. Some children who are immunocompromised may still be susceptible after 2 doses with Pfizer-BioNTech Comirnaty, so their period of susceptibility until receipt of the additional dose will also increase if the interval between doses is increased.

***** Children 5 to 11 years of age who are considered moderately to severely immunosuppressed includes individuals with the following conditions:

- Active treatment for solid tumour or hematologic malignancies;

- Receipt of solid-organ transplant and taking immunosuppressive therapy;
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy);
- Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation;
- HIV with prior AIDS defining illness OR prior CD4 count ≤ 200/mm3 OR prior CD4 fraction ≤ 15% OR perinatally acquired HIV infection;
- Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to Immunization of Immunocompromised Persons, Immunosuppressive Therapy in Part 3 of 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.

Summary of evidence, additional considerations and rationale:

- Children 5 to 11 years of age who are immunocompromised may be at increased risk of severe outcomes from COVID-19 compared to children who are not immunocompromised, and data from older populations suggests individuals who are moderately to severely immunocompromised may have a reduced immunological response to a 2-dose mRNA COVID-19 vaccine primary series.
- In general, NACI recommends immunization of individuals who are immunocompromised at a time when the immune response can be maximized. However, delaying COVID-19 vaccinations to optimize the response (including delaying offering an additional dose) needs to be weighed against the increased period of susceptibility and risk of infection and subsequent serious complications.
- Several studies in adults who are immunocompromised have reported a third dose of an mRNA COVID-19 vaccine led to a modest increase in antibody levels compared to the response following dose 2. However, not all vaccine recipients who are immunocompromised may respond to the third dose. Therefore, individuals who are immunocompromised should continue to follow recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission. It is also important that household members, healthcare workers providing care, and other close contacts of individuals who are immunocompromised be vaccinated to provide indirect protection for these individuals.
- For guidance on the timing of vaccination for transplant recipients and those requiring immunosuppressive therapies, refer to Immunization of Immunocompromised Persons chapter in the Canadian Immunization Guide, Part 3 - Vaccination of Specific Populations for a more fulsome list of conditions leading to primary immunodeficiency, and for further information on immunosuppressive therapies.

Other considerations informing NACI recommendations on the use of COVID-19 vaccines for children 5 to 11 years of age

- Due to high transmissibility and partial immune evasion in vaccinated individuals, children, and older populations alike, continue to be at risk of infection with the Omicron variant regardless of vaccination status, although risk of severe disease is lowered with 2 or 3 dose of a COVID-19 vaccine. It is anticipated that many children will be infected with SARS-CoV-2 during the Omicron wave of the pandemic.
- Children 5 to 11 years of age are at low risk of severe outcomes of COVID-19. Emerging evidence suggests that children are also at low risk of severe illness with the Omicron variant. While hospitalizations may be increasing, this is likely due to the magnitude of the increase in infection incidence.
- Overall evidence is limited on the long-term consequences of Omicron infection in children 5 to 11 years of age.
- Program planning should ensure equitable access to vaccination information and services and minimize inequities in vaccine acceptance and uptake based on socioeconomic status.

NACI is continuing to monitor the evidence and will update guidance as required.

Refer to the chapter on COVID-19 vaccine in the Canadian Immunization Guide for further information on COVID-19 vaccines.

RESEARCH PRIORITIES

- NACI recommends continuous monitoring of data on the safety, immunogenicity, efficacy, and effectiveness of the Pfizer-BioNTech COVID-19 vaccine in children through clinical trials and studies in real-world settings, including clinical implications of previous history of SARS-CoV-2 infection, MIS-C, myocarditis, or pericarditis, on the safety, efficacy, and effectiveness of COVID-19 vaccines in pediatric populations and in children considered moderately to severely immunocompromised.
- NACI recommends continuous monitoring of vaccine uptake, particularly according to the socioeconomic status of families with children 5 to 11 years of age.
- NACI recommends vigilant reporting across Canadian jurisdictions for timely assessment of myocarditis and pericarditis cases as well as other potential rare or very rare AEs in pediatric populations following COVID-19 vaccination. In addition, efforts should be made to facilitate investigation of previous SARS-CoV-2 infection in cases of suspected adverse events following immunization (AEFI). Global collaboration should be prioritized to enable data sharing so decision makers around the world can weigh benefits and risks of COVID-19 vaccination for their own specific pediatric populations.
- NACI recommends that further evaluations of dosage intervals and the impact of the interval on effectiveness and safety in children 5 to 11 years of age should be undertaken.
- NACI recommends that further evaluations of the optimal interval between previous infection and vaccination be undertaken (for both COVID-19 vaccine primary series and

additional doses) to ensure vaccine safety and to maximize effectiveness, duration, and breadth of protection.

TABLES

Table 1. Strength of NACI Recommendations

Strength of NACI Recommendation *based on factors not isolated to strength of evidence* (e.g., public health need)	**STRONG**	**DISCRETIONARY**
Wording	"*should/should not be* offered"	"*may/may not be* offered"
Rationale	Known/anticipated advantages outweigh known/anticipated disadvantages ("should"), OR Known/Anticipated disadvantages outweigh known/anticipated advantages ("should not")	Known/anticipated advantages are closely balanced with known/anticipated disadvantages, OR uncertainty in the evidence of advantages and disadvantages exists
Implication	A strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.	A discretionary recommendation may be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

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NACI members: S Deeks (Chair), R Harrison (Vice-Chair), M Andrew, J Bettinger, N Brousseau, H Decaluwe, P De Wals, E Dubé, V Dubey, K Hildebrand, K Klein, J Papenburg, A Pham-Huy, B Sander, S Smith, and S Wilson.

Liaison representatives: L Bill /M Nowgesic (Canadian Indigenous Nurses Association), LM Bucci (Canadian Public Health Association), E Castillo (Society of Obstetricians and Gynaecologists of Canada), A Cohn (Centers for Disease Control and Prevention, United States), L Dupuis (Canadian Nurses Association), D Fell (Canadian Association for Immunization Research and Evaluation), S Funnell (Indigenous Physicians Association of Canada), J Hu (College of Family Physicians of Canada), M Lavoie (Council of Chief Medical Officers of Health), D Moore (Canadian Paediatric Society), M Naus (Canadian Immunization Committee), A Ung (Canadian Pharmacists Association).

Ex-officio representatives: V Beswick-Escanlar (National Defence and the Canadian Armed Forces), E Henry (Centre for Immunization and Respiratory Infectious Diseases (CIRID), PHAC), M Lacroix (Public Health Ethics Consultative Group, PHAC), C Lourenco (Biologic and Radiopharmaceutical Drugs Directorate, Health Canada), D MacDonald (COVID-19 Epidemiology and Surveillance, PHAC), S Ogunnaike-Cooke (CIRID, PHAC), K Robinson (Marketed Health Products Directorate, HC), G Poliquin (National Microbiology Laboratory, PHAC), and T Wong (First Nations and Inuit Health Branch, Indigenous Services Canada).

NACI High Consequence Infectious Disease Working Group

Members: R Harrison (Chair), N Brousseau, Y-G Bui, S Deeks, K Dooling, K Hildebrand, M Miller, M Murti, J Papenburg, D Smith, and S Vaughan.

PHAC participants: NK Abraham, N Alluqmani, L Coward, N Forbes, C Jensen, CY Jeong, A Jirovec, A Killikelly, R Krishnan, SH Lim, N Mohamed, J Montroy, A Nam, S Pierre, R Pless, M Salvadori, A Sinilaite, A Stevens, R Stirling, E Tice, A Tuite, MC Tunis, B Warshawsky, E Wong, R Ximenes, MW Yeung, J Zafack.

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