



Children should be offered vaccination against COVID-19

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Since the start of the COVID-19 pandemic, there has been conflicting evidence on SARS-CoV-2 infection and transmission in children (Stawicki et al. 2020; Bialek et al. 2020; Wu and Mcgoogan 2020). Early studies reported only anecdotal outbreaks in school settings and low case numbers in children (Danis et al. 2020), driving speculation that the virus may not be as easily spread in this age group (Cao et al. 2020; Goldstein et al. 2020; Ludvigsson 2020b). However, these reports are unlikely to have represented the true frequency of infections, given the widespread school closures implemented to cut transmission opportunities and limitations of swab testing in children (lower uptake, swab volumes) resulting in missed cases (Corman et al. 2021; Han et al. 2021). Indeed, subsequent studies measuring viral load in children reveal similar levels and trajectories as adults, indicating that children can readily transmit the virus (Jones et al. 2021; Jacot et al. 2020, Yonker et al. 2020; Baggio et al. 2021). Moreover, in children under 5 years, significantly higher levels of SARS-CoV-2 viral nucleic acid have been detected (Heald-Sargent et al. 2020), while those under 3 years of age are more likely to transmit the infection compared to older siblings (Paul et al. 2021). Together, current available evidence confirms that children, even if asymptomatic or with mild disease, are an important source of SARS-CoV-2 who can accelerate infections throughout communities.

The highly contagious B.1.617.2 (delta) variant, first identified in December 2020 in India (ECDC 2021), has

now been detected in 130 countries worldwide. The delta variant is more transmissible than earlier SARS-CoV-2 strains and confers greater risk of hospitalization, ICU admission and death, particularly in those who are unvaccinated (Sheikh et al. 2021; Fisman and Tuite 2021). In response to a recent outbreak in Massachusetts, U.S., where 74% (346/469) of delta variant-infected cases were found to be fully vaccinated and 79% of those (274/346) were asymptomatic (Brown et al. 2021a), the U.S. Centers for Disease Control and Prevention updated their guidance to recommend masking indoors (28th July 2021 (CDC 2021)).

Vaccination against COVID-19, currently authorized for those 12 years and older, remains the most effective way to prevent symptomatic disease and more severe outcomes (Lopez Bernal et al. 2021b; Hall et al. 2021; Shrotri et al. 2021; Dagan et al. 2021). In Canada, there are presently 4 COVID-19 vaccines available, two based on mRNA technology (Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273)), and two utilizing viral-vector platforms (AstraZeneca (ChAdOx1-S), Janssen (Ad26.COV2.S)). A newly developed COVID-19 vaccine by Novavax (NVX-CoV2373), based on the more traditional ‘protein-subunit’ approach (similar to the pertussis and hepatitis B vaccines), recently reported results of its phase III trials in adults (Heath et al. 2021). Unlike the mRNA or viral-vector COVID-19 vaccines, NVX-CoV2373 contains parts of the recombinant SARS-CoV-2 spike protein and an adjuvant to stimulate host immune responses. The overall efficacy for preventing

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symptomatic disease was shown to be comparable to mRNA vaccines (89%), with the benefit of both fewer and milder adverse effects — an important consideration when deciding among vaccines for children. While not yet authorized for use in Canada, it is expected that NVX-CoV2373 will become available within the coming months.

Since the start of the vaccination program in Canada, SARS-CoV-2 infections have occurred predominately in the unvaccinated population (89.4% versus 0.6% in those who are fully protected). Similarly, of those who were hospitalized or died, unvaccinated individuals accounted for 84.8% and 82.1%, respectively (Goldstein et al. 2020). For the delta variant, studies estimating vaccine efficacy after 2 doses suggest reduced levels of protection against symptomatic disease compared to the original SARS-CoV-2 strain (Pfizer-BioNTech vaccine: 88% vs. 93.7%, respectively; AstraZeneca COVID-19 vaccine: 67% vs. 74.5%, respectively) (Lopez Bernal et al. 2021a). Additionally, over a 7-month period in which the predominant SARS-CoV-2 strains changed from the alpha to delta variant, a separate study reported a 2-fold risk reduction against breakthrough infections in those vaccinated with the Moderna compared to the Pfizer-BioNTech vaccines (Puranik et al. 2021). Together with the observed decline of antibody levels over time, a strong argument for a booster shot can be made (Roifman and Vong 2021a).

Now, as Canada enters a fourth wave with a strong resurgence of cases, it is children who are most vulnerable to infection and should be fast-tracked for vaccination. Early reports that children don't develop severe symptoms of COVID-19 disease are being surpassed by evidence of long-term effects, some lasting months after the initial infection (Thomson 2021; Buonsenso et al. 2021; Ludvigsson 2020a). Serious complications, including multi-system inflammatory syndrome, have also been reported (Riphagen et al. 2020; Waltuch et al. 2020), and there are likely other effects that have yet to be accounted for.

In May 2021, the delta variant accounted for just 8% of positive cases in Ontario, while in July those cases jumped to 78% (Brown et al. 2021b). Documentation of 72,000 new pediatric COVID-19 cases in the U.S., the largest weekly increase since the start of the pandemic (American Academy of Pediatrics 2021), prompted the American Academy of Pediatrics and Children's

Hospital Association to urge the FDA to fast-track the review of COVID-19 vaccines for pediatric cohorts (<12 years) (Beers 2021). Especially concerning are reports of increased hospitalizations of children infected with the delta variant, with pediatric ICU beds at maximum capacity in numerous hospitals across the U.S. (Conlen et al. 2020). Although the numbers are low compared to adult admissions, to date, they are the highest recorded for children from the start of the pandemic.

Taken together, it is imperative that COVID-19 vaccines are made available for children under 12 years of age as soon as possible. With children returning to school in a matter of weeks, the lack of protection exposes them not only to greater risk of infection and complications, but also of spreading the virus throughout communities and potentially becoming a source for new variants. For those who have compromised immune systems, including children and adults with primary immunodeficiency (Roifman 2020), gatherings among unvaccinated individuals (particularly in the classroom setting) poses a high risk for SARS-CoV-2 transmission (Roifman and Vong 2021a, 2021b).

Recommendations

1. We urge Health Canada to approve the use of COVID-19 vaccines in school-aged children (5–12 years).
2. We support the recommendations of the American Academy of Pediatrics and Children's Hospital Association in urging the FDA to approve COVID-19 vaccines for school-aged children.
3. Pediatricians should be given the ability to provide off-label COVID-19 vaccine doses for children aged 10–12, if developmentally appropriate.
4. The planned one third dosage of the Pfizer-BioNTech vaccine (10 micrograms compared to 30 micrograms currently administered in adults) for children aged 10–12 may not be sufficient for protection against SARS-CoV-2 and should be investigated further.
5. Given the high reported efficacy and relatively lower side effects identified in clinical studies of the Novavax vaccine, it may, in the future, be considered for use in children. Because it is a more a traditional type of vaccine, it could also be preferred by both parents as well as caregivers.
6. The decision to vaccinate children should be made in consultation with your physician/healthcare

provider. Meanwhile, protective measures including social distancing, hand hygiene, and masking should continue as the mainstay for protection against COVID-19.

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