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Coronavirus Disease 2019 and Vaccination of Children and Adolescents: Prospects and Challenges

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The ongoing coronavirus disease 2019 (COVID-19) pandemic has caused over 1 000 000 deaths worldwide and over 200 000 deaths in the US to date.[1] Most, but not all of the deaths and more severe consequences of COVID-19 have been among older individuals.[2] However, in addition to the direct morbidity and mortality figures, there have been enormous disruptions in the lives of persons of all ages, with attendant emotional, economic, and social stresses.[3,4] Approaches to managing the pandemic have relied upon what are referred to as nonpharmaceutical interventions (NPIs), such as social distancing, wearing masks, washing hands, and testing and contact tracing. These approaches can be effective at mitigating the damage caused by COVID-19, but only if they are widely accepted and implemented, which has generally not been the case in the US. NPIs often are characterized as stop-gap measures, "until a vaccine or cure is available." In fact, there have been unprecedented efforts to develop vaccines to prevent infection because of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. As of the writing of this report (October 2020), there were 44 candidate vaccines in human clinical trials, with 11 in phase 3 trials.[5] As a result, there is great expectation that a vaccine soon will be available. However, vaccination, like NPIs, will not be effective without well-designed public health policies, clear public health communication, and widespread acceptance among the population. In addition, we do not yet know how efficacious a vaccine will be or how long vaccine-induced immunity will last, including whether vaccination will need to be on a seasonal basis, like influenza vaccination. In addition, it is essential that a plan is in place for equitable allocation of any vaccine that becomes available, including for children and adolescents, to ensure that all are protected and that existing COVID-19 health disparities are not made worse.[6]

There are 2 steps to bringing any vaccine to use in the US (ie, licensure and recommendations for use). The first is the purview of the US Food and Drug Administration (FDA) and the second is that of the Centers for Disease Control and Prevention (CDC). In the case of a SARS-CoV-2 vaccine that is found to be immunogenic, safe, and efficacious in phase 3 trials, and considering the urgent need for a lifesaving vaccine, the FDA first might give emergency use authorization (EUA), with licensure pending later results of additional requested/required data. Following EUA and/or licensure, the CDC, through the Advisory Committee on Immunization Practices (ACIP), considers the specifics of the vaccine's performance in trials, burden of disease, and public health issues to recommend the specifics of the vaccine's use in the US population and prioritization.

In this commentary, we address the prospects of a SARS-CoV-2 vaccine for the pediatric population, including discussions of the rationale for vaccinating minors, the challenges involved, the potential impact on acceptability of other vaccines, and reasons for moderating the uncritical optimism that a vaccine for children or adults, by itself, will solve our COVID-19 pandemic problems.

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus disease 2019
EUA	Emergency use authorization
FDA	Food and Drug Administration
HPV	Human papillomavirus
NASEM	National Academies of Sciences Engineering and Medicine
NPI	Nonpharmaceutical intervention
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2

What Is the Rationale for Vaccinating Minor Children and Adolescents?

Morbidity and mortality associated with SARS-CoV-2 infection are significantly lower in young children and in adolescents, and children may be less susceptible to infection.[7] However, there have been reports of COVID-19 disease symptoms, some severe, and some instances of death in children and adolescents. As of October 2020, the American Academy of Pediatrics reported that nearly 700 000 child and adolescent COVID-19 cases had been reported in the US (10.7% of all cases), with over 5000 cumulative hospitalizations and over 100 deaths.[8] These numbers pale compared with cases, hospitalizations, and deaths among individuals age 65 years and older (eg, as of October 14, there were over 160 000 cumulative deaths in this age group).[2] Therefore, vaccination of older adults has significantly more potential direct benefit than vaccination of children. However, there are additional factors to consider.

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Although most vaccines provide direct personal health benefits, the primary public health goal of vaccination is herd immunity. The key question, then, is are children vectors of transmission to more vulnerable adults? Increasingly, the evidence suggests that infected children and adolescents can infect other children and adults.[9-12] To protect society as a whole, including older adults, and to decrease household transmission of SARS-CoV-2, it may make sense to vaccinate children and adolescents, as well as adults. An additional factor is that the childhood and adolescent vaccination infrastructure is very well developed in the US, so that it should be possible to integrate new SARS-CoV-2 vaccines into existing immunization platforms.

The CDC, National Academies of Sciences Engineering and Medicine (NASEM), and Johns Hopkins Center for Health Security all consider adults working as teachers and staff in K-12 schools and in out-of-home childcare settings to be critical populations needed to maintain core societal functions and should receive prioritized access to SARS-CoV-2 vaccines when supplies are limited. None of their allocation frameworks considers minor children as a high priority group.[6,13,14] One could argue that part of protecting teachers and staff working in K-12 schools would be to also prioritize vaccination of students.

When Will a SARS-CoV-2 Vaccine Be Available for Children and Adolescents?

Up until mid-October 2020, no minors had been enrolled in any SARS-CoV-2 vaccine clinical trials.[15] However, some researchers and groups, including the American Academy of Pediatrics, have called for clinical trials with minor adolescents to begin as soon as possible.[16,17] In fact, one of the pharmaceutical companies with a candidate SARS-CoV-2 vaccine in phase 3 clinical trials with adults was approved by the FDA to begin enrollment of children down to age 12 years,[18] and reportedly had enrolled 100 children age 12-15 years and 200 children age 16-17 years by the end of October 2020.[19] It is not clear, however, how rapidly they will be able to continue enrolling children and minor adolescents into this clinical trial and we are not aware of any research that has examined parental and child willingness to participate in SARS-CoV-2 vaccine clinical trials. Historically, the typical course of research would be to conclusively demonstrate efficacy and safety in adults, then do immune-bridging studies in younger adolescents and children, which was the approach undertaken for human papillomavirus (HPV) vaccine.[20] The process of developing and testing SARS-CoV-2 vaccines has been accelerated significantly by enacting steps simultaneously, rather than sequentially.[21] Moreover, the bioethical and procedural infrastructures for ethical conduct and implementation of vaccine prevention trials are underdeveloped for minors. The process of ensuring ethical conduct of vaccine prevention trials for minors is complex and uncertain, particularly in the context of incomplete data about potential individual benefit and safety. Lessons from trials of HPV vaccines, as well as consideration of trials for potential HIV vaccines,[22,23] provide sound basis for SARS-CoV-2 vaccine research. The process could be supported additionally by detailed guidance in considering topics such as community benefits, diverse racial/ethnic enrollment, youths' vulnerability, preventive misconception, as well as the operationalization of informed, shared youth-parent decision-making and assent/consent.[24,25]

Even in the most optimistic of circumstances, if SARS-CoV-2 vaccine development and FDA's EUA/licensure and ACIP's recommendations follow the same general course as previous vaccine trials, it is unlikely that a large enough number of minors could be enrolled in such studies before early- to mid-2021. In addition, getting vaccine EUA/licensure and recommendations for minors may be a lengthier process than for adults, and recommendations for implementation and prioritization will be complex, making it unlikely that a vaccine for minors would be available before 2022.

Another issue is that vaccine trials focus on safety and efficacy in reducing the vaccinee's morbidity and mortality. They do not offer insight into how the vaccine might affect infectiousness. As noted in the NASEM publication, *Framework for Equitable Allocation of COVID-19 Vaccine*, "The ongoing COVID-19 vaccine trials are not designed to estimate the impact of the vaccine candidates on transmission and evidence of the vaccines' actual impact on transmission might not be available for some time after FDA approval" (Section S-6).[6] Given that the primary goal of vaccinating children and adolescents would be reduction in transmission of SARS-CoV-2 to older adults, determining the impact of candidate vaccines on infectiousness will be essential.

At the core of efforts to first recruit minors into vaccine trials and hopefully participate in SARS-CoV-2 vaccination programs lies the need to restore and expand widespread belief in the trustworthiness of scientific and public health authorities. Erosion of trust in these authorities' perspectives on vaccination research and vaccination began well before the ongoing COVID-19 pandemic,[26] but has been accentuated during this pandemic.[27,28] Marked disparities in SARS-CoV-2 transmission and mortality, as well as politization of public health implementation of NPIs, contribute to the difficulties to be faced in developing and implementing policy for use of a vaccine licensed by the FDA (or with FDA's EUA) and recommended by ACIP for children and adolescents. This is an important issue for adolescents, as many have adopted skeptical perspectives on vaccine research and vaccination, based in larger societal issues of pervasive racism and discrimination, medical mistrust, and systematic misinformation programs addressed to social media platforms widely used by young people.[29,30]

Do We Have to Wait for Vaccine Availability to Move Toward a More Normal, Pre-COVID-19 Lifestyle?

We currently have tools to limit the spread of SARS-CoV-2, including wearing masks, social distancing, handwashing, testing and tracing, and isolating those who test positive or

who have had close contact with others who have tested positive. Although widespread, long-term implementation of NPI protocols during the pandemic has introduced an array of sociocultural and developmental risks for children and adolescents (NASEM, page 1-15),[6] these kind of approaches appeared to be quite effective at protecting children from infection at summer camps in Maine,[31] which implemented comprehensive NPIs, compared with a summer camp in Georgia,[10] which did not.

One challenge is that NPIs have been implemented inconsistently and have become politically polarized.[32] However, there is reason to believe that the same will be true for any SARS-CoV-2 vaccine. Research shows that those who identify as conservative have lower intent to get a vaccine than those who identify as liberal.[33,34] Also, a recent Axios-Ipsos poll indicated that only 39% of adults polled would get a COVID-19 vaccine as soon as it is available (43% of Democrats; 33% of Republicans).[35] We need national and local strategies to promote both NPIs and future vaccines and to overcome the significant attitudinal barriers, including with respect to NPIs and vaccines for children. As noted by Danchin et al, "To build vaccine confidence in general practice, governments need to invest in understanding the factors that will influence COVID-19 vaccine acceptance and plan to co-design strategies with communities to optimise uptake when these vaccines become available" (p. 628).[36] We also clearly need to implement such national and community-based strategies based in expanded understanding of neurocognitive development in adolescence, and in leveraging technology to promote health-serving behaviors such as vaccination.[37,38]

Effective communication about SARS-CoV-2 vaccines also is important to maintain confidence in, and acceptability of, other pediatric and adolescent vaccines. This is particularly important given the significant disruptions in routine childhood and adolescent vaccination delivery due to the COVID-19 pandemic.[39-41] Failures to adequately explain how efficacy of SARS-CoV-2 vaccines will be evaluated and safety ensured, including potential limited efficacy, could result in heightened public hesitancy about vaccination in general. It is encouraging that a recent study found increased parental intent to vaccinate children against influenza due to the COVID-19 pandemic.[42] However, we need to remain vigilant about the potential for public skepticism about SARS-CoV-2 vaccination to spill over to childhood and adolescent vaccines.

Will Vaccine Availability Preclude the Need for NPIs?

"Until we have a vaccine, we have to rely on NPI to manage the pandemic." This sentence, or ones like this, which begin many COVID-19 articles related to NPIs, harken back to behavioral research on HIV prevention. Many research articles started with a similar sentence in reference to controlling HIV and other sexually transmitted infections.[43] As noted in a commentary published in 2000,[43] it is a comment that confers second class status to NPIs and implies that they will no longer be needed once a vaccine is developed and made available.

However, if used properly, NPIs are very effective at controlling the spread of SARS-CoV-2—in fact, possibly more effective than a vaccine with modest efficacy. In addition, accepting and getting vaccinated is, in fact, a behavior. The development and availability of a safe and sufficiently efficacious vaccine will not ensure vaccine impact in the real world. This is a lesson we should have learned from HPV vaccination in the US, when, over 14 years since HPV vaccine was first licensed, the rate of series completion among adolescents is only 54.2%.[41] We remain far from the Healthy People 2020 goal of 80% HPV vaccine series completion.[44]

In addition, without clear communication about vaccine efficacy (or limitations of efficacy) and length of protection, there exists the potential for risk-compensation. That is, if behavioral/social (NPI) mitigation efforts are substantially decreased due to reduced concerns about infection once a vaccine or vaccines are licensed by the FDA or receive FDA's EUA and are recommended by ACIP, and vaccines have only modest efficacy and/or low uptake, then vaccine availability could have the perverse consequence of increasing rates of SARS-CoV-2 infection.

Similarly, the availability of a vaccine also may result in school and public authorities prematurely lifting NPI restrictions or reducing enforcement of such policies, again potentially leading to continued outbreaks of infection. Although risk-compensation is not an issue with HPV vaccination,[45] the intense desire to return to pre-COVID-19 lifestyles and/or to moderate NPI-related sociocultural and developmental impacts suggest that risk-compensation may become an issue with SARS-CoV-2 vaccines. It is essential, therefore, that public health authorities and health professionals begin now to communicate with patients and the public in general about the likelihood that behavioral mitigation strategies will continue to be needed even in the context of an approved SARS-CoV-2 vaccine.

Conclusions

There is a strong rationale for including children and adolescents in SARS-CoV-2 vaccine clinical trials and for including minors as important targets for vaccination, principally to protect older adults with whom they interact and to achieve potential community protection. At the same time, it is essential that we temper the expectations that availability of 1 or more SARS-CoV-2 vaccines will allow children, adolescents, and adults to resume a normal, pre-COVID-19 life. The many uncertainties about COVID-19, about the efficacy and safety of candidate vaccines, and about the duration of vaccine-induced immunity make it particularly important that we are as clear as possible in our communications about COVID-19, potential vaccines, and the almost certain situation that NPIs will still be needed for some time to come. Such clarity of communication at the national and

community levels also will help to maintain confidence in other childhood and adolescent vaccines. The development and availability of SARS-CoV-2 vaccines will represent important steps in managing the COVID-19 pandemic, but they are likely 1 element in a multifaceted set of strategies that we will need to employ. ■

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