World Health Organization

Interim statement on COVID-19 vaccination for children

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WHO, with the support of the Strategic Advisory Group of Experts (SAGE) on Immunization and its COVID-19 Vaccines Working Group, is reviewing the emerging evidence on the need for and timing of vaccinating children and adolescents with the currently available COVID-19 vaccines, which have received Emergency Use Listing (EUL). SAGE is continuously reviewing the literature and has reached out to vaccine manufacturers, the research community and Member States to obtain the most complete and recent data on this issue. This interim statement was developed with additional support from the Strategic and Technical Advisory Group of Experts (STAGE) on maternal, newborn, child, and adolescent health, and nutrition.

This interim statement is not a policy recommendation. It examines the role of COVID-19 vaccines in children and adolescents in the global context of inequitable vaccine distribution and access across countries at a time when many countries have not yet achieved high vaccine coverage rates in the highest and high priority-use groups.

Background

The greatest burden of disease in terms of severe disease and deaths remains among older persons and those with comorbidities. This evidence informed the WHO Prioritization Roadmap, which identifies high priority-use groups according to vaccine supplies available to countries(1). WHO recognizes that various countries are in different pandemic phases with different vaccination coverage rates.

Significant progress has been made on the vaccination front: nearly every country has implemented COVID-19 vaccination and over 12 billion doses have been administered globally,

resulting in WHO Member States reaching on average 60% of their populations(2). This massive and unprecedented COVID-19 vaccine deployment has led to major reductions in severe disease, hospitalization and deaths (so-called de-coupling of cases and deaths), allowing societies to re-open and averting an estimated 19.8 million deaths in 2021. Continued use of currently licensed vaccines based on the index virus confers high levels of protection against severe disease for all variants.

However, global disparities in vaccination continue; and many countries have not yet achieved high vaccine coverage of the most at-risk populations. Specifically, only 25% of older populations have received a complete primary series of COVID-19 vaccines in lower income countries, the very places where healthcare access is more limited(2).

The updated WHO global vaccination strategy targets 100% coverage for all older adults and health workers(2). Furthermore, countries should strive towards broader population immunity, measured as progress against the global target of 70% of the total national population, and against context-specific country targets. This acknowledges that countries will determine the breadth of their COVID-19 national vaccination programmes considering factors such as: local COVID-19 epidemiology, demographics, opportunities to leverage COVID-19 to strengthen primary health care systems, other health priorities, socio-economic risks from future waves of disease, population demand for breadth of vaccination, and sustainability of vaccination efforts.

There are currently no vaccine supply constraints. Although the majority of COVID-19 vaccines are only approved for use in adults aged 18 years and above, an increasing number of vaccines are now also being authorized for use in children. Some countries have given emergency use authorization for mRNA vaccines (Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273) for use in the age groups of 6 months and above. Trials in children as young as age 3 years were completed for two inactivated vaccines (Sinovac-CoronaVac and BBIBP-CorV) and these products were approved by Chinese authorities for the age indication of 3-17 years. Although COVID-19 vaccines such as CoronaVac, Novavax and BBIBP-CorV have received EUL for adults, they have not yet received WHO EUL for the use in children. Covaxin, an adjuvanted inactivated vaccine developed by Bharat, was approved in India for the age indication of 12-17 years; but has not yet received WHO EUL for this age indication. Several other COVID-19 vaccines, not yet emergency use listed by WHO, have obtained paediatric age indication in various countries.

Burden of disease in children and adolescents

SARS-CoV-2 typically causes less severe illness and fewer deaths in children and adolescents compared to adults. Nonetheless, children and adolescents remain susceptible to SARS-CoV-2 infection and may transmit the virus to others, with the risk of both infection and transmission increasing with age(3). The risk of transmission to and from children also depends on the level of

community transmission, the public health and social measures implemented to control the virus as well as biological factors related to the virus itself (i.e., the type of variant circulating).

During the initial pandemic phase with the ancestral strain, age-disaggregated cases reported to WHO, covering the time period from 30 December 2019 to 25 October 2021(4) show that children under five years of age represent 2% (1 890 756) of reported global cases and 0.1% (1 797) of reported global deaths. Older children and younger adolescents (5 to 14 years) account for 7% (7 058 748) of reported global cases and 0.1% (1 328) of reported global deaths while older adolescents and young adults (15 to 24 years) represent 15% (14 819 320) of reported global cases and 0.4% (7 023) of reported global deaths. Deaths for all those aged under 25 years represented less than 0.5% of reported global deaths.

Reported COVID-19 cases among children spiked dramatically in 2022 during the Omicron variant surge at a time when most countries relaxed public health and social measures. For example, in the United States, by July 2022, 14,003,497 cases in children were reported, and children represented 18.6% (14,003,497/75,463,921) of all reported cases, with an overall rate of 18,605 cases per 100,000 children in the population(5). Globally, by 24 July 2022, children below the age of 5 years and those aged 5-14 years presented 2.47% and 10.44% respectively(6). Adolescents and young adults aged 15 to 24 years presented 13.91% of all cases. Children aged 5 years and below account for 0.11% of all global deaths, while children aged 5 to 14 years accounted for 0.089% and adolescents and young adults 0.37% of all globally reported deaths(6).

Milder symptoms and asymptomatic presentations may mean less frequent care seeking in these groups, thus children and adolescents tend to be tested less and cases may go unreported. An age-dependent risk of severe disease with those under one year of age experiencing more severe disease has been suggested(7, 8) with neonates (infants in the first 28 days of life) and premature infants at higher risk of severe COVID-19, although several reviews show that neonates tend to have mild disease when compared with other paediatric patients(9, 10). It is important to note that children under the age of five years have a higher risk of other diseases with clinical presentations that overlap with COVID-19, such as pneumonia and other viral upper respiratory tract infections, which may lead to misclassification. Additionally, age disaggregation has not been systematically provided in the literature, and the results of these studies are context-specific depending on factors such as timing within the pandemic and an emphasis on hospitalized patients(8).

Children and adolescents can experience prolonged clinical symptoms (known as “long COVID-19”, post COVID-19 condition(11), or post-acute sequelae of SARS-CoV-2 infection), however, the frequency and characteristics of these conditions are still under investigation, and to date they appear to be less frequent compared to adults. Additionally, a hyperinflammatory syndrome, although rare, has been reported to occur world-wide and complicates recovery from COVID-19(12,

13). This is referred to as paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS) in Europe and multisystem inflammatory syndrome in children (MIS-C) in North America(14).

Several risk factors for severe COVID-19 in children have been reported, including older age, obesity, and preexisting conditions. The preexisting conditions associated with higher risk of severe COVID-19 include type 2 diabetes, severe asthma, heart and pulmonary diseases, seizure disorders and other neurologic disorders, neurodevelopmental (e.g. Down Syndrome) and neuromuscular conditions(15), and moderate to severe immunocompromising conditions.

The most substantive evidence on the risk of severe COVID-19 and death in children and adolescents comes from studies in high resource settings, so the generalizability of the following observations to lower resource settings remains to be determined. One systematic review suggests that there may be larger impact of paediatric COVID-19 related fatality in low to middle income countries versus high income countries (16).

The role of children and adolescents in transmission of SARS-CoV-2

Outbreaks of COVID-19 have been identified in secondary schools, summer camps and day care centres, particularly when neither physical distancing nor masks were used to reduce transmission risks. There is some preliminary evidence that younger children may be less infectious, as measured by secondary attack rates, than adolescents and adults(17). Data on the global incidence of COVID-19 suggest adolescents test positive for SARS-CoV-2 at a higher proportion than younger children, however seroprevalence surveys are required to provide more conclusive information on infection rates.

Children who become infected with SARS-CoV-2 shed the virus in their respiratory tract and also in their faeces(18). Amongst individuals positive for SARS-CoV-2 who were tested at the same time point after symptom onset, levels of SARS-CoV-2 viral RNA shedding in the respiratory tract appeared similar in children, adolescents, and adults(19). The relationship between age, viral load, and transmission across the full symptom spectrum of SARS-CoV-2 infection has not been comprehensively investigated because people with no, or mild symptoms are seldom tested systematically. The relative transmissibility of SARS-CoV-2 at different ages remains uncertain, largely due to the challenges involved in disentangling the influences of biological, host, virus, variants of concern, and environmental factors(20).

Persistence of anti–SARS-CoV-2 spike receptor-binding domain IgG was investigated in a household cohort study in Italy. Even following asymptomatic infections, antibodies persisted until 12 months after infection in all age groups, showing significant higher antibody peaks for younger

individuals at every follow-up time point. Children younger than 3 years were found to develop higher levels of binding antibodies compared with adults older than 18 years(21).

Socio-economic impact of the COVID-19 pandemic and pandemic response on children and adolescents

Despite their lower risk of severe COVID-19 disease, children and adolescents have been disproportionately affected by COVID-19 control measures. The most important indirect effects are related to school closures which have disrupted the provision of educational services and increased emotional distress and mental health problems(22). When unable to attend school and socially isolated, children are more prone to maltreatment, sexual violence, adolescent pregnancy, and child marriage, all of which increase the probability of missing further education and of poor pregnancy outcomes.

A range of follow-on effects of school closures occur. These include disruption in physical activity and routines and loss of access to a wide range of school-provided services such as school meals, health, nutrition, water, sanitation and hygiene (WASH) and services targeted to children with special needs such as learning support, speech therapy and social skills training. Children not attending school face enhanced risks of cyberbullying from other children, and the potential for predatory behavior from adults related to spending more time online.

Longer-term, prolonged school closures lead to education loss and exacerbation of pre-existing inequalities. It is estimated that 24 million children were at risk of not returning to school owing to the pandemic(23); those affected have been estimated to incur a US$10 trillion loss in lifetime earnings (24). At a societal level, the economic devastation wrought by COVID-19 may take years to overcome, exacerbating economic inequalities, poverty, unemployment, household financial insecurity, food insecurity, and malnutrition, all of which negatively impact children, often disproportionately.

Routine immunization services have also been negatively affected as a result of the pandemic response, thereby exacerbating the potential resurgence of vaccine-preventable diseases such as measles, tetanus, yellow fever, HPV, and others(25). The COVID-19 pandemic caused the largest backslide in immunizations in the past three decades(26); about 23 million children missed their routine childhood vaccinations.

Safety of COVID-19 vaccines in adolescents and children:

In Phase 2/3 trials for both mRNA vaccines, efficacy and immunogenicity were similar or higher compared to adults; safety and reactogenicity profiles in adolescents were similar to young adults. During the Phase 3 trials in young children aged 6 months to 5 years no safety signal was identified,

but the sample size was too small to identify rare events.

In post-introduction studies and real-world experience, a very rare serious adverse event was reported: myocarditis/pericarditis. Cases of myocarditis/pericarditis occurred more often in younger men (16-24 years of age) and after the second dose of the vaccine compared to older adults and also children. These cases of myocarditis and pericarditis typically occurred within a few days after vaccination, are generally mild, respond to conservative treatment, and are less severe with better outcomes than classical myocarditis or COVID-19 related myocarditis. The risk of myocarditis/pericarditis associated with SARS-CoV-2 infection is higher than the risk after vaccination(27). In October 2021, the Global Advisory Committee on Vaccine Safety (GACVS) concluded that in all age groups the benefits of mRNA COVID-19 vaccines in reducing hospitalizations and deaths due to COVID-19 outweigh the risks.

The risk of Thrombosis with Thrombocytopenia Syndrome (TTS) following adenoviral-vector vaccines, although overall low, was higher in younger adults compared to older adults, but no data are available on the risk below the age of 18 years(28).

Post-introduction effectiveness data of COVID-19 vaccines in children and adolescents

Here we only present data for vaccines which have received WHO EUL in children and/or adolescents.

In Israel, during the Omicron dominant period, the estimated vaccine effectiveness (VE) of BNT162b2 against symptomatic COVID19 was 18% (95% CI, −2 to 34) at 14 to 27 days after the first dose and 48% (95% CI, 29 to 63) at 7 to 21 days after the second dose. There was a trend toward higher VE in the youngest age group (5 or 6 years of age) than in the oldest age group (10 or 11 years of age) (29).

In the United States, during the period of Omicron predominance, COVID-19–associated hospitalization rates in children aged 5–11 years were studied in the COVID-19-Associated Hospitalization Surveillance Network. The cumulative hospitalization rate during the Omicron-predominant period was 2.1 times as high among unvaccinated children (19.1 per 100,000 population) as among vaccinated children (9.2). Non-Hispanic Black children represented the largest group of unvaccinated children. Thirty percent of hospitalized children had no underlying medical conditions, and 19% were admitted to an intensive care unit. Children with diabetes and obesity were more likely to experience severe COVID-19(30).

The effectiveness of 2 doses of BNT162b2 vaccine received ≥28 days before hospital admission in preventing MIS-C was assessed using a test-negative case-control design among hospitalized patients aged 12-18 years during the Delta variant predominance. Patients with MIS-C (case-

patients) and two groups of hospitalized controls matched to case-patients were evaluated. Among 102 MIS-C case-patients and 181 hospitalized controls, estimated effectiveness of 2 doses of BNT162b2 vaccine against MIS-C was 91% (95% CI = 78%-97%). All 38 MIS-C patients requiring life support were unvaccinated. Receipt of 2 doses of the BNT162b2 vaccine is associated with a high level of protection against MIS-C in persons aged 12-18 years(31).

Leveraging a population-based cohort in Chile of 490,694 children aged 3-5 years, administering a two-dose schedule, 28 days apart, of Sinovac CoronaVac VE was 38% (95% confidence interval (CI), 37-40) against symptomatic COVID-19, 65% (95% CI, 50-75) against hospitalization and 69% (95% CI, 19-88) against ICU admission(32).

The vaccine impact on transmission within households prior to the emergence of Delta was reported to be about 50% (33). However, the impact of vaccination on reducing transmission in the context of the more transmissible delta variant appears to be lower(34) and even lower for Omicron.

COVID-19 in comparison with influenza

In the United States, in the setting of extensive mitigation measures during the COVID-19 pandemic, the annual COVID-19-associated hospitalization rate during 2020-2021 was higher among adolescents and similar or lower among children <12 years old compared with influenza during the three seasons before the COVID-19 pandemic(35). In children 0-4 years (COVID-19: 25.0 per 100,000), and 5-11 years (COVID-19: 66.8 per 100,000), the rate of hospitalization is similar for COVID-19 and influenza while the rate of hospitalization in those aged 12-17 years is higher for COVID-19 (COVID-19: 59.9 per 100,000; Influenza: 12.2-14.1 per 100,000). Among hospitalized children, 22% with influenza and 26% with COVID-19 required ICU admission. More data to compare COVID-19 with influenza are needed beyond the United States.

Considerations for vaccinating adolescents and children

COVID-19 vaccines with WHO EUL that have undergone clinical trials in children and adolescent are safe and effective in preventing disease in children and adolescents. Children with comorbidities and severe immunocompromising conditions should be offered vaccination(36).

Although benefit-risk assessments clearly underpin the benefit of vaccinating all age groups, including children and adolescents to reduce the number of infections, hospitalizations, deaths and long-COVID , the direct health benefit of vaccinating healthy children and adolescents is lower compared with vaccinating older adults due to the lower incidence of severe COVID-19 and deaths in younger persons. As children and adolescents tend to have milder disease compared to adults, unless they are in a group at higher risk of severe COVID-19, it is less urgent to vaccinate them than older people, and those with chronic health conditions and health workers.

However, there are benefits of vaccinating children and adolescents that go beyond the direct health benefits. Minimizing disruptions to education for children and maintenance of their overall well-being, health and safety are important considerations. Vaccination that decreases SARS-CoV-2 transmission in this age group may reduce transmission from children and adolescents to older adults, and may help reduce the need for mitigation measures in schools. However, during the current Omicron dominant period, vaccine impact on transmission is only modest and short-lived.

Countries' strategies related to COVID-19 control should facilitate children's participation in education and other aspects of social life, and minimize school closures, even without vaccinating children and adolescents (37). UNICEF and WHO have developed guidance on how to minimize transmission in schools and keep schools open, regardless of vaccination of school-aged children(38). Teachers, family members, and other adult contacts of children and adolescents should ideally all be vaccinated for direct protection.

Countries should consider the individual and population benefits of immunizing children and adolescents in their specific epidemiological and social context when developing their COVID-19 immunization policies and programs.

Aligned and coordinated action is needed to achieve the global COVID-19 vaccination targets. The decision to vaccinate adolescents and children must account for prioritization to fully protect the highest risk subgroups through primary vaccination series, and as vaccine effectiveness declines with time since vaccination, through booster doses. As such, before considering implementing primary vaccination series in adolescents and children, attaining high coverage of primary series - and booster doses as needed based on evidence of waning and optimizing vaccination impact - in highest and high priority-use groups, such as older adults, must be pursued(39). Furthermore, it is of utmost importance for children to continue to receive the recommended childhood vaccines for other infectious diseases.

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