Ethical Viewpoint Paper

Equitable Use of Vaccines: A Pandemic Perspective

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Introduction
Coronavirus disease-19 (COVID-19), caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), started as an outbreak of atypical pneumonia in the Wuhan region of China in December 2019 and since then, has become a global pandemic [1]. The pandemic continues to cause a significant morbidity and mortality with multiple waves already hitting the globe with over four hundred eighty-three million cases and six million deaths reported as per latest literature [2]. The vaccination campaign for COVID-19, which is the biggest in the history of mankind, began on 13th December 2020 and brought with it hope and promise, albeit, not without ethical dilemmas. The global vaccination strategy by World Health Organization (WHO), which aimed to achieve 40% coverage of each country's population by end of 2021 and 70% by mid-2022, was established to ensure an equitable rate of vaccine rollout across the globe as well as prioritization of those at highest risk [3]. According to WHO data, as of 8th September 2021, about 5.5 billion vaccine doses were administered, though unfortunately about 80% in only high- and upper-middle income countries. While almost 90% of high-income countries had reached the 10% target, and more than 70% had reached the 40% target, not a single low-income country has reached either target [4]. In this paper, we discuss the fundamental characteristics of booster doses and vaccination of children and adolescents followed by the ethical conundrums related to them using the bio-ethical pillars of beneficence, non-maleficence and justice.

Booster Doses
Booster doses, as described by WHO, are "vaccine doses that are administered to a vaccinated population that has completed a primary vaccination series when, with time, the immunity and clinical protection has fallen below a rate deemed sufficient in that population" [5]. The main aim of this booster dose is to replenish antibody titres in the body from levels that are deemed no longer sufficient for providing protection. These are single doses given following a specified period after completion of the primary course (one or two doses depending on the type).

Need for booster
The concept of further decreasing the COVID-19 cases by augmenting immunity in already vaccinated people sounds appealing, but the same should be evidence-based and only after weighing the risk-benefit ratio at an individual and community level.

Data from various observational studies have shown a decline in vaccine effectiveness against COVID-19 as time elapses, the decrease being more significant in older age groups [6]. A recent meta-analysis across four vaccines showed similar results, with effectiveness against severe disease in all age groups decreasing by around 8% over a six month period from the last dose. A more significant reduction of 10% and 32% were noted in those over 50 years of age against severe and symptomatic disease respectively. This demonstrates the waning effect of protection against the clinically important forms of the disease [7]. Important factors that influence the degree of waning protection include type of vaccine, primary schedule used, variant of circulating virus, and extent

of community infection at the time of vaccination, though the contributory role of each cannot be quantified. Booster doses might ultimately be necessary because of waning immunity or because of newly evolving variants against which the available vaccines are ineffective, while children and adolescents may benefit from vaccine coverage, though, not without its clinical benefit being proven.

Children And Adolescents

During the pandemic, infection with SARS-CoV-2 has been reported in all age groups including neonates, infants, children, and adolescents. Unlike adults, children have different disease characteristics with respect to disease load, clinical presentation and community transmission.

Burden of disease in children and adolescents

Overall, the pandemic has seen a lower proportion of symptomatic infections as well as severe disease and deaths due to COVID-19 infection in children and adolescents as compared to adults. WHO data from 30 December 2019 to 21 March 2022 showed that of the total 483,556,595 cases and 6,132,461 deaths, children below five years of age accounted for 1.2% (5,756,585) of reported global cases and 0.04% (2,442) of reported global deaths. Among the older children and younger adolescents (5 to 14 years), 5.3% (25,410,148) was the reported global case load and 0.03% (1,735) represented reported deaths worldwide. Older adolescents and young adults (15 to 24 years) represented 7% (33,840,582) and 0.14% (8,649) of reported global cases and deaths respectively.(2) Initially it was postulated that infants (children below 1 year of age) might be at increased risk of a more severe clinical course [8], though it was subsequently discarded as infants, and even neonates, were also found to have predominantly mild or asymptomatic presentations [9-10]. Mortality for all age groups below 25 years comprised barely 0.2% of the number of reported global deaths [2]. A population-based study in Switzerland found that a significantly lower seroprevalence was observed for children aged between 5-9 years and adults over than 65 years, compared with those aged 10-64 years, highlighting the possibility of reduced burden of morbidity and mortality in children [11].

Milder illness

While adults were commonly affected by COVID-19, young children and adolescents were not spared. Children affected by COVID-19 were noted to have a clinical presentation that ranged from asymptomatic individuals to those with mild-moderate symptoms. A meta-analysis of early data reported that a fifth (21.1%) of all SARS-CoV-2 infections in children were clinically asymptomatic, and severe cases accounted for only 3.8% of them [12]. A similar meta-analysis published in April 2021 also found similar results with children having milder clinical presentations, better prognosis, and lower mortality rate compared with adult patients [13]. Milder or asymptomatic clinical presentations could eventually result in less healthcare seeking behaviour, reduced testing and under-reporting of cases. As a result, exact numbers of children affected during the pandemic are difficult to ascertain.

Lower Transmission Rates

It has been postulated that differences in the innate immune system of children leads to mounting of a better immune response, thus rendering them less susceptible to acquiring the infection [14]. Though the association of SARS-CoV-2 viral load and severity of symptoms is doubtful [15], patients with higher viral load have higher risk of transmission. The exact role that children play as a source of infection to adults, and particularly the highly vulnerable older relatives in the house, has not yet been determined. A study found a lower secondary attack rate and SARS-CoV-2 positivity rate among students compared to school staff thereby suggesting that children may not be as infectious as adults. National lockdowns and school closures which characterized the pandemic period had restricted the mobility of the children and thereby reduced the number of non-household persons meeting the children. However, with the opening of schools, summer camps and day-care centres, particularly when masking of children remains challenging, providing them with protection is essential to ensure their safety.

Beneficence

The benefits of vaccine doses on the level of protection attained have been extensively researched globally, though limited data is available on certain niche areas such as booster doses and vaccination in children.

i. Effectiveness And Benefits of Booster Doses

The beneficial value of the booster vaccination needs to be considered at two levels – individual and community.

a) **Individual protection:** An increasing number of studies have demonstrated a beneficial effect of booster doses in protection of the individual against infection, mild disease along with reduction in severe disease and death [16-18]. Though limited in size and duration of follow-up, they suggest that the booster would reduce the risk of the vaccinee contracting the infection and the severity of the illness should he/she fall sick, thereby improving overall outcomes. A recent study by Spitzer and colleagues has shown an increase in protection by around 7% after the booster dose [19]. Heterologous booster schedules were also evaluated and found to substantially increased protection, though this beneficial effect waned over a period [20].

b) **Community benefit:** At a community level, vaccination of individuals with booster doses, thereby augmenting their immunity, would appear to have a beneficial role though limited data is available. Booster doses reduce the viral load and as a result, the community transmission. As the infection rate would reduce, particularly in unvaccinated individuals, this would directly reduce the potential for mutations and formation of variant strains, leading us closer to the end of the pandemic. In addition, boosting immunity to reduce symptomatic and severe cases reduces the number of patients requiring admission to hospitals [21]. This prevents overburdening of the healthcare system allowing for better utilization of resources and health care personnel in other health promoting activities and services. Booster vaccination for healthcare workers would have an additional benefit of reducing the spread of virus from hospital to the general community. This evidence confirms that booster vaccinations significantly benefit not only the individual, but also the community at large.

ii. Effectiveness and benefits of vaccination in children:

a) **Vaccine efficacy:** Various trials have studied the effectiveness of COVID vaccinations in adolescents and children, though with methodological limitations. A case control study by the Overcoming Covid-19 Investigators analysed 445 case patients and 777 controls to identify the benefit of BNT162b2 vaccine in adolescents. The study reported an overall effectiveness of 94% against hospitalization for COVID-19, 98% against intensive care admission and 98% against receipt of life support [22]. A phase 2-3 randomized trial revealed that for children aged 5-11 years, the same vaccine had a 90.7% efficacy with a favourable safety profile [23]. However, despite these promising results, there remains a lack of robust scientific evidence on the efficacy of vaccines in these age groups.

b) **Other key benefits of vaccination in children:** The key areas in which children were disproportionately affected as compared to adults were related to closing of schools leading to disruption of educational services as well as increased emotional and psychological distress [24]. Prolonged confinement at home, reduced fellowship with peers, absence of school and extracurricular activities, increased sedentary habits, and increased reliance on media and electronic equipment to pass time, have all contributed to psychological and psychiatric symptoms. Though home should be the safest place for a child, there has been a significant escalation in physical, sexual, and psychological abuse [25-26]. An unpublished study in the Shaanxi province of China identified that the most common psychosocial and behavioural problems among 320 children and adolescents in the pandemic included inattention, clinginess, distraction and fear of asking questions about the pandemic [27]. This risk is further augmented in those children with pre-existing mental health conditions. Vaccination of children, thereby

allowing them to go outdoors and lead a relatively normal life without additional risk of infection, would help to limit these harmful effects of the pandemic and advance other highly valued societal goals. The long-term impact of these goals might play an important role in reducing psychological and mental illnesses.

Non-Maleficence

While use of vaccines for both booster doses and vaccination of children and adolescents has their definite benefits, the other side of the coin remains considerably less researched at the moment. In the available literature, adverse effects of the vaccine have been reported with increasing number of doses and younger age groups.

i. **Adverse effects of vaccine:** While the benefits of primary vaccination against COVID-19 clearly outweigh the risks, increased adverse events could be seen if boosters are introduced too early (without adequate safety data) or too frequently (reduced inter-dose interval). This is especially true for vaccines that could have immune-mediated side-effects such as myocarditis and Guillain-Barre syndrome. Myocarditis observed following m-RNA vaccine has been previously described, most commonly after the second dose [28]. A large meta-analysis of over 2100 individuals with post-vaccine myocarditis showed that it was more common among young males, most of whom had no comorbidities [29]. Though the overall risk of Thrombosis with Thrombocytopenia Syndrome (TTS) after adenoviral-vector vaccines was low, it was found to be higher in younger adults compared to older adults [30]. However, no data is available on the risk below 18 years. Guillain-Barre syndrome has also been associated with vaccination with adenovirus-vectored COVID-19 vaccines [31-32]. A collation of adverse events along with their frequency, severity, treatment and complications should be undertaken to improve the scientific knowledge on the same.

ii. **Effect on other vaccination programs:** Another long-term effect of premature booster dose roll-out is the negative implications that increased adverse effects are likely to have on overall vaccine acceptance beyond COVID-19 vaccines. A qualitative study in India in 2009 demonstrated how a similar intensified frequency of vaccination against polio in a bid to accelerate the eradication process was correlated with increased patients' doubt and fear in the efficacy of the vaccine [33]. This could result in a multitude of vaccine preventable diseases flaring up culminating in an even more overburdened healthcare system with severe morbidity and mortality particularly among children. This unseen pandemic could have catastrophic implications on the health care system in the years to come.

iii. **Rise of the mutants:** The pandemic is a global fight and victory cannot be achieved by countries on their own. The current situation of inequitable vaccine distribution across countries amidst globally limited vaccine supply has resulted in achieving high levels of protection in one nation with a simultaneous rise in cases in another. When scarce vaccines are used as boosters, rather than for primary vaccination of the unvaccinated, it allows the virus to spread, replicate and mutate, potentially creating variants of concern that undercut the vaccine-derived protection and allow the pandemic to propagate.

Justice:

When discussing the principle of justice, we need to look not only at the availability, but also at the utilization of the vaccines and the hierarchy of priority that should be followed when the vaccine doses are rolled out to ensure ethical and equitable distribution.

i. **Availability:** The production of COVID-19 vaccines has rapidly surged globally since their approval by the WHO and other regulating bodies. It had been projected that the global vaccine supply would be adequate for vaccination of the entire global adult population along with boosters for high-risk populations only by the first quarter of 2022 [3]. These projections also show that supply would be sufficient for extensive booster use in all adults only later in

the year 2022. This highlights the fact that inadequacy of doses for booster till the latter half of 2022 was anticipated. This was very close to reality as data from April 2021 concurs with this as 25% of population in high-income countries had been vaccinated as compared to a mere 0.2% in low-income countries. In a public address, WHO Director General Dr. Tedros Adhanom Ghebreyesus acknowledging this global divide said, "There remains a shocking imbalance in the global distribution of vaccines. On average in high-income countries, almost one in four people have received a COVID-19 vaccine. In low-income countries, it's one in more than 500". By September 2021, over 4 billion vaccine doses had been administered around the world with more than 80% having been given in high-income and upper-middle income countries, even though they make up less than 50% of the global population [4]. In view of the above, he called for a moratorium on booster doses, to enable more appropriate distribution of vaccine doses to the countries that were still struggling to vaccinate 40% of their population. However, as of December 2021, at least 126 countries had already issued advisories on booster vaccination with greater than 120 having started programmatic implementation. A majority of these countries were high-income, or upper middle-income, with no low-income country having yet introduced a booster vaccination programme [5].

ii. **Utilization:** While there is a strong ethical argument for delaying boosters, many people feel it is not strong enough to override a nation's duty to protect its own citizens. Some believe in adopting an "influenza standard, which is that governments may be justified in prioritizing their own citizens until the COVID-19 risks are like that of the influenza season. After that point, the governments would be expected to send vaccine supplies to countries with greater needs. Another justification for boosters and vaccination of children and against donation of vaccines to low-income countries was lack of infrastructure for the safe storage, distribution and utilization of vaccines. Many African countries encountered difficulties in maintaining proper storage of vaccinations leading to a huge number of doses being discarded. It was found that the acceptance rate of COVID-19 vaccines among a young adult population in Cameroon was barely 15% [34]. The major issues, as reported by the study participants, included anti-vaccine campaigns and confusing information on social media warning locals not to take the vaccines, negative perceptions of the vested interests of the pharmaceutical industry, concerns about the validity and efficacy of the vaccines, and economic burden to the individuals. The gross disparities noted between vaccine haves and have-nots violate the basic ethical principle of health equity. Equitable distribution of vaccines would thus also necessitate building of infrastructure to overcome these implementational difficulties.

iii. **Prioritization:** To optimize the impact of the available doses, it is essential to maximize vaccine coverage among the vulnerable and high-risk population. This population includes all those who are most likely to become severely ill such as older adults and immunocompromised individuals, as well as those who are essential for the functioning of the health care system and essential services. Using this logic, booster doses to senior citizens, immunocompromised individuals, health care and essential workers can be justified. However, opening booster doses to low-risk population seems like a gross waste of valuable life-saving resources. This needs to be viewed from a global perspective and not just at a national level with blinders on. When compared with each other, global coverage of primary schedule takes priority over selective booster vaccinations and these options must be weighed and prioritized carefully. Sadly, as of December 2021, globally around one out of five vaccine doses are used for booster or additional dose vaccination daily, defying all principles of equitable distribution [5]. Even if booster doses were shown to decrease the risk of severe disease, currently available vaccine supplies could save more lives (and reduce morbidity as well) if given to previously unvaccinated individuals than if used as boosters in vaccinated populations

In an aptly titled paper "Three for me and none for you? An ethical argument for delaying COVID-19 boosters", the authors vehemently argue the need for delaying booster doses until low-income countries can vaccinate a substantial proportion of their population [35].

Describing utility as showing equal consideration to the interests of everyone affected by a distributive policy, irrespective of place of residence and level of wealth or income, Jecker et al highlights the great divide in vaccination availability, need and distribution. The additional benefit of 7-10% protection with boosters is too small compared to the 85-90% benefit conferred on unvaccinated individuals after the primary vaccination is complete. Similarly, with children and adolescents, given the fact that the protection received by them is lower than that received by adults receiving primary vaccination, the latter must be prioritized, especially in resource limited and under-developed settings. Factors in low-income countries such as restricted access to medical facilities, lack of sanitation and isolation facilities, overcrowding, and non-availability of adequate personal protective equipment among health care providers stresses the importance of primary vaccination in these countries.

Future research needs:

Prior to the recommendation of booster doses to the general low-risk population and primary vaccination of children and adolescents, more data is required on dynamic factors such a burden of disease and its impact on the healthcare system, vaccine booster dose effectiveness, duration of protection, and comparison of heterologous versus homologous dosing schedules. Other aspects that need evaluation include the optimum timing of the booster dose, possibility of fractional doses for booster (dose-sparing) to ensure greater coverage, benefit of booster doses in recently infected individuals, in addition to improvement in the supportive framework to ensure feasibility and sustainability along with community demand for the vaccine. A predictive model could be developed based on available literature, taking all the above into consideration, to identify those at most need of the vaccination. This would ensure objectivity in the prioritization process and avoid inequity in the distribution of the few available doses. In addition to health benefits in the form of survival and hospitalization, quality of life and other indicators such as mental health and psychological impact should also be factored in.

Conclusions

The current trend of giving vaccines to enhance coverage in form of adult booster doses or as part of primary vaccination of children, while a large proportion of vulnerable adults in various parts of the world remain unvaccinated, poses an ethical dilemma that is bigger than even the debate over the two. Even if boosters and vaccination of children save lives and prevent severe disease, the benefit is far less than primary vaccination itself. The optimal strategy of vaccine coverage would include primary vaccination in countries lagging, with simultaneous building of infrastructure to facilitate the same. Booster doses could then be implemented in a phased manner among the high-risk groups depending on availability and priority. Adequate robust data is essential in children and adolescents, particularly about adverse effects, before their primary vaccination can be made a recommendation. The on-going profound inequities in global vaccine access need to be tackled at an international level, with developed countries coming forward and leading the way for a more united front against the worst pandemic of our time.

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