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Opinion

Coronavirus (COVID-19) Vaccine for Children and Teens: Is it an Urgent Priority?

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On May 10th, the Unites States. Food and Drug Administration (FDA) extended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of coronavirus disease 2019 (COVID-19) to include adolescents 12 through 15 years of age [1].

The legitimate question:: is this an urgent priority. To know the answer, we have to address the following questions or concerns:

1. Research in children is recognized as a moral duty based on several ethical principles [2,3]. In research, children are considered a vulnerable (minor) group and so different ethical, efficacy and safety are important factors to be considered differently from adults. Relative risks and benefits to be asses according to the component analysis [4]. Component analysis distinguishes risks that are associated with therapeutic risks (and the prospect of direct benefit to the child) from nontherapeutic risks (wherein procedures are undertaken solely to satisfy the needs of the research question). This is true for all research projects in paediatrics but more important in case of vaccines. Vaccines to be licensed, should go through many long period of research and rigorous evaluation by the regulatory health organizations addressing safety and efficacy standards. An active follow--up for the safety should be at least for 6 months after the end of the trial.

   Children differ from adults in several aspects including the developmental changes in the immune system during childhood. This has big impact on the effectiveness of childhood vaccines for other diseases and conditions and could affect COVID-19 immunization responsiveness in this special population.

2. **COVID-19 in children:** Children and teens comprise only 1 - 2% of cases of COVID-19 disease worldwide [5]. In surveillance from different countries, children comprise up to 15% of laboratory- confirmed cases. COVID-19 related death in children and adolescents is rare. Data from countries (France, Germany, Italy, South Korea, Spain, the United Kingdom, and the United States) the COVID-19-related death rates among children (age 0 - 19 years) was 0.17/100,000. Testing data t from March 2020 to February 2021 to identify Children (< 18 years) who died with a positive COVID-19 test utilizing National Child Mortality Database (NCMD) which was linked to Public Health England (PHE), it was estimated that the infection fatality rate is 5 per 100,000 indicating >99.995% of children younger than18 years old recover from SARS-CoV-2 infection [6]. SARS-CoV-2 contributed to 0·8% of the 3105 deaths from all causes [6].

   Multisystem inflammatory syndrome in children (MSI-C): It accounts for less than 1% of children with documented COVID-19 infection. It varies by race and ethnicity. It has been reported more in Black and Hispanic children and Asian children

accounting for less number of cases [7]. The pathophysiology of MIS-C not clear. It has been proposed that MIS-C results from immune dysregulation which is triggered by COVID-19 infection resulting in cytokine storm. A post infection is suggested. Host factors are more likely are responsible for this immune dysregulation.

3. **The effects of virus variants on COVID-19 vaccines:** Virus mutation increases when the circulating virus in the population and infections are high. Available vaccines are still effective against the current variants though not optimal. There is potential that available vaccines will be r not be effective in the future if the virus continues to mutate. According to WHO, only 1.1% of people in low-income countries have received at least one dose of COVID-19 vaccine.

Conclusion:

Considering what have been mentioned above:

- No necessity at this time to grant Emergency Use Authorization (EUA).
- COVID-19 infection in children is rare, mild and benign.
- Children are do not have major role in spreading of the virus.
- There is potential of immune dysregulation from the stimulation of the vaccine similar to COVID-19 in certain children.
- Universal COVID-19 vaccine of adults is still low. This could potentiate development of more vaccine-resistant variants that necessitating development of new vaccines.

I think, COVID-19 immunization of children and teen is not an urgent priority.

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