

COVID-19 vaccination in children in India: A way forward

Srinivas Mantha*

Research Consultant & Pain Physician,
Division of Pain Medicine, Mantha
Heart Clinic, Barkatpura, Hyderabad,
India

*Author for correspondence:
Email: smantha@srinivasmantha.com

Received date: December 26, 2021
Accepted date: January 07, 2022

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India has an estimated population of 1.39199 billion and current vaccination approach plans to cover adult population (>18 y, about 67.53%) very soon. As on 24 December 2021, the country completed about 1.41 billion doses of COVID-19 vaccines, in about eleven months since the drive began. In adults, Covaxin (indigenous, Bharat Biotech) or Covishield are used and each type requires 2 doses administered a few weeks apart. Recently, Sputnik-V vaccine was also included [1]. Surveys indicate that current vaccine hesitancy among adults is about 7%. Recently, Covaxin for use in children between 2 to 18 years has completed phase-2 and phase-3 trials and got the government's approval for Emergency Use Authorization (EUA). Similarly, Zydus Cadila's indigenously developed needle free COVID-19 vaccine, ZyCoV-D, would be available in India for those in the age group of 12 to 18 years. Very recently, Covaxin, was granted Emergency Use Listing (EUL) by the World Health Organization (WHO).

Recovery from infection can confer protection related to spike-specific memory B cells. Undisputedly, the quality and durability of vaccine-induced immunity is far higher than that conferred by natural infection [2]. A recent model relevant to India found Median and 95% uncertainty interval for vaccine-induced immunity was 43.17 (26.14 to 59.97) when expressed as % of total population and it contributed predominantly to the total immune pool (natural and vaccine-induced) [3]. Inclusion of children in the vaccination drive is imperative to further enhance vaccine-induced immunity. The goal of vaccination is to ensure adequate number of people achieve community-level immunity as quickly as possible. The benefits of pediatric COVID-19 vaccines are clear. Vaccinations protect children, decrease spread to families and communities. Uninterrupted schooling improves quality education with interaction with peers and mentors [4].

Few key issues need to be addressed for success of vaccination rollout in children. "Childism" represents systematic prejudice against children during COVID-19 pandemic and appears to manifest in vaccination as well [5]. In other words, policy decisions seem to be prioritizing adults at the cost of wellbeing of children. Logistic and ethical issues including parental consent have been cited as reasons for their exclusion [6]. Experts are also seeking more safety data for their inclusion. Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare but serious complication of COVID-19 in children and adolescents ($\geq 12y$). The Danish Medicines Agency is investigating whether MIS-C can also occur after vaccination after observing it in a child aged 17 years [7].

In medical technology assessment, two definitions are important: "Efficacy" and "Effectiveness" [8]. Efficacy studies examine the benefits and harms of an intervention under highly controlled conditions in a small homogenous sample with experiment done under close monitoring and is protocol driven, typically exemplified by phase-2 and phase-3 trials. In contrast, effectiveness studies examine interventions in large heterogenous population in real-world situations governed much less by protocol. Specific to medications and vaccines, "pharmacovigilance" refers to the science relating to the detection, assessment, understanding, and prevention of adverse effects and other safety issues during the course of general use. Such surveillance also attempts to identify rare complications. After efficacy is established, there are both "early" and "late" adopters during diffusion of a technology [8]. In case of COVID-19 vaccination rollout in children, promotion of early adopters is vital.

The Emergency Use Authorization for Covaxin in children implies that the vaccine is ready for general use without further formal evaluations. In other words, "effectiveness" trails are not mandatory.

Citation: Mantha S. COVID-19 vaccination in children in India: A way forward. J Allergy Infect Dis. 2022;3(1):1-2.

Parental consent for vaccination of their children is another key issue that needs to be addressed [9].

With the country awaiting to commence vaccination in children, a way forward is to commence vaccinating children simultaneously with the ongoing drive in the adults. The rationale in first choosing the age group 12-18 years is to capture potential “MIS-C” with “pharmacovigilance” surveillance. Keeping in mind the aphorism “Children are not little adults, but they are future adults” [10], India should start the vaccination drive in children (12-18 y) at the earliest possible with dissemination of safety information to promote early adopters not only in that age group but also in younger children subsequently. In the present context, awareness of the safety information facilitates easy parental consent. The issue gains prominence with the WHO recently stating that vaccination is the key to handling Omicron variant as well.

Conflicts of Interest

The author declares no conflicts of interest.

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