# Jabbing Children

The article is related to General Studies-Paper-III (Science & Technology)

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## As Covaxin gets closer to approval for children, data transparency is vital

As a milestone, the Subject Expert Committee's (SEC) recommendation to the Drugs Controller to grant emergency use authorisation (EUA) for Covaxin among children aged 2-18 years, is huge. If the Drugs Controller General of India (DCGI) goes ahead and grants approval, it will be the first vaccine to be administered to children in India. While one other vaccine, ZyCoV-D, has been granted EUA, it is still to be administered.

Trials have started with the Serum Institute's Covovax for children, extending the timeline of any other COVID-19 vaccine for actual use in children. On the front of it, it seems like a tremendous achievement within a short period.

While the data seem to have convinced the SEC that there is cause to make its considered recommendation, none of that is yet in the public domain, at the time of SEC's announcement. Bharat Biotech presented interim data from the phase II/III trials to the DCGI, as the safety follow-up is longer in this case. One month after the two doses, an immunogenicity check and safety follow up are done, according to reports.

The company claimed the data indicated that the vaccine used — the same product and presentation as the adult vaccine — was safe. The two-dose Covaxin was administered to 525 children 28 days apart, after it received the nod to conduct trials on children in May this year.

A possibly unintended but welcome outcome of the pandemic is the stress on being transparent about scientific data generated in trials.

Data from other vaccine trials have routinely been posted in the public realm, not just with state regulators.

Working on vaccine or drug regimens with children is challenging on many fronts; to start with, it is not merely a case of sizing down adult dosage for children. Children have distinct developmental and physiological differences, and WHO recommends that clinical trials in children are essential to develop age-specific, empirically verified therapies and interventions to determine the best possible treatments for them.

Their bodies work in very different ways and they undergo many changes as they grow from infancy towards adolescence and adulthood, calling for age de-escalation studies in trials, beginning with an older age group, and working towards the youngest group. Another question experts are raising is whether the cohort of 525 children is large enough to wing an EUA, or if incremental numbers should be added, given the size of the target paediatric/teen population.

Many of these questions are easily addressed with publication of the data. While a recommendation is only that, it has indeed raised extraordinary expectations in the community. The DCGI, as it considers the SEC's advice, should address the concerns raised, and reinstate the issue of transparency to its rightful place as the cornerstone of scientific temper, besides infusing confidence in the public.

## Expected Questions (Prelims Exams)

**Q. Recently which vaccine in India has been recommended for emergency use authorization for children?**

**(a)** Covishield

**(b)** Co-vaccine

**(c)** Zyrov-D

**(d)** None of the Above

## Expected Questions (Mains Exams)

**Q. 'Vaccination of children is an important issue for protection against Covid-19 globally, which is said to be urgently completed, but its trial and findings so far are also raising doubts about its immediate approval.' Analyse this statement.**

**(250 Words)**



**Note: - The question of the main examination given for practice is designed keeping in mind the upcoming UPSC main examination. Therefore, to get an answer to this question, you can take the help of this source as well as other sources related to this topic.**