Corbevax For Adolescents: What we know & what we don’t

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Conflict of Interest: None

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1 CORBEVAX : A MASS NATIONAL EXPERIMENT ON ADOLESCENTS

*'**If you're going to use a vaccine on billions of people, you better know what that vaccine does**."– Kenneth Frazier, Merck CEO, July 13th, 2020*[1]

1.1 Summary

1. **An overwhelming majority of the population aged 12-14 on whom the vaccine is being currently administered were not represented in the clinical trials, implying no safety & efficacy data from trials for this group will ever be available**.
2. We estimate this unrepresented population to be between 87%-100% of the total population on whom the vaccine is being administered
3. From what we know so far
   a. Children are at low risk from severe disease
   b. Omicron is the dominant variant which has an even lower CFR than the original strains
   c. Preliminary research from other vaccines administered is signalling higher rate of adverse events in naturally immune population, which represents a huge chunk of kids on whom the vaccines are being administered. This is a big red flag

It remains to be asked as to why the vaccine is being administered on a population on which it has not even been trialed. How is this scientific, ethical, legal and permissible?

1.2 How many children have acquired natural immunity?

On Feb 21st, 2022, Corbevax was approved for children aged 12-18[2]. Since then, an estimated 20 million children in the 12-14 age group have received the first dose of the vaccine[3].

In this piece, the argument will be made that this vaccine is being mass administered despite several unknown factors. The first unknown factor is the safety & efficacy of the vaccine on children who are naturally immune, a group that has been excluded from clinical trials. Let us estimate how many children in India are naturally immune, or to be more specific, infected by the novel coronavirus known to cause Covid19 at least once.

In order to answer this question, we need to look at information coming out of serosurveys. Most of the serosurveys, were conducted pre-omicron, so we will need to estimate seropositivity post-Omicron using the information on seroprevalence pre-Omicron, the number of reported cases post-Omicron as well as an estimate of number of subjects that were infected naturally but do not have detectable level of antibodies. Here's what we know

- An nationwide ICMR survey in June/July 2021 found 61.6% of the children in the 10-17 age group were seropositive[4].
- Some other data points. Note that all the below sero surveys were pre Omicron wave
  - Sero survey in Chandigarh in the Jun -Aug 2021 timeframe had found ~73% of children aged 6-18 to be seropositive[5]
  - Sero survey in Pune conducted in June 2021 found 70% of kids had antibodies[6]
  - A seroprevalence study by AIIMS in June 2021 found seroprevalence among children was 56% across 5 study sites, including 75% in Delhi & 88% in Gorakhpur[7]
  - A seroprevalence study in Himachal Pradesh in June/July timeframe had found 61.5% of children in the 10-17 age group had antibodies[8]
  - A sero survey conducted in Thane in conducted in Oct-2021 pre-Omicron found 83.4% of children aged 6-18 had antibodies[9]
  - A sero survey conducted in Delhi in Sep/Oct 2021 pre-Omicron wave found 82% of kids had antibodies[10]

- Additionally, there are some studies that suggest that not all who are exposed to the virus actually develop antibodies
  - According to data collected by health science company ZOE, about 19% of subjects who tested covid positive did not have detectable level of antibodies[11]
  - According to 4 different studies reported in Forbes [12], of all patients testing positive, detectable antibodies were found in 15% to 95% of the subjects (depending on the study). One of these studies also observed that detectable antibodies were less likely to be observed in younger populations.
  - Among the above studies, ZOE's study had the largest sample size (8,193 contributors).

To conclude:

- Since the ICMR survey, the cumulative number of reported cases is up another 41% (as of Feb 21st when the vaccine was approved for kids aged 12-14). So, assuming a proportionate increase in seropositivity, the estimated seropositive population at the time of approval works out to 87%
- If one were to overlay the above estimate with findings from the ZOE study (which has a sizable sample of 8,193 contributors) to estimate the % of children exposed to Sars-Cov-2, the estimate works close to 100%
- We also know from Corbevax's clinical trial registry, that children living in the same household of another COVID-19 positive person were excluded from trials [13]
- Hence, factoring in information from various sero surveys, and also accounting for the population that was covid positive but without detectable antibodies, we are estimating anywhere between **87%-100%** of the adolescents in India had a prior infection or lived in a household with another member who had tested Covid Positive

1.3 Should we be concerned about safety of naturally immune getting vaccinated?

The short answer is yes. Primarily because studies link both younger age groups as well as prior infection to be associated with a higher likelihood of adverse reaction. Most Covid vaccines authorized for Emergency use had excluded naturally immune from trials. Hence, we have to rely on emerging evidence from real world data. While more research is needed, there are several studies done so far on the covid vaccines that indicate naturally immune & young are much more likely to experience an adverse event post vaccination. Here are a few examples

- A study of 974 healthcare workers who were administered Pfizer's mRNA Covid vaccine in North East England found that a previous Covid-19 infection was associated with a 50% higher likelihood of an adverse event. It also found adverse events were more prevalent in younger age groups and women[14]
- A study of 1634 healthcare workers who were administered Covishield in Northern India found that those with prior Covid-19 infection were 2.4 times as likely to experience an adverse event. Consistent with other studies, it also found adverse events to be more prevalent among females & younger age groups[15]
- A study of 159 recipients of mRNA vaccines found that 89% of seropositive survey respondents experienced some side effects, compared to 46% seronegative survey respondents[16]
- A study of 1090 healthcare workers who were administered the Pfizer mRNA vaccine found a higher proportion of seropositive individuals who reported post vaccine symptoms compared to infection naïve individuals after 1st dose (36% vs. 25%)[17]
- A higher incidence of hospitalization post second dose of mRNA vaccines among seropositive individuals was reported in a study of about 3 million veterans in US who were vaccinated [18]
- A study of 255 individuals who were vaccinated with the Pfizer mRNA vaccine found that severe symptoms requiring medical attention were observed in 6.8% of the those who had a prior infection before vaccination, compared to 0.6% in the infection naïve population [19]

While all but one of the above studies were on the mRNA vaccines, it is a strong enough signal to warrant caution & proper safety studies before mass administering any covid vaccine on a young population where an overwhelming majority have been infection previously

1.4 Conclusion

As demonstrated above, the vaccine is being administered on an overwhelming majority of the population unrepresented in clinical trials. Even after the conclusion of Phase 2/3 clinical trials (scheduled for August 2022

per information obtained from the clinical trials registry of India), the safety & efficacy of the subgroup will be unknown from the data from clinical trials. Emerging evidence is also suggestive of disproportionately higher incidence of adverse events in populations that were previously infected. It therefore remains to be questioned as to why the vaccine is being administered on adolescents in India.

2 Corbevax: Where's the data evaluating risks versus benefits?

*'**Remember: You're giving this vaccine, likely, to healthy people -- who are not the people typically who are dying from this infection,"So you better make sure that you are holding it to a high standard of safety. The worst possible thing you do is vaccinate somebody to prevent infection and actually make them worse**" – Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia, April 1st 2020* [20]

2.1 Summary

1. Post Omicron, the estimated mortality from COVID-19 among children is 3 deaths per million infections.
2. The rate of severe side effects among existing COVID vaccines is estimated between 120-146 severe side effects per million fully vaccinated subjects (where fully vaccinated is assumed to be 2 doses).
3. Based on the above, even if we have a vaccine which is 100% effective and durable (i.e. no more than 2 doses required), assuming a similar side effects' profile, we are risking 40-50 severe side effects for every life saved.
4. The above estimates of severe side effects are from official estimates published by national health agencies in Singapore & Canada. We know from existing literature that severe side effects from vaccine administration are likely understated.
5. The bar for safety is very high, and current trials are inadequate to measure if risks outweigh benefits.
6. 2 NTAGI members reportedly confirmed that NTAGI had not recommended Corbevax. Mr. Jayaprakash Muliyil has suggested that there is no "post-Omicron data"
7. MD of Biological E, Mahima Datla, is on record saying that there's no sufficient data regarding vaccine protection from Omicron.
8. Corbevax's fact sheet shows that safety & efficacy have been evaluated for a very short time duration. The fact sheet clearly states that "The duration of protection is unknown"

Unfortunately, neither regulators nor vaccine manufacturers have been confronted with tough questions. It remains to be asked – where's the evidence that risks outweigh benefits?

2.2 Scale of underreporting of adverse events related to drugs & vaccines

Below are observations of a few studies that emphasize the scale of underreporting of adverse events from vaccines or drugs

- The Lazarus report had identified less than 1% of vaccine adverse events, 0.3% of drug related adverse events and 1-13% of serious drug related adverse events ever get reported. [21]
- Another report identified that about 75% of serious adverse events reported to VAERS in US for the HPV vaccine Gardasil were incorrectly classified as not serious [22]
- A Swedish study in 2008 estimated that at least 90% of serious side effects are not reported [23]

- An analysis of 37 studies on underreporting of severe adverse drug reactions concluded the median under-reporting rate was 94% [24]

2.3 What's the administration of covid vaccines around the world telling us about safety?

Should we be concerned about the safety of the covid vaccines? After all, billions around the world have been inoculated.

The answer is 'Yes'. For 2 reasons – adverse events tend to be underreported as reported above & also several safety signals have been observed in the administration of covid vaccines authorized for emergency use after millions in the general population have already been jabbed.

With the above, backdrop, let us know look at some of the safety issues identified with the current Covid vaccines

- AstraZeneca/Covishield/Vaxzevria
  - The vaccine has been discontinued in several countries & provinces due to risk of blood clots. [25, 26]
  - Since June 26th, 2021, Public Health Canada has identified Guillain-Barré Syndrome (GBS) as a side effect of the vaccine.[27, 32]
  - On January 14th, 2022, EMA identified transverse myelitis as a side effect of the vaccine with unknown frequency. [28]
  - On January 26th, 2022, UK's MHRA (Medicines and Healthcare Regulatory Agency) added transverse myelitis to the "Warnings and precautions of neurological events" section given to healthcare professionals. [29]
- Janssen (Johnson & Johnson)
  - Health Canada identified a risk of blood clots with low platelets in May 2021. [30]
  - In July 2021, EMA's PRAC (Pharmacovigilance Risk Assessment Committee), recommended adding capillary leak syndrome as a rare side effect of the vaccine. [31]
  - In November 2021, EMA recognized transverse myelitis as a side effect of Janssen. [33]
  - In December 2021, CDC recommended that other covid vaccines be preferred over Janssen due to increased risk of blood clots [34]
- Moderna
  - In October & November 2021, Moderna was discontinued for younger age groups (mostly the under 30 age group) in several countries including Germany, France, Sweden, Denmark, Norway & Finland due to risk of heart inflammation. [35]
  - On October 8th, 2021, Moderna was discontinued in Iceland. [36]
  - On December 3rd, 2021, the National Advisory Committee on Immunization (NACI) in Canada recommended that Pfizer be preferred over Moderna as the mRNA vaccine for administration to people in the 12-29 age group due to risk of myocarditis and/or pericarditis. [37]
  - In November 2021, EMA added a warning that capillary leak syndrome can reoccur among patients with a history of the disease. [38]
  - In June 2021, Health Canada identified myocarditis & pericarditis as a rare side effect and occurring more frequently than expected in younger population (less than 40 years of age). [39, 40]
- Pfizer
  - In June 2021, Health Canada identified myocarditis & pericarditis as a rare side effect and occurring more frequently than expected in younger population (less than 40 years of age). [39, 40]
  - On February 5th, 2021, Pfizer withdrew it's application for Emergency Use Authorization in India after it was reported that India's expert committee would recommend against the approval due to " incidents of palsy, anaphylaxis and other SAE's have been reported during post marketing" and because "the firm has not proposed any plan to generate safety and immunogenicity data in Indian population". [41]
  - The side effects myocarditis and pericarditis were not part of the original EUA fact sheet for recipients and caregivers. [42] They were added on June 26th, 2021. [43]
- Sinovac & Sinopharm
  - According to media reports, a Chinese National Health Commission (NHC) document showed that the Chines COVID-19 vaccines caused leukemia. [44, 45]
- Thailand
  - The government has compensated 12,714 people for vaccine injuries. For context, prior to the start of the vaccination campaign, there had been only 84 covid deaths. [46, 47]

- A study conducted by CDC found the risk of myocarditis to be 133 times greater than background risk in population. [48]
- In March 2022, WHO acknowledged Tinnitus as a potential side effect of COVID-19 vaccines. [49]
- A report from Nova Scotia Canada indicated significant underreporting of adverse events following administration of COVID-19 vaccines due to a number of reasons including lack of guidance from public health, laborious reporting system, reluctance on part of doctors to identify an adverse event as potentially linked to the vaccine & hence reportable. [50]

2.4 How frequent are severe side effects from COVID-19 vaccines on adolescents?

There is no way to deduce what the rate of severe side effects for Corbevax is going to be. But this is what we know about the rate of severe side effects from primarily MRNA vaccines administered in other countries

- Canada: 73 severe side effects per million doses in the 12-17 age group. Given that 2 doses are administered per child, this works out to 146 severe side effects per million adolescents. [51]
- Singapore: Singapore reported 60-70 severe side effects per million across all age groups for the mRNA vaccines as well as Sinopharm/Sinovac which are on a traditional platform. Again, this adds up to about 120-140 severe side effects per million adolescents. [52]

2.5 What's the covid19 survival rate among adolescents?

CDC had estimated the survival rate as 99.997%, implying 30 deaths per 1 million infections for adolescents against the original strain. [53] Another study arrived at the same estimate. [54] However, today we know Omicron is the dominant variant & studies are estimating the risk of deaths from Omicron to be 82%-91% lower compared to Delta. [55, 56, 57] Factoring in this information, the estimated death rate among adolescents with the dominant strain today works out to 3 deaths per 1 million infections, or survival rate of 99.9997%.

In short, if the rate of severe side effects estimated in the previous section (120-146 per million fully vaccinated subjects) were to hold consistent for Corbevax, & the vaccine is 100% protective against death, we are still risking at least 40 severe side effects for every life saved from Covid-19.

2.6 Will we have a covid vaccine which is durable & 100% protective against death?

Given what we have seen from other Covid vaccines administered around the world, we are yet to see any covid vaccine that provides durable long term protection against infection & deaths. Here are some red flags that hint towards waning immunity

- Data from Scotland had shown gradually declining immunity & eventually, 40-56% higher likelihood of death among the double jabbed compared to unvaccinated population. [58]
- Data from England showed no material difference in deaths rates among triple jabbed versus the unjabbed in the 18-49 age group. [59]
- When decision was made to administer the third dose, Israel had acknowledged that vaccine effectiveness against symptomatic infection had dropped to 16%, [60] & vaccine effectiveness against death had dropped to 55% (in the 65+ age group), both over a period of 6 months. [61] This was a rapid decline from the original claims of 95% efficacy and very close to the original FDA cutoff for emergency authorization which was 50%. [62]
- A preprint study from Sweden deduced vaccine effectiveness against severe disease at 42% after 6 months, [63] below the FDA cutoff of 50%.
- Here are a few examples of proportion of covid deaths that were vaccinated with at least one dose (in their most recent reporting period) in countries who have regularly reported covid deaths by vaccination status
    - 91% in England [59]
    - 88% in Scotland [64]
    - 92% in Sweden [65]
    - 83% in Norway [66]
- Many countries are now administering the 4th booster dose to elderly populations and have administered the third booster dose to 12+ age groups (indicating 2 shots not enough) [67, 68]

Based on the above, there's no reason to believe that Corbevax will be 100% protective & the protection will be long lasting with no requirement for additional boosters. Corbevax' own fact sheet states that **"Duration of**

protection is unknown". [69] Based on real world evidence from other Covid vaccines, any protection will be short lived. Should we risk potentially unforeseen severe side effects for this?

2.7 What is the Corbevax clinical trial registry information, package insert & fact sheet telling us?

Safety

There are no published safety studies of the vaccine for children in the 12-17 age group. For this age group, the safety information can only be found on the package insert [70] & Fact sheet [69]. The phase 1 trials had enrolled healthy adults in the 18-65 age group. [71]

1. Duration of observation window for safety: Given that the trial start date was Oct 10th, 2021, & approval received in Feb 2022, the observation window for the safety of the vaccine would be a maximum of 4 months in 200 subjects. Safety information beyond this duration is unknown.
2. Trial size: 624. The safety information on the package insert is based on interim results from 150 vaccinated subjects. Such a small size will unlikely cover severe adverse events of lower frequency.
3. Adjuvant Aluminum hydroxide: Aluminum hydroxide as an adjuvant has been a subject of controversy. [72], [73], [74], [75] It is therefore imperative that safety studies rule out any potentially harmful impact this adjuvant may have, especially given the low mortality risk children have from Covid.
4. Experimental – According to clinical trials registry, the studies conclude 10 months after the trial start date, which works out to Aug 2022. Why has the vaccine been provided EUA even before trials are complete? Moreover, why is the trial duration only 10 months?

Efficacy

1. Methodology: While claims are made that vaccines are not meant to prevent infection, but severe disease & hospitalizations, no such metrics are available for Corbevax for adolescents given the small trial size & the trial design. How will the trials determine how protective the vaccine is against death & severe disease given the trial size & low mortality risk, and for how long? The fact sheet clearly mentions that the "Duration of Protection is unknown"

2.8 What are the regulator & manufacturer telling us about the efficacy of the vaccine?

- NTAGI members reportedly confirmed that NTAGI had not recommended Corbevax. Mr. Jayaprakash Muliyil has suggested that there is no "post-Omicron data". [76]
- MD of Biological E, Mahima Datla, is on record saying that there's no sufficient data regarding vaccine protection from Omicron. [77]

So, both the regulator & manufacturer are acknowledging there's insufficient data regarding the protective effects, if any, of the vaccine against Omicron. How can one deduce any benefit based on this information? Moreover, given that such a huge population is naturally immune, what additional protective benefit will the vaccine provide? The trials are not designed to measure this since those with a prior infection were excluded from trials. There are several studies now that highlight the superior protective benefits of natural immunity compared to vaccination. [78], [79], [80], [81], [82], [83], [84]

2.9 Conclusion

We have deduced the rate of severe side effects from existing covid vaccines at about 120-140 per 1 million people, and covid-19 mortality from Omicron among adolescents at 3 deaths per million. We also know that an overwhelming majority of the target population is naturally immune. Based on the way the clinical trials are designed, it will be really hard to answer the below questions

1. What's the safety profile of the vaccine? What's the likelihood of potential severe side effects?
2. What's the efficacy? How durable is the protection?
3. What are the additional protective benefits for someone who is naturally immune?
4. Do the risks outweigh the benefits?

3 Conclusion

In this paper, we have emphasized the below

- A significant proportion of the population on whom the vaccine is being administered are not represented in trials because they are naturally immune & this group was excluded from trials. We estimate the size of the group at 87-100% of the total population on whom the vaccine is being administered.
- Based on existing information, the rate of severe side effects from existing covid vaccines works out to 120-146 side effects per million people. The mortality rate from COVID-19 for adolescents is existing at 3 per million.
- Based on the existing trial design, there's no way to deduce if potential benefits will outweigh risks.
- Additionally, we will not know from the trial design, what are the additional protective benefits the vaccine offers to someone naturally immune.

Is the authorization of Corbevax for children scientific and ethical?

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