

# **Vaccinating kids 5-11: Does the real world evidence support mass administration?**

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Conflict of Interest: None\_

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## 1 COVID VACCINES FOR KIDS AGED 5-11: EVIDENCE FROM AROUND THE WORLD

*'The overall safety and effectiveness data are limited for children.'*– National Advisory Committee on Immunization, Canada, November 19<sup>th</sup>, 2021 (NACI 2021)

### 1.1 Summary

In this paper, by looking at vaccine surveillance data from various places around the world for administration of primarily Pfizer BioNTech mRNA vaccine in kids aged 5-11, we will demonstrate that

- The vaccine effectiveness (VE) against infection is negative few weeks after the second dose.
- The VE against hospitalization is close to 0 when impact of the first dose is factored in, and 2 dose VE is below the threshold of 50% that FDA had set for vaccine approval. (U.S. Department of Health and Human Services 2020)
- There are safety issues that pivot the risk benefit equation towards more risk vs. no benefit given the low mortality rate of COVID infection among kids in the 5-11 age group.

Based on the above, it remains to be asked as to why vaccines continue to be administered to kids around the world in the 5-11 age group. This paper is calling for an immediate halt to the mass vaccination program for kids in the 5-11 age group.

### 1.2 Limitations of clinical trials

The below is from published clinical trial results. Notice the statement made regarding the durability of the protection and safety profile. (E. B. Walter, et al. 2022)

*“At the data cutoff date, the **median follow-up time was 2.3 months**”*

*“Limitations of the study include the lack of longer-term follow-up to assess the duration of immune responses, efficacy, and safety. However, **longer-term follow-up from this study, which will continue for 2 years, should provide clarification. This study was also not powered to detect potential rare side effects of BNT162b2 in 5-to-11-year-olds**”*

With the above, it is important to note that the study completion date per clinical trials registry is **June 14<sup>th</sup>, 2024**, well into the future and more than 2 & a half years after EUA (emergency use authorization) was provided in many countries. (NIH US National Library of Medicine 2021)

Additionally, below are some of the observations from NACI (National Advisory Committee on Immunization, Canada) from November 19<sup>th</sup>, 2021 regarding the clinical trials information made available at that time. (NACI 2021)

- *“Unlikely that any AE (adverse events) occurring at a frequency less often than 1 in 1,000 would be detected (in clinical trials).”*
- *“Data did not include estimates of vaccine efficacy against severe outcomes such as hospitalization,*

*MIS-C or death”*

- “Preliminary efficacy data were limited to the evaluable efficacy population from Cohort 1 (individuals who did not have evidence of SARS-CoV-2 infection prior to dose 2”*
- “The overall safety and effectiveness data are limited for children”*
- “Given the short-term uncertainties surrounding pediatric vaccination at this time, children and their parents or guardians should be supported and respected in their decisions regarding COVID-19 vaccinations for the child, whatever decisions they make, and should not be stigmatised for accepting, or not accepting, the vaccination offer.”*

From the above, it is clear that the information from clinical trials was very limited in terms of safety and effectiveness. Also, it's important to note that trials provide no information on the community impact of mass vaccinations in the form of transmission reduction. The rationale for EUA is not clear. Given that EUA has been granted and many parents have opted to vaccinate their kids, real world data is key in further evaluating the safety and effectiveness of this vaccine for kids.

### **1.3 Evaluation criteria for assessing continued administration of the vaccines**

The following parameters have been set to assess criteria for evaluation

- Safety:** What information is available on long term & short term side effects of the vaccine?
- Efficacy in immune naïve populations:** What's the VE immune naïve (i.e. no prior infection) population? Is it above the threshold of 50% set by FDA?
- Efficacy in those previously infected:** What's the VE in population previously infected?
- Efficacy against severe outcomes:** Given mortality rate of 99.998% pre-Omicron, high degree of seroprevalence, & less lethality of Omicron, does the vaccine prevent severe outcomes? Is VE above the threshold of 50% set by FDA?
- Prevention of long covid:** Does the vaccine prevent long Covid in children?

### **1.4 Safety**

- Infection Fatality Rate & ICU Admission rate from COVID-19:**
  - Pre-Omicron, mortality rate estimates varied between 13-23 deaths per million infections. (COVID-19 Forecasting Team 2022) (Axfors and Ioannidis 2021)
  - For healthy young kids with no co-morbidities, the fatality rate was estimated as 2 deaths per 1 million infections. (Ghisolfi, et al. 2020)
  - A German study estimated ICU admission rates at 20 per 1 million infections among healthy kids with no co-morbidities. (AL, et al. 2021)
- Rate of Severe Side effects from vaccines:** Based on adverse events reporting from Singapore (Health Science Authority Singapore 2022) & Canada (Government of Canada 2022), the rate of severe side

effects ranges from **54 to 105 side effects per 1 million fully vaccinated children**. Clearly, given that for healthy children, ICU admission rates are much lower compared to the above estimate, this rate of side effects is much higher, and on the basis of this metric alone, one can argue that there is no justification for the current vaccination program.

▪ ***What about traditional vaccine platforms?***

- The report from Singapore for other age groups that were vaccinated with Sinopharm/Sinovac (which are traditional platforms) shows that the rate of severe adverse events is comparable to the mRNA vaccines.
- Also, any such claim that traditional platform will have a better safety profile needs to be backed with proper clinical trials, which are absent at present. Even if a platform is traditional, the coronavirus was considered novel, which is why proper clinical trials are necessitated.

▪ ***What about safety profile of vaccinating the naturally immune?***

- Given that 66-75% of kids have been infected at least once per seroprevalence studies from places like USA & British Columbia, what is the safety profile of vaccinating the naturally immune? We do not have data to answer this question, but there are studies among adults showing a worse side effect profile among vaccinating people who are immune due to prior infection or have been infected once previously. Given this fact, tremendous caution should be exercised in administering the vaccine to kids. (Raw, Kelly and Chadwick 2021), (Joshi, Muralidharan and Sahoo 2021), (Various Authors, New England Journal of Medicine 2021), (Ebinger, Fert-Bober and Sobhani 2021), (Li, et al. 2021), (Efrati, et al. 2021)

▪ ***Real World example of Ontario***

- In Ontario, in the period Feb 28<sup>th</sup>, 2022 to April 24<sup>th</sup>, 2022 there were 24 Covid-19 hospitalizations among unvaccinated kids in the 5-11 age group. In the same timeframe, there were 28 hospitalizations among vaccinated kids (at least 1 dose) due to Covid-19. Additionally, there were 28 adverse events reported, that can be considered serious or concerning, including
  - 4 cases of arthritis
  - 2 cases of myocarditis
  - 1 case of acute cardiovascular injury
  - 1 case of Kawasaki disease
  - 1 case of MIS-C
  - 1 case of convulsions/seizure
  - 1 case of syncope (fainting)
  - 17 cases of “Other severe or unusual events”

Note that unvaccinated kids made up approximately 45% of the population. The above data is a strong signal that vaccinated kids likely suffered disproportionately. (Public Health Ontario 2022), (Public Health Ontario 2022), (Public Health Ontario, Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario 2022), (Public Health Ontario, Confirmed Cases of COVID-19 Following Vaccination in Ontario 2022)

- To conclude, real world data is signalling the likelihood of harms outweighing benefits, especially among healthy children. It is important to consider this fact especially in the backdrop of high seroprevalence, and a relatively milder variant with mortality rate estimated to be ~90% lower compared to Delta variant. (Nyberg, et al. 2022) (Ulloa, et al. 2022) (Lewnard, et al. 2022)

## 1.5 Efficacy in immune naïve populations

While Pfizer's own study indicated 90% efficacy against symptomatic infection (Walter, et al. 2021), real world observations & several studies are painting a different picture. Below are 3 examples:

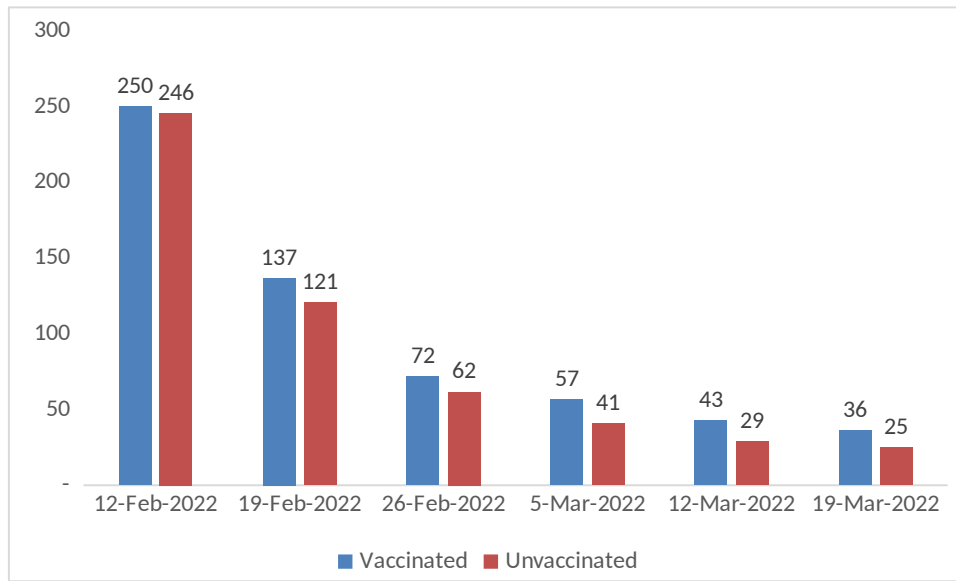
- A study of 1052 children in 4 US states deduced VE at 31% 14-82 days after 2<sup>nd</sup> dose, well below the threshold of 50% set by FDA. (Fowlkes, et al. 2022)
- A preprint study of over 365,000 children in the 5-11 age group in New York State indicated that VE declined to just 12% 4 weeks after second dose and then further declined to negative territory at **-41%** at 6 weeks after second dose. It also indicated VE had declined to 46% against hospitalization 6 weeks after the second dose. (Dorabawila, et al. 2022)
- An Austrian study indicated vaccine efficacy turned negative ~4 months after second dose. (INSTITUT FÜR INFEKTIONSEPIDEMIOLOGIE & SURVEILLANCE, et al. 2022)

It is also important to remember that none of the studies actually calculated VE after the first dose. In spite of this bias, 2 of the 3 studies above have indicated VE actually turned negative within a very short time frame.

## 1.6 Efficacy in those previously infected

- In US, about 75% of children 17 & below have been infected at least once per CDC's estimate (Associated Press 2022). In British Columbia, Canada, seroprevalence studies indicated ~67% of kids under the age of 10 had been infected at least once (CBC News 2022).
- Given the above facts, it is important that information about the benefit of vaccination in the cohort of those previously infected be assessed. While we do not have VE estimates on previously infected from studies or from published clinical trial results, here's what we are observing in terms of incidence rates between vaccinated & unvaccinated populations in US, Ontario and Germany.
  - **US:** Since Feb 12<sup>th</sup>, 2022, covid incidence has been consistently higher among fully vaccinated children. In the most recent reporting period end of March, covid incidence was 45% higher (CDC 2022)

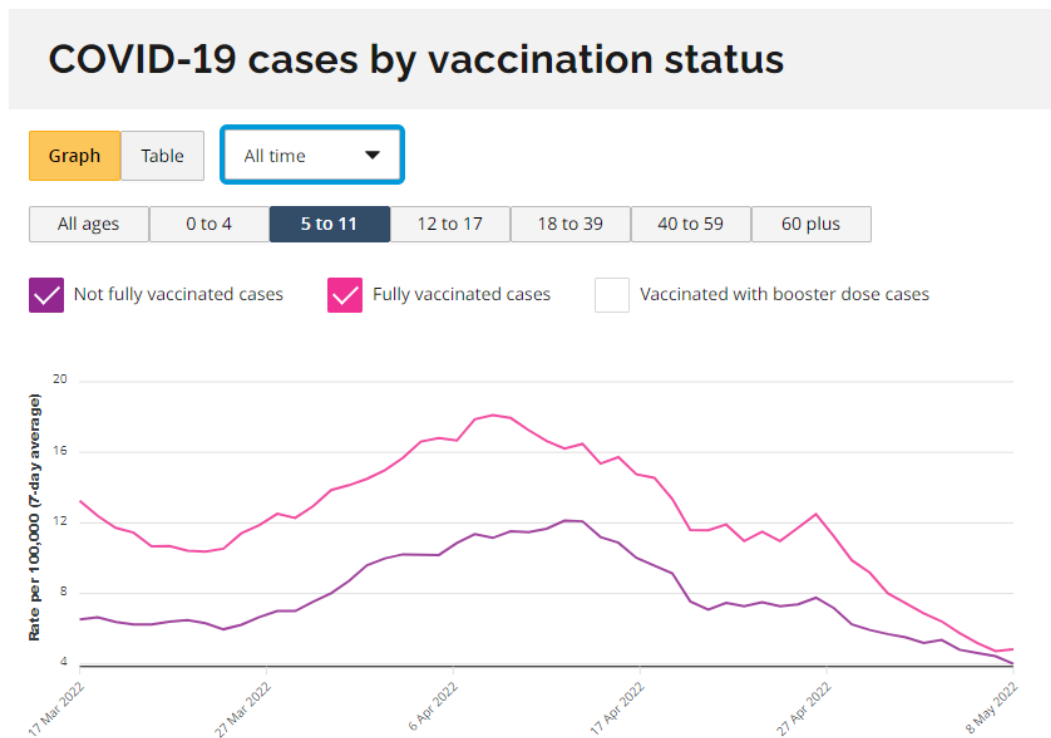
**Figure 1 - Covid incidence per 100,000 by vaccination status in the 5-11 age group in US: Feb 12th to March 19th, 2022**



□ **Ontario:** A similar observation was made in Ontario with Covid incidence being ~29% higher in the fully vaccinated population compared to the “not fully vaccinated” population. Not fully vaccinated category includes partially vaccinated and cases where less than 2 weeks have elapsed since the second dose.

(Government of Ontario 2022)

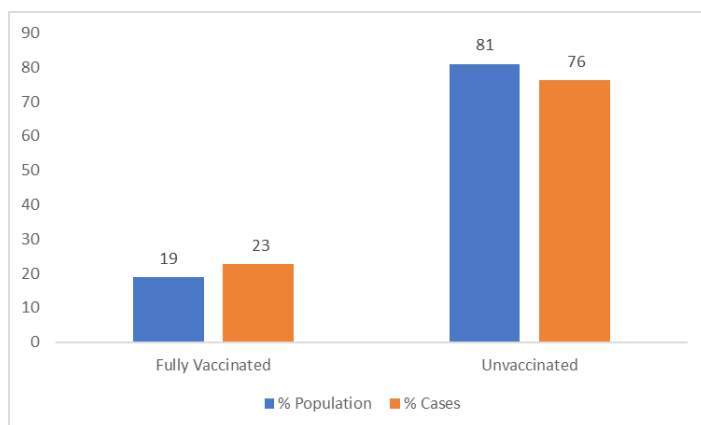
**Figure 2 Ontario: Covid Incidence in the 5-11 age group**



□ **Germany:** In Germany, a 27% higher incidence was observed in the fully vaccinated group

in the 4 week period ending April 26<sup>th</sup>, 2022 (Robert Koch Institut 2022).

**Figure 3 Germany: Covid Incidence in the 5-11 age group for the 4 weeks ending April 26th, 2022**



- To conclude, Covid incidence was **consistently higher by 27%-45% in the fully vaccinated population** compared to the unvaccinated/not fully vaccinated population, implying that vaccinated population is more likely be infected and hence VE is likely negative in the current population mix when prior infection is factored into the assessment.

## 1.7 Efficacy against severe outcomes

As far as VE against severe outcomes is concerned, most studies have ignored the likelihood of a severe outcome after the first dose, and only calculate the vaccine effectiveness 14 days after the second dose, when the subject is considered fully vaccinated. Despite this bias, in 3 of the 4 examples below, the VE was below the threshold of 50% set by FDA for EUA:

- A study of over 9000 kids in the 5-11 age group who recorded an emergency department or urgent care visit indicated a VE of 46%, 14-67 days after second dose. (Klein, Stockwell and Verani 2022)
- A preprint study of VE against cases & hospitalizations for kids in the 5-11 age group in New York State indicated that VE had declined to 46% against hospitalization 6 weeks after the second dose. (Dorabawila, et al. 2022)
- According to current CDC data, the VE for hospitalization for kids aged 5-11 in the month of March, 2022 works out to 42% (partially vaccinated & fully vaccinated <= 14 days are excluded from the reporting). (CDC, Rates of laboratory-confirmed COVID-19 hospitalizations by vaccination status 2022)
- ▣ In Germany, VE of 57% against hospitalization the 4 week period ending April 26<sup>th</sup>, 2022 was deduced (Robert Koch Institut 2022)

It's important to note that in every single one of the examples listed above, the partially vaccinated were excluded from the analysis. This can potentially bias the data if in fact, the likelihood of hospitalization after the first dose is higher. In order to assess if such a bias exists, we have two examples of provinces from Canada, that are reporting hospitalization numbers for the single dose vaccinated as well.

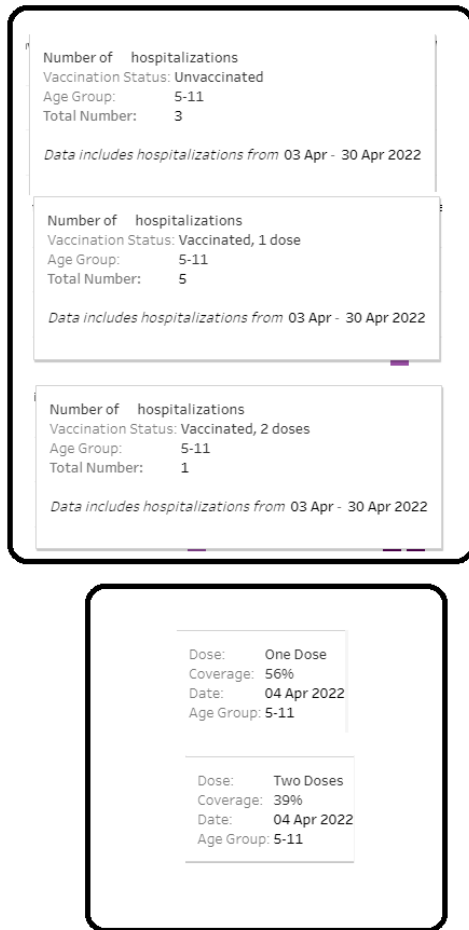
**Ontario:** Over the last 8 weeks, unvaccinated kids accounted for 45% of the population & 46% of the hospitalizations. (24 out of 52). 16 kids were vaccinated with 1 dose and 12 kids were vaccinated with 2 doses.



This statistic indicates that the data so far is indicating no benefit of protection from hospitalization in vaccinated subjects. (Public Health Ontario 2022), (Public Health Ontario 2022), (Public Health Ontario, Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario 2022), (Public Health Ontario, Confirmed Cases of COVID-19 Following Vaccination in Ontario 2022)

**BC (Province of British Columbia):** In BC, per the latest report, in the timeframe April 3<sup>rd</sup> to 30<sup>th</sup>, 2022, 6 out of the 9 children hospitalized with covid were vaccinated with at least 1 dose. So, while unvaccinated made up 44% of the population, they only made up 33% of the hospitalizations. (BC Centre for Disease Control 2022), (BC Centre for Disease Control, BCCDC COVID-19 Surveillance Dashboard 2022)

**Figure 4 Rate of Covid-19 hospitalization by vaccination status in BC (April 3rd to 30th, 2022)**



**Snapshots from BCCDC's regional dashboard posted online on Thursday, May 5th, 2022 (for April 3rd to 30th, 2022)**

**Total COVID-19 hospitalizations in the 5-11 age group: 9**  
**Breakdown of hospitalizations:**  
**Unvaccinated: 3**  
**Vaccinated with 1 dose: 5**  
**Fully Vaccinated: 1**

**% Population (5-11) vaccinated with at least 1 dose: 56%**  
**% Hospitalized (5-11) vaccinated with at least 1 dose: 67%**

With the 2 examples above, once can infer that the clearer picture for protection from severe outcomes arrives when we factor in the risk of severe outcome after the first dose, thereby eliminating survivorship bias in the analysis. Currently, there are 2 provinces in Canada that are sharing this information, one of which actually counts partially vaccinated within 21 days of the first dose as unvaccinated. Despite this, we see no evidence of reduction in hospitalizations among the vaccinated population. Based on the above, it is reasonable to infer that vaccines have provided no protection against hospitalization and the claim that vaccines protect against severe

outcomes is not backed by real world data.

To conclude

1. Vaccine efficacy/effectiveness, despite ignoring effects of a single dose, has been found to be **below 50%** in 3 of the 4 instances highlighted above, breaching the threshold set by FDA for vaccine approval back in June 2020. In the 4<sup>th</sup> instance, Germany, the vaccine effectiveness was only marginally higher than the 50% threshold, at 57%. In all these examples, the vaccine effectiveness has been deduced over a very short time frame (all are deduced over a time frame of less than 5 months since the launch of the vaccination campaign), indicating protection if any, wanes quite rapidly.
2. When impacts on hospitalization post first dose is factored in, using the 2 live examples from Canada, combining effects from both doses, **we do not see evidence yet of the vaccine preventing hospitalization from Covid-19 in kids aged 5-11.**

## 1.8 Does the vaccine prevent long covid/MIS-C?

One of the considerations on whether to vaccinate children or not is based on the assumption that vaccine may potentially prevent long Covid and/or MIS-C (multisystem inflammatory syndrome in children, also called PIMS – TS - Pediatric multisystem inflammatory syndrome temporarily associated with SARS-CoV-2). However, it's important to emphasize here that we have very limited information about the prevalence of long covid in kids aged 5-11, and no information on whether the vaccine prevents long Covid in this age group. Mentioned below are a few observations:

- A study from June 2021 observed that *“The pathogenesis of PIMS-TS is not understood and so neither safety nor efficacy of vaccines in its causation and prevention, respectively, is known.”* (Li, Finn and Pollard 2021)
- NACI observed that the clinical trials provided no information on vaccine efficacy against MIS-C. (NACI 2021)
- NACI also observed that evidence of long Covid in kids aged 5-11 is limited. Below are their observations:

*“While evidence is limited in children 5 to 11 years of age, SARS-CoV-2 infection may lead to post COVID condition/post acute COVID syndrome (i.e., long COVID or post acute COVID-19 syndrome. Current evidence suggests the risk is lower in children compared to older age groups.”*

*“Overall evidence is limited on the long-term consequences of Omicron infection in children 5 to 11 years of age.”*

- Another study from July 2021 on long Covid in children observed that *“Similar proportions of seropositive and seronegative children reported excellent or good health.”*
- While there is one study from Jan 2022 that does infer that the vaccine provides protection against MIS-C in adolescents aged 12-18 (Zambrano, Newhams and Bowens 2022), these findings cannot be extrapolated to the 5-11 age group with a great degree of confidence based on the above observations. Also, the findings

are subject to several limitations, including

- The study excluded partially vaccinated subjects, as well as fully vaccinated subjects if the hospitalization took place less than 28 days after second dose.
- The study did not account for waning protection, if any, against MIS-C.
- The study did not account for waning protection against infection from the vaccines and was time bound to ~6 months or less after administration second dose.

## **1.9 Are there examples of countries not recommending vaccination for kids aged 5 - 11?**

Sweden and Norway have indicated that there's no indication of benefits outweighing risks and hence Public Health in both these countries has not recommended vaccinating kids. Below are the statements made by Public health authorities in these countries:

- --*"With the knowledge we have today, with a low risk for serious disease for kids, we don't see any clear benefit with vaccinating them,"* Health Agency official Britta Bjorkholm said during a news conference, Reuters reported.--(Fox News 2022)
- --*"Children rarely become seriously ill, and knowledge is still limited about rare side effects or side effects that may arise at a distant time. There is little individual benefit for most children, and the Norwegian Institute of Public Health has not recommended that all children aged 5–11 be vaccinated. However, it has agreed that all parents and guardians may be offered a vaccine for their children; this will be most relevant to only a few groups of children"* says Minister of Health and Care Services Ingvild Kjerkol.-- (Ministry of Health and Care Services, Norway 2022)

## **1.10 Conclusion**

To conclude, the following facts have been demonstrated

- The vaccines have a concerning safety profile, relative to the risk of severe outcomes of Covid-19 among children. Per government estimates, risk of severe outcome is 54-105 side effects per million. The infection fatality rate post Omicron in a population with high level of seroprevalence is indeterminate and likely well below the original estimate of 2 deaths per million among healthy kids estimated against the original strain which had a higher fatality rate, accompanied with low population seroprevalence.
- Vaccine effectiveness against symptomatic infection is negative 6-17 weeks after the second dose.
- Vaccine effectiveness against severe outcome is below the threshold of 50% set by FDA, and if we adjust for hospitalizations after the first dose, the vaccine effectiveness works out to be close to 0.
- Countries like Sweden & Norway have not recommended vaccinating kids in this age group emphasizing harms outweigh benefits.
- It can therefore be argued that there's no case to be made for vaccinating kids in the 5-11 age group, and it is recommended that the vaccination program for this age group be abandoned.



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