



Covid-19 vaccine information for children aged 5-11 y/o (last updated 2/26/22)

We have had many calls regarding our opinion about the new recommendations for the Covid vaccine in children 5-11 years old. We advise all parents to look at as much data as possible and weigh the risk and benefits when making a decision to vaccinate your child. We generally look at the CDC data, which is usually the most robust but also look at smaller studies and studies from other countries as well, especially when there seems to be some discrepancy in data interpretation. Regarding the Covid-19 vaccine, Israel has a lot of high quality data in our opinion that has been very useful. Anecdotal stories, e.g., facebook post of a child losing their eyesight after a vaccination, can be interesting and sometimes lead us to do more research but we rarely use them to make a medical decision. Even though we speak with physicians to get a sense of what they are experiencing on a larger scale through patient care, we generally will use multiple research articles to draw a conclusion. At the end of this review, we offer an example of a research article and how we might use it for a recommendation.

Dr. Lams' current thoughts about the Covid-19 vaccine...

Basics:

- Pfizer makes the vaccine.
- For children 5-11 y/o, the dose is 1/3rd (10mcg) of the >12 y/o dose (30 mcg).
- Pfizer tried different doses in kids and settled on 10mcg that seemed to give adequate antibody response without having as many side effects.
- FDA Safety data was based on 3,100 vaccinated children, and 1,538 placebo. No serious side effects to date but we know that statistically it will take millions of vaccinated children to find a rare side effect, if one exists.
- Effectiveness: Immune system response was comparable to those of individuals 16-25 years of age. The vaccine was found to be 90.7% effective in preventing Covid-19. Mortality was not studied as they will need a much larger sample size before drawing any conclusions. Generally it would be logical to think that if it prevents over 90% of Covid-19 cases that mortality would likely decrease.
- It will have an orange cap to help differentiate it from the adult vial.
- It is not given in our office. Please see Kauai.gov -> Covid -> Vaccine Information for more information on where you can receive this vaccine.

Here is a table we created to compare Covid-19 Infection to Covid-19 Vaccine Side Effects and tried to match them up as closely as we could to help give some perspective. *****We used 12-17 y/o age group vaccine data for side effects as there is not enough data in the 5-11 y/o age group to compare at a large scale*****

Covid-19 Infection (5-11 y/o)	Covid Vaccine (12-17 y/o)
>1.9 million infections in ages 5-11 years between 3/1/2020-10/10/2021	8.9 million doses of Pfizer vaccine given to 12-17 y/o age group between 12/14/2020-7/16/2021
	VAERS received 9,246 reports (Vaccine Side Effects), this is a rate of 1/1,000 vaccines. *** Remember the VAERS is a passive vaccine surveillance system that accept reports from ANYONE ***
Hospitalization rate in 5-11 y/o: 4/1,000 infections	Serious side effects were 9.3% of VAERS reports, which is a rate of 9.6/100,000 vaccines. Serious side effects include any of the following: Hospitalization, life threatening illness, permanent disability, congenital anomaly or birth defect or death. All reports of serious side effects receive follow up to obtain additional information. The vast majority are shown to not be related to the vaccine, but to be extremely cautious I use the reported rate as a guide.
Death rate in 5-11 y/o: 5/100,000 infections	14 deaths were reported (2 pulmonary embolisms, 2 suicide, 2 intracranial hemorrhage, 1 heart failure, 2 more that were definitely not related, and 6 pending further review. Again to be extremely conservative and extra safe let's say all 14 deaths were due to the vaccine, that would be a rate of 1.5/1,000,000 vaccines.
Common Symptoms: Fever, Headache, Fatigue, Cough, Runny Nose, Sore throat, Abdominal Pain, Vomiting, Diarrhea	Non Serious side effects: 90.7% of VAERS reports, which is a rate of 9/10,000 vaccines. Of these reported most common were dizziness, syncope, nausea, headache, and fever
Myocarditis for children <16 y/o between 3/2020-1/2021: 1.3 cases of myocarditis per 1,000 cases of Covid (a limitation is that MISC was included in this group) vs 3.6 cases of myocarditis per 100,000 children	Myocarditis from vaccine per VAERS, 4/100,000 vaccines (this is about the same rate that some of our pediatric cardiologist colleagues thought they had been seeing, about 1/20,000). All cases were monitored in

without covid (large multi centered study). Another study: Myocarditis from Covid infection in males age 12-17 y/o was 4.5/10,000 infections (population based analysis, not peer reviewed).	the hospital and most discharged after a few days without complication.
Extended (long haul) symptoms from Covid: Various studies suggest 1-10% of school children have symptoms lasting at least 1-2 months. Headache, fatigue, sleep disturbance, abdominal pain, difficulty concentrating, and loss of smell are most common prolonged symptoms. Most seem to resolve by 3 months.	Extended symptoms from Vaccine: Unknown, but even if all common reported vaccine side effects lasted 3 months it would be 0.0009%
Antibodies from natural immunity seem to last around 6 months but are inconsistent overall. It seems that you get better immunity after a severe infection.	Antibodies from Pfizer vaccines seem to last about 6 months or so, making infection increasingly likely after 6 months. Although protection against severe disease and death seems to last much longer.
Multi Inflammatory Syndrome in Children (MIS-C): Autoimmune response from Covid that occurs 2-8 wks after infection, it is very serious. Most common in ages 6-12 y/o, with a rate of about 1/3,200 infections. 60% of MIS-C patients are admitted to the ICU, with a death rate of 1-2%.	MIS-C from vaccine: Unknown
Increase risk that a child will spread Covid to adults or elderly in the family.	
Increasing the spread of Covid, which increases the chances of mutations.	Decreases the spread of Covid, which decreases the chances of mutations.

Responses to common parent Questions and Comments:

- Comment:** We don't know any long term complications from the vaccine. I am worried about what might happen years after taking the vaccine?

Response: That is correct we will not know any long term complications for years from now, nor do we know any long term complications that might occur from Covid infection that might happen years from now. Generally speaking, it is more common to have autoimmune reactions from a large natural infection than from a small amount of viral particles in a vaccine. Past examples of this are shingles from the chickenpox virus and subacute sclerosing panencephalitis from the measles virus. Both of these nasty reactivation of the virus or autoimmune response are significantly more common from

natural infection. Updated information about the MIS-C data supports that as expected there is less autoimmune issues from the vaccine than from the actual virus itself!

2. **Comment:** I heard that the vaccine causes infertility problems? My child can't take this risk.

Response: Not that I am aware of. I have not come across any data to date to suggest this. I have asked Ob-Gyn physicians who have also not seen any study that suggests this nor any anecdotal stories from them that would suggest this is possible or likely. BUT!!! There is mounting evidence that covid does attack the testicles in cases and that animal studies shows that after covid they have atrophy of their testicles, rather frequently in fact. Thus, there may be a mechanism that a vaccine could cause autoimmune issues to the testicles. As noted above, all data would suggest that any autoimmune reaction from the vaccine would be less than that of getting a natural covid infection.

3. **Question:** What if the vaccine causes a higher rate of myocarditis in the 5-11 y/o age group?

Response: The data is in!!! As expected cases of myocarditis in the 5-11 y/o age group does occur after covid vaccine, but it is much more rare than the 11-21 y/o group. Again, myocarditis and cardiac complications from a natural covid infection are significantly higher.

4. **Question:** What if the vaccine causes MIS-C?

Response: The data is in!!! As anticipated the vaccine can cause MIS-C, but it is extremely rare, and seems to be less severe. Although still uncommon, it is much more likely to get MIS-C from a natural covid infection.

5. **Question:** Does the mRNA vaccine actually give you Covid?

Response: No, the mRNA is an instruction only for the spike protein of the virus. It cannot make the entire virus.

6. **Comment:** A prominent French Virologist claims that the mRNA vaccine will cause mutations that will lead to dangerous new variants.

Response: First, all the significant variants like Delta were mutations that occurred BEFORE the vaccine and not after the vaccination was given to people. Second, the mutations that occur in a virus are random and are occurring all the time when the virus replicates. Thus, the more a virus replicates across a large population the more mutations will occur, so having more people vaccinated will result in less mutations. If a mutation is able to escape our immune system that is created by natural infection or vaccination it would not necessarily be more dangerous. It could be, but again it would have nothing to do with the vaccine nor natural infection. Third, we have not seen this to be the case for other vaccines that have been around for decades, i.e., Hep B, MMR, Hep A, or Varicella. Fourth, please spend some time reading opinions from almost every other respected virologist.

7. **Comment:** It is better to get a natural infection because you will get a "better" longer lasting immune response than a vaccine and the main study out of Israel suggests that you have a higher risk of getting hospitalized after vaccination than those who have had natural infection.

Response: The main cited study out of Israel that suggests natural infection gives you more protection than the Pfizer vaccine does suggest there is better immunity. In contrast there is a study from the CDC that suggests vaccination is slightly better. BUT please do not get confused!!! This is very important, NEITHER study nor country is saying or suggesting that you should GET Covid because it will give you a better immune response to protect from future reinfection. Both studies are just addressing the question of which gives a better immune response, and this might have implications on when to get a booster. The Israel study didn't include the over 5,000 people who had died from Covid at the time of their study because dead people cannot catch Covid again. Also, out of the entire study only about 30 people from the vaccinated group were hospitalized and out of those hospitalized covid patients "NO Covid-19-related deaths were recorded."

8. **Question:** Will I have to get a booster shot for Covid every year?

Response: This is unknown at this time. I suspect that we will need booster shots, although I am not sure it will be yearly. Similarly, if you had a Covid infection it is likely that you will also need a booster at some point as we see both vaccinated and people previously infected covid getting the Omicron variant at high levels.

9. **Comment:** There is a pill or treatment now that reduces severe Covid by 80-90%, why do we need vaccines anymore?

Response: Treatments (therapeutics) for Covid, like pills and injections that prevent severe disease are therapeutics and need to be taken within the first few days of symptoms to make a significant difference, which would mean getting tested every time a person has symptoms of a common cold. They are also expensive, require a test to confirm you have Covid, and come with side effects that are probably worse than vaccine side effects. Vaccines are prophylactic (preventative), and by all indications extremely safe, so they would be the preferred method to decrease death and disability from Covid.

As physicians and parents of three children, we are always trying to process as much information as possible to make the best decisions for our patients and children. Although we come to the conclusion to recommend the Covid-19 vaccine and vaccines in general, we think it is most important for our parents to have clarity about their decisions.

Aloha,

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Here is one example of a study from the CDC to help illustrate the type of study/data we use to help us make a decision.

Title: “COVID-19 Vaccination and Non–COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021”

Authors: “Stanley Xu, PhD1; Runxin Huang, MS1; Lina S. Sy, MPH1; Sungching C. Glenn, MS1; Denison S. Ryan, MPH1; Kerresa Morrisette, MPH1; David K. Shay, MD2; Gabriela Vazquez-Benitez, PhD3; Jason M. Glanz, PhD4; Nicola P. Klein, MD, PhD5; David McClure, PhD6; Elizabeth G. Liles, MD7; Eric S. Weintraub, MPH8; Hung-Fu Tseng, MPH, PhD1; Lei Qian, PhD1”

This study used a cohort of 6.4 million people who were vaccinated with Covid-19 and compared them to 4.6 million persons with similar characteristics who were not vaccinated, in order to see if there was a significant difference in non-Covid-19 mortality (death from something other than covid) rates between the two groups. Specifically, it was to look if there was possibly any increase in death from the Covid vaccine. They excluded all deaths caused by Covid-19 as this would have unfairly increased the number of deaths in the unvaccinated group. The study found that those who took the vaccine had a lower non-Covid-19 mortality risk, thus suggesting that there is no increased risk of mortality among those who take the Covid-19 vaccine.

Generally speaking, these large studies are very hard to do because they require so many resources, and tremendous funding, thus they are usually done by the CDC or other large medical centers. While no one study is perfect, we usually believe these studies to be more accurate than compared to a smaller study, especially when looking for something that is likely to be rare.

So when asked about the chance of a Covid-19 vaccine causing death, we would use personal experience, discussion with colleagues in our medical field, and studies like this and others to draw a conclusion to the best of our knowledge. Thus, our response might be something like, “We have heard of personal stories, of people dying, even two grandparents of our patients within just a couple days after receiving the Covid-19 vaccine. Although it may be difficult to prove death from a vaccine, we do believe that the vaccine can cause death, and although this is devastating, studies show that there is no increase in death rate in those who have taken the vaccine, and in fact one of the most well done studies suggests that the you have a lower death rate after you get the vaccine, even when you remove deaths from covid from the equation.”