

Talking About Covid-19 Vaccines for Children Six Months to Four Years Old

On Friday, June 17, the [FDA authorized](#) both Moderna and Pfizer vaccines for children six months to four years old. This evidence summary is provided by a team of doctors and scientists convened by the Brown University School of Public Health in an effort to provide timely knowledge and evidence-based talking points for public health professionals, healthcare workers and others engaging in conversations about vaccinations for children under 5 years old.

Physicians and researchers who have reviewed and summarized the evidence include [Megan L. Ranney MD MPH](#), [Anand K. Swaminathan MD MPH](#), [Jeremy Faust MD MS](#), [Darrin Long MD MBA](#), and [Katelyn Jetelina MPH PhD](#).

We all want to protect our children

We now have a safe and effective way to protect our youngest children against Covid-19 – vaccines for children between six months and four years old.

- ▶ This is important progress in our fight against Covid-19.
- ▶ We know from vaccinations in 5-17 year olds that hospitalization, critical illness and deaths are all [more common](#) among kids and teens who are **not** vaccinated than kids and teens who are vaccinated and boosted.
- ▶ Some kids do get [Long Covid](#), and don't recover for weeks or months.

Covid is a real threat for our youngest children

- ▶ During the Omicron surge this winter, children under five years old were hospitalized at a [rate 5 times greater](#) than when Delta was the dominant variant.
- ▶ Only [about half](#) of hospitalized young children had an [underlying medical condition](#) – the other half were healthy children with no prior conditions.
- ▶ Young children are also at risk of the rare syndrome known as [MIS-C](#) (Multisystem Inflammatory Syndrome in Children), which is caused by Covid-19.
- ▶ Covid-19 is among the leading causes of death for children in this age group

Extensive trials prove the vaccines are safe and effective for children ages 6 months to 4 years old

- ▶ The two vaccines for children 6 months to 4 years old are now authorized by the Food and Drug Administration (FDA) because these clinical trials prove the **vaccines are safe and effective**.
- ▶ For our youngest children, these vaccines will be delivered in 2 doses ([Moderna](#)) and 3 doses ([Pfizer](#)).
- ▶ Each shot has less vaccine in it than the dosage for older children and adults.

- ▶ Vaccines will be available through physicians offices and pharmacies (so far, CVS, Walmart and Rite Aid have announced they will provide vaccinations for children under 5).
- ▶ Independent scientists and medical experts have reviewed safety and effectiveness data from these trials.
- ▶ The Pfizer study included more than 4,500 children and the Moderna study included more than 6,300 children. These studies continued during different phases in the Omicron wave.
- ▶ These studies included children who had previously been infected with Covid-19.
- ▶ In both studies, side effects were minimal, and the chance of a severe reaction was very low.
- ▶ In both studies, vaccinated children saw fewer infections. Vaccines reduced the rate of ANY infection by between 37-80%. Although the overall number of cases were low, both vaccines are expected to decrease hospitalizations and ICU stays, as well.
- ▶ There were no myocarditis cases reported in these clinical trials. This is great news but also to be expected with such a rare event. Doctors and authorities will closely follow the real world data on this. The dosing at this age group is so low that myocarditis as an issue for very young kids is possible, but unlikely. But kids can get myocarditis from infection, and if they do, it is much more severe than vaccine-induced myocarditis.

Vaccines can get kids back to daycare, camp and preschool safely

- ▶ Young kids have difficulty with other protective measures (like masks and social distancing).
- ▶ In the short term, Covid-19 means missed school days. If large numbers of kids or teachers are sick, entire schools can be forced to close.
- ▶ Getting vaccinated and boosted reduces the chance of infection and the need to miss preschool or daycare if sick.
- ▶ Kids are very effective at transmitting Covid-19 – they can get their grandparents, parents, and members in the community sick.
- ▶ Data on older children and adults shows Covid-19 vaccinations have been safe
- ▶ Almost a billion doses of mRNA vaccines have been safely administered across the world, and we know a lot about the ingredients of these vaccines and how they work: mRNA molecules are broken down within 72 hours. They do not enter the cell nucleus or change DNA. Other vaccine ingredients, like fats, are broken down within 4 days. Ingredients do not linger within the body.
- ▶ There is extensive data from adults and adolescents that the mRNA vaccines have no impact on fertility. COVID-19 infection, though, does lead to temporary infertility among males.

The virus will continue to mutate

The virus is continuing to mutate to become more transmissible, which means more kids will get infected – and the more kids get sick, the more kids end up in the hospital (as we saw during Omicron).

A Quick Breakdown of the Moderna and Pfizer Trial Data

Both Moderna and Pfizer vaccines are effective

- ▶ Moderna: Children 6 months through 5 years receive a two-shot series, with two doses spaced four weeks apart. The dosage for each shot is one-quarter of the adult dosage (25 mcg per dose).
- ▶ Pfizer: Children 6 months through 4 years old receive a three-shot series, with two doses spaced three weeks apart and followed by a third at least two months later. (The Pfizer vaccine was already approved for children 5 and older) The dosage for each shot is one-tenth the adult dosage (3 mcg per dose).
- ▶ Moderna is most effective starting 14 days after dose #2; Pfizer is most effective starting 7 days after dose #3.
- ▶ Both vaccines are effective in reducing the rate of infection (37-80%) and create similar levels of immunity in kids, as in teens and adults. It is estimated that both vaccines decrease the rate of hospitalization, the rate of MIS-C, and the rate of ICU stays, as well.
- ▶ Effectiveness was similar in kids who had previously been infected with Covid, compared to those who had not previously been infected with Covid (although the overall numbers of kids with prior Covid was small, so data is still being collected).

Both Moderna and Pfizer vaccines are safe

- ▶ Side effects reported in the trials were minimal. Consistent with trials in other age groups, Moderna recipients reported slightly higher rates of side effects than Pfizer recipients.
- ▶ The most common side effects were dependent on age group:
 - ▶ For children 6-23 months old, irritability and drowsiness was most common.
 - ▶ For children 2-5 years, pain at injection site, low fever, and fatigue was most common.
- ▶ Side effects, like fever and joint pain, were more common after dose 2 than after dose 1 (which is consistent with other age groups)
- ▶ No myocarditis cases were reported in clinical trials.