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## **Understanding COVID-19 Vaccine Safety for Babies and Children**

How do we know the vaccines are safe?

The science behind COVID-19 vaccines is not new. COVID-19 vaccines were developed using technology that has been evolving since the 1980s. They also were not the first coronavirus vaccines ever made. Scientists have been working on vaccines for the COVID-19 virus' cousins, SARS and MERS, for nearly two decades. These two viruses gave scientists a head start on understanding how to combat COVID-19. mRNA technology also allows us to develop vaccines more quickly. No steps are skipped, it's just a new technology that moves quicker, like moving from dial-up internet to fiberoptic cable.

ALL vaccines are rigorously tested and evaluated before approval. Before a vaccine can be considered for approval or emergency use authorization by the FDA, a vaccine manufacturer must show it is safe and effective through clinical trials. A group of independent experts, the Vaccines and Related Biological Products Advisory Committee, review the science and make a recommendation to the FDA as to whether a vaccine should be approved or authorized. The FDA only licenses vaccines that have data that shows that the vaccines' benefits outweigh the potential risks. If there is any question about the data, or any holes in the data, the FDA will request further studies before approving the vaccine. After the FDA approves a vaccine, the Advisory Committee on Immunization Practices (ACIP) – a group of public health and medical experts – carefully reviews all the data from the vaccine's clinical trials and any other studies available to decide whether to recommend it and, if it is recommended, for what ages. The CDC Director then reviews the ACIP's recommendations and decides whether to officially approve them.

Once a vaccine is approved, it is still monitored for safety. Both CDC and FDA run reporting and monitoring systems, including new ones established primarily for COVID-19 vaccines, and will change recommendations based on this data. When these systems revealed a slight risk from the J&J COVID vaccine, for example, the CDC changed its recommendations. Between clinical trials and real-world use, we have more data on the safety of COVID vaccines than we will EVER have for most medicines, vitamins, or nutritional supplements.

## Why should children be vaccinated against COVID-19?

**COVID-19** is a serious threat to children. Over 118,000 children ages 0 to 17 have been hospitalized with COVID-19 and 1445 have died (data as of April 5, 2022). COVID has claimed the lives of 440 children under the age of 5. This is an unacceptable number of deaths – each represents families who now have empty highchairs and booster seats at their table each morning. During the most recent Omicron wave, hospitalizations rose sharply in young children. Healthy children are at risk, too – more than half of the children who have been hospitalized with COVID don't have any underlying medical conditions. We now have a safe, effective vaccine available for children that works well to prevent hospitalization and death. Each child lost is a tragedy and we have a responsibility to use the tools available to us to prevent more suffering.

Children are also at risk of long-term health conditions due to COVID-19 infection (commonly called "long COVID"), including the very serious Multisystem Inflammatory Syndrome in Children (MIS-C), a condition where different body parts become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. Over 7,800 cases of MIS-C have been reported so far.

COVID vaccines will save children's lives, and they can also keep kids healthy and in school, avoiding further disruptions to their routines.