COVID-19 Vaccine FAQs

This document was developed by Megan Culler Freeman MD, PhD and Michael Green, MD MPH from UPMC Children's Hospital of Pittsburgh Division of Pediatric Infectious Disease, and Tim Shope MD, MPH from UPMC Children's General Academic Pediatrics to provide school, out-of-school time, and early childcare staff and personnel with the most up-to-date information on COVID-19 vaccine. This document is updated frequently to reflect the current situation.

If you have any immediate questions or concerns regarding COVID-19 **please contact 2-1-1**. Their staff are trained to assist school, out-of-school time, and early childcare staff with navigating COVID-19 in the school setting.

Have a question about COVID-19 Vaccine that is not on this document and would be helpful to schools? Submit your question here to be added to the document.

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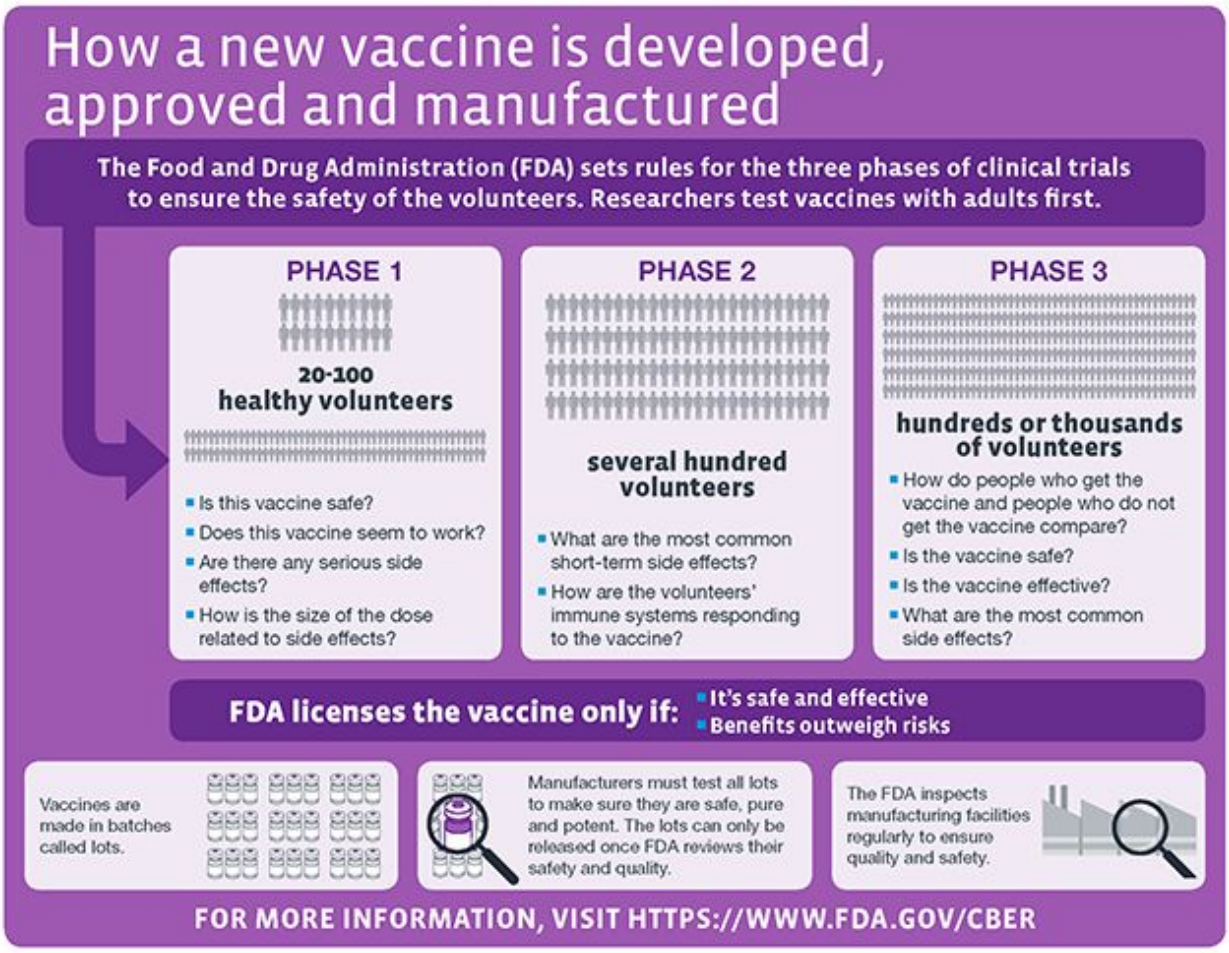
Vaccine Development Basics

What are the different phases of vaccine development?

Prior to Phase 1 (see graphic below) there are years of research in scientific labs to understand the virus or bacteria that causes the disease, leading to the development of a vaccine, which is one of the reasons funding for the National Institutes of Health (NIH) is so important (the government agency that provides research grants to scientific investigators throughout the country). While the SARS-CoV-2 vaccine was developed in under one year of time, scientific research on other coronaviruses, including creating vaccines for SARS-CoV-1 and MERS, helped to lead the way.

https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fparents%2Finfographics%2Fjourney-of-child-vaccine-text.html



Why were the vaccines developed so quickly?

As far as the accelerated timeline for development, there were a couple of differences about the approach to these vaccines that led to increased speed.

1. Strategies based on decades of basic science and previous successful vaccine candidates against other coronaviruses, allowing for a bit of a 'head start' when applying those techniques to this new virus.
2. Decreased time between administrative tasks. Any paperwork regarding these vaccines was jettisoned to the front of the line. Delays in review of these materials can add years to the development process.

3. Financing by the government up front, which saved the companies from raising their own funds for research, development, and distribution-which is otherwise a significant hurdle.
4. Uncontrolled community spread in the US, meaning that those who participated in the vaccine trial had the 'opportunity' to be exposed to the virus, thus testing the effectiveness of the vaccine.

Information on Approved Vaccines

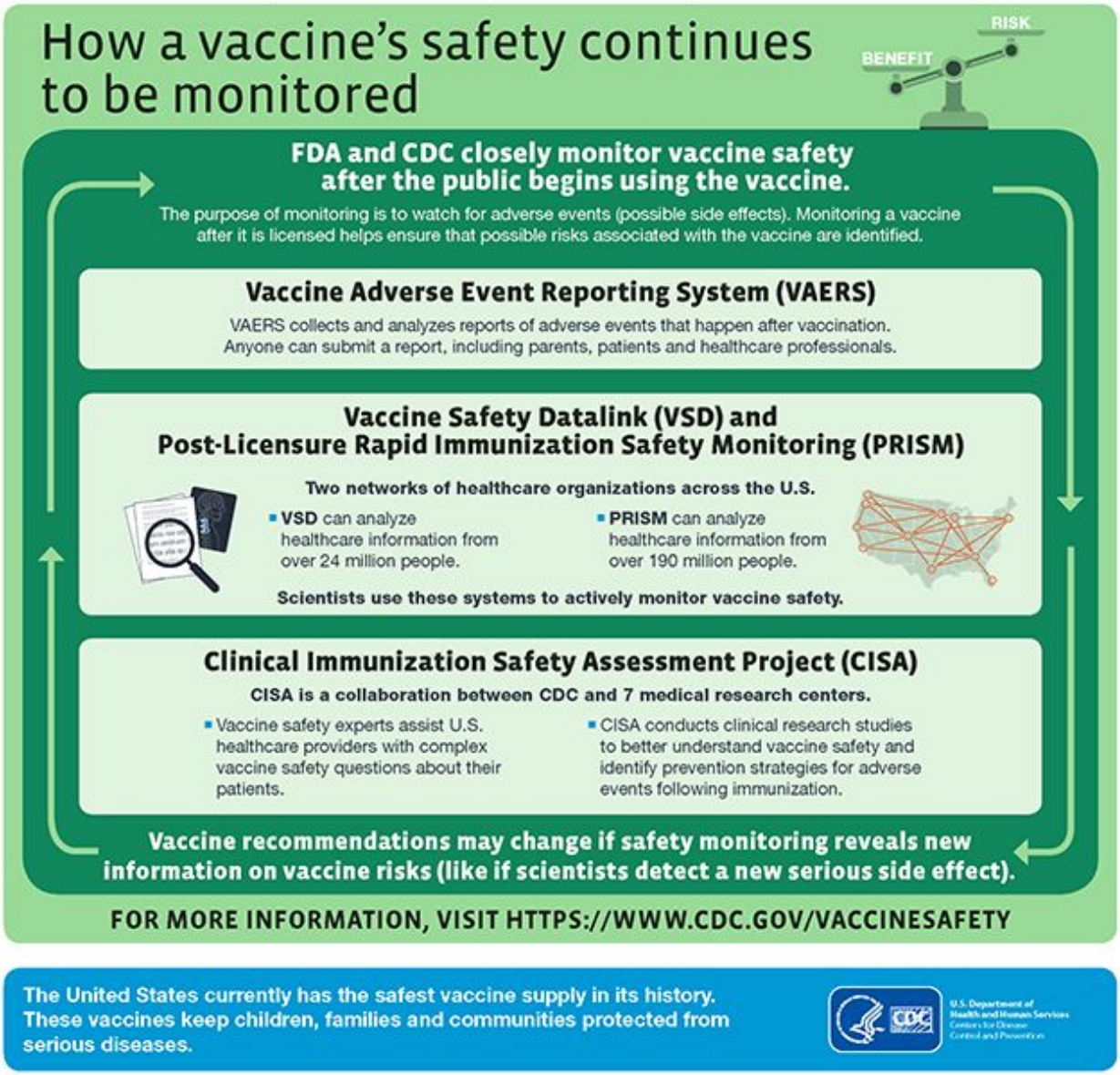
Which companies have vaccines that have passed phase III trials?
Moderna and Pfizer have SARS-CoV-2 vaccines that have passed these trials in the US. Both vaccines are an mRNA platform. There will likely be additional companies that generate effective vaccines that may use a different platform.

What is an mRNA vaccine?
mRNA, or messenger RNA, are the 'instructions' that your cells use in order to make proteins of all kinds. Delivery of the 'instructions' to make the spike protein of SARS-CoV-2 can help your body make an immune response to that part of the virus. Antibodies to that protein can prevent the virus from entering the cells and being able to replicate so it can't cause disease. It does not alter a person's DNA.

How do I know they are safe?
So far, over 70,000 people have been involved in these trials (about half having received placebo and half vaccine). No serious adverse events were reported such as hospitalizations. One of the vaccines did report that a small percentage of participants reported headache or fatigue. We anticipate additional information about minor side effects once the data is made public.

Vaccines and vaccine data are reviewed by independent (not related to the company) data safety monitoring boards. They are also reviewed by the FDA. There are strict standards in place for vaccine safety and penalties in place for not being forthcoming with data such as those regarding adverse events. It is in everyone's best interest that these vaccines are safe!

After the phase III trial, there is an additional period of monitoring by the FDA (see graphic below) after the vaccine starts to have wider distribution. Any adverse events will continue to be reported, so we will continue to collect data on this over time.



<u>What do the vaccines prevent?</u>

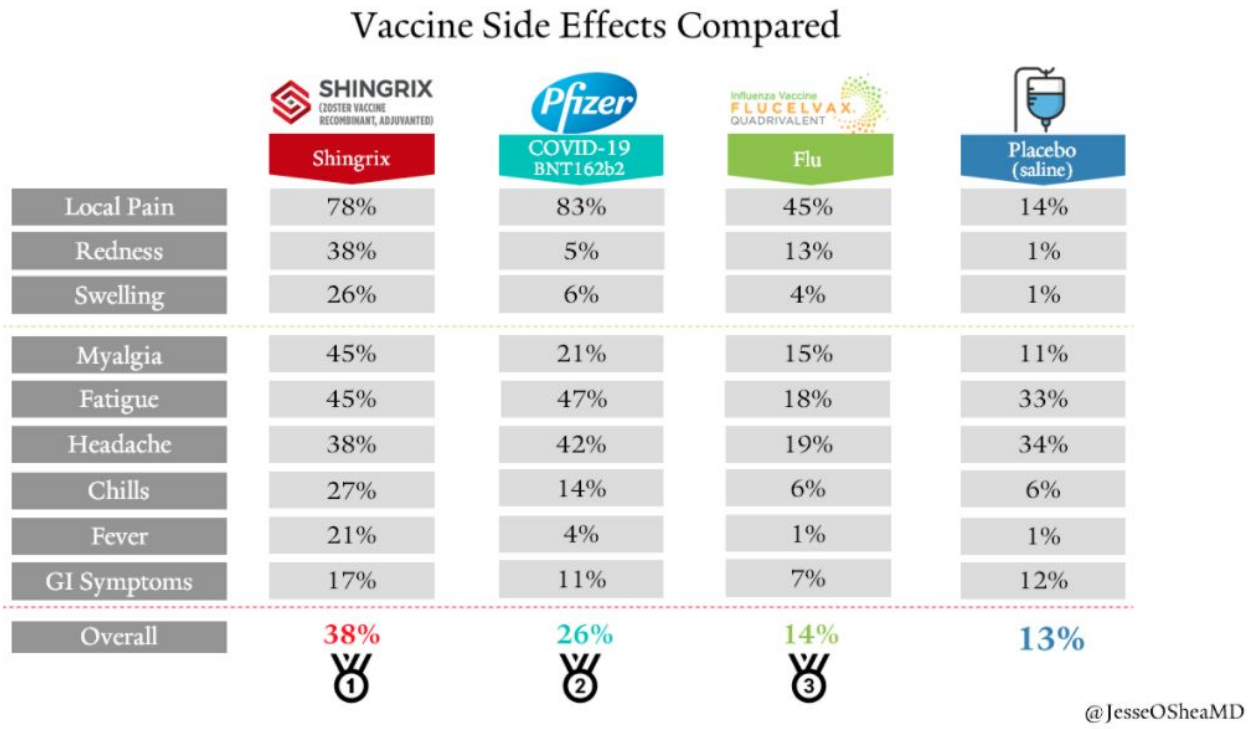
So far both vaccines have claimed to prevent symptomatic disease and one has made a distinction about the prevention of severe disease (requiring hospitalization). We do not yet know the impact on asymptomatic infections.

Why do we need two doses?

Often the immune system requires a 'priming' exposure and a 'boosting' exposure to make an optimal immune response. The companies haven't yet released any data regarding efficacy after one dose, but it is likely that the vaccines were more efficacious after two doses.

What are the potential side effects of the vaccine? How concerned should I be about side effects?

For the Pfizer vaccine, the most common adverse reactions were injection site reactions, fatigue, headache, muscle pain, chills, joint pain, fever. Most adverse reactions did not interfere with daily activities. Note how many participants who received an injection of saline (the placebo) also reported adverse reactions in the trial in the 4th column of the graphic, below.



What are the chances of an allergic reaction to the vaccine?

Just like any vaccine, if a person has a history of allergic reaction to one of the vaccine components, then they should not receive the vaccine without discussing with their physician or Allergy specialist. The two patients in the UK recently in the news for vaccine allergic reactions had a history of reactions to other vaccines.

When the vaccine becomes available to the general population, for what ages will it be made available?

The FDA just voted to approve Emergency Use Authorization (EUA) for people age 16 and older. We do not yet have information from the Moderna vaccination.

Once I get vaccinated, can I still get sick with COVID-19?

The trials have indicated that the vaccine reduces the chances of becoming infected with SARS-CoV-2, but a small number of people who get the vaccine will become infected. The vaccines also have shown to prevent **severe** disease, so vaccinated people will be unlikely to need hospitalization for their illness if they do become infected. As more people in the population become immune due to the vaccine, there will be less circulating virus, so the risk of infection in the community should also decrease-but for this to work, we'll need everyone to pitch in and get the vaccine when they can!

After people start getting vaccinated, will we still need to wear masks?
Yes. We will continue to need masks for two reasons. First of all, it is so far unknown if the protection that the vaccine provides (which is protection from having symptoms of COVID or severe disease) also prevents an exposed person from spreading SARS-CoV-2 to others. That means that even vaccinated people should continue to wear masks! Secondly, it is going to take time to vaccinate enough people in the community to decrease viral spread, so while vaccination is one tool in our toolbox, we need to continue to use our other prevention strategies of masking, distancing, and hand hygiene until we have decreased community transmission. And finally, although these vaccines are highly effective (>94% is really excellent for a vaccine), it is possible to get COVID even after getting the vaccine in a very small number of cases.

Children and Vaccination

Can children and pregnant women get the vaccine?
Neither vaccine has been studied in these populations yet. It is unlikely to be able to be given to these groups before the studies are complete. Both vaccines either have initial data or plans to involve patients age 12-17 in a trial, so hopefully we will know more about that group soon. The Moderna vaccine will begin to study children 12-18 in January and Pittsburgh will be a participating site. Interested parents can register their children in our registry at PVTU.org.

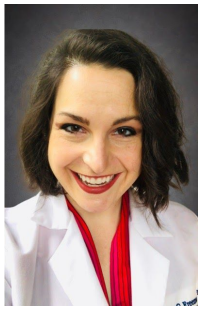
What is the timeline on a vaccine for children?

See above about trials in children.

What risks exist for people who have autoimmune disorders?

In general, people with autoimmune diseases have weakened immune systems due to the autoimmune disease and the medications taken to control the disease. They benefit from vaccination to help protect them from infections, as they are more susceptible than others to many infections. Depending on the type of autoimmune disorder and medication, it is sometimes recommended that they avoid vaccines that contain 'live' virus. The vaccines for SARS-CoV-2 are NOT live virus vaccines. Specific safety data in these populations has not yet been made available by either company.

About the Authors



Megan Freeman, MD, PhD

College/Medical School: University of Kentucky/Vanderbilt University

Residency: UPMC Children's Hospital of Pittsburgh

Career/Research Interests: I plan to run a lab and see patients on the Peds ID Consult service. I'm interested in cell biology of viral infections, in particular in enteroviruses and how they get from the primary site of replication in the gut to other locations where they cause disease, such as the CNS (AFM), skin (HFMD), and the heart (myocarditis). My previous research was investigating the cell biology of coronavirus infections.

Honors/Awards: Pediatric Infectious Diseases Society – St. Jude Children's Research Hospital Fellowship Program in Basic and Translational Research, 2019 1st year fellow of the year awarded by graduating residents

Publications

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Michael Green, MD, MPH

Michael Green, MD, MPH, is Professor, Pediatrics, Surgery, and Clinical and Translational Science, at the University of Pittsburgh School of Medicine. He received his medical degree from the University of Illinois in Chicago and his master's degree from the University of Pittsburgh in Pennsylvania. He completed a pediatric residency and a fellowship in pediatric infectious diseases at Children's Hospital of Pittsburgh.

Throughout his career, Dr. Green's clinical and research interests have focused on the prevention and treatment of infections in immunocompromised children with a particular interest in the care of children undergoing solid organ transplantation. Among his professional affiliations, Dr Green is a member of the Pediatric Infectious Disease Society, the American Pediatric Society, the Infectious Diseases Society of America, the International Pediatric Transplant Association, and the American Society of Transplantation (AST). Dr Green has published more than 160 peer-reviewed articles, has been invited to author over 45 publications, and has written more than 75 review articles or textbook chapters. He serves as an Associate Editor for both Pediatric Transplantation and the Journal of the Pediatric Infectious Disease Society. He was co-editor of the First Edition of the Guidelines for the Prevention and Management of Infectious Complications of Solid Organ Transplantation published by the American Society of Transplantation and was the

Editor-in-chief for the recently published 4th edition the guidelines which were published in 2019. He currently serves on the Pediatric Infectious Diseases Sub board of the American Board of Pediatrics and is a member of the FDA Antimicrobial Advisory Committee.

Publications

Timothy R. Shope, MD, MPH

Dr. Shope joined the faculty of Department of Pediatrics, Division of General Academic Pediatrics, in 2011. Previously, he served 21 years in the U.S. Navy, retiring at the rank of Captain. His significant roles included associate and pediatric residency program director from 2000-2008 at the Naval Medical Center Portsmouth, Va. and the Specialty Advisor to the Navy Surgeon General from 2008-2011. As the Specialty Advisor, he managed and mentored the Navy's 150 pediatricians stationed across the world and advised the Navy on child health policy. At UPMC Children's Hospital of Pittsburgh, Dr. Shope engages in direct patient care, education for medical students and residents, and clinical research involving improving the diagnosis and treatment of common pediatric infectious diseases such as UTIs, sinusitis, acute otitis media and pneumonia. Dr. Shope is nationally known for developing exclusion and return to care criteria for mildly ill children in childcare, and has written a book entitled, "Managing Infectious Diseases in Child Care and Schools," published by the American Academy of Pediatrics, now in its 5th edition. In 2020, Dr. Shope became

the Medical Director, Quality and Value Based Payment Programs for the Pennsylvania Pediatric Health Network (PPHN) – a clinically integrated network in Western Pennsylvania encompassing 55 pediatric practices and UPMC Children's Hospital. The goal of the PPHN is to improve quality of care and decrease costs for the ~300,000 children cared for by its member practices.

Publications