Community Reach
of Montgomery County

Why should I be vaccinated for COVID-19?

- **COVID-19 is still widespread –** here locally, throughout the U.S., and the world. People who have it and are asymptomatic and those who do not yet have symptoms can unknowingly transmit it. Wearing masks, washing hands, keeping social distance, and avoiding large groups help to decrease your chances of getting COVID, but are not 100% effective.

- **COVID-19 infection can cause serious illness and death** – Although some have contracted COVID and did not know it because they had no symptoms, over 500,000 in the U.S. have died from the disease. Additionally, more than 1 in 4 people infected with COVID, including those with mild symptoms, have experienced serious long-lasting side effects. Because COVID-19 is new in people, we do not know how long these health issues may continue, if they will get worse with time, or whether additional complications will appear over time.

- **Being younger is no guarantee of being safe -** While COVID-19 infections tend to be worse in older people or those with health issues, some young and healthy people have had serious and long-lasting symptoms and have even died.

- **Being vaccinated also protects those around you** – Vaccination appears to reduce the chance that you will spread the virus to others, although this is still being studied. An unvaccinated person can contract COVID, have no symptoms, and still pass the infection on to family and friends who may become very sick and even die. Being vaccinated reduces this risk and is the best way to protect your family, friends and even strangers who come near you.

- **The vaccines are very effective -** The vaccines used here in the U.S. dramatically reduce the chances of getting infected, becoming seriously ill or dying from COVID-19.

- **The vaccines are very safe** – Tens of thousands of people volunteered to test the vaccines used in the U.S. and the FDA carefully reviewed these tests before the vaccines were approved for use. The FDA continues to monitor reported side effects. Serious side effects are very rare. Soreness where the shot was given or cold/flu-like symptoms for 1-3 days following an injection sometimes occur and are not a cause for concern.

- **Reopening our communities depends on you -** Opening our schools, work sites, restaurants, and more depends on reducing the number of cases and infections. Getting vaccinated will help all of this happen more quickly.

Maryland State government website page on COVID-19 FAQs:
https://covidlink.maryland.gov/content/faqs/

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How are vaccines tested, approved, and determined to be safe?

Before vaccines can be used in the U.S., they must pass a rigorous testing process and receive approval for use from the U.S. Food and Drug Administration (FDA).

- A new vaccine is tested first in animals. Only after it has been shown to be safe in animals are studies begun with people who have volunteered to be part of the vaccine study.

- The studies using volunteers are called “clinical trials.” They include three separate phases. Each phase has more test subjects than the last. Volunteers are provided with information about study including any known potential risks. They must voluntarily choose to participate.

- Phase 1 focuses on confirming the safety for further testing in humans. This phase involves small numbers of volunteers (fewer than 100) who may also receive different amounts of the vaccine. The study can only move to Phase 2 of the results show the vaccine is safe for this volunteer group.

- Phase 2 includes hundreds of healthy volunteers who must reflect the age, race and genders of the population the vaccine is intended to protect. If Phase 2 results are successful, the study can move to Phase 3.

- Phase 3 includes many more people (tens of thousands for current COVID vaccines), and must continue to include a mix of volunteers from all the age, race and gender groups who might later use the vaccine. About half the volunteers receive the vaccine; the other half receive a “placebo” – something that looks like the vaccine but has no health benefit. Volunteers do not know which they receive. Side effects and infection are studied and compared between the groups. If the vaccine is effective, those who receive the vaccine should show substantially less infection or illness than those who receive the placebo. Since this phase includes so many different people who might receive the vaccine, the results are expected to be similar if the vaccine is approved for wide use.

- After Phase 3 is completed, the manufacturer and testing company can apply to the FDA for approval to distribute the vaccine for use in the U.S. An independent (non-FDA) scientific advisory group reviews the data and recommends that the FDA approves or does not approve the vaccine. The FDA’s own experts consider this recommendation, and make the final decision. Even with approval, the FDA may say it can only be used for people with specific conditions (i.e. people age 16 – 100, women who are not pregnant, people without heart conditions, etc.).

Though these vaccines were developed very quickly, they went through the same testing and analysis as other vaccines. Scientific knowledge and research from the development of previous vaccines helped build the COVID vaccines. Much of these previous vaccines used messenger RNA (mRNA) or genetic engineering, or were cell-based vaccines. These technologies are also being applied in the ongoing work of vaccines for influenza, Ebola, and other infectious diseases. Scientists have combined their knowledge and governments have provided funding to move the research forward in a way that has never before happened. Together, these factors and the interest of so many have been responsible for number of effective vaccines in a short period of time.

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What were the demographics of the COVID-19 Vaccine Phase 3 volunteers?

Pfizer Phase 3 Volunteers: https://www.fda.gov/media/144245/download
Phase 3 included more than 37,000 test volunteers for two doses

- 49.4% female, 50.6% male
- 81.9% White, 9.8% African American, 4.4% Asian, and <3% other racial groups.
- 26.2% Latino.
- 21.4% were 65 years old or younger and the median age of participants was 51.
- Frequently reported health issues in test volunteers included obesity (35.1%), diabetes (8.4%), and pulmonary diseases (7.8%).
- Overall, 46.2% of all observed patients had health issues that were expected to affect their likelihood of infection or serious illness.
- More than three-fourths (76.7%) of participants were from the US.
- The vaccine was slightly more effective for 16-55 year olds (95.6%) than for those over 55 (93.7%).

Moderna Phase 3 Volunteers: https://www.fda.gov/media/144434/download
Phase 3 included more than 28,207 test volunteers for two doses (one month apart).

- 47.3% female, 52.7% male
- 79.2% White, 10.2% African American, 4.6% Asian, 0.8% American Indian or Alaska Native, 0.2% Native Hawaiian or Pacific Islander, 2.1% Other, and 2.1% Multiracial.
- 20.5% Latino.
- The demographic characteristics were similar among those who received vaccine and those who received placebo.
- The mean age of the trial population was 52 years (range 18-95);
- 22,831 (75.2%) were 18 to 64 years of age and 7,520 (24.8%) 65 years or older.

Janssen (J&J) Phase 3 Volunteers: https://www.fda.gov/media/146217/download
Phase 3 included approximately 40,000 test volunteers who received 1 dose of vaccine or placebo. Trials took place with volunteers living in eight different countries, and after COVID variants were discovered.

- 44.5% female, 55.5% male
- 62.1% White, 17.2% Black or African American, 8.3% American Indian or Alaska Native, 3.5% Asian, 0.3% Native Hawaiian or other Pacific Islander, and 5.4% multiracial
- 45.1% Latino
- 20.4% were 65 years old or older
- 39.9% of participants had health issues determined to make them more susceptible to COVID-19
- 46.7% of subjects participated in the United States, 17.3% in Brazil, 12.7% in South Africa, and the remaining 23.3% in 5 different countries in Latin America.

FDA Website Page on COVID-19 Vaccines:
https://www.fda.gov/consumers/consumer-updates/learn-more-about-covid-19-vaccines-fda

CDC Website page on COVID-19 Vaccines: https://www.cdc.gov/vaccines/covid-19/index.html