Frequently Asked Questions about the COVID-19 Vaccines

Q **What is Emergency Use Authorization (EUA) and how is that different from FDA approval?**

A An EUA is a process by which the US Food and Drug Administration (FDA) can authorize a preventive, diagnostic, or therapeutic agent or device by an expedited process during a declared Public Health Emergency, such as the current COVID-19 pandemic. There must be good evidence that the benefits outweigh any risks. For a vaccine to obtain an EUA, there still must be the normal three-phase testing process to determine safety and effectiveness. Most safety concerns with vaccines will show up in the first 6 weeks after they are administered. The FDA has required that all vaccines must have at least 2 months of safety data after the full vaccine course is administered in Phase 3 clinical trial to apply for an EUA. More information is available on the FDA's website.

Q **What are the planned phases of COVID-19 vaccine distribution?**

A Currently, there is not enough approved vaccine available for everyone in the country. Vaccine distribution has been prioritized according to those who are at high risk. Each local authority (usually at the state, Tribal, or local level) can prioritize distribution based on local situations, but in general, this is the priority guidance for the country:

Phase One includes about 15% of the US population, and is further subdivided:

Phase 1a – Healthcare workers, first responders, and long-term care facility staff and residents.

Phase 1b – Adults who have multiple health problems that put them at high risk.

Phase Two includes about 30 to 35% of the population and will include the vulnerable workforce, everyone 65 and older, and people who have health problems that put them at moderate risk.

Phase Three includes about 40 to 45% of the population and will cover most of the rest of the country, including people in less vulnerable jobs (those not having much public contact).

Phase Four includes about 10 to 15% of the population and will include those at the lowest risk.

More information is available on the Centers for Disease Control and Prevention's (CDC) website.

Q **Are there different vaccines for COVID-19?**

A There are currently three vaccines that have received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA). Pfizer/BioNTech and Moderna are both mRNA vaccines, and both require two doses spaced 3-4 weeks apart to be fully effective. Although the mRNA vaccines are similar, they are not interchangeable; in other words, people will need to get the same vaccine for both doses. The third vaccine to receive an EUA is made by Janssen/Johnson & Johnson and is a non-replicating viral vectored vaccine. It only requires one dose. In the coming year, it is anticipated that several more vaccines will obtain an EUA from the FDA.

Q **Why are there different COVID-19 vaccines?**

A There are approximately 330 million people in the US and almost eight billion people in the world. With current technology, no single vaccine can be made fast enough to cover eight billion people in a timely fashion. To end the pandemic, most of the world's population will need to be vaccinated. That is why we need multiple vaccines. Also, until they are fully tested in a Phase 3 trial, it is not known how effective and safe a vaccine will be. That is another reason that multiple vaccines are being developed.

Q **Are the COVID-19 vaccines approved for use in children?**

A The Pfizer/BioNTech vaccine is approved for people 16 and over. The Moderna and Janssen/Johnson & Johnson vaccines are approved for people 18 and over. All three vaccine companies are conducting trials in adolescents 12 and over, but it will be weeks or months before the safety and effectiveness data is available for these ages. If the vaccines prove to be safe and effective for 12 and over, they will then be tested on younger children, but we are months away from having an approved vaccine for younger children.

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Q **Do the COVID-19 vaccines have any side effects?**

A As with all vaccines, temporary and non-serious side effects are common with all of the currently authorized vaccines. Common side effects are soreness at the site of injection, and sometimes redness and swelling as well. Headache, feeling tired, body aches, chills, fever, and nausea are also common temporary side effects. These rarely last more than 2 days and are caused by the body's immune system working as it should. The mRNA vaccines made by Moderna and Pfizer/BioNTech have proven to be remarkably safe; as of the end of April, about 225 million doses of these vaccines had been administered in the US. Other than a small number of allergic reactions, no serious side effects have been reported. About 6 weeks after the Janssen/Johnson & Johnson vaccine was released for use, the FDA and CDC paused the use of this vaccine for about 10 days while they investigated reports of very rare but serious blood clots. Out of nearly 8 million doses of vaccine given, 15 people developed a rare but serious form of blood clot. Of the 15 cases, 13 cases were in women under the age of 50. The FDA and CDC decided after careful analysis that risk of serious disease, hospitalization, and death from COVID-19 is far greater than the very small of risk blood clots from Janssen/Johnson & Johnson vaccine.

Q **What are some of the logistics of the COVID-19 vaccine distribution and administration?**

A The mRNA vaccines are very fragile and are not stable for long at room temperature. The Pfizer/BioNTech vaccine requires ultra-cold storage (-70° C, or 94° below 0° F) that is not achievable with regular freezers. The Moderna vaccine must also be kept frozen, but not quite as cold (-20° C, or -4° F). This presents challenges in shipping and storing. The Janssen/Johnson & Johnson vaccine is less fragile, and only requires refrigeration for storage. All vaccines come in preservative-free, multi-dose vials (five dose vials for Pfizer/BioNTech, and 10 dose vials for Moderna and Janssen/Johnson & Johnson). Once the vaccine is thawed or taken out of the refrigerator, it must be used quickly (within 6 hours once the vial is pierced), so there must be careful planning to avoid wasting any vaccine.

Q **How is the Indian Health Service (IHS) distributing vaccines?**

A The IHS receives an allocation of vaccine from the federal government allocation system, then distributes that allocation based on population. Tribal Nations also have the option of procuring vaccine through their state, and some have opted to do this.

Q **Do the COVID-19 vaccines prevent transmission of the virus by asymptomatic carriers?**

A The Phase 3 trials were designed to see how effective the vaccines were at keeping people from getting sick from the virus. The trials did not specifically test to see if they prevented transmission of the virus from asymptomatic individuals to other people. Studies that have been done since the vaccines were released have shown that all three currently available vaccines reduce asymptomatic cases of the virus, but not by 100%. For this reason, mask-wearing and social distancing will still be critically important for vaccinated persons as well as unvaccinated until we reach community immunity and the pandemic ends (see below).

Q **Once COVID-19 vaccinations start, can things go back to normal (life pre-pandemic)?**

A Unfortunately, it will be some time before things get back to normal. In order for the pandemic to end, enough people must have good immunity to the virus to stop it from spreading. Vaccination is our best hope for achieving this. But it will take a long time to vaccinate the vast majority of the nearly eight billion human inhabitants of the planet. Even when the pandemic eventually ends, there will probably still be sporadic outbreaks of COVID-19. This will require a strong public health infrastructure to effectively deal with.

Q **Why do we need to obtain a critical mass target to reach community immunity?**

A Community immunity, also called herd immunity, for COVID-19 can only happen when a certain percentage of people become immune or vaccinated. Right now, we don't know the exact percentage of the population that needs to be vaccinated to stop transmission of COVID-19. However, science from past vaccines and the data available on COVID-19, such as its ability to spread and cause infections in people, shows that between 70 to 90% of the population would need to be vaccinated to reach community immunity and end the pandemic. Until this percentage is reached—whatever it turns out to be—it is recommended to continue to follow social distancing guidelines and wear a mask when you are outside of your house.

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