COVID-19 VACCINES: DEVELOPMENT AND SAFETY

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Developing a vaccine can take many years. Yet, the first COVID-19 vaccines came out less than a year from the discovery of the virus that causes COVID-19. How did that happen?

It is important to know that the vaccines completed all the steps to test them and check for safety. Nothing was skipped.

COVID-19 vaccines are going through all the usual steps for approving a vaccine -- research, three trial phases, careful review and many approvals.



This time, cooperation between researchers, the federal government and private companies shortened the usual timeline. Here are some reasons why the process was quicker for COVID-19 vaccines:

- **Scientists had a head start.** The COVID-19 vaccine effort builds on earlier worldwide research on the coronavirus (especially the SARS and MERS viruses) and advances in vaccine technology.
- **Funding was available.** Sometimes finding money for vaccine studies can take a lot of time. For COVID-19 vaccine, the federal government provided a lot of money right away to fund the vaccine effort.
- **Studies overlapped.** Researchers recruited people for all three phases of the clinical studies at the same time. Due in part to extra funding, they were able to run all three phases of the study at the same time instead of one after the other.
- **Production began early.** Backed by help from the federal government, manufacturers began making and packaging the vaccines while the clinical studies were still happening.
- Less red tape. The new COVID-19 vaccines are authorized with an Emergency Use Authorization (EUA) from the FDA. This takes much less time than a usual approval process. Groups at the federal level are not letting anything delay them from reviewing vaccines. For example, the FDA added a lot of staff to shorten the review process from months to weeks.
- Safety first. A vaccine is only approved if the studies show that it is safe and that it works. As more people take the vaccine, the FDA and the CDC will collect information about the vaccine and continue to study how well they work.
- Study vaccines worked. Because COVID-19 is so widespread, scientists
 could see fairly quickly how many vaccinated people got COVID-19
 compared to how many got sick without the vaccine.

COVID-19 Vaccine Development Steps Vaccine Clinical Studies Vaccine Safety Data Review Vaccine Is Being Made Research Phase 1 Clinical Study **Advisory Committee FDA Review** Manufacturing Built on Is the vaccine safe? FDA looked on Immunization Manufacturing began studies at the data Practices (ACIP) early, as reviews and Phase 2 Clinical Study of other Review and gave authorizations were Does the vaccine work? Emergency Use Recommended who coronaviruses. happening. **Phase 3 Clinical Study** Authorization should get the vaccine. Is the vaccine safe AND does (EUA) to use the it work? vaccine. Clinical study phases overlapped. The Western States Scientific Safety **Review Workgroup** Reviewed the safety and effectiveness.

We have more to learn

The vaccine studies are ongoing and real world information is being added all the time to what we know from the studies. Data to date show the vaccines are very safe and effective. There are still things that we need to learn about the COVID-19 vaccine:

(Oregon, Washington, California, Nevada)

- How long will protection from the vaccine last?
- Can vaccinated people still spread the disease to others?
- Will changes in the virus mean new vaccines need to be developed in coming years?
- Are there other rare side effects we will learn about once millions of people are vaccinated? If a rare side effect occurs (like in April with Johnson & Johnson), the reporting and review process allows scientists to quickly identify it and take action.

These are all good questions that need more study. But they are not reasons to delay getting a vaccine that is safe and effective out to people right now.

You may have questions and mixed feelings

You may feel hopeful about vaccines and keeping friends and family safe from COVID-19. You may feel worried about getting a vaccine yourself. If you are a person of color, you may be wondering if you can trust vaccines from a medical system that has broken trust with your community before. It's understandable to have concerns. Learn more and get support:

- Search COVID-19 on your county website to get local information.
- Talk with your doctor or clinic. If you don't have a doctor, call 2-1-1 or <u>Multnomah County Primary Care Clinic</u>s: 503-988-5558
- Call or visit Oregon Statewide Safe + Strong Helpline for emotional support and resource referral. You don't need to be in crisis. 1-800-923-HELP (4357), linesforlife.org/obhsl/

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