Essential terms doctors need to know about COVID-19 vaccines

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There is a sprint to develop a safe and effective vaccine to fight SARS-CoV-2—the novel coronavirus causing COVID-19—with several currently in phase 3 clinical trials. As the vaccines continue to move forward, questions have come up about the approval process. Understanding the essential terms about vaccine approval can help physicians and other health professionals educate their patients.

“We’ve got to make sure that corners aren’t cut, that it’s safe,” said Sandra Fryhofer, MD, an Atlanta general internist who serves as the AMA’s liaison to the Advisory Committee on Immunization Practices (ACIP) and a member of ACIP’s COVID-19 Vaccine Work Group. “We must have confidence in the vaccine that becomes available.”

As COVID-19 vaccine trials move forward, Dr. Fryhofer—a member of the AMA Board of Trustees—took time to discuss the types of COVID-19 vaccine platforms under study as well as essential terms physicians should know.

Clinical development

“The first one is a preclinical testing in animals and then in phase 1, you're testing small groups of people, maybe 20 to 100 at most,” said Dr. Fryhofer, adding that throughout the process, “you're looking for side effects and you're trying to figure out the right dose to use.”

“In phase 2, you’re looking at several hundred volunteers. Again, you’re looking at side effects and how the dose affects any response,” she explained. “Then phase 3—that’s really fine-tuning, so to

speak, and giving it to thousands of people."

Manufacturers for three potential multidose vaccines have agreed to trials with 30,000 people, while the maker of a single-dose vaccine has agreed to enroll 60,000, Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, recently told physicians. He said those numbers will provide large data sets capable of answering safety and efficacy questions.

"Then there's phase 4, which is the post-marketing studies," said Dr. Fryhofer. "It's very likely that the FDA will require additional post-marketing studies to evaluate future potential adverse serious effects."

Learn how to ready patients now so they'll get a COVID-19 vaccine later.

Emergency use authorization

"The FDA [U.S. Food and Drug Administration] has also discussed a possible EUA—which is emergency use authorization—of an investigational vaccine, which is different from full FDA licensure," said Dr. Fryhofer. "For licensure, you need substantial evidence that the product is both safe and effective."

Guidance from the FDA on what is considered safe and effective is "any vaccine would have to be at least 50% effective," she said.

Learn how the FDA plans to build physician trust for a COVID-19 vaccine.

Vaccine distribution

Initially there will be limited doses of the vaccine or vaccines available, which will require a phased approach.

"Many groups have weighed in on this" and "agree that health care personnel should be in that group of first recipients," said Dr. Fryhofer. "Other groups that should be included in phase one are essential workers" as well as medically vulnerable groups, which include adults 65 and older and individuals with preexisting conditions.

"We also want to make sure that when we do have a vaccine, there's a way to get it to people and that they will take it," said Dr. Fryhofer. "It doesn't do anybody good if it's sitting in a freezer. That is a real concern for a vaccine that has to be stored ultra-cold."

AMA President Susan R. Bailey, MD, explains why we must be able to trust the FDA vaccine approval process.

Vaccine coverage

The Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Families First Coronavirus Response Act “is supposed to ensure no one desiring a vaccination will face an economic burden,” said Dr. Fryhofer.

Under the CARES Act, health insurance, insurers and plans are required “to cover any ACIP recommended COVID-19 preventive service, including vaccines, without cost sharing within 15 days of such recommendation” to the Centers for Disease Control and Prevention, she said.

Vaccine safety monitoring

There is understandable concern about whether the effort to quickly produce an effective vaccine will come at the expense of safety, said Dr. Fryhofer. But, she noted, there is “a plan for something called V-SAFE, and this stands for vaccine safety assessment for essential workers.”

“It is a smartphone-based text, text-to-web survey and email-to-web survey active surveillance program for early vaccine recipients,” she said. “They will email these people daily during the first week and then weekly for six weeks post vaccination. This is a way to try to get some real time information about potential adverse effects.”

“Then of course the classical sorts of vaccine safety-monitoring systems will also occur,” said Dr. Fryhofer.

Herd immunity

“Typically, herd immunity is achieved when you've got 70% to 90% of a population immune through natural infection or vaccination,” said Dr. Fryhofer. However, “even if herd immunity is achieved, it might not be uniform across the population, so you still have pockets of infection.”

Dr. Marks recently told physicians that a return to normal requires a vaccine that is 70%–80% effective being administered to 70%–80% of the population.

“There’s little evidence to suggest that spread of SARS-CoV-2 may stop naturally before at least 50% of the population has become immune,” Dr. Fryhofer said. “We've already hit more than 200,000 deaths. How many more people will die before we have a vaccine?”

Physicians will play a key role in answering patients’ questions about SARS-CoV-2 vaccination. Two AMA-hosted webinars arm doctors with some information they need to do so. They are available for viewing at your convenience:

- FDA review process for COVID-19 vaccine candidates
- CDC update on COVID-19 vaccine