What do you need to know about COVID-19 vaccines?

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Ohio Gov. Mike DeWine announced Friday that, once federally approved, COVID-19 vaccines could begin arriving in the state as soon as Dec. 15. We asked medical school Interim Dean Stan Gerson to address some of the most common questions about the vaccine itself, as well as its distribution.

What does the Food and Drug Administration's (FDA) approval entail and how difficult is it to obtain?

The FDA is expected to approve two vaccines under emergency authorization (an approach also used for COVID-19 tests), given the risk-benefit-ratio estimations that have been drawn from available data. The formal public assessments will take place Thursday (Dec. 10) for the Pfizer vaccine and the following Thursday (Dec. 17) for the Moderna vaccine. During a recent conference call with medical school deans nationally, Peter Marks, FDA director of biologics, indicated both are expected to be approved.

The public can view the FDA advisory committee's public sessions online; find information about this Thursday's session and the Dec. 17 meeting.

The FDA will consider the presentations and comments in those sessions in its formal approval process but is not bound by them. It is likely that, given their direct involvement in the oversight of these clinical trials, the conclusions of the data and safety monitoring committee already have provided sufficient information for safety and efficacy.

Since COVID-19 vaccines are being created in record time, should we be concerned about a thorough vetting process?

There remains much we do not know. Vaccinating studies included only 70,000 individuals, 35,000 of whom received the two doses of vaccine, which does not completely inform the full spectrum of individuals worldwide. We are learning how immune genomic signatures influence

vulnerability and protection; issues of age, immunosuppression and other diseases will undoubtedly influence immune responses.

What do effective rates of 90% and 94%, as we've heard about, really mean?

These rates of efficacy—and especially removing any evidence of severe infection—are absolutely remarkable and portend a wonderful reduction of risk. However, it takes a randomized trial of 5,000 breast-cancer patients to prove efficacy for a new treatment.

Here, while 35,000 patients were vaccinated, only 180 individuals in the control group were infected, so we remain with slim evidence of efficacy. However, the statistics indicate incredible protective efficacy, at least over the short term.

Realistically, when will FDA-approved COVID-19 vaccines be available to the general public and how would it be distributed?

Dr. Anthony Fauci (director of the National Institute of Allergy and Infectious Diseases and member of the White House COVID-19 task force), reflecting on the public announcements from Pfizer and Moderna, discussed this most recently at the American Society of Hematology session on Saturday, Dec. 5, from which I drew these conclusions in broad timelines:

- January and February: domiciled elderly, health-care professionals and perhaps health-care students (2 million to 5 million doses)
- March and April: broader distribution to population elderly and those with risk co-morbidity (5 million to 25 million doses)

- May to July: open distribution at hospitals and other administration centers (25 million to 100 million doses)

While not all will be vaccinated, I would hope we achieve 40% vaccination by late summer and look forward to herd immunity to benefit the entire population when we hit about 50% to 60%. Also, it appears that previously infected individuals will be advised to also be vaccinated. But it is advisable to keep an eye on those recommendations.

Should people get the first vaccine available to them, even though some are more effective than others?

It is impossible to advise on this issue. Personally, I will take first available, since time is of the essence and comparable efficacy is likely. Other vaccines may also become available, such as the adenovirus-based vaccine, and more information will be needed for that.

We've heard about rounds of doses. How many will people need?

Both mRNA vaccines (a new type of vaccine to protect against infectious diseases) require two doses about 21 days apart, with immunity emerging within two weeks and sustained at least four months after the second dose. But this does not mean you get to discard your mask, since prevalence of spreading infections will remain well into the summer at least.

What are possible side effects and other risks?

At the moment, take the day off the day after vaccination, but expect to be just fine the day after that. Many side effects have been described, but be thankful your body is protecting you by mounting an immune

response. Everything from fatigue, body aches, some fogginess, muscle aches and loss of appetite appear common. But most appear back to normal in two days.

How long will a vaccine last/how long are you protected?

We will all learn these data over the next year. Consider us in a worldwide clinical trial! But it looks to be consistent to four months and, beyond that, time will tell.

Will people need to get vaccinated annually, like a flu shot?

I would expect that this will be considered over the next few years. Investigators are conducting real-time tracking for variants—where the virus mutates within an individual—in real time and so they will be able to identify a new variant quickly. The nature of these vaccines mean that scientists could well develop a variant vaccine in a few months. This speed is remarkable, and a recognition of the incredible advances in our research community. The fact that so many investigators worldwide (and at Case Western Reserve University) could "pivot" to address this crisis is the understated but dramatic development and a credit to National Institutes of Health (NIH) research and our international investment in academic and pharmaceutical research.

From what we've heard, these vaccines are for adults. Any timetable for vaccines for teens and children?

Soon. Studies are ongoing and, hopefully, will encourage their vaccination by summer. But a firm timeline is lacking. Attention from

the Centers for Disease Control, FDA and NIH on this issue is quite intense.

Will vaccines be free? Covered by insurance?

It's impossible to say for an individual, but, in general, yes.

How will each of us indicate we've been vaccinated? Will there be certificates, so to speak?

The FDA is considering a certificate—primarily to encourage the double vaccine—but it will also be helpful to validate vaccination for workforce and workspace concerns.

Provided by Case Western Reserve University

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