

Should I Be Vaccinated for COVID-19?

Information for Dental Professionals' Consideration

Key Points:

- As of Oct. 7, no vaccine currently undergoing phase 3 clinical trials has yet received emergency use authorization (EUA) approval
- Once a vaccine has been approved, dentists, dental hygienists and other healthcare workers appear to be prioritized to receive it in the first wave of distribution
- EUA could be granted based on the vaccine's short term ability to reduce the risk or severity of infection with the SARS-CoV-2 virus by one-half, or 50%.
- Concerns about likelihood of infection and subsequent sequelae as well as the wellbeing of those you may encounter need to be balanced with concerns about as yet unknown risks associated with the vaccine
- Dentists, dental hygienists and chairside assistants will each need to decide whether to be vaccinated. It remains to be seen if the vaccine will be required for health care workers

At this point in time, the decision about whether to be vaccinated against the SARS-CoV-2 virus is a personal decision. Concerns about likelihood of infection and subsequent sequelae as well as the wellbeing of those you may encounter need to be balanced with concerns about as yet unknown risks associated with the vaccine. It remains to be seen if the vaccine will be required for health care workers.

It is anticipated that the initial supply of COVID-19 vaccines will not be sufficient to cover everyone in the U.S. Given that limitation, the National Academies of Science, Engineering and Medicine (NASEM) shared its [framework](#) of a phased approach for equitable allocation of the vaccine.

The framework prioritizes healthcare workers (including dentists and dental hygienists) and first responders in Phase 1a, followed by people with comorbid and underlying conditions at significantly higher risk of mortality and severe morbidity in Phase 1b.

During the development of the NASEM framework, the ADA has supported [dentists and dental team members](#) to be in the highest priority group for receiving the vaccine. Since dentists and hygienists are included in the framework for receiving the initial supply of approved, available vaccines, each dental professional will need to decide whether or not to receive the vaccine.

The overall, [typical timeframe](#) involved in approving a vaccine is several years and includes exploratory work, pre-clinical studies, clinical trials and regulatory review. [Operation Warp Speed](#) has condensed this timeframe to one year by skipping the exploratory work and pre-clinical studies and utilizing the Emergency Use Authorization (EUA) mechanism rather than the typical regulatory review process.

Vaccines for COVID-19 are expected to be authorized under the FDA's Emergency Use Authorization (EUA). The FDA issued [Guidance for Industry](#) and indicates its expectation that for a COVID-19 vaccine to receive EUA, the data would need to demonstrate that it prevented disease or decrease disease severity in at least 50% of people receiving the vaccine with the lower bound of the confidence interval being > 30%.

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Although the Phase 3 vaccine trials are designed and powered to answer questions about longer term outcomes related to safety and efficacy, it is possible that a vaccine could be granted EUA by the FDA based on their short term ability to reduce the risk or severity of infection with the SARS-CoV-2 virus by one-half, or 50%.

As of October 2020, several potential vaccines have already completed Phase 1 and Phase 2 clinical trials. Phase 1 is an initial demonstration of whether the vaccine was safe. Phase 2 clinical trials demonstrate whether the vaccine has any biologic activity or effect, and determine therapeutic doses.

Whereas the Phase 1 and 2 trials enrolled hundreds of people, with Phase 3 trials, tens of thousands of participants are recruited. The Phase 3 trials, which are currently underway, are to determine the safety and efficacy of the potential vaccine, whether or not there are adverse effects in such a large, diverse group of people, and the trial may also look at the longevity of the immune response triggered by the tested vaccine.

Phase 3 trials can be conducted with healthy individuals when researching vaccines that will prevent disease, or the trials can be conducted with individuals who have a condition to look for a therapeutic effect. The most common side effects will also be uncovered during this phase.

Phase 4 trials are optional studies that drug companies may conduct after a vaccine is released. The manufacturer may continue to test the vaccine for safety, efficacy and other potential uses.

Typically, after successful completion of Phases 1-3, a vaccine developer would submit all their data to the Food and Drug Administration (FDA) for review and then evaluation by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) to develop its recommendation about the use of the vaccine in the U.S. ADA policy on Infection Control in the Practice of Dentistry (Trans.2012:470; 2019) supports implementation of CDC recommendations for vaccinations.

On behalf of the dental profession, the ADA will continue to monitor and provide updates on the progress of the clinical trials as well as the government's plans to distribute a vaccine once approved.