COVID-19 Vaccination: Key Facts

Dentists, as trusted healthcare providers, have an opportunity to serve as a resource for evidence-based information, helping to educate colleagues and the public about COVID-19 vaccination. Answering questions, helping to allay concerns, and providing up-to-date guidance based on available data will enable individuals to make informed decisions regarding COVID-19 vaccination and bring us closer to putting an end to the current pandemic.

Status of COVID-19 vaccines in the U.S.

- Only a vaccine with Emergency Use Authorization (EUA) or approval from the U.S. Food and Drug Administration (FDA) can be administered in the U.S.
- The advisory committee to the FDA recommended EUA for the vaccine produced by Pfizer/BioNTech, and the FDA granted EUA on Dec. 11, 2020.
- A second vaccine, produced by Moderna, is before the advisory committee to the FDA on Dec. 17, 2020.
- The Pfizer/BioNTech COVID-19 vaccine was also granted EUA in United Kingdom (U.K.) and vaccine administration began there on December 8, 2020.
- On Dec. 9, 2020 the Pfizer/BioNTech COVID-19 vaccine was approved by Health Canada, the regulatory agency of Canada.

Are Dentists Included in the First Wave of Vaccination?

- Final authority rests with the individual states to prioritize populations to be offered the vaccine.
- Current CDC guidance indicates that once a COVID-19 vaccine has EUA, during the initial phase of the COVID-19 vaccination program, the vaccine should be offered to both 1) healthcare personnel with potential for direct or indirect exposure to patient or infectious materials; and 2) residents of long-term care facilities. This is based, in part, on the National Academies of Science, Engineering and Medicine (NASEM) framework of a phased approach for equitable allocation of the vaccine, which prioritizes healthcare workers (including dentists and dental hygienists) and first responders in Phase 1a.

Safety and Effectiveness of COVID-19 Vaccines

- Data suggest that widespread use of the Pfizer/BioNTech and other vaccine(s) with similar safety and efficacy profiles have great potential to reduce the circulating levels of this virus.
- Data on the Pfizer/BioNTech COVID-19 vaccine far exceed the original FDA criterion of 30% efficacy in phase 3 clinical trials.
- Current guidance from CDC is that the second dose should be the same product as the first dose as per clinical trial protocol.
- Some details in the FDA analysis of the Pfizer/BioNTech COVID vaccine, indicate the following:
- Vaccine efficacy after the second dose, against confirmed COVID-19 infection, was 95.0%.
- Vaccine efficacy after the second dose, against serious COVID-19 disease, was nearly 100%. Mild-tomoderate adverse reactions to the vaccine were more frequent in study participants younger than 55

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years of age; otherwise. The safety profile was similar across age groups, genders, ethnic and racial groups as well as those with or without medical co-morbidities.

- Follow-up with participants in the phase 3 clinical trials noted that patients experienced the same sort of minor discomforts known to commonly occur following any sort of vaccination, such as injection-site reactions and some generalized malaise.
- Read the full details from the Pfizer/BioNTech FDA report.
- Monitoring where vaccines are being administered to populations is ongoing; some adverse reactions have been reported in individuals who have had previous serious allergic reactions to previous vaccines.

The ADA will continue to monitor developments related to COVID-19 vaccine approval and administration on behalf of the profession and public. Please visit ADA.org/virus for information for dental professionals and MouthHealthy.org for information for patients.

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