

Dentists, as trusted health care providers, have an opportunity to serve as a resource for evidence-based information, helping to educate colleagues and the public about the 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 the 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. The FDA granted EUA on Dec. 11, 2020. The [FDA appraisal of the Pfizer/BioNTech data](#) is available on the FDA website.
- The advisory committee to the FDA recommended EUA for a second vaccine, produced by Moderna. The FDA granted EUA on Dec. 18, 2020. The [FDA appraisal of the Moderna data](#) is available on the FDA website.
- 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, and vaccine administration began there on December 14, 2020.

## Are dentists included in the first wave of vaccination?

- Final authority rests with the individual states to prioritize the 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:
  - health care personnel with potential for direct or indirect exposure to patients or infectious materials; and
  - 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 health care workers (including dentists and dental hygienists) and first responders in Phase 1a.
- A [map of the U.S. with hyperlinks to state and local information](#) about population vaccination prioritization details, as well as any information about dentists' ability to vaccinate, can be found on the ADA website.

## Safety of the COVID-19 Vaccines

- Data on safety of the Pfizer-BioNTech and Moderna vaccines is very good though the fatigue, fever, headache, and achiness that some people will experience might be sufficient to miss a day of work.

# COVID-19 Vaccination: Key Facts

- The safety profiles for both vaccines are similar across age groups, genders, ethnic and racial groups, as well as those with or without medical co-morbidities.
- People who have previously had an anaphylactic reaction to any vaccine or any component of the Pfizer-BioNTech or Moderna vaccines should not receive these vaccinations. The [standing order for the vaccine](#) indicates that those who have experienced a severe allergic reaction to any foods or other medications should be under medical observation for 30 minutes after vaccination.

## Effectiveness of COVID-19 Vaccines

- Data suggest that widespread use of the Pfizer-BioNTech, Moderna, 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 and Moderna vaccines are better than had been required by the original FDA efficacy criterion in phase 3 clinical trials.
- Current guidance from the CDC is that the second dose should be the same product as the first dose as per clinical trial protocol.
- 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.

## Information about the clinical trials

	Pfizer-BioNTech	Moderna
Link to FDA appraisal of the submitted data	<a href="#">Pfizer BioNTech data</a>	<a href="#">Moderna data</a>
Vaccine	BNT162b2	mRNA-1273
ClinicalTrial.gov registration	<a href="#">NCT04368728</a>	<a href="#">NCT04470427</a>
Number of people enrolled in the phase 3 clinical trial	36,621 participants randomized 1:1 to vaccine or placebo	27,817 participants randomized 1:1 to vaccine or placebo
Age of people in the trial	≥ 16 - 85 years of age	≥ 18 - 87 years of age
Second vaccine dose	21 days after 1 <sup>st</sup> dose	28 days after 1 <sup>st</sup> dose

# COVID-19 Vaccination: Key Facts

## Safety

	Pfizer-BioNTech	Moderna
Injection site reactions	84%	92%
Flu like symptoms		
Fatigue	63%	69%
Headache	55%	63%
Muscle pain	38%	60%
Joint pain	24%	45%
Chills	32%	43%
Fever	14%	15%
Non-fatal serious adverse events	<0.5% in vaccine group <0.5% in placebo group	1% in vaccine group 1% in placebo group
Deaths in the reporting period	N=2 in vaccine group N=4 in placebo group	N=6 in vaccine group N=7 in placebo group

## Efficacy

	Pfizer-BioNTech	Moderna
Vaccine efficacy against confirmed COVID-19 disease after 1 dose (95% CI)	82.0% (75.6, 86.9)	80.2% (55.2,92.5)
Vaccine efficacy against confirmed COVID-19 disease after 2 <sup>nd</sup> dose (95% CI)	95.0% (90.3, 97.6)	94.5% (86.5,97.8)

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](https://www.ada.org/virus) for information for dental professionals and [MouthHealthy.org](https://www.mouthhealthy.org) for information for patients.

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