COVID Vaccine Talking Points/FAQs

Pfizer (BNT162b2)

How is this vaccine given?

This vaccine is given as an injection into the muscle of your upper arm (similar size and location to the flu shot). You need to get two doses, 21 days apart.

How does this vaccine work?

Like all vaccines, this vaccine is designed to mimic a natural viral infection in order to get the body to produce immunity without the risks of natural infection. The vaccine contains a synthetic messenger RNA (mRNA) which encodes the SARS-COV-2 spike glycoprotein (S) antigen encapsulated in lipid nanoparticles. The lipid nanoparticle coat allows the mRNA to enter the host cell and cause it to produce the viral spike glycoprotein (S) antigen. The host's immune system can then recognize and begin to produce antibodies against this viral antigen. The antibodies are protective against future SARS-COV-2 infection. mRNA is broken down rapidly by the host cells through natural processes so this process has a built in "off-switch" in the body. Because the RNA for only one viral protein is present, the host cell cannot produce infectious virus. **The vaccine cannot cause SARS-COV-2 infection.**

Are there other vaccines that work like this?

There are no other currently FDA approved vaccines that work through this specific mechanism.

What studies have been done to evaluate this vaccine?

BNT162-01 was a study testing the safety and immunogenicity (ability to make the host produce antibody against the virus) of the vaccine in 60 healthy adults.

C4591001 is an ongoing study with 38,000 participants including adults and adolescents (12-17 years of age). This study is looking at safety, immunogenicity, and efficacy (are people who've had the vaccine protected against COVID-19 infection compared to those who have not). This is a randomized, placebo-controlled trial occurring in multiple countries including the US.

Is this vaccine safe?

The rate of serious safety events in the study was low (0.5%) and there was no difference noted between the placebo and vaccine groups (0.5% vs 0.4%).

The rate of discontinuations (people not receiving the 2nd dose due to a reaction to the first dose) was low (0.2%) and there was no difference noted between the placebo and vaccine groups (0.2% vs 0.1%).

The follow up in the study (so far) has been two months so we can't exclude the possibility of adverse events that occur more than 2 months after receipt of the vaccine. Given the number of people in the trial we also can't rule out the possibility of adverse events that are less common than ~1/10,000 recipients.

While no vaccine is perfectly safe, the evidence strongly indicates that the vaccine is likely much less risky than the risk of acquiring SARS-COV-2 infection during a pandemic situation.

Does the vaccine work?

Vaccine recipients produced antibody levels comparable or higher to those found in persons who had natural illness with SARS-COV-2 and which lasted at least 1 month after receipt of the 2nd dose of vaccine. Vaccine recipients also had strong T-cell responses which typically correlate with protection against viral infection.

When examining new infections with SARS-COV-2 that began at least 7 days after receipt of the 2nd dose of vaccine, 8 vaccine recipients went on to have SARS-COV-2 infection. In comparison, 162 non-vaccine recipients developed infection with SARS-COV-2. The data indicates that the vaccine efficacy is almost certainly somewhere between 90-97% (point estimate 95%). This means a vaccine-recipient's chance of getting SARS-COV-2 infection is reduced by 90% compared to doing nothing.

Vaccine efficacy was similar to the overall group for sub-groups of age, sex, race/ethnicity, and country. Vaccine efficacy was also similar for those with co-morbidities.

There was also an estimated vaccine efficacy of 82% after dose 1 overall and 52.4% between dose 1 and dose 2. Immunity appears to begin developing about 14 days after receipt of dose 1.

How long does immunity last?

We know it lasts at least 2 months. Data from the ongoing clinical trials will continue to accrue and will be 2-4 months ahead of the first recipients of the vaccine outside of a clinical trial.

What are the common side effects I may experience?

Persons <55 years of age appear to experience a slightly higher rate of side effects after receipt of the vaccine. About 80% of younger participants and 70% of older participants reported pain at the injection site. This was not significantly different between dose 1 and dose 2. Other local reactions included redness and swelling at the injection site (about 5% each). Only 0.6% of participants reported severe local reactions.

Systemic reactions were also generally mild to moderate in severity. Most began 1 or 2 days after receipt of the vaccine and resolved within 1 day after they began. Common systemic reactions are summarized below. Participants > 55 years generally experienced similar reactions to the younger group but at a lower rate. Systemic reactions were more common after the second dose.

Systemic Events within 7 days of Vaccine Receipt 16-55 years				
	Dose 1		**Dose 2**	
Reaction	**Vaccine**	**Placebo**	**Vaccine**	**Placebo**
Fatigue	47%	33%	59%	23%
Headache	42%	34%	52%	24%
Muscle Pain	21%	11%	37%	8%

Chills	14%	0%	35%	4%
Joint Pain	11%	5%	22%	5%
Diarrhea	11%	12%	10%	8%
Fever	4%	1%	16%	0%
Vomiting	1%	1%	3%	1%

What if I have a history of severe allergic reaction to other vaccines, foods, or drugs?

There were no immediate allergic reactions to the vaccine reported in the clinical trial. The UK National Health Service has anecdotally reported two employees with known severe allergies to other things who had an allergic reaction after receipt of the vaccine. Currently they are recommending that no one with a known severe allergy to a vaccine, food, or drug receive the vaccine. The US FDA has not made a recommendation on this subject.