COVID-19 Infection Prevention Team
Webinar 4: COVID Vaccine – Advanced Questions & Projections

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Funded by CalOptima

Initial Success:
3 Days of Vaccine Clinic

Vaccine Clinic Impact

- Pharmacy partnership: CVS and Walgreens
- 3 clinics, two opportunities to start vaccine series
- December 2020-March 2021
- Uptake in OC nursing homes
  - ✓ Staff 1st doses: Median: 61%, Range: 40-100%
  - ✓ Resident 1st doses: Median: 75%, Range: 24-100%
  - ✓ Remarkable start for 3 days

Data thanks to CDPH/OCHCA

Goal: High Immunity for Nursing Homes

- 70-85% vaccination to stop community pandemic spread
- Nursing homes should aim higher for protection
  - ✓ Protect residents from high risk of death
  - ✓ Protect staff from outbreaks
  - ✓ Avoid bringing COVID-19 into the nursing home
- Aim for 100% vaccination

Addressing Vaccine Hesitancy

Why Be Vaccinated?
Safety, Side Effects, and Allergies

Why Be Vaccinated?

- COVID-19 is a serious threat
  - Highly infectious
  - Post-infection syndromes: chronic pain, aches, brain fog
  - Reinfection
  - Hospitalization
  - Death
- Still tens of thousands of U.S. COVID-19 cases of every day
- Still hundreds of people dying daily due to COVID-19 in U.S.

Will the Vaccine Make Me Sick?

- Not a live vaccine. Does not make you infectious.
- Stimulates immune response: common fatigue, headache, muscle aches, chills, joint pain, fever, nausea for 1-3 days
- How many have any symptoms?
  - ✓ Vaccine group: 55-59% after 1st dose, 70-79% after 2nd dose
  - ✓ Placebo group: 42-47% after 1st dose, 34-37% after 2nd dose

COVID-19 Variants: Do the Vaccines Work?

- Variants: UK, South Africa, Brazil, California, and more to come
- Current mRNA vaccines are effective

Variant	Current Status of Vaccine Escape
UK	Pfizer,[1] Moderna[2] vaccine sera effective
S. African (Y501)	Vaccine sera neutralizes[2] [3]
California	Healthcare worker cases dropped rapidly with vaccination
Brazil	Vaccine sera neutralizes[4]

- mRNA vaccines can be modified each year to address variants

[1] Biorxiv.org/content/10.1101/2021.01.18.426984v1
[2] investors.modernatx.com/node/10841.pdf
[3] www.biorxiv.org/content/10.1101/2021.01.07.425740v1.full.pdf
[4] nejm.org/doi/full/10.1056/NEJMc2102017

Vaccinate If You Have Already Had COVID-19

- COVID-19 infection does not provide solid protection
- Human body does not always develop the right antibodies
- Vaccine helps body make the most protective antibodies
- When after infection can you get the vaccine?
  - As soon as you are no longer infectious, feeling well
  - Can assume protection exists for 2-3 months post-infection
  - Remember vaccine takes 1+ month for 2 doses to take effect

How Common is Allergy to the COVID Vaccine?

- The only allergy preventing you from getting the vaccine is a serious allergy to the vaccine or its ingredients
- Not made in chicken eggs. No risk for egg allergic persons
- Risk of anaphylaxis is <5 people per million vaccinated [1]
- If you have a tendency for severe allergies:
  - ✓ Discuss your situation with your allergist
  - ✓ Be observed for 30 min instead of 15 min
  - ✓ All vaccine teams have emergency allergy medication

[1] Shimabukuro et al. JAMA online Feb 12, 2021

Pregnancy and Immunocompromise

- Trials often do not enroll pregnant, immunocompromised persons
  - Pregnant, immunocompromised high risk for severe disease
  - mRNA will not cross placenta, but protective antibodies will
  - Protective antibodies pass to the baby from breastfeeding
  - Issue for immunocompromised is not safety, but partial benefit
  - Discuss with your doctor, your personal choice and best timing
  - National societies of obstetrics, transplant recommend vaccine

Which COVID-19 Vaccine is Best?

Available U.S. COVID-19 Vaccines

Vaccine	Type	Doses	Efficacy	Trial Size	Variant Protection	US Authorization
Pfizer	mRNA	2	95% [1]	44K	UK/SA [4]	Yes (16+)
Moderna	mRNA	2	94% [2]	30K	UK/SA [4]	Yes (18+)
Janssen (J&J)	Adenovirus vector (DNA)	1	66% [3]	44K	57% SA [5]	Yes (18+)
Novavax	Protein	2	89% [4]	15K	86% UK [5] 60% SA [5]	No
Astra-Zeneca	Adenovirus vector (DNA)	2	62%	9K	75% UK [5] 22% SA [5]	No

[1] Polack FP et al NEJM 2020; 383(27): 2603-15
[2] Baden LR et al. NEJM Dec 30, 2020 (online)
[3] Outcome of moderate-severe COVID disease
[4] 30K trial pending
[5] Neutralization with vaccinated sera
[6] Population effect in trial, unpublished

Janssen (J&J) Vaccine

- **Single dose** COVID-19 vaccine
  - Adenovirus (live, non-replicating virus) makes Spike protein
  - FDA Emergency Use Authorized: February 27, 2021
  - 44K randomized clinical trial for ***moderate-severe disease***
    - 66% protective for moderate-severe COVID disease
    - 60% White, 45% Hispanic, 19% Black, 3% Asian
    - Side effects: headache (39%), fatigue (38%), muscle ache (33%), nausea (14%)

FDA.gov/media/146217/download

Janssen (J&J) Vaccine: Value and Use Case

- One dose advantage vs 66% protection
  - Value when follow up or transportation is difficult or unlikely
  - Ideal to offer to patients unlikely to seek vaccine
- Not ideal for nursing homes
  - High risk setting, need maximum protection
  - 94-95% protective mRNA vaccines are better alternatives
  - Logistics available for 2-dose follow up

FDA.gov/media/146217/download

COVID-19 Vaccines: Efficacy Comparison

	Symptomatic Disease Protection	Moderate-Severe Disease Protection	Protection for Elderly	Protection for Diabetics
Pfizer	95%	75% (87% in Israel)	94% in >55yo	95% (any symptomatic COVID)
Moderna	94%	100%	86% in >=65yo	100% (any symptomatic COVID)
Janssen (J&J)	Not studied	66%	60% in >60yo (43% in >60yo with comorbidity)	23% (mod-severe COVID)

Vaccine Myths and Myth Busters?

Myth: I'm Protected As Soon As I'm Vaccinated

- Not true. Each dose of the vaccine takes time to work
- It can take up to a month post-vaccine to generate antibodies
- The trials showed ~95% protection
  - 1 week after the 2nd dose for Pfizer
  - 2 weeks after the 2nd dose for Moderna
- The 5% remaining risk will be affected by the amount of community cases and the behavior in the community

Myth: One Dose is Enough (mRNA vaccines)

- The mRNA vaccines provide the greatest protection at 95%
- Both are 2 dose vaccines
  - Early studies in both companies suggested 2 doses needed
  - The first dose produces an effect
  - The second dose helps lock in that effect
- To reach 95% protection, you need both doses
- The J&J vaccine is 66% protective with one dose

Myth: The Vaccine Will Make Me More Likely to Shed Virus Through Asymptomatic Infection

- Can a fully vaccinated person shed COVID-19?
  - ✓ Vaccine is not alive → cannot give you COVID-19
  - ✓ Vaccine does NOT make you sick with COVID or shed COVID
  - ✓ 95% protection, but if you get sick with COVID-19, you are likely to be shedding virus
  - ✓ Asymptomatic disease also stopped with vaccine
  - ✓ No “colonization state” with COVID-19

Myth: The Vaccine Causes…

- **Myth: The vaccine causes cancer**
  - Not true. In fact, mRNA vaccines are used to fight cancer
  - mRNA does not mix with your DNA/genes
- **Myth: The vaccine implants a microchip**
  - Not true. Nothing is implanted. Nothing is permanent.
- **Myth: The vaccine causes infertility**
  - Not true. Vaccine components stay in your arm, don't make it to your reproductive organs, don't mix with your DNA/genes

Myth: Variants Mean It's Useless to Vaccinate

- Variants arise from COVID-19 infections
- The more infections, the more reproducing virus
- Reproducing virus can mutate
- Best solution to variants
  - ✓ Rapidly reduce circulating virus through vaccination
  - ✓ Rapidly reduce circulating virus through infection prevention

Myth: More Time is Needed for Safety Reasons

- Clinical trials provide estimate of common side effects
- Post-marketing use confirms common effects, finds rare ones
- Pandemic: vaccine use in weeks exceeds years of other vaccines
  - 61 million people in the US have received mRNA vaccine
  - 40 million outside of US have received mRNA vaccine
  - Confirmed brief mild side effects, rare allergic reaction
- Pandemic still a reality. Protection is urgently needed.

When Will the COVID-19 Pandemic Come to an End?

Herd Immunity Threshold by Pathogen

Disease	Reproduction number (Ro)	Vaccine coverage needed
Diphtheria	6-7	85%
Measles	12-18	92-94%
Mumps	4-7	75-86%
Pertussis (whooping cough)	12-17	92-94%
Polio	2-15	50-93
Rubella	6-7	83-85%
Smallpox	5-7	80-85%
Influenza	1.4-4	30-75%

Plans-Rubio. Hum Vacc Immunother 2012. 8(2):184-8

What If We Don't Reach 70-85% Vaccination?

- **COVID cases falling after the latest winter surge**
- **Seasonal virus, so likely to see summer decline like last fall**
- **Will it really be gone?**
  - Risk of cases depends on good behavior + vaccination speed
  - Next winter, if insufficient vaccination, COVID-19 will resurface
    - Nursing home outbreaks
    - Community outbreaks
    - Hospitalization and death

Can I Stop Masking If I'm Vaccinated?

- No. The SARS-CoV-2 virus will wax and wane by the season and based upon human behavior and vaccine uptake
- Public health will decide when we can stop masking. Likely when:
  - Safer Tier: when cases fall to very low levels, less spread
  - Safer Season
  - More Vaccine Availability
  - More Vaccine Uptake
- We are in this pandemic together. We need to encourage good behavior and protect one other

What Can I do If I'm Vaccinated?

- CDC newly-released guidance for personal time (*not healthcare*)
  - A few fully vaccinated persons can be indoors without masks
  - A few fully vaccinated persons can carpool without masks
  - A fully vaccinated person can meet indoors with a low risk unvaccinated individual
  - *No moderate or large gatherings regardless of vaccination*
  - *Outdoors: mask, socially distance regardless of vaccination*

cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

Can We Allow More Visitors?

- Continue entry symptom screening, masks, hand hygiene
- Indoor visitation allowed in green and yellow areas IF
  - Fully vaccinated resident (>2 weeks post last dose) in any tier
  - If unvaccinated resident but OC not in purple tier
  - Visitor must have neg COVID test within 2d if purple tier
  - Visitor must wear PPE if yellow area
  - Visit should be separate from or without roommate
- ***Fully vaccinated visitor can briefly hug, hold hands, feed/assist a fully vaccinated resident***

Cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-22.aspx

Orange County Cases & Vaccination

OC COVID Cases & Deaths Continue

AS OF MARCH 9, 2021

OC Tier: Purple (Widespread COVID)

% OC Fully Vaccinated: Only 8%

Cases in Past Day: 108

Deaths in Past Day: 61

Total OC Cases:
248,022

Total OC Deaths:
4,313

Orange County Projections & Needed Focus

	March	June	Sept	Dec
Tier	Purple/red	Orange?	Yellow?	??
Vaccines	Limited	Wide Open	Wide Open	Wide Open
% Fully Vaccinated	8%	30%?	65%?	?
Season	Winter → Spring	Spring → Summer	Summer → Fall	Fall → Winter
Biggest Concern	More vaccine	Spring Fever	Child vaccine, import variant	Coming winter
Goal	Pre-vaccine behavior, await vaccine	Cautionary behavior, get vaccine	Caution in schools, get vaccine	Need herd immunity; variants?

Importance of Continuing Vaccination Support

- Herd immunity requires 70-85% vaccination
- Need continued effort to vaccinate
  - ✓ Ongoing turnover of staff and residents
  - ✓ High risk setting should get high priority
  - ✓ Need data to garner support
  - ✓ Quarterly status checks of current staff/residents will help

Each Quarter: One Time Vaccine Status Check

Employee Name	Job Title	Worked in Past Month	Partially Vaccine	Full Vaccine
Name 1		Yes		x
Name 2		Yes		x
Name 3		Yes		
Name 4		Yes		x
Name 5		Yes		x
Name 6		Yes		x
Name 7		Yes	x	
Name 8		Yes		x
Name 9		Yes		x
Name 10		Yes		x
Name 11		No		
Name 12		Yes		x
Name 13		Yes		x
Name 14		Yes		x

Vaccine Tracker: Quarterly Checks

COVID-19 Vaccine Tracking

Facility Name: _____

Quarter	Assessment Date	# Active Employees *	# Fully Vaccinated Active Employees	% Fully Vaccinated Active Employees	# Partially Vaccinated Active Employees	% Partially Vaccinated Active Employees	Residents by Short and Long Stay Subsets	Today's Census	# Fully Vaccinated Residents	% Fully Vaccinated Residents	# Partially Vaccinated Residents	% Partially Vaccinated Residents
2021 Q1	___/___/21						# Residents					
							# Short-Stay					
							# Long-Stay					
2021 Q2	___/___/21						# Residents					
							# Short-Stay					
							# Long-Stay					
2021 Q3	___/___/21						# Residents					
							# Short-Stay					
							# Long-Stay					
2021 Q4	___/___/21						# Residents					
							# Short-Stay					
							# Long-Stay					

Importance of Continuing Vaccination Support

- Herd immunity requires 70-85% vaccination
- Need continued effort to vaccinate
  - ✓ Ongoing turnover of staff and residents
  - ✓ High risk setting should get high priority
  - ✓ Need data to garner support
  - ✓ Quarterly status checks of current staff/residents will help
- OCHCA exploring continued vaccination of long stay residents

Vaccine FAQs

- 40 Top Questions Answered
- Questions Grouped
  - ✓ Why vaccinate? Which vaccine? What's in the vaccine?
  - ✓ How well do the vaccines work?
  - ✓ Who should get vaccinated?
  - ✓ Timing of doses
  - ✓ Safety & side effects
  - ✓ Vaccine myth busters

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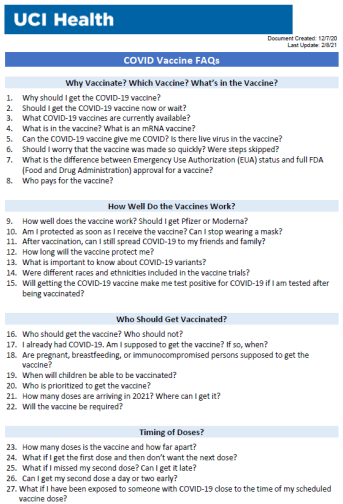
Vaccine FAQs

- 40 Question Vaccine FAQ: hyperlinked and publicly available



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COVID Vaccine FAQs

Why Vaccinate? Which Vaccine? What's in the Vaccine?

1. Why should I get the COVID-19 vaccine?
2. Should I get the COVID-19 vaccine now or wait?
3. What COVID-19 vaccines are currently available?
4. What is in the vaccine? What is an mRNA vaccine?
5. Can the COVID-19 vaccine give me COVID? Is there live virus in the vaccine?
6. Should I worry that the vaccine was made so quickly? Were steps skipped?
7. What is the difference between Emergency Use Authorization (EUA) status and full FDA (Food and Drug Administration) approval for a vaccine?
8. Who pays for the vaccine?

How Well Do the Vaccines Work?

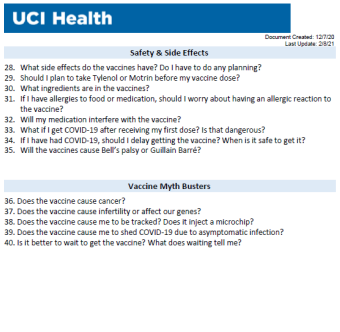
9. How well does the vaccine work? Should I get Pfizer or Moderna?
10. Am I protected as soon as I receive the vaccine? Can I stop wearing a mask?
11. After vaccination, can I still spread COVID-19 to my friends and family?
12. How long will the vaccine protect me?
13. What is important to know about COVID-19 variants?
14. Were different races and ethnicities included in the vaccine trials?
15. Will getting the COVID-19 vaccine make me test positive for COVID-19 if I am tested after being vaccinated?

Who Should Get Vaccinated?

16. Who should get the vaccine? Who should not?
17. I already had COVID-19. Am I supposed to get the vaccine? If so, when?
18. Are pregnant, breastfeeding, or immunocompromised persons supposed to get the vaccine?
19. When will children be able to be vaccinated?
20. Who is prioritized to get the vaccine?
21. How many doses are arriving in 2021? Where can I get it?
22. Will the vaccine be required?

Timing of Doses?

23. How many doses is the vaccine and how far apart?
24. What if I get the first dose and then don't want the next dose?
25. What if I missed my second dose? Can I get it late?
26. Can I get my second dose a day or two early?
27. What if I have been exposed to someone with COVID-19 close to the time of my scheduled vaccine dose?



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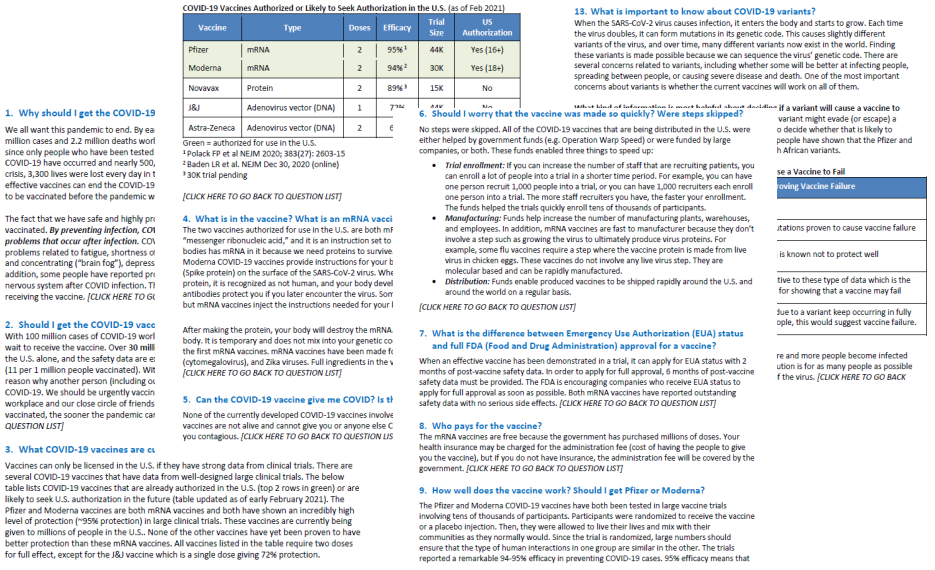
Safety & Side Effects

28. What side effects do the vaccines have? Do I have to do any planning?
29. Should I plan to take Tylenol or Motrin before my vaccine dose?
30. What ingredients are in the vaccines?
31. If I have allergies to food or medication, should I worry about having an allergic reaction to the vaccine?
32. Will my medication interfere with the vaccine?
33. What if I get COVID-19 after receiving my first dose? Is that dangerous?
34. If I have had COVID-19, should I delay getting the vaccine? When is it safe to get it?
35. Will the vaccines cause Bell's palsy or Guillain Barré?

Vaccine Myth Busters

36. Does the vaccine cause cancer?
37. Does the vaccine cause infertility or affect our genes?
38. Does the vaccine cause me to be tracked? Does it inject a microchip?
39. Does the vaccine cause me to shed COVID-19 due to asymptomatic infection?
40. Is it better to wait to get the vaccine? What does waiting tell me?



COVID-19 Vaccines Authorized or Likely to Seek Authorization in the U.S. (as of Feb 2021)

Vaccine	Type	Doses	Efficacy	Trial Size	US Authorization
Pfizer	mRNA	2	95% [1]	44K	Yes (16+)
Moderna	mRNA	2	94% [2]	30K	Yes (18+)
Novavax	Protein	2	89% [3]	15K	No
J&J	Adenovirus vector (DNA)	1	72%	44K	No
Astra-Zeneca	Adenovirus vector (DNA)	2	6		

Green = authorized for use in the U.S.
[1] Polack FP et al NEJM 2020; 383(27): 2603-15
[2] Baden LR et al. NEJM Dec 30, 2020 (online)
[3] 30K trial pending

[CLICK HERE TO GO BACK TO QUESTION LIST]

1. Why should I get the COVID-19

We all want this pandemic to end. By ea
million cases and 2.2 million deaths worl
since only people who have been tested
COVID-19 have occurred and nearly 500,
crisis, 3,300 lives were lost every day in t
effective vaccines can end the COVID-19
to be vaccinated before the pandemic w

The fact that we have safe and highly pr
vaccinated. ***By preventing infection, CO***
problems that occur after infection. CO
problems related to fatigue, shortness o
and concentrating ("brain fog"), depress
addition, some people have reported pr
nervous system after COVID infection. TI
receiving the vaccine. *[CLICK HERE TO G*

2. Should I get the COVID-19 vacc

With 100 million cases of COVID-19 worl
wait to receive the vaccine. Over **30 mill**
the U.S. alone, and the safety data are e
(11 per 1 million people vaccinated). Wit
reason why another person (including o
COVID-19. We should be urgently vaccin
workplace and our close circle of friends
vaccinated, the sooner the pandemic ca
QUESTION LIST]

3. What COVID-19 vaccines are c

Vaccines can only be licensed in the U.S. if they have strong data from clinical trials. There are several COVID-19 vaccines that have data from well-designed large clinical trials. The below table lists COVID-19 vaccines that are already authorized in the U.S. (top 2 rows in green) or are likely to seek U.S. authorization in the future (table updated as of early February 2021). The Pfizer and Moderna vaccines are both mRNA vaccines and both have shown an incredibly high level of protection (~95% protection) in large clinical trials. These vaccines are currently being given to millions of people in the U.S.. None of the other vaccines have yet been proven to have better protection than these mRNA vaccines. All vaccines listed in the table require two doses for full effect, except for the J&J vaccine which is a single dose giving 72% protection.

4. What is in the vaccine? What is an mRNA vacci

The two vaccines authorized for use in the U.S. are both mr
"messenger ribonucleic acid," and it is an instruction set to
bodies has mRNA in it because we need proteins to survive
Moderna COVID-19 vaccines provide instructions for your b
(Spike protein) on the surface of the SARS-CoV-2 virus. Wh
protein, it is recognized as not human, and your body devel
antibodies protect you if you later encounter the virus. Sor
but mRNA vaccines inject the instructions needed for your

After making the protein, your body will destroy the mRNA
body. It is temporary and does not mix into your genetic co
the first mRNA vaccines. mRNA vaccines have been made fo
(cytomegalovirus), and Zika viruses. Full ingredients in the v
[CLICK HERE TO GO BACK TO QUESTION LIST]

5. Can the COVID-19 vaccine give me COVID? Is th

None of the currently developed COVID-19 vaccines involve
vaccines are not alive and cannot give you or anyone else C
you contagious. *[CLICK HERE TO GO BACK TO QUESTION LIS*

13. What is important to know about COVID-19 variants?

When the SARS-CoV-2 virus causes infection, it enters the body and starts to grow. Each time the virus doubles, it can form mutations in its genetic code. This causes slightly different variants of the virus, and over time, many different variants now exist in the world. Finding these variants is made possible because we can sequence the virus' genetic code. There are several concerns related to variants, including whether some will be better at infecting people, spreading between people, or causing severe disease and death. One of the most important concerns about variants is whether the current vaccines will work on all of them.

[illegible] if a variant will cause a vaccine to variant might evade (or escape) a o decide whether that is likely to people have shown that the Pfizer and h African variants.

se a Vaccine to Fail

oving Vaccine Failure

/tations proven to cause vaccine failure

is known not to protect well

tive to these type of data which is the for showing that a vaccine may fail

ue to a variant keep occurring in fully ople, this would suggest vaccine failure.

re and more people become infected ution is for as many people as possible f the virus. *[CLICK HERE TO GO BACK*

6. Should I worry that the vaccine was made so quickly? Were steps skipped?

No steps were skipped. All of the COVID-19 vaccines that are being distributed in the U.S. were either helped by government funds (e.g. Operation Warp Speed) or were funded by large companies, or both. These funds enabled three things to speed up:

- ***Trial enrollment:*** If you can increase the number of staff that are recruiting patients, you can enroll a lot of people into a trial in a shorter time period. For example, you can have one person recruit 1,000 people into a trial, or you can have 1,000 recruiters each enroll one person into a trial. The more staff recruiters you have, the faster your enrollment. The funds helped the trials quickly enroll tens of thousands of participants.
- ***Manufacturing:*** Funds help increase the number of manufacturing plants, warehouses, and employees. In addition, mRNA vaccines are fast to manufacturer because they don't involve a step such as growing the virus to ultimately produce virus proteins. For example, some flu vaccines require a step where the vaccine protein is made from live virus in chicken eggs. These vaccines do not involve any live virus step. They are molecular based and can be rapidly manufactured.
- ***Distribution:*** Funds enable produced vaccines to be shipped rapidly around the U.S. and around the world on a regular basis.

[CLICK HERE TO GO BACK TO QUESTION LIST]

7. What is the difference between Emergency Use Authorization (EUA) status and full FDA (Food and Drug Administration) approval for a vaccine?

When an effective vaccine has been demonstrated in a trial, it can apply for EUA status with 2 months of post-vaccine safety data. In order to apply for full approval, 6 months of post-vaccine safety data must be provided. The FDA is encouraging companies who receive EUA status to apply for full approval as soon as possible. Both mRNA vaccines have reported outstanding safety data with no serious side effects. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

8. Who pays for the vaccine?

The mRNA vaccines are free because the government has purchased millions of doses. Your health insurance may be charged for the administration fee (cost of having the people to give you the vaccine), but if you do not have insurance, the administration fee will be covered by the government. *[CLICK HERE TO GO BACK TO QUESTION LIST]*

9. How well does the vaccine work? Should I get Pfizer or Moderna?

The Pfizer and Moderna COVID-19 vaccines have both been tested in large vaccine trials involving tens of thousands of participants. Participants were randomized to receive the vaccine or a placebo injection. Then, they were allowed to live their lives and mix with their communities as they normally would. Since the trial is randomized, large numbers should ensure that the type of human interactions in one group are similar in the other. The trials reported a remarkable 94-95% efficacy in preventing COVID-19 cases. 95% efficacy means that

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Questions?

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