

Teachers, thank you for ALL of your efforts this school year, it has been an unprecedented time and it would not have been possible without your diligence and dedication. For that, we thank you.

Right now, there is a lot of buzz about the Covid-19 vaccine. There are opinions being shared on social media, on the news, on the radio, people compare this vaccine to the flu shot and their past experiences, and more. I'm sure your students will ask you if you are planning to be vaccinated against Covid-19 and I want to ensure that we are sharing correct information as incorrect information is so easy to locate. At the link you will find a series of videos intended to educate students about the immune system, the history of vaccines, and how they work to protect us from disease. For older students, in middle and high school, I have taken some screenshots of the data tables in Pfizer report to the FDA and developed questions to go along with them. Please use these items to help educate your students with vetted information about the Covid-19 vaccine so that they (and their family) will make informed decisions.

https://www.sciencerockhill.com/covid-19.html

Place a check in the box for each statement you believe is TRUE.

	Vaccines are medicine.
	Vaccines cause autism.
TRUE	Vaccines and immunizations are the same thing.
	Vaccines cause the diseases they are meant to prevent.
	Vaccines contain unsafe chemicals.
	If I don't get vaccinated, it only affects me.
TRUE	Vaccines help the immune system.

Give this as a pretest then discuss with students, again, after they have watched the videos to see if their minds have changed.

Video Link: https://www.youtube.com/watch?v=vkEZiHBTXyY

- Vaccines originated in ancient Asia and Africa as people sought to stop the spread of smallpox.
- A technique called variolation was performed by placing fluid from an infected person's smallpox bumps under the skin of a healthy person. This method did cause a smallpox infection, but it was not as serious as a full smallpox infection AND it gave the person lifelong immunity.
- 3. This technique was viewed with much skepticism, although smallpox killed 400,000 Europeans per year.
- 4. In 1796, Dr. Edward Jenner showed that cowpox could prevent smallpox because the human immune system couldn't tell the difference. Jenner intentionally exposed a child to cowpox, but he didn't develop a major infection. Jenner later exposed the boy to smallpox and he didn't get very sick.
- 5. The word vaccine comes from the word vacca which means cow.
- 6. Other vaccines now prevent Polio, Measles, Mumps, and Rubella, Vaccines have dramatically reduced the number of cases of these illnesses.
- 7. What questions do you now have about vaccines?
 - Engage your class in a discussion about what they viewed.
 - Has anyone in the class ever had smallpox? Have they ever known anyone to have smallpox? Introduce the term irradicate.
 - Many teachers, due to their age, had the chickenpox tell about that experience.
 It was commonly known that a person could only get chicken pox once explain
 this in light of the video. In 1995 a chicken pox vaccine became available. Read
 more.

Video Link: https://www.youtube.com/watch?v=IXMc15dA-vw/rel=0

- 1. What is the Immune System? The immune system is the body system that protects us from infectious agents such as bacteria, viruses, and other germs (pathogens).
- 2. Which body cells make up the immune system? The white blood cells are a major part of this system.
- 3. If a virus, such as the flu (influenza) enters the body, the immune cells get "armed" and replicate (make copies of themselves) to release germ-killing agents called antibodies that mark the germs for disposal.
- 4. Once the germ is gone, the immune response stops, but leaves behind memory cells that remember the invader in case it appears again.
- 5. The first immune response can take a week, but the next time, the immune response can happen in 1 day. As the immune cells mount their defense, you may feel the effects (fever, body aches, tiredness, etc.) but because the threat is low, you don't get sick from a full scale infection.

Relate what you learned in this video to the previous video.

- 6. A bit of fluid from a smallpox bump can trigger the immune cells to get armed and ready to fight releasing germ-killing agents called antibodies that mark the smallpox virus particles for disposal. Once the immune system has rid the body of the smallpox virus, memory cells remain in case smallpox viruses try to invade the body again.
- 7. Why might someone opt for a vaccine rather than the actual virus? With a vaccine an immune response happens without you having to be sick.
- 8. Some viruses change their configuration regularly preventing the immune system from recognizing it. The different configurations of the same virus are called strains. For this reason, a vaccine may only protect against a single strain. A different strain of the virus could still infect the person. This is why we must get a flu shot (influenza vaccine) each year to be protected against that year's flu. If you were vaccinated against the flu in 2016, are you still immune to that strain of the flu? Explain.

 No, the flu changes, it even changes by the end of flu season. Someone who gets a flu shot in September may get the flu in April (a different strain).

Video Link: https://www.youtube.com/watch?v=LK-QG5XXgjQ/rel=0

- 1. There are 2 main goals of a Covid-19 Vaccine:
- a. It must be safe to administer.
- b. It must protect against the pathogen (virus).
 - -Does it produce a significant immune response?
 - -Does it reduce the chance of getting the disease it's supposed to protect against?
- 2. Once a potential vaccine is developed, lab mice are the first organisms to be injected with it. Scientists observe the mice for side effects, including death.
- -Blood samples are taken that measure the number of antibodies (which will result in immunity).
- -Mice are also tested to see if they get the disease if they are exposed.
- -If efficacy is shown, the vaccine moves on to clinical trials which involve injecting humans.
- -Healthy adults are typically chosen for clinical trials.
- 3. There are 3 phases of clinical trials.
- -Phase I a few dozen people are injected with the vaccine at different dosages. This helps to determine the best dose to generate the desired immune response, and any side effects that may occur.
- -Phase II a few hundred people are injected with the vaccine.

 The goal is to determine if the vaccine produces a significant immune response.
- -Phase III a few thousand people are injected with the vaccine. Phase III data can take months or years to compile.
- -Two big questions the trials seek to answer are: Did anyone who was vaccinated get Covid-19? If so, how severe were the symptoms?
- -If the vaccine data shows significant efficacy, it can be submitted for approval and distribution.
- 4. On December 10, 2020, a panel of doctors representing the US Food and Drug Administration voted to authorize the use of the Covid-19 vaccine for individuals 16 and over, produced by Pfizer Pharmaceuticals. Based on what you know about how the trials work, what are your thoughts about this vaccine? See article for more information. Have an informed discussion with your students.

For middle and high school students: Teachers, feel free to add questions! :-)

Pfizer report to the FDA

- 1. What is an EUA? Emergency Use Authorization permission from the FDA to begin administering this vaccine based on the current Phase 3 vaccine data.
- 2. We say "Coronavirus" and "Covid-19," and "the rona," but what is the scientific name of the virus? SARS-CoV-2
- 3. How much of the vaccine serum is recommended? (be specific) 2 doses, 30 µg each (this measurement is micrograms or 30 millionths of a gram)
- 4. Did this vaccine undergo 3 phases of clinical trials? How many people were tested? approximately 44,000 participants

Note: "double-blinded and placebo-controlled trial of BNT162b2" In this report, the vaccine is abbreviated as BNT162b2. Double Blind and placebo-controlled means...44,000 people were injected, but not all of them were injected with the actual vaccine. Some were injected with a saltwater solution, but none of the 44,000 know which they were injected with. This is done because some people, if they know they have been vaccinated will behave differently putting themselves at greater risk of infection which could cause the results to have bias.

- 5. The phase 3 clinical trial data showed that 7 days after the 2 doses of vaccine 8 of those who received BNT162b2 tested positive for Covid-19. Of those who received the placebo 162 tested positive for Covid-19.
- Approximately how much time was there between the doses of vaccine?
 days
- 7. What were the most common side effects? Was death a side effect for any of the participants?
- injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%); severe adverse reactions occurred in 0.0% to 4.6% of participants
- 8. What are your thoughts about the vaccine after reading this? Discuss with students.

Video Link https://www.youtube.com/watch?v=XTLYXmgG8DU/rel=0

Teachers, consider pausing the video to review RNA and the process of translation

- 1. What are the benefits of mRNA vaccines? Why are mRNA vaccines potentially safer than conventional vaccines? They contain viral elements, but not the actual virus, weakened or otherwise. Less risk of contamination. The sequence can be changed if the virus mutates.
- 2. Since this is an mRNA vaccine, some people worry that it could change their DNA. According to the video, is this a valid fear? No. It is a complex process that requires enzymes cells don't have.
- 3. What is herd immunity? Herd immunity is having enough of the community protected against the pathogen that an outbreak could not occur.
- 4. What people tend to rely on herd immunity? Very young or very old people, and immunocompromised people cannot be vaccinated
- 5. Are you planning to be vaccinated against Covid-19? Why or why not? Answers may vary.

Demographics chart

- 1. 44,000 people signed up for the phase 2/3 clinical trial, but only 37,586 received a shot. How many (n) received BNT162b2? 18,801 How many received the placebo? 18765
- 2. Of the people in the BNT162n2 group who ranged in age from 18 to 65 years old, what was the average (mean) age? 44.9
- 3. Of the people in the placebo group who ranged in age from 16 to 18 years old, how many were female? 26
- 4. Of the people in the phase 2/3 trials how many were Hispanic or Latino? What percent of the people were Hispanic or Latino? 10,522 (28%)
- 5. How many of the 37,586 people did not answer the question about ethnicity? 221
- 6. What percent of the people in the phase 2/3 trials were obese or overweight (combined)? 35.0+34.6=69.6%

bottom chart

7. How many of the people who received BNT162b2 tested positive for the virus prior to the clinical trial? 3

Final Analysis of Efficacy

- 1. What is efficacy? Efficacy is the ability of the vaccine to provide/cause immunity to Covid-19 without serious adverse reactions.
- 2. How many of the participants from 16-55 years old who were given the BNT162b2 shot tested positive for Covid-19? 5 How about those over 55 years old? 3
- 3. How many of the participants from 16-55 years old who were given the placebo shot tested positive for Covid-19? 114 How about those over 55 years old? 48
- 4. What efficacy percentage does this data mean for the BNT162b2 vaccine? 95.0%

Cumulative Incidence Curves

- 1. At a glance, were there more positive tests from those who received the vaccine or those who received the placebo? More who received the placebo tested positive.
- -Why does this make sense? Those who received the placebo were given a saline shot, not the vaccine, so we should expect them to still be susceptible to the virus.
- 2. By day 70, how many severe cases of Covid had occurred in the placebo group? 7 In the vaccine group? 1
- 3. How would this type of data have been obtained? How does this data make you feel about the efficacy of the vaccine? Answers may vary. I didn't see this in the report, but to get this data all would have had to be tested for Covid-19 each day for 119 days...I think! This data tells me that the vaccine is effective.

Frequency of Solicited Systemic Adverse Events

- 1. In layman's terms, we say "side effects," but the report calls those occurrences that may be attributed to the vaccine adverse events and abbreviates them as AEs.
- 2. Normal human body temperature is 98.6 degrees Fahrenheit. Convert this temperature to Celsius. Use this formula. $(F 32) \times .55 = C$ 37.0°C
- 3. What is 38°C Celsius in degrees Fahrenheit? 100.4°F Use this formula. C x1.8 +32 =F
- 4. How many people experienced a fever less than or equal to of 38.0 degrees Celsius in the vaccine group after dose 1? 28 In the placebo group? 7 after dose 2 181 In the placebo group? 4

(Fever is a sign of an immune system response. It appears that there was a more widespread immune response after the second dose, which may help us to understand why two doses are recommended. If we only take one dose, we should not consider ourselves protected. Why would people in the placebo group have reported a fever? Chance? Other factors?)

- 5. List, in order, from the most to least adverse events for the vaccine group after dose
- 2. Fatigue, Muscle Pain, Headache, Chills, Joint Pain, Feve, Diarrhea, Vomiting
- 6. List, in order, from the most to least, adverse events for the placebo group after dose
- 2. Fatigue, Headache, Diarrhea, Muscle Pain, Join Pain, Vomiting, Fever
- 7. Overall, did more participants experience adverse events following dose 1 or dose 2? Dose 2
- 8. Why do you think the placebo group experienced adverse events? How does this data compared with the vaccine group help scientists to analyze this data? Answers may vary. Other ailments, in their mind, expecting side effects, etc.