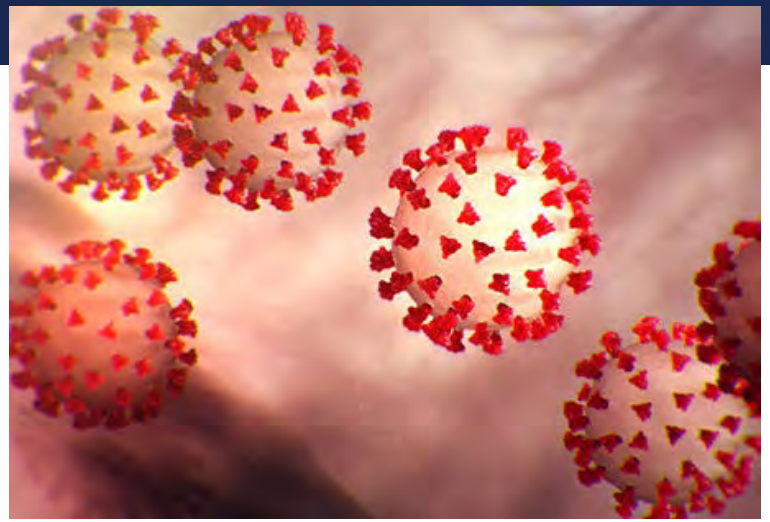



# Covid-19 Vaccines and the Delta Variant and YOU

Michael A. Kaufmann, MD, FACEP, FAEMS
State EMS Medical Director
Indiana Department of Homeland Security

# COVID UPDATE

## Advisory Level

Advisory level refers to the current guidelines the county must follow. A county must remain at a lower Weekly Two-Metric Score for two consecutive weeks to move down to a lower advisory level.

## Weekly 2-Metric Score

- Blue (0 and .5)
- Yellow (1 and 1.5)
- Orange (2 and 2.5)
- Red (3)

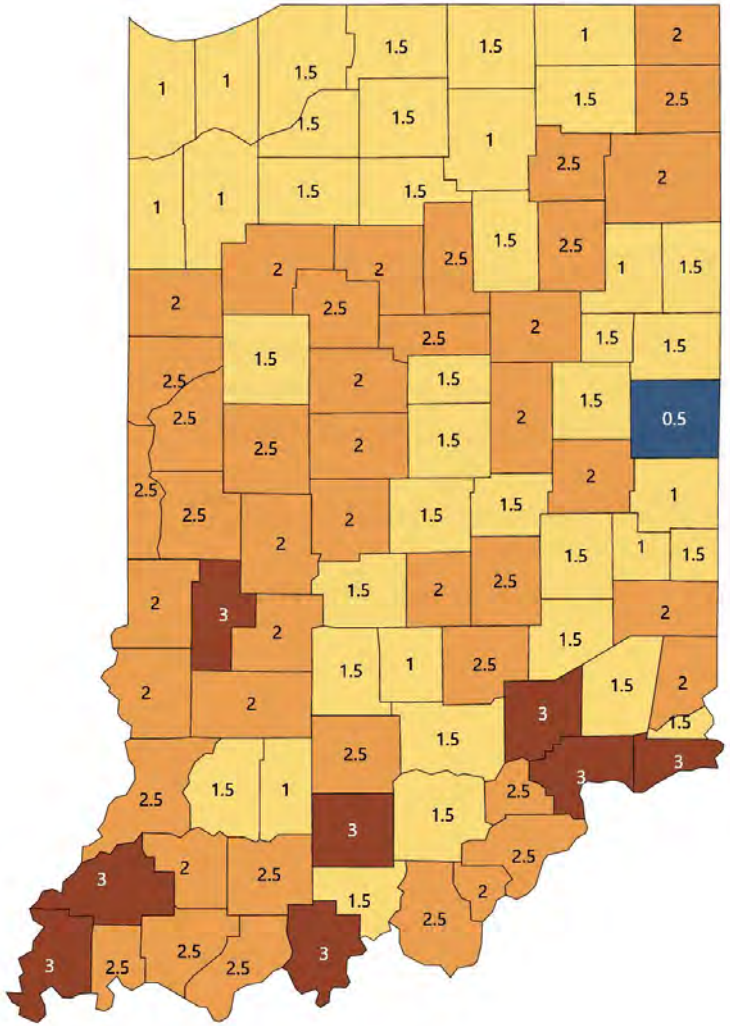
## Weekly Cases Per 100,000 Residents

- Less Than 10 new cases(0)
- 10 to 99 new cases(1)
- 100 to 199 new cases(2)
- 200 or more(3)

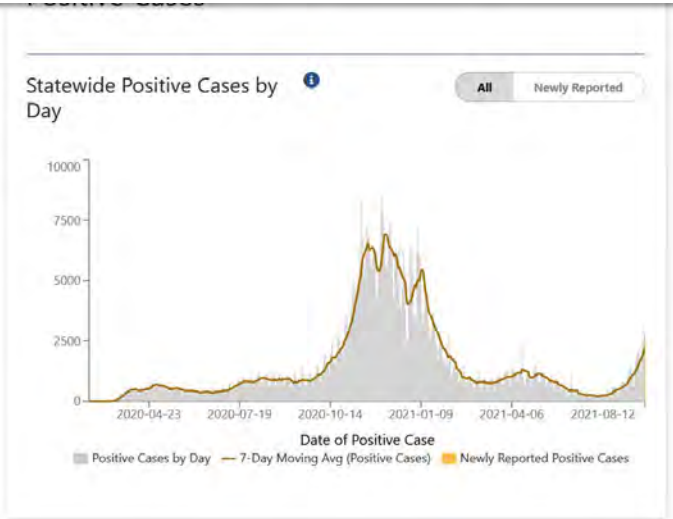
## 7-Day All Tests Positivity Rate

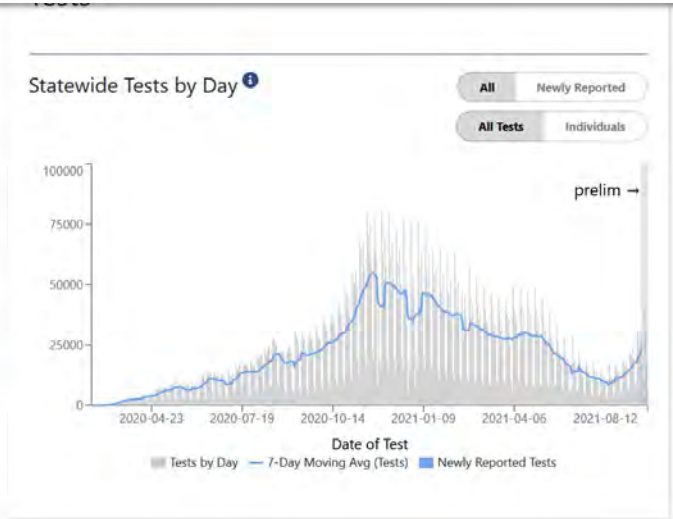
- Less than 5% (0)
- 5% to 9.9% (1)
- 10% to 14.9% (2)
- 15% or greater (3)

The ⚠ indicates a disclaimer alert for the county. Hover over the symbol for additional details.



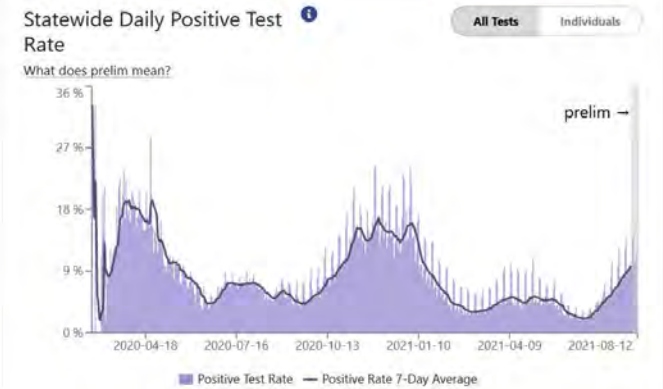
# COVID UPDATE




## Deaths


## Positivity




## Variants

More Info on Variants

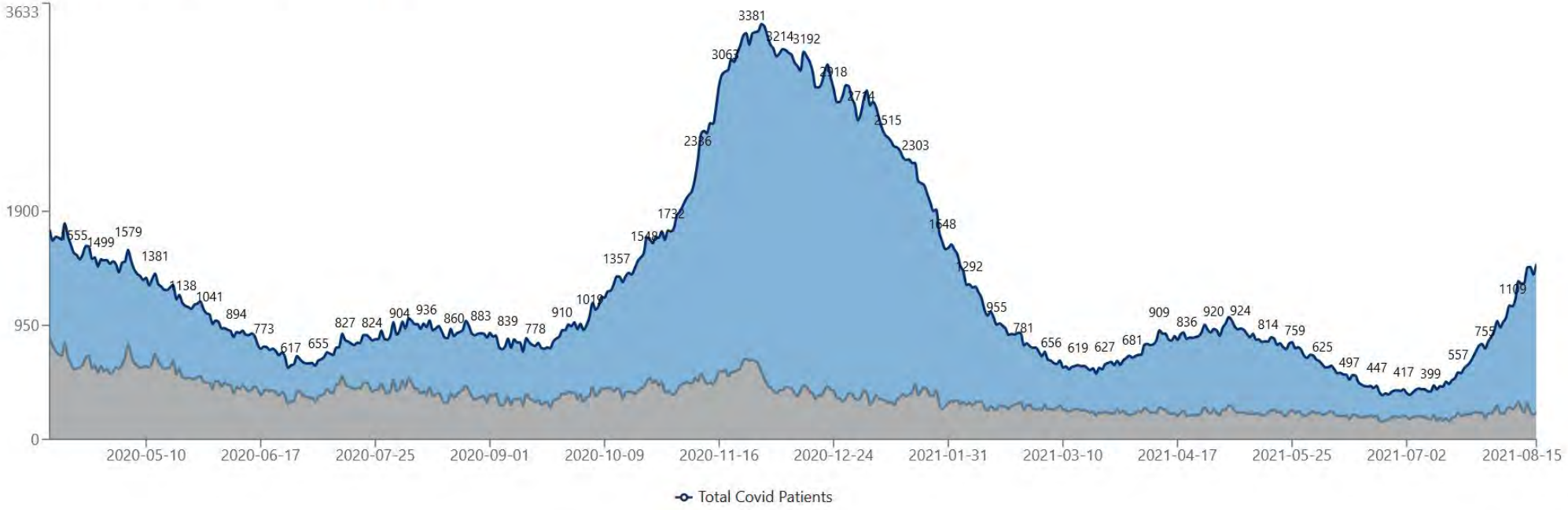
| Variant | % of Samples (in current month) | Change in % of Samples (from previous month) |
|---|---|---|
| **Delta** / B.1.617.2 | 87.2% | 23.7% |
| **Not Variant of Concern** | 7.3% | -2.2% |
| **Alpha** / B.1.1.7 | 2.9% | -20.2% |
| **Gamma** / P.1 | 2.6% | -1.3% |
| **Beta** / B.1.351 | 0% | 0% |

# COVID UPDATE

## Hospitalizations

Census | Admissions

Statewide COVID-19 Hospital Census

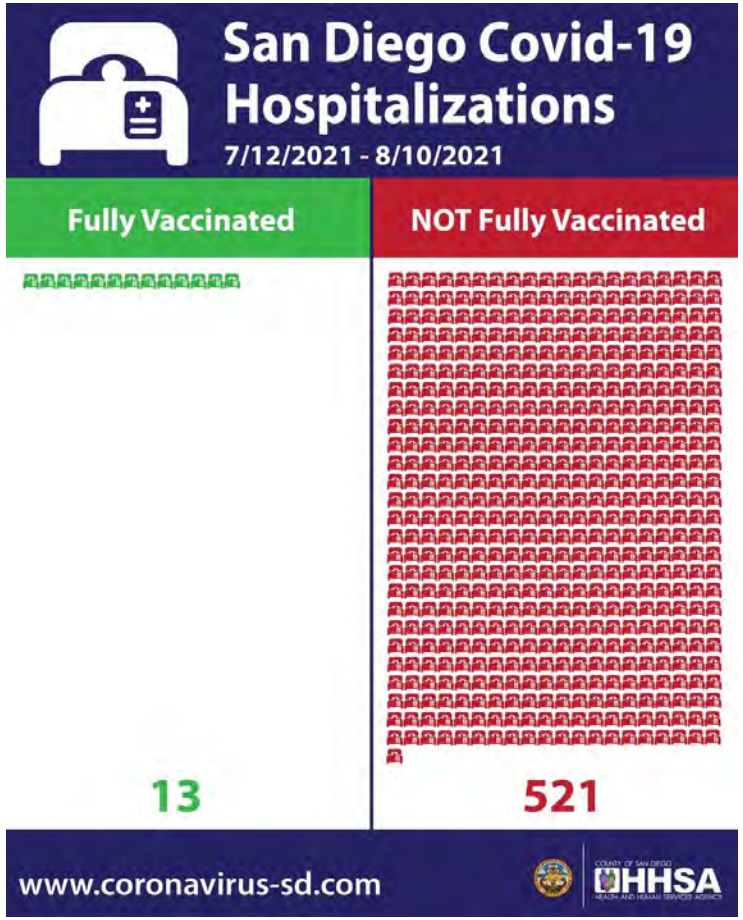


# Younger, Healthier Patients

OFFICER.COM

**27-Year-Old Florida Police Officer Dies After Contracting COVID-19 On Duty**

# Similar Here in Indiana

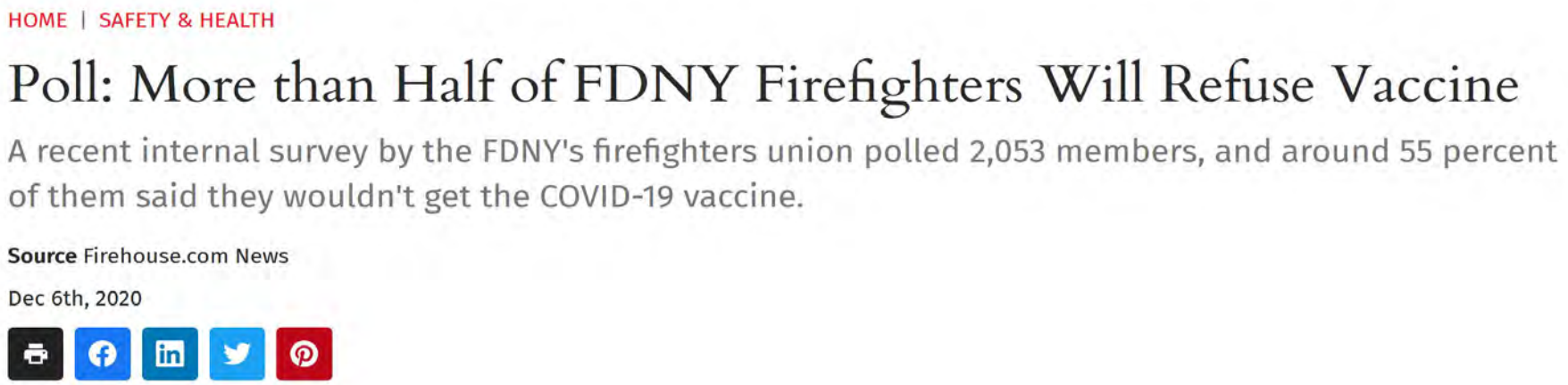


# Vaccines – Putting it all into Context

- How many of you have had the Polio Vaccine?
- How about Measles, Mumps, Rubella?
- What about Tetanus?
- Influenza?  More than once?
- Hepatitis B ?
- How many employers (healthcare) require Hep B vaccine?
- Have you received Chickenpox vaccine?  Meningitis?  HPV?

- So then why is COVID so different?

# Public Safety Concerns



HOME | SAFETY & HEALTH

## Poll: More than Half of FDNY Firefighters Will Refuse Vaccine

A recent internal survey by the FDNY's firefighters union polled 2,053 members, and around 55 percent of them said they wouldn't get the COVID-19 vaccine.

**Source** Firehouse.com News

Dec 6th, 2020

- In a joint statement last month, the  International Association of Fire Chiefs, the International Association of Fire Fighters, the National Association of State Fire Marshals, and the National Volunteer Fire Council urged governors and state health officials to give top priority to firefighters and EMS workers when it came to receiving the vaccine. The National Fallen Firefighters Foundation announced Tuesday that at least 104 first responders have died from the virus this year.
- A Centers for Disease Control advisory panel, however, recommended last week that health care workers and long-term care facility workers and residents be placed in the 1a priority group for the vaccine.

# Public Safety Concerns

- **Majority of Summit EMS workers opt out of COVID-19 vaccine**

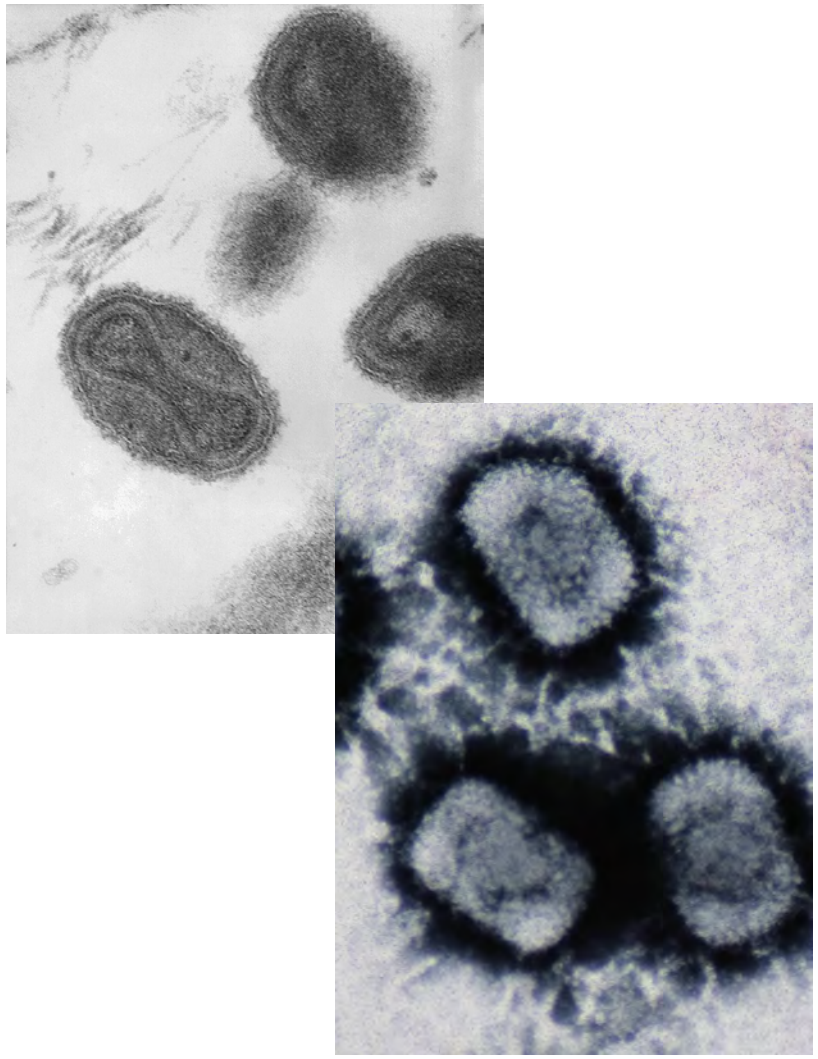

**4.1. Differences in Vaccination Willingness**

Our results show a higher acceptance to be vaccinated among the following groups:

- males;
- those with higher levels of education;
- older individuals;
- those who have first hand experience of the burden caused by the pandemic.

These results are comparable with other studies that have investigated the willingness to be vaccinated in the general population [40,41].

# Vaccination technology through the years



Edward Jenner 1796

The Latin word for cow is vacca, and cowpox is vaccinia; Jenner decided to call this new procedure vaccination.

# Advances in medical technology

- Killed Virus: e.g. Hepatitis A
- Live Attenuated Virus: e.g. Measles – took 10 years to produce
- Genetic manipulation of a benign virus
  - Astra Zeneca
  - Johnson and Johnson
- Piece of a Virus: e.g. Novavax – Purified Spike Protein
- Messenger RNA in a man-made virus-like lipid nanoparticle
  - Pfizer
  - Moderna

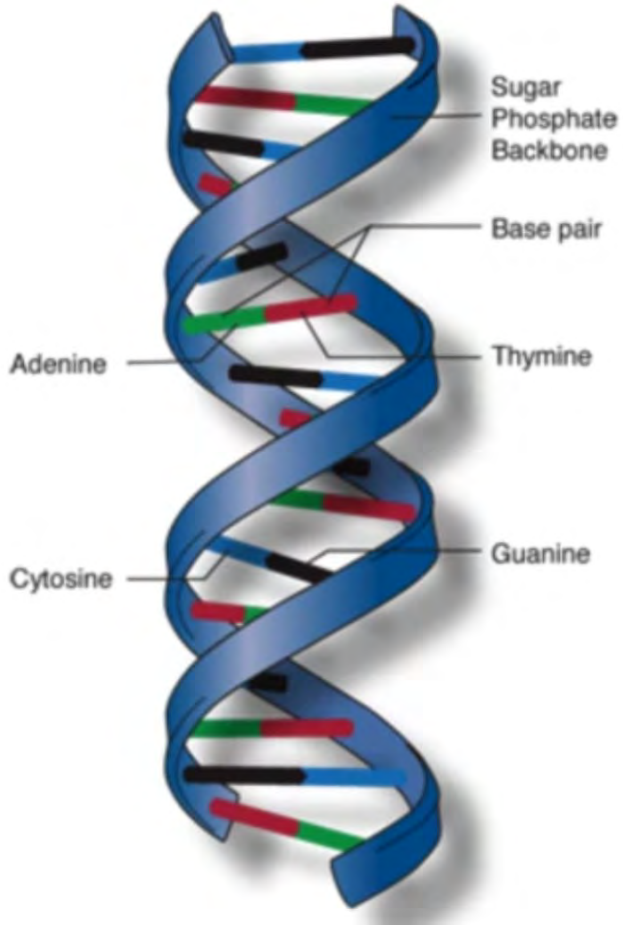
# How did we get a vaccine so fast?

- Smallpox vaccine took thousands of years
- Next major advances took hundreds of years
- Measles live attenuated vaccine took a decade
- The Human Genome project was key for the next major advance

# Human Genome Project

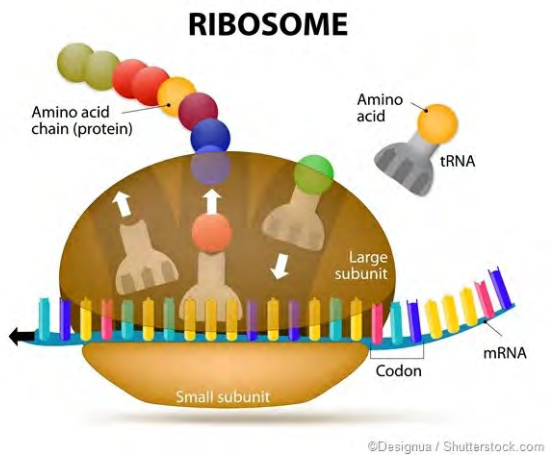
- 3 Billion Dollars
- Over 200 Labs in USA
- 18 other countries collaboration
- Took 13 years (1990 – 2003)

- <u>Currently:</u> Can decode entire human genome in 24 to 48 hours for less than $1k

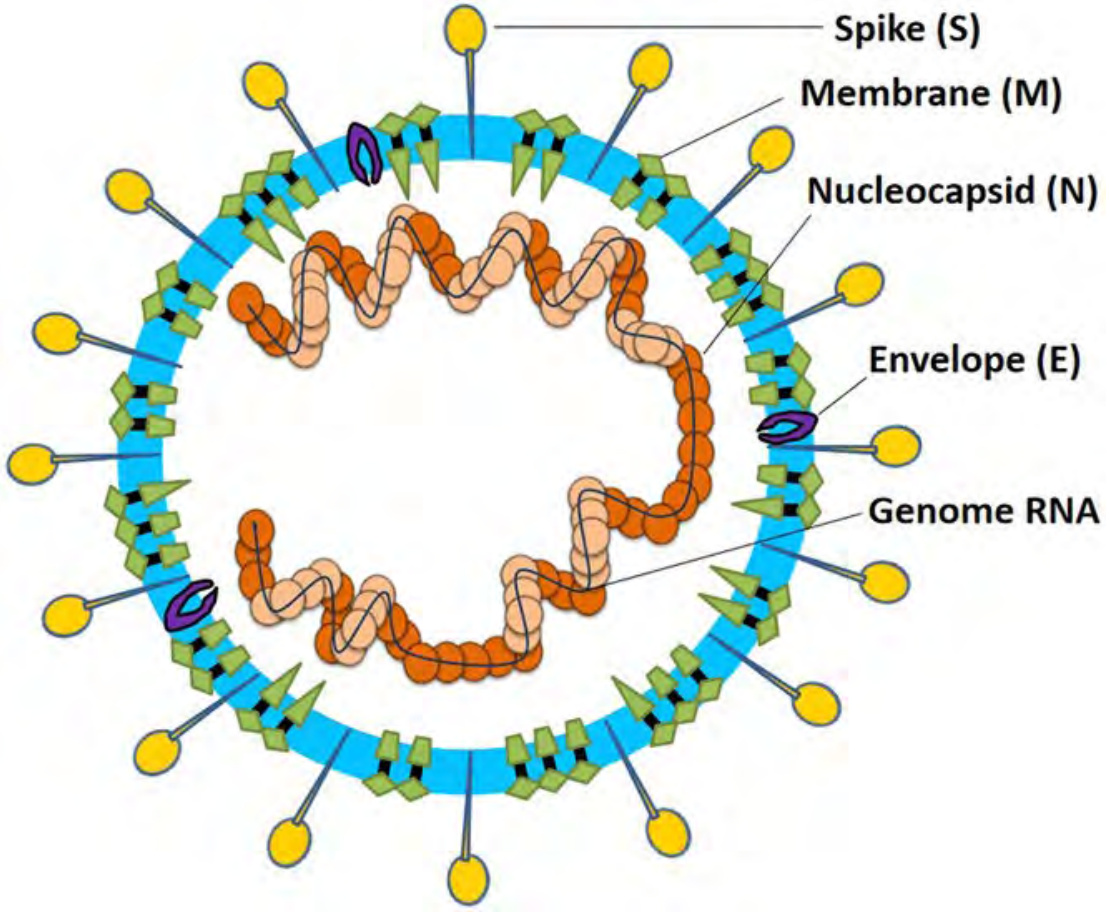


# Comparative Size of Genetic Databases

- Human: 6 Billion Bases
- Fruit Fly: 123 Million Bases
- E Coli: 5 Million Bases
- COVID: 30 Thousand Bases

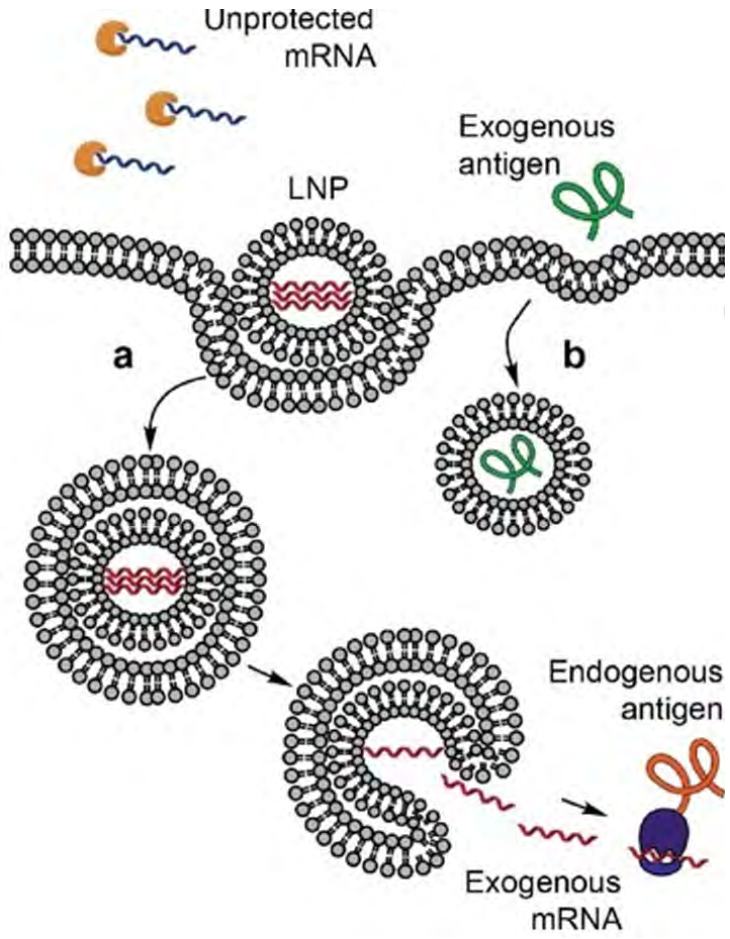






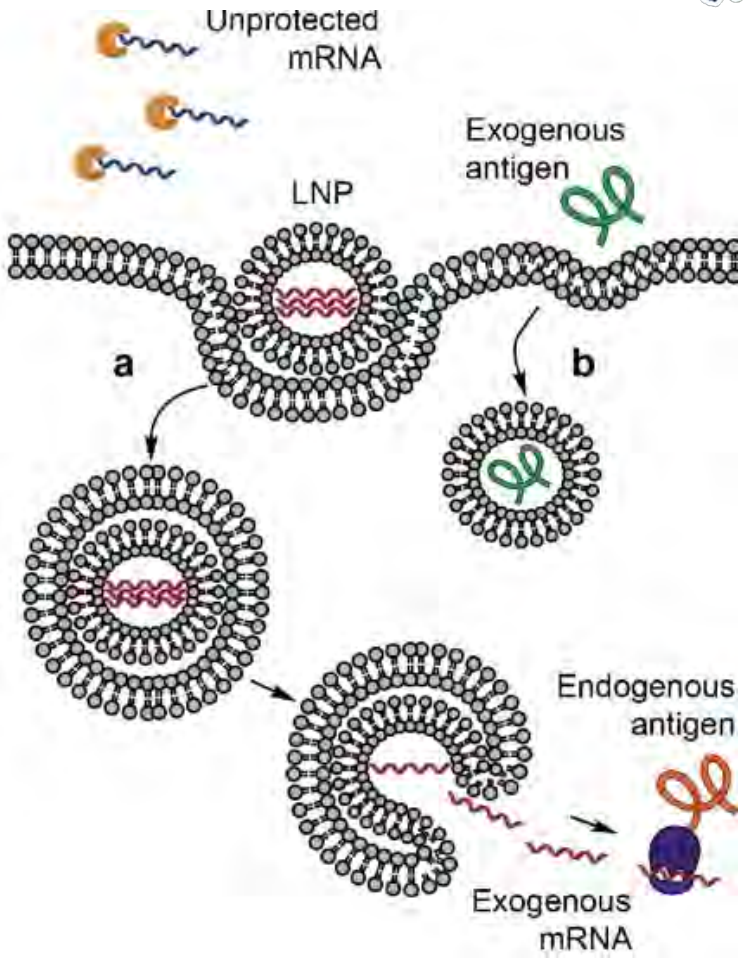
# Messenger RNA vaccines

- NOT A VIRUS!!
- mRNA codes for the target protein
- Can be used for infectious diseases and even cancer therapy
- Ultra rapid development process compared to prior vaccination technology
- 62 Days from SARS-CoV-2 genetic decoding to first human vaccine test injection
- Pandemic causes rapid exposure of treatment groups



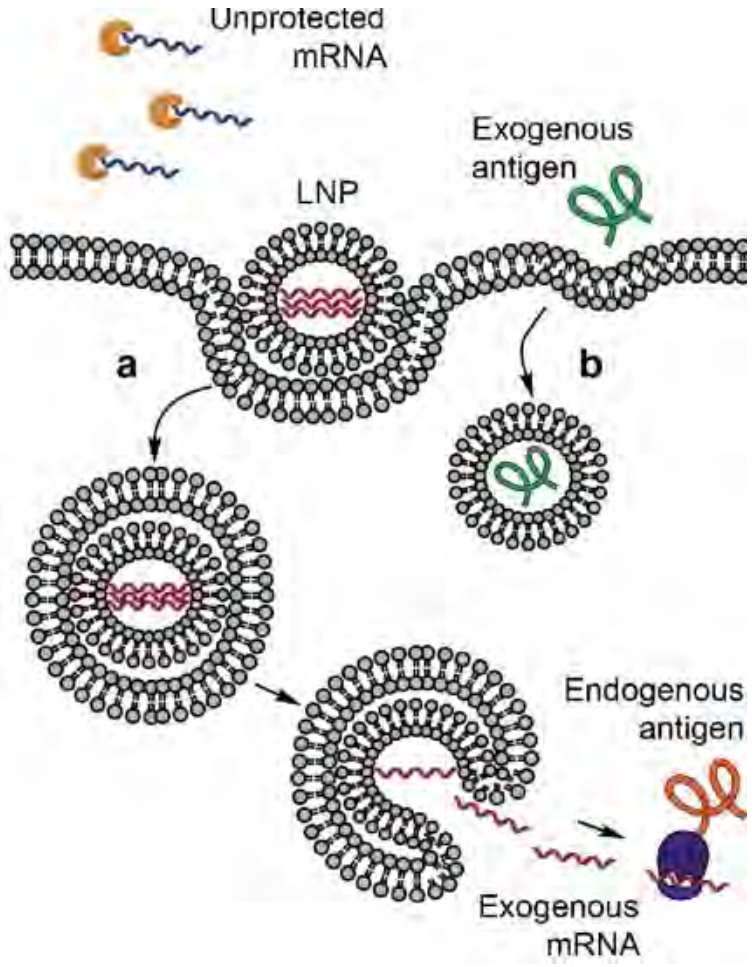
# Pfizer-Biontech

- mRNA Vaccine
- Ultracold storage -80C: 6 months
- Refrigerator storage: 5 days
- Room Temperature: 6 Hours
- 44k Study Participants, Diverse background
- Zero safety concerns
- 95% Effective
- Both Antibody and T Cell Immunity



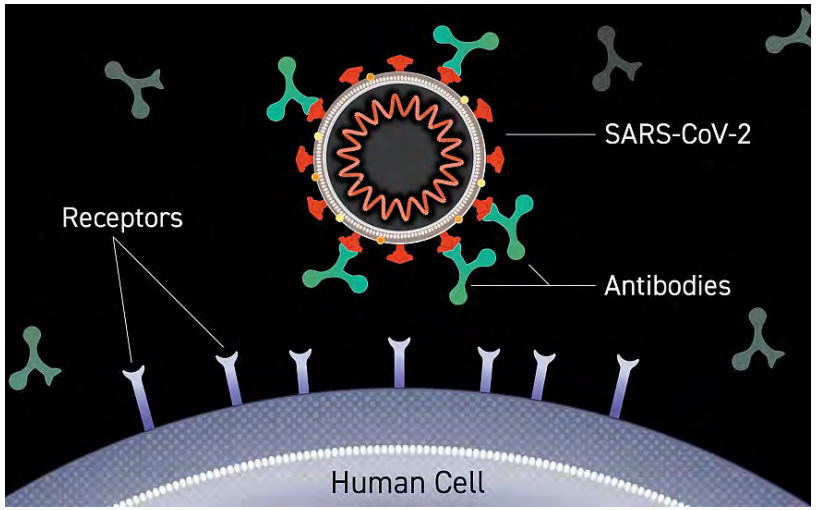
# Moderna

- mRNA Vaccine
- Normal Freezer storage: 6 months
- Refrigerator storage: 7 days (Maybe 30 days)
- Once opened:  6 Hours
- 30k Study Participants, Diverse background
- Zero safety concerns
- Greater than 94% Effective
- Both Antibody and T Cell Immunity



# Astra Zeneca

- AZD1222 Vaccine: Chimpanzee Adenovirus
- Unable to replicate
- Genetically modified to carry the COVID-19 Spike Protein
- Both Antibody and T-Cell Immune Response



# Johnson and Johnson

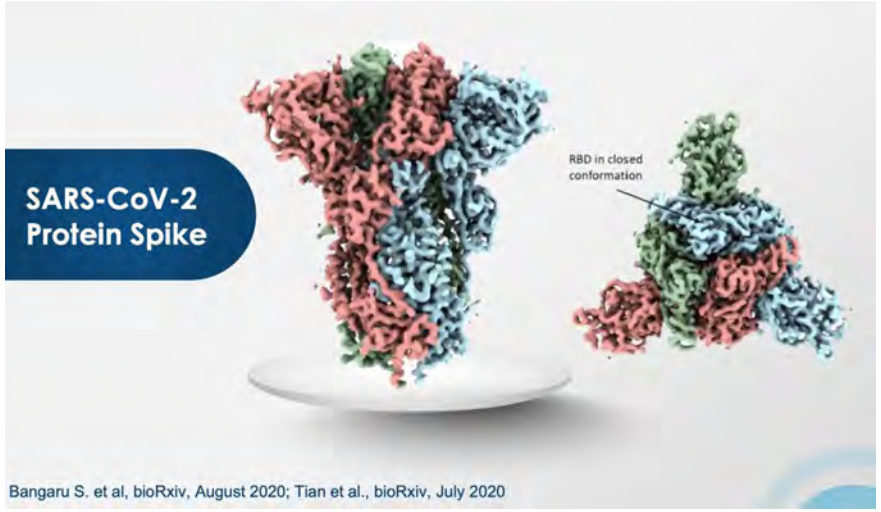
- Ad26 Single Shot Vaccine: Adenovirus Vector similar to AZ
- Unable to replicate
- Genetically modified to carry the COVID-19 Spike Protein
- Results show both Antibody and T-Cell Immune Response

## Safety Data Summary

- In clinical trials, side effects were common within 7 days of getting vaccinated and were mostly mild. Some people had side effects that affected their ability to do daily activities.
- Side effects were more common in people 18–59 years old compared to people 60 years and older.
- There is a plausible causal relationship between J&J/Janssen COVID-19 Vaccine and a rare and serious adverse event—blood clots with low platelets (thrombosis with thrombocytopenia syndrome, or TTS).
  - It occurs at a rate of about 7 per 1 million vaccinated women between 18 and 49 years old.
  - For women 50 years and older and men of all ages, this adverse event is even more rare.

# Novavax

- NVX-CoV2373: Adjuvanted, recombinant, full-length spike protein manmade nanoparticle vaccine
- No virus, no viral nuclear material, just purified viral spike protein
- Studies showed both antibody and T cell immunity
- Normal Refrigerator Storage
- May become available later this year.



# Two Shots – Same Flavor

- Most vaccines require a 2-shot series
- Second shot must be from same manufacturer
- Only J and J is single shot candidate

# Vaccine Side Effects

**SHOT NUMBER 1 Ages <55 and >55 y/o**

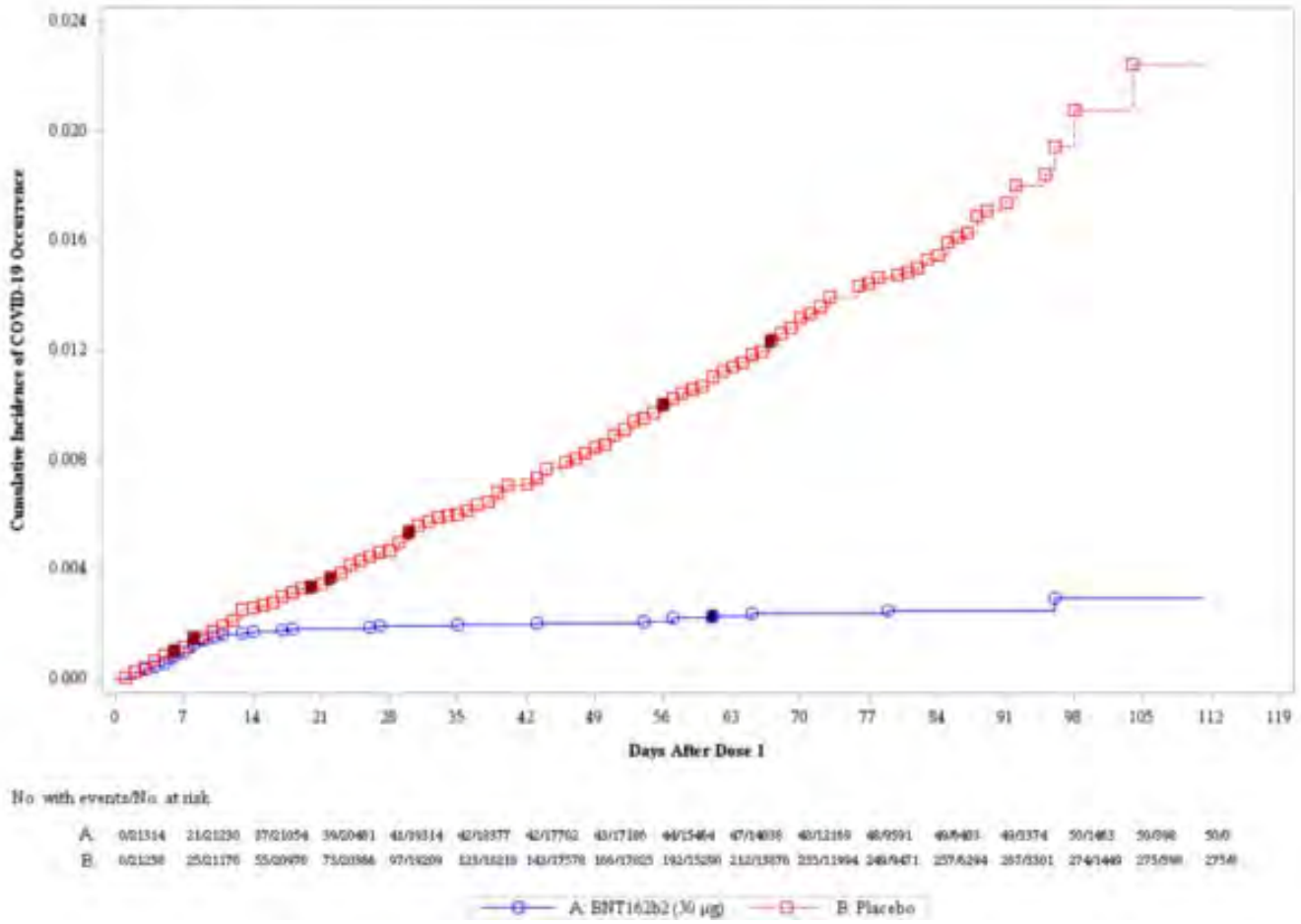
- **Fatigue** 47.4% and 30.4%
- **Headache** 41.9% and 25.2 %
- **Muscle Pain** 21.3% and 13.9%
- Chills 14% and 6.3%
- Fever: 3.7% and 1.4%

**SHOT NUMBER 2 Ages <55 and >55 y/o**

- **Fatigue** 59.4% and 50.5%
- **Headache** 51.7% and 39%
- **Muscle Pain** 37.3% and 28.7%
- Chills 35.1% and 22.7%
- Fever: 15.8% and 10.9%

# But Does It Work?

**Figure 13 Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population**



# Vaccine Side Effects vs. COVID

## Post Vaccination Symptoms vs COVID

- https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html

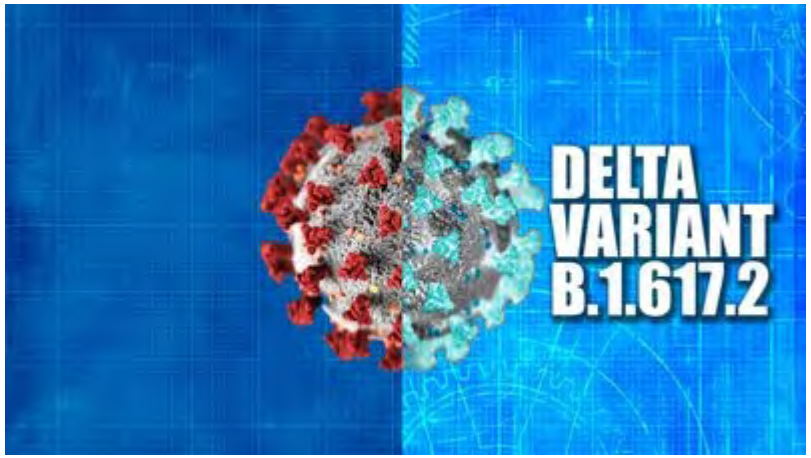
Differentiating Symptoms:

- Cough
- Sore Throat
- Shortness of Breath
- Runny Nose
- Altered Taste/Smell

- PCR and Antigen Test Results are UNAFFECTED by vaccine
- If positive, assume positive COVID

# COVID-19 – Delta Variant

- **1. Like Gorilla Glue.** The delta variant (lineage B.1.617.2) has a particular collection of mutations in the spike protein (that knob-like projection you see in renderings of the virus) that make it extremely effective in attaching to human cells and gaining entry. If the original COVID strains were covered in syrup, this variant is covered in ultrafast-drying Gorilla Super Glue (industrial strength).



# COVID-19 – Delta Variant

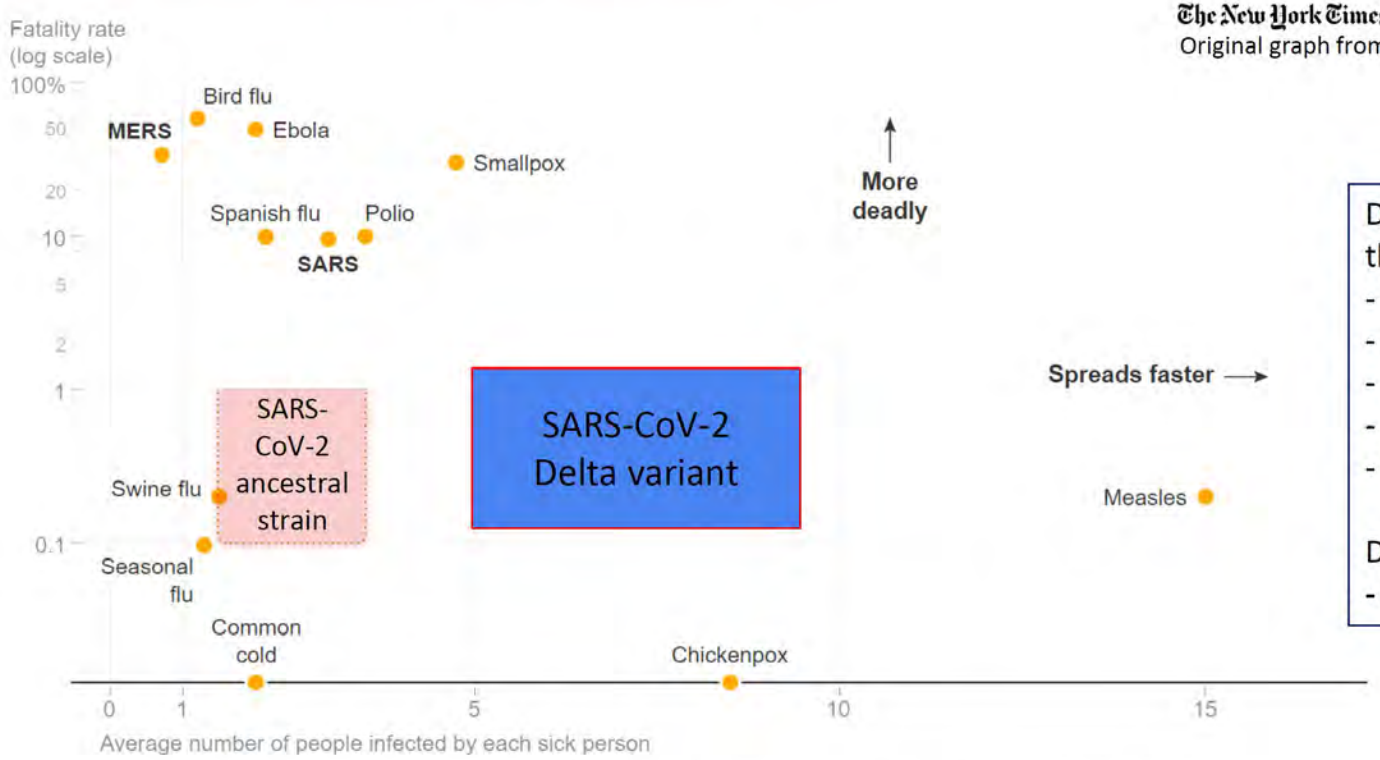
- **2. 1,000 times higher.** There are two recent publications which demonstrate that the viral loads in the back of the throats of infected patients are 1,000 times higher with the delta than with previous variants. I can tell you from data in my own labs, that is absolutely true. We are seeing viral signals we never saw last year using the exact same assays.

# COVID-19 – Delta Variant

- **3. Much more infectious.** This much higher load plus the ultra "stickiness" of the delta strains for adhering to human cells makes it remarkably more infectious than previous strains. You may have heard of R0 (Pronounced R naught) which is, in a nutshell, the number of people to which an infected person would be expected to transmit the virus.
- Early versions of the virus had a 2 to 2.5 R0 value. So one infected person would infect two or so people on average.
- Delta has an R0 of about eight! In the infectious disease world, that's almost unheard of. Chickenpox and measles are about all we have ever seen that spread that efficiently from human to human. This changes the story line completely from earlier in the pandemic and makes this surge, in many ways, like a completely different pandemic event.

# COVID UPDATE

## Transmission of Delta variant vs. ancestral strain and other infectious diseases




The New York Times
Original graph from 2/28/2020.

Delta variant is **more** transmissible than:
- MERS & SARS
- Ebola
- Common cold
- Seasonal flu & 1918 ("Spanish") flu
- Smallpox

Delta variant is **as** transmissible as:
- Chicken Pox

Note: Average case-fatality rates and transmission numbers are shown. Estimates of case-fatality rates can vary, and numbers for the new [illegible] are likely to vary as well.

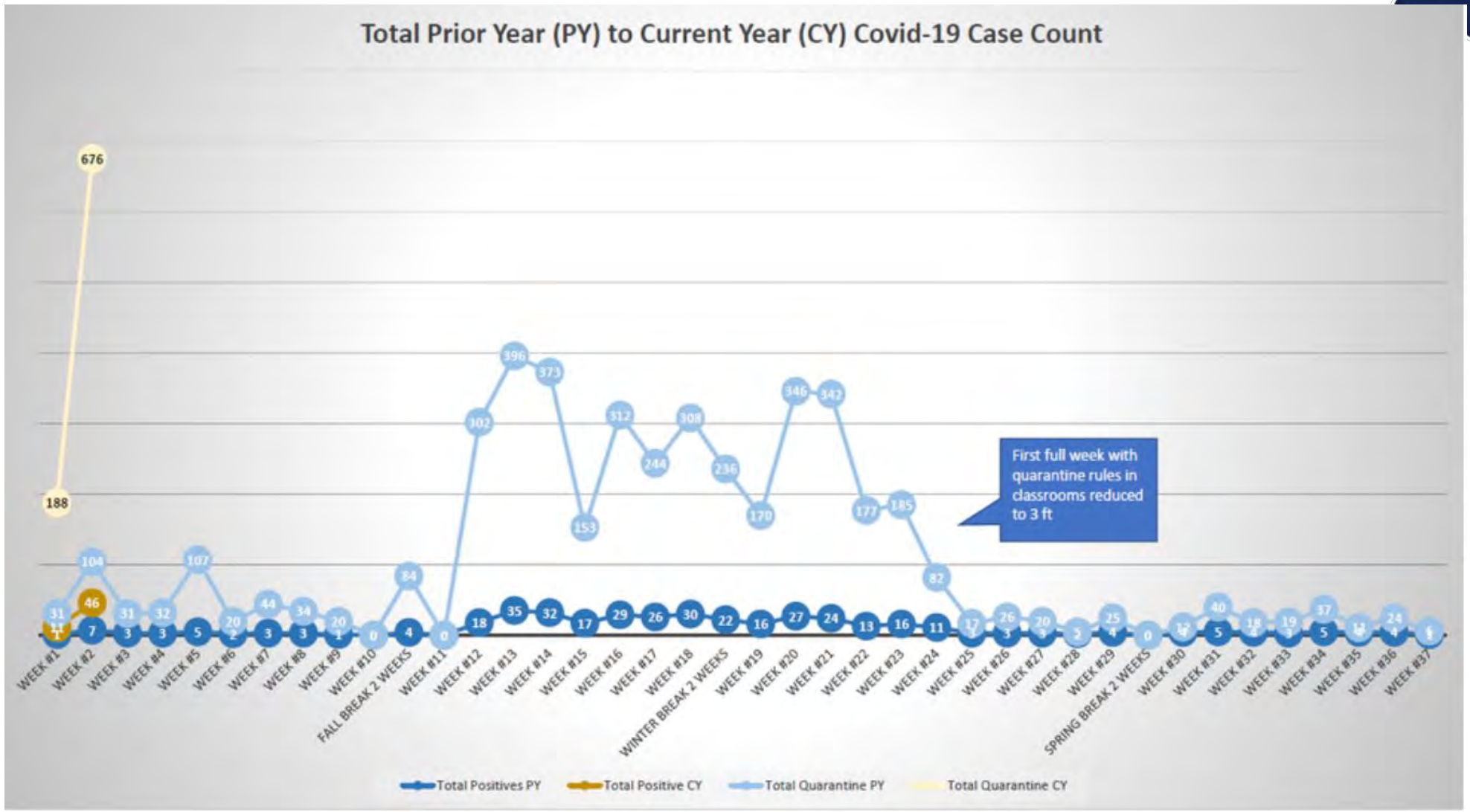
# COVID-19 – Delta Variant

- **4. Five days.** There is another recent publication out of Singapore with data that confirms something we suspected. I will explain more about the "why" on this below when I talk about vaccines, but the gist is this: The viral loads in the *throats* of vaccinated persons who become infected with delta rises at identical rates as in unvaccinated persons, but only for the first few days. After five days or so, the viral loads in the vaccinated person start to quickly drop whereas those in the unvaccinated person persist. This key set of observations is important for several reasons relating to vaccinated persons serving as vectors for spread (see below).

# COVID-19 – Delta Variant

- **5. Young people.** This pandemic, Round 2, is primarily being observed in younger patients than in Round 1. Our children's hospitals are even already filling up or full. Because of the delta viral dynamics, it is much more capable of causing severe disease in a larger swath of the population. You spew enough of any human pathogen on someone without immunity, and it's not going to end well. This sets up very poorly for the beginning of the school year — which has already started in Florida — and it scares me. Check that. It is actually terrifying. I sure hope we have vaccines for the 5- to 11-year-olds soon.

# Brownsburg Experience



# COVID-19 – Delta Variant

- **6. Vaccines work!** Speaking of vaccines. Are they working? Yes! They are absolutely doing their expected job. We know a lot about vaccines for upper respiratory viruses, as we have been giving the population one every year for decades (influenza). To explain all of this, I need to provide some biological context. When you get a vaccine as a “shot,” the “antigen” in the vaccine leads to formation of an antibody response. You probably knew that. What’s important, though, is that it primarily leads to a specific Immunoglobulin G (IgG) response. That’s the antibody type that circulates around in really high numbers in the blood, is located some in tissues and is more easily detectable by blood tests, etc.

# COVID-19 – Delta Variant

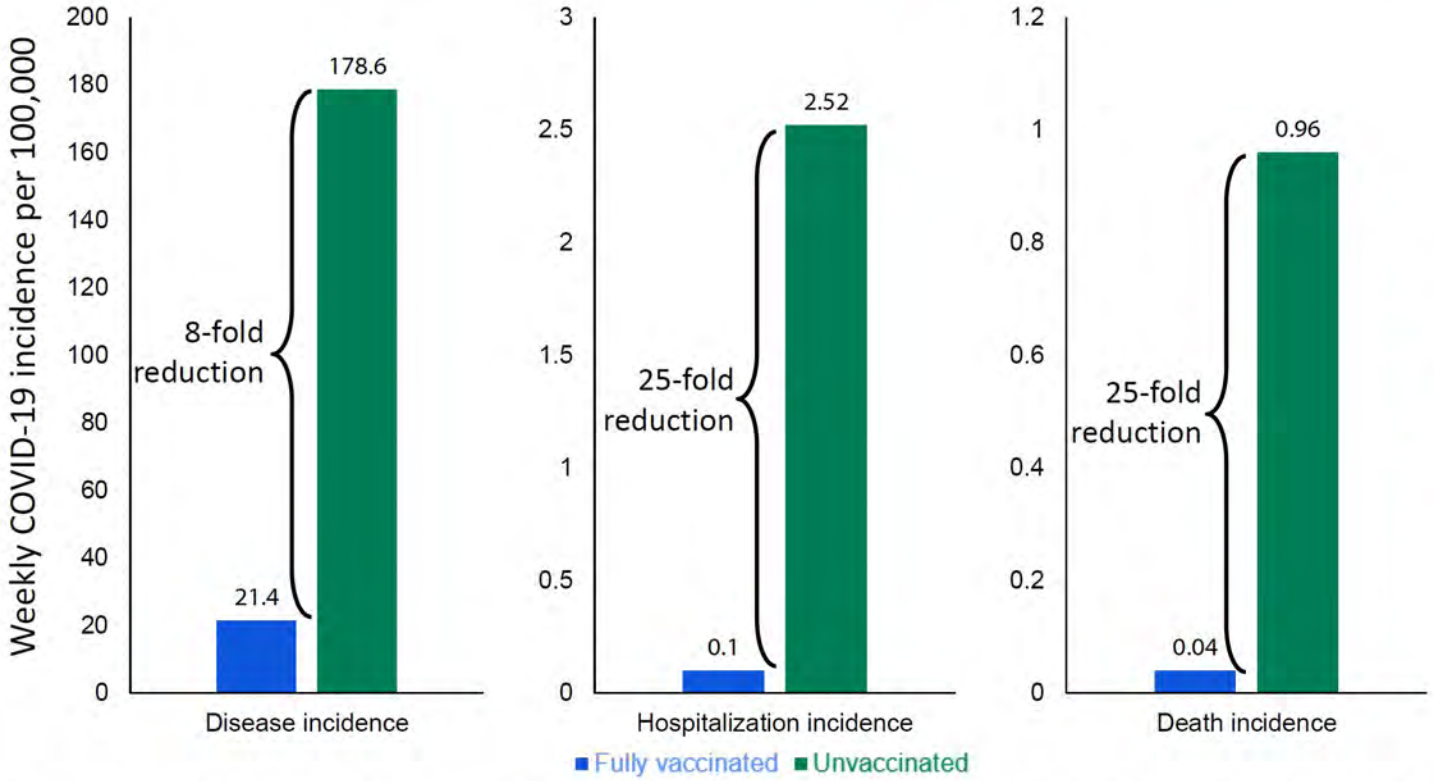
- What that shot does *not* do is produce an Immunoglobulin A (IgA) antibody response to the virus at the surface of the throat mucosa. That's the antibody type that could prevent the virus from ever binding in the first place. As such, in a vaccinated person, the virus can still attach like it's about to break into the house, but it doesn't realize that there is an armed homeowner on the other side of the door. When that virus is detected, the IgG beats it up and clears it before the person gets very ill (or ill at all).

# COVID-19 – Delta Variant

- **7. Preventing disease and death.** The COVID-19 vaccines are designed to prevent disease/death through that IgG response (though it does also reduce infections somewhat). How good are the vaccines at doing all of this with delta? The Centers for Disease Control and Prevention has just released data addressing that very question. Punchline: They're remarkably good! The vaccine shows an 8-fold reduction in the development of any symptomatic disease secondary to delta. For hospitalization, it is a 25-fold reduction. That's 25 times! Remarkable. For death, it is also 25 times! This is a very effective pharmaceutical class when looking at overall efficacy toward the intended/expected purpose. When looking at the very tiny side effect profile, I'd personally consider it one of the best overall pharmaceuticals on the market in any class of drugs.

# COVID-19 – Delta Variant

## Greater risk of disease, hospitalization and death among unvaccinated vs. vaccinated people: National estimates



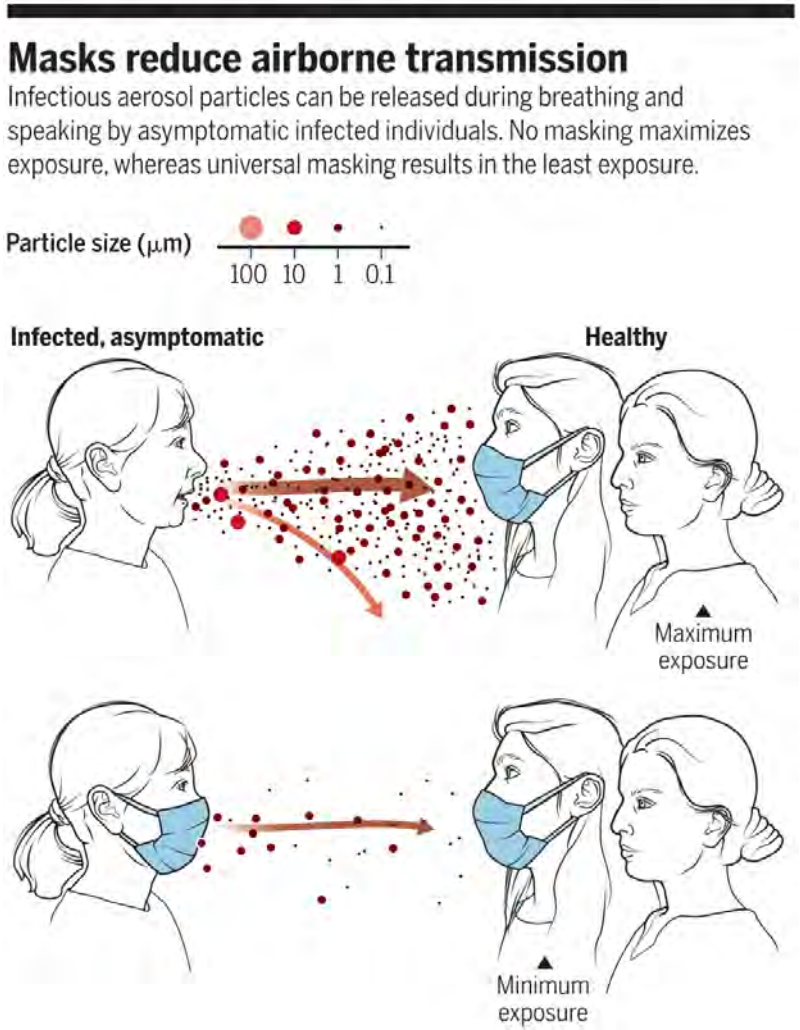

**At current incidence, 35,000 symptomatic infections per week among 162 million vaccinated Americans**

Data from COVID Tracker as of July 24, 2021. Average incidence 100 cases per 100,000 persons per week. Vaccine effectiveness against symptomatic illness = 88% (Lopez Bernal et al. NEJM 2021), where risk is [1 – VE] or 12%. Vaccine effectiveness hospitalization (or death) = 96% (Stowe et al. PHE preprint), where risk is [1 – VE] or 4%. Rate in unvaccinated = Community rate/((1-fully vaccinated coverage) + (1-VE)*fully vaccinated coverage). Rate in fully vaccinated=(1-VE)*Rate in unvaccinated. Fully vaccinated coverage and population are from COVID Data Tracker as of July 24, 2021 (50% for US,).

# COVID-19 – Delta Variant

- **8. So, you're vaccinated?** First of all, a sincere, heart-felt thank you! But you may now ask, so why do I again need to wear a mask? We talked about disease, hospitalizations and death above, but what about infections themselves? The vaccines are now estimated to provide a 3-times reduction in infection. For reasons that I tried to make clear above, it isn't surprising that the vaccine is less effective at preventing infection vs. preventing disease. We are indeed seeing detectable virus, at high levels, in asymptomatic, vaccinated persons when we test them prior to procedures, etc. We have a few that are mildly symptomatic, too.
- While we now understand that the virus fades from the back of the throat pretty quickly in a vaccinated person, we also know that an infected, vaccinated person can transmit this very infectious virus to others for at least a couple of days. So, as before, you are being asked to wear a mask to primarily protect others.
- We need you again to interrupt the transmission cycle of the virus, as you don't know when you might be infectious. The vaccine alone cannot interrupt this cycle when there is a lot of virus in the community within unprotected persons.

# Masking Reduces Transmission




**'Volusia County just lost two public servants:' Paramedic, teaching assistant die of COVID-19, family says**

2 victims were siblings, sheriff says


**Friends, colleagues remember Citrus County EMT who died from COVID-19**

# COVID UPDATE

## Early evidence in health care providers that vaccination may reduce transmission and attenuate illness (HEROES/RECOVER)

- Period: December 14, 2020 – April 10, 2021
- VE against infection was **91%** (CI 76-97) among fully vaccinated; **81%** (CI 64-90) for partially vaccinated
- Compared to unvaccinated cases, vaccinated cases (full or partial) had:
  - 40% lower mean RNA viral load (2.3 v. 3.8 copies/mL)
  - shorter mean duration of detectable viral RNA (2.7 v. 8.9 days)
  - lower risk of febrile symptoms (25.0% v. 63.1%)
  - shorter mean duration of symptoms (10.3 v. 16.7 days)

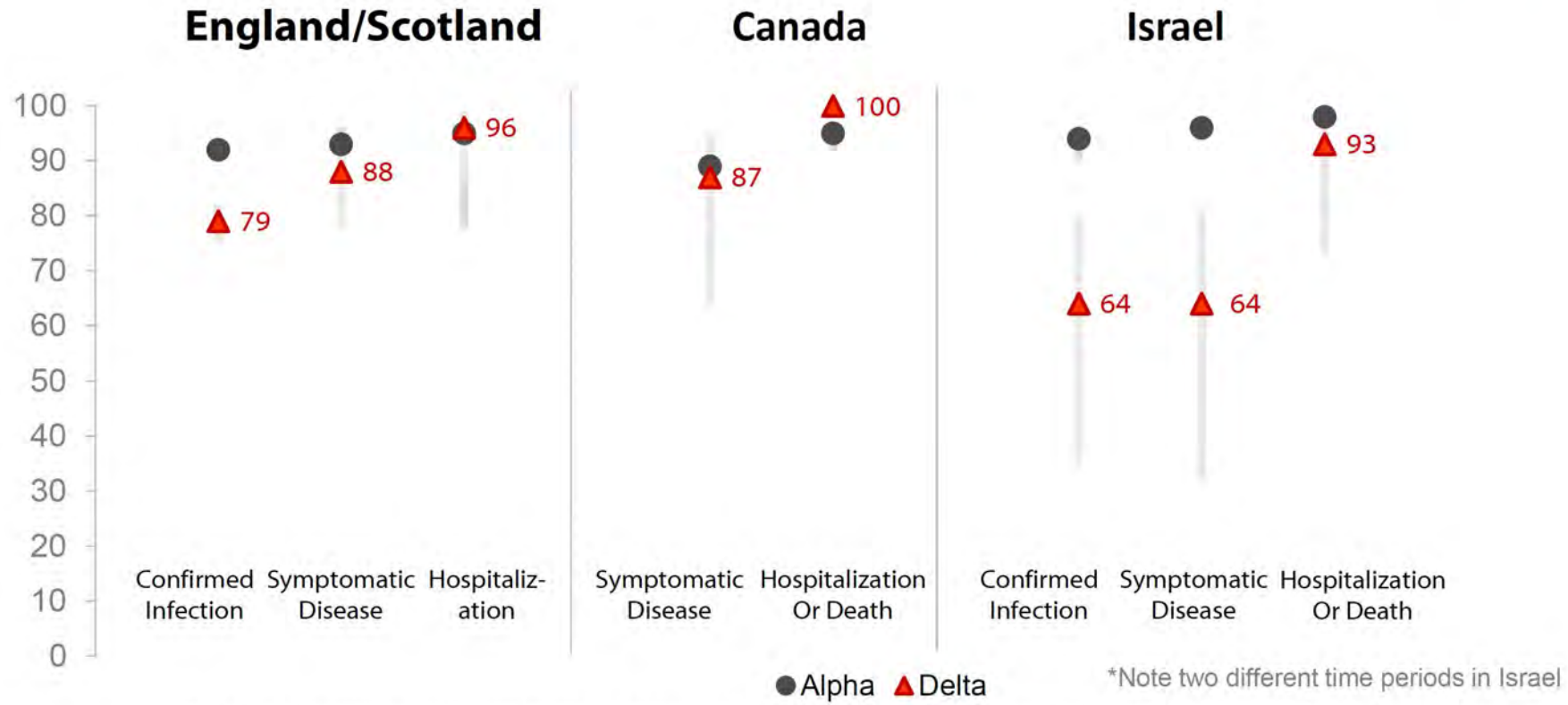
# COVID UPDATE

## Delta variant may cause more severe disease than Alpha or ancestral strains: Published evidence

- Canada: Higher odds of hospitalization [aOR 2.20 (CI 1.93-2.53)], ICU admission [aOR 3.87 (CI 2.98-4.99)], and death [aOR 2.37 (CI 1.50-3.30)][1]
- Singapore: Higher odds of oxygen requirement, ICU admission, or death [aOR 4.90 (CI 1.43-30.78)] and pneumonia [aOR 1.88 (CI 0.95-3.76)][2]
- Scotland: Higher odds of hospitalization [HR 1.85 (CI 1.39-2.47)][3]

# COVID UPDATE

## Pfizer 2-Dose Vaccine Effectiveness for Alpha vs. Delta




Sheikh et al. Lancet (2021): https://doi.org/10.1016/S0140-6736(21)01358-1; Lopez Bernal et al. medRxiv preprint; https://doi.org/10.1101/2021.05.22.21257658; Stowe et al. PHE preprint: https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZlEig/view/479607266; Nasreen et al.medRxiv preprint: https://doi.org/10.1101/2021.06.28.21259420; https://www.gov.il/en/departments/news/06072021-04

19

# COVID UPDATE

## Summary

- Delta is different from previous strains
  - Highly contagious
  - Likely more severe
  - Breakthrough infections may be as transmissible as unvaccinated cases
- Vaccines prevent >90% of severe disease, but may be less effective at preventing infection or transmission
  - Therefore, more breakthrough and more community spread despite vaccination
- NPIs are essential to prevent continued spread with current vaccine coverage

# Other FAQs

The safety and efficacy of this has been studied across the globe in people over the age of 12 with lots of different characteristics. There are things researchers are still studying and learning that will help us over time. A couple of quick highlights:

- We aren't sure how long immunity lasts. At least six months for sure.
  - Pfeizer and Moderna both show 97-98% effective against severe disease.
  - Immune response is likely to last years.
- Data is coming for kids under the age of 12, but it looks good. Coming soon.
- Side effects so far have been minor and short lived like: redness where the shot goes in, a low grade fever, headache, muscle aches and feeling tired. These are indicators that your body is revving up for an immune response. It looks like this occurs in about 5-15% of people and goes away in about three days.
- If you've had COVID, you will still likely benefit from getting the vaccine.
  - Stronger immune response from the vaccine vs. variable response when you get the disease.

# Additional FAQs from the CDC

- The mRNA disintegrates rapidly – I think this is important since some persons will worry about producing viral proteins for the rest of their life or some other prolonged period of time. These do not stick around that long. They did not say for how long they are able to produce proteins (obviously long enough to elicit an immune response) but their word is it disintegrates rapidly.
- What happens if someone accidently mixes vaccines (e.g., gets Pfizer for shot one and Moderna for shot two) – The short answer is they don't know. The just haven't studied it. There is no reason to assume it would have some untoward effect though. If that happens the persons should not get a third shot. They are done after two regardless.
- What happens if someone gets the second short before the 21 (Pfizer) or 28 (Moderna) time frame – the short answer is it will probably add to your immunity but maybe not as much. They have evidence from other vaccines that having a longer period of time between doses improves immunity. The Pfizer study is 21 days and we know that spacing results in 95% efficacy. So if someone get's a shot at 14 days it will probably add to their immunity but perhaps not as much as waiting that additional week. If that does happen they should not get a third shot. They are done after the second dose.
- Is it safe to give in people who are asymptomatic carriers? – Yes, at least to the best of our knowledge there is no reason to think the vaccine would not work or would have untoward effects if given to someone who has the virus but no symptoms. I would think the biggest risk is if they develop symptoms from their infection a few days after the shot they may falsely attribute the shot to giving them COVID-19. We see this every year with the flu.

# Additional FAQs from the CDC

- Is it safe to give in people who have had COVID-19? Yes, in the trials they did serology on participants and know that some of the people who got the COVID-19 vaccine had antibodies suggesting a prior infection. The CDC recommends persons who have had COVID-19 get the vaccine. It makes sense that in those with active infection wait till they recover (to not expose persons giving the vaccine) and for those with infections in the last 90 days perhaps let their colleagues get ahead of them in line since they will have some immunity.
- Can you give the vaccine to persons who have received monoclonal antibodies or convalescent plasma – They don't have any data on that. Since the mRNA makes spike proteins and the antibodies are generated against spike proteins it makes sense to say anyone who has received a monoclonal antibody or convalescent plasma wait 90 days until the receive the vaccine.
- Can you give the vaccine to someone in quarantine? There is nothing about quarantine that would prevent the vaccine from working or cause an untoward effect but since individuals may be carrying COVID (either asymptomatic or pre-symptomatic) they should not get the vaccine till out of quarantine to protect those working at vaccine sites. There is one important exception to this rule. ***Those in long-term care facilities (LTCs) in quarantine can get the vaccine***. Because persons in LTCs are often exposed and re-exposed to persons with COVID and they are high risk, the recommendation is to vaccinate them regardless of being in quarantine.
- Will the vaccine work in persons with HIV or those immunosuppressed? They do not have data on this population at this time. They would recommend offering the vaccine but explaining to anyone who fits this description that there is little data on its use in this population. Just so they are informed.

# Additional FAQs from the CDC

- After you are vaccinated can you stop wearing masks and not have to quarantine if exposed? No. They were pretty firm on this. They mentioned that the studies only looked at whether someone who received the vaccine developed COVID-19 (symptoms and Positive test). They did not study whether receiving the vaccine decreased the chance that someone who was exposed to virus might not be able to carry it and pass it on. They did mention that Pfizer is conducting these studies right now and they hoped in several months to have an answer to this. But till then, wear your damn mask, wash your damn hands, and yes, quarantine if you are exposed to someone with COVID.
- What about this anaphylaxis business? Important to note. The studies did exclude people with prior vaccine allergic reactions. But, in a tribute to the adverse monitoring system in place, two person in the initial rollout in England developed anaphylaxis. The real deal. Not the I feel queezy or syncope from being vagal but real anaphylaxis. It is important to not that only TWO cases have been observed. This is an incredible low number. And in both cases they had had prior anaphylactic reactions to injections. They don't' know exactly what the ingredient in the vaccine that caused it but believe it is the lipid nanoparticles. Although not yet proven, they suspect persons with allergies to polyethylene glycol injections would be at risk.
- What about other causes of anaphylaxis? CDC was clear the only caution at this time is in giving this vaccine to someone who has had anaphylaxis to **an injectable** (IV, IM, SQ) medication or vaccine.
  - What about shellfish? Not a problem they can get the vaccine?
  - What about other food allergies? Not a problem they can get the vaccine?
  - What about bee stings or insect allergies? Not a problem they can get the vaccine?
  - What about oral medication allergies? Not a problem they can get the vaccine?
  - **The only contraindication at this time is if the have had an anaphylactic reaction to an injectable medication or vaccine**

# Additional FAQs from the CDC

- If someone has had anaphylaxis to an injectable medication or allergy can they still get the vaccine? Short answer is yes, but the provider needs to let them know of the risk (My commentary – The provider must be able to manage anaphylaxis. They did not mention this but I would consider pretreating someone with Benadryl and having an epi shot at the bedside. We would run into this with antivenom for snake bites [lots of people, well lots of men, are bitten by snakes more than once and have severe anaphylaxis to the antivenom]. We would pretreat them with Benadryl and have epi ready to give in case they developed symptoms. We were usually still able to treat them though.
- How long to watch someone after the vaccine shot? 15 minutes if they have no history of anaphylaxis or allergic reactions to injectables. 30 minutes if they have a history of allergic reactions or anaphylaxis to injectables.
- Will the vaccine make antibody tests positive? Yes and No. Some antibody tests are to the spike protein. These new vaccines will, hopefully, make antibodies to spike proteins so the antibody tests will be positive after someone is vaccinated. There are antibody tests, however, to the nucleocapsid protein. These tests will not be positive after the vaccine and would be able to diagnosis someone has having had a prior infection.
- Will the vaccine cause an autoimmune flair in individuals with autoimmune disorders? It makes sense to worry about this, but fortunately to date this had not been seen. There were individuals with autoimmune disorders in the Pfizer and Moderna trials. They did not see flairs of disease form the vaccine. No doubt this will continue to be looked at but right now it appears safe.
- What are the components of the Pfizer vaccine? Only the mRNA and lipid nanoparticles There is no preservative. This is why they think the lipids are the cause of the very rare case of anaphylaxis.

# Thank you.

- To estimate range to get to herd immunity use the following: 1 - 1/R0  R0 is the transmission rate. For the original virus it was 1 person infects 2 or 2.5. But Delta is 1 person infects up to 8 so 1 - 1/8 = 87.5% to get to herd immunity. So we are very near to making a choice get vaccinated or get infected.
- We KNOW your risk of M/M is low with the vaccine.
- We don’t know your M/M with getting COVID.
- The choice is yours.