

COVID-19 VACCINES

Christine Pontus, MS, RN, COHN-S/CCM
Kevin Kavanagh, MD, MS



The Labor Guild of the Archdiocese of Boston, Braintree MA Feb. 25, 2021

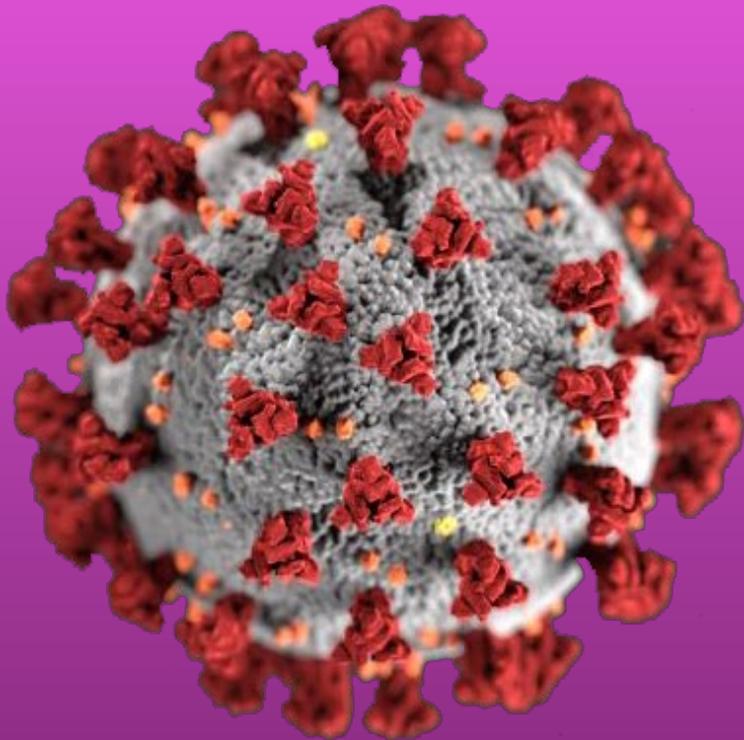
TOPICS TO BE DISCUSSED

1. COVID-19 Virus & Spike Protein
2. Severity of COVID-19 & Reinfections
3. Vaccines
 - Types
 - Efficacy
4. Diagnostic Tests
5. Public Health Measures
6. Economic Impact
7. Variants
8. Treatment
9. Side Effects
10. Vaccine Hesitance
11. Safety Monitoring

SARS-COV-2



SARS-COV-2 COVID-19



Unlike the “cold” coronaviruses, SARS-CoV-2 attaches to a special receptor (ACE-2) which is found throughout the body. A runny nose which is often caused by common coronaviruses, is a rare symptom with COVID-19.

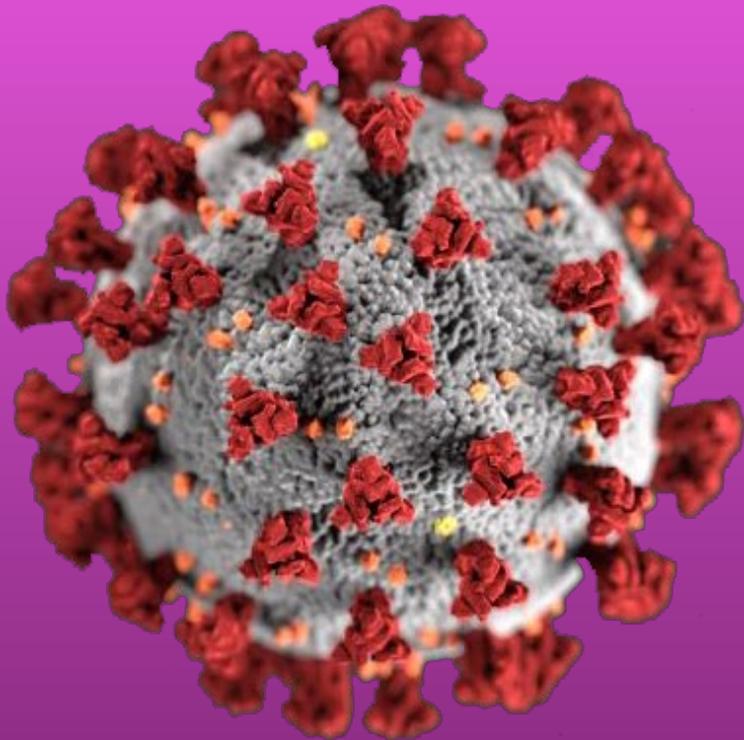
The virus attaches and enters the cells of many different types of organs in the body, not just the lungs.

- Blood Vessels, Heart, Central Nervous System
- Liver, Gastrointestinal Tract
- Kidney
- Testes

COVID-19 SEVERITY



SARS-COV-2



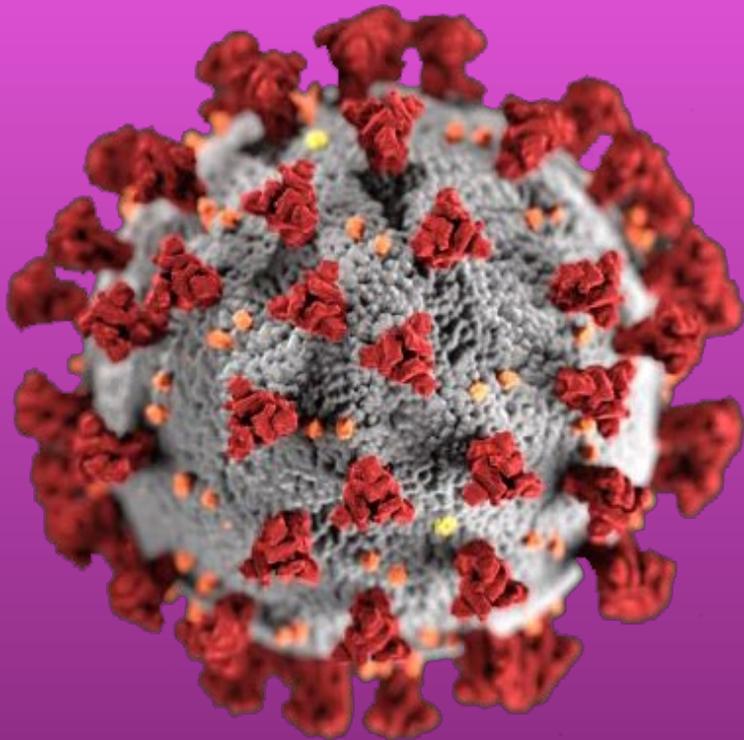
1. US Life Expectancy has fallen by one year.

National Center for Health Statistics: Life expectancy at birth:

- Total U.S. population declined from 78.8 years in 2019 to 77.8 years for January through June 2020.
- non-Hispanic Black decreased by 2.7 years (74.7 to 72);
- for Hispanic, 1.9 years (81.8 to 79.9);
- for non-Hispanic white, 0.8 years (78.8 to 78)."

<https://www.statnews.com/2021/02/18/u-s-life-expectancy-fell-by-a-year-in-the-first-half-of-2020-cdc-report-finds/193>

SARS-COV-2



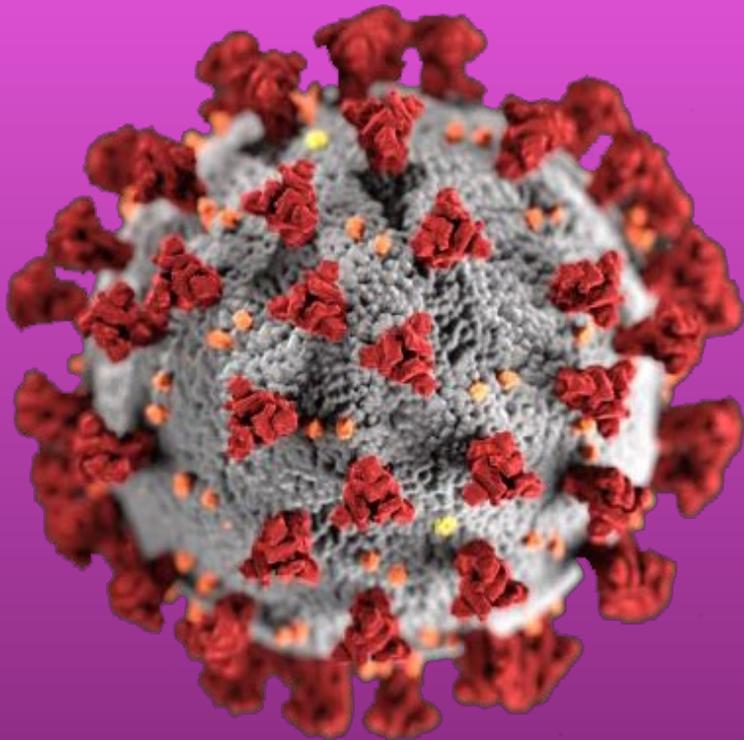
1. US Life Expectancy has fallen by one year.

Frontline workers have a greater decline.

The virus is aerosolized. N-95 masks and proper building ventilation (both air sanitization and increased air exchanges) are needed.

In the absence of the above, vaccinations are imperative.

SARS-COV-2



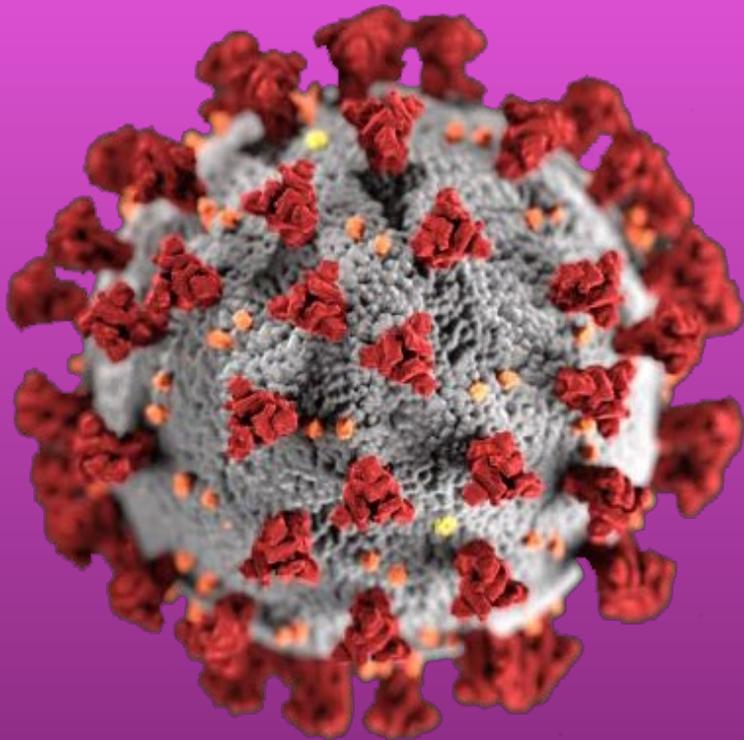
2. 600,000 deaths in 1 year as measured by excess mortality.

NEWSMAX: CDC: Excess US Deaths During Pandemic Nearing 600K

"The true death toll from the coronavirus pandemic in the United States is massively higher than the mere data from those who died COVID-19 positive, according to the Centers for Disease Control and Prevention. Data shows excess deaths in the past year to be approaching 600,000, which takes the number of people who die from any cause in a given region and period and then compares it with a baseline from recent years."

<https://www.newsmax.com/us/cdc-death-rate/excessdeaths/2021/02/14/id/1009969/>

SARS-COV-2



3. 30% Still Having Symptoms at 6 Months

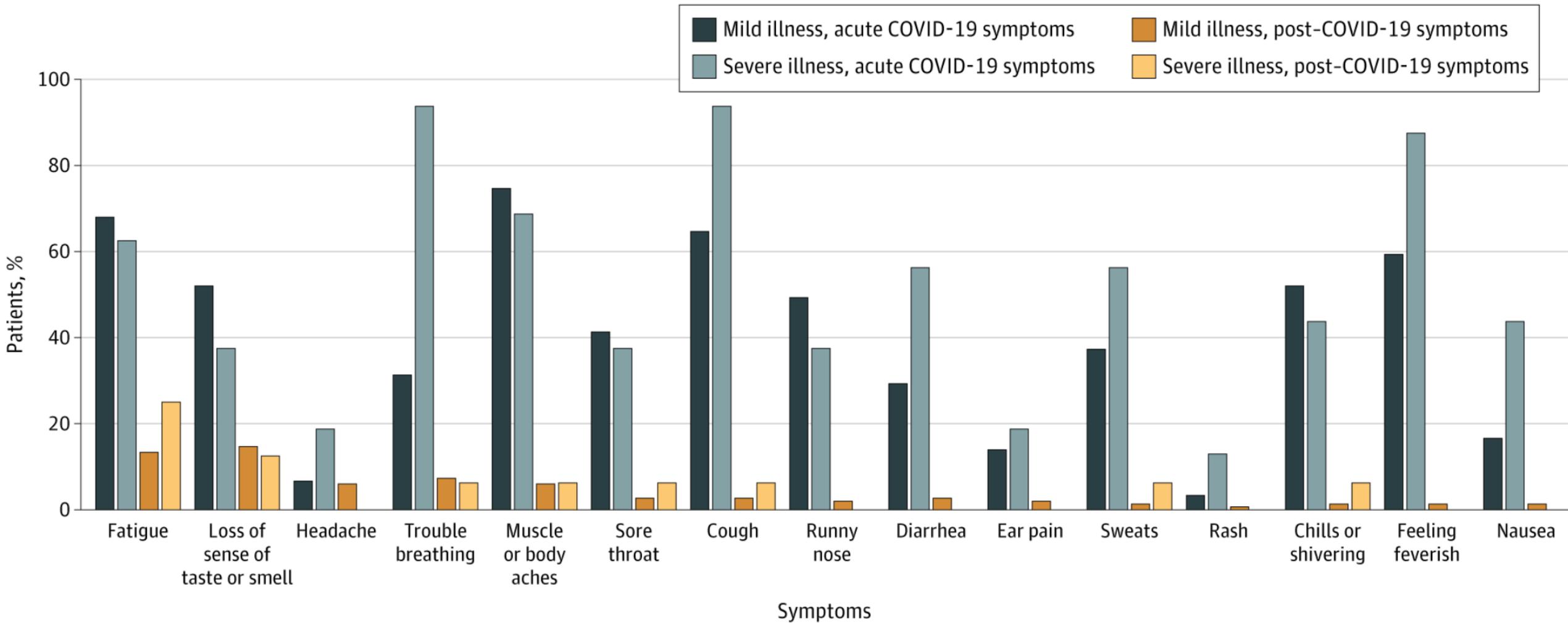
A total of 177 of 234 participants (75.6%; mean [range] age, 48.0 [18-94] years; 101 [57.1%] women) with COVID-19 completed the survey. Overall, 11 (6.2%) were asymptomatic, 150 (84.7%) were outpatients with mild illness, and 16 (9.0%) had moderate or severe disease requiring hospitalization.“

The most common persistent symptoms were

- fatigue (24 of 177 patients [13.6%]) and
- loss of sense of smell or taste (24 patients [13.6%])

https://www.cnn.com/world/live-news/coronavirus-pandemic-vaccine-updates-02-19-21/h_f2d7307839fbe68e7ee270be6e858cf4

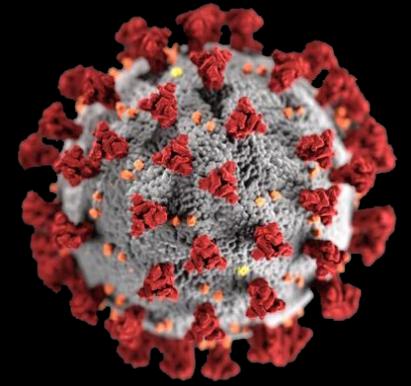
B Percentage of participants who reported COVID-19 symptoms during acute illness and at follow-up



Logue JK, Franko NM, McCulloch DJ, et al. Sequelae in Adults at 6 Months After COVID-19 Infection.

JAMA Network Open. Feb. 19, 2021. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776560>

Past COVID-19 infection provides some immunity but people may still carry and transmit virus



People infected with COVID-19 in the past are likely to be protected against reinfection for several months, a [Public Health England \(PHE\) study](#) has found, although experts cautioned those with immunity may still be able carry the virus in their nose and throat and therefore have a risk of transmitting to others.

PHE scientists working on the study have concluded naturally acquired immunity as a result of past infections provide 83% protection against reinfection, compared to people who have not had the disease before. This appears to last at least for 5 months from first becoming sick.

From Public Health England. Jan. 14, 2021: <https://www.gov.uk/government/news/past-covid-19-infection-provides-some-immunity-but-people-may-still-carry-and-transmit-virus>

Congressman tests positive for COVID-19 after receiving second dose of vaccine



"Congressman Lynch had received the second dose of the Pfizer vaccine and subsequently received a negative COVID-19 test prior to attending President Biden's Inauguration," said Molly Rose Tarpey, Lynch's communications director. "While Mr. Lynch remains asymptomatic and feels fine, he will self-quarantine and will vote by proxy in Congress during the coming week."

The Vaccine Does NOT Fully Protect Against Infection. Vaccines are Designed to Prevent Symptoms From Developing.

<https://www.cbsnews.com/news/stephen-lynch-covid-19-positive-vaccine/>

Does Pfizer's COVID Vaccine Protect Against Asymptomatic Infection?

— Israeli health records examine effectiveness by proxy

MEDPAGE TODAY®

Using a proxy for asymptomatic infection, they estimated 29% vaccine efficacy (95% CI 17-39%) at days 14-20 following the first dose and 90% (95% CI 83-94%) at 7 or more days after the second dose, as noted in the *New England Journal of Medicine*.

<https://www.medpagetoday.com/infectiousdisease/covid19/91350>

<https://www.nejm.org/doi/full/10.1056/NEJMoa2101765>

REINFECTIONS - BRAZIL

Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence

Manaus, Brazil, a study of blood donors indicated that 76% (95% CI 67–98) of the population had been infected with SARS-CoV-2 by October, 2020.

The estimated SARS-CoV-2 attack rate in Manaus would be above the theoretical herd immunity threshold (67%), given a basic case reproduction number (R_0) of 3.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00183-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00183-5/fulltext)

BRAZIL

Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence

Sabino EC, Buss LF, Carvalho MPS, et al. Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence. *The Lancet*. Feb. 6, 2021. 397(10273):452-455 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00183-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00183-5/fulltext)

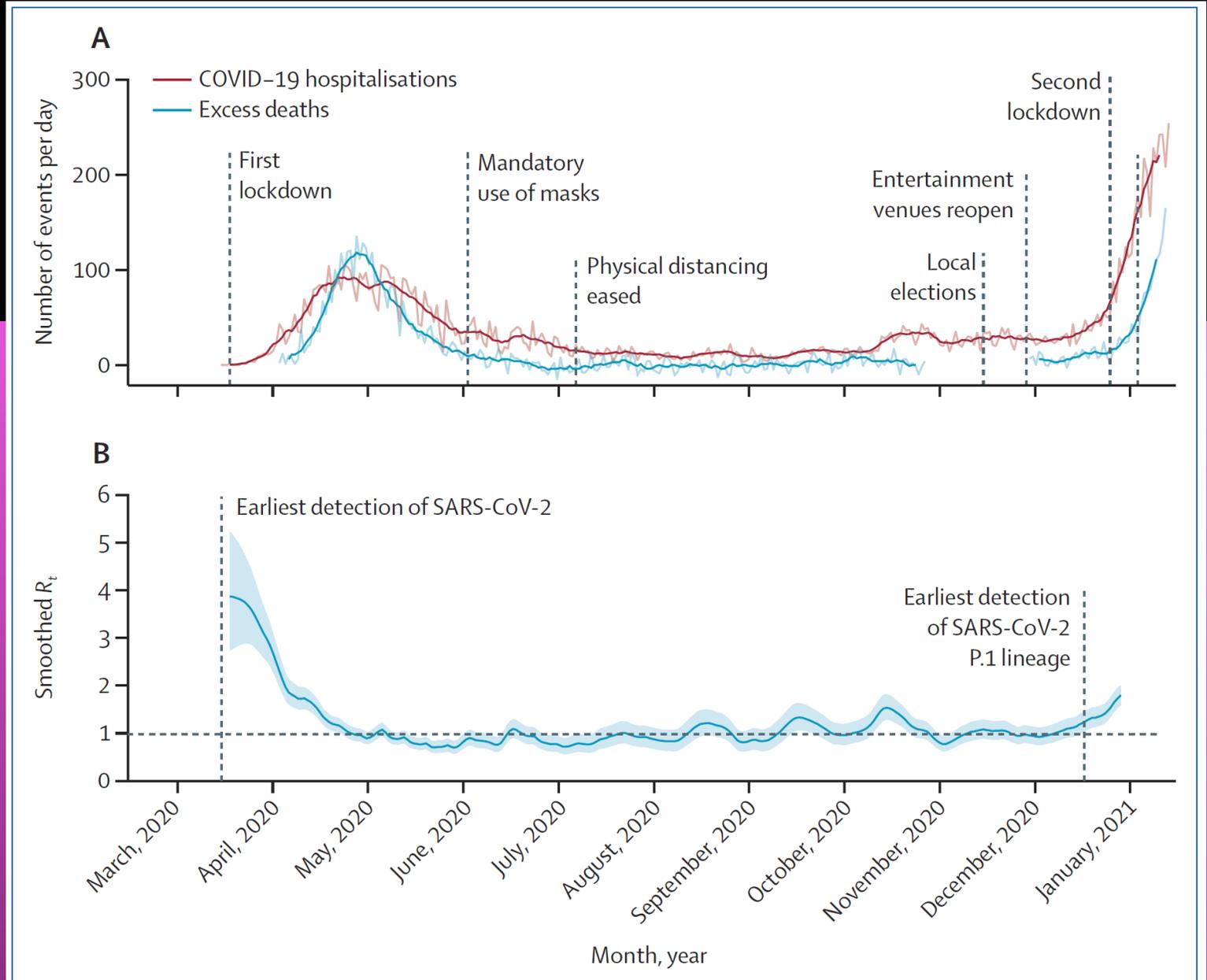
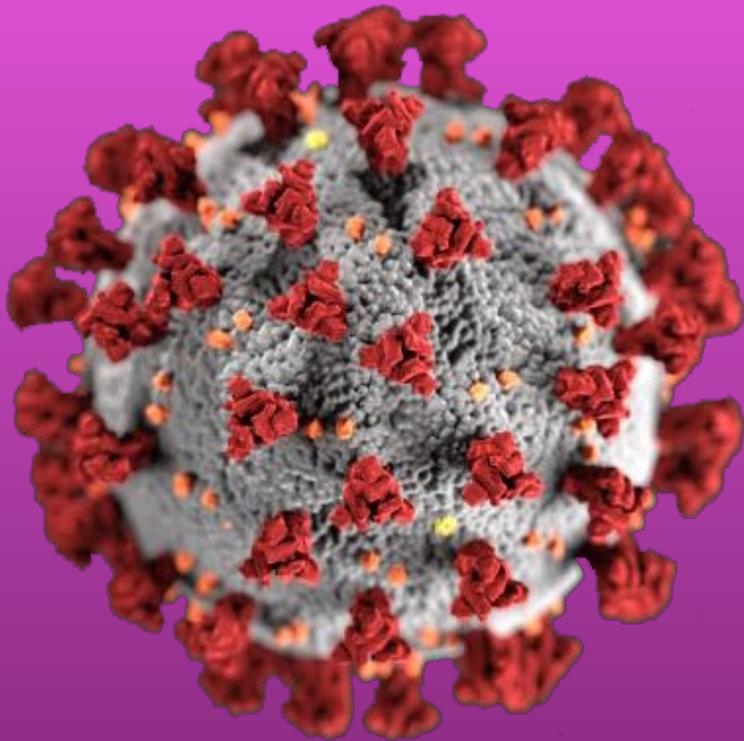


Figure: COVID-19 hospitalisations, excess deaths, and R_t in Manaus, Brazil, 2020–21

SARS-COV-2



SARS-COV-2



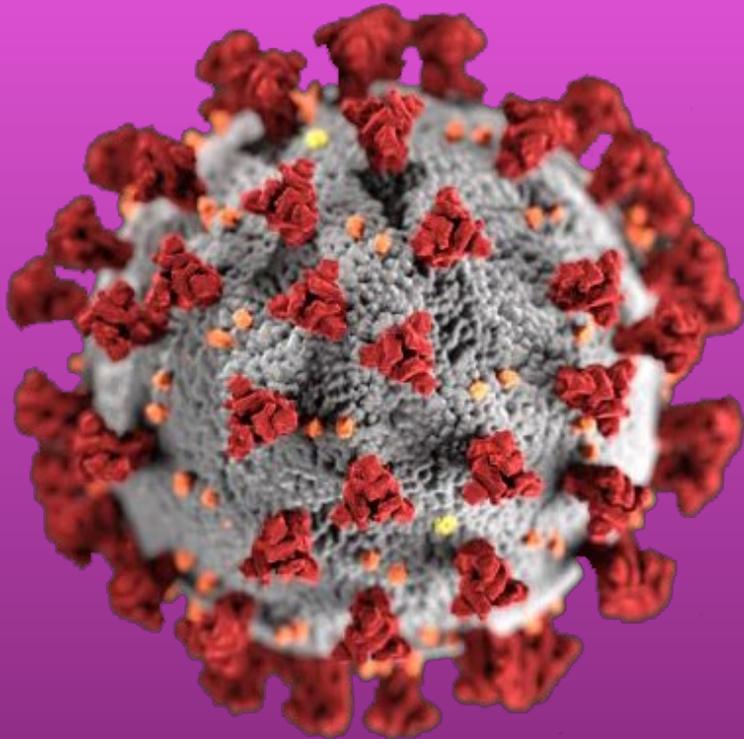
The Corona Virus is composed of a strand of RNA surrounded by a lipoprotein capsule. The capsule is surrounded by spike proteins which are key to cellular entry.

RNA viruses have a high mutation rate. The mutations involving the spike protein are of importance.

There are two types of antibodies:

- Binding, which binds to the not critical parts of the virus.
- Neutralizing, binds to the spike proteins and inhibits cell entry.

SARS-COV-2



The Spike Protein Is Key To

- The body's immunity
- Vaccines
- PCR and Antigen Tests

VACCINES



VACCINES- MODERNA & PFIZER

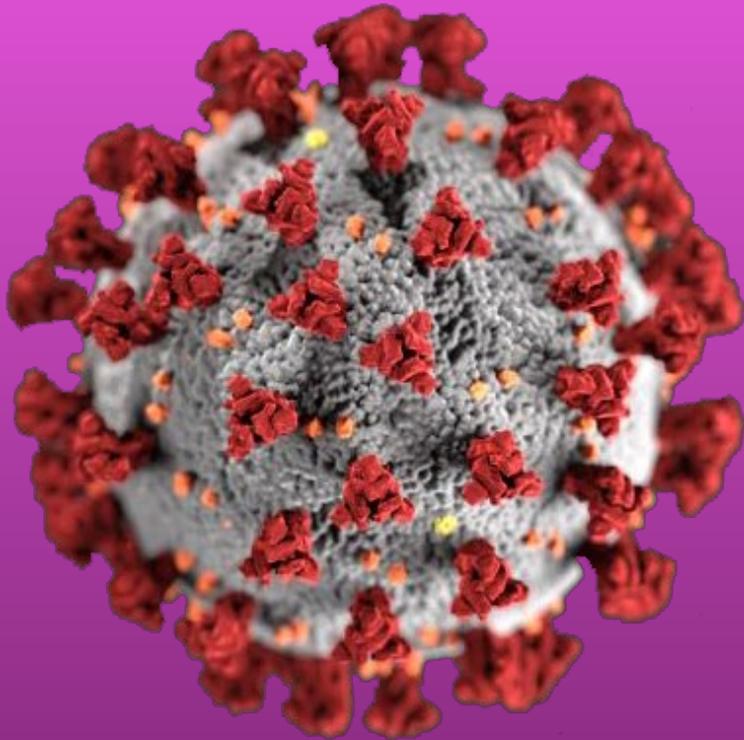
Most Are Designed Around the Spike Protein.

– mRNA Vaccines (Moderna, Pfizer-BioNTech)

These vaccines deliver mRNA to the cellular machinery which makes the spike protein. The cells then makes the spike protein which elicits the immune response.

– These vaccines do not affect the DNA, they bypass the DNA and directly instruct the machinery of the cell.

VACCINES- MODERNA & PFIZER



Moderna & Pfizer-BioNTech.

– The Vaccine delivers mRNA using a synthetic capsule composed of polyethylene glycol (PEG).

(Johnson & Johnson's Vaccine delivers DNA using the capsule from a modified adenovirus virus.)

QUESTION

Was the Moderna or Pfizer/BioNTech Vaccine Rushed to Market?

No, they were not rushed to market.

- Coronavirus was well known with SARS & MERS outbreaks.
- Working on Vaccines for over a decade.
- Thus, there was already a coronavirus vaccine. Just had to plug in the new genetic code for the new spike protein.

QUESTION

Can mRNA alter DNA?

No, the vaccines cannot change your DNA.

- mRNA is very fragile. It does not last long. Why they are stored in ultra-cold.
- They are designed to do their work in the cell body and not the nucleus where DNA resides. mRNA has not been found to enter the nucleus.

<https://www.nebraskamed.com/COVID/you-asked-we-answered-can-mrna-vaccines-alter-human-dna>

VACCINES - NOVAVAX

Most Are Designed Around the Spike Protein.

- Spike Protein stuck on microparticles.
- The vaccine delivers the antigen which directly elicits the immune response.

Currently in Phase III Trials.

<https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3>

VACCINES - ASTRAZENECA

Oxford AstraZeneca.

- Delivers DNA using a modified capsule of a chimpanzee's adenovirus virus.
- The virus delivers the DNA into the cells, which makes mRNA which then makes the spike protein.
- DNA is more stable and does not require freezing.

<https://www.nytimes.com/interactive/2020/health/oxford-astrazeneca-covid-19-vaccine.html>

VACCINES – EFFICACY VARIANTS

D614G (our current) Variant.

– Moderna and Pfizer/BioNTech are over 90% effective in preventing COVID-19.

United Kingdom (B117) Variant

– Up to 70% more lethal and 70% more infectious.

– Moderna and Pfizer/BioNTech have been shown to be highly effective in preventing disease.

VACCINES – EFFICACY VARIANTS

Brazilian (P1) & South African (B1351) Variants

- Initial Data: More Lethal, More Infectious.
- Moderna and Pfizer/BioNTech have a 3 to 6 fold decrease in efficacy. But they have such a high efficacy with original variant, that they are still felt to be protective for severe disease, hospitalizations and deaths.

Pfizer/BioNTech and Moderna announced they are taking necessary steps to develop a booster shot or updated vaccine.

<https://www.washingtonpost.com/nation/2021/02/18/coronavirus-covid-live-updates-us/>

VACCINES – EFFICACY VARIANTS

Brazilian (P1) & South African (B1351) Variants

- Initial Data: More Lethal, More Infectious.
- AstraZeneca Vaccine has been discontinued in South Africa since it was shown to have no effect in preventing mild and moderate COVID-19. Severe disease was not studied.

Pfizer/BioNTech and Moderna announced they are taking necessary steps to develop a booster shot or updated vaccine.

<https://www.washingtonpost.com/nation/2021/02/18/coronavirus-covid-live-updates-us/>

QUESTION

Is Natural Immunity Better?

No. A vaccine produces a stronger immune response.

- 1. The natural immunity to coronavirus is not long lasting, maybe 1 to 2 years.**
- 2. Its duration is felt to be linked to the severity of disease.**
- 3. Asymptomatic & mildly symptomatic individuals have short lived immunity.**
- 4. South African & Brazilian Variants Cause Reinfections.**

NUMBER OF VACCINATIONS

Overall US COVID-19 Vaccine Delivery and Administration; Maps, charts, and data provided by the CDC, updated daily by 8 pm ET[†]

Total Doses
Delivered

74,979,165

Total Doses
Administered

61,289,500

Number of
People
Receiving 1 or
More Doses

42,809,595

Number of
People
Receiving 2
Doses

17,895,667

CDC | Data as of: Feb 20 2021 6:00am ET | Posted: Feb 20 2021 4:19PM ET

VACCINE SIDE EFFECTS



VACCINATION SIDE EFFECTS

“Of these, more than 70% reported pain, 33% fatigue, 30% headaches, 23% muscle pain and about 11% chills, fever, swelling or joint pain.”

“There was little difference in reported side effects between the two vaccines (Moderna and Pfizer/BioNTech).”

“People generally had a harder time with the second dose than the first.”

<https://www.usatoday.com/story/news/health/2021/01/28/covid-19-vaccines-cdc-safety-data-pfizer-moderna-coronavirus/4281434001/>

VACCINATION SIDE EFFECTS

What is NOT a vaccine side effect?

- Loss of Taste and Smell
- Shortness of Breath
- Sore Throat.
- Diarrhea

VACCINATION SIDE EFFECTS

If you feel you have COVID-19 after a vaccination, GET TESTED

- PCR Tests (Molecular) NOT Affected by Vaccination
- Antigen Tests NOT Affected by Vaccination
- Antibody Tests (Serology) IS Affected by Vaccination

VACCINE SEVERE REACTIONS

Most Major Reactions and Side Effects Occur Within 2 Months After Administration. We now have 6 months of data.

Allergic Reactions to Vaccine:

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—
December 14, 2020-January 18, 2021 "Pfizer-BioNTech vaccine, for a reporting rate of 4.7 cases/million doses administered, and 19 following Moderna vaccine, for a reporting rate of 2.5 cases/million doses administered."

No one has died and most allergic reactions occur within 15 mins after administration.

<https://jamanetwork.com/journals/jama/fullarticle/2776557>

VACCINE DEATHS

VAERS received reports of 196 deaths after COVID-19 vaccination.

"Findings suggest that short-term mortality rates appear unrelated to vaccination for COVID-19 in skilled nursing facility residents," according to a summary of the study's results.

The CDC found no causal link between vaccination and deaths among younger, healthier people. (Remember first groups of patients are high risk individuals)

Among 13.7 million people under 65, 168 people would be expected to suffer a sudden, lethal heart attack over a typical 35-day period. By comparison, 18 such deaths were reported to VAERS among people who had been vaccinated.

Jan 26, 2021 <https://www.usatoday.com/story/news/health/2021/01/28/covid-19-vaccines-cdc-safety-data-pfizer-moderna-coronavirus/4281434001/>

VACCINE HESITANCY



VACCINE HESITANCY - USA

Jan. 2021: Now 56% of those surveyed say they will get the vaccine as soon it was available to them, a jump of 10 percentage points since the USA TODAY poll in December and up 30 points since October.

<https://www.usatoday.com/story/news/health/2021/01/18/poll-covid-vaccine-acceptance-rises-pessimism-future-suffolk-poll/4196840001/>

VACCINE HESITANCY - USA



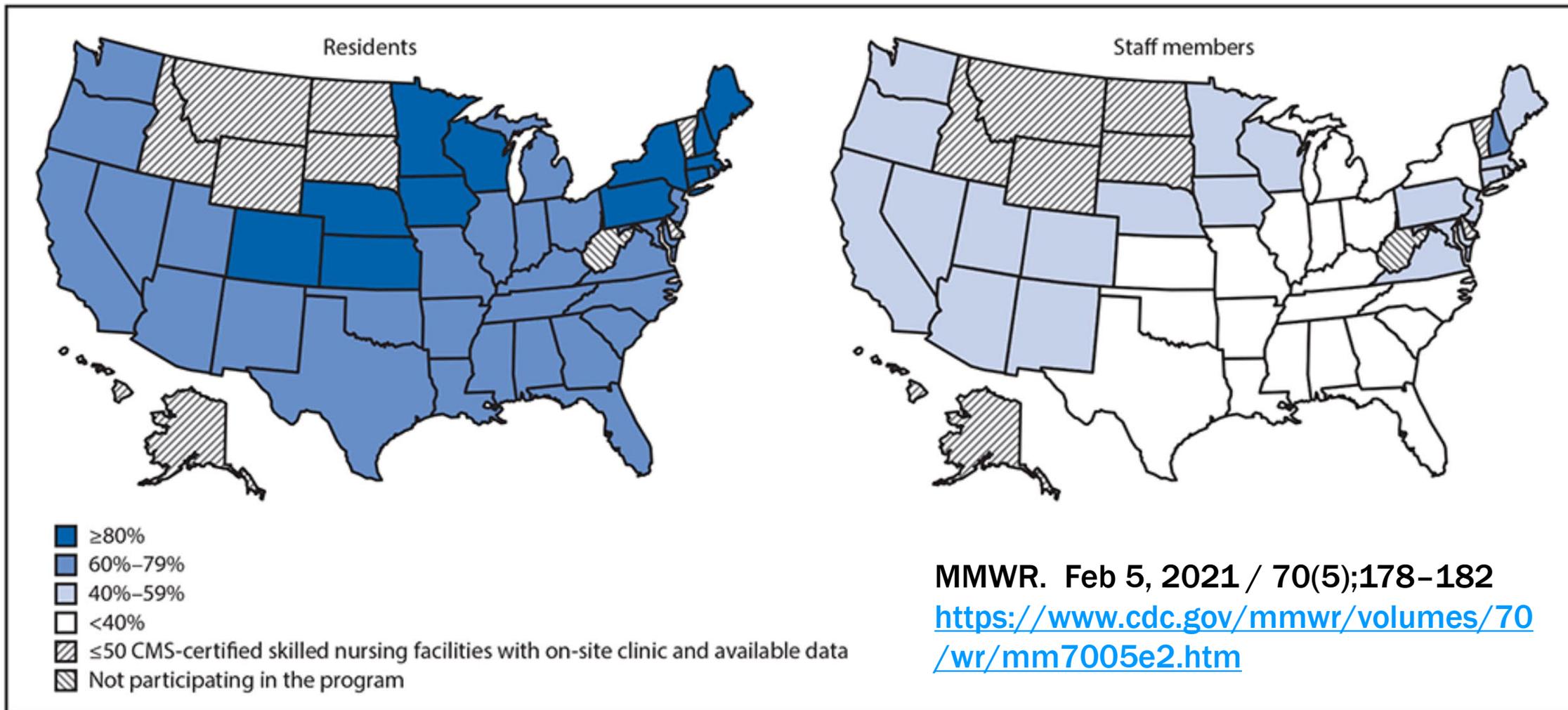
Among the other countries, intent to take a COVID-19 vaccine is:

- Very high in Brazil (88%), China (85%), Mexico (85%), Italy (80%), Spain (80%), Canada (79%), and South Korea (78%);
- Fairly high in Australia (73%), the **United States (71%)**, and Germany (68%);
- Middling in Japan (64%), South Africa (61%), and France (57%); and,
- Low in Russia (42%).

The global survey of adults under the age of 75, conducted on January 28-31, 2021

<https://www.ipsos.com/en-us/global-attitudes-covid-19-vaccine-january-2021>

FIGURE 2. Estimated median percentage of residents* and staff members† at skilled nursing facilities§ enrolled in the Pharmacy Partnership for Long-Term Care Program who received ≥1 dose of COVID-19 vaccine, by jurisdiction¶ — United States, December 18, 2020–January 17, 2021



MMWR. Feb 5, 2021 / 70(5);178–182
<https://www.cdc.gov/mmwr/volumes/70/wr/mm7005e2.htm>

HESITANCY – FRONTLINE WORKERS

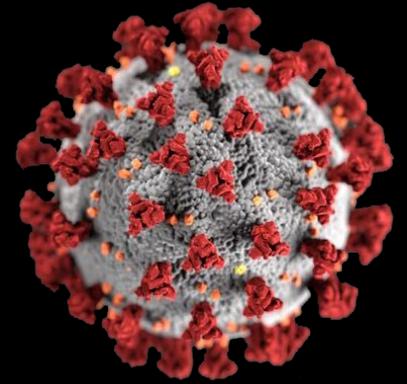
“In western Kentucky, some school districts are finding 50% to nearly 70% of school staff are declining the vaccine, for example, and some Ohio nursing facilities struggle to get more than half of the staff to get a shot.”

“Kentucky Gov. Andy Beshear said during a January press conference that he believed the percentage of school district employees wanting a vaccine across Kentucky is about 70%, and urban school districts such as Jefferson County Public Schools have also seen higher willingness for vaccinations. ”

With COVID Vaccinations Underway, Some Frontline Workers Are Hesitant To Receive It. NPR

<https://www.wkyufm.org/post/covid-vaccinations-underway-some-frontline-workers-are-hesitant-receive-it#stream/0>

DISINFORMATION

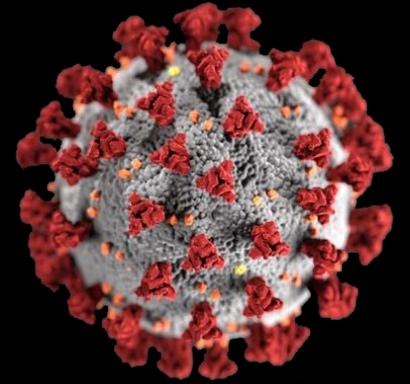


Researchers: Nearly Half Of Accounts Tweeting About Coronavirus Are Likely Bots

"We do know that it looks like it's a propaganda machine, and it definitely matches the Russian and Chinese playbooks, but it would take a tremendous amount of resources to substantiate that," said Kathleen Carley, a professor of computer science at Carnegie Mellon University who is conducting a study into bot-generated coronavirus activity

Allyn B. Researchers: Nearly Half of Accounts Tweeting About Coronavirus are Likely Bots. NPR. May 20, 2020.
<https://www.npr.org/sections/coronavirus-live-updates/2020/05/20/859814085/researchers-nearly-half-of-accounts-tweeting-about-coronavirus-are-likely-bots>

DISINFORMATION



Russia deploying coronavirus disinformation to sow panic in West, EU document says

The EU document said the Russian campaign, pushing fake news online in English, Spanish, Italian, German and French, uses contradictory, confusing and malicious reports to make it harder for the EU to communicate its response to the pandemic.

Emmott R. Researchers: Russia deploying coronavirus disinformation to sow panic in West, EU document says. Reuters. March 18, 2020. <https://www.reuters.com/article/us-health-coronavirus-disinformation/russia-deploying-coronavirus-disinformation-to-sow-panic-in-west-eu-document-says-idUSKBN21518F>

VACCINE MONITORING



v-safe

- Smartphone-based tool using text and web surveys
- Health check-ins
 - Daily for first week
 - Weekly for next 5 weeks
 - 3, 6, and 12 months
- Does not provide medical advice based on reported symptoms
- Depending on answers, CDC may call respondent



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>



Vaccine Adverse Event Reporting System (VAERS)

- Co-managed by CDC and FDA.
- Reports can be filed by patients, caregivers, healthcare personnel
- Early warning system for events that might be higher than expected in population
- Does not imply causality

<https://vaers.hhs.gov/>

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS

Report an Adverse Event

VAERS Data

Resources

Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte un evento adverso utilizando el formulario de VAERS en línea *en Español. Nuevo!*



COVID-19 vaccine EUA reporting requirements for Providers



Healthcare providers are required to report to VAERS the following adverse events after COVID-19 vaccination:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically-significant AEs following vaccination, even if they are not sure if vaccination caused the event.

Serious AEs per FDA are defined as:

- Death;
- A life-threatening AE;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Syndromic Surveillance Data COVID-19 Adverse Reactions

- National Syndromic Surveillance Program (NSSSP)
- Commonly referred to as “ESSENCE”
- Uses hospital visit data
- Consists of Emergency Department (ED), Inpatient (INP), Outpatient (OP) visits types
- 83 out of 88 acute care hospitals in Kentucky submit syndromic surveillance data (94%)



IMPORTANT WEB LINKS

V-Safe: <http://cdc.gov/vsafe>

VAERS: <https://vaers.hhs.gov/>

THANK YOU

