# Delaware Judiciary Town Hall

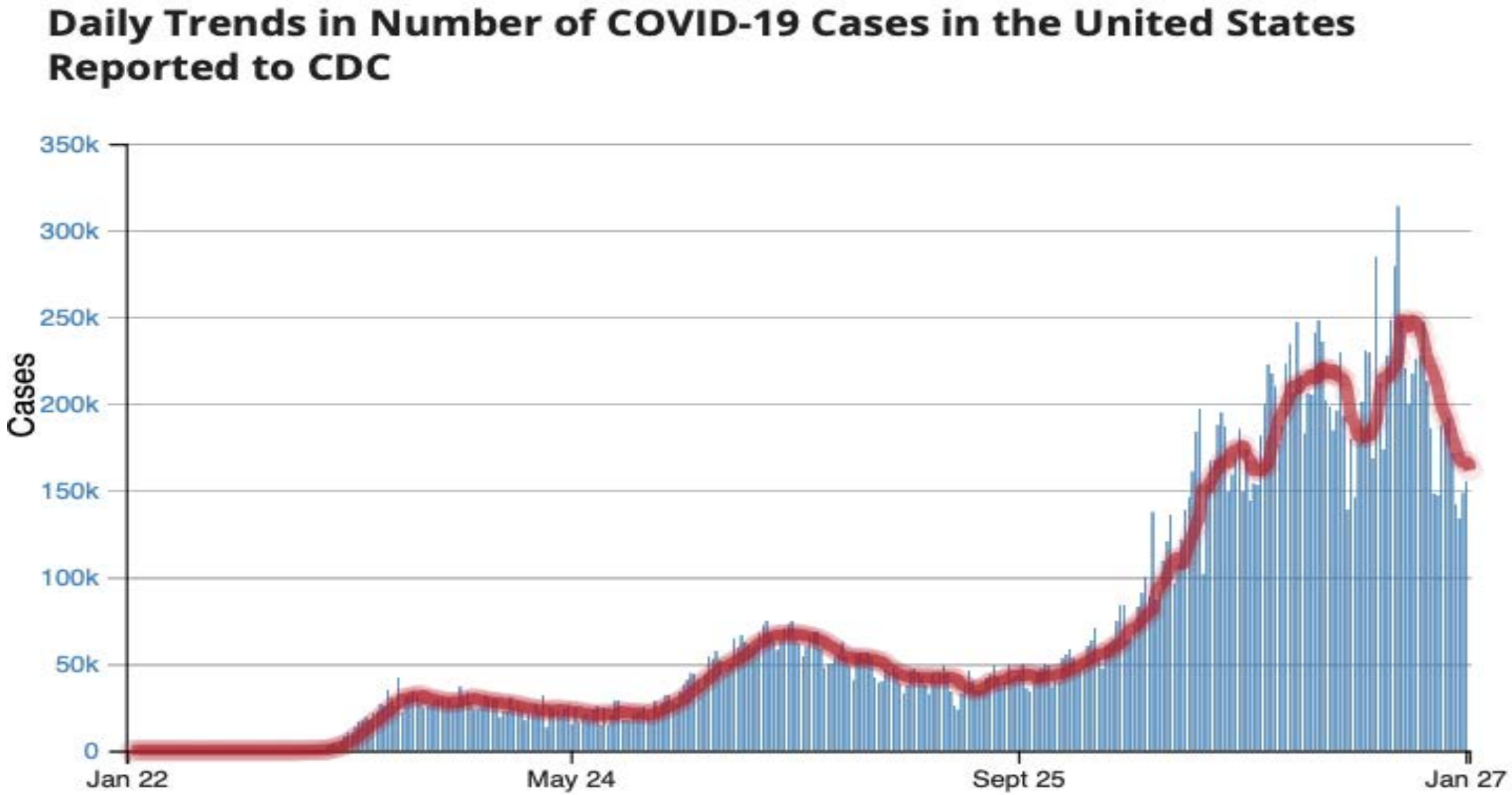
Delaware
Courts

Alfred E. Bacon, III MD FACP

February 4, 2021

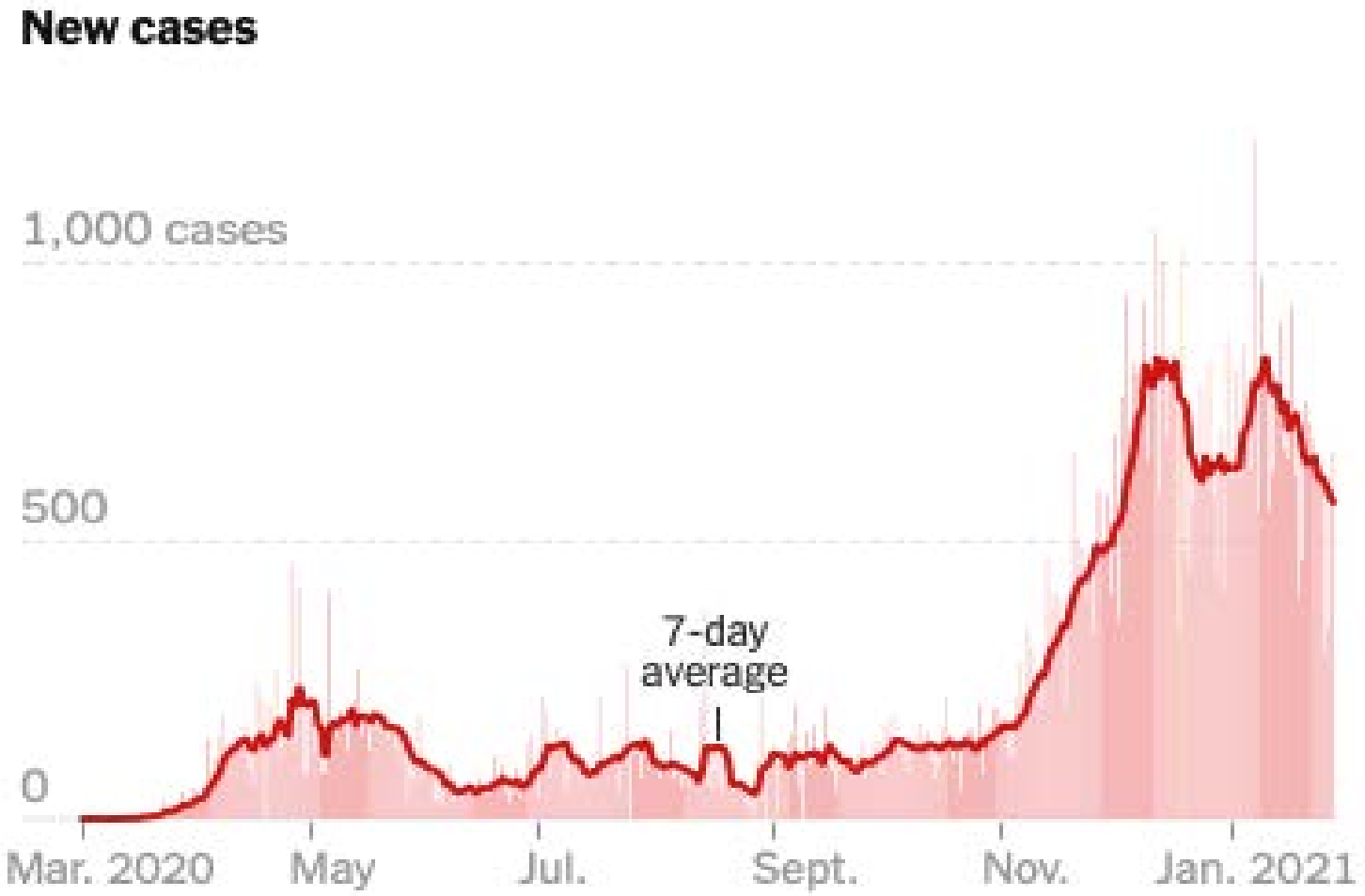
# COVID 19- Topics

- Epidemiology
- Treatment
- Vaccine development
- Variant strains
- Questions / answers



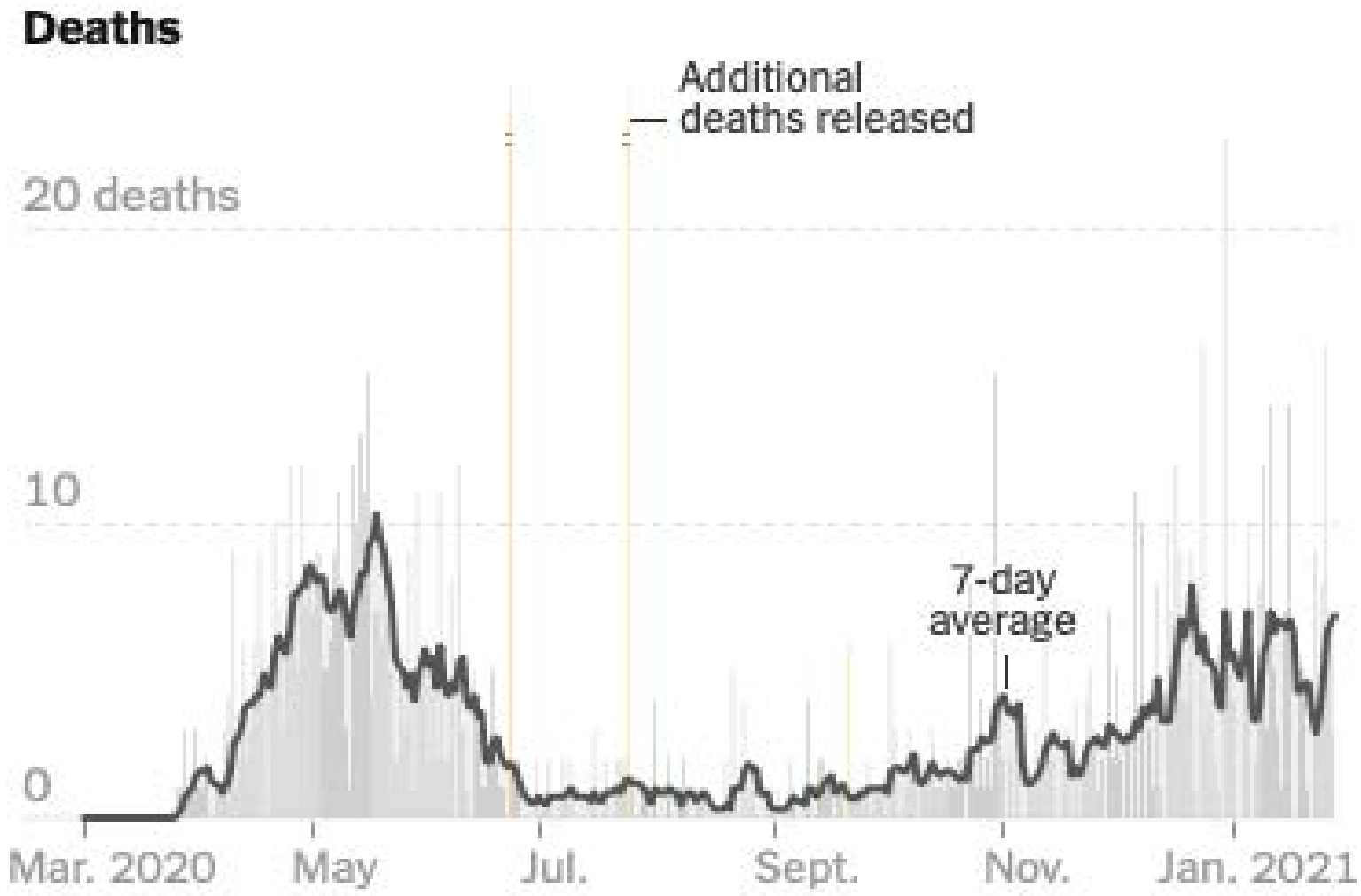

Source: CDC.gov 1/29/21

# Delaware New COVID Cases



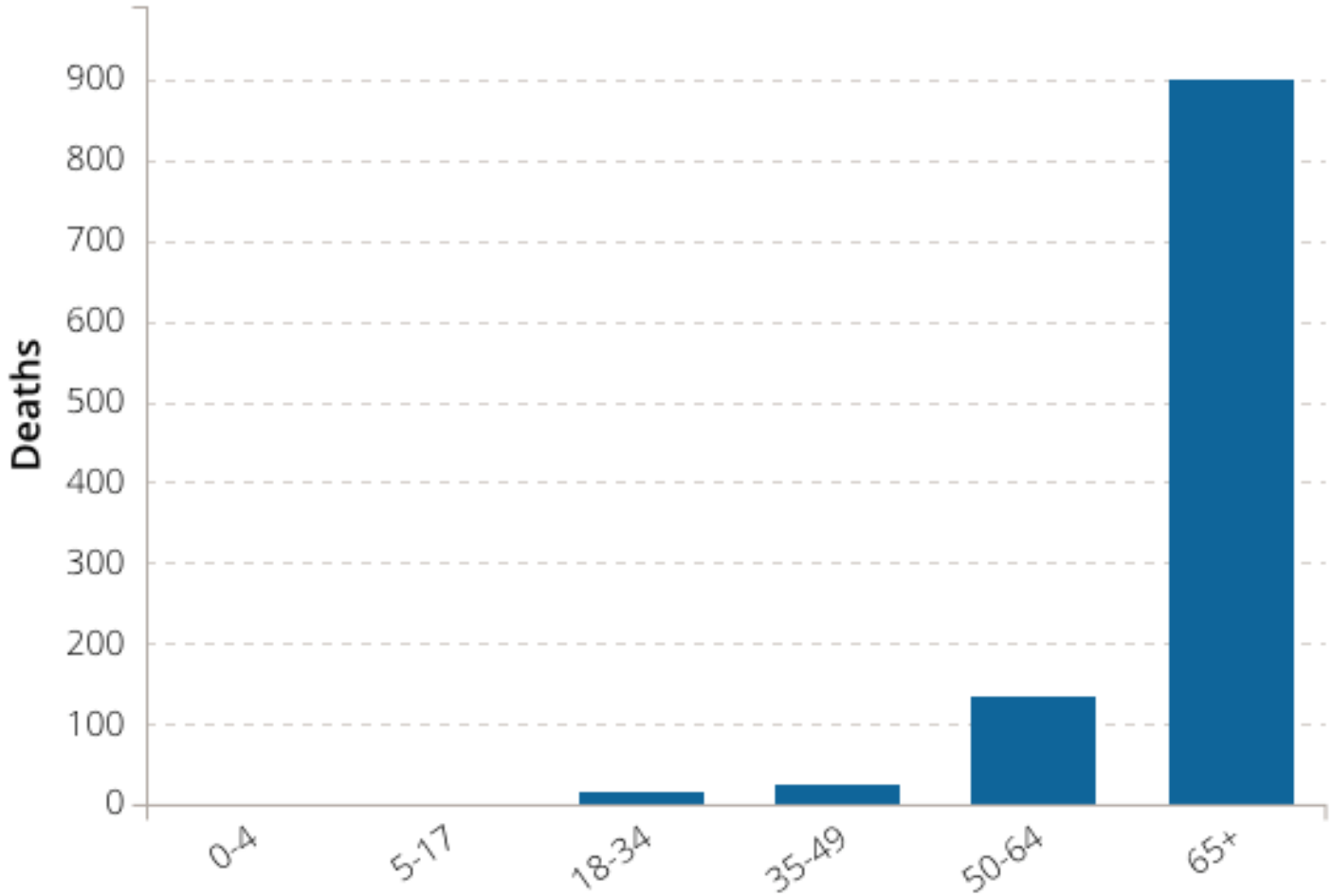

- Source NYT 1/29/21

# Delaware COVID Deaths



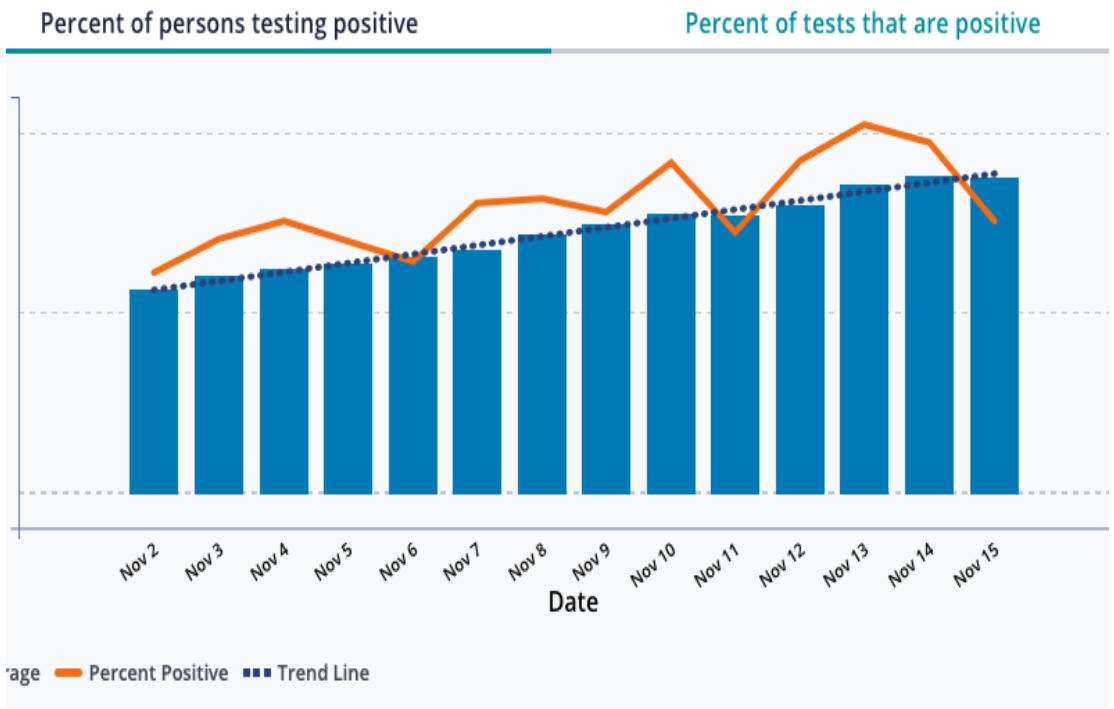

- Source NYT 1/29/21

## Total Deaths by Age

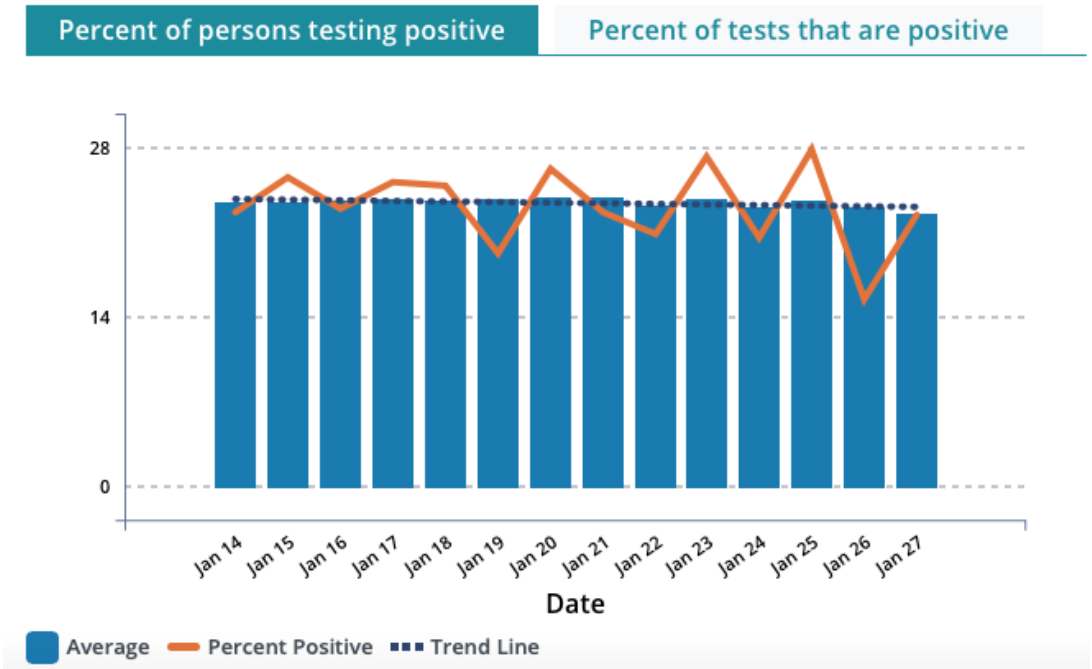



Source DPH 1/29/21

DELAWARE Percent of persons testing positive November 2020 vs. January 2021




November 2020

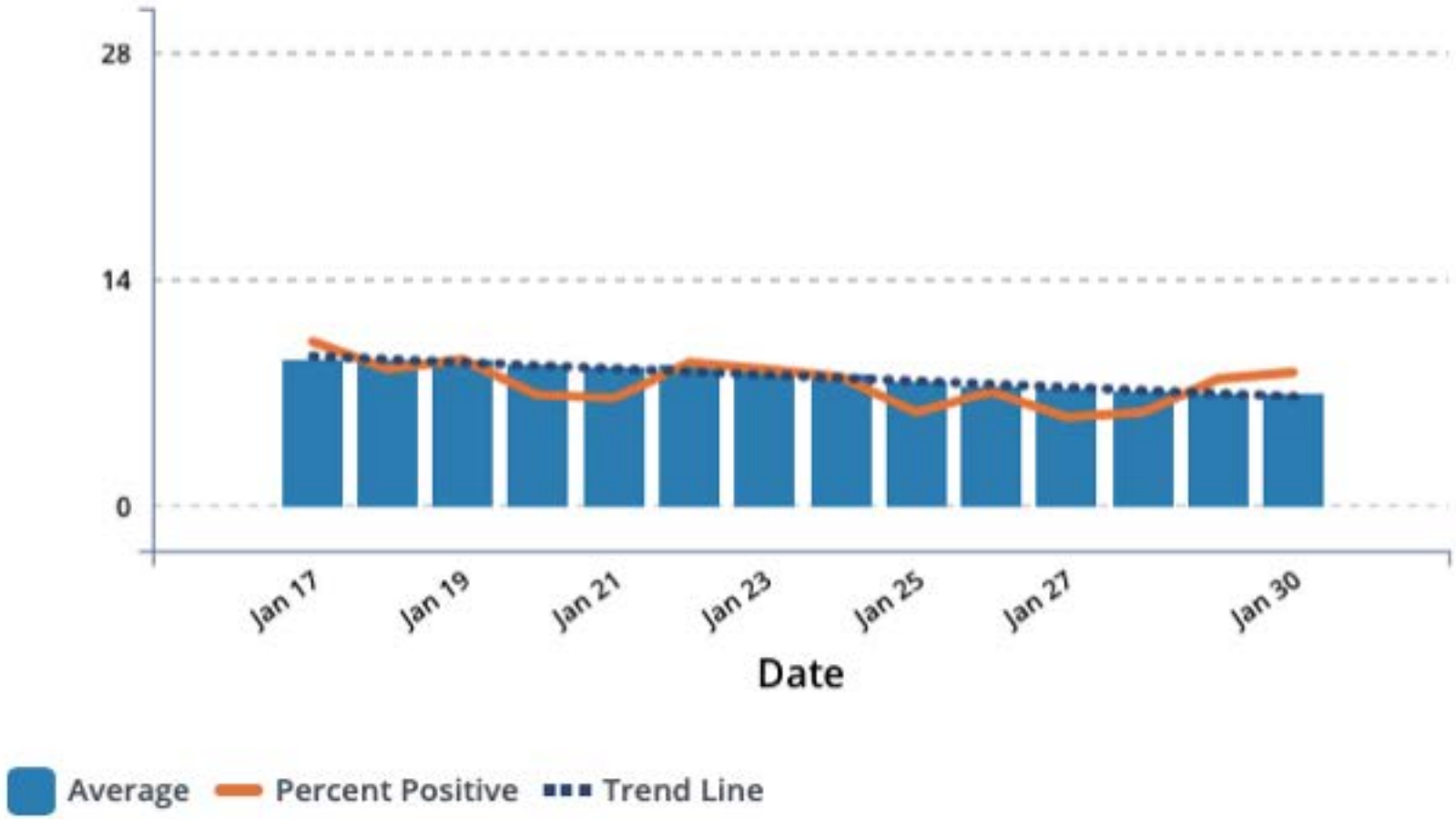



January 2021

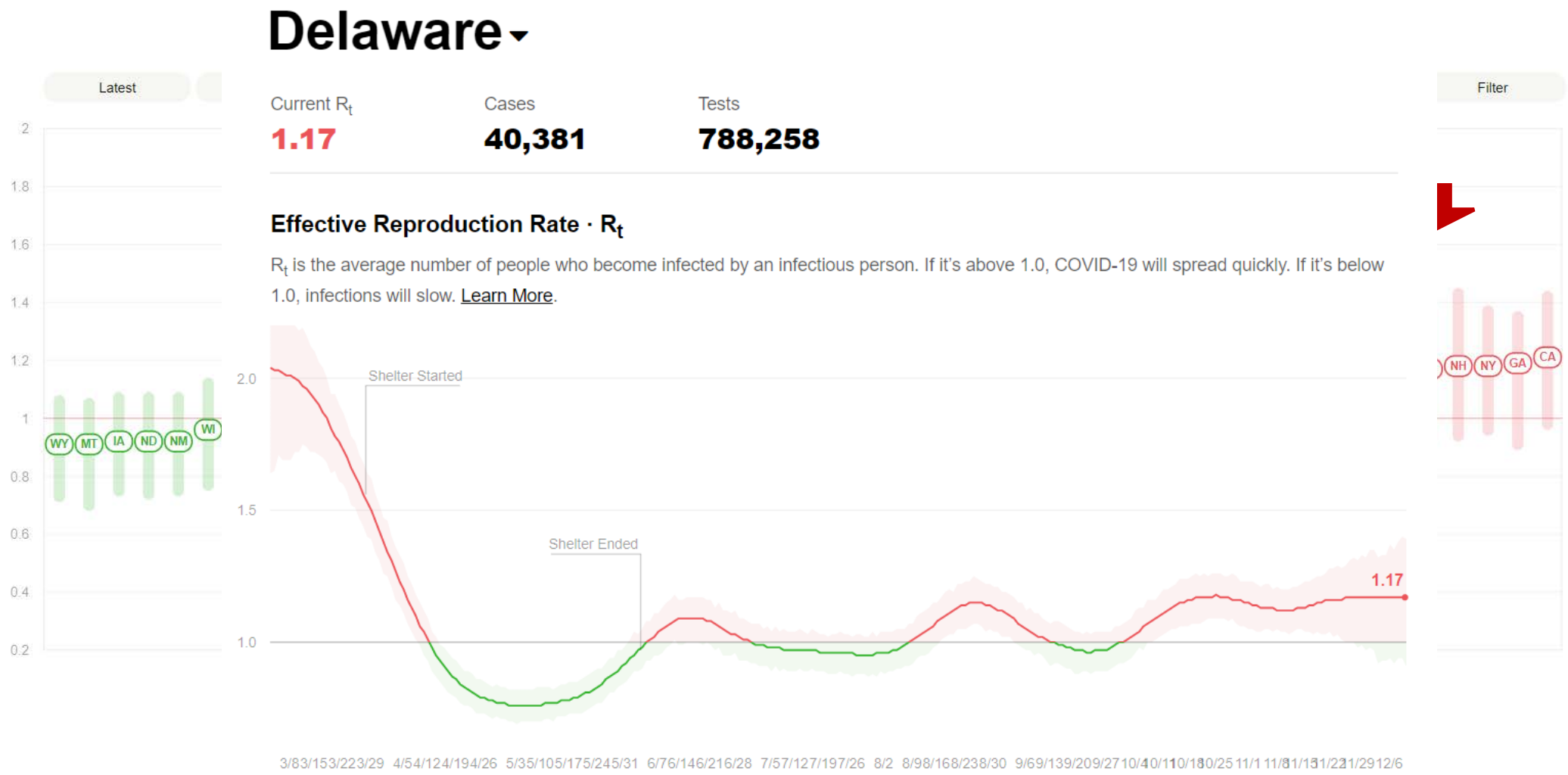
Source DPH 1/29/21

Percent of persons testing positive

Percent of tests that are positive

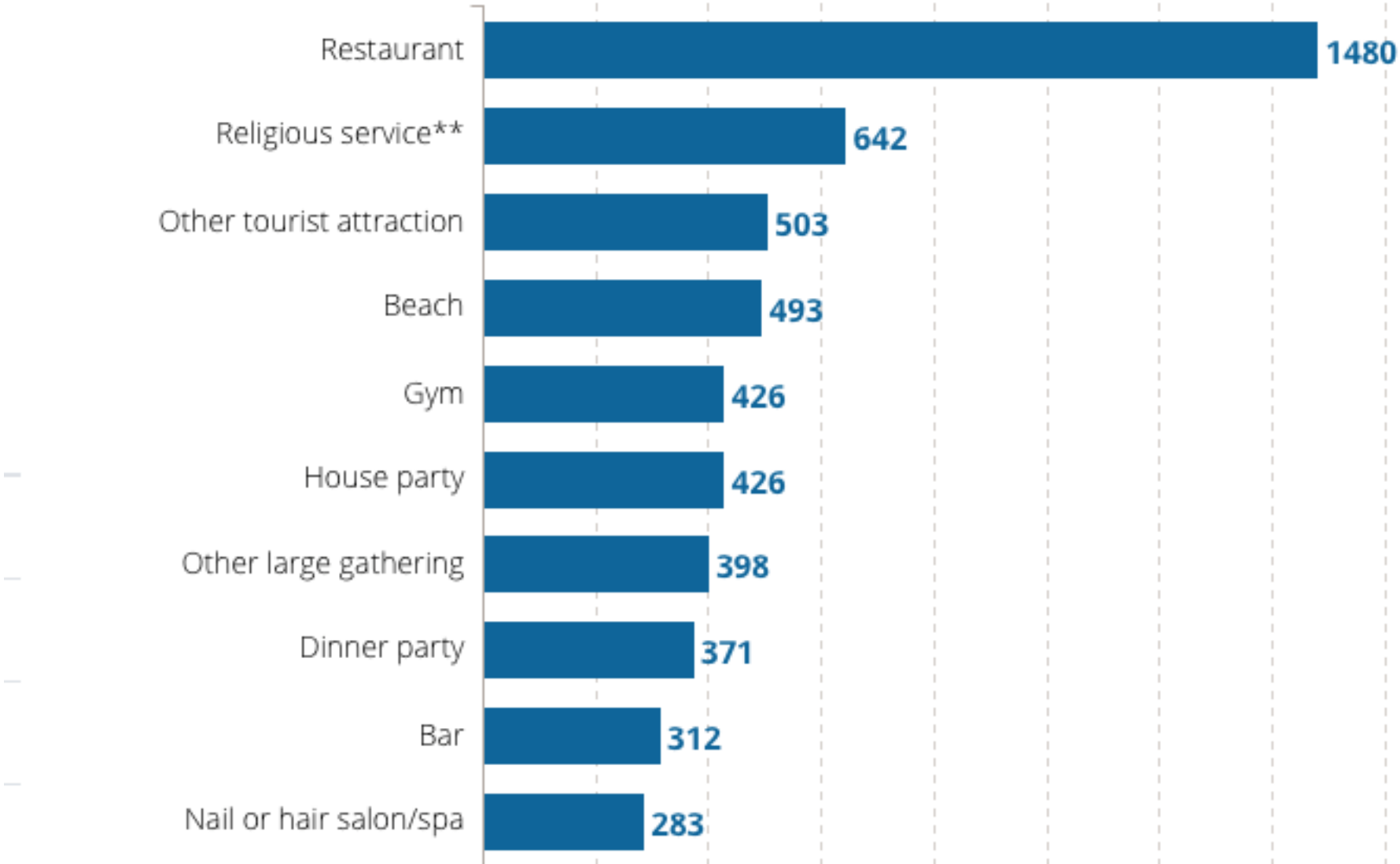


# $R_0$ by State




https://rt.live/

# Cases Who Visited Venues (Reported All Weeks)




Source DPH 1/29/21

# Diagnostic Testing

## Expanded Respiratory Panel PCR

- Went live 9/23
- Includes:
  - COVID-19
  - Flu A/B (also H1 v. H3)
  - RSV A/B
  - Other human CoVs
  - Parainfluenza 1-4
  - hMPV
  - Bordetella spp.
  - Rhinovirus/enterovirus
  - *Mycoplasma pneumoniae*
  - *Chlamydia pneumoniae*
- Default option for admitted patients in CH/MED
- Should not be repeated within 7d

## New! Flu/RSV/COVID-19 PCR

- Going live 12/10!
- Includes:
  - COVID-19
  - Flu A/B
  - RSV
- Preferred test at WH (performed in-house → shorter TAT)
- Admitted and ED discharged patients
  - Ambulatory coming soon!
- Isolated flu/RSV testing no longer available

**COVID-only surveillance testing still available**

# COVID 19- Outpatient

- Monoclonal antibody –Regeneron, Lilly
- 1 time infusion
- 0-10 days symptoms, > 65, high risk population
- DBM,HTN, BMI, Immunosuppressed
- 1.6 % vs 6.3 % hospitalization
- Well tolerated

  - NEJM Jan 2021

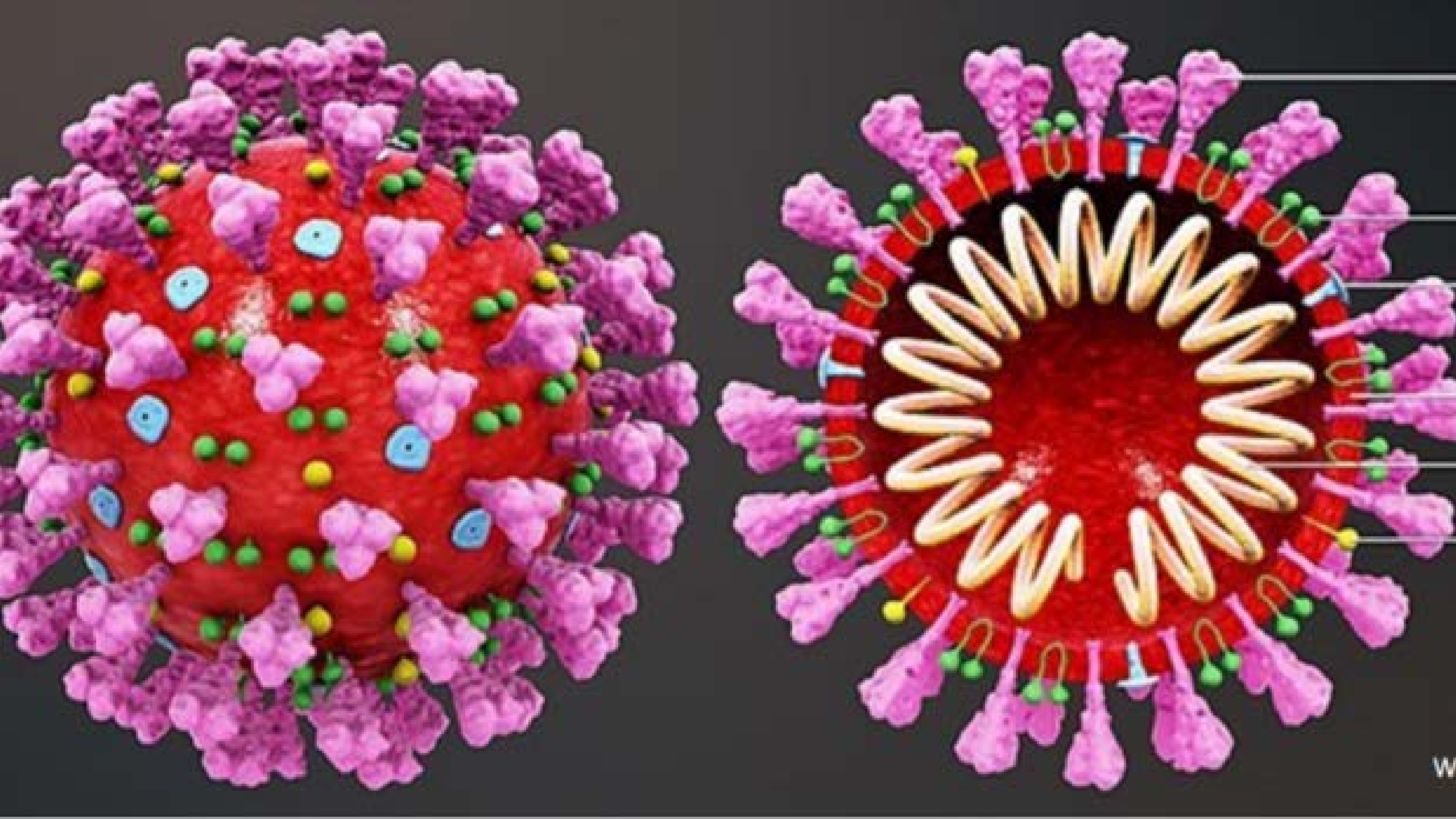
# Monoclonal Antibody

- 452 patients – 70 % at least 1 risk factor
  - 309 Mab,143 placebo
- Adverse event 22% Mab vs 24 % placebo
- Viral load decreased 99.7%
- Hospitalization – 4 fold decrease
  - Mab-  1.6 % (high risk 4.2%)
  - Placebo 6.3% (high risk 14.6%)

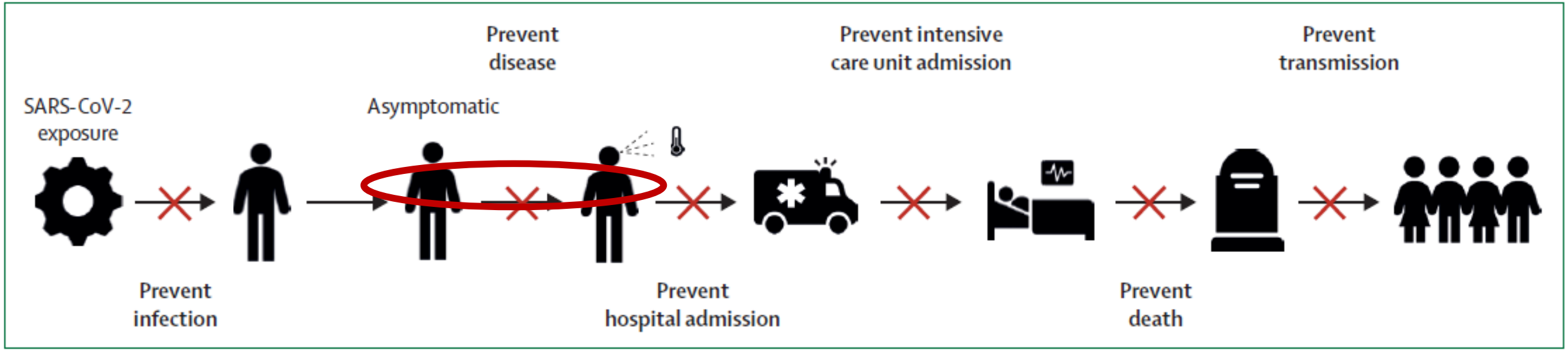
NEJM Jan 2021

# COVID 19 Treatment- Hospitalized

- Steroids – RECOVERY trial – 30% reduction mortality
- Remdesivir- Improved LOS, 3-4 % decrease mortality
- Interleukin 6 blocking agents (Tocilizumab) 10 % improved mortality
- Anticoagulation/prevention/treatment
- Prone position, avoid intubation



# What Do We Want a Vaccine to Do?




Difficult to detect

Need sufficient power

Difficult to detect

Hodgson SH, et al, *Lancet Inf Dis*, published online 10.27.2020

# Herd Immunity

- AKA ‘population immunity’
  - Population can be protected if certain threshold of vaccination reached
  - Reduces overall amount of disease able to spread → not every single person needs to be vaccinated to be protected
- Threshold varies based on disease
  - Measles: 95%
  - Polio: 80%
  - COVID-19:  50-70%?
- Estimated current U.S. population immunity: <10%

**WHO:**

*“Attempts to reach ‘herd immunity’ through exposing people to a virus are scientifically problematic and unethical. Letting COVID-19 spread through populations, of any age or health status will lead to unnecessary infections, suffering and death.”*

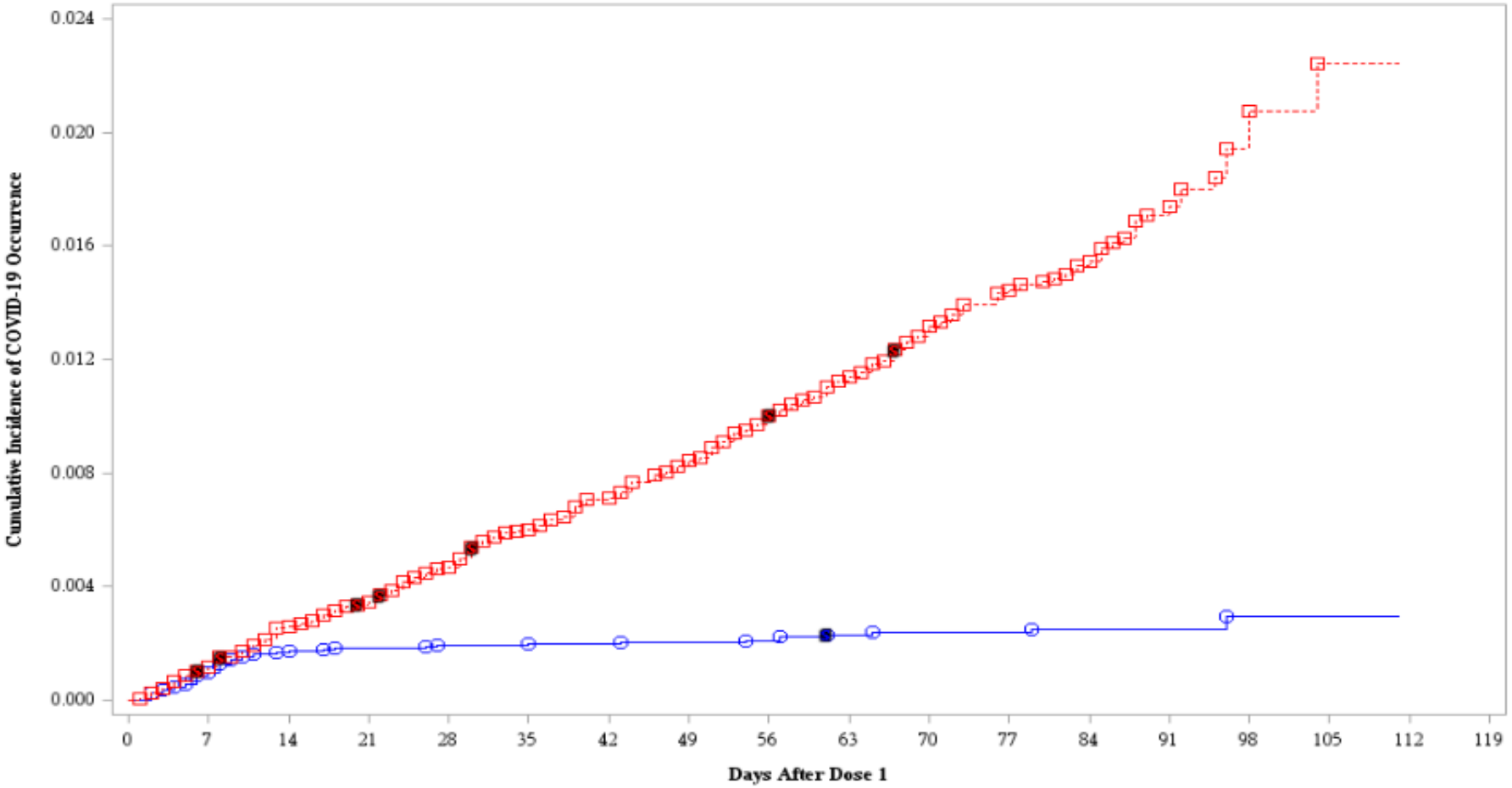
# COVID-19 vaccines in human clinical trials – United States*

| Candidate | Manufacturer | Type | Phase | Schedule | Age | Size | Trial # | Recruiting |
|---|---|---|---|---|---|---|---|---|
| mRNA-1273 | Moderna | mRNA | III | 2 doses (0, 28d) | ≥18 years | 30,000 participants | NCT04470427 | Enrollment complete |
| mRNA-BNT162 | Pfizer, Inc./ BioNTech | mRNA | III | 2 doses (0, 21d) | 12-85 years | 44,000 participants | NCT04368728 | ✓ |
| AZD1222 | U of Oxford/ AstraZeneca | Viral vector (Non-replicating) | III | 2 doses (0, 28d) | ≥18 years | 40,000 participants | NCT04516746 | ✓ |
| Ad26COVS1 | Janssen | Viral vector (Non-replicating) | III | 1 dose | ≥18 years | 30,000 participants | NCT04614948 | ✓ |
| NVX-CoV2373 | Novavax | Protein Subunit | I/II | 2 doses (0, 21d) | 18-84 years | 1400 participants | NCT04368988 | Enrollment complete |
| -- | Sanofi/GSK | Protein Subunit | I/II | 1 dose or 2 doses (0, 21d) | ≥18 years | 440 participants | NCT04537208 | ✓ |

*As of Nov 21, 2020

Sources: https://milkeninstitute.org/covid-19-tracker; https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines; https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ ; https://clinicaltrials.gov/; https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

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




172 cases in placebo group, vs. 9 in vaccine group

No. with events/No. at risk

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A: | 0/21314 | 21/21230 | 37/21054 | 39/20481 | 41/19314 | 42/18377 | 42/17702 | 43/17186 | 44/15464 | 47/14038 | 48/12169 | 48/9591 | 49/6403 | 49/3374 | 50/1463 | 50/398 | 50/0 |
| B: | 0/21258 | 25/21170 | 55/20970 | 73/20366 | 97/19209 | 123/18218 | 143/17578 | 166/17025 | 192/15290 | 212/13876 | 235/11994 | 249/9471 | 257/6294 | 267/3301 | 274/1449 | 275/398 | 275/0 |

A: BNT162b2 (30 µg) B: Placebo

Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adc19ef Table Generation: 17NOV2020 (21:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: /nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_f001_km_d1_aai

https://www.fda.gov/media/144246/download

# Severe COVID-19

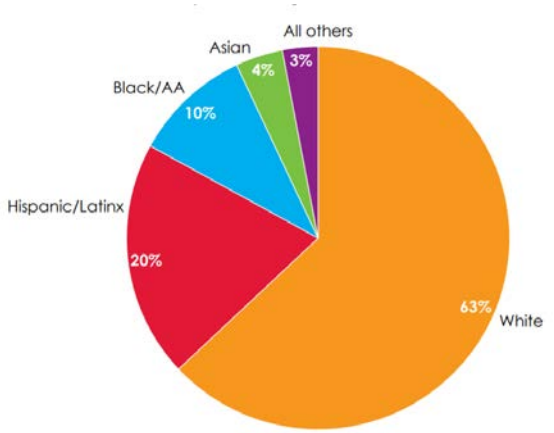
- 10 cases total
  - 9 in placebo group
    - 1 O2 sat 92%
    - 7 hospitalized
    - 3 ICU
  - 1 in vaccine group
    - O2 sat 93%, not hospitalized

**Table 12. First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population**

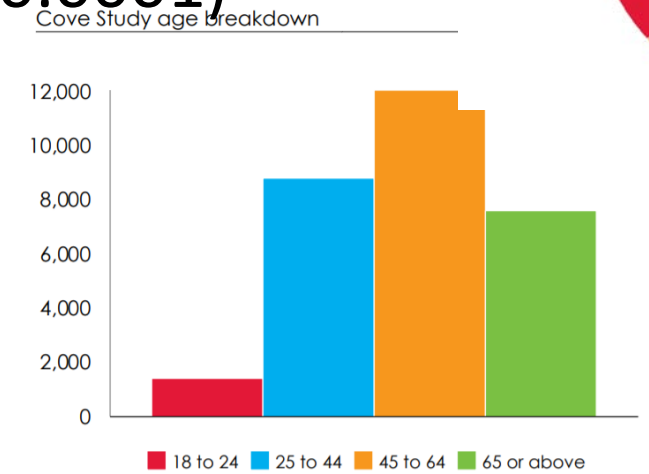
| Secondary Efficacy Endpoint | BNT162b2 N[a]=21669 Cases n1[b] Surveillance Time[c] (n2[d]) | Placebo N[a]=21686 Cases n1[b] Surveillance Time[c] (n2[d]) | Vaccine Efficacy % (95% CI) |
|---|---|---|---|
| First severe case occurrence after Dose 1 | 1<br>4.021 (21314) | 9<br>4.006 (21259) | 88.9<br>(20.1, 99.7)[f] |
| After Dose 1 to before Dose 2 | 0 | 4 | 100.0 (-51.5, 100.0) |
| Dose 2 to 7 days after Dose 2 | 0 | 1 | 100.0 (-3800.0, 100.0) |
| ≥7 Days after Dose 2 | 1 | 4 | 75.0 (-152.6, 99.5) |

[a] N = number of participants in the specified group.
[b] n1 = Number of participants meeting the endpoint definition.
[c] Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint.
[d] n2 = Number of participants at risk for the endpoint.
[e] Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.
[f] Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

# Moderna Phase III Data

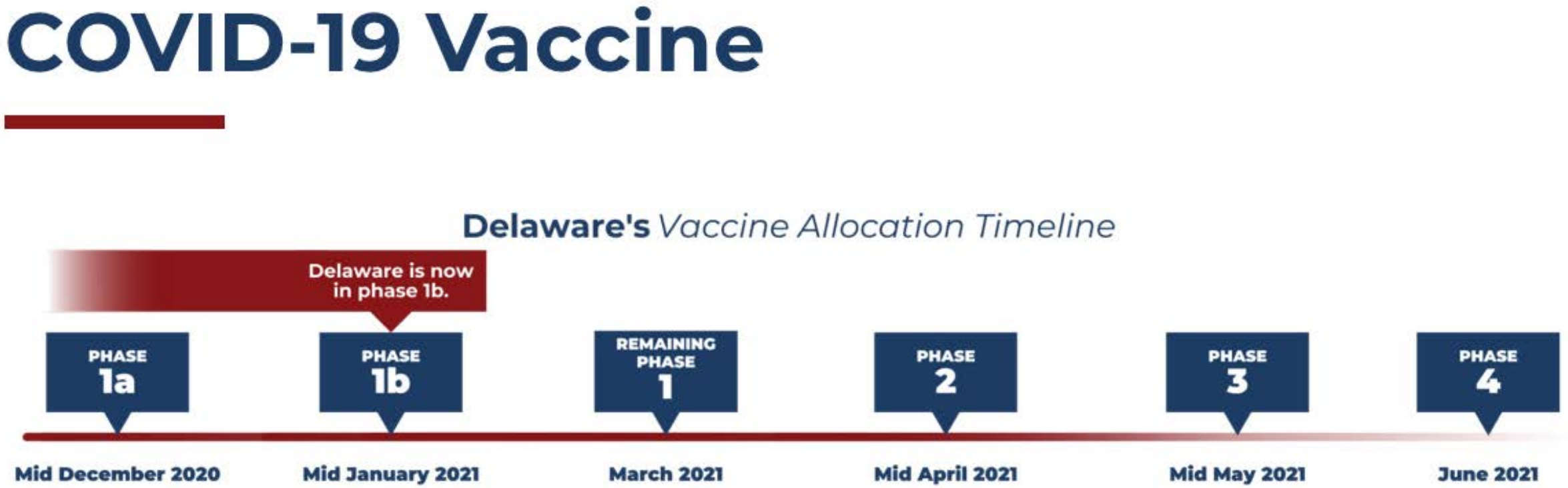



- >30,000 participants enrolled
- Primary efficacy endpoint met: 94.5% (p<0.0001)
  - 14 days after 2nd dose
  - 95 confirmed COVID-19 cases
    - 90 in placebo group, 5 in vaccine group
    - Of 11 severe cases, all in placebo group
  - Consistent across all subgroups
- "Well-tolerated across all populations"
  - Grade 3 AE >2% frequency: injection site pain (2.7%), fatigue (9.7%), myalgias (8.9%), arthralgia (5.2%), pain (4.1%), erythema at site (2.0%)
  - Generally short-lived




Press release 11/16/2020: https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy
https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf

# VACCINATIONS IN DELAWARE




Source DPH 1/29/21

# We Are Currently in Phase 1B

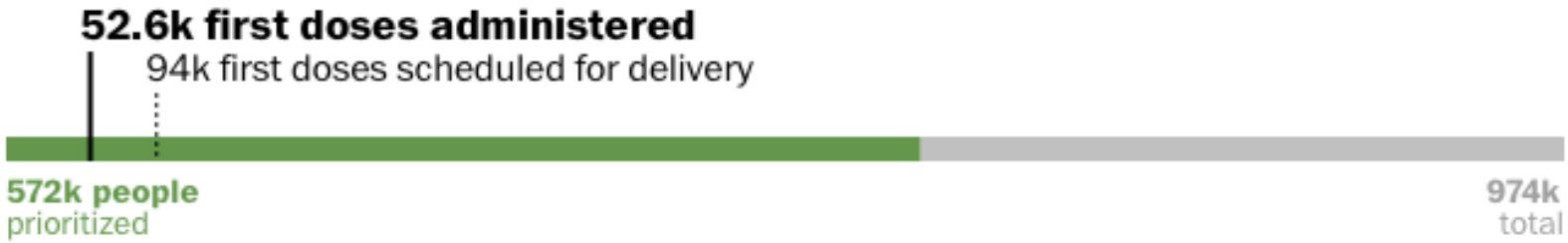
## Facts at a Glance

People covered in Phase 1A and 1B are eligible to get vaccinated.

- Phase 1A includes health care personnel with direct patient contact and care, Emergency Medical Services agencies, and long-term care staff and residents. Efforts will continue to vaccinate individuals in this group.
- Long-term care residents and staff will continue to be vaccinated by either CVS or Walgreens pharmacy staff as part of a federal program.
- Phase 1B includes all individuals 65 and over, and frontline essential workers including: fire, police, correctional officers, teachers and education staff (including child care providers), U.S. postal workers, food manufacturing, agriculture, transportation, and grocery store workers.

Source DPH 1/27/21

# Delaware




Note: The prioritized population includes everyone the state has identified so far as a priority. State's population includes people ages 15 and under who are not yet eligible.

Delaware has administered at least **52,586 first doses**

covering **9.2% of the prioritized population**...

and **5.4% of the state's population.**

At least **11,464 people** have been fully vaccinated.

---

The state has been allocated **94,000 first doses**,

enough to vaccinate **16.5% of the prioritized population**...

and **9.7% of the state's population**. *Read the methodology*

Source Washington Post 1/29/21

# What Phase is Next?

## Remaining Phase 1

### Who:

Persons aged 16-64 with high-risk medical conditions (Obesity, Severe Obesity, Diabetes, COPD, Heart Condition, Chronic Kidney, Cancer, Smoking, Solid Organ Transplant, Sickle Cell Disease, Intellectual/Developmental Disabilities, Severe and persistent mental/behavioral health conditions).

Persons living in high-risk group settings such as correctional facilities, homeless shelters, and group homes.

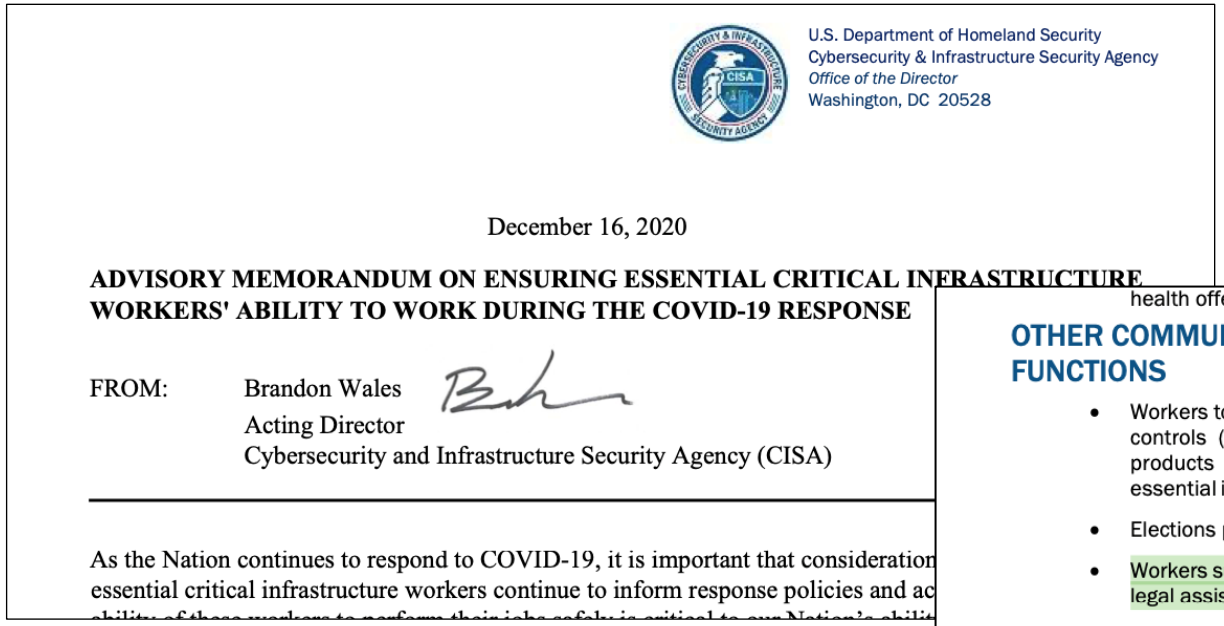
Other essential workers (Transportation and Logistics, Food Service, Shelter and Housing (construction), Finance, IT and Communications, Energy, Media, Legal, Public Safety (Engineers), Water and Wastewater). Vaccines may be available through employers.

### When:

Starting by end of February into early March. Not all essential workers in each category will be eligible at first. Those with more frequent public contact, and higher health risks will likely be eligible first.

Source DPH 1/27/21

# Certain employees in the Delaware Court system are classified as “essential workers” and are eligible for the vaccine in phase 1B



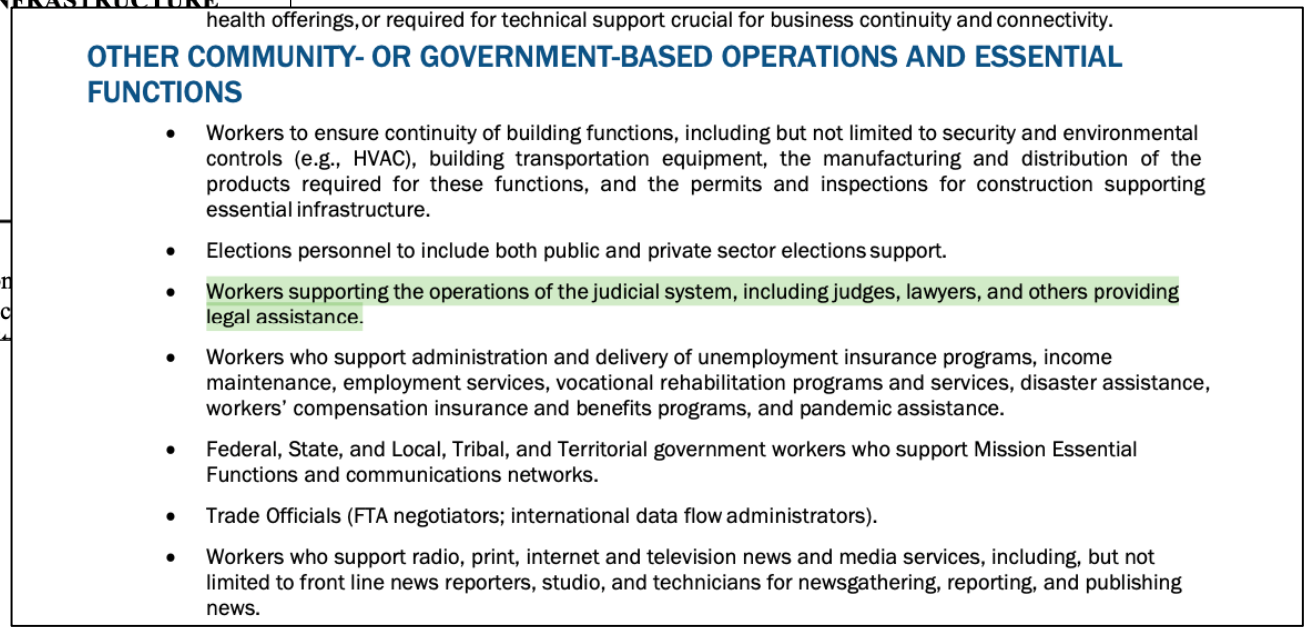
U.S. Department of Homeland Security
Cybersecurity & Infrastructure Security Agency
*Office of the Director*
Washington, DC 20528

December 16, 2020

**ADVISORY MEMORANDUM ON ENSURING ESSENTIAL CRITICAL INFRASTRUCTURE WORKERS' ABILITY TO WORK DURING THE COVID-19 RESPONSE**

FROM: Brandon Wales
Acting Director
Cybersecurity and Infrastructure Security Agency (CISA)

As the Nation continues to respond to COVID-19, it is important that consideration
essential critical infrastructure workers continue to inform response policies and ac



health offerings, or required for technical support crucial for business continuity and connectivity.

**OTHER COMMUNITY- OR GOVERNMENT-BASED OPERATIONS AND ESSENTIAL FUNCTIONS**

- Workers to ensure continuity of building functions, including but not limited to security and environmental controls (e.g., HVAC), building transportation equipment, the manufacturing and distribution of the products required for these functions, and the permits and inspections for construction supporting essential infrastructure.
- Elections personnel to include both public and private sector elections support.
- Workers supporting the operations of the judicial system, including judges, lawyers, and others providing legal assistance.
- Workers who support administration and delivery of unemployment insurance programs, income maintenance, employment services, vocational rehabilitation programs and services, disaster assistance, workers’ compensation insurance and benefits programs, and pandemic assistance.
- Federal, State, and Local, Tribal, and Territorial government workers who support Mission Essential Functions and communications networks.
- Trade Officials (FTA negotiators; international data flow administrators).
- Workers who support radio, print, internet and television news and media services, including, but not limited to front line news reporters, studio, and technicians for newsgathering, reporting, and publishing news.

Department of Homeland Security GUIDANCE ON THE ESSENTIAL CRITICAL INFRASTRUCTURE WORKFORCE v4.0

# Highly Fit SARS CoV 2 Variant

- UK, South Africa– G614 strain
- Altered spike protein
- Likely predominant worldwide strain
- Higher viral load in trachea/upper airways
  - More readily spread
- NOT associated with more severe disease
- Neutralized by current Ab, vaccines

  - NEJM Dec 2020

# Variant -Vaccine efficacy

- Janssen single dose – 57% vs S. Africa , 87% vs US
- Novovax – similar data
- Moderna/Pfizer– can exchange mRNA for variant m RNA
- Race--- vaccine vs variant
- 1000 people vaccinated at 66% vs 10 at 95%
- Timing in communities/countries/cost/accessibility
- Shelf life – 2 years Janssen vaccine

# Vaccine Questions

- **Should I get the COVID-19 vaccine as soon as it is available to me?**
  - Yes. Consult with your doctor if you are concerned about any underlying medical conditions Be sure to notify vaccine staff about any allergies or past allergic reactions.
- **Should I get the vaccine if I already have had COVID-19?**
  - Yes. Reinfection is possible with COVID-19 so the CDC recommends getting the vaccine. This is also true for so-called “long-haulers” who suffer COVID symptoms for months longer than typical.
- **Should I get the vaccine if I *currently* have COVID-19 or I was recently exposed to someone with COVID-19??**
  - No. You *should not* get the shot until your symptoms have passed and/or the isolation period has passed.
- **Should I get the vaccine if I am pregnant?**
  - WHO recommends vaccine in pregnancy. No data.

# Vaccine Questions

- **If I received a two-dose vaccine, when should I get my second dose?**
  - The CDC recommends getting a second dose within 3 weeks for the Pfizer vaccine and within 4 weeks for the Moderna vaccine. However the CDC has said that a delay of up to 6 weeks is allowed.
- **If I received a first dose of one vaccine can I get a second dose of the other vaccine?**
  - The CDC said the two mRNA vaccines are “not interchangeable” and so you should stick with the same vaccine. However, the CDC said in unusual circumstances it can be allowed but it is not ideal.
- **Is there anyone who should *not* get the COVID-19 vaccine?**
  - There is no COVID-19 vaccine yet for children under age 16. Several companies have begun enrolling children as young as age 12 in COVID-19 vaccine clinical trials. COVID-19 vaccination might not be recommended for people with certain health conditions. Talk to your doctor if you have questions about getting the vaccine.

# Vaccine Questions

- **What about reported issues/problems with the vaccines?**
  - There is a great deal of disinformation/misinformation/bad information out there, particularly on social media. Check with credible sources – your doctor or the Centers for Disease Control (at CDC.gov) or Delaware Public Health (at coronavirus.delaware.gov).
- **What are the side effects of the vaccine (Pfizer and Moderna)?**
  - The side effects are typical for vaccines. That includes a mild fever, pain at the injection site and general body aches, tiredness or a headache. The side effects should not last more than a day or two.
- **Are there any medications that interfere with the vaccine?**
  - Currently, there is no evidence to suggest that taking any specific medications, alter vaccine efficacy. Currently CDC recommends NOT taking ibuprofen prophylaxis before vaccination.
- **Are there any long-term effects of the vaccine?**
  - long term adverse side effects have yet been identified or reported.

# Vaccine Hesitancy

## What is getting in the way of vaccine confidence in the US?

**There has been a considerable decline in COVID-19 vaccine acceptability in the past 4 months**

Factors weighing on acceptance include:

- Concern about side effects
- Efficacy
- Risk perception/need for vaccine
- Associated costs

Tyson, A, Johnson, C, & Funk, C. (2020, September 17). *U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine*. Pew Research Center. https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/

**Perceived safety, cost, and accessibility can all affect COVID-19 vaccine acceptance**

…but attributes that made COVID-19 vaccine more acceptable included:

- if your healthcare provider said it was safe
- if there are no costs to the individual
- if it would help get back to school and work
- if they could get it easily, from a walk-in or drive-thru clinic, pharmacy or doctor's office

Jackson, C., & Newall, M. (2020, September 29). *Despite COVID-19 spike, few individual behaviors are changing*. Ipsos. https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index