Vaccines, Variants and Vaccination

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NOTE: Information in this power point slide set may have changed since the date of presentation due to publication of new findings.

Vaccines

Platform	Developer	Vaccine	Phase
mRNA	Moderna	mRNA-1273	EUA—US
	BioNTech/Pfizer	ChAdOx1 nCoV-19	EUA—US
Viral Vector	Janssen	Non-replicating human adenovirus 26 Ad.26.COV2.S (JNJ-78436725)	EUA—US
	AstraZeneca/ Oxford	Non-replicating simian adenovirus ChAdOx1 nCoV-19 (AZD-1222)	Approved—UK Pending—US
	Merck	Withdrawn	Withdrawn
Protein Subunit	Novavax	Recombinant protein NVX-CoV2373	Phase 3 UK & US
	Sanofi-GSK	Withdrawn	Withdrawn

3 Vaccine Platforms

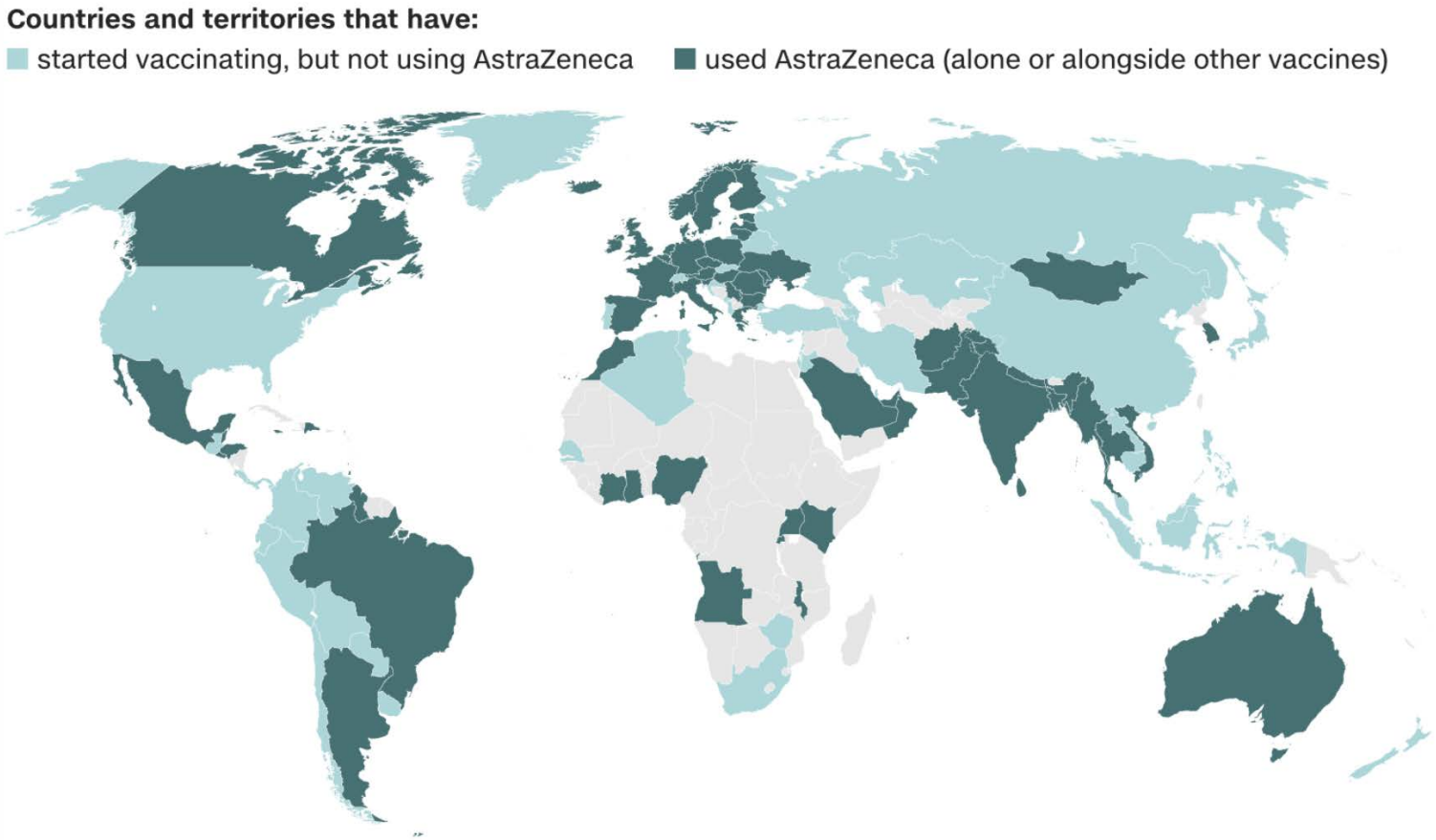
- **mRNA (Pfizer & Moderna)**
  - Lipid nanoparticle delivers a bit of genetic code (mRNA) to muscle cells.
  - mRNA contains the recipe for the spike protein of SARS-CoV-2.
  - Spike proteins made activate the immune system to recognize the spike protein as foreign and to develop antibodies and other immune weapons with which to fight it.
  - WILL NOT CHANGE YOUR DNA!

- **Viral Vector (AstraZeneca & Janssen)**
  - Harmless adenovirus (simian for AZ and human for J&J) engineered to carry the genetic code (DNA) for the spike protein.
  - Once adenovirus enters cells, cells use the code to make spike proteins.
  - Rest of process is the same as for nucleic acid platform.
  - WILL NOT CHANGE YOUR DNA!

- **Protein Subunit (Novavax)**
  - Provides the spike protein itself

Viral Vector Vaccines

AstraZeneca—Widespread Global Utilization



Astra Zeneca—Viral Vector Vaccine

- **July 2020**
  - Transverse myelitis case
- **March 2021**
  - Data concerns
- **April 2021**
  - Reports from Germany, Austria and Norway of rare blood clotting disorders after receiving
  - EU's drug regulator said a warning should be added to the AstraZeneca COVID-19 vaccine indicating a possible link to rare and unusual blood clots but stopped short of recommending it be pulled from use, saying its benefits outweigh its risks.

Janssen (J&J)—Viral Vector Vaccine

- 12 April 2021—CDC and FDA began reviewing data involving ***15 reported U.S. cases*** of a rare and severe type of blood clot cerebral venous sinus thrombosis (CVST) in individuals after receiving the J&J vaccine.
  - https://doi.org/10.1056/NEJM2105869

- All cases occurred ***among women*** between the ***ages of 18 and 48***, and symptoms occurred 6 to 13 days after vaccination. Although an earlier case not thought to be associated with Janssen was a male.
  - Vaccine-induced immune thrombotic thrombocytopenia (VITT)
  - Risk of the clotting is likely greater for women under 50

- 13 April—CDC/FDA recommended a pause in the use of the J&J vaccine.

- 14 April—CDC's ACIP reviewed and requested more data.

- 23 April 2021
  - ACIP voted to recommend 10 to 4 (with one abstention) to resume use of the Janssen vaccine.
  - An updated warning will be added to the label indicating that women under the age of 50 should be aware of the risk of blood clots and low platelets from the vaccine.

Janssen Vaccine: FDA Warning

The Janssen COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.

FDA-agreed Warning and Precaution Regarding Thrombosis with Thrombocytopenia

5.2 Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination *[see Overall Safety Summary (6.2)]*. Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal. Specific risk factors for thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

Pfizer and Moderna Vaccine Updates

- **Children—12 to 15 Years**
  - On 10 April, FDA approved Pfizer vaccine for adolescents ages 12 to 15 years.

- **Children—6 months to 11 years**
  - Pfizer has begun a global study to test the vaccine in children ages 6 months to 11 years.

- **Biologics License Application for Pfizer and Moderna**
  - Pfizer and Moderna will file a biologics license application (BLA).
  - An approved BLA would allow the companies to market the vaccine directly to consumers and make it easier for schools, employers and the military to require vaccination against COVID-19.

Vaccines—Do They Work?

Evidence from Phase 3 Trials

Evidence from Real World

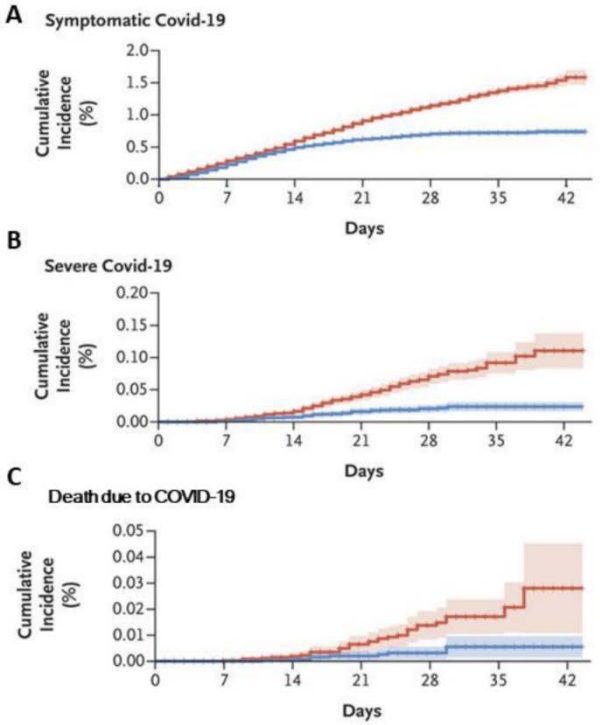
Company	Platform	Doses	Protection from Hospitalization & Death	Protection from Severe Disease	Protection from Mild Disease (Percentages not comparable because trials were conducted at different times/places where there might have been different circulating variants)
moderna	mRNA mRNA-1273	2	100%	100% 30 Placebo Arm 0 in Vaccine Arm	94.1%
Pfizer	mRNA BNT16262	2	100%	100% 9 Placebo Arm 0 in Vaccine Arm	95%
AstraZeneca	Non-replicating simian adenovirus/DNA AZD 1222	2	100%	100% 15 Placebo Arm 0 Vaccine Arm	76%
Johnson & Johnson	Non-replicating human adenovirus/DNA JNJ-78436725	1	100%	100% 16 Placebo Arm 0 in Vaccine Arm	74.4% U.S. 64.7% Latin America 52% S. Africa
NOVAVAX	Spike protein NVX-CoV2373	2	100%	100% (Press Release)	89.7% U.K. 55.4% S. Africa

Vaccine Efficacy

Israel Population Study

- This 600K person study in a nationwide mass vaccination setting suggests that the Pfizer mRNA vaccine is effective for a wide range of COVID-19-related outcomes, including severe outcomes and death, and represents a real-world finding consistent with that of the Phase 3 randomized trial.

- Dagan N et al. BNT161b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. New Eng J Med. 2021;384:1412-23
  - https://doi.org/10.1056/NEJMoa2101765

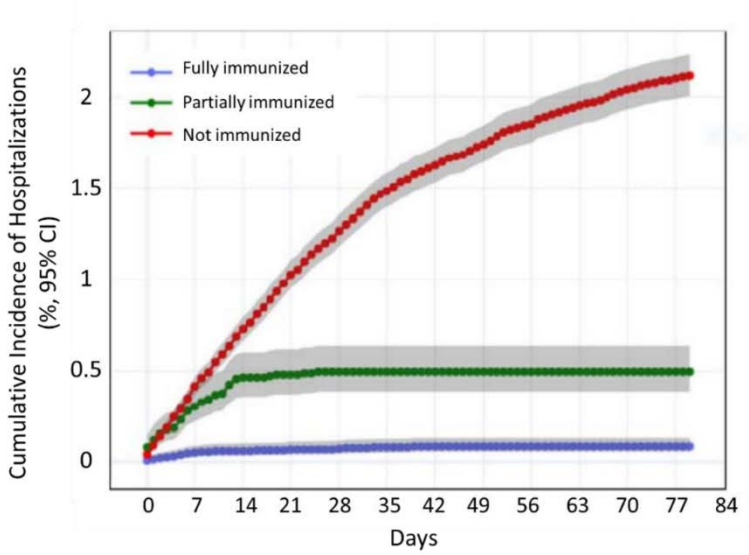


Note: Adapted from Dagan *et al.* Cumulative incidence curves for COVID-19 outcomes (**A.** Symptomatic COVID-19, **B.** Severe COVID-19, **C.** Death due to COVID-19) among **vaccinated** and **unvaccinated** persons, starting from the first dose of vaccination. Shaded areas represent 95% confidence intervals. From NEJM, Dagan *et al.*, BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. Copyright© (2021) Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

Real World Effectiveness—United States

https://doi.org/10.1101/2021.04.21.21255873

- In a cohort of 91,134 patients in the Houston Methodist healthcare system, hospitalization with COVID-19 occurred in
  - 0.7% of fully immunized
  - 3.4% of partially immunized, and
  - 2.7% of non-immunized patients.
- Only one of the 225 deaths among COVID-19 hospitalizations was a fully immunized patient.

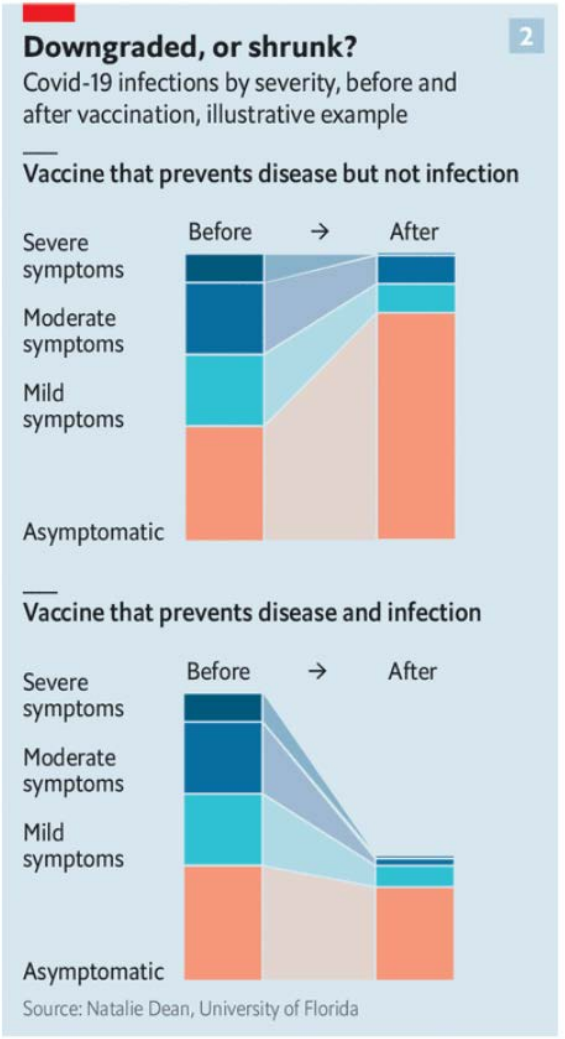


Note: Adapted from Vahidy *et al*. Cumulative incidence of COVID-19 hospitalization among **fully immunized**, **partially immunized**, and **unimmunized** individuals. Gray shaded areas show 95% confidence intervals. Used by permission of authors.

Vaccines Protect You
But Do They Protect Others from You?

- While multiple vaccines have demonstrated efficacy in terms of preventing COVID-19 disease, including severe disease and death, evidence is continuing to emerge regarding their ability to mitigate infection or forward transmission risk.

- **Potential Predicted Scenarios**
  - **Scenario One**
    - Vaccine that prevents disease **but not** infection
  - **Scenario Two**
    - Vaccine that prevents disease **and** infection



Studies Show Vaccines Reduce Asymptomatic Infection

Setting	Finding of xx% reduction in asymptomatic	Reference
Healthcare workers in England	85%	Hall Lancet, April 23, 2021
Healthcare workers in Israel	75%	Amit, Lancet, March 6, 2021
Patients in Mayo Clinic health system	88.7%	Pawlowski medRxiv, February 27, 2021
Israel Ministry of Health (nationwide)	94% (largest study)	Pfizer press release, March 11, 2021 (and Goldberg Medrxiv, April 24, 2021)
Israel general population (Pfizer)	90%	Dagan NEJM, February 24, 2021
Pre-surgical patients in Mayo Clinic system swabbed asymptomatically	80%	Tande Clin Inf Dis, March 10, 2021
Healthcare workers in Cambridge University Hospitals	75%	Weekes Authorea, February 24, 2021
First-line responders and HCWs in US	90%	Thompson A. MMWR, March 30, 2021
Israel population (>16) with children unvaccinated	For every 20-point increase in adult vaccination, rates of kids testing positive halves	Milman O. Medrxiv. March 31, 2021
Long-term care facility, Spain	90%	Salazar P. Medrxiv. April 13, 2021
Nursing home, U.S.	100%	Cavanaugh MMWR, April 21, 2021

Breakthrough Infections: Illness Risk After Vaccination

https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html **(16 April 2021)**
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html **(21 April 2021)**
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html **(30 April 2021)**

- Vaccine breakthrough cases are expected
  - No vaccines are 100% effective at preventing illness. There will be a small percentage of people who are fully vaccinated who still get sick, are hospitalized, or die from COVID-19. *No breakthrough infection has reported to have been transmitted*.
  - Theories
    - Person could be infected just before or just after vaccination
    - Variants might cause illness in some people after they are fully vaccinated.
    - Immunosuppression by medication—antimetabolites or disease (cancer, HIV)
    - Failure of cold chain logistics

Total number of vaccine breakthrough infections reported to CDC	9,245
Females	5,827 (63%)
People aged ≥60 years	4,245 (45%)
Asymptomatic infections	2,525 (27%)
Hospitalizations*	835 (9%)
Deaths†	132 (1%)

Will We Need COVID-19 Vaccine Booster? Probably

- **Current Vaccines**
  - Seem durable for 6 to 8 months at preventing severe disease
- **Future Need**
  - Appearance of severe disease in the fully vaccinated
  - Assessing whether duration of vaccine immunity wanes
- **Studies**
  - Natural history studies
    - Vaccinees' frequency and severity of breakthrough infections
    - Role of variants
- **Timing**
  - mRNA vaccines easier to modify and manufacturers are doing that now

Variants

Variants

https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

- **Fact**
  - Viruses constantly change through mutation and variations in the SARS-CoV-2.

- **Definition**
  - Variant is a viral lineage carrying one or more ***notable*** mutations.

- **Variant Attributes**
  - Evidence of negative impact on diagnostics, treatments and vaccine efficacy
  - Evidence of increased transmissibility
  - Evidence of increased disease severity

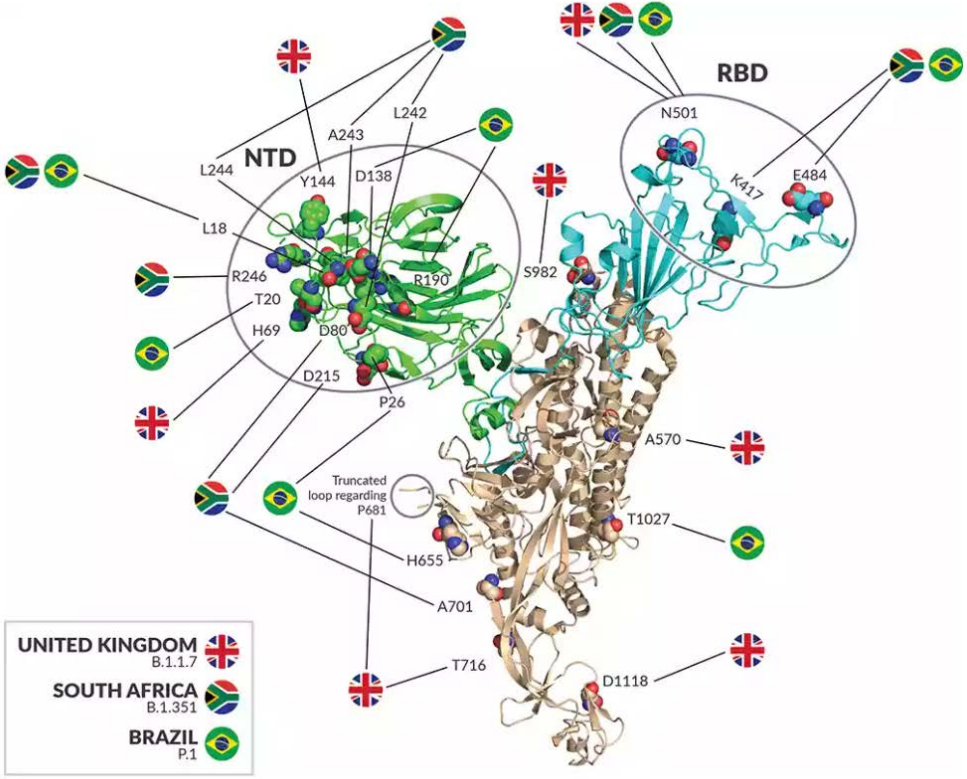
- **Solution**
  - High SARS-CoV-2 incidence rates act to increase the vaccine escape risk
  - Out vaccinate the variants!

Variants and Notable Mutations

- **Variants of Interest**
  - B.1.526 (New York)
  - B.1.525 (New York)
  - P.2 (Brazil)

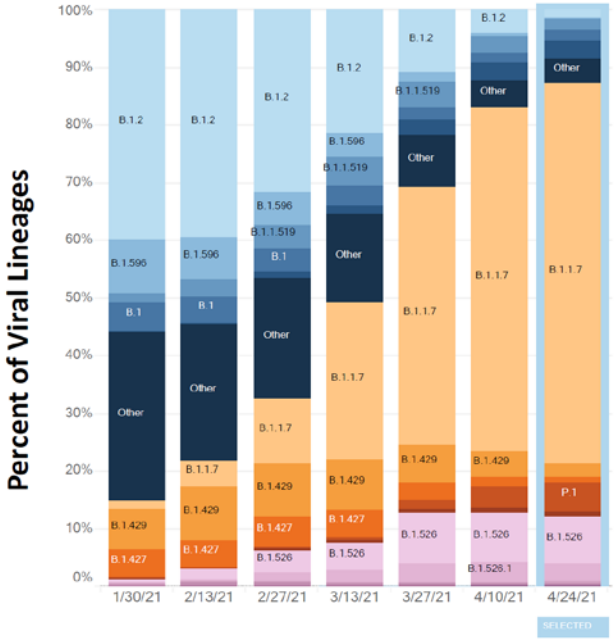
- **Variants of Concern**
  - B.1.1.7 (United Kingdom)
  - P.1 (Japan/Brazil)
  - B.1.351 (South Africa)
  - B.1.427 and B.1.429 (California)

- **Variants of High Consequence**
  - Clear evidence of reduced effectiveness of vaccines and prevention measures
  - Currently there are no SARS-CoV-2 variants that rise to the level of high consequence



National Estimates of SARS-CoV-2 Variants

U.S. 1/17/2021 – 04/24/2021



U.S. 4/11/2021 – 4/24/2021

	Lineage	Type	%Total	95%CI
Most common lineages	B.1.1.7	VOC	66.0%	62.0-69.7%
	B.1.526	VOI	8.2%	5.9-11.1%
	P.1	VOC	5.0%	3.3-7.5%
	B.1.526.1	VOI	3.0%	2.2-4.0%
	B.1.526.2		3.0%	2.2-4.0%
	B.1.429	VOC	2.3%	1.5-3.6%
	B.1.1.519		1.9%	1.4-2.6%
	B.1		1.8%	1.5-2.2%
	B.1.2		1.3%	1.1-1.7%
	B.1.596		0.2%	0.1-0.3%
Additional VOI/VOC lineages	B.1.427	VOC	0.9%	0.6-1.4%
	B.1.351	VOC	0.9%	0.6-1.4%
	B.1.617.2	VOI	0.5%	0.3-0.7%
	B.1.525	VOI	0.3%	0.2-0.5%
	B.1.617.1	VOI	0.2%	0.1-0.2%
	P.2	VOI	0.1%	0.0-0.2%
	B.1.617.3 □	VOI	0.0%	0.0-0.1%
	B.1.617 □	VOI	0.0%	NA
Other*	Other		4.5%	3.8-5.2%

* Other represents >200 additional lineages, which are each circulating at <1% of viruses

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

□ Fewer than 10 observations of this variant during the selected time/location context

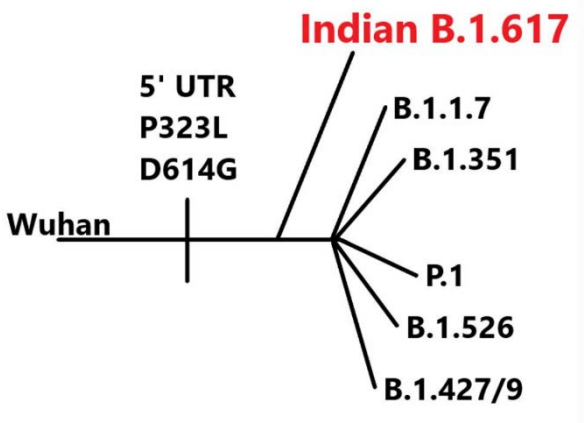
Weighted estimates

- ↑B.1.1.7 VOC increased to 66.0%
- ↑P.1 VOC increased to 5.0%
- ↓B.1.351 VOC decreased to 0.9%
- ↓B.1.427/429 VOC decreased to 3.2%
- ↓B.1.526/526.1 VOI decreased 8.2%/3.0%
- B.1.617 VOI lineages <1.0%
- Weighted estimates 4/11/21 - 4/24/21 **fall within Nowcast prediction intervals**

B.1.617 Variant

https://www.biorxiv.org/content/10.1101/2021.04.23.441101v1

- **New variant detected in the U.S.**
  - San Francisco Bay Area
    - So-called “double variant” has at least ten mutations, but two mutations—L452R and E484Q are notable—the latter is closely related to a more well-known mutation known as E484K.
  - Michigan
    - B.1.617 case in traveler from India identified in Michigan
  - India
    - Originally detected in Maharashtra, India.



- **Two Notable Mutations**
  - L452R mutation is found in the B.1.427/B.1.429, a strain that more transmissible that might cause reduced immunity in people who have been vaccinated.
  - E484Q mutation is closely related to the E484K mutation, found in B.1.351; P.1 and P.2; and B.1.526.
    - Concerning because it might give the virus the ability to partly evade the immune system’s protective response among vaccinated people or those who have survived a natural COVID-19 illness.

Will vaccines work against variants?

Short Answer is Yes

But the Complete Answer is More Complicated

Vaccine Effectiveness Against Variants

- While some variants cause more breakthrough infections than other variants, existing vaccines have been shown to protect people against serious disease and death from current variants of concern.

- Israel (Pfizer)
  - B.1.351 associated with higher rate of breakthrough infections, but number was low
- Qatar (Pfizer)
  - 97.4% effective against severe disease from B.1.351.

- Variants and their effects on vaccine effectiveness will shape the future of the COVID-19 pandemic for years to come

Vaccination

Production

Distribution

Prioritization

Acceptance

Administration

Pharmacovigilance

CDC COVID Data Tracker

https://covid.cdc.gov/covid-data-tracker/#vaccinations

COVID-19 Vaccinations in the United States

Overall US COVID-19 Vaccine | Deliveries and Administration; Maps, charts, and data provided by CDC, updates daily by 8 pm ET†
Represents all vaccine partners including jurisdictional partner clinics, retail pharmacies, long-term care facilities, dialysis centers, Federal Emergency Management Agency and Health Resources and Services Administration partner sites, and federal entity facilities.

Total Vaccine Doses

Delivered	337,089,765
Administered	264,680,844

Learn more about the distribution of vaccines.

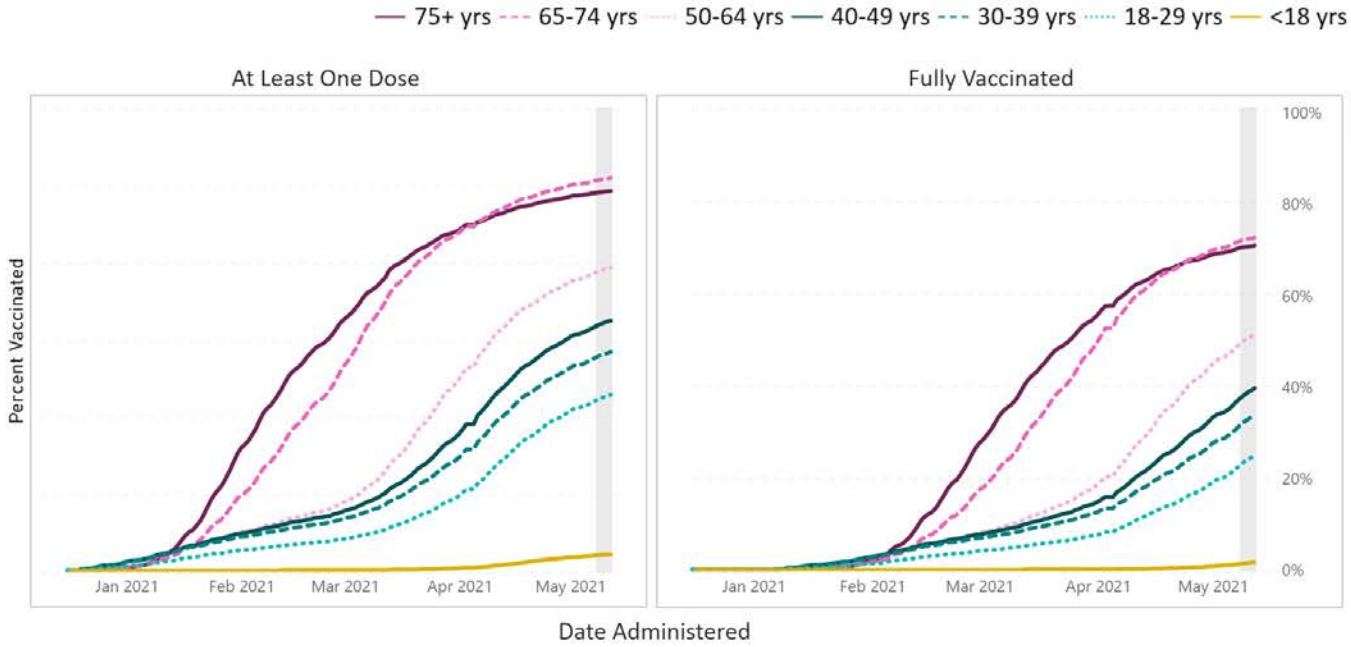
People Vaccinated	At Least One Dose	Fully Vaccinated
Total	153,986,312	117,647,439
% of Total Population	46.4%	35.4%
Population ≥ 18 Years of Age	151,455,299	116,387,534
% of Population ≥ 18 Years of Age	58.7%	45.1%
Population ≥ 65 Years of Age	45,926,146	39,303,599
% of Population ≥ 65 Years of Age	84%	71.9%

About these data

CDC | Data as of: May 12, 2021 6:00am ET. Posted: Wednesday, May 12, 2021 2:01 PM ET

Percent of People Receiving COVID-19 Vaccine by Age Group and Date Administered, United States

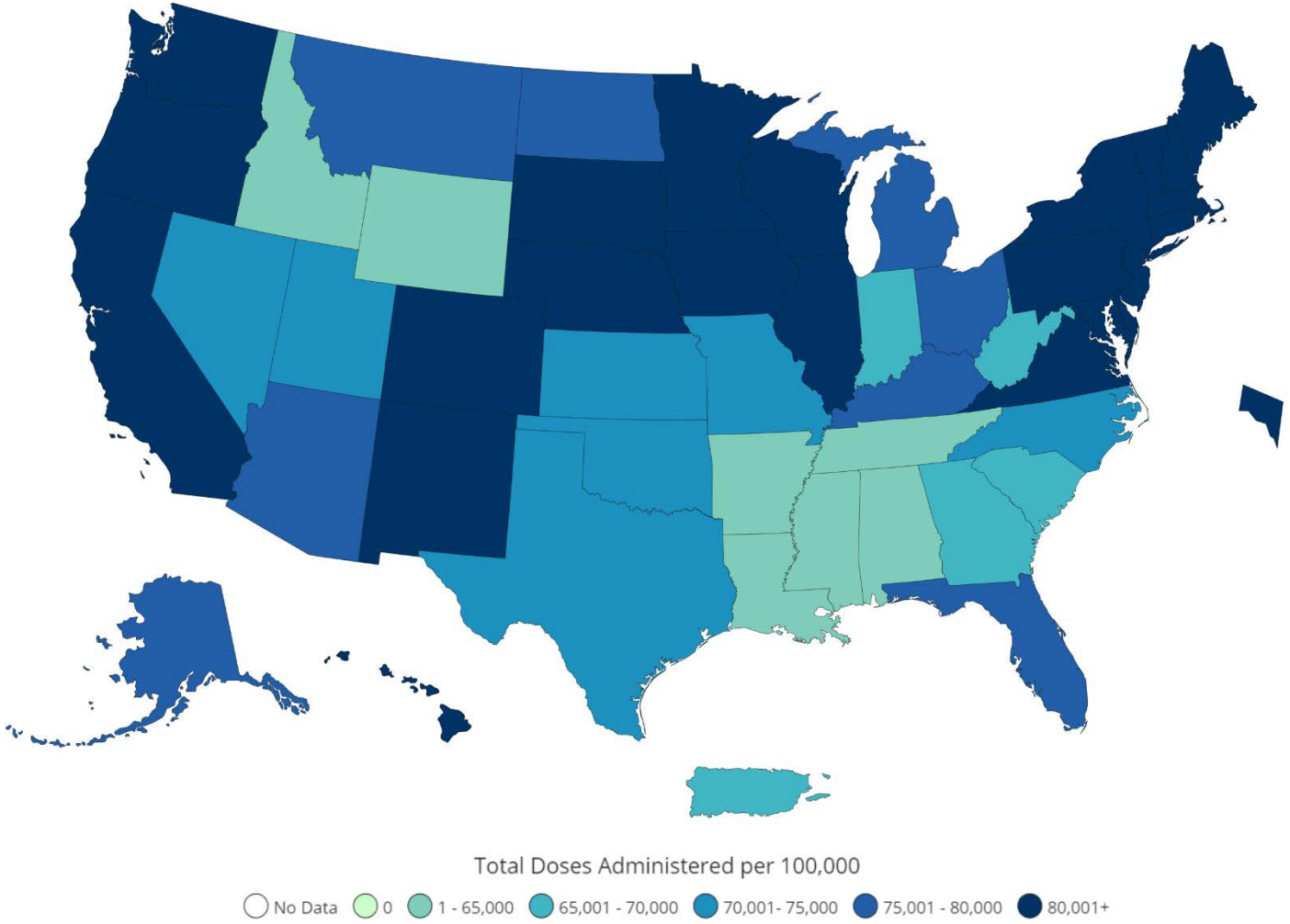
December 14, 2020 – May 12, 2021



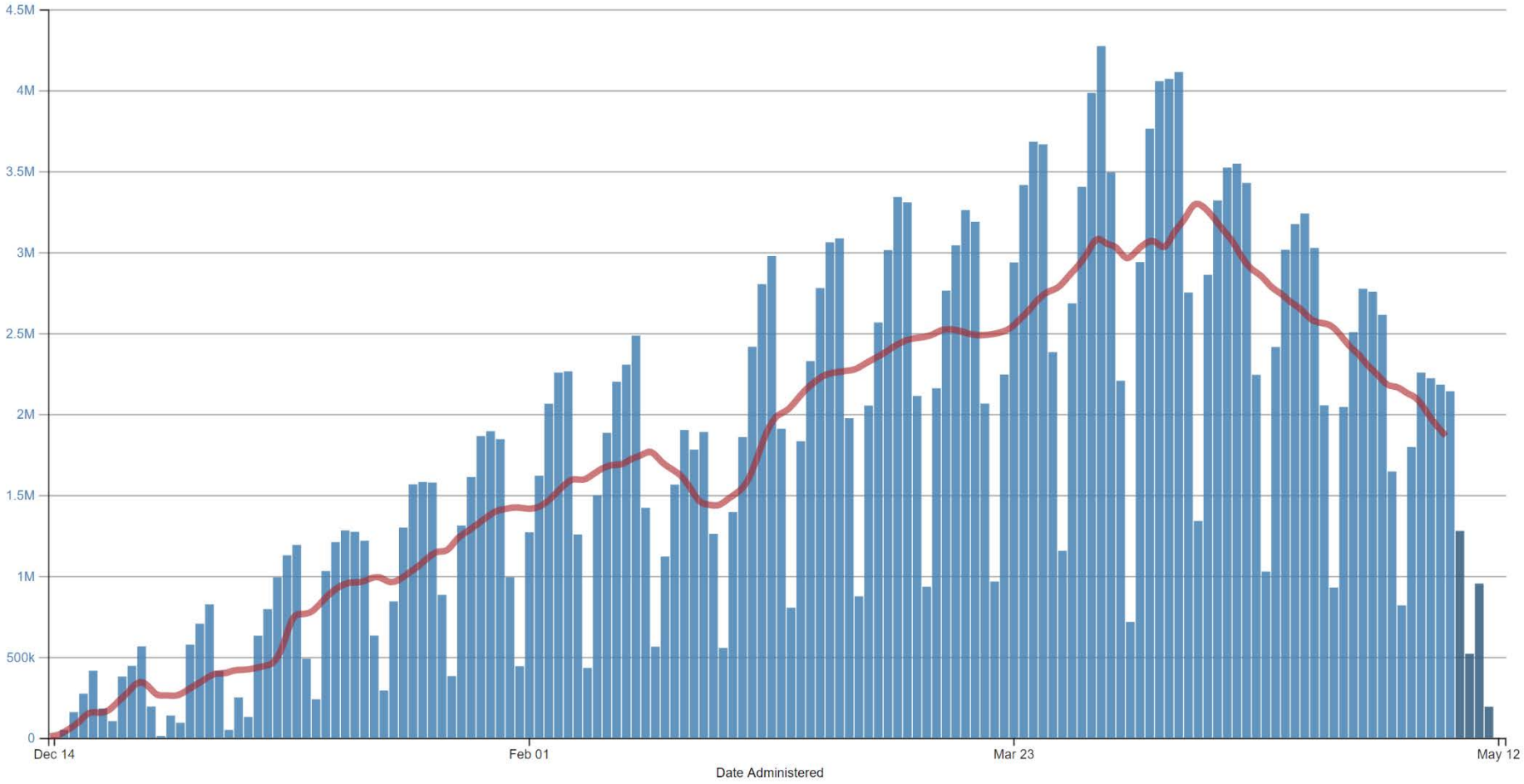
Race | Sex | Age

Age	Receiving at Least One Dose	Fully Vaccinated
75+ yrs	82.7%	71.0%
65-74 yrs	85.5%	72.7%
50-64 yrs	66.0%	51.4%
40-49 yrs	54.4%	39.7%
30-39 yrs	47.6%	33.7%
18-29 yrs	38.3%	25.0%
<18 yrs	3.5%	1.7%

Age data were available for 99.0% of vaccinations. Texas has been excluded from all calculations on this page.*


Total Doses Administered per 100,000
No Data
0
1 - 65,000
65,001 - 70,000
70,001- 75,000
75,001 - 80,000
80,001+

Daily Count of Total Doses Administered and Reported to the CDC by Date Administered, United States



Construction Workers and COVID-19 Vaccination

- **Possible solutions for those offering vaccines**:
  - Consider offering or recommending one-dose vaccine (J&J vaccine).
  - Work with local health departments to administer vaccines at a construction site.
  - Offer flexible, non-punitive sick leave options (e.g., paid sick leave) for employees to get vaccinated and for employees to recover from any vaccination reactions.
  - Allow time for ***vaccine confidence*** to grow.
    - Workers who are hesitant at first may become more confident after seeing coworkers, friends, and family get vaccinated.
  - Offer more than one opportunity for vaccination, if hosting an on-site clinic.

Recommendations for Fully Vaccinated

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html **(27 April 2021)**

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing
- Visit with unvaccinated people (including children) from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing
- Participate in outdoor activities and recreation without a mask, except in certain crowded settings and venues
- Resume domestic travel and refrain from testing before or after travel or self-quarantine after travel

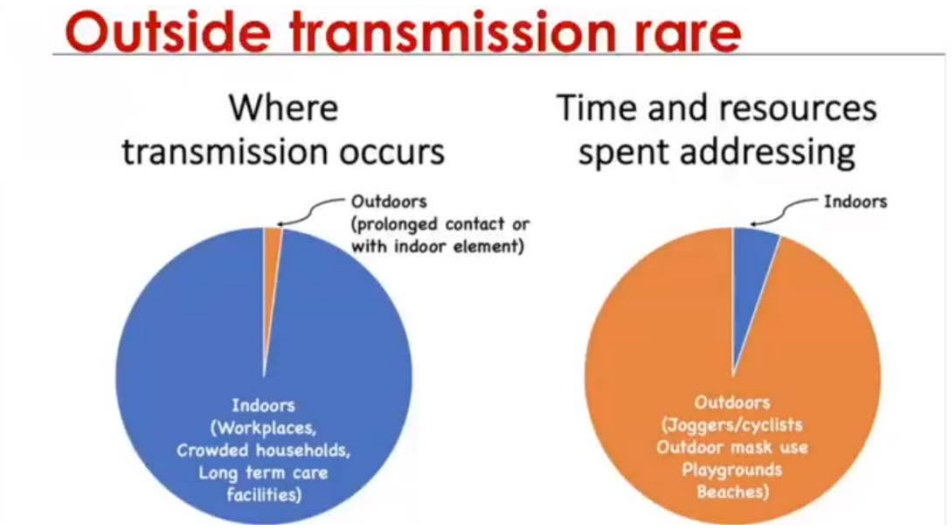
- Refrain from:
  - Testing before leaving the U.S. for international travel (unless required by the destination) and refrain from self-quarantine after arriving back in the U.S.
  - Testing following a known exposure, if asymptomatic, with some exceptions for specific settings
  - Quarantine following a known exposure if asymptomatic
  - Routine screening testing if asymptomatic and feasible

- For now, fully vaccinated people should continue to:
  - Take precautions in indoor public settings like wearing a well-fitted mask
  - Wear well-fitted masks when visiting indoors with unvaccinated people who are at increased risk for severe COVID-19 disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease
  - Wear well-fitted masks when visiting indoors with unvaccinated people from multiple households
  - Avoid indoor large-sized in-person gatherings
  - Get tested if experiencing COVID-19 symptoms
  - Follow guidance issued by individual employers
  - Follow CDC and health department travel requirements and recommendations

Outdoor Construction Sites

- Participate in outdoor activities and recreation without a mask, except in certain crowded settings and venues.

- What is a crowded setting or venue?



Indoor Construction Sites?

- Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

- Healthcare Personnel
  - "In general, fully vaccinated HCP should continue to wear source control while at work. However, fully vaccinated HCP could dine and socialize together in break rooms and conduct in- person meetings without source control or physical distancing. If unvaccinated HCP are present, everyone should wear source control and unvaccinated HCP should physically distance from others."

- Broader Application to other workplace and other types of workers?

Legal and Policy Issues

Vaccination Laws

- **State Vaccination Laws**
  - *Jacobsen v. Massachusetts*, 197 U.S. 11 (1905)
    - U.S. Supreme Court upheld the authority of states to enforce compulsory vaccination laws.
    - Individual liberty is not absolute and is subject to the police power of the state.

- **Federal Laws**
  - Immigration and Nationality Act
    - 8 U.S.C. § 1182.
  - Food, Drug and Cosmetic Act
    - 21 U.S.C. §§ 301-392 Suppl. 5.
  - Americans with Disabilities Act
    - 42 U.S.C. § 12101 (1990)
  - Title VII of the Civil Rights Act of 1964
    - 42 U.S.C. § 2000e et seq, §7.
  - Genetic Information Nondiscrimination Act
    - 42 U.S.C. § 300gg-51 et seq.

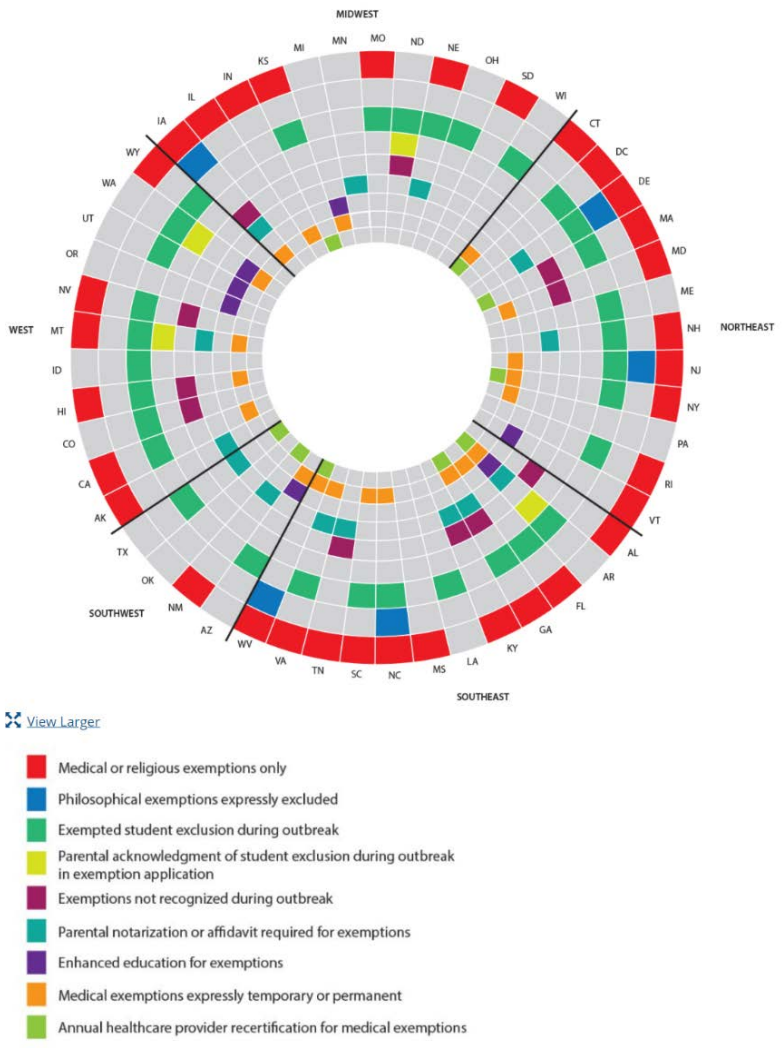
State Vaccination Laws

https://www.cdc.gov/phlp/publications/topic/vaccinations.html

- **Existing Requirements**
  - School
    - Children in public and private schools
    - Children in daycare settings
    - College/university students
  - Healthcare Facilities
    - Healthcare workers
    - Patients in certain facilities

- No state vaccination laws related to COVID-19 vaccines.

- No COVID-19 vaccines are licensed biologics, current vaccines authorized for emergency use.
  - https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states



Vaccination—EEOC

- **Guidance**
  - December 16, 2020
    - https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws
  - Updated guidance coming soon!

- **General**
  - Federal EEOC laws do not prevent an employer from requiring employees physically entering the workplace be vaccinated against COVID-19 subject to reasonable accommodation provisions of the ADA and Title VII.
    - Employer must maintain Information about an employee's vaccination status as confidential medical information
    - Requiring employee to show proof of receipt of a COVID-19 vaccination is not a disability-related inquiry but asking ***why*** employee has not been vaccinated may elicit information about a disability and such questions would have to be "job-related and consistent with business necessity."

Mandatory (EUA) Vaccination: Legal Arguments

- **Not permissible**
  - Legal—Federal statutory right of refusal
    - 21 U.S.C. 360bbb-3 (Authorization for Medical Products for Use in *Emergencies*) *"individuals to whom the product is administered are informed…of the option to accept or refuse administration of the product … "* Section (e)(1)(A)(ii)(III). A federal right of vaccine refusal.
  - Policy—Review standards for emergency use are lower than for a licensed biologic (vaccine)

- **Permissible**
  - Legal
    - FD&C Act EUA provisions are not directed at employers (directed at HHS Secretary)
      - No evidence that the FD&C Act is intended to abridge employer's authority to establish conditions of employment or mitigate an employer's obligation to provide for safety & health of workers.

Mandating an *EUA* Vaccination:

Federal District Court Cases

- **California**
  - Seven employees of the Los Angeles School District have filed a federal lawsuit challenging the District's right to mandate that its employees receive the COVID-19 vaccine.
    - https://www.jdsupra.com/legalnews/lawsuit-challenging-school-district-s-3272280/

- **New Mexico**
  - *Legaretta v. Dona Ana County*
  - Corrections officer is suing a New Mexico county in federal court over requirement that first responders and other employees be vaccinated
    - https://www.law360.com/articles/1361918/attachments/0

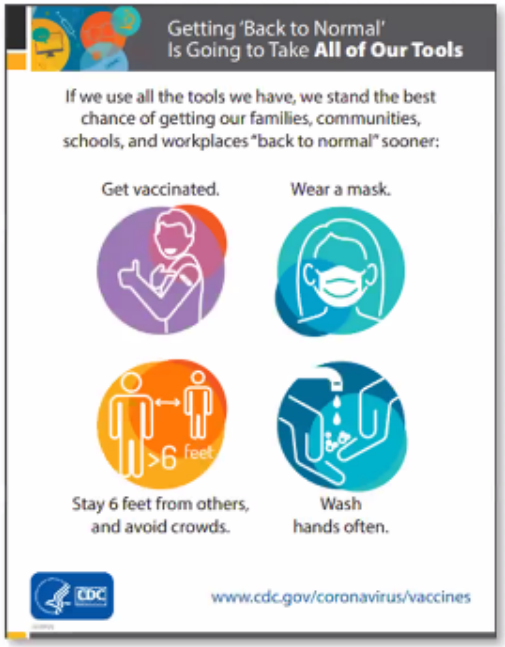
- **Federal Vaccine Law**
  - *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
    - U.S. Supreme Court case in which the Court upheld the authority of states to enforce compulsory vaccination laws.
    - Court articulated the view that individual liberty is not absolute and is subject to the police power of the state

Mandatory Licensed Vaccine for Armed Services?

- President Biden says he has not ruled out requiring all U.S. troops to get the COVID-19 vaccine after the shots are fully licensed by the FDA but cautions such a decision would be a “tough call.”
    - “I don’t know. I’m going to leave that to the military,” Biden told NBC News in an interview that aired Friday, in response to a question on whether he would mandate the vaccine for U.S. service members once it is fully approved by the FDA.
- The comments from the commander in chief come as the Pentagon has sounded the alarm about service members refusing the vaccine in large numbers, with roughly a third of troops declining to take the shot as of February, according to congressional testimony from military officials. Earlier this month, the Pentagon reported that nearly 40 percent of Marines who had been offered the vaccine turned it down.

Encourage Employees to Get Vaccinated

- If your business can't offer COVID-19 vaccinations on site, encourage employees to seek COVID-19 vaccination in their community and provide them with information about where they can get the vaccine.
  - Be flexible in your human resources policies. Establish policies that allow employees to take paid leave to seek COVID-19 vaccination in the community. Support transportation to off-site vaccination clinics.
  - Use promotional posters/flyers to advertise locations offering COVID-19 vaccination in the community. Display posters about COVID-19 vaccination in break rooms, cafeterias, and other high traffic areas.
  - Post articles in company communications (e.g., newsletters, intranet, emails, portals) about the importance of COVID-19 vaccination and where to get the vaccine in the community.



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/essentialworker/workplace-vaccination-program.html

How Much Encouragement?

https://www.eeoc.gov/regulations/rulemaking

- **January 7**
  - EEOC released set of proposed rules that amend the 2016 ADA wellness program rules. The proposed rules limit the value of incentives employers may use to encourage participation in wellness programs that track employees' health data
    - Guidance permitted items of minimal, or "de minimis" value
    - Unclear whether those incentives include vaccinations
  - If program incentives are too high, they would be considered to violate the ADA and GINA by coercing participation

- **January 20**
  - Earlier January 2021 rules were vacated in Biden Administration under its *"regulatory freeze pending review."*

- **February 1**
  - Letter to EEOC from Fortune 500 companies
    - "asking the EEOC to quickly issue guidance clarifying the extent to which employers may offer employees incentives to vaccinate without running afoul of the Americans with Disabilities Act and other laws enforced by the EEOC."

- **April 15, 2021**
  - Your letter specifically asks the EEOC to "clarify[…] the extent to which employers may offer employees incentives to vaccinate without running afoul of the Americans with Disabilities Act [ADA] and other laws enforced by the EEOC."
  - "The agency expects to update its technical assistance about COVID-19 to address these issues, among others, and that work is ongoing."
  - Issue:
    - A very large incentive could make employees feel pressured to disclose protected medical information.

Vaccination Credential: Issues

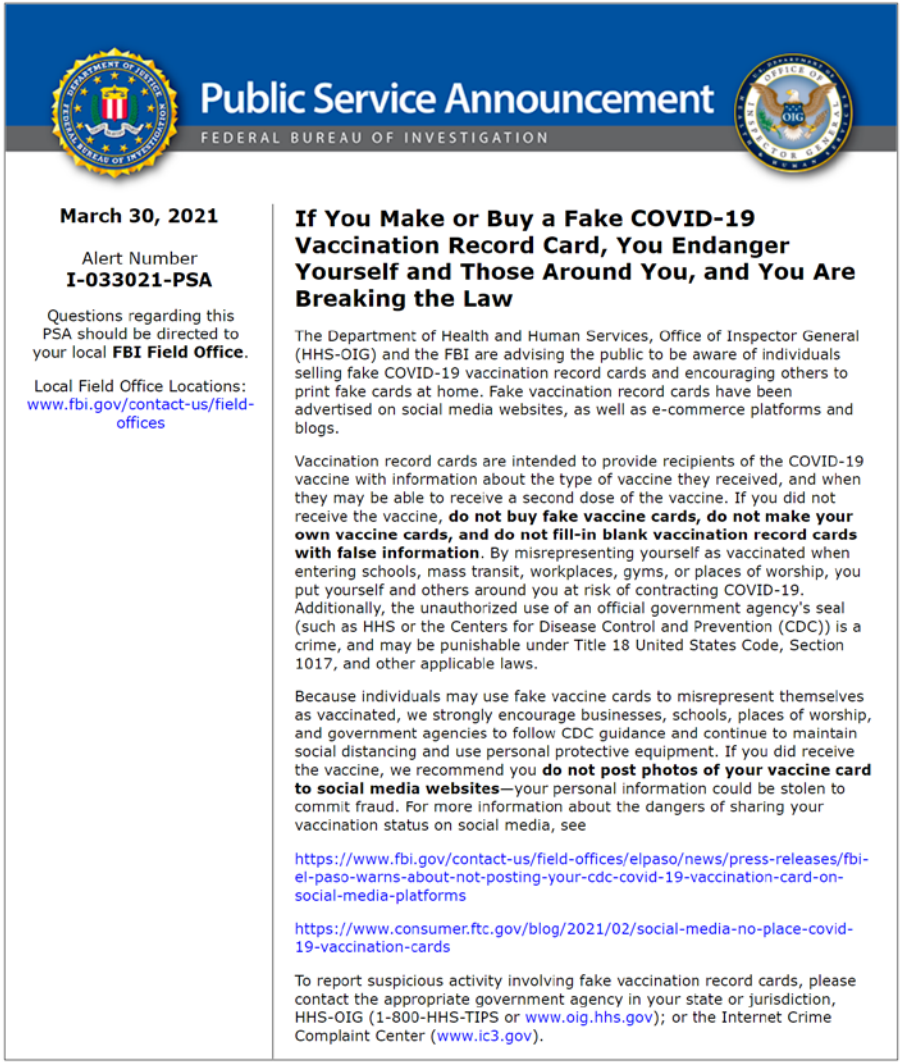
- **Core Rationale**
  - Economic
    - Promotes safe return to commercial, social and leisure activities—especially **travel eligibility**
  - Public health
    - One precaution to ensure that those who are gathering in places where an airborne transmissible virus that could lead to severe sickness is to screen some people in and screen some people out.
- **Concerns**
  - **Health**
    - Extent of protection conferred by vaccination—particularly against new variants—is not yet known
    - Duration of immunity unknown—will there be a standard expiration date based on vaccine administration?
  - **Ethical**
    - Privileging people who are fortunate enough to have gained early access is discriminatory
  - **Operational**
    - Lack of consensus approach to accurately certifying vaccination—public or private?
    - Fraud and counterfeiting (Facebook, Twitter, eBay, Shopify, and Etsy)
      - https://www.nytimes.com/2021/04/08/technology/vaccine-card-scam.html
      - https://www.washingtonpost.com/health/2021/04/18/scams-coronavirus-vaccination-cards/

Counterfeit Vaccination Cards

- FBI issued a warning about the counterfeit vaccination cards, emphasizing that making or purchasing the cards or filling in a blank card with false information are all illegal.

- FBI encouraged the continued use of COVID-19 risk mitigation measures (e.g., mask use, physical distancing) to mitigate the risk posed by counterfeit vaccination cards.

- The National Association of Attorneys General issued a statement calling on social media and e-commerce companies to take immediate action to prevent the sale of fraudulent vaccination cards.



Public Service Announcement

FEDERAL BUREAU OF INVESTIGATION

March 30, 2021

Alert Number
I-033021-PSA

Questions regarding this PSA should be directed to your local **FBI Field Office**.

Local Field Office Locations: www.fbi.gov/contact-us/field-offices

If You Make or Buy a Fake COVID-19 Vaccination Record Card, You Endanger Yourself and Those Around You, and You Are Breaking the Law

The Department of Health and Human Services, Office of Inspector General (HHS-OIG) and the FBI are advising the public to be aware of individuals selling fake COVID-19 vaccination record cards and encouraging others to print fake cards at home. Fake vaccination record cards have been advertised on social media websites, as well as e-commerce platforms and blogs.

Vaccination record cards are intended to provide recipients of the COVID-19 vaccine with information about the type of vaccine they received, and when they may be able to receive a second dose of the vaccine. If you did not receive the vaccine, **do not buy fake vaccine cards, do not make your own vaccine cards, and do not fill-in blank vaccination record cards with false information**. By misrepresenting yourself as vaccinated when entering schools, mass transit, workplaces, gyms, or places of worship, you put yourself and others around you at risk of contracting COVID-19. Additionally, the unauthorized use of an official government agency's seal (such as HHS or the Centers for Disease Control and Prevention (CDC)) is a crime, and may be punishable under Title 18 United States Code, Section 1017, and other applicable laws.

Because individuals may use fake vaccine cards to misrepresent themselves as vaccinated, we strongly encourage businesses, schools, places of worship, and government agencies to follow CDC guidance and continue to maintain social distancing and use personal protective equipment. If you did receive the vaccine, we recommend you **do not post photos of your vaccine card to social media websites**—your personal information could be stolen to commit fraud. For more information about the dangers of sharing your vaccination status on social media, see

https://www.fbi.gov/contact-us/field-offices/elpaso/news/press-releases/fbi-el-paso-warns-about-not-posting-your-cdc-covid-19-vaccination-card-on-social-media-platforms

https://www.consumer.ftc.gov/blog/2021/02/social-media-no-place-covid-19-vaccination-cards

To report suspicious activity involving fake vaccination record cards, please contact the appropriate government agency in your state or jurisdiction, HHS-OIG (1-800-HHS-TIPS or www.oig.hhs.gov); or the Internet Crime Complaint Center (www.ic3.gov).

Vaccine Credentials: Government

- **Con**
  - 18 states have initiated legislation or issued executive orders banning or severely restricting the use of vaccine passports and prohibiting discrimination based on vaccine status for state agencies.
    - Arizona, Arkansas, California, Iowa, Florida, Louisiana, Maryland, Minnesota, Missouri, Montana, Nebraska, Ohio, Pennsylvania, South Carolina, South Dakota, Wisconsin and Wyoming.
  - Unlike Florida that prohibits private businesses from asking whether customers have been vaccinated.
    - "…businesses in Florida are prohibited from requiring patrons or customers to provide any documentation certifying COVID-19 vaccination or post-transmission recovery to gain access to, entry upon, or service from the business…".
- **Pro**
  - Hawaii
  - Illinois
  - New York
  - Nevada
- **Legal**
  - "No shirt, no service"
  - Private businesses can decide who they are willing to admit and serve so long as they do not violate either the federal 1964 Civil Rights Act or applicable state laws

Vaccination Credentials—Universities

- Some universities have implemented policies requiring students to be fully vaccinated if they wish to attend in-person classes this fall:
  - Rutgers, Brown, Northeastern, Cornell University, Duke, Fort Lewis College, Nova Southeastern University, Syracuse, St. Edwards University, Roger Williams University. University of California, and Cal State.

- Rationale
  - Data suggests college campuses might be a significant contributor to local SARS-CoV-2 transmission due to factors such as congregant living and travel from various geographic regions.

Los Angeles Times

CALIFORNIA

California's massive UC and Cal State systems plan to require COVID-19 vaccinations this fall

Alex Harris, right, waits in line with a friend for COVID-19 vaccination at Cal State L.A. on April 9. The UC and Cal State systems announced that COVID-19 vaccinations will be required for students and staff. (Al Seib / Los Angeles Times)

CDC Resources

- **Guidance for Businesses and Employers Responding to COVID-19**
  - https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html

- **Keeping up with CDC Guidance**
  - **What's New?**
    - Updated daily
      - https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html
- **Data**
  - **CDC COVID Data Tracker**
    - Case Trends, Vaccinations, County View, Laboratory, Global Cases, COVID-19 Home
      - https://covid.cdc.gov/covid-data-tracker/

Thank You!