COVID-19:
Vaccines, Variants, Vaccinations and Work

John Howard
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

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Questions: abackus@hsph.harvard.edu

Thank you.

Daily Change in COVID-19 Cases, United States

January 22, 2020* - March 6, 2021

28,771,749
Total Cases Reported

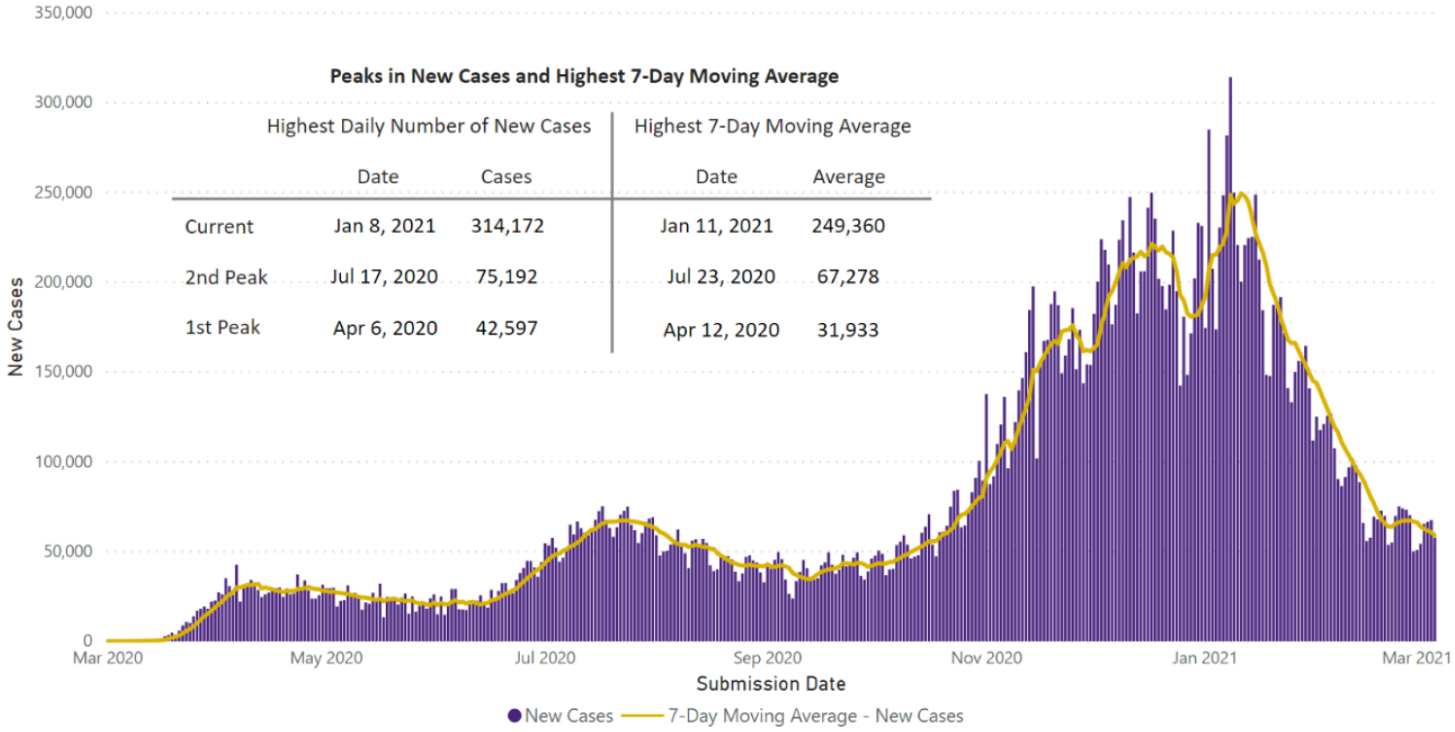
57,586
New Cases Reported

58,872
Current 7-Day Average
Feb 28, 2021 - Mar 6, 2021

67,271
Prior 7-Day Average
Feb 21, 2021 - Feb 27, 2021

-12.5%
Change in 7-Day Average

-76.4%
Change Since Peak Average



Vaccines

Platform	Developer	Vaccine	Phase
mRNA	Moderna	mRNA-1273	EUA—US
	BioNTech/Pfizer	mRNA BNT16262	EUA—US
Viral Vector	Janssen	Non-replicating simian adenovirus—26 JNJ-78436725	EUA—US
	AstraZeneca/ Oxford	Non-replicating simian adenovirus AZD-1222	Approved—UK Phase 3—US
	Merck	Withdrawn	Withdrawn
Protein Subunit	Novavax	Recombinant protein NVX-CoV2373	Phase 3 UK and US
	Sanofi-GSK	Withdrawn	Withdrawn

Vaccine Platforms

https://www.statnews.com/2021/02/02/comparing-the-covid-19-vaccines-developed-by-pfizer-moderna-and-johnson-johnson

- **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.

- **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.

- **Protein Subunit (Novavax)**
  - Subunit vaccines contain fragments of protein and/or polysaccharide from the pathogen, which have been carefully studied to identify which combinations of these molecules are likely to produce a strong and effective immune response.

Janssen Vaccine

Phase 3 Trial—45,000 participants in 8 countries, 3 continents (aged 18 to 100)

- **Phase 3 Trial Results**
  - 66.3% overall efficacy against symptomatic COVID-19 after ≥ 14 days and 65.5% ≥ 28 days after vaccination.
    - U.S. 74.4%
    - Latin America 64.7%
    - South Africa 52% (94.5% of virus were B.1.351 lineage)
  - 100% efficacy in preventing *severe* disease requiring hospitalization in all locations (regardless of variant).

- **Advantages**—single dose, no cold chain requirements
  - Study of vaccine in 2 doses underway

- **FDA**
  - Authorized the Janssen vaccine for Emergency Use on 27 February 2021

- **Advisory Committee on Immunization Practice ACIP**
  - Issued interim recommendations for use in persons ≥ 18 years for prevention of COVID-19 on 28 February 2021

- **CDC**
  - CDC Director approved ACIP recommendations 28 February 2021

Novavax

Phase 2b/Phase 3

- **Phase 1/II Trial Results**
  - 89.3% overall efficacy (trial in the UK)
    - 95.6% against original strain
    - 85.6% effective against B.1.1.7 variant
  - 60% efficacy against South Africa variant B.1.351
    - Company is developing booster shots against new strains

- **Dosing**—2 doses—21 days apart
  - Can be stored for 6 months at refrigerator temperatures

- Novavax based in Maryland, has never brought a vaccine to market
  - Enrolling participants in U.S. clinical trial—30,000 by early February

- Novavax reportedly developing a new version of the vaccine to better protect against emerging South African variant

Astra Zeneca/Oxford—UK

https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2900432-3

- **Studies**
  - Data from 3 single-blind randomised controlled trials—one phase 1/2 study in the UK (COV001), one phase 2/3 study in the UK (COV002), and a phase 3 study in Brazil (COV003)—and one double-blind phase 1/2 study in South Africa (COV005).
- **Approval**
  - ChAdOx1 nCoV-19 (AZD1222) vaccine has been approved for emergency use by the UK regulatory authority, *Medicines and Healthcare Products Regulatory Authority* (MHRA)
    - 2 doses given with an interval of between 4 and 12 weeks
- **Efficacy**
  - Vaccine efficacy after a single standard dose of vaccine from day 22 (59%) to day 90 (86%) post vaccination was 76%.
  - Protection did not wane during this initial 3-month period. Similarly, antibody levels were maintained during this period with minimal waning by day 90 day.
- **Transmission**
  - Participants has their noses sampled every week to detect signs of the virus.
  - Researchers found a 67% reduction in positive swabs among those vaccinated which provides evidence vaccine could also protect against transmission.

Astra Zeneca/Oxford—US

https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2900432-3

- In U.S., we await data from a clinical trial that has enrolled about 30,000 participants, mostly Americans.
- Results from that study are expected later in 2021.
- Study is expected to produce enough safety data to allow AstraZeneca to seek authorization to provide the vaccine for emergency use.
- U.S. has agreed to buy 300 million doses of AstraZeneca's vaccine, but neither the company nor the federal government has said when and in what quantities those doses will be available after the vaccine is approved.

Company	Platform	Doses	Protection from Hospitalization	Protection from Severe Disease	Protection from Mild Disease
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	90% ½ full dose 70% overall 76% one dose
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%	89.3% overall (UK) 60% S. Africa	89.3% U.K. 60% S. Africa

ACIP Guide for mRNA COVID-19 Vaccination

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- **Age groups**
  - Pfizer-BioNTech ≥ 16 years
  - Moderna ≥ 18 years

- **2-Dose Administration**
  - Doses given within 4 days earlier than recommendation are valid
  - No need to restart series if dose is given > 3 weeks (Pfizer) or 4 weeks (Moderna) after 1st dose
  - Interval between doses extended to six weeks after the first dose

- **Interchangeability**
  - Generally, not interchangeable, but can be changeable in “exceptional circumstances”
  - If advertently administered, no additional doses are recommended

- **Co-administration**
  - Should be administered alone with 14 day minimum before or after other vaccine is given

Interchangeability Study—British Study

https://www.gov.uk/government/news/world-first-covid-19-alternating-dose-vaccine-study-launches-in-uk

- Researchers in the UK are initiating a clinical trial to evaluate the efficacy of vaccination using doses from 2 different vaccines
- Allowing (or potentially recommending) individuals to receive 1 dose from each of 2 different vaccines could introduce flexibility into vaccination programs and potentially even increase the degree of protection from the vaccination.
- Trial will initially involve the Pfizer-BioNTech and AstraZeneca-Oxford University vaccines.
- The team said preliminary data will be available by early summer.

ACIP Guide for mRNA COVID-19 Vaccination

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- **Persons with:**
  - Current SARS-CoV-2 infection
    - Deferred until recovery occurs
  - Prior history of SARS-CoV-2 infection
    - Should be offered regardless of history
  - Previous received passive antibody therapy
    - Vaccination should be deferred at least 90 days
  - Known SARS-CoV-2 exposure
    - Vaccinate after quarantine period is over, except persons living in congregate settings
  - Underlying conditions
    - mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination
  - Pregnancy
    - ACIP—Little data on mRNA vaccines, but unlikely to post a risk to fetus or pregnant person
    - ACOG—Vaccine should not be withheld from pregnant women
    - SM-FM—Pregnant women should be offered vaccine

ACIP Guide for Janssen COVID-19 Vaccine

https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm

- Janssen COVID-19 vaccine has high efficacy against COVID-19–associated hospitalization and death.

- ACIP does not state a vaccine product preference. Persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.

- Administration:
  - Shipment and storage at 2-8^{o} C
  - Single dose regimen
  - Intramuscular injection (0.5 ml)
  - Not interchangeable with other COVID-19 vaccines

Vaccines—Do They Work?

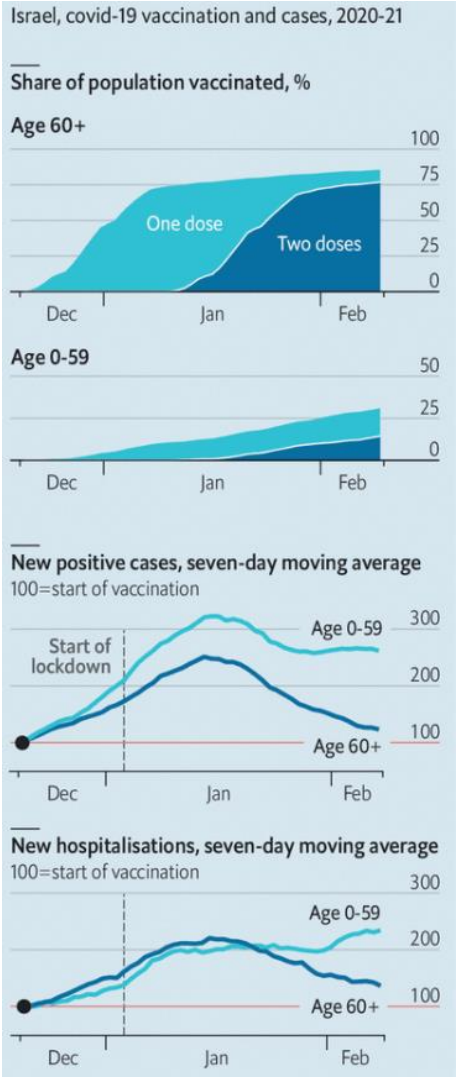
Evidence from Phase 3 Trials

Real World Evidence

Vaccine Efficacy—Real World Data—Israel

https://www.medrxiv.org/content/10.1101/2021.02.08.21251325v1.full.pdf

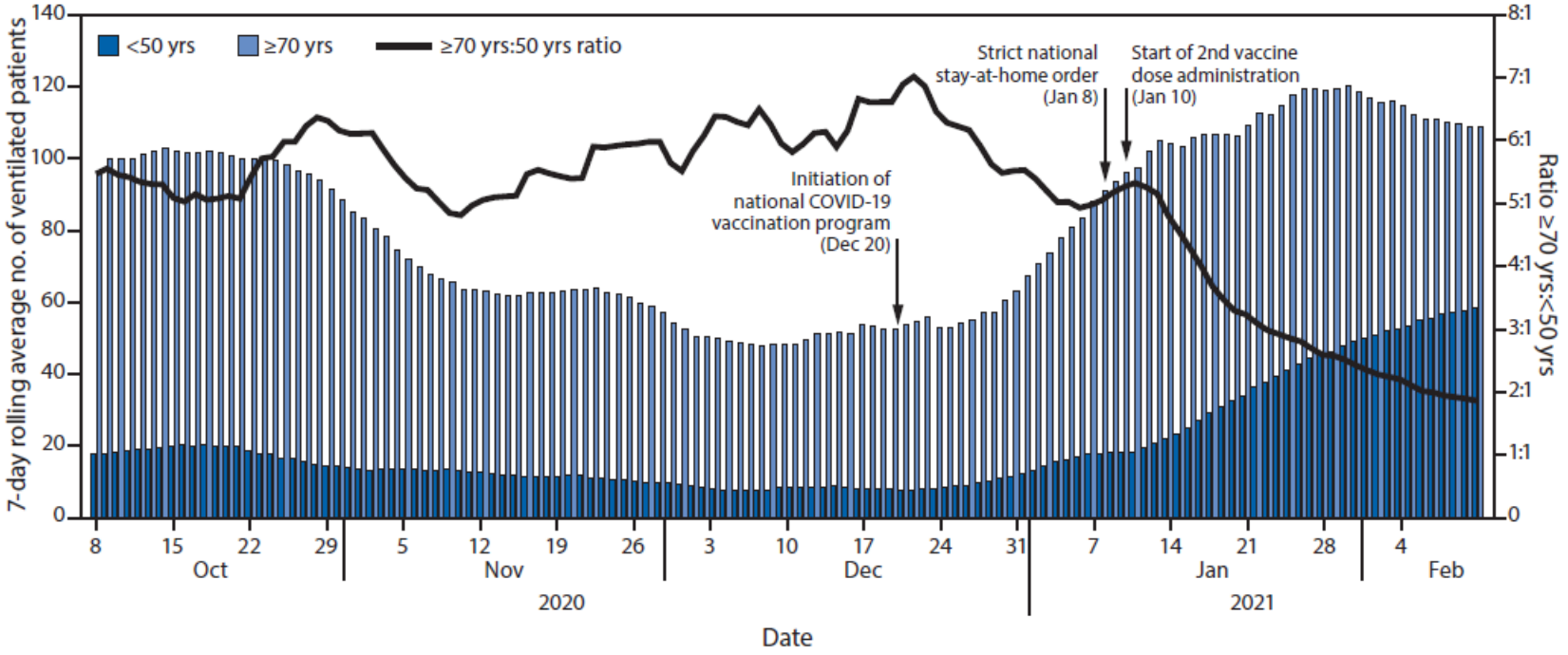
- By February 6th about 85% of the over-60s population group had received at least one dose of a mRNA vaccine. 75% had received their second dose.
- Only about 25% of those aged 0 to 59 years had been vaccinated
- Results:
  - 7-day average of new COVID-19 cases decreased in age 60+ while cases did not decrease in the aged 0 to 59 years
  - New hospitalizations decreased in the over-60s age group and increased in the 0 to 59 years group



Vaccine Efficacy—Real World—Israel

https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e3.htm?s_cid=mm7009e3_x

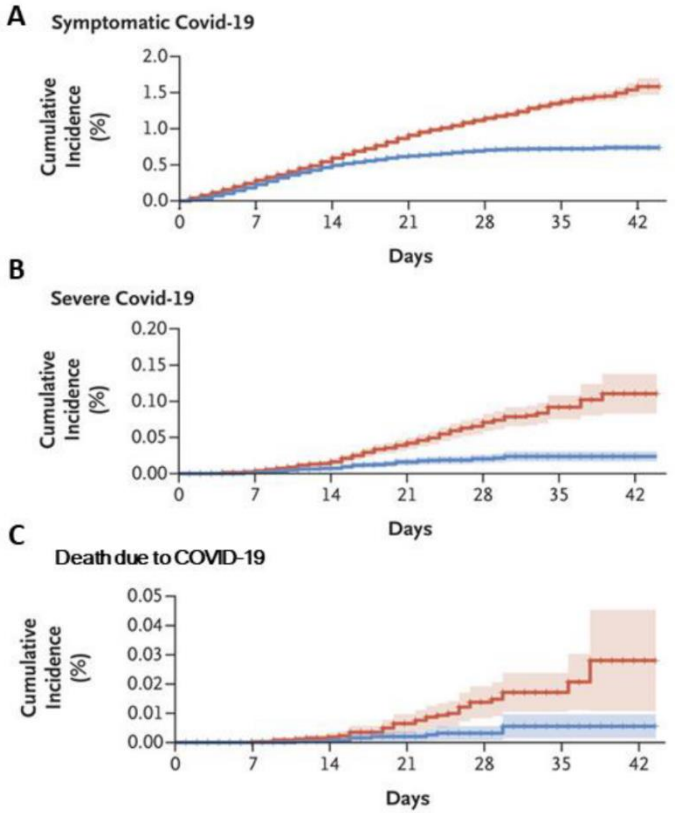
FIGURE 2. Number and ratio of COVID-19 patients aged <50 and ≥70 years requiring mechanical ventilation — Israel, October 8, 2020–February 9, 2021



Vaccinated v. Unvaccinated

- These data provide evidence of real-world effectiveness of the BNT162b2 vaccine for a wide range of COVID-19 outcomes including severe outcomes and death, suggesting that widespread vaccination can mitigate COVID-19 burden.

- Dagan N et al. BNT161b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. New Eng J Med (March 2021)
  - https://doi.org/10.1056/NEJMoa210765



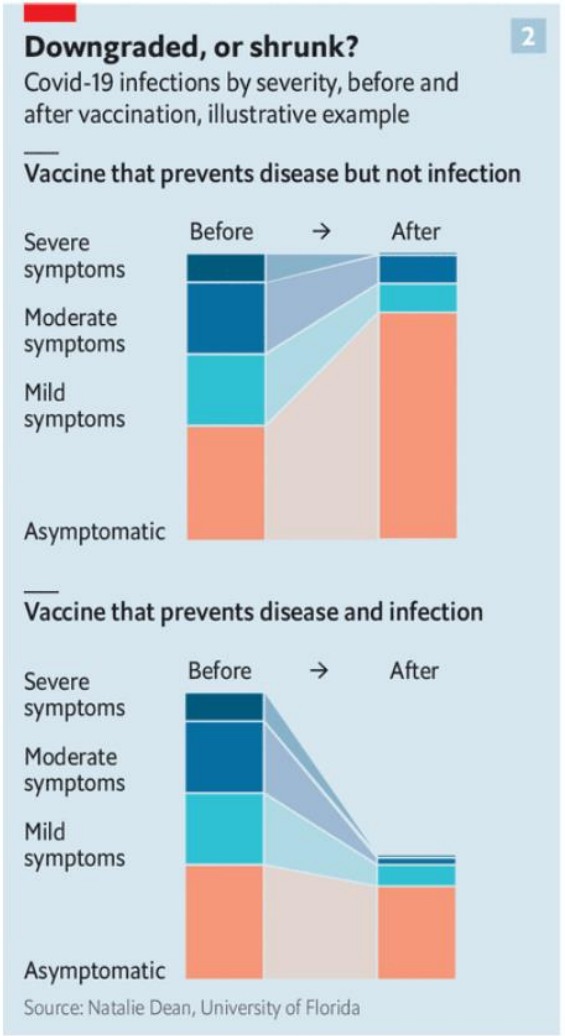
Note: Adapted from Dagan *et al.* Cumulative incidence curves for COVID-19 outcomes (**A.** Symptomatic COVID-19, **B.** Severe COVID-19, **C.** Death due to COVID-19) among **vaccinated** and **unvaccinated** persons, starting from the first dose of vaccination. Shaded areas represent 95% confidence 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.

Vaccines Protect You But Do They Protect Others?

- 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 transmission risk.

- **Scenario One**
  - Vaccine that prevents disease but not infection

- **Scenario Two**
  - Vaccine that prevents disease and infection



Developing Evidence of Transmission Risk

- **Public Health England**
  - Viral loads in vaccinated HCWs tended to be lower than in unvaccinated HCWs, although these results were not statistically significant. While not a placebo-controlled and randomized clinical trial, this study does provide real-world evidence that the Pfizer-BioNTech vaccine could provide protection against infection.
    - https://www.authorea.com/users/332778/articles/509881-single-dose-bnt162b2-vaccine-protects-against-asymptomatic-sars-cov-2-infection?access_token=-hDTQsMUXcCPSpdZV_Lmpg

- **Israel**
  - Between 14 and 20 days after the first Pfizer dose, the vaccine demonstrated 46% efficacy in preventing SARS-CoV-2 infection. At Day 7 or later after the second dose, the vaccine efficacy was 92% in terms of preventing infection.
    - https://www.nejm.org/doi/full/10.1056/NEJMoa2101765
  - Limitation
    - Asymptomatic individuals were not systematically tested for infection

Janssen Efficacy Against Asymptomatic Infection

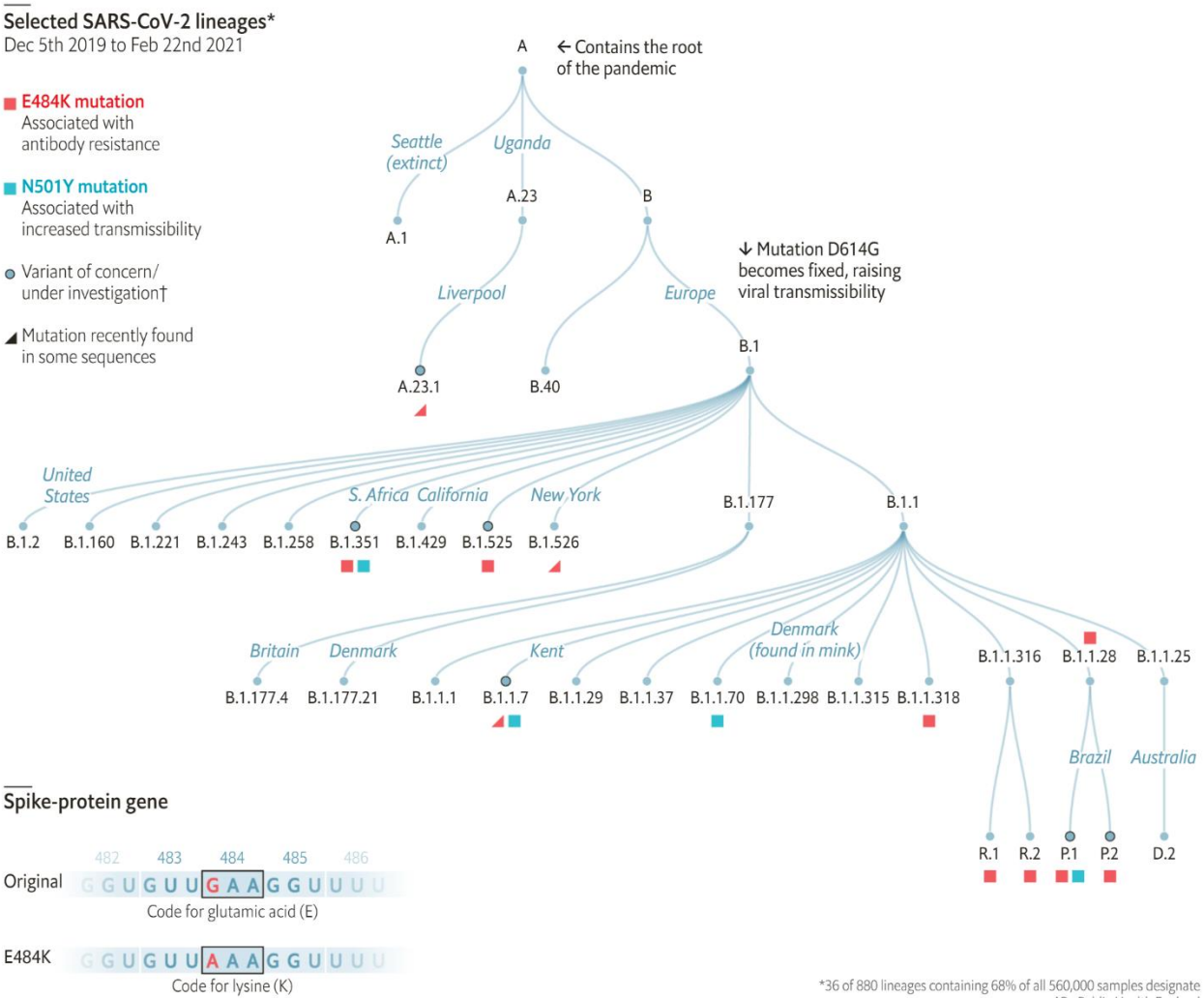
https://www.fda.gov/media/146217/download

- Days 1—29, the data show only modest, non-statistically significant vaccine efficacy against asymptomatic SARS-CoV-2 infection. VE% = 22.6%

	Day 1-Day 29			After Day 29[e]		
	Ad26.COV2.S No. of Cases (Person-yrs)	Placebo No. of Cases (Person-yrs)	VE% (95% CI)	Ad26.COV2.S No. of Cases (Person-yrs)	Placebo No. of Cases (Person-yrs)	VE% (95% CI)
Seroconverted without previous symptoms[c,d]	84 (1109.4)	108 (1103.7)	22.6% (-3.9, 42.5)	10 (310.9)	37 (296.6)	74.2% (47.1; 88.6)

- Analysis after Day 29. VE% = 74.2%
  - Limitations:
    - Although these results may suggest potential efficacy against asymptomatic infection after Day 29, this observation should be interpreted with caution as follow-up time is limited, and only a small percentage of participants had available N-serology data to contribute to this endpoint.

Variants


Selected SARS-CoV-2 lineages*
Dec 5th 2019 to Feb 22nd 2021
E484K mutation
Associated with antibody resistance
N501Y mutation
Associated with increased transmissibility
Variant of concern/ under investigation†
Mutation recently found in some sequences
A
← Contains the root of the pandemic
Seattle (extinct)
Uganda
A.23
B
A.1
Liverpool
Europe
↓ Mutation D614G becomes fixed, raising viral transmissibility
B.1
A.23.1
B.40
United States
S. Africa
California
New York
B.1.177
B.1.1
B.1.2
B.1.160
B.1.221
B.1.243
B.1.258
B.1.351
B.1.429
B.1.525
B.1.526
Britain
Denmark
Kent
Denmark (found in mink)
B.1.316
B.1.28
B.1.25
B.1.177.4
B.1.177.21
B.1.1.1
B.1.1.7
B.1.1.29
B.1.1.37
B.1.1.70
B.1.1.298
B.1.1.315
B.1.1.318
Brazil
Australia
R.1
R.2
P.1
P.2
D.2
Spike-protein gene
482 483 484 485 486
Original
G G U G U U G A A G G U U U U
Code for glutamic acid (E)
E484K
G G U G U U A A A G G U U U U
Code for lysine (K)
*36 of 880 lineages containing 68% of all 560,000 samples designate
†By Public Health England

Variants of Concern

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

- To mutate, viruses need to replicate.
  - Stop or slow replication, you stop/slow mutations

- **Problem**
  - Some mutations or combinations of mutations may provide the virus with a selective advantage:
    - Increased transmissibility
      - Increased period of viral shedding (lengthens the infectiousness period)
      - Increased environmental stability
    - Increased virulence
    - Increased ability to evade the host immune response

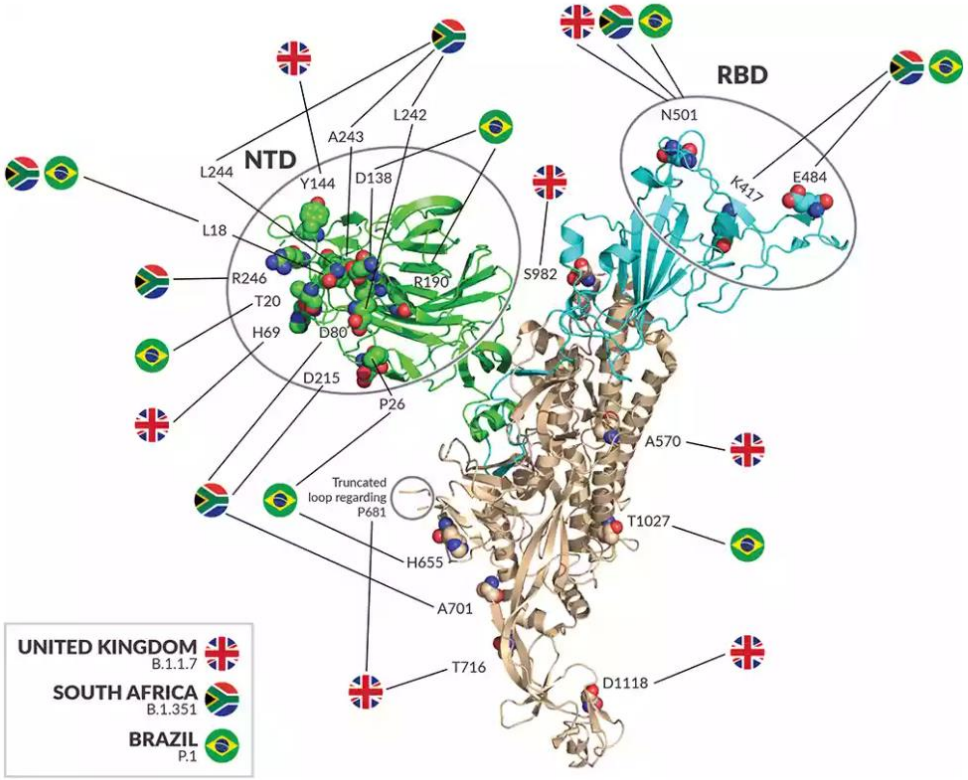
- **Solution**
  - Out vaccinate the variants!

SARS-CoV-2 Variants of Concern

Same Mutations Are Appearing in Different Places

- By country and lineage
  - United Kingdom (B.1.1.7)
  - South Africa (B.1.351)
  - Brazil (P.1, P.2)
  - New York (B.1.526)
  - California (B.1.427/429)

- By mutation
  - 41,000 mutations identified so far falling into 880 lineages
  - Recent MAJOR mutations of the receptor-binding region of the spike protein:
    - N501Y
    - K417N
    - E484K



Prevalence of Variants—U.S.

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

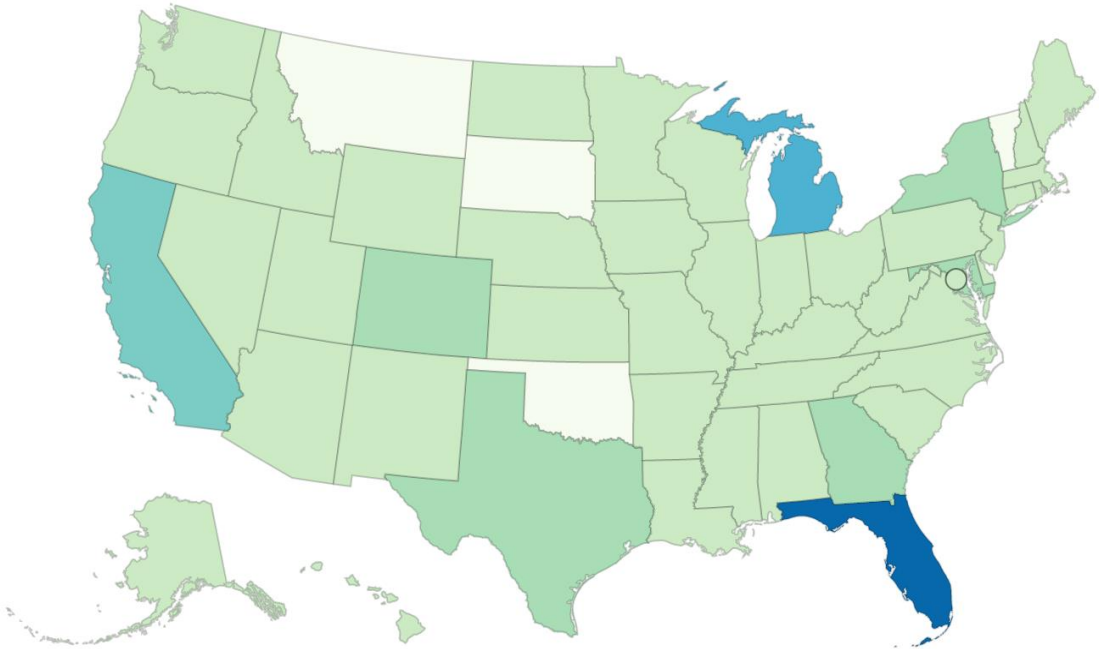
4 March 2021

Variant	Reported Cases in US	Number of Jurisdictions Reporting
B.1.1.7	2672	48
B.1.351	68	17
P.1	13	7

B.1.1.7 Variant

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

4 March 2021



Number of Cases

- 0 to 0
- 1 to 100
- 101 to 200
- 201 to 300
- 401 to 500
- 601 to 700

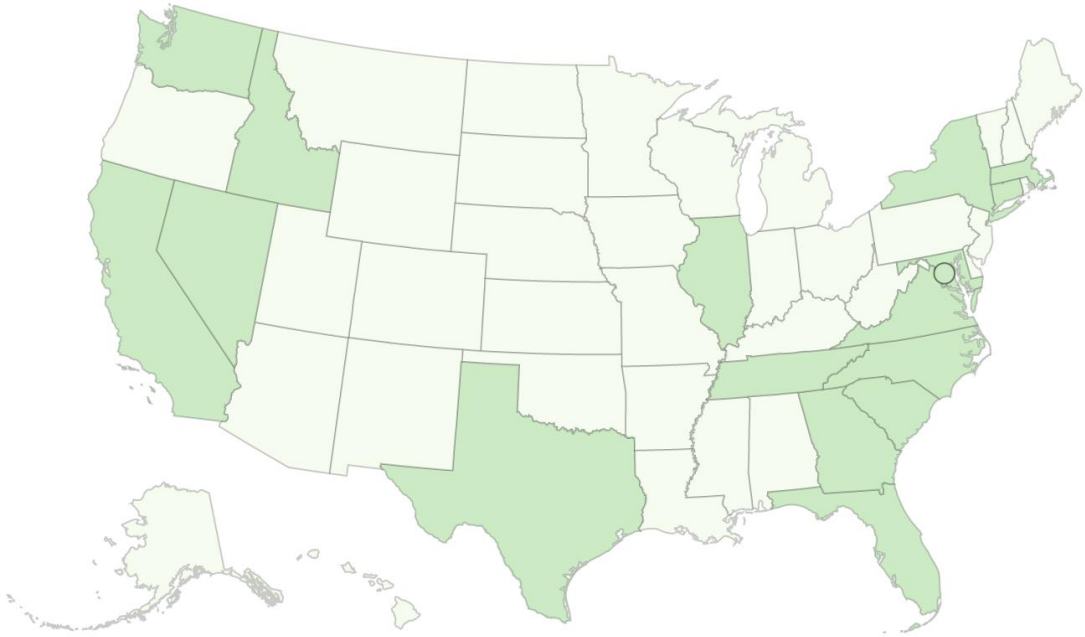
Filters

Variant B.1.1.7

B.1.351 Variant

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

4 March 2021



Number of Cases

- 0 to 0
- 1 to 100
- 101 to 200
- 201 to 300
- 401 to 500
- 501 to 600

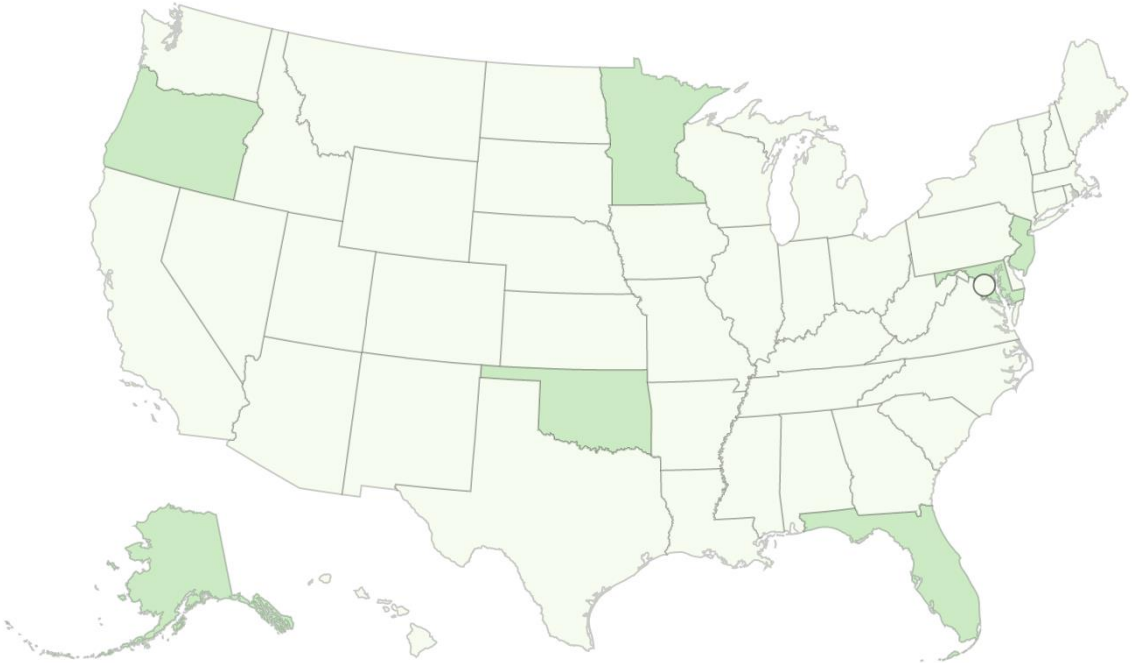
Filters

Variant B.1.351

P.1 Variant

https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

4 March 2021



Number of Cases

- 0 to 0
- 1 to 100
- 101 to 200
- 201 to 300
- 401 to 500
- 601 to 700

Filters

Variant P.1

Vaccination

Production

Distribution

Acceptance

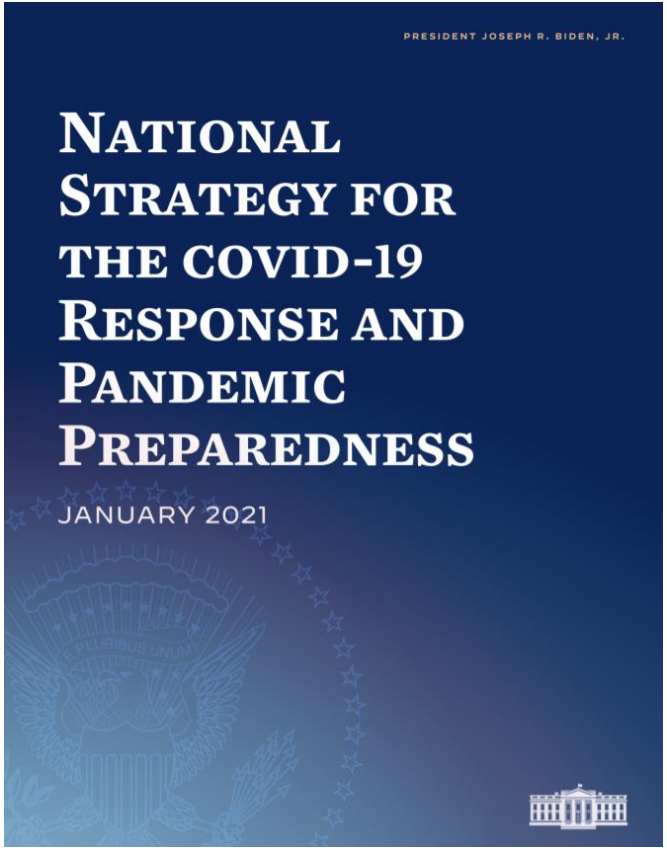
Administration

Pharmacovigilance

National COVID-19 Strategy: Goal 2

https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf

- Loosen the restrictions on who can get vaccinated and when
  - Prevent wasted doses
- Set up more vaccination sites
  - Mass vaccination sites for urban areas
  - Pharmacies, retail, medical offices, community centers
  - Rural health clinics
- Mobilize more medical personnel to administer vaccinations
  - FEMA and National Guard
  - Retired medical personnel
  - Medical and nursing students
- Increase needed vaccine-related supplies through Defense Production Act
- Increase vaccine allotments to States



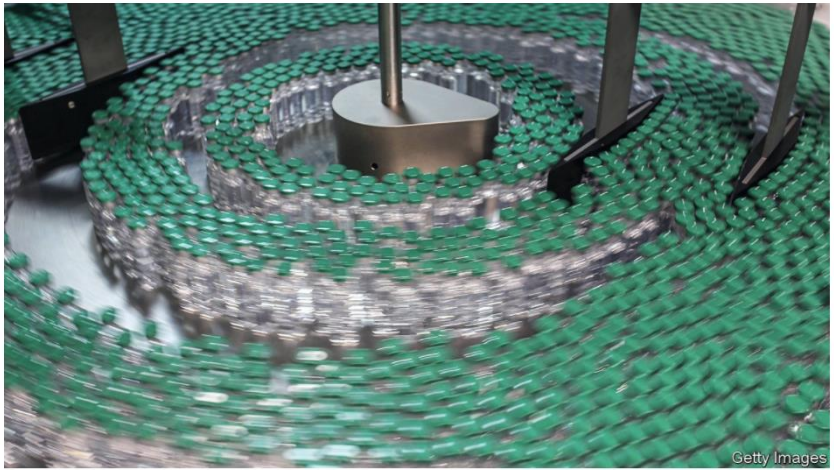
J&J—Merck Partnership

2 March 2021

- Industry competitors Johnson & Johnson (J&J) and Merck & Co. are expected to announce that they will work together to manufacture the J&J-Janssen SARS-CoV-2 vaccine. Currently, there are only approximately 4 million doses available for distribution. J&J was supposed to produce 12 million doses by the end of February, but it fell behind schedule.

- In order to augment production, the US government worked with the 2 pharmaceutical companies to establish a joint partnership to manufacture the vaccine. Merck will convert 2 of its manufacturing facilities to produce the new vaccine.

- Officials from J&J have indicated that the company is on track to produce an additional 16 million total doses by the end of March and more than 100 million total doses by the end of 2021.



Overview of Groups Prioritized by Advisory Committee on Immunization Practices (ACIP)

Phase 1a

- ✓ Healthcare personnel
- ✓ Long-term care facility residents

Phase 1b

- ✓ Frontline essential workers
- ✓ Persons aged 75 years and older

Phase 1c

- ✓ Persons aged 65-74 years
- ✓ Persons aged 16-64 years with high-risk conditions
- ✓ Essential workers not recommended in Phase 1b

Phase 2

- ✓ All people aged 16 years and older not in Phase 1 who are recommended for vaccination

Initiation of phases will be overlapping

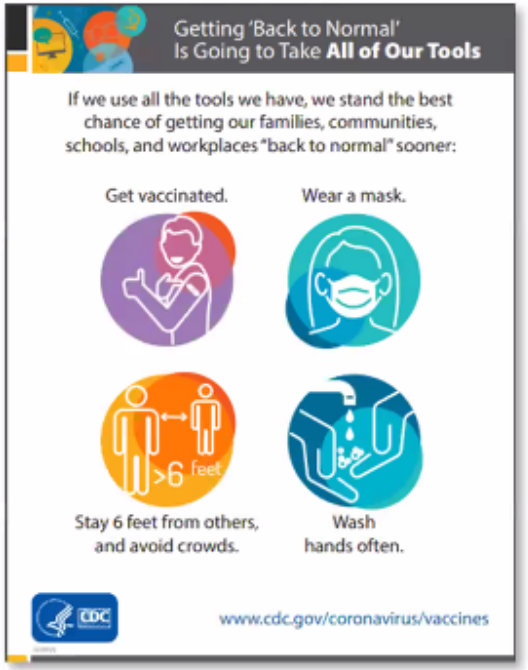
Workplace Vaccination Program

- Employers considering implementing a workplace COVID-19 vaccination program should contact the health department in their jurisdiction for guidance.
- The planning process should include input from management, human resources, employees, and labor representatives, as appropriate.
- Other important preliminary steps include:
  - Obtaining senior management support
  - Identifying a vaccine coordinator
  - Enlisting expertise from local public health authorities, occupational health providers, and pharmacies
- Offer the vaccination at no charge and during work hours.
- Offer flexible paid leave policies for those workers that may experience post-vaccination symptoms.

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

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

Essential Workers

Frontline Essential Workers (~30M)

- First Responders (Firefighters, Police Officers)
- Education (Teachers, Support Staff, Daycare Workers)
- Food & Agricultural Workers
- Manufacturing Workers
- Corrections Officers
- U.S. Postal Service Workers
- Public Transit Workers
- Grocery Store Workers

Other Essential Workers (~57M)

- Transportation & Logistics
- Food Service
- Shelter & Housing (Construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

Frontline Essential Workers: workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

*CISA: Essential Critical Infrastructure Workers: https://www.cisa.gov/news/2020/08/18/cisa-releases-updated-guidance-essential-critical-infrastructure-workers

Special Considerations and Challenges for Vaccination of Frontline Essential Workers

- Large number of frontline workers
- State and local health authorities may need to sub-prioritize vaccination
- Workers may work in one state but live in another
- Coordination and planning for if, where, and when staff are eligible and can be vaccinated
  - Possible use of worksites to administer vaccine
- Transient workforces or workers whose jobs involve interstate transportation may have difficulty getting 2nd dose

Special Considerations and Challenges for Vaccination of Frontline Essential Workers (continued)

- Concerns about vaccine safety among some workers
- Need for culturally appropriate vaccination information in multiple languages
- Rural areas have limited access to health care and health providers
- Methods of communication may be different (e.g. radio, print)
- Rely on community leaders to serve as trusted sources for information
- Some missed days may occur due to post-vaccination side effects
- Critical infrastructure employers have an obligation to manage the continuation of work in a way that best protects the health of their workers and the general public

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/essential-workers.html

Vaccines

Frequently Asked Questions about Vaccination

Who Gets Vaccinated First?

What to Expect at Your Vaccine Appointment

Benefits of Getting Vaccinated

Different Vaccines

Ensuring the Safety of Vaccines

Ensuring Vaccines Work

Toolkits

For Essential Workers

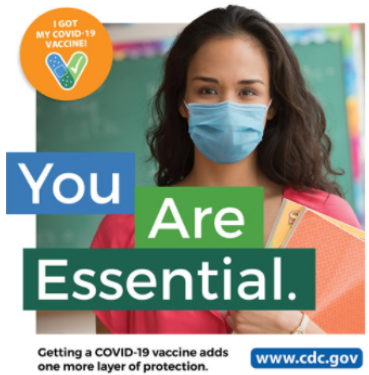
For Community-Based Organizations

Get Email Updates

COVID-19 Vaccine Communication Toolkit for Essential Workers: Getting Started

Updated Jan. 21, 2021 Languages Print

In some states, essential workers already have access to vaccines to help protect them against COVID-19. These vaccines will be available to essential workers across the nation soon. CDC has provided a toolkit to help employers educate their essential workers about this important new prevention tool.



Who is this toolkit for?

This toolkit is designed for employers of essential workers. Essential workers perform duties across critical infrastructure sectors and maintain the services and functions that U.S. residents depend on daily. Examples of the many types of essential workers include police officers, firefighters, and people working in education, child care centers, and grocery stores.

What is the purpose of this toolkit?

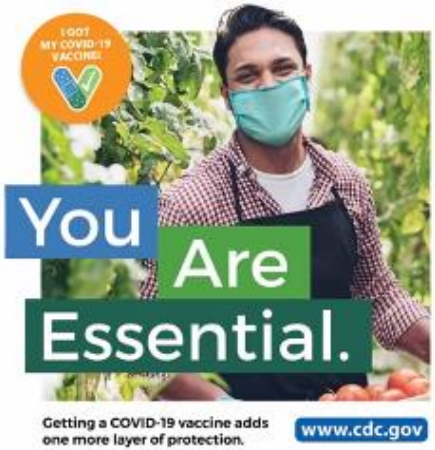
This toolkit will help your organization educate employees about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.

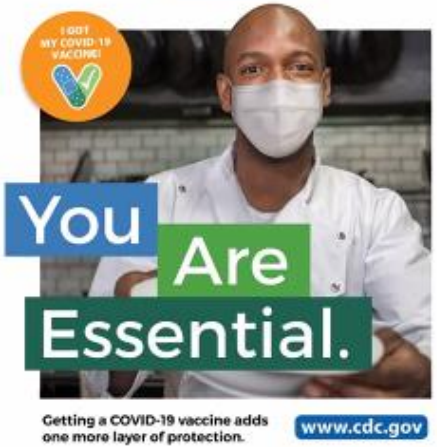
What is in the toolkit?

The toolkit contains a variety of resources that you can use virtually or in person (with proper COVID-19 safety precautions):

COVID-19 Vaccine Communication Toolkit for Essential Workers

- This toolkit will help your organization educate community members about COVID-19 vaccines, raise awareness about the benefits of vaccination, and address common questions and concerns.
  - Key messages
  - Slide deck
  - Frequently Asked Questions
  - Posters/Flyers
  - Newsletter Content
  - Letter to Members
  - Social Media Content





https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/essential-workers.html

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 the CDC, updated daily by 8 pm ET†
Represents all vaccine partners including jurisdictional partner clinics, retail pharmacies, long-term care facilities, Federal Emergency Management Agency and Health Resources and Services Administration partner sites, and federal entity facilities.

Total Vaccine Doses

Delivered	116,363,405
Administered	90,351,750

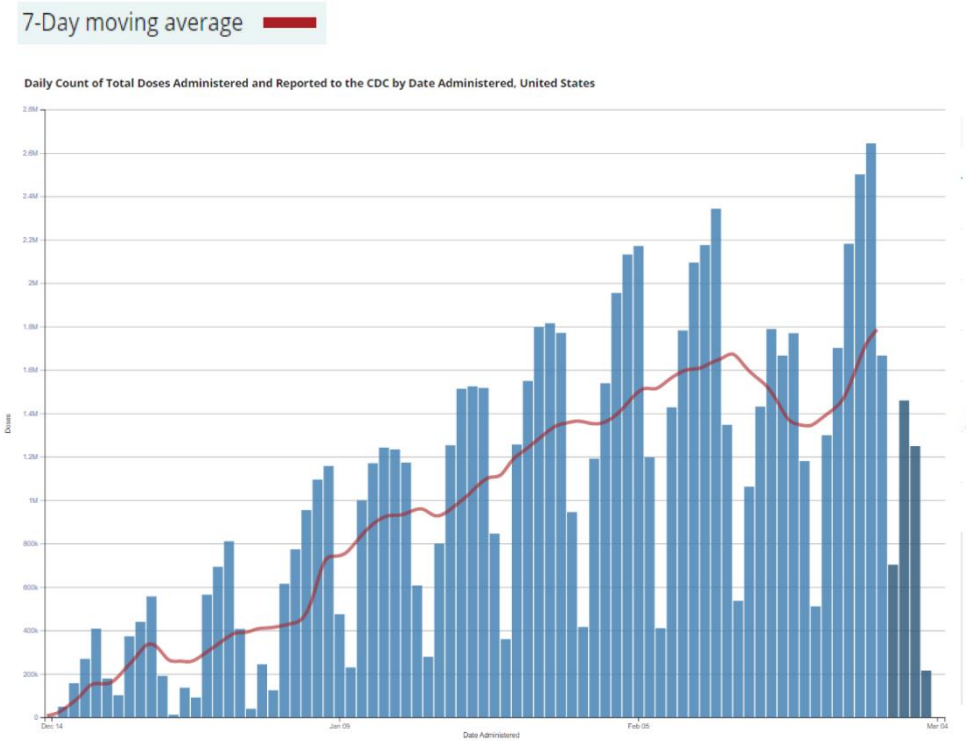
Learn more about the distribution of vaccines.

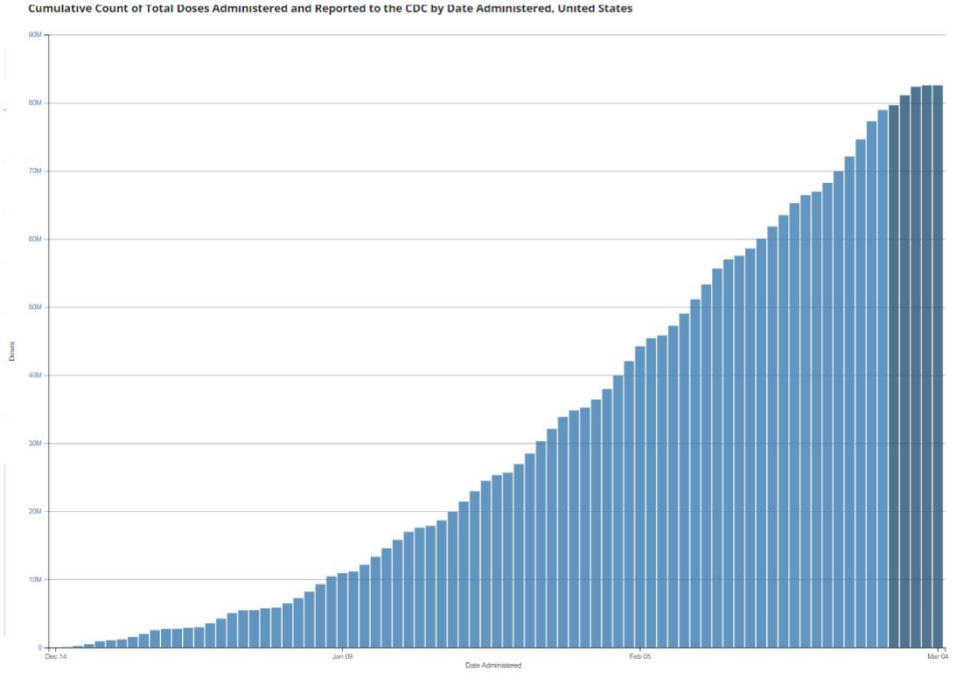
People Vaccinated	Receiving 1 or More Doses	Receiving 2 Doses
Total	58,873,710	30,686,881
% of Total Population	17.7%	9.2%
Population ≥ 18 Years of Age	58,817,059	30,665,771
% of Population ≥ 18 Years of Age	23%	12%

Read more about how these data are reported.

CDC | Data as of: Mar 07 2021 6:00am ET | Posted: Mar 7 2021 12:25PM ET

Vaccination Progress—U.S.





Key Metrics

	Total to date	Most recent day*	7-day daily average	Week-on-week change
Cases	28,714,163	67,484	60,674	-9.7%
		confirmed only:		
COVID hospital admissions	1,828,923	5,125	5,225	-16.1%
		confirmed and suspected:		
	3,405,086	10,781	10,810	-10.9%
Deaths	521,294	2,230	1,745	-17.5%
RT-PCR tests reported**	339,812,338	*omitted due to reporting lag*	1,066,458**	-11.0%**
Test positivity**	8.9%		4.4%	-11.4%
Vaccine doses administered	87,912,323	+2,904,229	+2,158,020	+31.2%

Work

Worker Vaccination: Mandatory or Voluntary?

https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

- **Implementation Issues**
  - Staffing
  - Supplies

- **Legal**
  - **State and Local Laws**
  - **Federal Laws**
    - Americans with Disability Act
      - 42 U.S.C. § 12101 (1990)
    - Title VII of the Civil Rights Act of 1964 of Civil Rights Act of 1964
      - § 7, 42 U.S.C. § 2000e et seq (1964).
    - Genetic Information Nondiscrimination Act
      - 42 U.S.C. § 300gg-51 et seq

VACCINATING: STAFFING

- [Police]
- [IT]
- Administrator (check-in)
- Pharmacist (talk)
- Host/ess (directs)
- Injectors
- Documentors
- Observation Nurses (2)
- EMS (cleans every chair, Oxyvir1)
- MD (ACLS trained)
- [Administrator (2nd booking)]

SUPPLIES

- Signage
- Folders (VIS/VSAFE)
- Gurney, Linens, BP/O2
- Modified Crash Cart*
  - Ambu Bag, O2 bottle
  - Oral airways
  - IV starts
- Medications
  - PO H1, H2, NSAID
  - IV H1, Steroid
  - IM Epinephrine x 3

Legal Issues—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

- **Vaccination as a Medical Examination**
  - K.1. Is vaccination administration to an employee by an employer (or 3rd party contractor) a "medical examination" for purposes of the ADA?
    - No
- **Pre-Vaccination Questions**
  - K.2. Vaccination is not itself a medical examination, but pre-screening questions may implicate the ADA's provision on disability discrimination.
- **Show Proof of Vaccination**
  - K.3. Is requiring employee to show proof of receipt of a COVID-19 vaccination a disability-related inquiry?
    - No, but asking ***why*** may elicit information about a disability and such questions would have to be "job-related and consistent with business necessity."

Legal Issues: EEOC Guidance

https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

- **Medical Disability**
  - K.5. If employer *requires* vaccination, what should employer do when employee indicates that he or she is unable to receive a vaccination because of a disability?
    - ADA allows a qualification standard that includes "a requirement that an individual not pose a ***direct threat*** or the health or safety of individuals in the workplace."
      - If safety-based qualification standard screens out individuals with a disability, employer must show that an unvaccinated employee would pose a ***direct threat*** due to a significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation
        - Employer must satisfy a 4-factor test to determine whether a direct threat exists.

    - If employer determines that an employee who cannot be vaccinated poses a **direct threat**, employer cannot exclude employee from the workplace—or take any other action—unless there is not way to provide reasonable accommodation (absent *undue hardship, i.e.,* significant difficulty or cost) that would eliminate or reduce the direct threat risk. If there is a direct threat that cannot be reduced by accommodation, exclusion possible, but not automatic termination.

Legal Issues: EEOC Guidance

https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

- **Sincerely-Held Religious Practice or Belief**
  - K.6. If employer requires vaccination, what should employer do when employee indicates that he or she is unable to receive a vaccination because of a sincerely-held religious practice or belief?
    - Employer must provide a reasonable accommodation for the religious belief, practice, or observance unless it would pose an ***"undue hardship"*** under Title VII, i.e., more than "de minimis" cost or burden on employer.
    - Definition of religion is broad. "Employer should ordinarily assume that an employee's request for religious accommodation is based on a sincerely held religious belief."
    - If, however, the employer has an objective basis for questioning either the religious nature or the sincerity of a particular belief, practice, or observance, the employer would be justified in requesting additional supporting information."

Legal Issues: EEOC Guidance

https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

- **Employer Inability to Provide Reasonable Accommodation**
  - K.7. What happens when employer cannot exempt or provide a reasonable accommodation to an employee who cannot comply with a mandatory vaccination?
    - If employee cannot get vaccinated because of disability or sincerely held religious belief, practice or observance, and there is no reasonable accommodation possible, then it would be lawful to the employer to ***exclude*** the employee from the workplace, but not automatic termination.
    - Other rights may apply under the EEO laws or other federal, state and local authorities.

Wellness Incentives (Vaccinations)

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

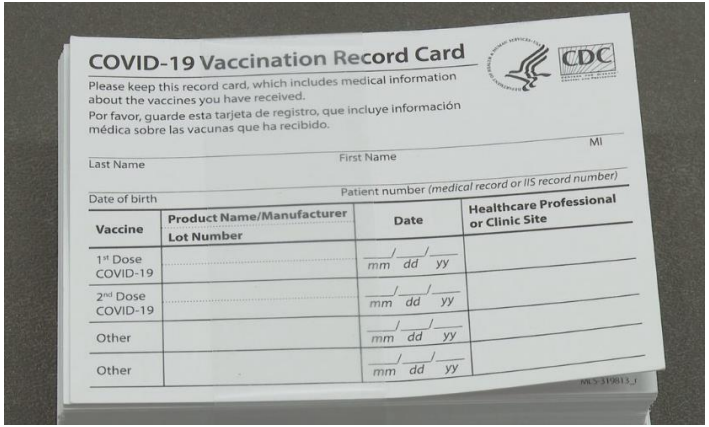
- January 20
  - Earlier January 2021 rules were vacated in Biden Administration under its regulatory freeze.

- 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."
- Current
  - Many employers want to incentivize their employees to receive a COVID-19 vaccination.
  - Complex area of law and employers need to consider the EEOC's proposed and final ADA rules as well as the implications under ERISA, COBRA, ACA, HIPAA, GINA, the U.S. Code, and the FLSA.

Vaccination Certificates: Vaccine Passports or Workplace Reentry

- **Advantages**
  - Proof of vaccination could speed international travel and economic reopening.
  - Growing number of countries/firms planning to introduce vaccine passports.
  - Digital certificates could be added onto biometric passports or other smart ID cards that already contain a small chip used to confirm holder's identity for entry on commercial airlines or entry into workplace

- **Obstacles**
  - **Health**
    - Unknown how effective vaccinations are at preventing onward transmission of COVID-19—variants render some vaccine less effective. Could be misused as "immunity certificates."
  - **Ethical**
    - **C**ould cause discrimination between those who can show proof of vaccination and those who cannot and could reinforce vaccine hesitancy.
  - **Operational**
    - Passports for international travel are regulated by governments and have decades of history behind them, but there's no such unified system for vaccine passports, which are being introduced by governments and businesses with different standards, making them a target for fraud.



Selected Return-to-Work Issues

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- **Rules for COVID-19 Workplace**
  - Possibility
    - If public-health authorities' worst predictions come true, SARS-CoV-2 may never disappear. That means workplaces will have to live with the virus and develop procedures to conduct work with endemic virus.
  - Workforce Risk Characterization
    - Vaccinated—Vaccinated
    - Vaccinated—Unvaccinated
    - Unvaccinated—Unvaccinated

- **For example: What are the rule for quarantine for vaccinated workers as close contacts?**
  - Vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet all of the following criteria:
    - Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
    - Are within 3 months following receipt of the last dose in the series
    - Have remained asymptomatic since the current COVID-19 exposure
  - Persons who do not meet all 3 of the above criteria should continue to follow current CDC quarantine guidance after exposure to someone with suspected or confirmed COVID-19.

Selected Return-to-Work Issues

- **Post-Acute Sequelae of COVID-19 (PASC)**
  - University of Washington researchers found that approximately 30% of COVID-19 patients experienced persistent symptoms for up to 9 months following illness. That could correlate to more than 8 million Americans to date.
    - *Sequelae in Adults at 6 Months After COVID-19 Infection* (JAMA Network Open)(19 February)
      - https://doi.org/10.1001/jamanetworkopen.2021.0830
  - NIH) has announced a $1.5B over 4 years into research on PASC
  - Workplace Issues
    - Medical disability under Social Security Administration
    - Reasonable accommodation in the workplace under Americans with Disabilities Act

- **COVID-19 Contact Tracing Wearables in the Workplace**
  - Welcome back to the office—please wear this tracking device!
  - Mobile contact-tracing technology has emerged as a measure to track population movements and alert individuals when they come into contact with an infected person.
    - https://www.brookings.edu/techstream/contact-tracing-apps-face-serious-adoption-obstacles/

The New *Coronormal?*

- Plan for COVID-19 as an endemic disease, not just a 2020-2021 emergency that will pass
  - Workplace hazard assessments and infection control measures
- Increasing vaccination of essential workplaces and increasing acceptance for the hesitant
- Increased surveillance of SARS-CoV-2 variants
  - Increased transmissibility
  - Increased virulence
  - Ability to evade vaccine-related immunity
- Tweaking vaccines to confer protection against variants—booster vaccinations?
- Individual non-pharmaceutical interventions
  - Masks, distancing, handwashing
- Organizational and societal interventions
  - Managing indoor workplaces with workers in close proximity
  - Managing indoor ventilation
  - Determining whether vaccine passports will be used for travel
  - Limiting lockdowns and closures

When You've Been Fully Vaccinated

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html **(8 March 2021)**

- **What's changed If you've been fully vaccinated:**
  - You can gather indoors with fully vaccinated people without wearing a mask.
  - You can gather indoors with unvaccinated people from one other household (for example, visiting with relatives who all live together) without masks, unless any of those people or anyone they live with has an increased risk for severe illness from COVID-19.
  - If you've been around someone who has COVID-19, you do not need to stay away from others or get tested unless you have symptoms. However, if you live in a group setting (like a correctional or detention facility or group home) and are around someone who has COVID-19, you should still stay away from others for 14 days and get tested, even if you don't have symptoms.

- **What hasn't changed for now, if you've been fully vaccinated:**
  - Still wear a mask, stay at least 6 feet apart from others, and avoiding crowds and poorly ventilated spaces. Take these precautions whenever you are in public; gathering with unvaccinated people from more than one other household; and visiting with an unvaccinated person who is at increased risk of severe illness or death from COVID-19 or who lives with a person at increased risk
  - You should still avoid medium or large-sized gatherings.
  - You should still delay domestic and international travel. If you do travel, you'll still need to follow CDC requirements and recommendations.
  - You should still watch out for symptoms of COVID-19, especially if you've been around someone who is sick. If you have symptoms of COVID-19, you should get tested and stay home and away from others.
  - You will still need to follow guidance at your workplace.

CDC Resources

- **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!

Evaluation – John Howard, MD

SESSION EVALUATION (all participants please complete)

- Please scan the QR code using your phone's camera or the QR app on your phone
- Or enter the evaluation link into your browser
- Or request the evaluation link from Ann
- Please complete and submit the evaluation

https://harvard.az1.qualtrics.com/jfe/form/SV_830VRIwiRyay7yu

Questions: abackus@hsph.harvard.edu
Thank you.