HIGHLY PRELIMINARY

Update on the COVID-19 Vaccines

Meg Fisher, MD

July 28, 2021

Disclaimer

- Information about COVID-19 and SARS-CoV-2, the virus that causes the illness is evolving daily
- Recommendations change frequently
- What you hear today may be outdated soon
- Trusted sources of up-to-date information
  - NJ Department of Health - www.nj.gov/health/
  - Centers for Disease Control and Prevention - www.cdc.gov

What is COVID-19 and how does it spread?

COVID-19 is a disease caused by a virus**.** It can be serious and have lasting effects.

COVID-19 is spread easily, often through close contact between people (within about 6 feet)

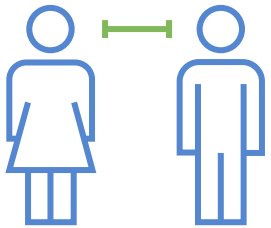
When people with COVID-19 breathe, talk, cough, or sneeze, they produce droplets that can **infect others nearby**

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

Transmission

How to help prevent the spread

Wear a mask that covers your nose and mouth



Stay at least 6 feet (about 2 arms lengths) from others

Avoid crowds and sick people

Wash your hands often

Get vaccinated

Source: https://www.cdc.gov/coronavirus/2019-ncov/your-health/need-to-know.html

COVID-19 Basics

COVID-19 is real and can be serious

- Disease varies from asymptomatic to mild upper respiratory illness to pneumonia to multiorgan involvement and death – to date, 609,012 deaths in US, 23, 860 in NJ
- Disease in children usually either asymptomatic or mild but not always, 349 deaths in US, 7 in NJ
    - Multisystem inflammatory syndrome – Children (MIS-C) is a rare post-infectious complication – as of June 28, 2021 - 4196 cases, 37 deaths, 130 in NJ, 0 deaths

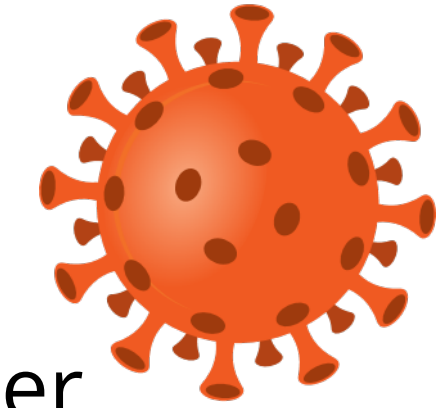
covid19.nj.gov/vaccine

COVID-19 vaccines are

SAFE **EFFECTIVE** **FREE** for all

You can get a vaccine if you are **uninsured,** and / or **undocumented**

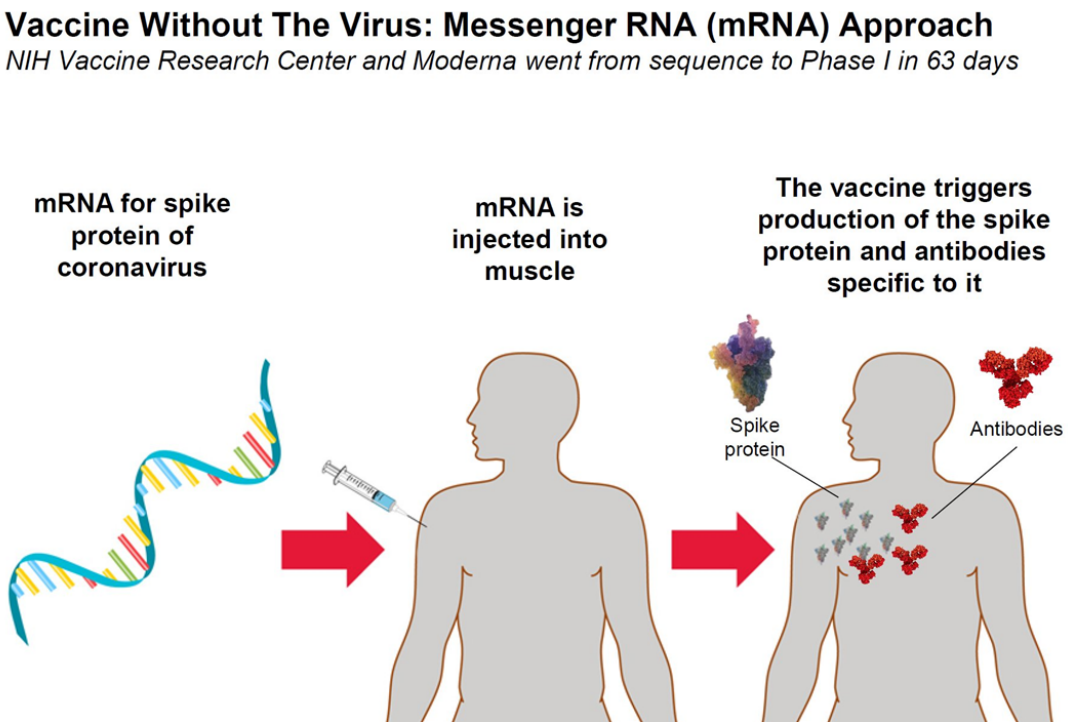
COVID-19 Vaccines



- Messenger RNA (mRNA) vaccines
  - Pfizer – 12/11/20 – for ages 16 years and older
  - Moderna – 12/18/20 – for ages 18 years and older
- Adenovirus vector
  - J&J Janssen – 2/27/21 – for ages 18 years and older
  - AstraZeneca – not available in US

About mRNA COVID-19 Vaccines

- Messenger RNA codes for the spike protein of the virus
- Carrier is a lipid nanoparticle
- Lipid allows the mRNA to enter cells
- Code is read and spike protein produced
- Immune system responds with antibodies and cell mediated immunity

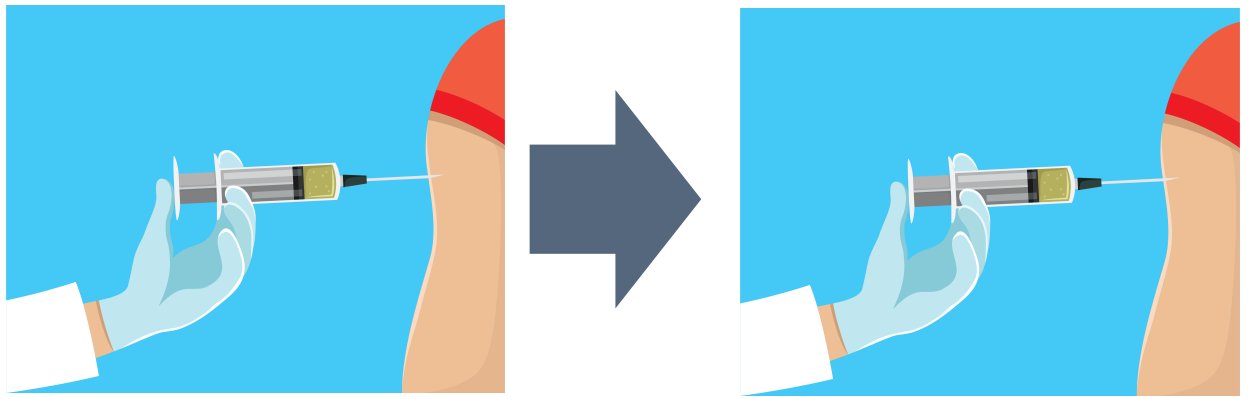


mRNA COVID-19 Vaccines

- Pfizer BioNTech (super cold freezer), dose 2 at 3 weeks
- Moderna (must be refrigerated), dose 2 at 4 weeks

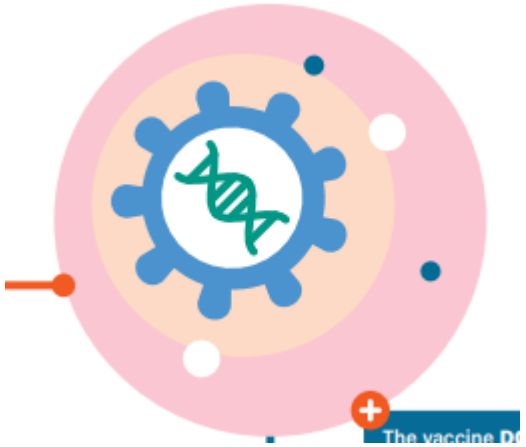
- Both doses should be the <u>same</u> vaccine

1st Dose **2nd Dose**

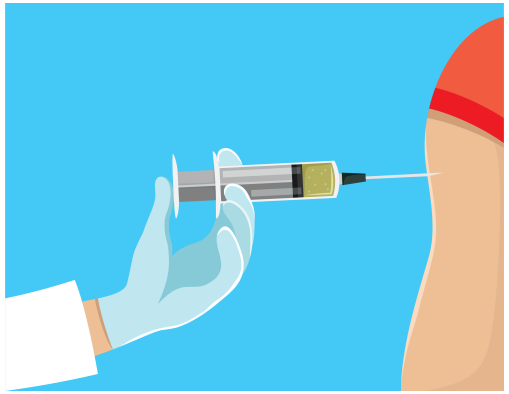


J&J Janssen COVID-19 Vaccine

- Code for the spike protein inserted into an altered human adenovirus (Ad26.COV2.S)
- Replication incompetent virus
- Adenovirus enters cells and releases code for the spike protein
- Immune systems responds to the spike protein

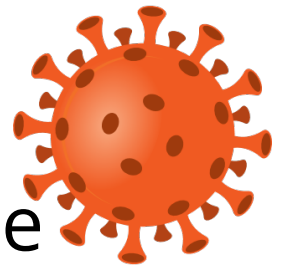


Single dose



How Were Vaccines Developed So Quickly?

- Messenger RNA vaccines and adenovirus vector vaccines are new but not unknown
- The research was basically already done!
  - The virus that causes COVID-19 (SARS-CoV-2) is VERY similar to other viruses (SARS and MERS), which had a lot of vaccine research starting in 2003
- Clinical trials overlapped instead of running one at a time
- Vaccine makers were able to begin production early to have supply ready as soon as vaccine authorized



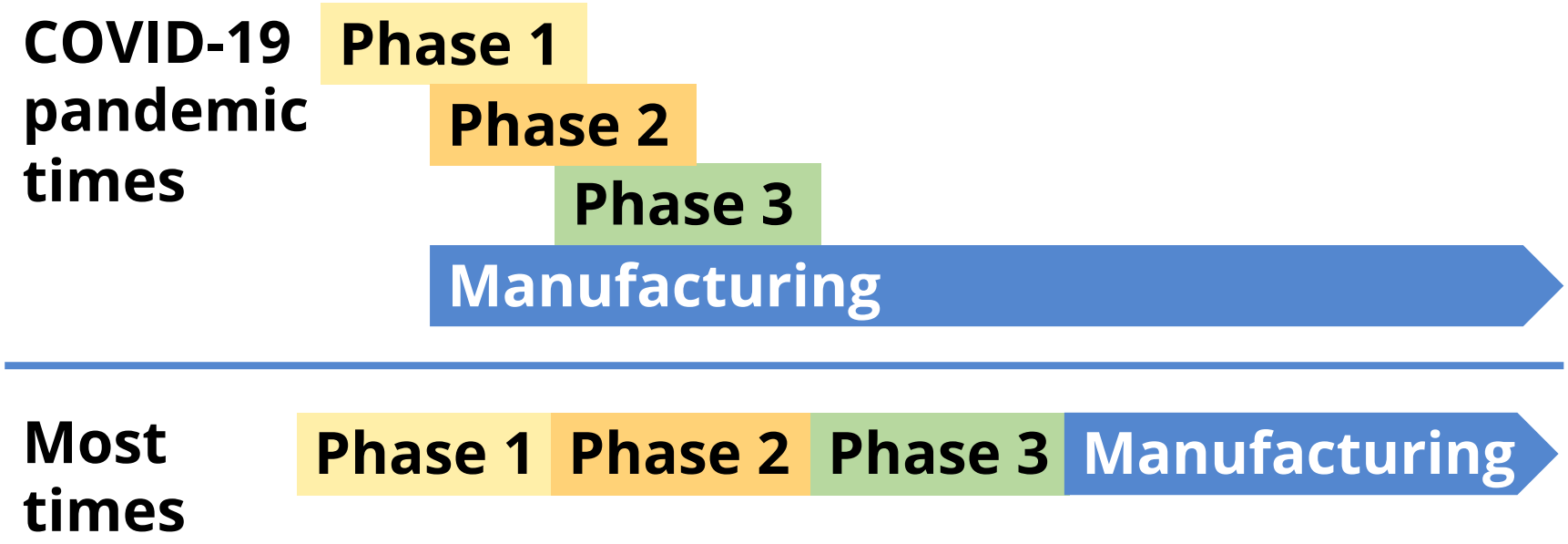
Krammer, F. SARS-CoV-2 vaccines in development. *Nature* **586,** 516–527 (2020). https://doi.org/10.1038/s41586-020-2798-3.

How were the vaccines developed so quickly?

We've had research on a similar virus and the vaccine technology for many years.

Testing a vaccine usually occurs in phases

For the COVID-19 vaccine, **phases overlapped** and **manufacturing efforts began early** so we could have vaccines available as soon as it was authorized



Source: https://www.cdc.gov/vaccinesafety; https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts

About the 3 COVID-19 vaccines:

	Pfizer / BioNTech	Moderna	Johnson & Johnson
Authorized by FDA for Emergency Use	12/11/20 ✓	12/18/20 ✓	2/27/21 ✓
Clinical trials	Tested on >43,000 people	Tested on >30,000 people	Tested on >43,000 people
Dose information	2 doses, 3 weeks apart	2 doses, 4 weeks apart	1 dose
Trial findings	**Similar efficacy findings across genders, racial and ethnic groups, and underlying diseases.**		
Side effects	**Serious side effects are rare. Common side effects include pain at the injection site, fatigue, headache, muscle aches, fever, and chills.**		

Clinical Trials for Authorized Vaccines

- All trials include people of different race and ethnicity
- All trials include people of different ages
- All trials include people with underlying conditions
- There are no head-to-head trials of efficacy
- Trials were done at different times and in different locations
- All trials are ongoing for another 2 years
- Trials are in progress for children
  - On 5/10/21, Pfizer granted EUA for children 12 to 18
  - Moderna applied for age extension on 6/10/21

Side Effects of mRNA COVID-19 Vaccines

- Most common complaint was pain at the injection site
  - Other common symptoms included fatigue, fever, and headache
  - These are common side effects after getting vaccinated
- Risk for severe reaction to the vaccine about 0.5%
- People with a history of severe allergies (anaphylaxis) to food or medicine should talk to their doctor before taking the vaccine
- Side effects less common in people over 50 years of age
- Side effects more common after the second dose

https://www.fda.gov/media/144246/download; https://www.fda.gov/media/144434/download
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

Anaphylaxis and mRNA COVID-19 Vaccines

- Pfizer-BioNTech
  - 21 cases after 1,893,360 first doses (11.1 cases per million doses)
  - 71% within 15 minutes of vaccination; 86% within 30 minutes
  - 90% of cases in women; 81% of cases had a history of allergic reactions
- Moderna
  - 10 cases of anaphylaxis after administration of a reported 4,041,396 first doses (2.5 cases per million doses administered)
  - 90% within 15 minutes of vaccination
  - 100% women; 90% history of allergic reactions

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm

Recommendations

- Ensure supplies available to manage anaphylaxis, especially epinephrine in prefilled syringes or autoinjectors
- Screen potential vaccine recipients to identify persons with contraindications and precautions
- Observation periods, 15 or 30 minutes depending on history
- Recognize the signs and symptoms of anaphylaxis early
- Treat suspected anaphylaxis with intramuscular epinephrine immediately
- Instructed people to seek immediate medical care if they develop signs or symptoms of an allergic reaction after they leave
- Report adverse events vaers.hhs.gov/reportevent.htmlexternal icon.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm

Myocarditis and Pericarditis

- Increased reports since April 2021
- Following mRNA vaccines
- Most in adolescents and young adults
- More common following second dose
- Most patients responded well to medications and recovered quickly
- CDC continues to recommend vaccination for everyone 12 years and older
- Monitoring continues

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

Side Effects of the Adenovirus Vector COVID-19 vaccines

- Most common complaint was pain at the injection site
  - Other common symptoms included fatigue, fever, and headache
  - These are common side effects after getting vaccinated
- Side effects less common in people over 60 years of age
- Single dose

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html

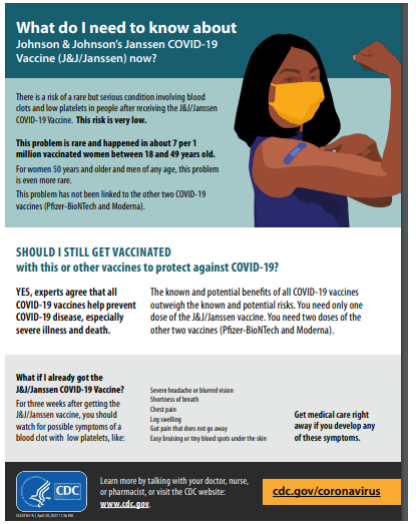
Serious Side Effects

- Thrombocytopenia and Thrombosis with J&J vaccine
  - Cerebral venous sinus thrombosis and other thromboses
  - Single case during studies: 25-year-old male
  - Six additional cases: women 18 to 48 years old, one fatal
  - Onset within 6 to 13 days of vaccination
  - PF4 HIT (Platelet Factor 4 Heparin Induced Thrombocytopenia) antibody positive

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

US FDA and CDC Recommendations

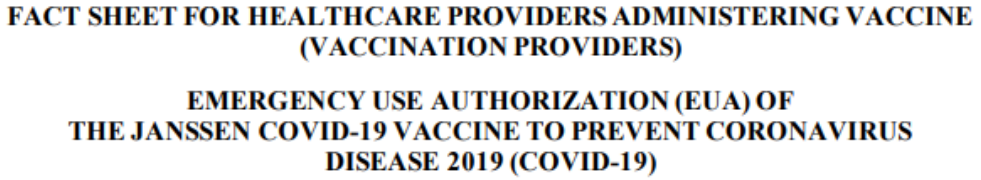
- Pause on use of J & J vaccine 4/13/21; reassessed; use resumed 4/23/21
- Vaccinees - seek medical treatment urgently for any of the following:
  - Severe headache or blurred vision
  - Shortness of breath
  - Chest pain
  - Leg swelling
  - Gut pain that does not go away
  - Easy bruising or tiny blood spots under the skin
- Healthcare providers – maintain awareness
  - Report adverse events vaers.hhs.gov/reportevent.htmlexternal icon.



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

Guillain-Barré Syndrome

- Ascending paralysis
- Usually self-limited with full recovery
- Incidence slightly more common after J&J vaccine than baseline
  - 100 cases reported after 13 million doses
  - Baseline is 3000 to 6000 cases per year
- Onset about 2 weeks after immunization
- FDA added warning to J&J EUA fact sheet on 7/12/21



FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE
(VACCINATION PROVIDERS)

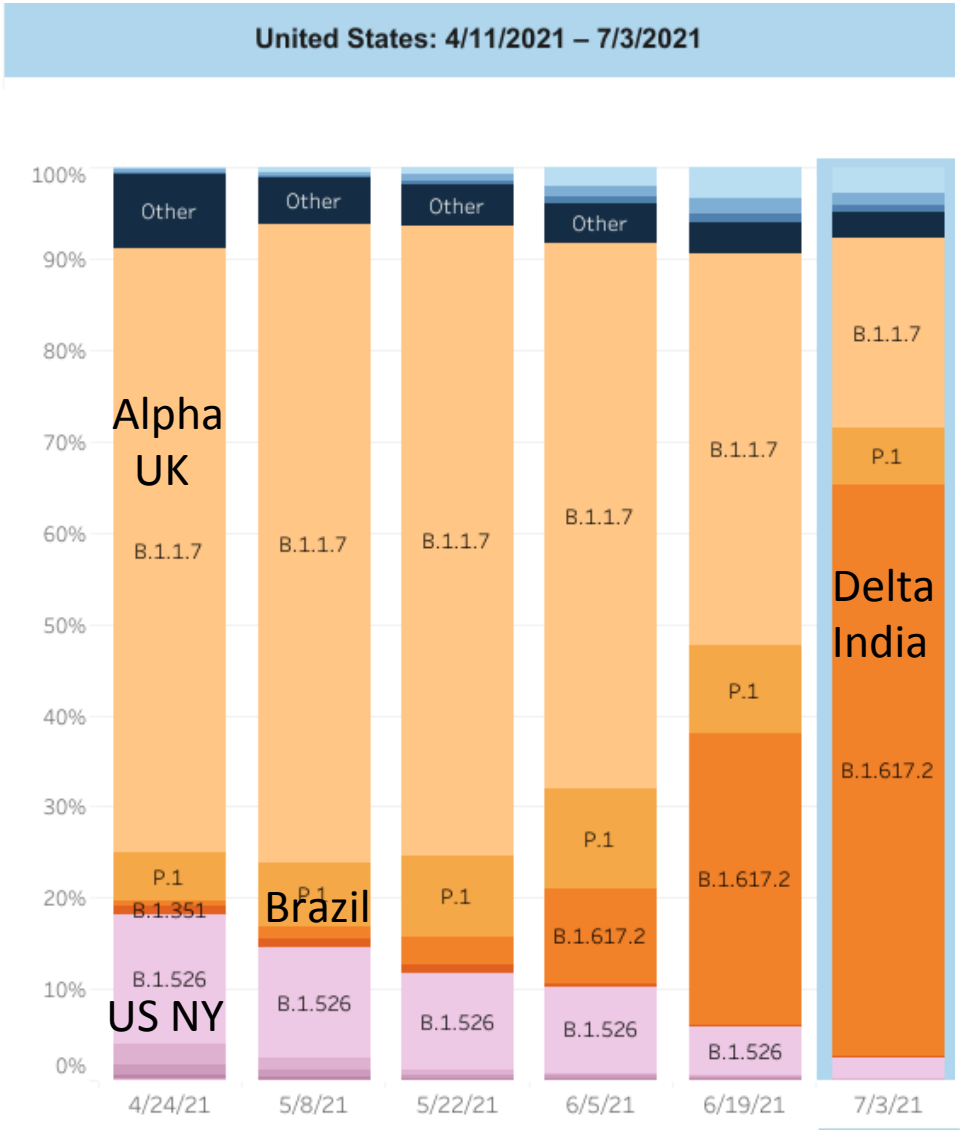
EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)

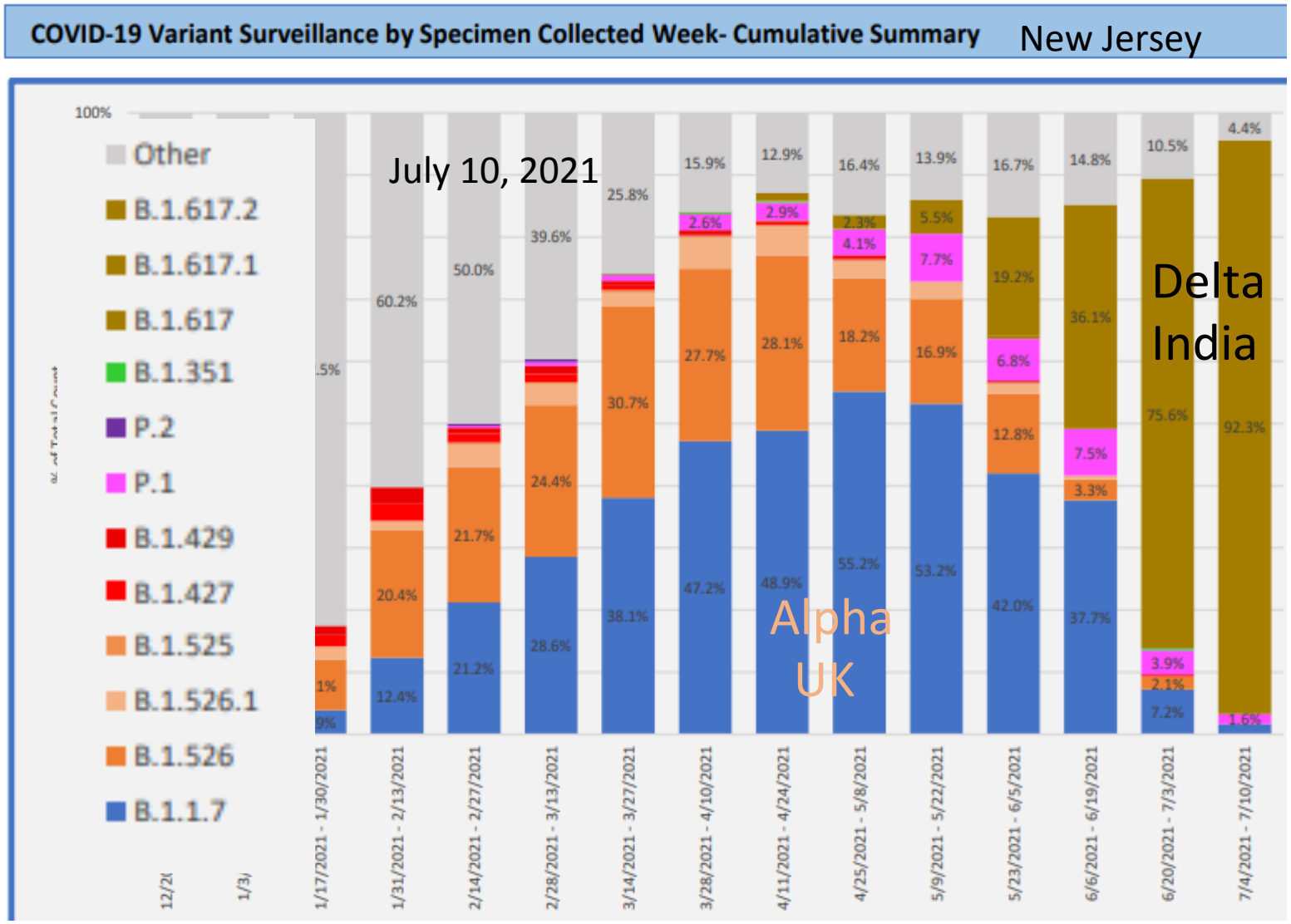
https://www.fda.gov/media/146304/download

COVID-19 Variants

- Arise as viruses multiply
- Variants of interest – changes in binding protein, therapy, possible increased illness and transmission
  - Many: arising in US and globally
- Variants of concern – increased transmission and illness, decreased susceptibility to antibodies and therapy
  - B1.1.7 alpha UK; B1.351 beta So Africa; B1.617.2 delta India; P1 gamma Japan/Brazil
- Variants of high consequence – reduced susceptibility to preventive measures and countermeasures
  - None yet

COVID-19 Variants

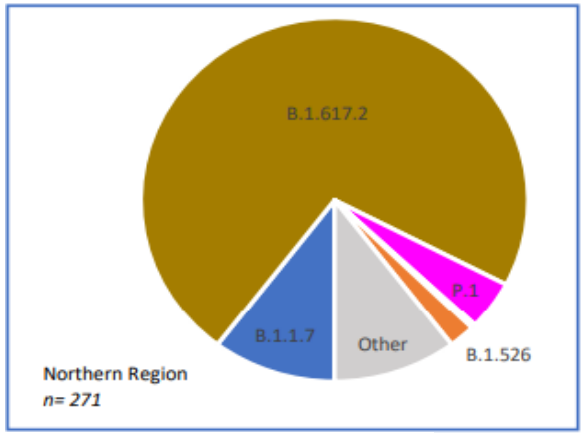


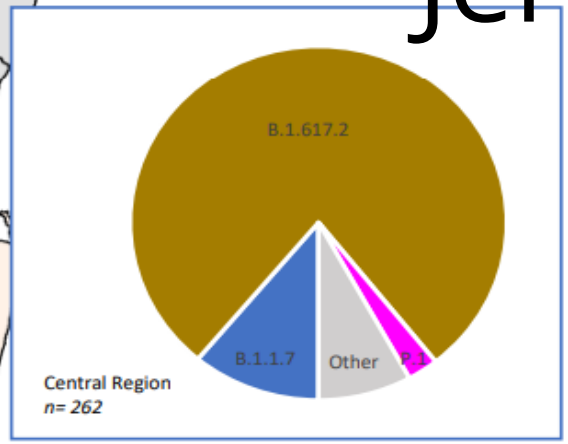


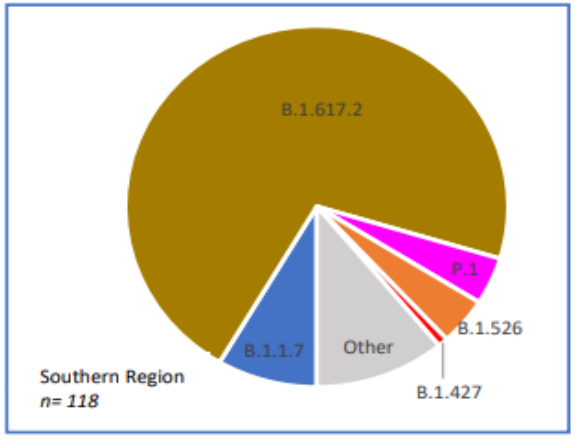
https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_19_Variant_Report_Week_2021_27.pdf

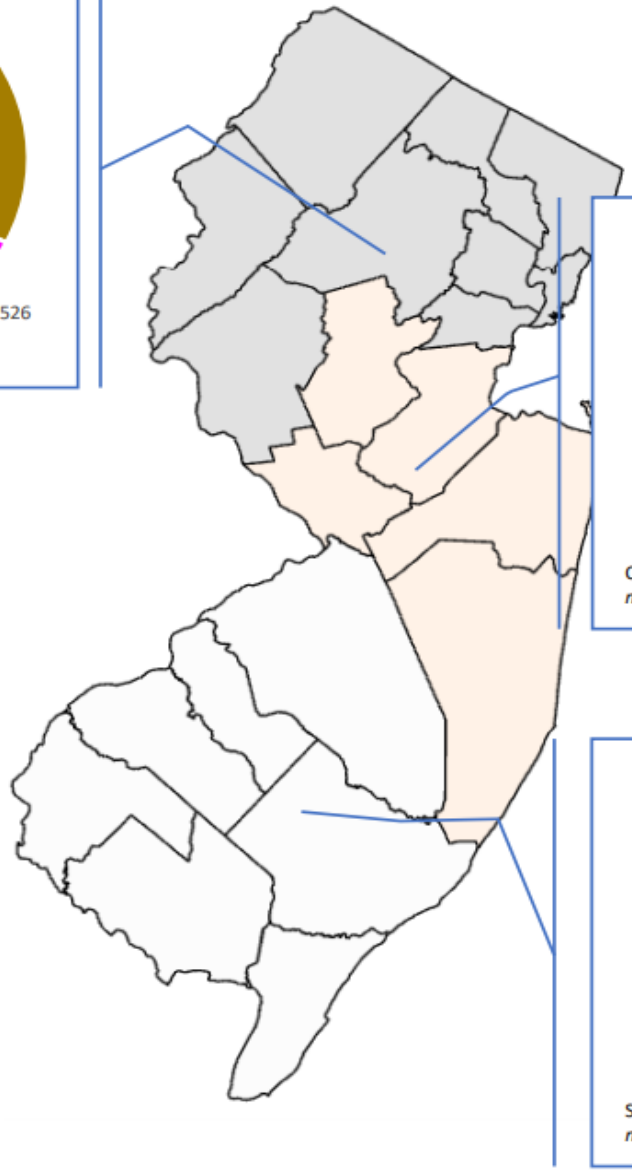
COVID-19 Variant Surveillance by State Region- Previous 4 weeks Summary*

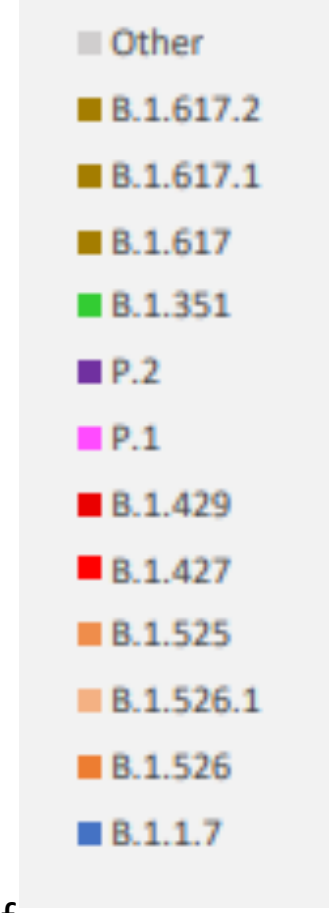
Variants in New Jersey









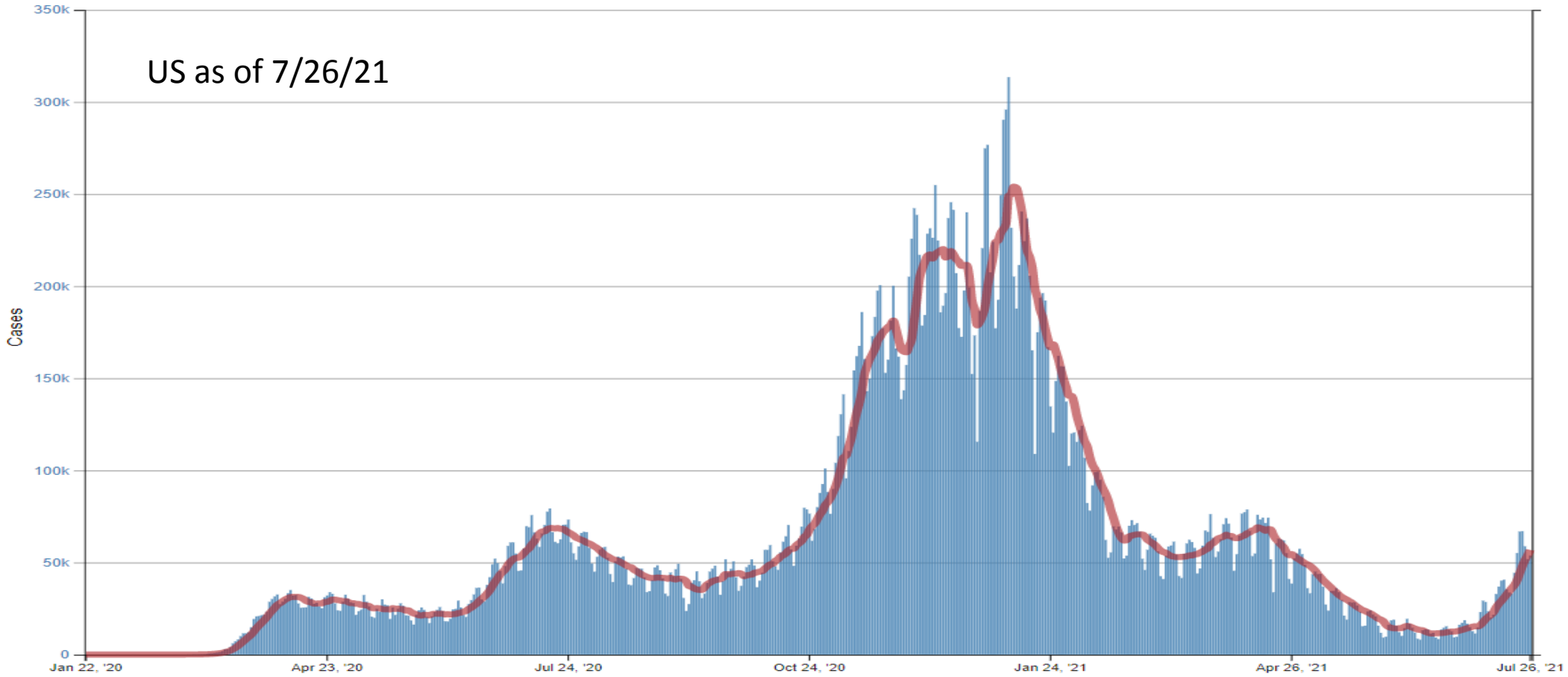


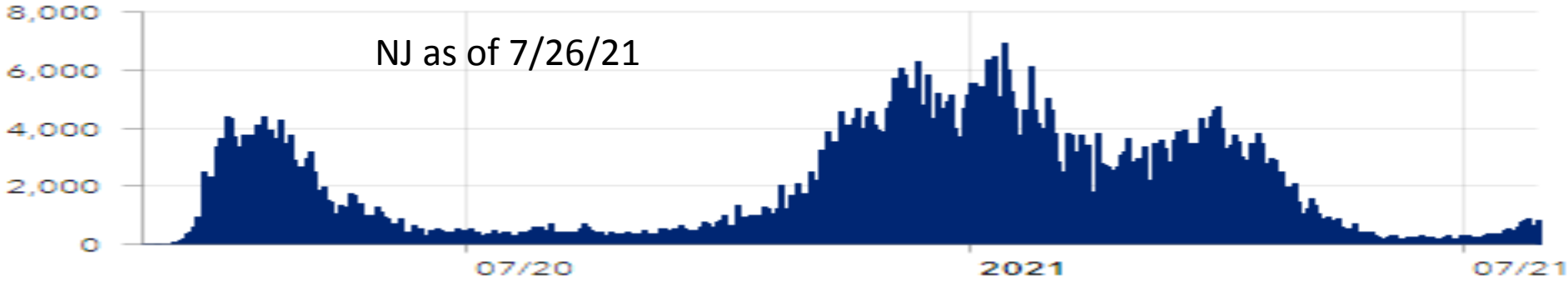
Variant Details

Name (Pango Lineage)	First Detected
B.1.1.7	United Kingdom
B.1.351	South Africa
B.1.617.2	India
P.1	Brazil
B.1.427, B.1.429	USA-California
B.1.525	USA-New York
B.1.526	USA-New York
B.1.526.1	USA-New York
P.2	Brazil
B.1.617	India
B.1.617.1	India

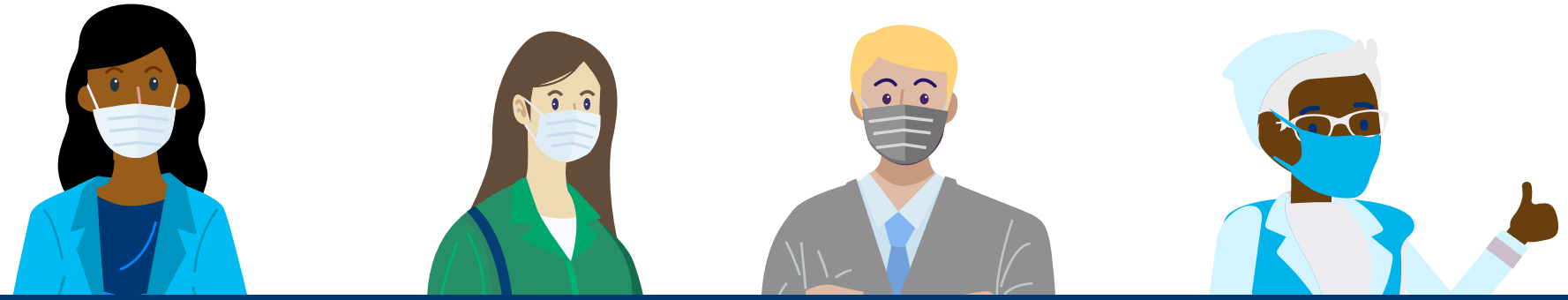
https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_19_Variant_Report_Week_2021_25.pdf

Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC





NJ Health
New Jersey Department of Health



ALL New Jerseyans age 12 and older are eligible for a COVID-19 vaccine.

Schedule an appointment or get help by phone at **855-568-9545**

Visit covid19.nj.gov/vaccine for links to online scheduling

Please check covid19.nj.gov/vaccine for updates. Appointment availability depends on vaccine supply.

covid19.nj.gov/vaccine

Everyone 12 or older who lives, works, or studies in New Jersey is now eligible for the COVID-19 vaccine.

COVID-19 vaccines are safe and highly effective at preventing you from getting sick. They are one of the most important tools to ending the COVID-19 pandemic and getting back to what you love.

ON THIS PAGE

How to get vaccinated

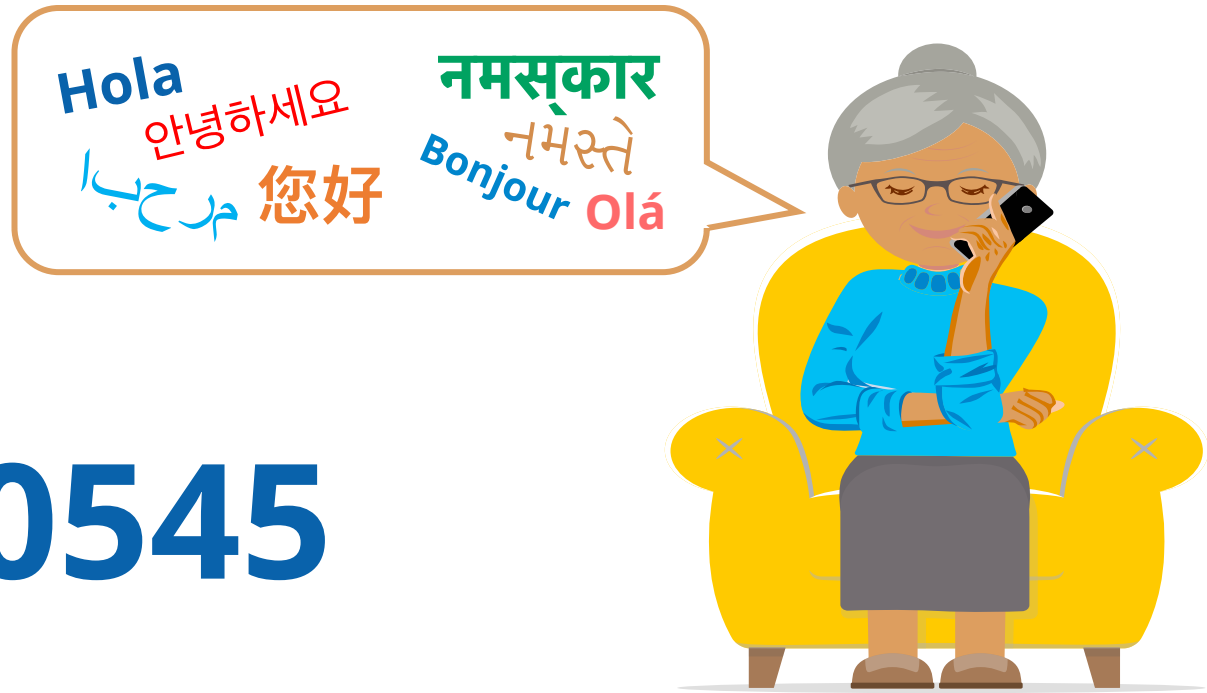
Find a vaccine appointment
Use the NJ Vaccine Appointment Finder to find vaccination locations near you with available appointments.

NJ Vaccine Appointment Finder

Visit a megasite for walk-in appointments
All six vaccine megasites are open for walk-in vaccinations, typically during the following times:

NJ COVID Vaccine Call Center

You can **make an appointment** for the COVID-19 vaccine, **get help** with the scheduling system, **check registration** status, and **ask vaccine questions** by phone



Interpreters are available

Call 855-568-0545

Vaccination Rates in New Jersey

Vaccine Doses Administered in NJ

10,384,905

+

376,789

Doses administered out of state and by federal programs

10,761,694

Total doses administered

People fully vaccinated at NJ sites

5,083,333

+

163,113

NJ residents vaccinated out of state and by federal programs

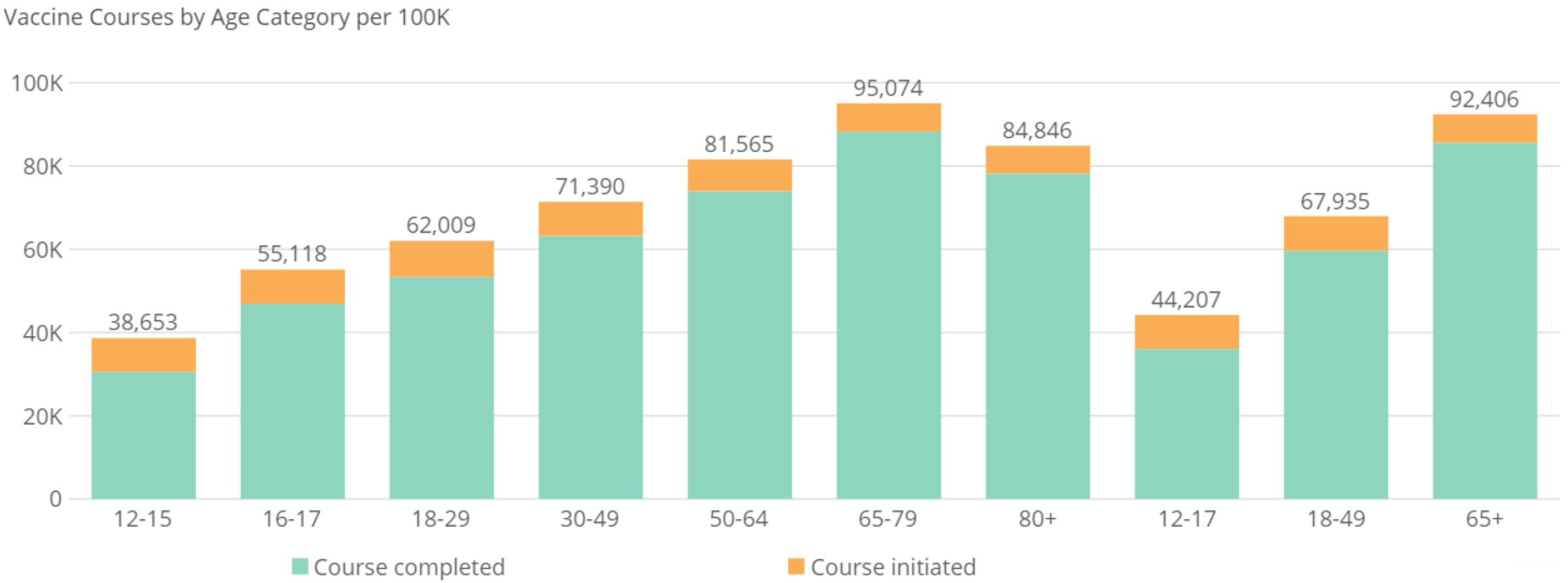
5,246,446

Fully Vaccinated People[2]

https://www.nj.gov/health/cd/topics/covid2019_dashboard.shtml

Daily report on vaccination (as of 10pm 7/26/2021)

Vaccination by age per 100K



NOTE: Includes all individuals who were vaccinated within New Jersey (those who live work or study within New Jersey). Excludes vaccines administered through select federal programs (e.g., Bureau of Prisons, Veterans Health, Indian Health Service, and Department of Defense) as well as NJ residents vaccinated in other states

Source: NJIIS, Vtrcks

Natural versus Vaccine Immunity

- More unknowns than known
- Natural immunity seems solid for at least 3 months
- Vaccine immunity seems even better
  - Trials with all 3 vaccines show protection at least 9 months
  - Immunity against the known variants is solid
- Trials are underway to see if one dose is enough to boost natural immunity

Help us **spread the word!**

The COVID-19 vaccine is **safe, effective, and free** for all

@NJDeptofHealth

#VaccinesWork

#LetsGetNJVaccinated