

# **COVID-19 HEALTH CARE PROVIDER UPDATE:**

## **RECOMMENDATION TO PAUSE USE OF JOHNSON & JOHNSON/JANSSEN COVID-19 VACCINE**

### **SARS-CoV-2 VARIANTS AND POTENTIAL IMPLICATIONS FOR NEW YORK CITY**

**APRIL 16, 2021**

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*Our understanding of COVID-19 is evolving rapidly.  
This presentation is based on our knowledge as of April 15, 2021, 5 PM.*

# OUTLINE



RECENT EPIDEMIOLOGY AND GUIDANCE



UPDATE: JOHNSON & JOHNSON/JANSSEN VACCINE



SURVEILLANCE FOR SARS-COV-2 VARIANTS



EPIDEMIOLOGY OF VARIANTS IN NYC



QUESTIONS AND DISCUSSION

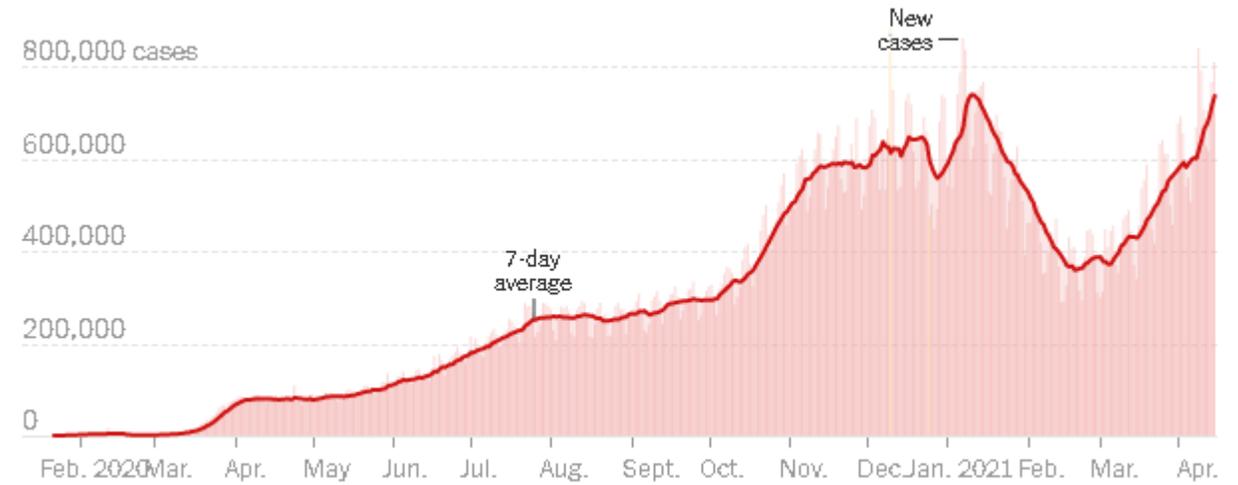
# CURRENT STATUS: GLOBAL

- Over 138 million cases
- Over 2.9 million deaths
- New cases rose 27% in past 2 weeks
- Americas and Europe represent almost 70% of new daily cases
- Current wave in Canada is driven largely by B.1.1.7 variant; P.1 variant also spreading in British Columbia (largest P.1 outbreak outside Brazil)
- Over 841 million vaccine doses administered worldwide

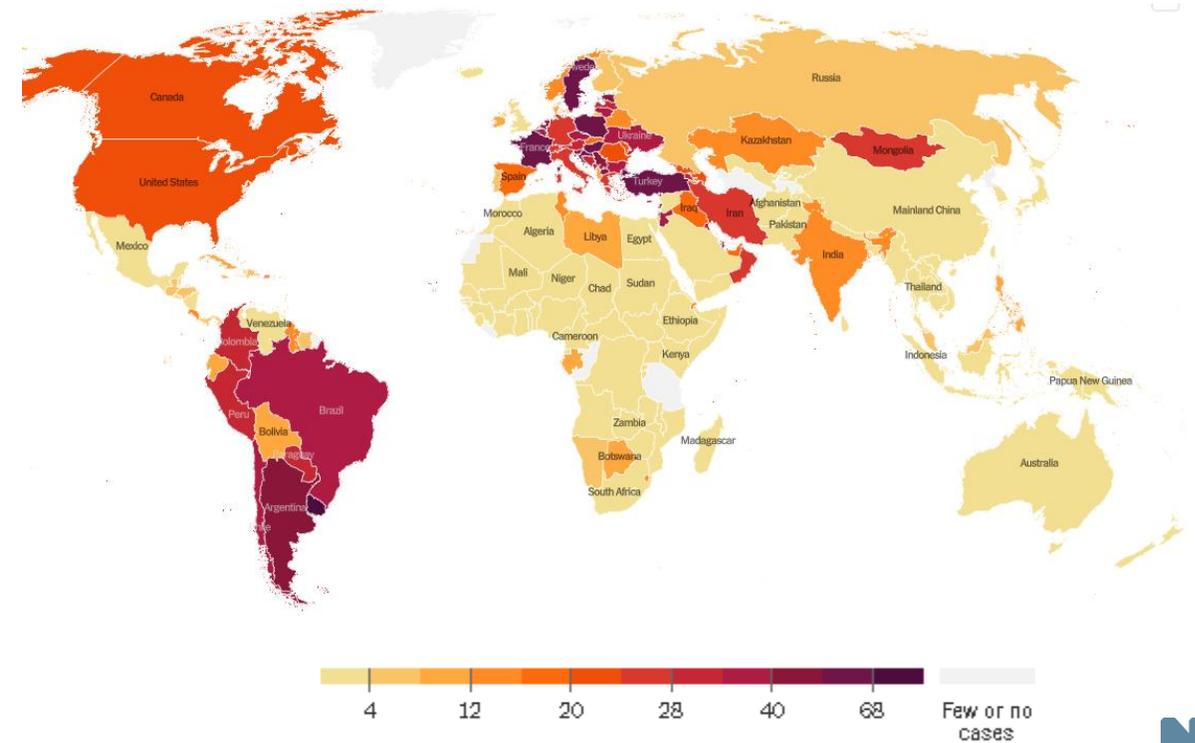
As of 4/15/2021

<https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>

COVID-19 CASES,  
FEB 2020-APR 2021



AVERAGE DAILY  
CASES PER 100,000,  
IN PAST WEEK



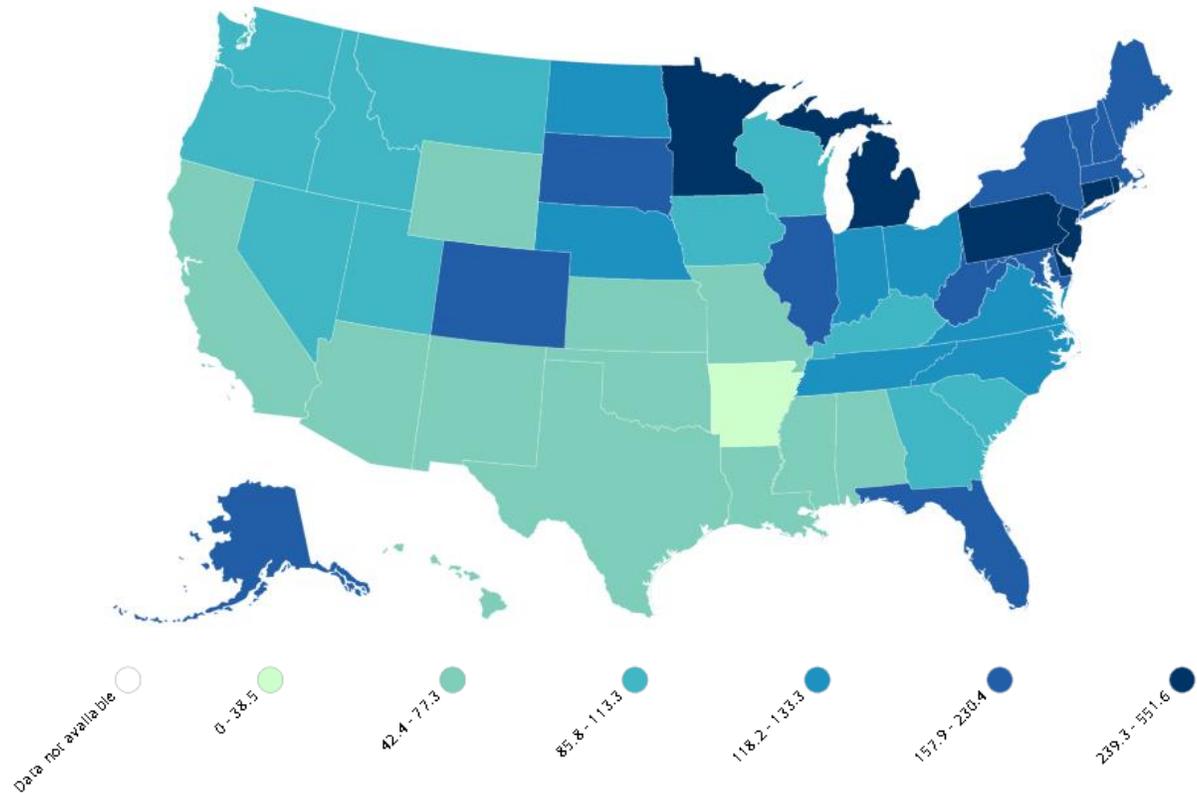
# CURRENT STATUS: U.S.

- Over 31.4 million cases
- Over 563,900 deaths
- New cases increased 11% in past 14 days
- Highest case rates in past week: Michigan, New York, Florida, Pennsylvania, New Jersey
- Approximately 23% of U.S. population has been fully vaccinated

COVID-19 CASES, JAN  
2020-APR 2021



7-DAY CASE RATE  
PER 100,000



As of 4/15/2021. Image sources:

<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>

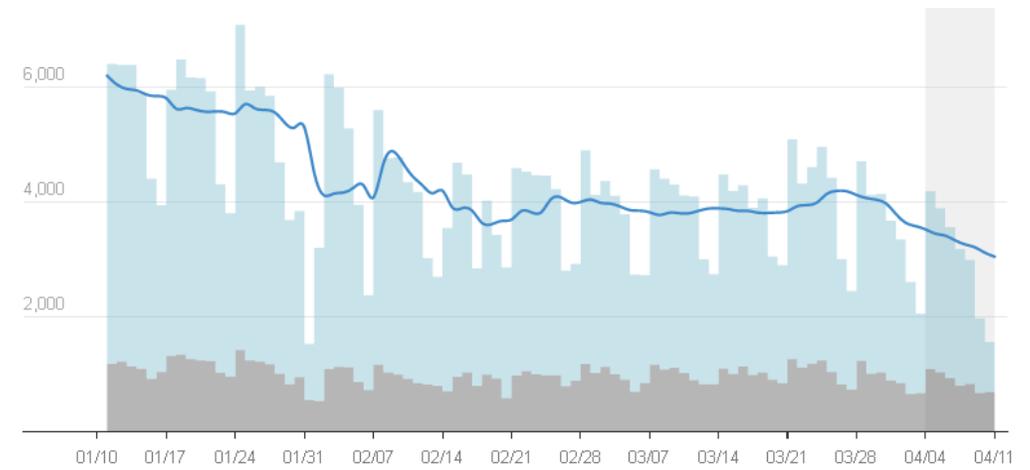
<https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

<https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses>

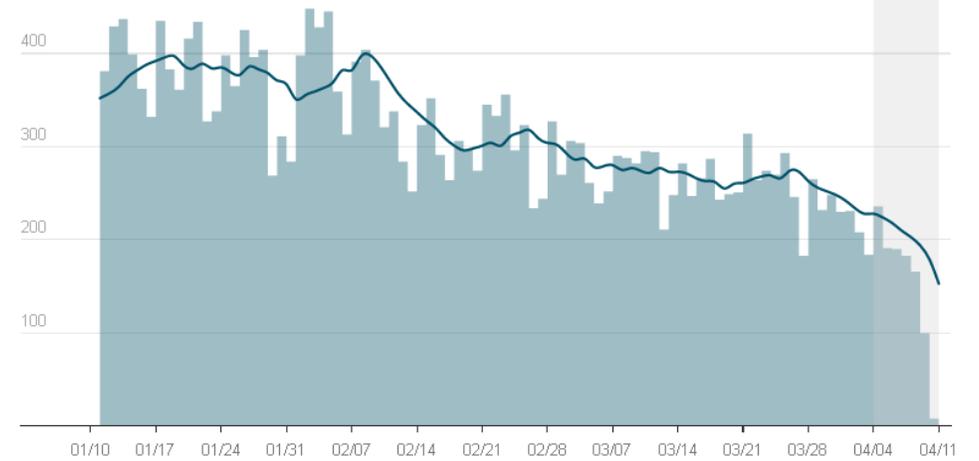
# CURRENT STATUS: NYC

- Over 893,000 total cases
- Over 26,800 confirmed deaths
- During past week, cases have trended downward
- Hospitalizations trending downward
- Deaths have stabilized

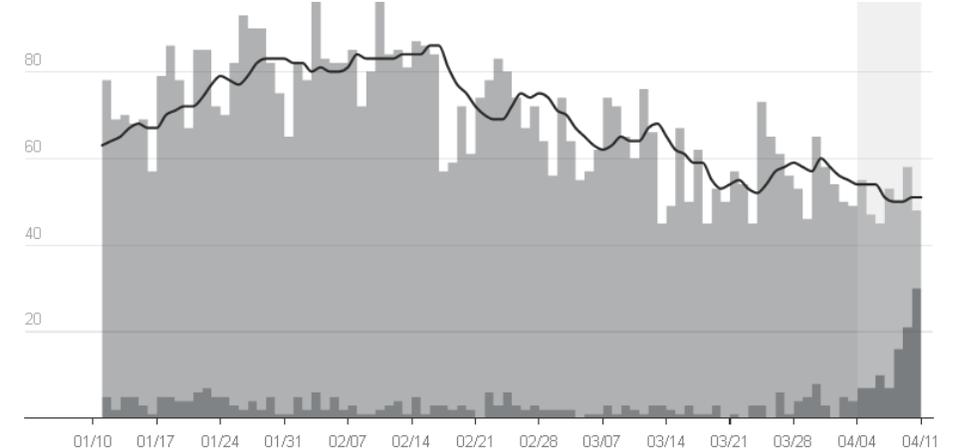
## COVID-19 CASES



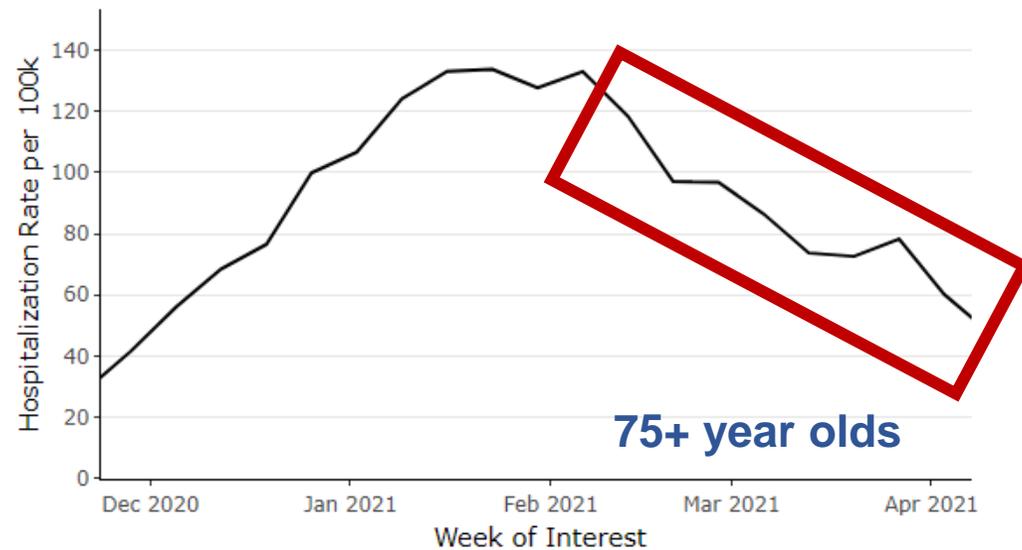
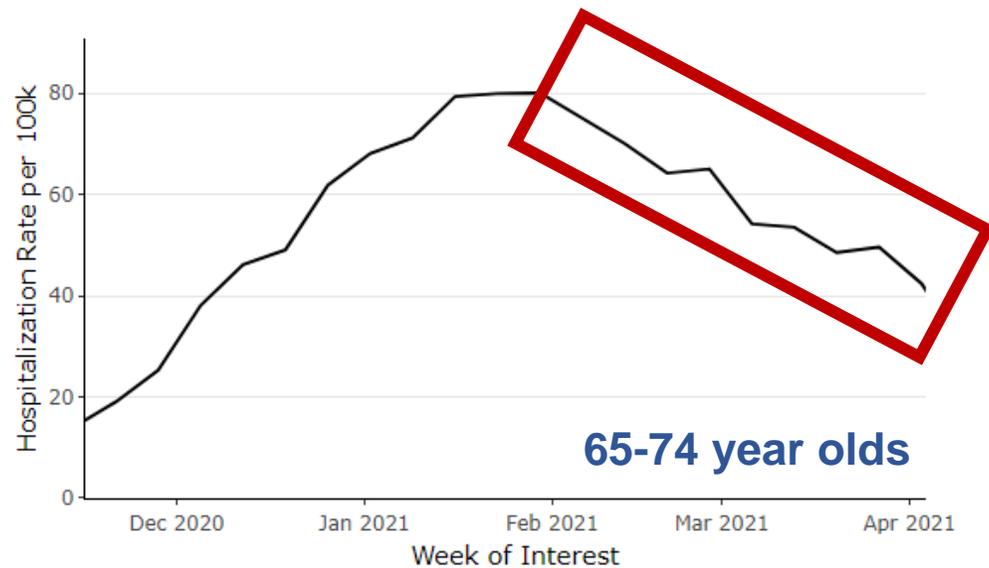
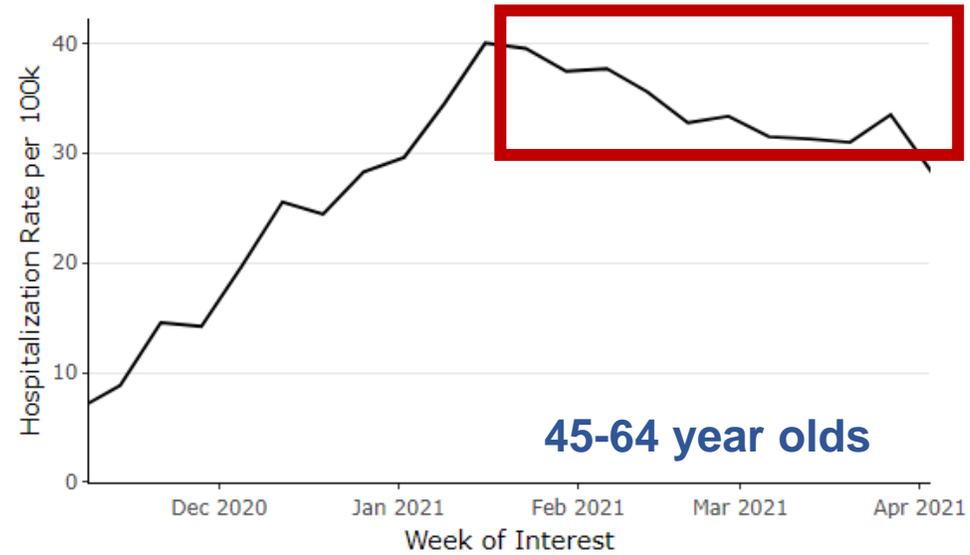
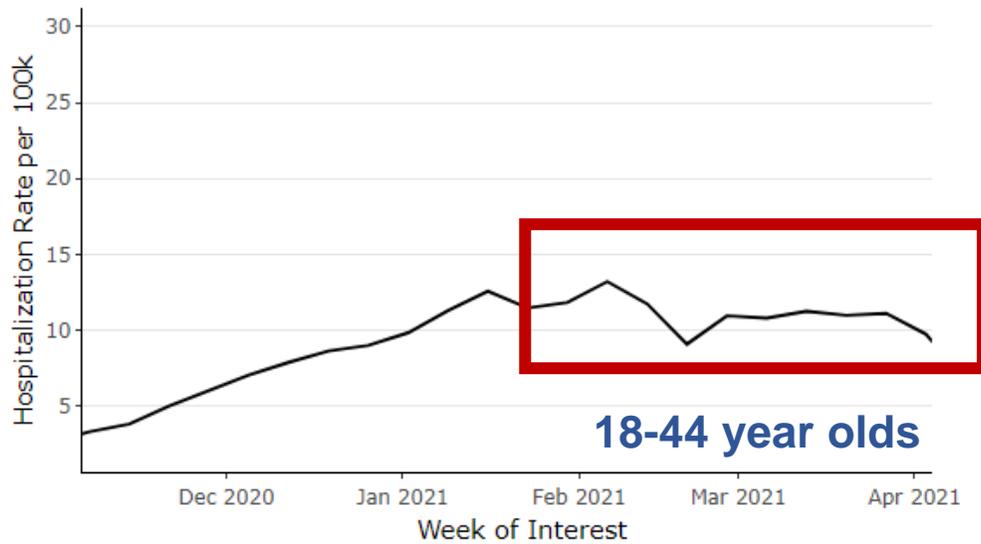
## HOSPITALIZATIONS



## DEATHS



# Hospitalizations, NYC: Decreasing in Older Age Groups, Stable in Other Age Groups



# CDC Scientific Brief: SARS-CoV-2 and Surface (Fomite) Transmission for Indoor Community Environments

- Weight of evidence as of April 5, 2021:
  - Risk of infection via fomite transmission, although present, is low
  - Principal route of transmission is via respiratory droplets
- Risk of fomite transmission can be reduced by:
  - Wearing face coverings (decreases respiratory droplets that may contaminate surfaces)
  - Routine cleaning
  - Hand hygiene
- Generally, cleaning surfaces with soap/detergent (not disinfecting) is sufficient to reduce risk
  - Disinfection is recommended in indoor community settings where there has been a suspected or confirmed case of COVID-19 within the past 24 hours
- CDC updated guidance on cleaning and disinfection accordingly

CDC scientific brief: <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html>

Updated CDC guidance on cleaning and disinfecting:

<https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>

<https://www.cdc.gov/coronavirus/2019-ncov/community/clean-disinfect/index.html>

# Updated NY State Recommendations on Quarantine After Domestic Travel

- Members of general public and most health care personnel:
  - If diagnosed with COVID-19 in previous 3 months or fully vaccinated\*: no quarantine
  - Quarantine is still recommended (though not required) for travelers who are not fully vaccinated\* or who were not diagnosed with COVID-19 in the preceding 3 months
- Health care personnel in nursing homes or adult care facilities certified as enhanced assisted living residences or licensed as assisted living programs:
  - Cannot return to work until the 15th day after arrival
- More detail: NYS DOH [Updated Interim Guidance for Quarantine Restrictions on Travelers Arriving in New York State](#)
- Information about international travel: [NYS COVID-19 Travel Advisory page](#)

\* Fully vaccinated is defined as  $\geq 2$  weeks after completing a vaccine series

# Updated NY State Recommendations on Quarantine After Exposure to Someone with COVID-19

- Members of general public and most health care personnel:
  - If diagnosed with COVID-19 in previous 3 months or fully vaccinated\*: no quarantine
  - If not diagnosed with COVID-19 in previous 3 months or fully vaccinated\*: quarantine required
- Health care personnel in nursing homes or adult care facilities certified as enhanced assisted living residences or licensed as assisted living programs:
  - If diagnosed with COVID-19 in previous 3 months or fully vaccinated\*: no quarantine
  - If not diagnosed with COVID-19 in previous 3 months or fully vaccinated\*:
    - Quarantine for 10 days
    - Cannot return to work until the 15th day
- More information: NYS DOH [Revised Protocols for Personnel in Health Care and Other Direct Care Settings to Return to Work Following COVID-19 Exposure](#)

\* Fully vaccinated is defined as  $\geq 2$  weeks after completing a vaccine series

# JOHNSON & JOHNSON/JANSSEN COVID-19 VACCINE AND OTHER VACCINE-RELATED UPDATES

**Jane R. Zucker, MD, MSc, FIDSA**

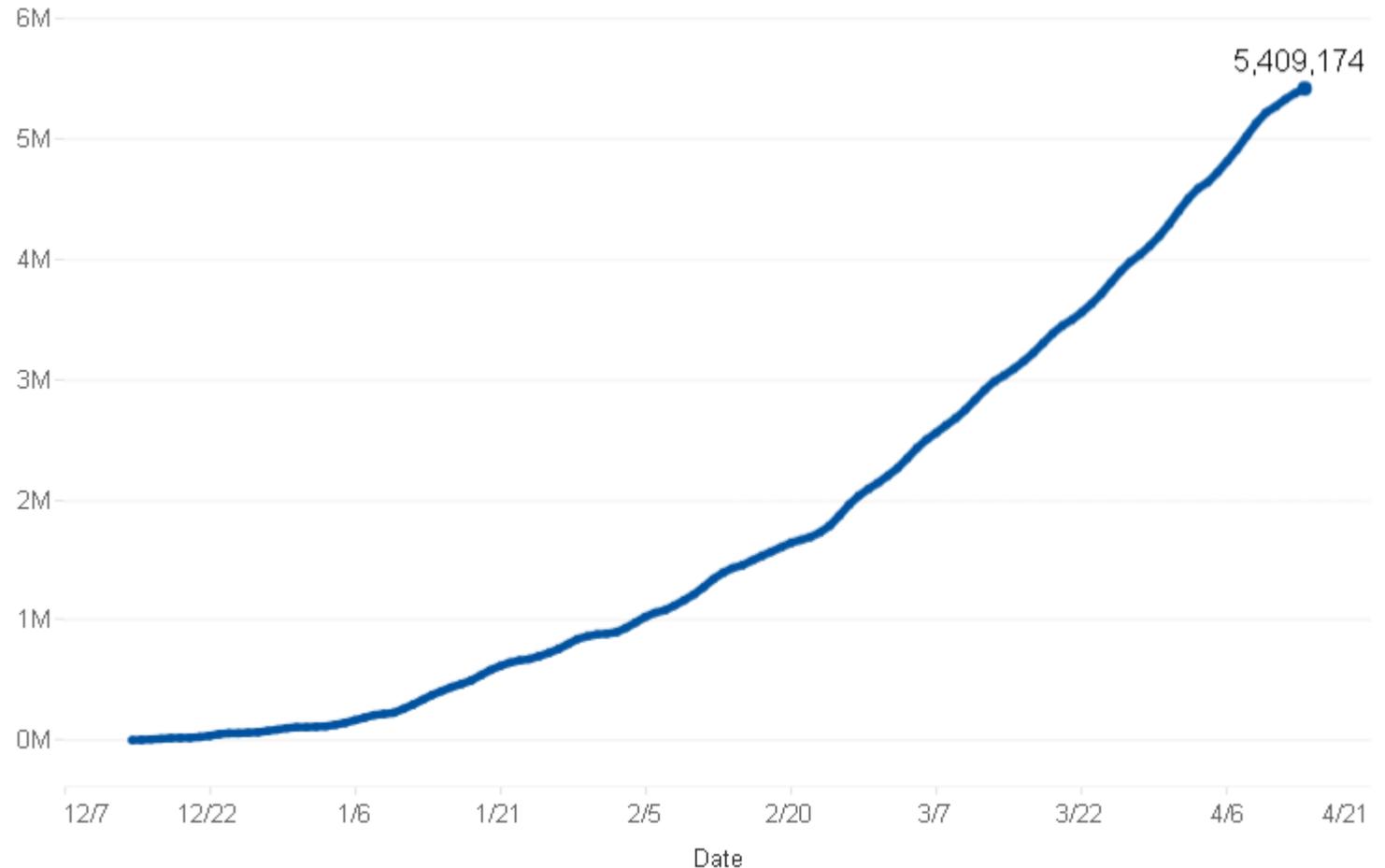
Branch Director, Vaccine Section

Assistant Commissioner, Bureau of Immunization

NYC Department of Health and Mental Hygiene

# COVID-19 VACCINE ADMINISTRATION, NYC

- Over 5 million doses administered
- Of NYC residents aged  $\geq 18$  years:
  - 44% received  $\geq 1$  dose
  - 29% fully vaccinated



Data are reported by providers to the Citywide Immunization Registry and may be delayed.  
<https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page>; updated 4/15/2021

# Johnson & Johnson/Janssen COVID-19 Vaccine

- Genetically modified adenovirus vector vaccine containing DNA that encodes SARS-CoV-2 spike protein
- Received Emergency Use Authorization (EUA) from FDA February 27, 2021
- Over 6.8 million doses administered in U.S. through April 12, 2021
- April 13, 2021:
  - CDC and FDA recommended a pause in use to investigate rare and severe type of blood clot in six J&J/Janssen COVID-19 vaccine recipients
  - Cases had been reported through Vaccine Adverse Events Reporting System (VAERS) in latter half of March through early April 2021
  - NYC Health Department directed providers and facilities in possession of J&J/Janssen vaccine to pause its use
- April 14, 2021: Advisory Committee on Immunization Practices (ACIP) met to review cases and assess significance
  - Decided more time needed to assess data and risk; will not vote on recommendation until meeting again in 7-10 days

CDC health alert: <https://emergency.cdc.gov/han/2021/han00442.asp>

NYC Health Department health alert: <https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2021/covid-19-jj-vaccine-cvst.pdf>

# Characteristics of Six Janssen COVID-19 Vaccine Recipients with Cerebral Venous Sinus Thrombosis (CVST) and Thrombocytopenia

- All White women; median age 33 years (range, 18-48 years)
- Onset of symptoms: 6-13 days after vaccination
- Initial presenting symptom:
  - Headache in 5 patients
  - Back pain (followed by headache) in the 6<sup>th</sup> patient
- Other symptoms:
  - Focal neurologic symptoms (weakness, aphasia, visual disturbance) – 4 patients
- All diagnosed with CVST by intracranial imaging
  - 3 also diagnosed with thromboses in other large vessels outside cerebral circulation
- All had thrombocytopenia
- Four developed brain hemorrhage; one subsequently died
- No obvious pattern of comorbid conditions detected

CDC health alert: <https://emergency.cdc.gov/han/2021/han00442.asp>

ACIP meeting presentation: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04/03-COVID-Shimabukuro-508.pdf>

# Potential Mechanism and Recommended Treatment of Vaccine-Associated Immune Thrombotic Thrombocytopenia

- Reports of thrombotic events among J&J/Janssen vaccine recipients are similar to reports of thrombotic events with thrombocytopenia after receipt of AstraZeneca COVID-19 vaccine in Europe
- Both J&J/Janssen and AstraZeneca vaccines contain adenovirus vectors that encode the SARS-CoV-2 spike glycoprotein (human and chimpanzee adenovirus vectors, respectively)
- Studies of patients with immune thrombotic thrombocytopenia after AstraZeneca vaccination in Europe suggest events may be associated with platelet-activating antibodies against platelet factor 4 (PF4)
- As with heparin-induced thrombocytopenia, heparin should be avoided in patients with possible vaccine-associated immune thrombotic thrombocytopenia (unless heparin-induced thrombocytopenia testing is negative)
- Treatment recommendations:
  - Non-heparin anticoagulants
  - High-dose intravenous immune globulin
  - Consultation with hematology specialists strongly recommended

CDC health alert: <https://emergency.cdc.gov/han/2021/han00442.asp>

# Key Steps for Providers Regarding J&J/Janssen COVID-19 Vaccine

- Do not administer J&J/Janssen COVID-19 vaccine pending further guidance
  - Continue to store the vaccine properly in the interim
- Remain vigilant for symptoms of possible serious thrombotic events or thrombocytopenia in recent J&J/Janssen COVID-19 vaccine recipients
  - Severe headache; backache; new neurologic symptoms; severe abdominal pain; dyspnea; leg swelling; petechiae; new or easy bruising
  - Obtain platelet counts and screen for immune thrombotic thrombocytopenia
- In patients with thrombosis and thrombocytopenia after J&J/Janssen COVID-19 vaccination:
  - Evaluate with screening platelet factor 4 enzyme-linked immunosorbent assay
  - Consult with hematologist
  - Do not treat with heparin unless heparin-induced thrombocytopenia testing is negative
- Report all serious or life-threatening adverse events to VAERS
  - <https://vaers.hhs.gov/reportevent.html>

CDC health alert: <https://emergency.cdc.gov/han/2021/han00442.asp>

NYC Health Department health alert: <https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2021/covid-19-jj-vaccine-cvst.pdf>

# How to report an adverse event to VAERS

- Go to [vaers.hhs.gov](https://vaers.hhs.gov)
- Submit a report online
- For help:
  - Call [1-800-822-7967](tel:1-800-822-7967)
  - Email [info@VAERS.org](mailto:info@VAERS.org)
  - video instructions
  - <https://youtu.be/sbCWWhcQADFE>
- Please send records to VAERS ASAP if contacted and asked

— HIPAA permits reporting of protected health information to public health authorities including CDC and FDA



# What Types of Facilities Have Received J&J/Janssen Vaccine

- Hospitals for administration to inpatients being discharged, in EDs, and for off-campus ambulatory care sites
- Federally Qualified Health Centers (FQHCs)
- Independent medical providers
- Special populations, e.g., homeless shelters and homebound programs
- Long-term care facilities
- Mass vaccination and pop-up clinics, e.g., NYC Housing Authority (NYCHA) sites, naturally occurring retirement communities, houses of worship
- Pharmacies
- University/college student health centers

# Changes to NYC Vaccine Distribution Plans

- All J&J/Janssen shipments are on hold and no new orders can be submitted to CDC
- Most New Yorkers who made appointments for J&J/Janssen vaccine will be offered Pfizer or Moderna vaccine at the scheduled appointment instead
- Some vaccination activities will be hold
- Assessing which programs can use mRNA vaccine products as an alternative
  - Limited by available supply

# Other COVID-19 Vaccine Updates

- All New York State residents aged  $\geq 16$  years are now eligible for COVID-19 vaccination\*
  - People aged  $\geq 65$  years and people with underlying conditions associated with increased risk for severe COVID-19 should be prioritized
  - For people aged 16 or 17 years
    - Pfizer vaccine is the only currently approved product
    - Must have identification to verify they are at least 16, or have a parent or guardian present
    - Parent or guardian must provide consent in person or via telephone at the time of vaccination
    - More information: <https://www1.nyc.gov/site/doh/covid/covid-19-vaccines.page#elgproof>

\*<https://www1.nyc.gov/site/doh/covid/covid-19-vaccines.page#elgproof>

# Real-World Interim Estimates of Effectiveness\* of mRNA COVID-19 Vaccines

- U.S.: mRNA vaccine effectiveness for 3,950 first responders, healthcare personnel and frontline workers was 90% against COVID-19 infections regardless of symptoms, after full immunization ( $\geq 14$  days after second dose); effectiveness of partial immunization ( $\geq 14$  days after first dose, but before second dose) was 80%. Study did not distinguish between effectiveness of Pfizer-BioNTech and Moderna products.<sup>1</sup>
- Israel: case-control study showed that two-dose effectiveness of Pfizer mRNA vaccine against hospitalization was 87% (95% CI, 55-100) and severe disease at 92% (95% CI, 75-100). Effectiveness in preventing COVID-19-associated death was 72% (95% CI, 19 to 100) for days 14 - 20 after first dose.<sup>2</sup>
- England: observational analysis showed 42% reduction in hospitalization among persons aged  $\geq 80$  years who received their first dose of Pfizer-BioNTech vaccine at least 14 days prior vs. those who had not.<sup>3</sup>

\*Vaccine effectiveness reflects how well vaccines work in real-world conditions (vs. efficacy, which is evaluated in trials)

1. Thompson MG, et al. MMWR Morb Mortal Wkly Rep 2021;70:495–500. DOI: <http://dx.doi.org/10.15585/mmwr.mm7013e3external icon>
2. Dagan N, et al. New Engl J Med. 2021 [www.nejm.org/doi/full/10.1056/NEJMoa2101765](http://www.nejm.org/doi/full/10.1056/NEJMoa2101765)
3. Public Health England.  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/971017/SP PH VE report 20210317 CC JLB.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/971017/SP_PH_VE_report_20210317_CC_JLB.pdf)

# What You Can Do to Increase COVID-19 Vaccination

- People want to hear to from their medical providers
- Give a strong provider recommendation
- For facilities that received vaccine, schedule patients for vaccination, prioritizing those aged  $\geq 65$  years
- For facilities that haven't received vaccine, help your patients make appointments:
  - NYC Vaccine Finder <https://vaccinefinder.nyc.gov/>
  - Call 877-VAX-4NYC

# Providing Guidance on COVID-19 Vaccination

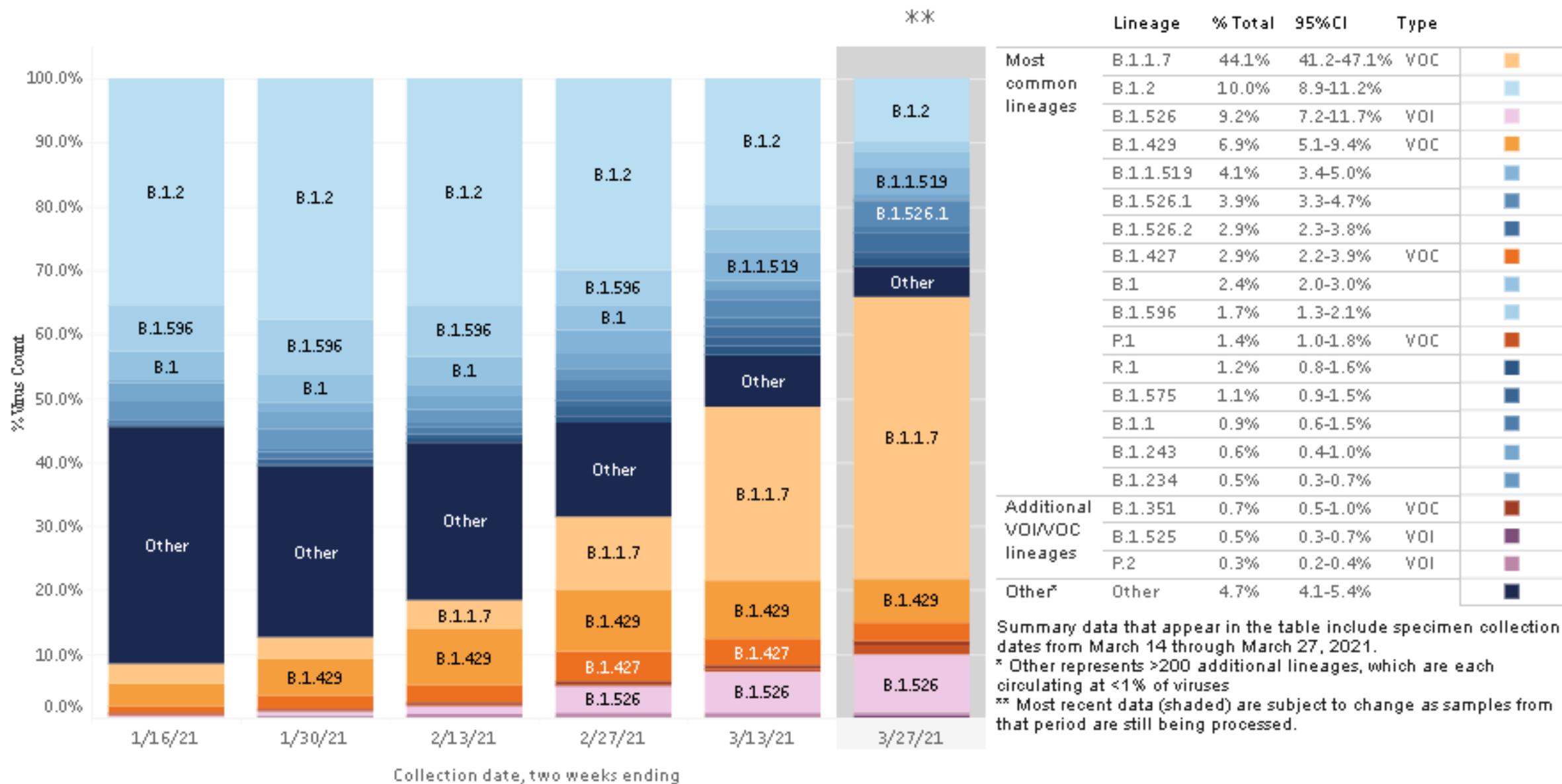
- Summary of what is known:
  - Out of caution, use of J&J/Janssen vaccine was paused promptly while thrombotic events are investigated
  - Risk for those who have already received this vaccine, if any, is extremely low
  - There have been no reports of cerebral venous sinus thrombosis with thrombocytopenia among the more than 180 million recipients of the Pfizer-BioNTech or Moderna vaccines
- Safety monitoring of all COVID-19 vaccines is ongoing
  - Updated information is being shared as soon as it is available
- Continue to strongly recommend COVID-19 vaccination
  - Particularly important for patients at increased risk for severe COVID-19

# SARS-CoV-2 VARIANTS AND POTENTIAL IMPLICATIONS FOR NYC

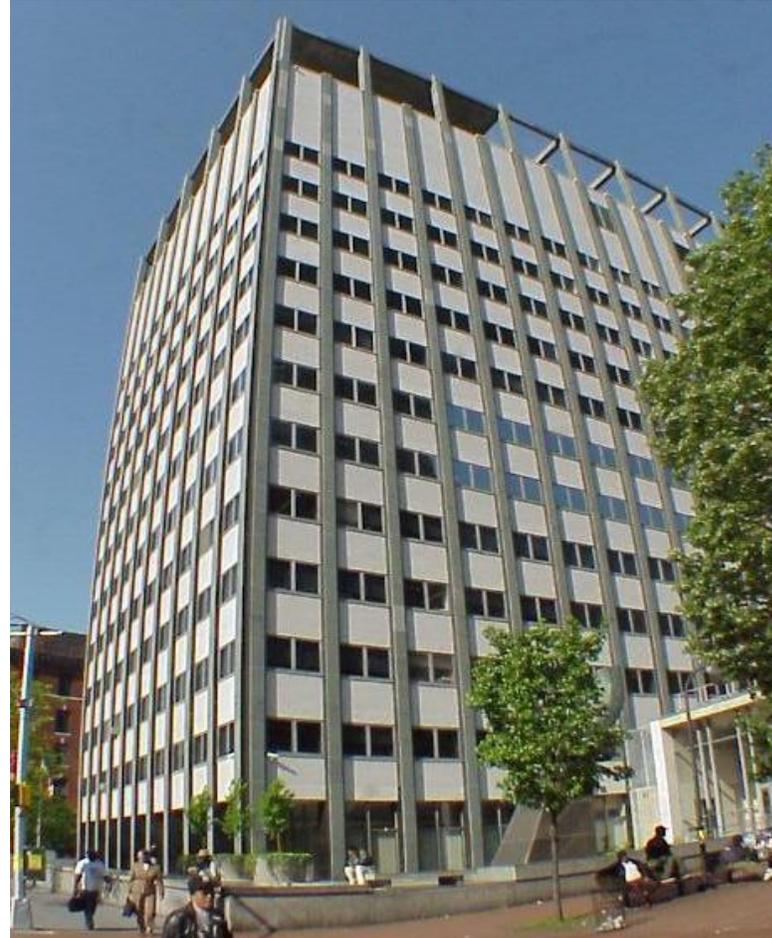
# Background: SARS-CoV-2 Variants

- SARS-CoV-2 mutates regularly, so changes in its genome are expected
  - After emerging, some variants disappear, others persist
  - Why some persist is an area of study; possible explanations include evolutionary advantage (e.g., increased transmissibility)
- CDC classification of variants
  - **Variants of concern** are variants for which evidence of  $\geq 1$  concerning characteristic exists:
    - Changes in receptor binding
    - Reduced neutralization by vaccine- or prior infection-related antibodies
    - Reduced efficacy of treatment efficacy
    - Increased transmissibility or disease severity
    - Diagnostic test detection failure
  - **Variants of interest** contain genetic markers that have been associated with  $\geq 1$  of the above concerning characteristics; however, evidence of an association between the specific variant and the concerning characteristic has not been established
  - **Variants of high consequence** – clear evidence that prevention measures or medical countermeasures have significantly reduced effectiveness
    - NO SARS-CoV-2 variants currently meet this definition

# SARS-CoV-2 Variants Circulating in U.S. January 3-March 27, 2021



# SARS-CoV-2 Whole Genome Sequencing



Scott Hughes, PhD  
Deputy Director, NYC Public Health Laboratory

variant



All



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**NEWYORKPOST**

South African COVID variant can 'break through' Pfizer vaccine: study

10 hours ago



**REUTERS**

South African variant can 'break through' Pfizer vaccine, Israeli study says

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**Forbes**

The Pfizer/BioNTech Covid-19 Vaccine Is Less Effective Against The South African And UK...

2 hours ago



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<https://www.cdc.gov> › [transmission](#) › [variant](#)

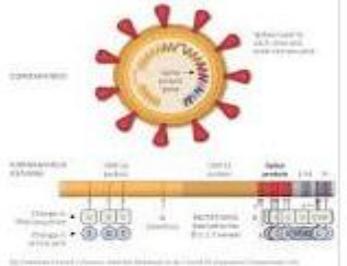
## About Variants of the Virus that Causes COVID-19 | CDC

Apr 2, 2021 — B.1.351: This **variant** was first identified in the US at the end of January 2021. It was initially detected in South Africa in December 2020. P.1: This ...

[Variant Cases in the US](#) · [SARS-CoV-2 Variants](#) · [Genomic Surveillance](#)

## Variant of Concern 202012/01

Virus



Lineage B.1.1.7, also known as 20I/501Y.V1, Variant of Concern 20DEC-01 or commonly as the UK variant, British variant or Kent variant, is a variant of SARS-CoV-2, the virus that causes COVID-19. [Wikipedia](#)

**Higher classification:** Severe acute respiratory syndrome coronavirus 2

### People also search for

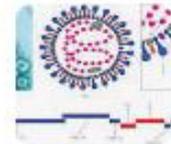
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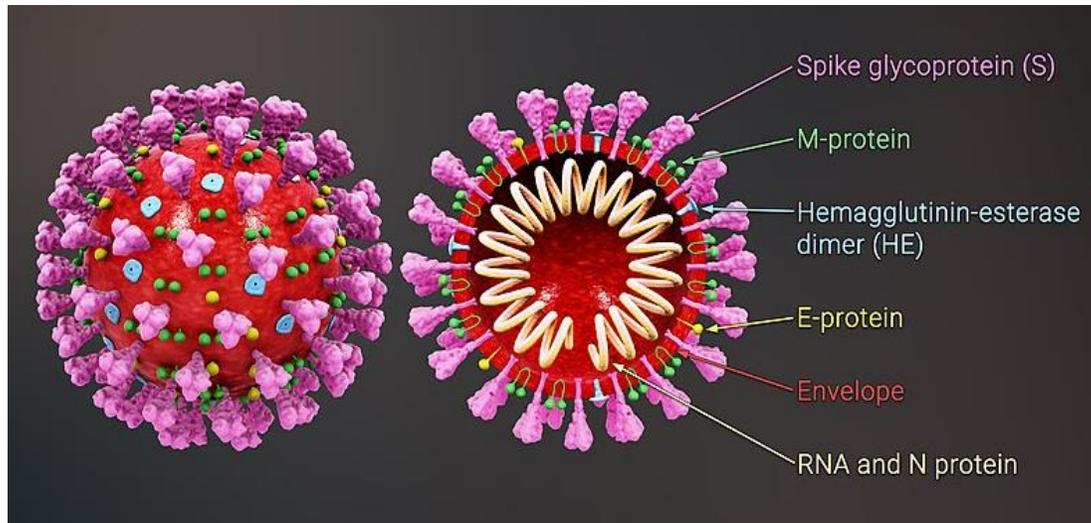
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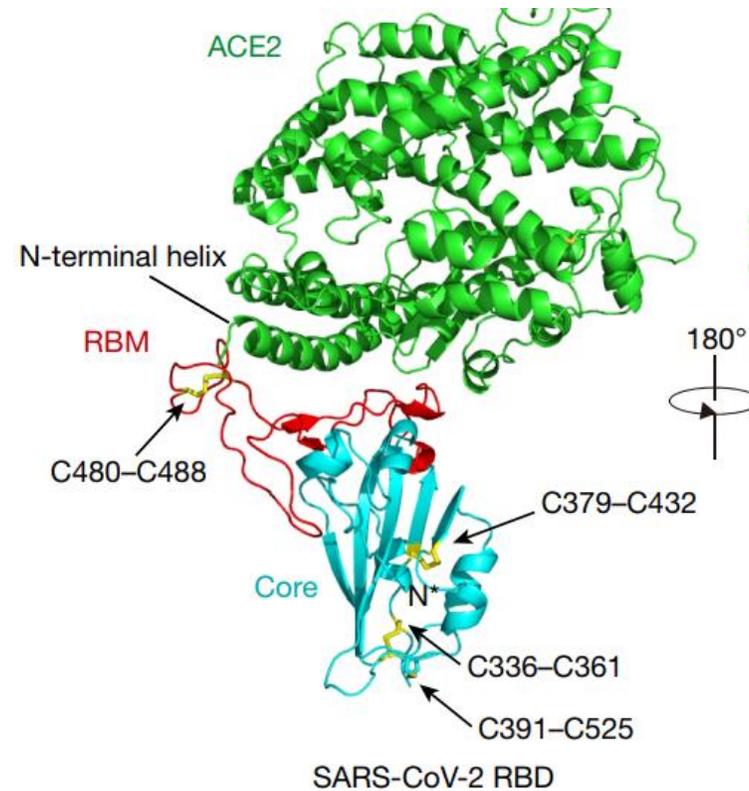
# SARS-CoV-2 Structure

SARS-CoV-2 3-D Model



[https://commons.wikimedia.org/wiki/File:3D\\_medical\\_animation\\_coronavirus\\_structure.jpg](https://commons.wikimedia.org/wiki/File:3D_medical_animation_coronavirus_structure.jpg)

Structural model of Spike Receptor Binding Domain bound to its Receptor ACE2



<https://www.nature.com/articles/s41586-020-2180-5.pdf>

# SARS-CoV-2 Genomic Characteristics

- Genome size: single-stranded RNA 26,000 – 32,000 bases (27 proteins)
- More than 200,000 SARS-CoV-2 genomes have been sequenced with data publicly available
- Mutation rate: two nucleotide changes per month in one genome (~ 24 per year)
  - Half that of influenza
  - One quarter that of HIV
- Whole genome sequencing is used to identify mutations that create **variants** from the original Wuhan strain
  - Most mutations either have no effect or are bad for the virus
  - A few mutations give the virus a selective advantage; may allow those variants to spread more quickly
- The ancestry of these variants is based on different mutations. Genetically similar SARS-CoV-2 isolates are grouped by lineage name (e.g., B.1.1.7 or B.1.526)
  - Within a common lineage there can be mutations that are associated with receptor binding, antibody neutralization, or vaccine breakthrough (e.g., N501**Y**, E484**K** )

# Whole Genome Sequencing (WGS) Workflow

## Specimen Requirements

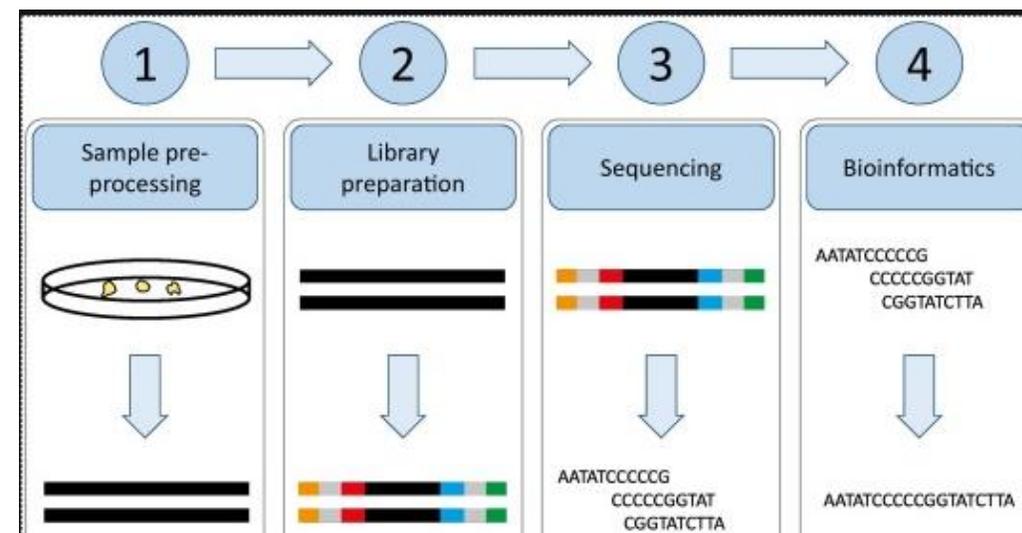
- Specimen type - respiratory swabs in viral transport media
- Specimen storage - 4°C for 3 days, -70°C for longer periods
- Specimen results - Using nucleic acid amplification testing, positive specimens should have a cycle threshold (Ct) value of less than 30-32 to be successfully sequenced

## WGS

- A multistep process of 5-7 days
- New methodologies can reduce workflow to 2-3 days
- WGS is expensive – each run of 32-48 specimens costs approximately \$3,500

## Bioinformatics

- Bioinformatics uses open-source and locally-developed software tools to decipher genomic data “pipelines”
- “Phylogenetic Assignment of Named Global Outbreak Lineages” (PANGOLIN) is an open-source tool used to assign lineage names (e.g., B.1.526)
  - PANGOLIN is updated based on new data



<https://www.sciencedirect.com/science/article/pii/S0734975020300343>

# GISAID

- **Global Initiative on Sharing Avian Influenza Data**
- A public domain initiative established in 2008 that promotes rapid and open access to influenza viruses and SARS-CoV-2 genomic and epidemiological data

## A network of collaborators



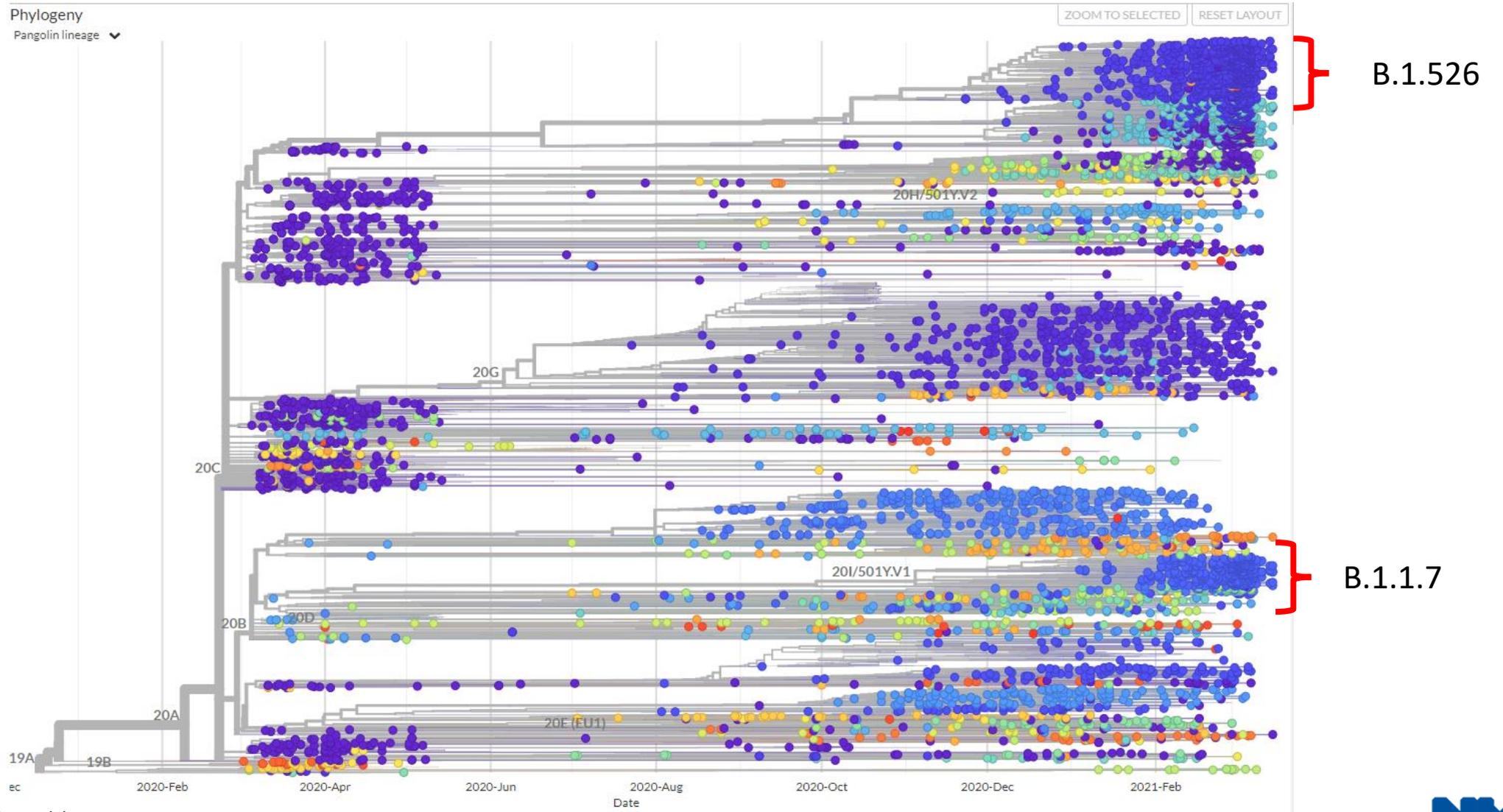
# Nextstrain

Close to real-time tracking of pathogen evolution

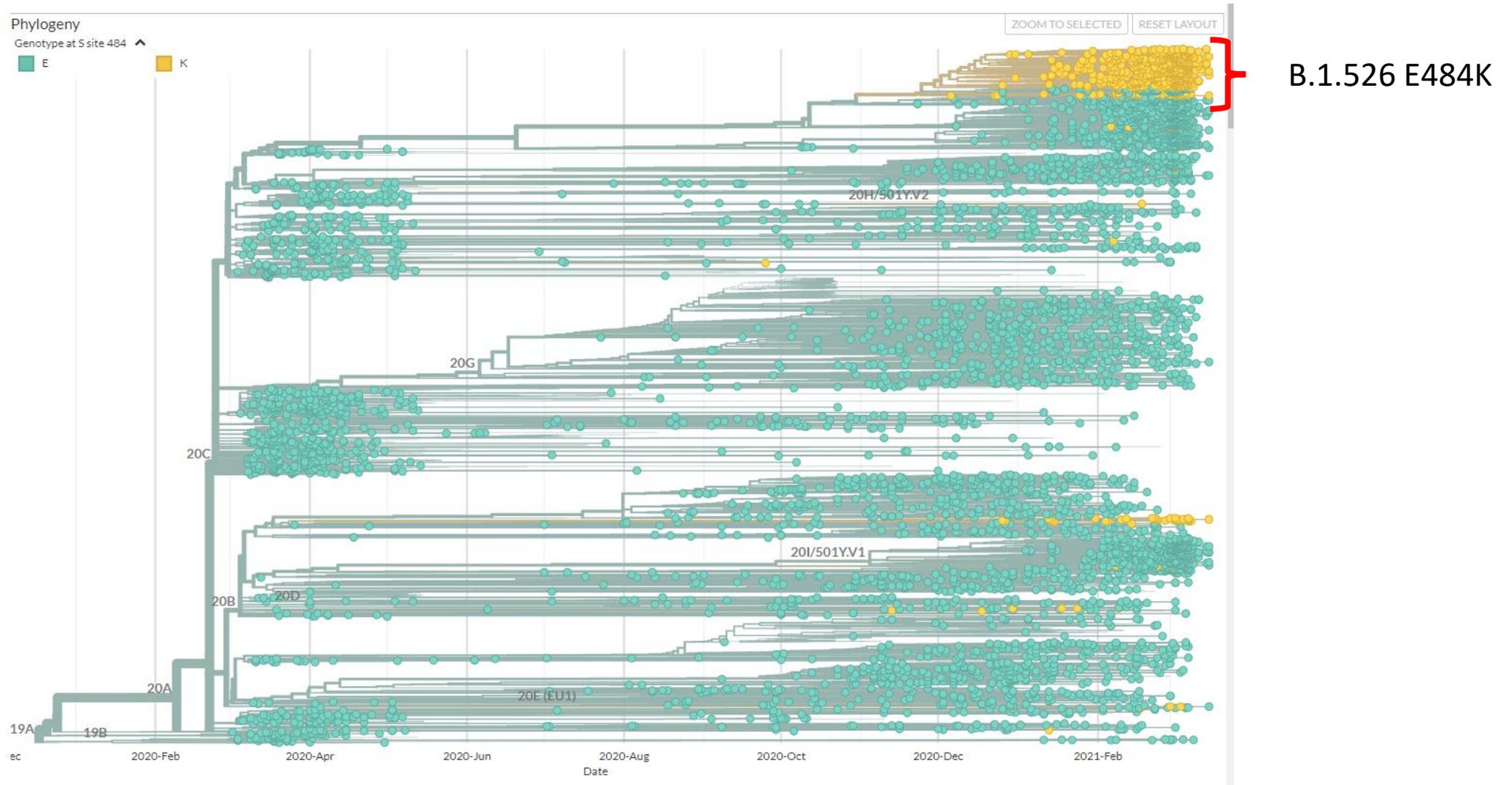
- International collaborative effort started in 2015 by academic researchers
- Provides open source analytic and visualization tools to harness the scientific and public health potential of pathogen genome data
- Spatiotemporal analysis of viral genomic evolution
- In a secure local environment: sensitive local data + GISAID global data



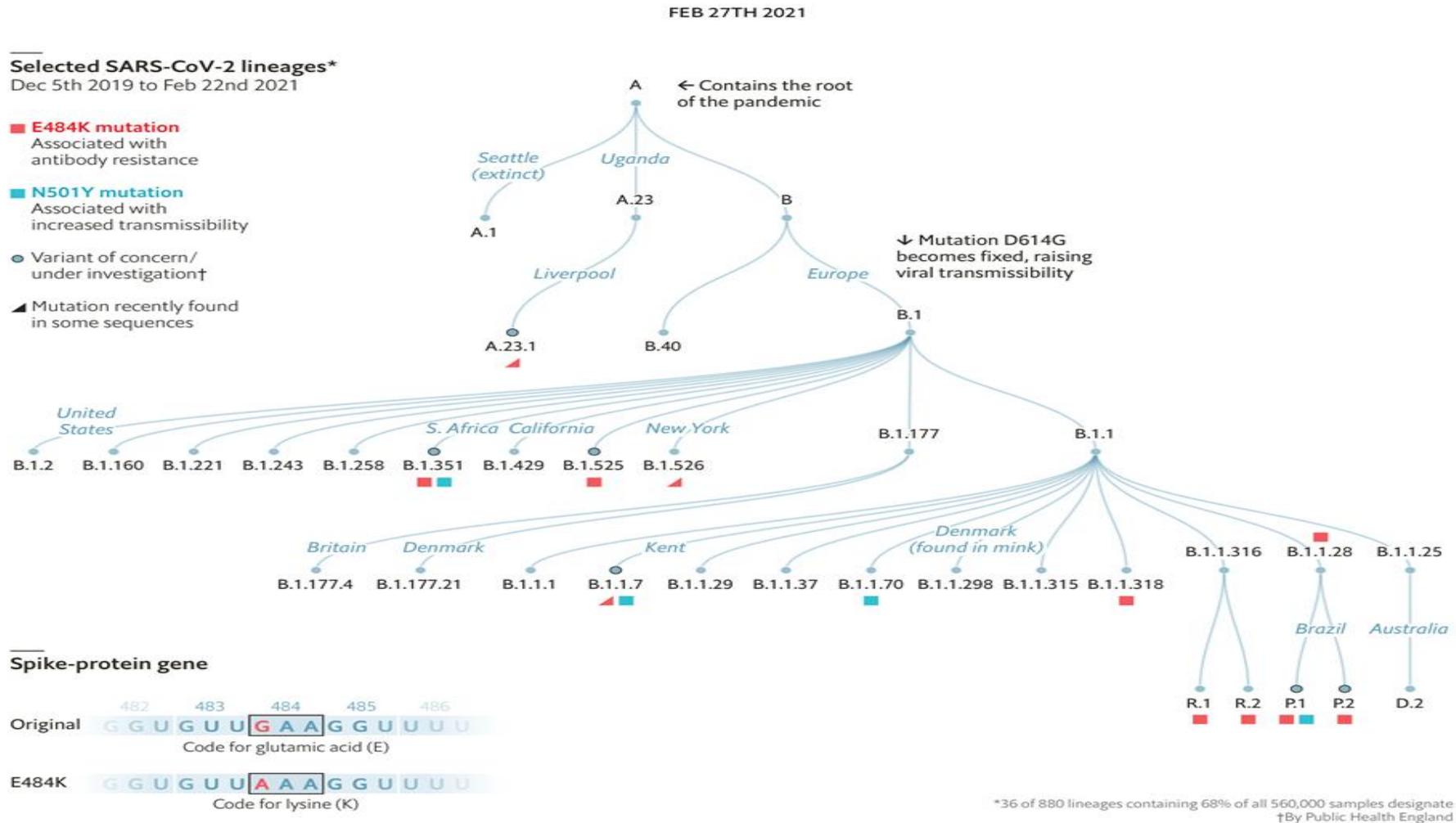
# Evolution of SARS-CoV-2 Genomes in NYC



# Mutational Analysis of SARS-CoV-2 Genomes in NYC



# Convergent Evolution of SARS-CoV-2 Receptor Binding Domain Variants



<https://www.economist.com/graphic-detail/2021/02/27/the-same-covid-19-mutations-are-appearing-in-different-places>

# SARS-CoV-2 Variants of Concern/Variants of Interest in NYC

Variant*	Potential concern**
B.1.1.7 "UK" (VOC)	More transmissible, more lethal
P.1 "Brazil" (VOC)	More transmissible, evidence of immunity evasion
B.1.351 "South Africa" (VOC)	More transmissible, immunity evasion
B.1.427 "California" (VOC)	More transmissible, more lethal
B.1.429 "California" (VOC)	More transmissible, more lethal
B.1.525 (VOI)	Reduction in neutralization
B.1.526/B.1.526.2 "New York" (VOI)	Variant has mutation(s) associated with immunity evasion
P.2 (VOI)	Reduction in neutralization

Data pulled 4/13/21 from GISAID; variants available in GISAID for NYC residents, cumulative\*

Variants of concern that are being monitored by CDC	
B.1.1.7	2,278
B.1.351	13
B.1.429	191
B.1.427	101
P.1	68
Other variants being monitored by NYC	
B.1.526	4,727
B.1.525	24
P.2	9
Number of <a href="#">genome sequences</a> from specimens from NYC residents in GISAID, cumulative*	
	13,344

\* [GISAID](#) is a global science repository for open-access to genomic data of SARS-CoV2. Cumulative refers to January 2021 – present. All sequences noted as "available in GISAID" have passed critical quality control checks and are publicly available.

<https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-data-variants-041321.pdf>

\*Variants of concern (VOC) or variants of interest (VOI) being monitored by CDC

\*\*Variant-specific potential concerns require further investigation

# Reporting Whole Genome Sequencing Results

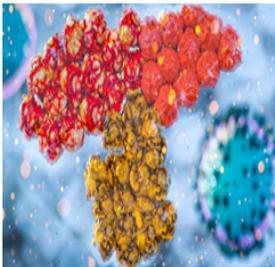
- Centers for Medicare and Medicaid Services is temporarily exercising enforcement discretion <https://www.cms.gov/files/document/clia-sars-cov-2-variant.pdf>

Generally, surveillance testing using sequencing technology to identify SARS-CoV-2 genetic variants can be performed in a facility that is NOT CLIA certified, provided that patient-specific results are **not** reported to (1) the individual who was tested or (2) their health care provider. If at any time a facility intends to perform testing on identified specimens and report a patient-specific SARS-CoV-2 genetic variant test result to the individual who was tested or to their health care provider, the facility must comply with CLIA and is thereby required to obtain the appropriate CLIA certificate in accordance with 42 CFR Part 493, laboratory requirements.

However, as indicated above, CMS will not take action against non-CLIA certified facilities that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific results to State or local Public Health Departments, provided that the facility only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. The Public Health Departments should only use these results for public health purposes, such as contact tracing, outbreak detection, etc. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA certified laboratory and in compliance with all applicable CLIA regulations (42 CFR part 493).

# Studies of Variants and Clinical Importance

- Neutralization studies in the lab measure the effect of monoclonal antibodies or convalescent sera and vaccinee sera against different spike gene variants
  - Note that these are artificial constructs and do not represent actual infection by SARS-CoV-2 and a person's immune response in total
- Information regarding effectiveness of therapeutics
- Potential effectiveness of vaccines

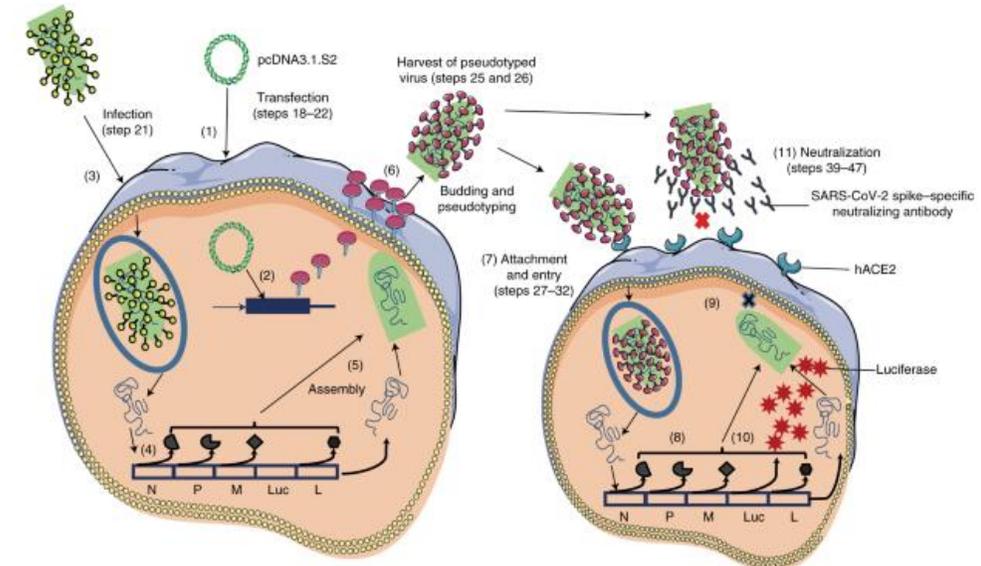


Regeneron Cocktail Stumbles Against SARS-CoV-2 Variant in Vitro | The Scientist Magazine®

On February 25, Regeneron halted the placebo arm of its outpatient trial of the cocktail's effectiveness after an independent review committee's declaration that the intervention protects well against different SARS-CoV-2 variants. The company's announcement did not include specific details about B.1.351. The trial is taking place in the United States, where B.1.351 has not been widely ...

[www.the-scientist.com](http://www.the-scientist.com)

<https://www.the-scientist.com/news-opinion/regeneron-cocktail-stumbles-against-sars-cov-2-variant-in-vitro-68503>



<https://www.nature.com/articles/s41596-020-0394-5>

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES



BMJ Yale

Evidence for increased breakthrough rates of SARS-CoV-2 variants of concern in BNT162b2 mRNA vaccinated individuals

<https://www.medrxiv.org/content/10.1101/2021.04.06.21254882v1>



# Summary and Next Steps

- SAR-CoV-2 mutations will continue to happen
- More “real world” data needed to determine impact that mutations and associated “variants of concern” have on effectiveness of vaccines and therapeutics
- Whole genome sequencing is a costly and time-consuming process and is not useful for making timely clinical decisions on an individual basis
- Sequencing results (e.g., lineage name) are not reportable unless the process is CLEP/CLIA\* validated
- Whole genome sequencing allows for ongoing tracking of how the virus evolves; information gained can be used to inform:
  - Public health decisions
  - Treatment with specific therapeutics
  - Vaccine design

\*CLEP – Clinical Laboratory Evaluation Program; CLIA - Clinical Laboratory Improvement Amendments

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*server and external lab data*

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Angel Aponte

GISAID

Nextstrain

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

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# EPIDEMIOLOGY OF SARS-CoV-2 VARIANTS IN NYC

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NYC Department of Health and Mental Hygiene

# Selected SARS-CoV-2 Variants Detected in NYC, Jan 1, 2021-March 27, 2021

Variant	Where and when first emerged	Classification	More transmissible	Causes more severe disease	Evades immunity due to previous infection or vaccination	Less responsive to mAb* treatment
B.1.1.7	U.K (Sept 2020)	Concern	Yes	Yes		
B.1.526	NYC (Nov 2020)	Interest	Possibly		Possibly	Possibly
P.1	Brazil (late 2020)	Concern	Yes		Possibly	

<https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-variants-overview.pdf>

\*mAb – monoclonal antibody

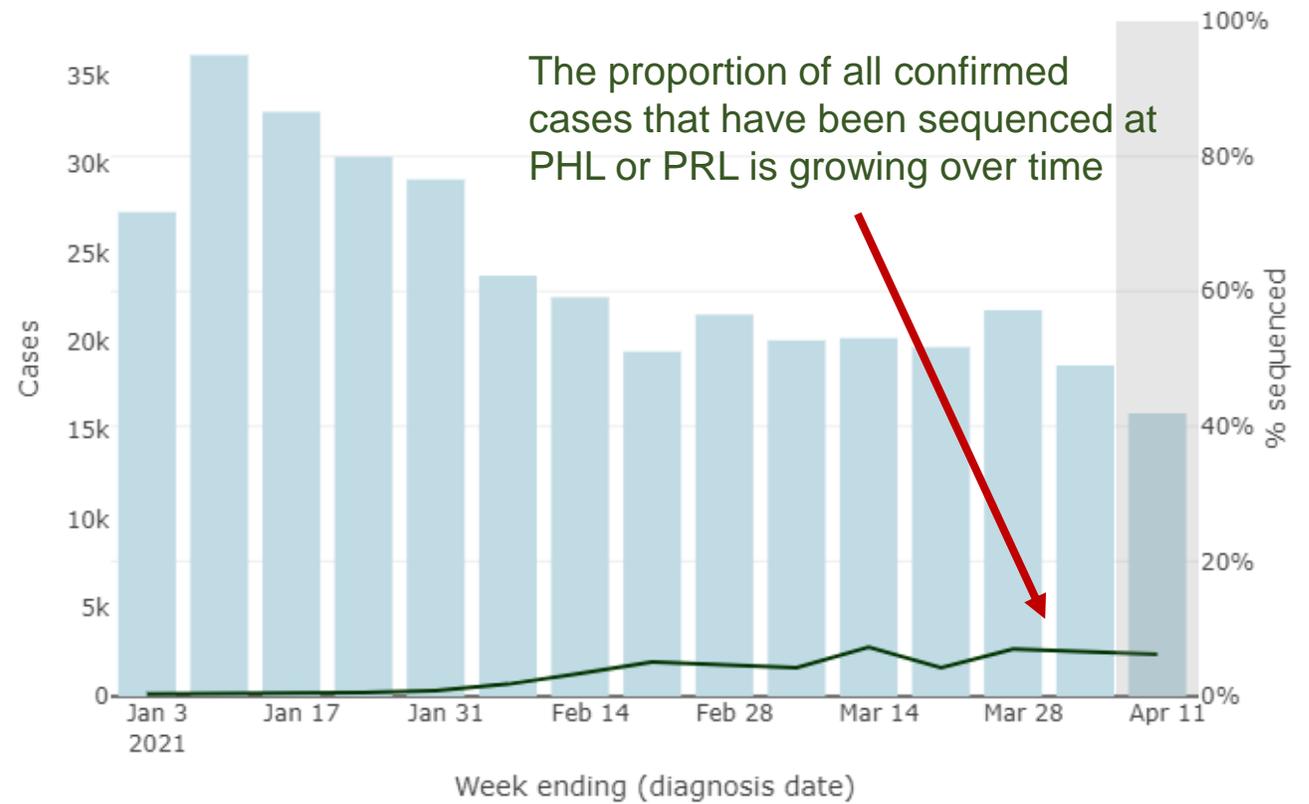
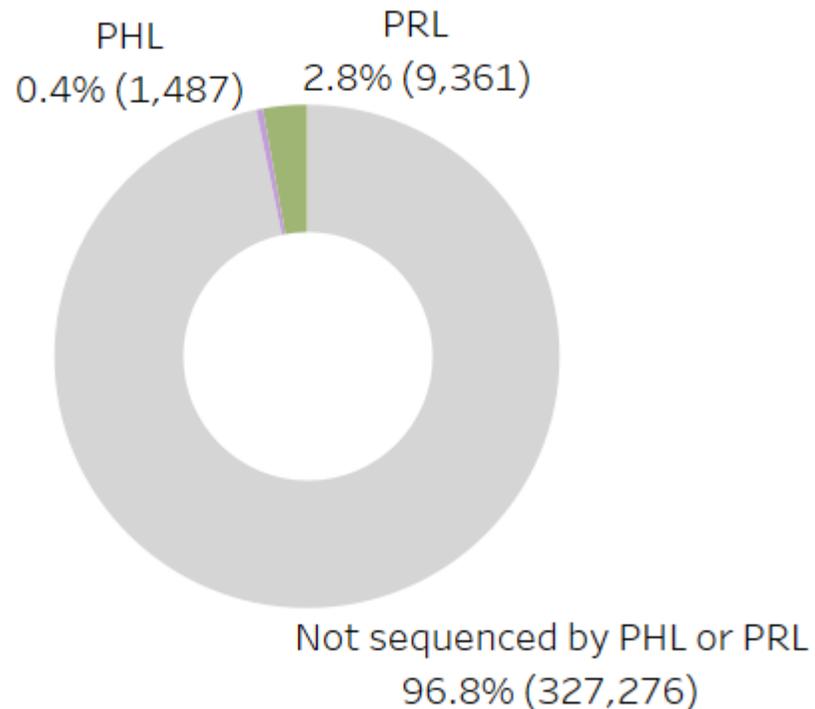
# Data on SARS-CoV-2 Variants in NYC

- NYC Health Department combines laboratory and epidemiologic data to investigate SARS-CoV-2 variants of interest or concern
- Since October 2020, all SARS-CoV-2 isolates received by the NYC Public Health Lab (PHL) that meet technical criteria (e.g., cycle threshold <31) have undergone whole genome sequencing
  - Specimens from nine NYC Health Department rapid express testing sites, shelters for unhoused persons, Office of Chief Medical Examiner (OCME)
- Since February 2021, Pandemic Response Lab (PRL) has been sequencing randomly selected specimens that meet technical criteria
  - Specimens from many H+H outpatient sites, some inpatient, mobile vans, ED admits
- Together, isolates that undergo sampling at PHL or PRL account for a small, but growing, proportion of all confirmed COVID-19 cases in NYC
  - In recent weeks, 6-7% of cases

<https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-variants-overview.pdf>

# Confirmed COVID-19 Cases Citywide and Percentage Sequenced

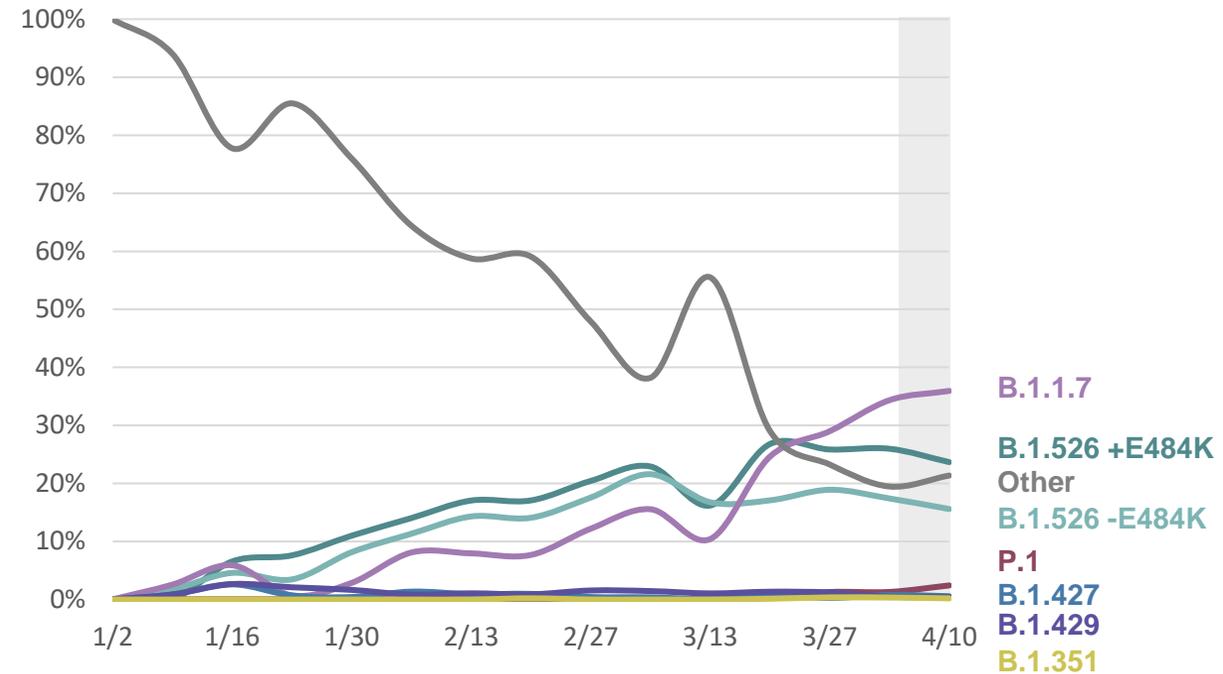
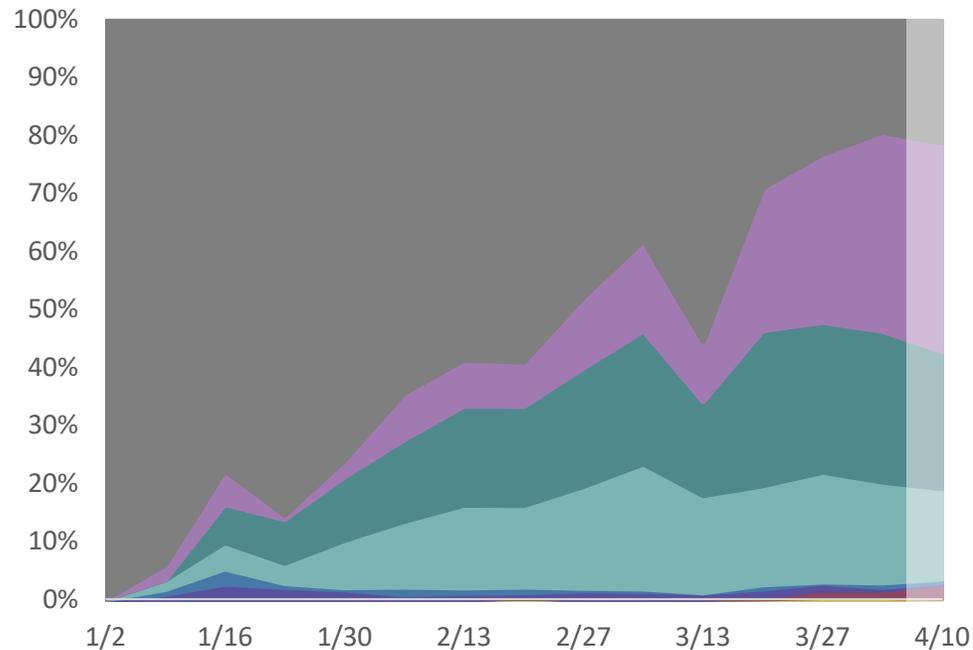
- Of confirmed COVID-19 cases among NYC residents diagnosed 1/1/2021 – 4/10/2021, 3.2% were sequenced at PHL (N=1487) or PRL (N=9361) as part of routine testing
- During week ending 4/10/2021, 6.2% of confirmed cases were sequenced



# Percent of Total SARS-CoV-2 Genomes Sequenced by PHL or PRL that are Variants of Concern or Interest *NYC residents, 1/1 – 4/10, for specimens collected by week ending date*

## All Sequenced Cases

n=10,947



- The proportion of sequenced viral genomes that are B.1.526, B.1.1.7, or other variants of concern or interest has grown over time
- For the week ending 4/3/2021: 80% of all isolates were variants of interest or variants of concern
  - 26% B.1.526 +484K
  - 34% B.1.1.7
  - 17% B.1.526 -484K
  - 3% additional variants of interest/concern
- Cases are classified by specimen collection date, not by diagnosis date for the case; total numbers may differ from other slides
- Data include routinely sequenced specimens from PHL or PRL, including those referred by the OCME

Recent data are incomplete. All data are preliminary and subject to change.

# Integrating Whole Genome Sequencing with Epi Data

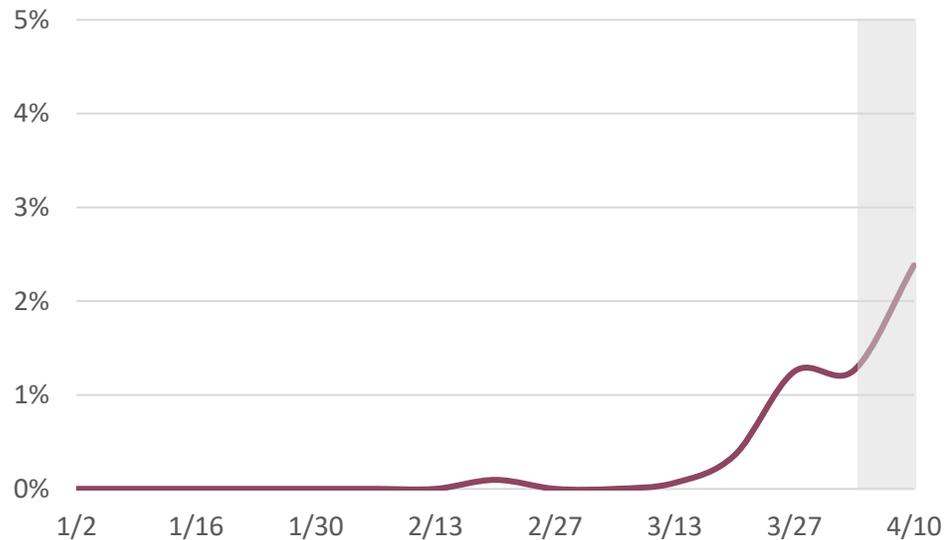
- Viral genomes sequenced at PHL or PRL are matched to COVID-19 cases from surveillance database
- COVID-19 surveillance database regularly matched to Citywide Immunization Registry and death registry
- Rates of immune escape - vaccine breakthrough, reinfection, infection among persons who were previously seropositive for individual VOI/VOC\* are being compared to similar rates for other non-VOI/VOC\* sequenced viruses (random sampling is essential)
- Severity of outcome and secondary attack rate among close contacts also compared across variants
- Additional studies of vaccine breakthrough infections and repeat positives underway

\*VOI - variant of interest; VOC - variant of concern

<https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-variants-overview.pdf>

# Basic P.1 Summary

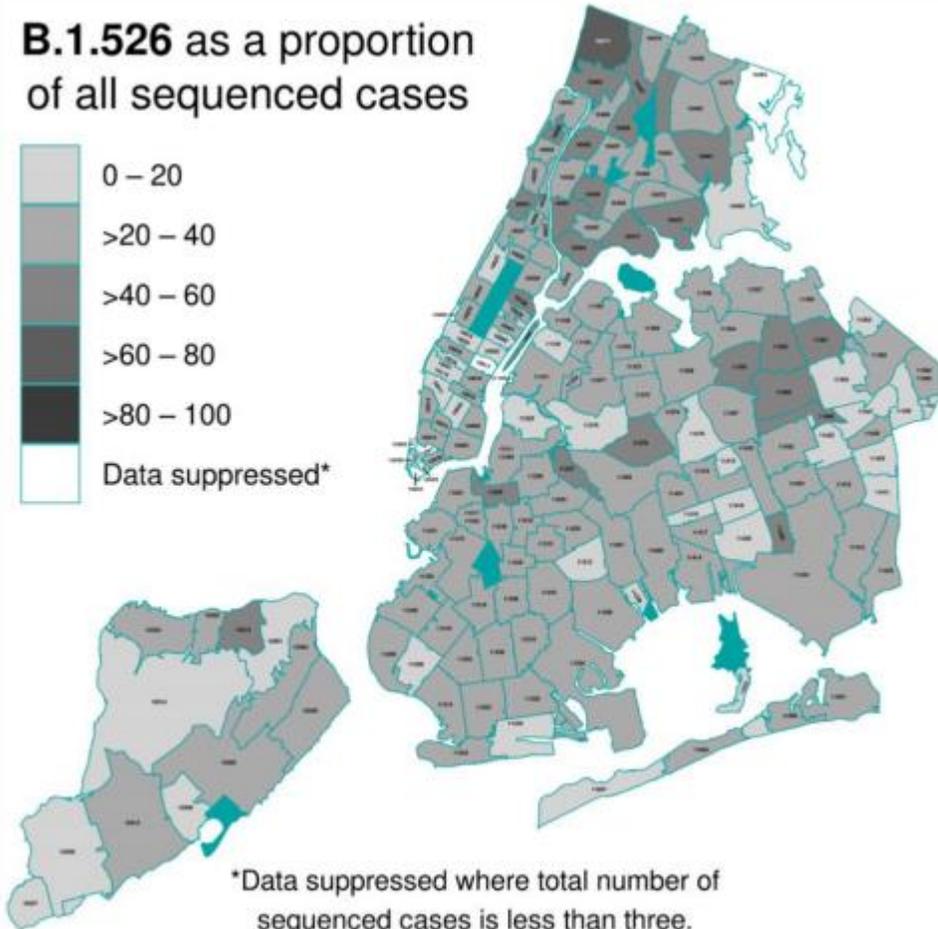
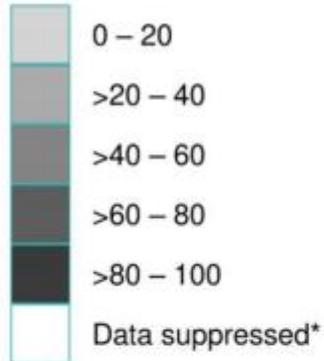
The proportion of sequenced specimens that are P.1 has grown over time



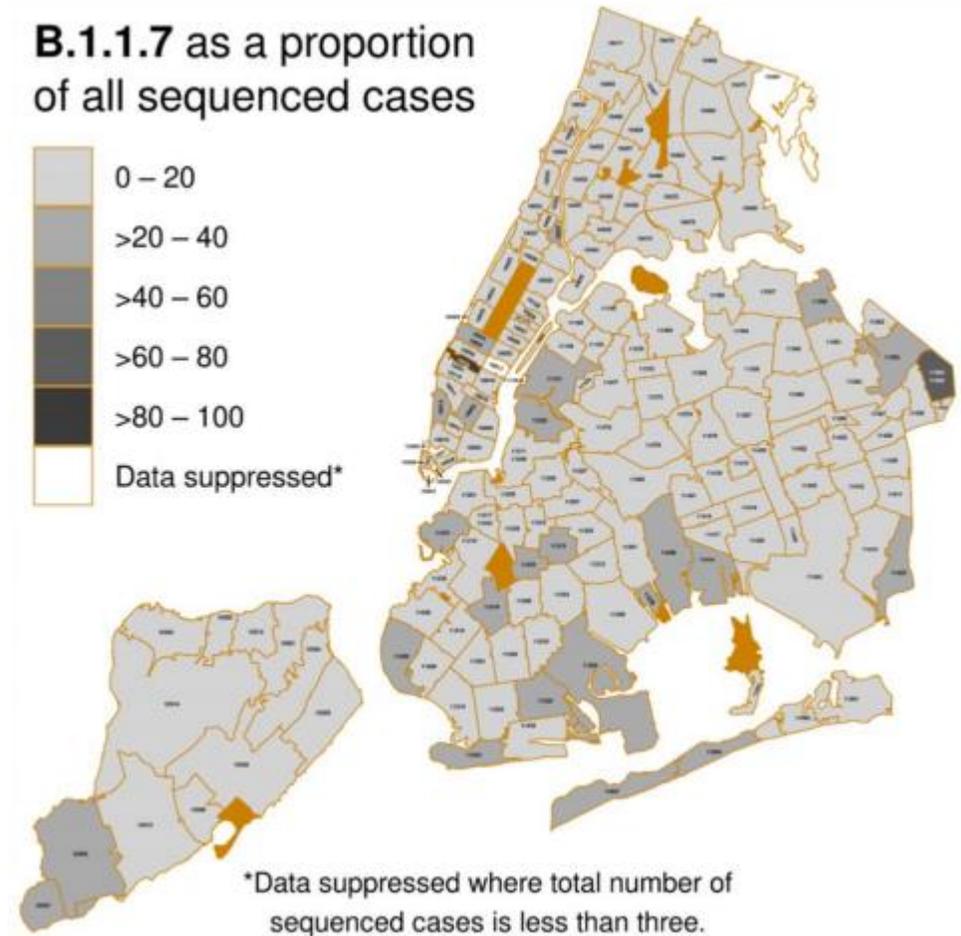
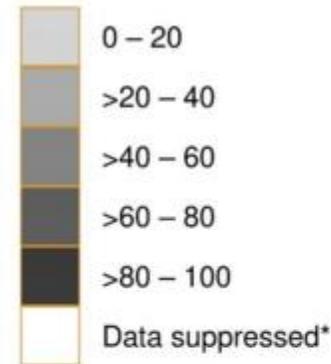
- P.1 is a variant of concern originally identified in Brazil
- Overall counts in NYC remain small: 66 P.1 isolates identified in routine specimens sequenced at PHL or PRL since 1/1/2021
- 2 possible reinfections (3%), where first positive was >90 days prior to the P.1 specimen collection
- No previous antibody positivity or full or partial vaccine breakthroughs
- 2 hospitalizations (3%) and no deaths, though too early to assess
- Age group
  - 0-17 years: 9
  - 18-44 years: 41
  - 45-64 years: 15
  - 65-74 years: 1

# Proportion of Sequenced NYC Cases Identified as Selected Variants, Jan 1 – March 27, 2021

**B.1.526** as a proportion of all sequenced cases



**B.1.1.7** as a proportion of all sequenced cases



# Summary of Findings on SARS-CoV-2 Variants in NYC

- Number of variants of interest and concern detected in NYC is increasing
- Among isolates that have been sequenced, an increasing proportion are variants of concern or interest (>70%)
- B.1.1.7 is increasingly common in NYC (~30% of sequenced isolates)
  - Higher vaccination coverage than initially thought may be needed to prevent this more easily transmitted variant
- B.1.526 is also very common but stabilized (~40% of sequenced isolates)
  - Clinical and epidemiologic characteristics of this variant are being studied and more information is expected soon
- P.1 is rare in NYC thus far but is increasing and being monitored closely (2% of sequenced isolates)
- Too early to know how these variants will impact reinfection or vaccine effectiveness
  - To date, reinfection and COVID-19 in people who were fully vaccinated have been rare
  - Area of active investigation

<https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-variants-overview.pdf>

<https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-data-variants-041321.pdf>

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# Things We Can All Do Right Now to Prevent COVID-19



- Answer questions from patients, colleagues, and others about COVID-19 vaccines
  - Explain that new information about vaccine safety is being shared as soon as it is available
  - Remind them that COVID-19 vaccines currently available in the U.S. are highly effective and have been used safely in many millions of people
- Support continued use of face coverings, physical distancing, and other preventive measures
  - Including after getting vaccinated
- Taking steps together helps counter COVID fatigue

*In memory of our dear colleague, Dr. Amita Toprani*

# Additional COVID-19 Resources

## COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccine:
  - Public: [nyc.gov/covidvaccine](https://www1.nyc.gov/site/doh/covid/covid-19-vaccine.page)
  - Providers: [nyc.gov/health/covidvaccineprovider](https://www1.nyc.gov/site/doh/covid/covid-19-vaccine-provider.page)
- Citywide Immunization Registry Reporting Assistance
  - <https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic>
- Vaccine Provider Assistance:
  - Email [nycimmunize@health.nyc.gov](mailto:nycimmunize@health.nyc.gov)

## General COVID-19 Resources

- Provider page: <https://www1.nyc.gov/site/doh/covid/covid-19-providers.page>
- Data page: <https://www1.nyc.gov/site/doh/covid/covid-19-data.page>
- Dear Colleague COVID-19 newsletters (sign up for *City Health Information* subscription at: [nyc.gov/health/register](https://www1.nyc.gov/site/doh/covid/covid-19-newsletters/register.page))
- NYC Health Alert Network (sign up at <https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page>)
- Provider Access Line: **866-692-3641**

## Next NYC Health Department provider webinar

- Friday, May 14, 1 p.m. (sign up on provider page)

# CONTINUING MEDICAL EDUCATION

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