

**COVID-19
HEALTH CARE PROVIDER UPDATE:
RECENT EPIDEMIOLOGY AND DEVELOPMENTS;
COVID-19 VACCINES AND VACCINATION PROGRAM**

MARCH 5, 2021

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New York City Department of Health and Mental Hygiene

*Our understanding of COVID-19 is evolving rapidly.
This presentation is based on our knowledge as of March 4, 2021, 5 PM.*

CONTINUING MEDICAL EDUCATION

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OUTLINE



UPDATES AND GUIDANCE



RECENT EPIDEMIOLOGY OF COVID-19 IN NYC



COVID-19 VACCINES AND VACCINATION PROGRAM, NYC



QUESTIONS AND DISCUSSION

NEW DEVELOPMENTS AND GUIDANCE

Mary Foote, MD, MPH

Health Systems Planning and Strategies Lead,
COVID-19 Response

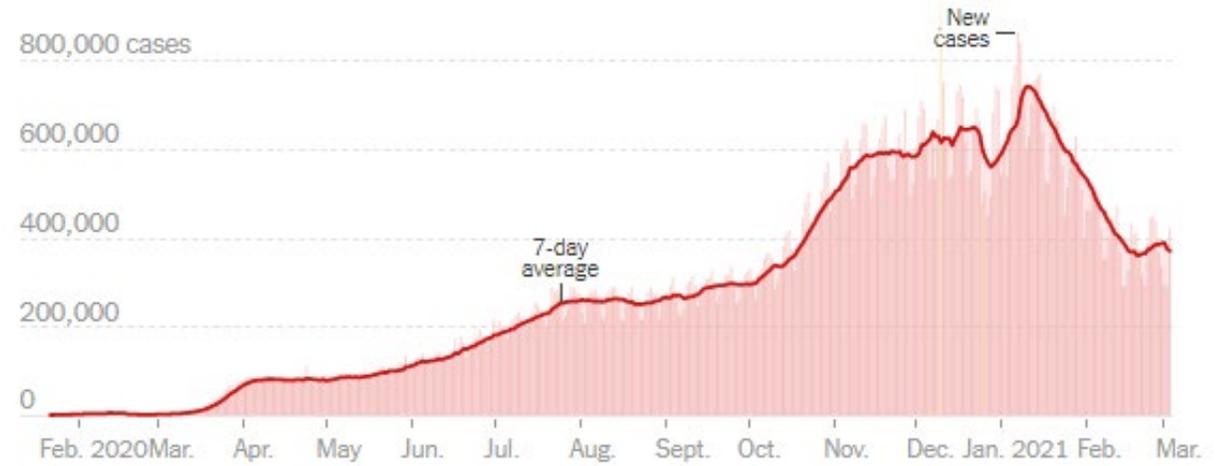
NYC Department of Health and Mental Hygiene

CURRENT STATUS: GLOBAL

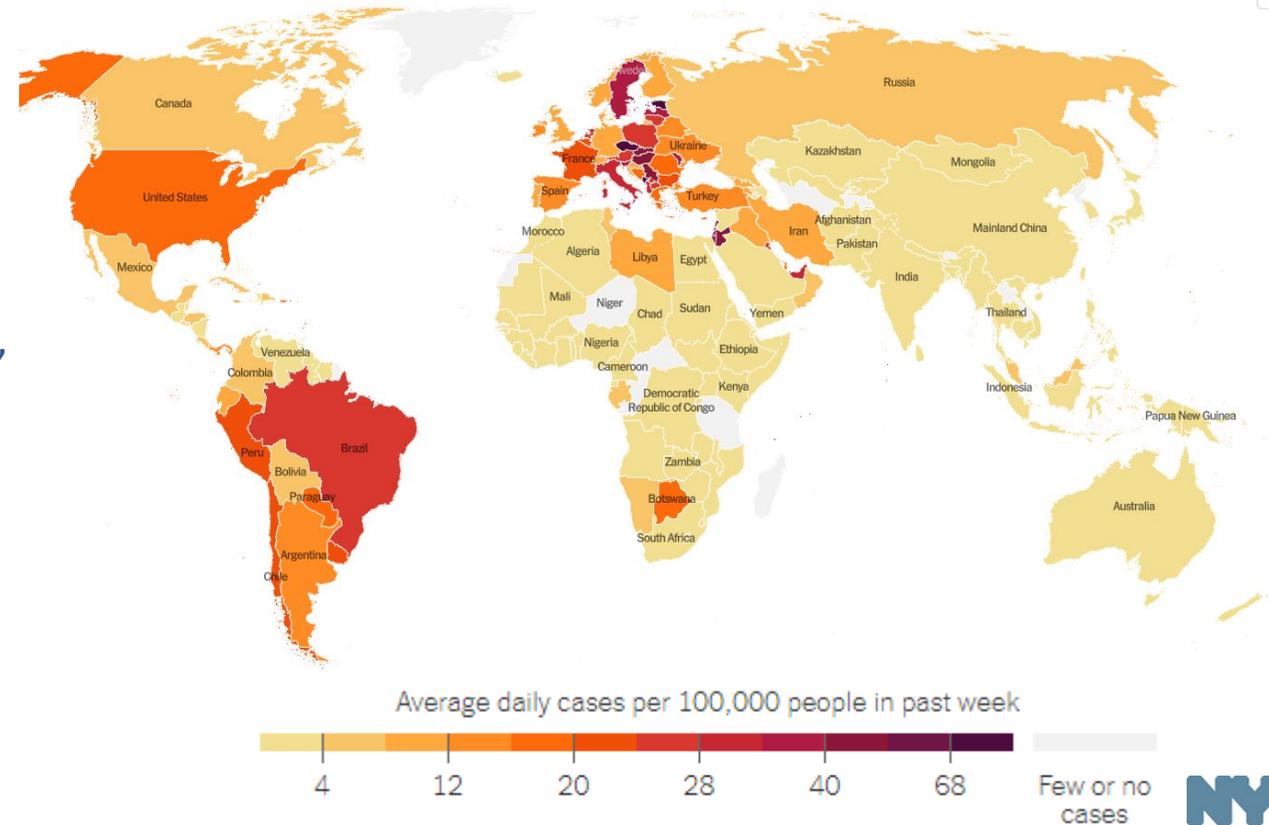
- Over 115 million cases
- Over 2.5 million deaths
- New cases rose for first time in 7 weeks

As of 3/4/2021
<https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>

COVID-19 CASES,
FEB 2020-MAR
2021



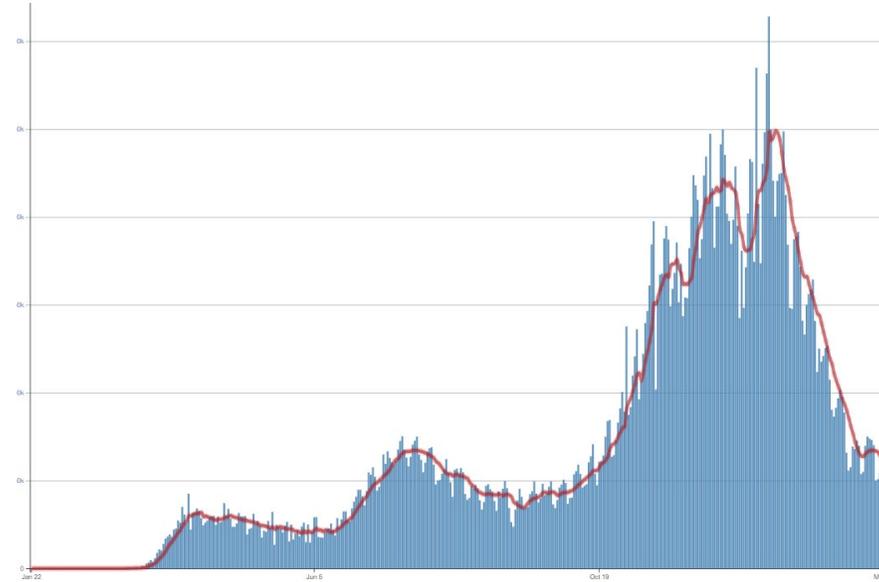
CASES PER 100,00,
PAST 7 DAYS



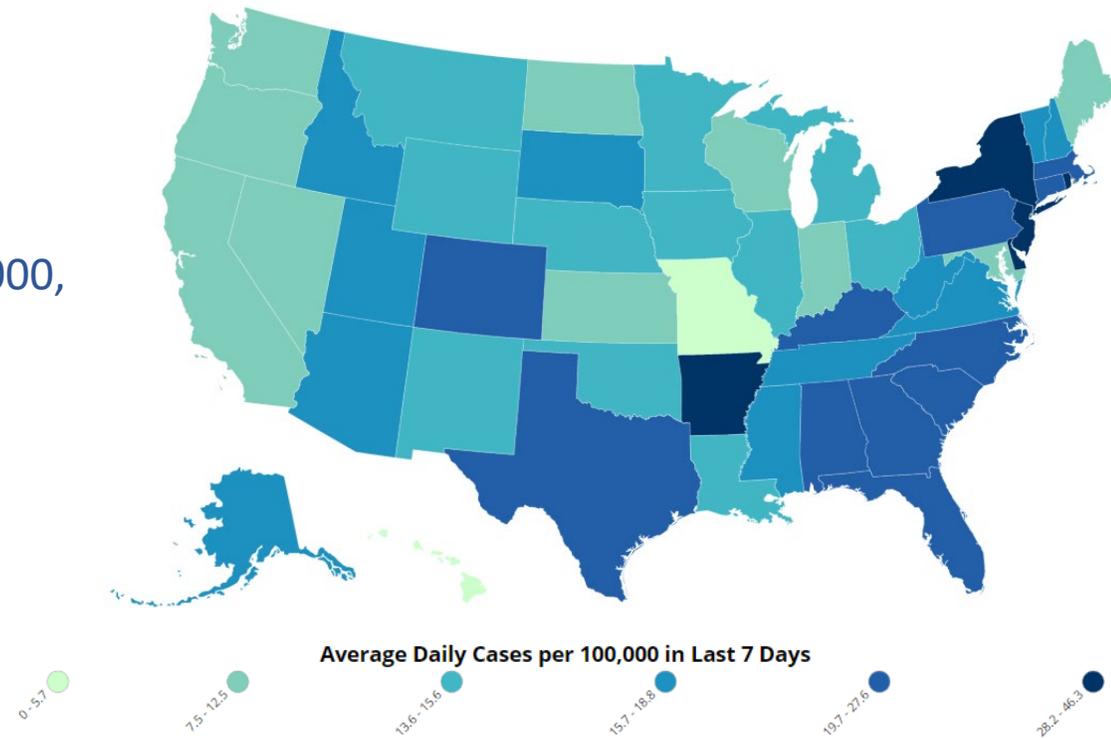
CURRENT STATUS: U.S.

- Over 28 million cases
- Over 518,000 deaths
- New cases have leveled off during past week
- States with highest recent case rates include New York, New Jersey and Rhode Island

COVID-19 CASES,
JAN 2020-MAR 2021



CASES PER 100,000,
PAST 7 DAYS



RECENT EPIDEMIOLOGY OF COVID-19 IN NYC

Corinne Thompson, PhD

Co-Lead, Epi Data Unit, COVID-19 Response

NYC Department of Health and Mental Hygiene



Emerging SARS-CoV-2 Variants, NYC

- B.1.526 (emerged in NYC November 2020)^{1,2}
 - Many B.1.526 isolates contain spike protein mutation E484K (may help evade antibodies)
 - As of 3/1/21, over 735 cases identified in 15 U.S. states; has spread extensively across NYC metropolitan area³
 - Potential impact on COVID-19 epidemiology under study
- B.1.1.7 (emerged in U.K. September 2020)
 - More easily transmitted than wild-type; may also be more virulent
 - Recently accounted for 7.9% of specimens submitted to NYC Pandemic Response Lab⁴
- B.1.351 (emerged in South Africa December 2020)
 - Several studies have shown potential for decreased efficacy of vaccines against this variant
 - 2 cases identified in NYC residents
- P.1 (emerged in Brazil, likely in late 2020)
 - Not reported in NYC to date

1. Annavajhala et al. A Novel SARS-CoV-2 Variant of Concern, B.1.526, Identified in New York. Preprint

2. West et al. SARS-CoV-2 lineage B.1.526 emerging in New York region. Preprint. <https://www.biorxiv.org/content/10.1101/2021.02.14.431043v1.full.pdf>

3. <https://www.bloomberg.com/news/articles/2021-03-01/new-york-covid-19-variant-drawing-concern-from-fauci-cdc?srnd=premium>

4. <https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-data-variants-022821.pdf>



Public Health Implications of Emerging SARS-CoV-2 Variants

- Currently available data suggest:
 - Vaccines authorized in U.S. are effective against wild-type strains and B.1.1.7 variant
 - Newly authorized Johnson & Johnson/Janssen vaccine offers protection against severe COVID-19 in geographic areas where other variants of concern, including B.1.351, were common
- Moderna and Pfizer are studying booster doses of current vaccines and second-generation vaccines against B.1.351 in case a modified vaccine is needed
- Physical distancing, use of effective face coverings, and other prevention measures remain essential, even after COVID-19 vaccination

Additional information on potential impact of variants on vaccines:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/07-COVID-Scobie.pdf>

New NYC Health Department Resources

- Information on SARS-CoV-2 variants in NYC
 - <https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-data-variants-022821.pdf>
- Dear Colleague: Building Confidence in COVID-19 Vaccines and Vaccination
 - <https://www1.nyc.gov/assets/doh/downloads/pdf/covid/providers/covid-19-providers-dear-colleague-updates-03012021.pdf>

NYC Health

New York City COVID-19 Cases Caused by SARS-CoV-2 Variants Report (2.28.2021)

Among a sample of specimens submitted to the... estimated 7.9% were B.1.1.7 (65 out of 824 sp... Feb 15-21 compared to 6.3% the prior week (...

As of 2/28, 2 cases caused by B.1.351 have b... below table once posted in GISAIID.

** Estimates are derived from a subset of specimens su... for diagnostic testing and may not be completely repres... samples may not be generalizable to all NYC COVID inf... Hospitals outpatient and inpatient facilities, including cor... Specimens are eligible for sequence analysis if they are...

Data pulled 2/24/21 from GISAIID

Total B.1.1.7 available in GISAIID for NYC re...
Number of B.1.1.7 in NYC residents, reported...
Number of genome sequences from specime... cumulative*
Number of sequences from NYC residents fr... NYC Health Department Public Health Lab w...

* GISAIID is a global science repository for open-access... present.

For national figures, see the CDC's US COVID-19 Case... [ncov/transmission/variant-cases.html](https://www.cdc.gov/ncov/transmission/variant-cases.html)

NYC Health

Dear Colleague COVID-19 Updates

March 1, 2021

Building Confidence in COVID-19 Vaccines and Vaccination

What Influences Decisions Around Vaccination?
Building Vaccination Confidence
Reduce Real and Perceived Barriers to Vaccine Access
Resources

Updated Guidance

- Next [Webinar for Providers](#) (March 5, 1 p.m.): Updates on COVID-19 Vaccines
- [COVID-19 Vaccines and Vaccination Program in NYC: An Overview for Health Care Providers](#) (February 22)
- [Health Advisory #3: Collect and Report Race and Ethnicity Data to Help Ensure Equitable Access to COVID-19 Vaccines](#) (February 2)
- [COVID-19 Provider FAQ](#) (January 23)
- [COVID-19 Vaccination: Building Vaccine Confidence Among Health Care Providers, Support Staff and Patients](#) (January 22)
- NYC Health Department [COVID-19](#) web pages
 - [Vaccine Information for Providers](#)
 - [Vaccine Eligibility](#)
 - [Vaccine Finder](#)
 - [Information for Providers](#)
 - [Resources for Health Care Facilities](#)
 - [COVID-19 Data](#)
 - [COVID-19 Vaccine Data](#)
 - [Telehealth Tips](#)

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NYC Health

Remain Alert for Other Communicable Infections, Including Ebola

- In addition to screening all patients entering health care facilities for COVID-19 symptoms, inquire about and document international travel histories
- Ebola outbreaks are currently occurring in Guinea and Democratic Republic of Congo
 - To date, outbreaks are relatively small and confined to remote areas; current risk to U.S. is low
- Travelers to U.S. from these locations are being routed through six airports, including JFK and Newark
- Be familiar with infection control precautions indicated for viral hemorrhagic fevers
- Immediately report suspected cases of Ebola to NYC Health Department by calling the Provider Access Line (PAL): 866-692-3641
- Information on Ebola: <https://www.cdc.gov/vhf/ebola/index.html>

COVID-19 VACCINES AND VACCINATION PROGRAM IN NYC

Jane R. Zucker, MD, MSc, FIDSA

Branch Director, Vaccine Section

Assistant Commissioner, Bureau of Immunization

NYC Department of Health and Mental Hygiene

OUTLINE

- UPDATES ON COVID-19 VACCINE ROLLOUT

- JOHNSON & JOHNSON/JANSSEN VACCINE

- ADDITIONAL VACCINE-RELATED UPDATES

- QUESTIONS AND DISCUSSION

COVID-19 VACCINE ROLLOUT

Global:

- Vaccination campaigns are ongoing on all continents
- COVAX initiative will deliver 237 million Oxford/AstraZeneca doses to 142 countries by late May

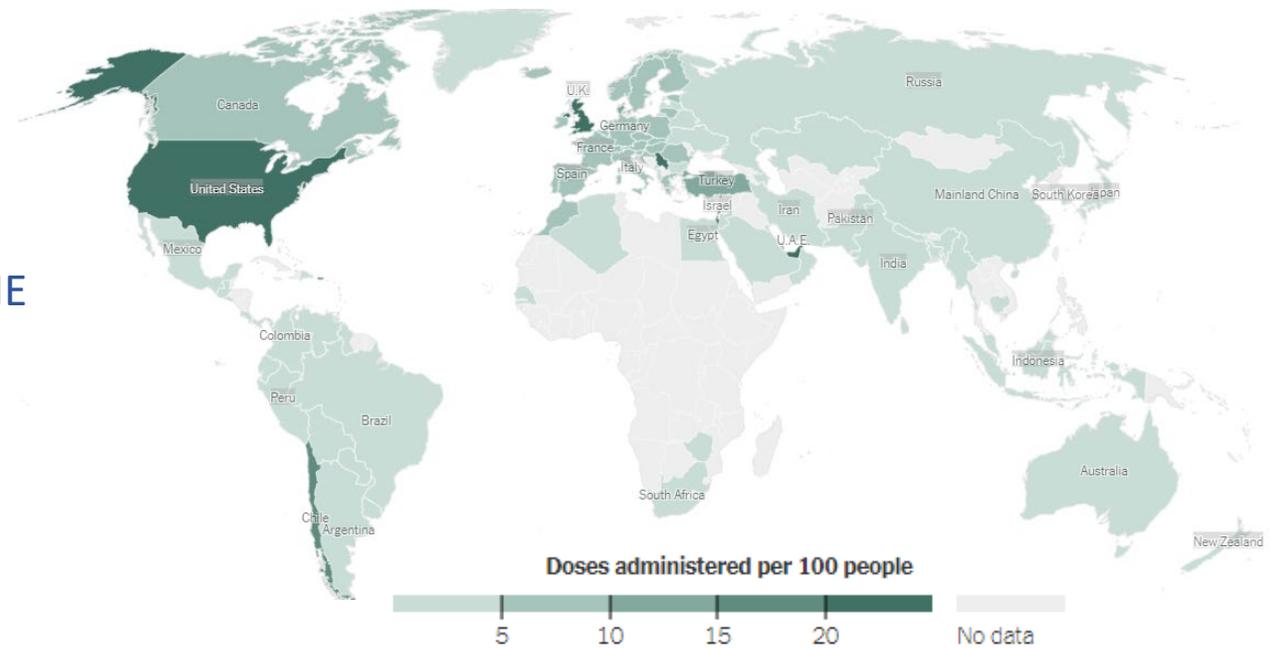
U.S.:

- Now averaging 2 million doses administered per day
- Approximately 8% of U.S. population is fully vaccinated
- Vaccine supply anticipated to be sufficient for all U.S. adults by late May
- Johnson & Johnson/Janssen vaccine authorized

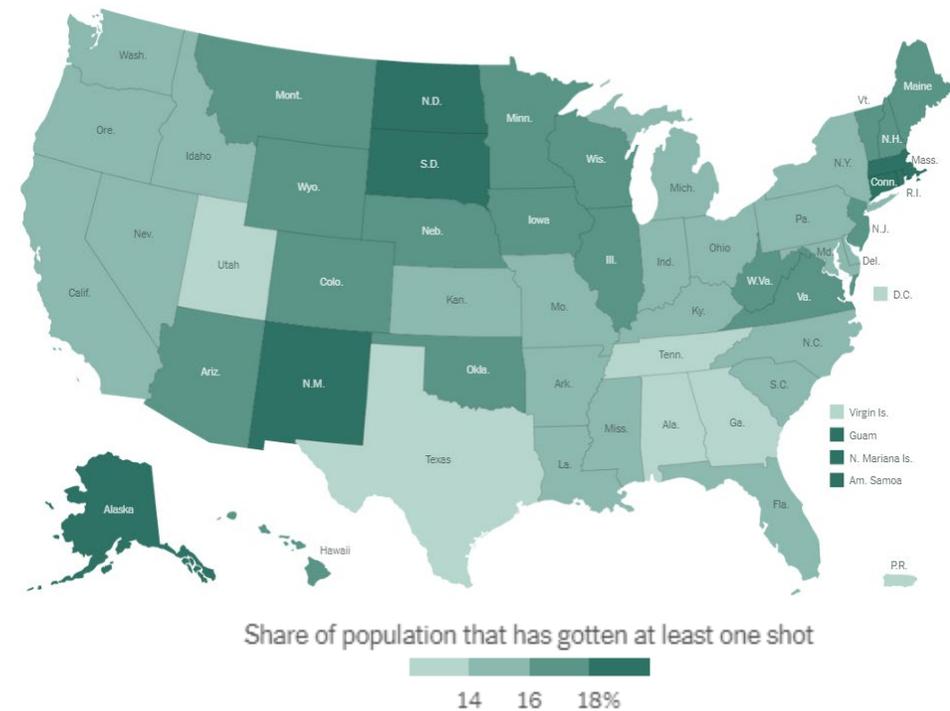
As of 3/4/21. Images:

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

GLOBAL VACCINE COVERAGE

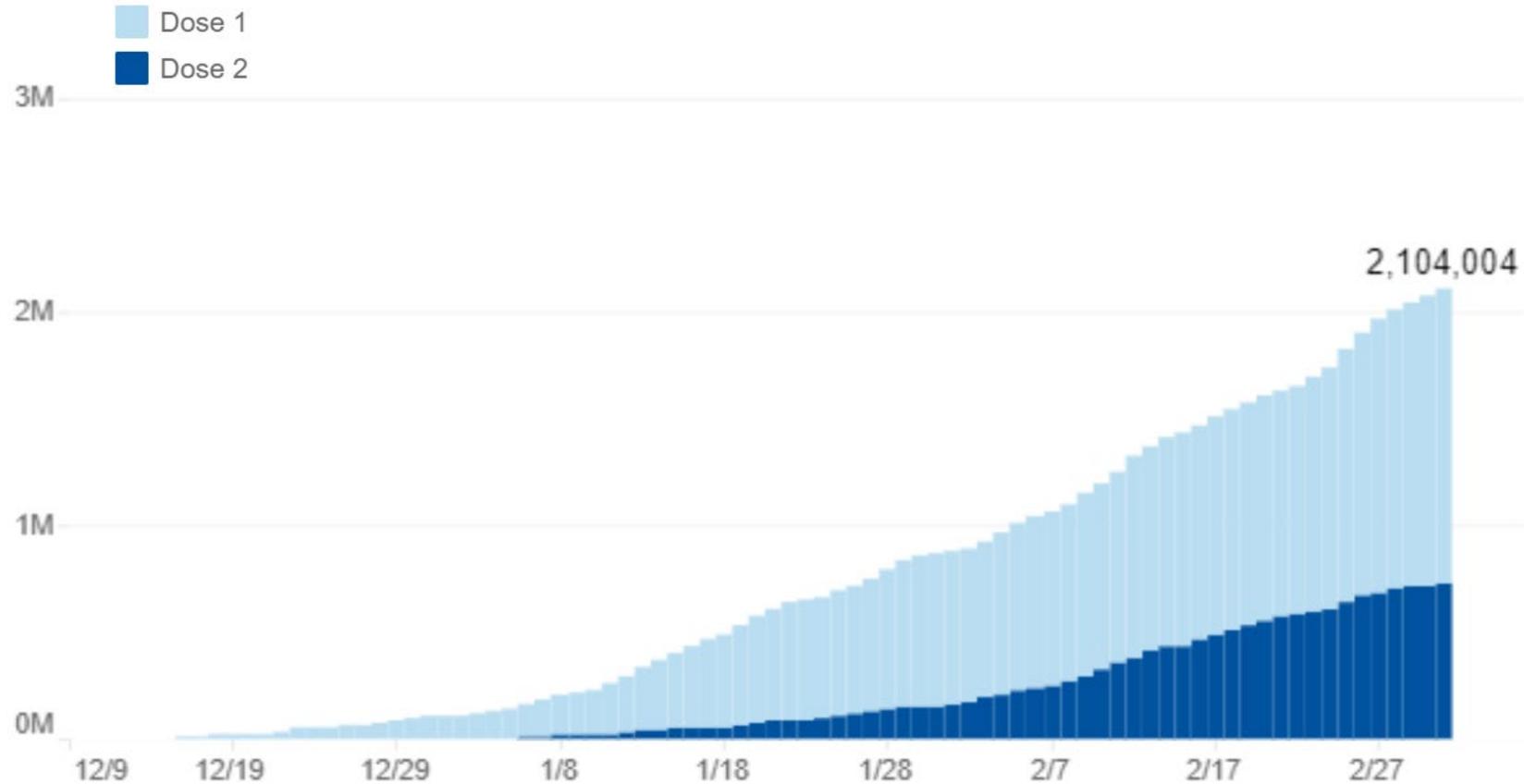


U.S. VACCINE COVERAGE



COVID-19 VACCINE ADMINISTRATION, NYC

- Over 2 million doses administered
- Pace of vaccination is increasing steadily



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 3/4/2021

Johnson & Johnson/Janssen COVID-19 Vaccine

- February 27, 2021: FDA issued Emergency Use Authorization (EUA)
- February 28, 2021: Advisory Committee on Immunization Practices (ACIP) voted to approve vaccine use for adults ages ≥ 18 years

Adenovirus Vector Vaccine

- Genetically modified adenovirus vector
- Cannot replicate
- Cannot cause disease
- Genetic code (DNA) for SARS-CoV-2 spike protein
 - Does not integrate into a person's DNA
- Technology used for development of other vaccines
- No adjuvants, antibiotics, or preservatives

Janssen COVID-19 Vaccine: Phase III Clinical Trial

- Single dose trial, ~40,000 participants
- U.S., Brazil, South Africa, Peru, Colombia, Mexico, Argentina, Chile
- Diverse enrollment
 - 62% White; 17% Black/African American; 8% American Indian/Alaska Native; 4% Asian; 0.3% Native Hawaiian/Pacific Islander
 - 45% Hispanic
 - 40% with ≥ 1 medical comorbidity
- Age
 - Median 53* years (range 18-100 years)
 - 20.4% aged ≥ 65 years

*Edited 3/10/21

Reference added 3/10/21: per-protocol set; www.fda.gov/media/146338/download

Interim Findings: Vaccine Efficacy (VE)

- Symptomatic, lab-confirmed COVID-19:
 - 66% at ≥ 14 and ≥ 28 days after vaccination*
- Moderate to severe/critical COVID-19 at ≥ 14 days after vaccination (varied across trial locations)**
 - U.S. (74%), Latin America (65%), South Africa (52.0%)
- Hospitalization (COVID-19-associated)
 - 93% at ≥ 14 days after vaccination; 100% at ≥ 28 days after vaccination
- Death
 - All-cause: 75% at ≥ 28 days after vaccination*
 - No COVID-19-associated deaths occurred among vaccine recipients*

*Edited 3/22/2021

Reference added 3/10/2021: Janssen COVID-19 Vaccine Emergency Use Authorization Review Memorandum.

www.fda.gov/media/146338/download. All symptomatic: Table 15; by region: Table 12; hospitalization: Table 18; death: All cause Table 21, COVID-associated Page 64

Clinical Trial: Age ≥ 60 years

- VE in participants aged ≥ 60 years was greater in persons without comorbidities
- 42% VE among persons aged ≥ 60 years with comorbid conditions
- Interpret with caution – limited numbers and follow-up
- No COVID-associated hospitalizations among vaccine recipients at ≥ 28 days after vaccination
- No COVID-associated deaths among vaccine recipients

Reference added 3/10/2021: Janssen COVID-19 Vaccine Emergency Use Authorization Review Memorandum. www.fda.gov/media/146338/download. COVID hospitalizations Table 13 and page 38; COVID death page 6.

Clinical Trial: Variants

- US: 96% of cases D614G*
- Brazil: 69% of cases P.2
 - Efficacy likely not impacted by P.2 since VE similar to U.S., where newly emerging strains don't predominate
- South Africa: 95% of cases B.1.351*
 - VE reduced, but nonetheless high, against severe/critical COVID-19 \geq 28 days after vaccination (82%)*

*Edited 3/10/2021

Reference added 3/10/2021: Janssen COVID-19 Vaccine Emergency Use Authorization Review Memorandum.

www.fda.gov/media/146338/download; page 7; severe/critical disease, table 22

Clinical Trial: Asymptomatic Infection

- Might also protect against asymptomatic SARS-CoV-2 infection
- 74% efficacy among a subset with serology results 71 days post-vaccine*

*In sensitivity analysis when removing persons with symptoms prior to serology

Reference added 3/10/2021: Janssen COVID-19 Vaccine Emergency Use Authorization Review Memorandum.

www.fda.gov/media/146338/download

Clinical Trial: Expected Reactions After Vaccine

- Common: injection site pain (48.6%*); headache (38.9%*); fatigue (38.2%*); myalgia (33.2%*); nausea (14.2%*); fever (9.0%*)
- Duration: 1-2 days (median)
- Less frequent in older adults
- Serious allergic reactions were rare
- No significant safety concerns identified

*Edited 3/10/2021

Reference added 3/10/2021: Janssen COVID-19 Vaccine Emergency Use Authorization Review Memorandum.

www.fda.gov/media/146338/download; Table 27

Distribution

- Johnson & Johnson/Janssen vaccine supply currently limited
- Priority to providers serving priority areas, hard-to-reach populations or where completion of multi-dose vaccine may be difficult:
 - Homebound
 - Homeless and/or residing in shelter
 - Residing in long-term care facility or other congregate setting
 - Incarcerated and meet other eligibility criteria
 - Ages ≥ 65 years discharging from hospital
 - Ages ≥ 18 years discharging from hospital to long-term care (e.g., skilled nursing)

Dosage, Storage, Handling

- 1 dose (0.5mL), intramuscular injection
- 5 doses per vial
 - Order comes with 100 dose ancillary kit
- No diluent or mixing
- Storage: 2° to 8°C for 3 months
 - After withdrawing first dose, hold at 2° to 8°C ≤6 hours or at room temperature (max 25°C) ≤2 hours; discard if not used within this time

Additional Johnson & Johnson Vaccine Studies

- Study of two-dose regimen
- Study in children ages 0-17 years
- Study in pregnant women planned
- Study in immunocompromised persons planned

Three U.S. Authorized COVID-19 Vaccines

- No product preference by ACIP
- People should get whichever vaccine is earliest available to them
- All show high efficacy against severe disease, including COVID-19 hospitalizations and deaths
- Similar safety profiles
- No head-to-head comparisons
- Johnson & Johnson/Janssen trial done during higher baseline COVID-19 incidence and with different circulating variants

Interchangeability of COVID-19 Vaccines

- Not interchangeable
- No mixed-product safety or efficacy evaluations conducted

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

Contraindications & Precautions

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† 	<p>Among people without a contraindication, a history of:</p> <ul style="list-style-type: none"> • Any immediate allergic reaction* to other vaccines or injectable therapies‡ <p>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#</p>	<p>Among people without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
<p>Actions:</p> <ul style="list-style-type: none"> • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.† 	<p>Actions:</p> <ul style="list-style-type: none"> • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated 	<p>Actions:</p> <ul style="list-style-type: none"> • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

ACIP Recommendations for Clinical Use

- Other guidance harmonized and unchanged for the three authorized COVID-19 vaccines, including:
 - Co-administration with other vaccines
 - Observation period after vaccination
 - Vaccination of persons with underlying medical conditions, prior COVID-19 infection, past receipt of monoclonal antibodies or convalescent plasma, or who are pregnant

CDC Update: Timing of Vaccination for People Planning to Receive Immunosuppressive Therapies

- Data are insufficient to inform optimal timing of COVID-19 vaccination; guidance is based on general best practices
- Ideally, vaccinate ≥ 2 weeks before initiation of immunosuppressive therapy
- NOT currently recommended:
 - Antibody testing to assess immunity after vaccination
 - Revaccination after someone who was immunosuppressed when vaccinated regains immune competence

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

CDC Update: Interpretation of SARS-CoV-2 Antibody Test Results in Vaccinated People

- Antibody tests are not authorized for assessment of immune response in vaccinated people
- Antibody testing against nucleocapsid protein will not detect vaccine-related immunity because vaccines encode a different protein; however, patients will not always know which test was used
- If antibody testing was done after first mRNA dose, second dose should be given regardless of result

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

Additional COVID-19 Vaccine Updates

- Newly eligible for COVID-19 vaccination in NY State as of March 1, 2021:
 - Food bank, food pantry, or home-delivered meal program workers (paid or unpaid)
 - Hotel workers who have direct contact with guests
 - Complete, updated list of currently eligible groups:
<https://www1.nyc.gov/site/doh/covid/covid-19-vaccine-eligibility.page>
- February 25, 2021: FDA announced undiluted frozen vials of Pfizer-BioNTech vaccine may be transported and stored at temperatures commonly found in pharmaceutical freezers for up to two weeks
 - Pfizer-BioNTech fact sheet for health care providers:
<https://www.fda.gov/media/144413/download>
- Revised storage and handling guidance for both Moderna and Pfizer vaccines:
 - <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>

Discussing Vaccination with Patients

- Give your strong recommendation
- Vaccination is the number one thing people can do to protect themselves from hospitalization and death due to COVID-19
- Patients consider their providers the most trusted source of information on vaccines
- A provider recommendation is one of the strongest predictors of vaccine receipt
- Start from a place of empathy and understanding
- Listen to and respond to questions in an understandable way
- Resources for answering questions: [CDC](#), [CHOP](#), [NYC Health Department](#)

Addressing Concerns About Fetal Tissue

- Johnson & Johnson/Janssen vaccine does not contain fetal tissue or human cells
- Fetal cell lines are cells that grow in a laboratory and were used in vaccine development to grow the adenovirus vector
- The origin of the cell line was from an elective abortion decades ago - not performed for the purpose of producing vaccines
- Multiple purification steps are taken to ensure that the cells and fetal material are not included in the final vaccine product

Additional COVID-19 Resources

COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccine:
 - Public: [nyc.gov/covidvaccine](https://www.nyc.gov/covidvaccine)
 - Providers: [nyc.gov/health/covidvaccineprovider](https://www.nyc.gov/health/covidvaccineprovider)
- 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

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://www.nyc.gov/health/register))
- 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, March 19, 1 p.m. (sign up on provider page)