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

CME Accreditation Statement for Joint Providership
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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
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

As of 3/4/2021
https://covid.cdc.gov/covid-data-tracker/#datatracker-home
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)**
  - 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 area
  - 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 Lab

- **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

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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:
New NYC Health Department Resources

- Information on SARS-CoV-2 variants in NYC

- Dear Colleague: Building Confidence in COVID-19 Vaccines and Vaccination
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
COVID-19 Vaccines and Vaccination Program in NYC

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Branch Director, Vaccine Section
Assistant Commissioner, Bureau of Immunization
NYC Department of Health and Mental Hygiene
• 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

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](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

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 ≥ 28 days after vaccination (82%)*

*Edited 3/10/2021
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
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
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°C to 8°C for 3 months
  - After withdrawing first dose, hold at 2°C 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

- History of the following:
  - 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†

## PRECAUTION TO VACCINATION

- Among people without a contraindication, a history of:
  - Any immediate allergic reaction* to other vaccines or injectable therapies†

  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.#

## MAY PROCEED WITH VACCINATION

- Among people without a contraindication or precaution, a history of:
  - 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

## Actions:

- Do not vaccinate.
- Consider referral to allergist-immunologist.
- Consider other vaccine alternative.†

- Risk assessment
- Consider referral to allergist-immunologist
- 30-minute observation period if vaccinated

- 30-minute observation period: people with history of anaphylaxis (due to any cause)
- 15-minute observation period: all other people

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[www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B](http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B)
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:

• 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](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](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
  • Providers: 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)
• 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)