COVID-19 Vaccines and Vaccination Program in NYC

An Overview for Health Care Providers

New York City Department of Health and Mental Hygiene

Information on COVID-19 vaccines is evolving rapidly.
This presentation was last updated June 26, 2021.

OUTLINE


COVID-19 VACCINE DEVELOPMENT


CLINICAL CONSIDERATIONS


SAFETY MONITORING


VACCINE DISTRIBUTION IN NYC


PREPARING TO OFFER VACCINATION


RESOURCES FOR COUNSELING PATIENTS

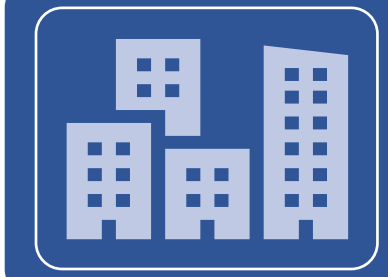
Impact of COVID-19

Global

- > 181 million cases
- > 3.9 million deaths*

U.S.

- > 34.4 million cases
- > 619,000 deaths



New York City

- > 954,000 cases
- > 28,300 confirmed deaths

Updated 6/26/2021

Sources: https://www.worldometers.info/coronavirus/; https://www1.nyc.gov/site/doh/covid/covid-19-data-totals.page

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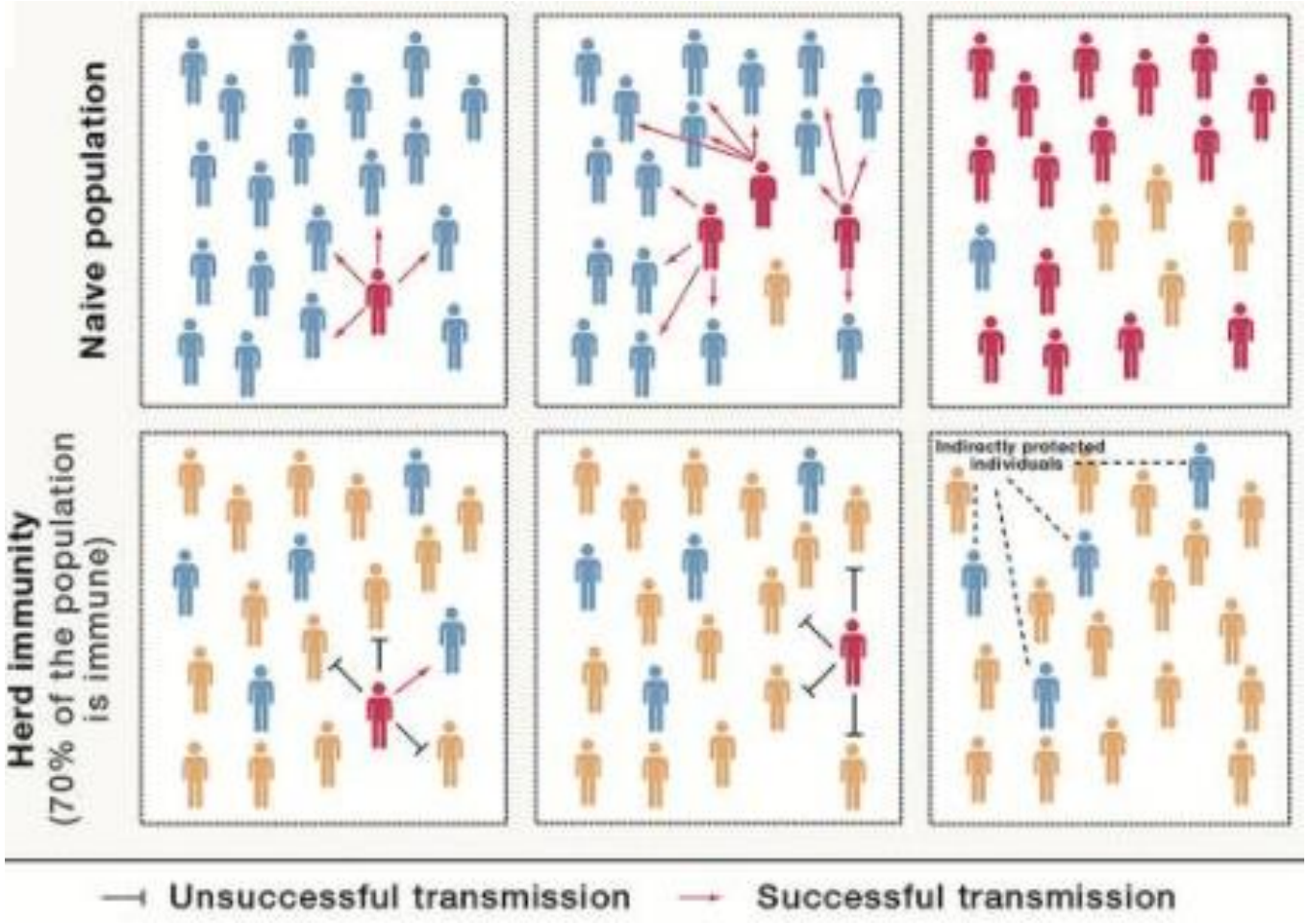
Benefits of COVID-19 Vaccination

- Individual level:
  - Prevent COVID-19, including possible long-lasting health effects after COVID-19 recovery
  - Reduce severity of COVID-19
  - Decreased need for precautionary measures such as face covering
  - Avoid need for quarantine after an exposure to COVID-19
- Community level:
  - Reduce transmission
  - Resume economic, educational, and other societal-level endeavors

Understanding Herd Immunity



- Vaccination or infection provide immunity
- When a sufficient portion of population is immune, protection is also provided to remainder of community
- This includes people who are unable to receive vaccination

Herd Immunity: Understanding COVID-19 Haley E. Randolph, Luis B. Barreiro. Immunity. 2020 May 19; 52(5): 737–741. Published online 2020 May 19. doi: 10.1016/j.immuni.2020.04.012.
PMCID: PMC7236739

Vaccination Coverage Needed to Achieve Herd Immunity

- How much COVID-19 vaccine coverage is needed?
  - Scientists do not yet know what level is necessary
- Estimates depend on various factors, including vaccine efficacy, duration of vaccine effectiveness, use of other prevention strategies (e.g. masking, distancing), susceptibility of the population
- Example based on modeling by Iboi et al.
  - Assuming vaccine efficacy of 80%, at least 83% of susceptible population needs to be vaccinated to achieve threshold
  - Combined with 30% of public using face covering, threshold decreases to 79%

Will an imperfect vaccine curtail the COVID-19 pandemic in the U.S.? Enahoro A. Iboi, Calistus N. Ngonghala, Abba B. Gumel. Infect Dis Model. 2020; 5: 510–524. Published online 2020 Aug 6. doi: 10.1016/j.idm.2020.07.006. PMCID: PMC7409819

COVID-19 Vaccine Development

COVID-19 Vaccine Development Process

- Same process that has been used for previous vaccines, but expedited because:
  - Built on years of research on related coronaviruses, including research on vaccines for other coronaviruses
  - Substantial funding allowed multiple trials to be run in parallel
  - Funding also allowed companies to began manufacturing vaccines early, enabling immediate distribution upon approval
- Safety was monitored closely during every phase of development
  - Tens of thousands of clinical trial participants received vaccines safely

Emergency Use Authorization vs. Licensure or Approval

- During a public health emergency, the Food and Drug Administration (FDA) can use Emergency Use Authorization (EUA) to allow use of vaccines before they are officially licensed so that they can be used sooner
- Certain criteria must be met, including that there are no adequate, approved, and available alternatives and that evidence strongly suggests that benefits outweigh any risks to patients
- Vaccines issued an EUA must go through the same clinical trials as all other licensed vaccines
- To support licensure of a vaccine, FDA generally requires at least 6 months of safety follow-up

https://fda.gov/news-events/fda-brief/fda-brief-fda-issues-guidance-emergency-use-authorization-covid-19-vaccines
https://fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

COVID-19 VACCINE DEVELOPMENT AND APPROVAL PROCESS

- Vaccine discovery and development by manufacturers
- Clinical trial Phases I, II, III by manufacturer to assess safety and efficacy
- Manufacturer submits EUA request
- Advisory Committee for FDA votes whether to recommend EUA
- FDA decides whether to issue EUA
- ACIP reviews data and votes to recommend vaccine and appropriate use
- Vaccine shipped for use in phases; post-vaccination monitoring begins

ACIP – Advisory Committee on Immunization Practices; EUA – Emergency Use Authorization; FDA – Food and Drug Administration

https://www.fda.gov/media/143890/download

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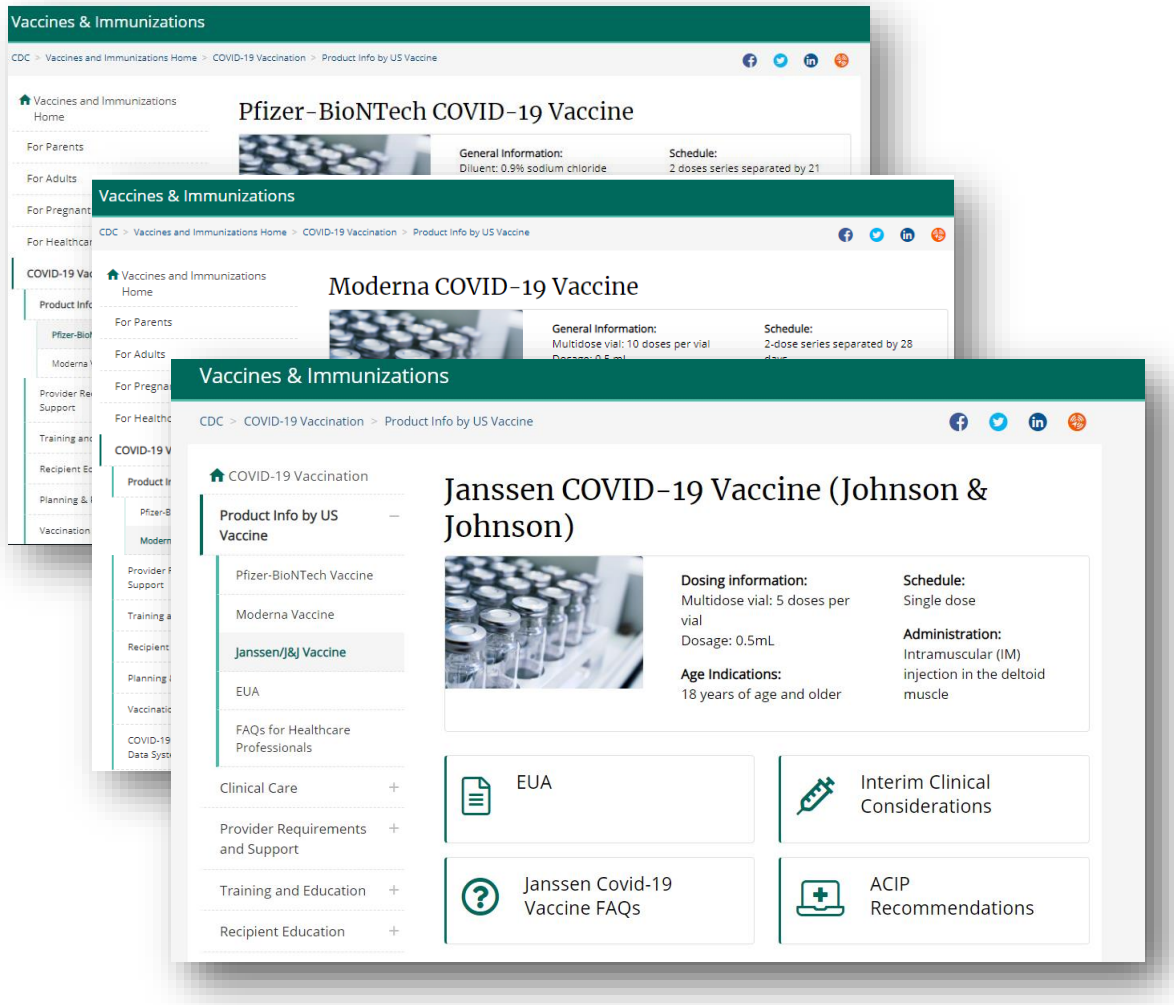
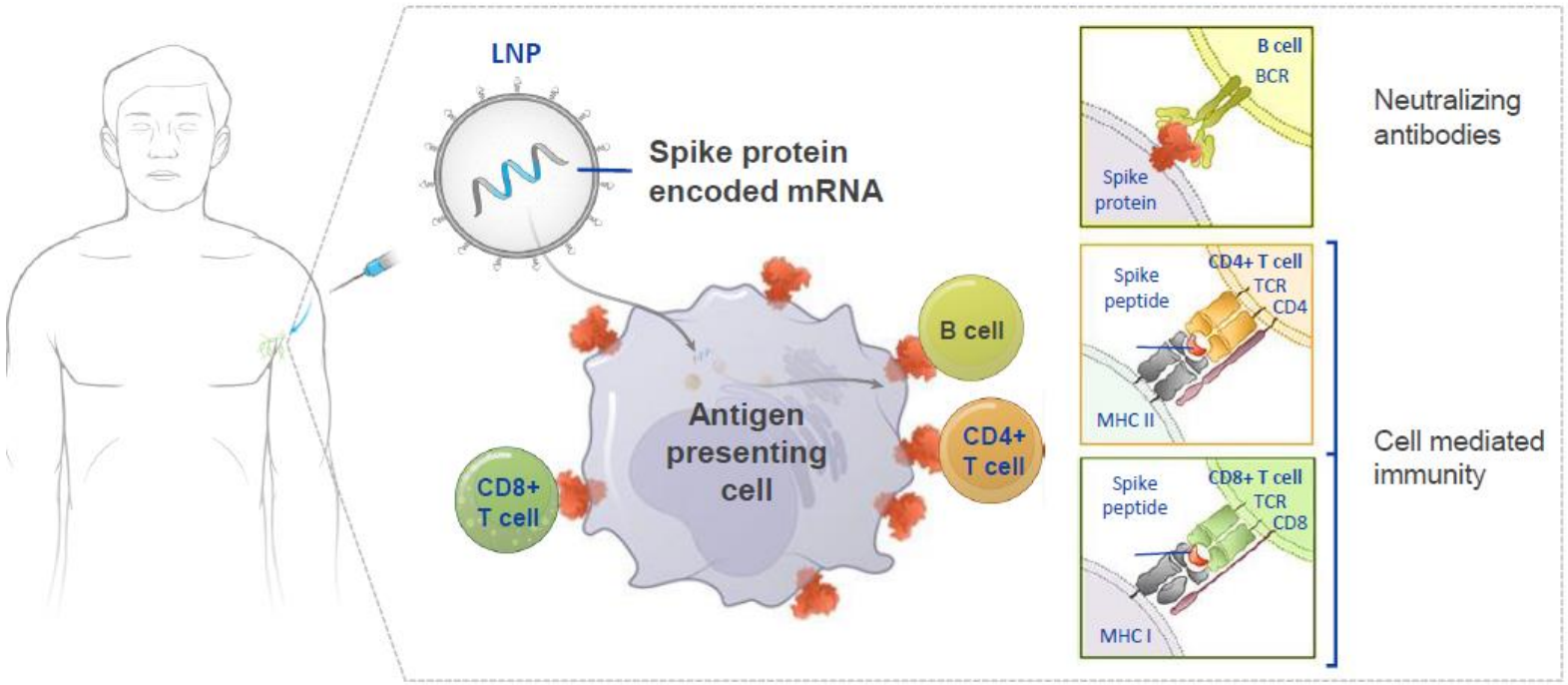
COVID-19 Vaccines Authorized and Recommended for Emergency Use in U.S.

- Emergency Use Authorizations issued for three vaccines
  - Pfizer-BioNTech - 12/11/2020
    - Expanded to include people age 12 to 15 5/10/21
  - Moderna - 12/18/2020
  - Johnson & Johnson/Janssen - 2/27/2021



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

mRNA Vaccines (Pfizer-BioNTech, Moderna)



- Contain genetic material from SARS-CoV-2 but not the actual virus
- mRNA provides instruction directly to the immune system
- Creates specific immune memory in a natural context
- mRNA never enters nucleus of cell; it can neither interact with nor integrate into the cell's DNA and is broken down quickly
- Although this is a new type of vaccine, mRNA vaccines have been studied for over 30 years

Image: https://www.fda.gov/media/144583/download

Adenovirus Vector Vaccine (Johnson & Johnson/Janssen)

- Genetically modified adenovirus vector
- Cannot replicate
- Cannot cause disease
- Does not contain SARS-CoV-2 virus
- Adenovirus carries genetic code (DNA) for SARS-CoV-2 spike protein into cells
  - Does not integrate into a person's DNA
- Technology has been used for previous vaccines
- No adjuvants, antibiotics, or preservatives

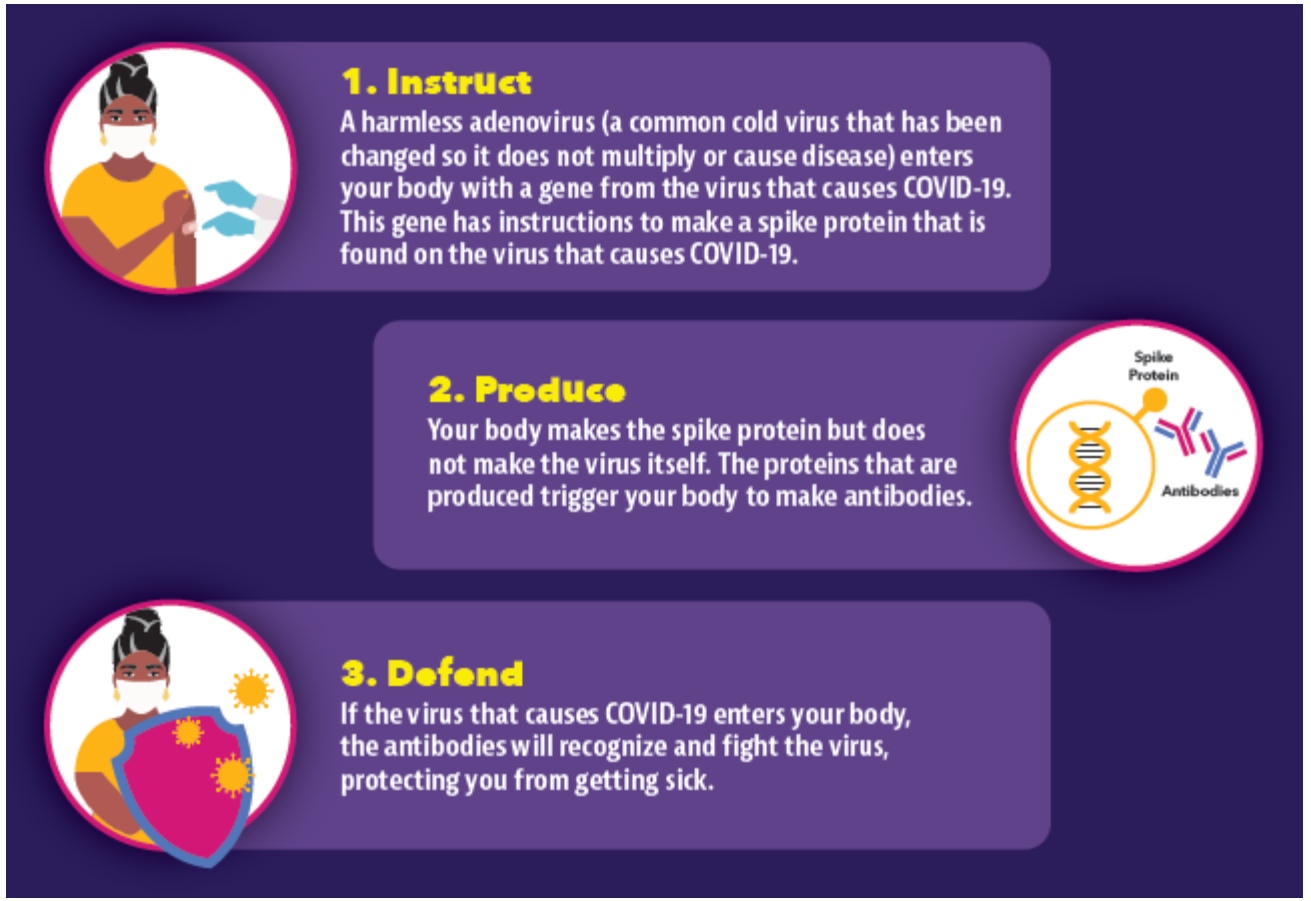


Image: https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-johnson-and-johnson-vaccine-infographic.pdf

Pfizer-BioNTech and Moderna Vaccine Clinical Trial Findings*

	Pfizer-BioNTech	Moderna
Phase III study population	• > 44,000 volunteers in U.S. and other countries • 26.2% of participants were Hispanic/Latino, 9.8% Black/African-American, and 4.4% Asian • 21.4% of participants were age 65 and older	• > 30,000 volunteers in U.S. • 20% of participants were Latino, 9.7% Black/African-American, and 4.7% Asian • 25.3% of participants were age 65 and older
Efficacy	• Overall: 95% • High efficacy maintained across age, gender, race and ethnicity	• Overall: 94.1% • High efficacy maintained across age, gender, race and ethnicity
Safety	• No serious safety concerns found	• No serious safety concerns found

*Trials described on this slide were in people age 18 or older (Moderna) or 16 or older (Pfizer-BioNTech)
Pfizer: Information about the Pfizer-BioNTech COVID-19 Vaccine | CDC
Moderna: Information about the Moderna COVID-19 Vaccine | CDC

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Pfizer-BioNTech COVID-19 Vaccine Clinical Trial Findings for Participants Aged 12-15 Years

- 2,260 adolescents in this age group randomly assigned to vaccine or placebo in 1:1 ratio
- Efficacy of two doses in preventing symptomatic, laboratory-confirmed COVID-19: 100%
- Side effects:
  - Mild to moderate; similar to those seen in people aged 16-25 years
  - Pain at injection site (79%-86%), fatigue (60%-66%), headache (55%-65%), chills (28%-42%), joint pain (10%-16%), muscle pain (24%-32%), fever (10%-20%)
  - More common after second dose (except pain at injection site)
- 0.4% of participants in vaccine group reported ≥ 1 serious adverse event vs. 0.2% in placebo group
  - No serious adverse events were considered related to vaccine by FDA

Frenck RW, et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. N Engl J Med. 2021 May 27. doi: 10.1056/NEJMoa2107456

Wallace M, et al. The ACIP's Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021. MMWR 2021;70:749–752. DOI: http://dx.doi.org/10.15585/mmwr.mm7020e1

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Johnson & Johnson/Janssen COVID-19 Vaccine: Phase III Clinical Trial Results

- 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

Oliver SE, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. MMWR Morb Mortal Wkly Rep 2021;70:329–332. DOI: http://dx.doi.org/10.15585/mmwr.mm7009e4external icon
Janssen COVID-19 Vaccine FDA Briefing Document: fda.gov/media/146217/download

Johnson & Johnson/Janssen COVID-19 Vaccine Interim Findings: Vaccine Efficacy

- Symptomatic, lab-confirmed COVID-19:
  - 66% at ≥ 14 and ≥ 28 days after vaccination
- Symptomatic, lab-confirmed COVID-19 across trial locations:
  - U.S. (74%), Latin America (65%), South Africa (52%)
- Hospitalization (COVID-19-associated)
  - 93% at ≥ 14 days after vaccination; 100% at ≥ 28 days after vaccination
- Death
  - No COVID-19-associated deaths occurred among vaccine recipients

Oliver SE, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. MMWR Morb Mortal Wkly Rep 2021;70:329–332. DOI: http://dx.doi.org/10.15585/mmwr.mm7009e4external icon

Johnson & Johnson/Janssen Vaccine Efficacy (VE), Continued

- Among participants aged ≥ 60 years
  - Point estimate for VE at ≥ 28 days was higher in persons without comorbidities (72%) than among those with comorbid conditions (42%)
  - Interpret with caution – limited numbers and follow-up; 95% confidence intervals overlap
  - No COVID-associated hospitalizations occurred among vaccine recipients at ≥ 28 days after vaccination
  - No COVID-associated deaths among vaccine recipients
- Against 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
Janssen COVID-19 Vaccine FDA Briefing Document: fda.gov/media/146217/download

COVID-19 Vaccine Comparison

	Pfizer-BioNTech	Moderna	J&J/Janssen
MECHANISM	mRNA	mRNA	Adenovirus vector
ADMINISTRATION	Intramuscular	Intramuscular	Intramuscular
STORAGE	Ultracold (-80°C to -60°C)*	-25°C to -15°C	2°C to 8°C
AGE INDICATIONS	≥ 12 years	≥ 18 years	≥ 18 years
SCHEDULE	2 doses separated by 21 days	2 doses separated by 28 days	1 dose

* FDA updates regarding Pfizer-BioNTech vaccine storage:
- Undiluted frozen vials may be transported and stored at temperatures commonly found in pharmaceutical freezers for up to two weeks (2/25/21)
- Thawed, undiluted vaccine may be refrigerated for up to 30 days (5/19/21)
- Updated fact sheet for health care providers: https://www.fda.gov/media/144413/download

Revised storage and handling guidance for Moderna and Pfizer vaccines: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Effect of Emerging SARS-CoV-2 Variants on COVID-19 Vaccines

- SARS-CoV-2 mutates regularly; changes in its genome are expected
  - Several recently identified variants appear more easily transmitted than other strains
  - Whether these variants can evade immunity induced by vaccines or natural infection is an area of study
- Evidence regarding Moderna and Pfizer vaccines:
  - Real-world effectiveness of Pfizer vaccine
    - ≥ 87% against B.1.1.7 (U.K./Alpha) and ≥ 72% against B.1.351 (South Africa/Beta) in studies conducted in Qatar
    - > 90% against end points ranging from asymptomatic infection through death in Israel where prevalence of B.1.1.7 was > 94%
    - 88% against symptomatic disease with B.1.617.2 (India/Delta) in a study conducted in the U.K.
  - In-vitro studies found decreased neutralization by post-mRNA vaccination sera against B.1.427/B.1.429 (California/Epsilon) and P.1 (Brazil/Gamma) variants

Abu-Raddad LJ, et al. Effectiveness of the BNT162b2 COVID-19 vaccine against the B.1.1.7 and B.1.351 variants. New Engl J Med. 2021 May 5. doi: 10.1056/NEJMc2104974
Galloway SE, et al. Emergence of SARS-CoV-2 B.1.1.7 Lineage — US, Dec 29, 2020–Jan 12, 2021. MMWR Morb Mortal Wkly Rep. January 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7003e2
Haas EJ et al. Impact and effectiveness of mRNA BNT162b2 vaccine in Israel. Lancet 2021 May 5. doi:https://doi.org/10.1016/S0140-6736(21)00947-8
Lopez Bernal J, et. al. Effectiveness of COVID-19 vaccines against the B.1.617.2 variant. Preprint:https://www.medrxiv.org/content/10.1101/2021.05.22.21257658v1.full.pdf
CDC SARS-CoV-2 variant information: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

Effect of Emerging SARS-CoV-2 Variants on COVID-19 Vaccines

- Evidence regarding Johnson & Johnson/Janssen vaccine:
  - Based on clinical trials in different countries with different rates of variants:
    - Efficacy likely not impacted by P.2 (a variant of interest common in Brazil)
    - Efficacy against infection may be reduced against B.1.351 but likely still high
    - Efficacy against severe/critical COVID-19 ≥ 28 days after vaccination: 82%

Janssen COVID-19 Vaccine FDA Briefing Document: fda.gov/media/146217/download
CDC SARS-CoV-2 variant information: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

Emerging Variants: Potential Implications for COVID-19 Vaccines and Vaccination Campaign

- Based on current evidence, all three vaccines available in the U.S. likely provide protection against variants, although protection against some variants may be diminished
- Even if a new variant cannot evade vaccine-induced immunity, widespread circulation of a highly infectious strain may require higher vaccine coverage than previously estimated to achieve control of the pandemic
- 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

Clinical Considerations

Expected Reactions After COVID-19 Vaccination

- Clinical trials suggest COVID-19 vaccines often elicit mild to moderate reactions
- More common in younger compared to older age groups
- Usually occur within the first 3 days of vaccination and resolve within 1-3 days of onset

	Moderna vaccine[1]	Pfizer vaccine[2]	J&J/Janssen vaccine[3]
Pain at injection site	100%	83%	49%
Fatigue	80%	75%	38%
Headache	60%	67%	39%
Myalgia	53%	58%	33%
Fever	40%	17%	9%

1. Jackson et al. An mRNA Vaccine against SARS-CoV-2-Preliminary report. NEJM 2020;20:1920-1931.
2. Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14, 2020.
3. Janssen COVID-19 Vaccine FDA Briefing Document: fda.gov/media/146217/download

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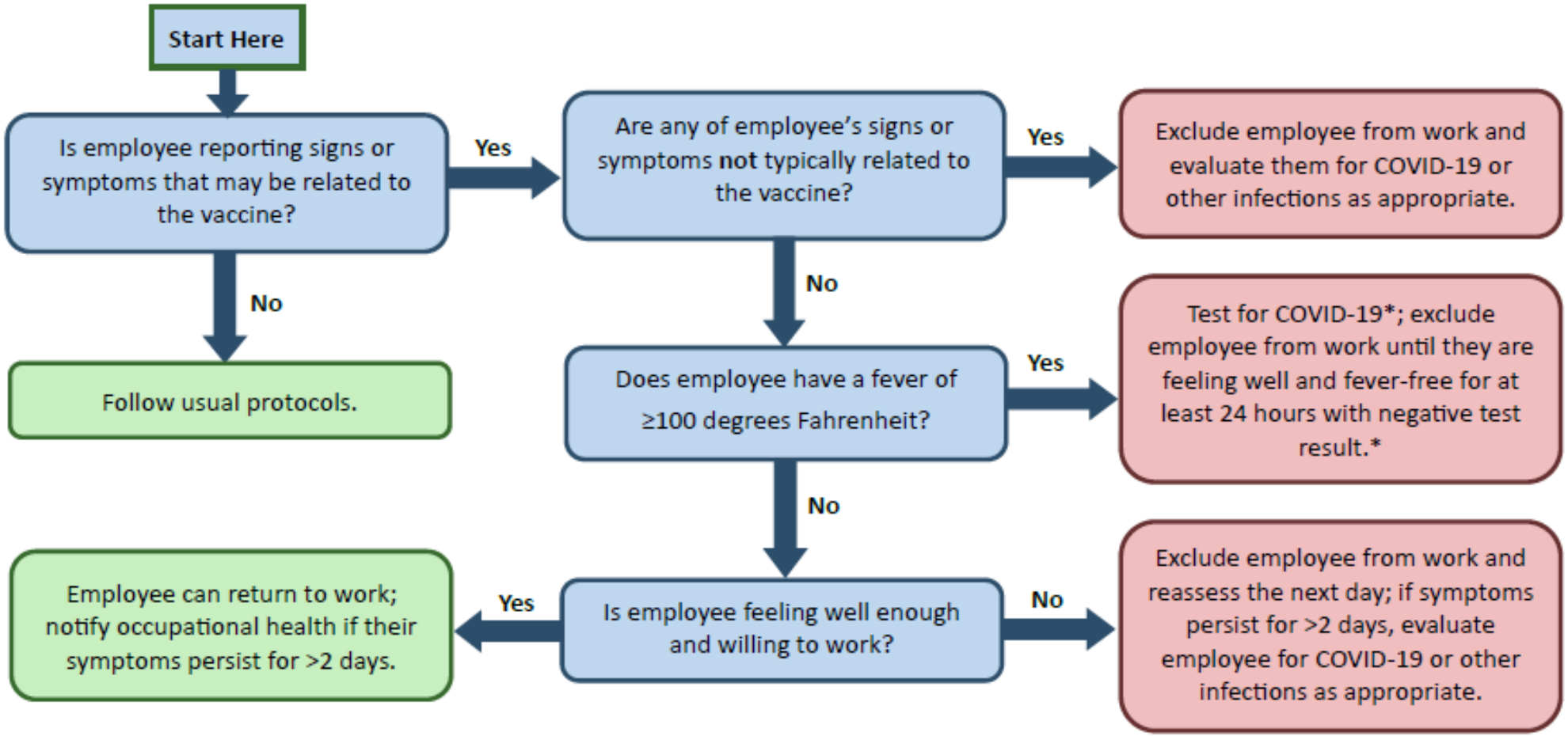
Prepare Patients for Reactions Expected After COVID-19 Vaccination

- Before vaccination, counsel patients on expected post-vaccination symptoms
- Persons who have received the first of a 2-dose series:
  - Should be encouraged to complete the series even if they develop post-vaccination symptoms, to optimize protection against COVID-19 (unless they developed a contraindication to vaccination)
- Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms
- Routine prophylaxis to prevent symptoms is not recommended due to lack of information on impact of use on vaccine-induced antibody responses

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html#Patient-counseling

Post Vaccine Considerations for Health Care Workers



*A nucleic acid amplification (NAA) test is preferred but a negative antigen test is acceptable per NYS Department of Health.

https://www1.nyc.gov/assets/doh/downloads/pdf/covid/providers/covid-19-vaccine-side-effects-in-providers.pdf

Post Vaccine Considerations for Residents of Long-Term Care Facilities

- The Centers for Disease Control and Prevention (CDC) offers guidance on managing post-vaccination signs and symptoms during the first 3 days after vaccination to avoid:
  - Unnecessary COVID-19 testing and implementation of transmission-based precautions for residents who have only post-vaccination signs and symptoms
  - Inadvertently allowing residents with infectious COVID-19 or another transmissible infectious disease to expose others in the facility
- Guidance could also be applied to patients in other healthcare settings
- See CDC post-vaccine considerations for long-term care facility residents
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html

Timing of Second Vaccine Dose: mRNA Vaccines

- Recommended schedule
  - Pfizer-BioNTech: 3 weeks (21 days) apart
  - Moderna: 1 month (28 days) apart
- Second doses administered within 4 days before the recommended date will be considered valid
  - Grace period for Pfizer: day 17-21; for Moderna: day 24-28
  - However, grace period should not be used routinely to schedule second dose
  - Doses inadvertently administered earlier than the grace period do not need to be repeated
- Second dose should be administered as close to the recommended interval as possible
  - If it is not feasible to adhere to recommended interval, second dose of Pfizer-BioNTech or Moderna vaccine may be scheduled for up to 6 weeks (42 days) after first dose
  - There are limited data on efficacy of COVID-19 vaccines administered beyond this window, though it is expected that immune response following the second dose would remain high
  - If second dose is administered beyond these intervals, there is no need to restart the series

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

Interchangeability of COVID-19 Vaccines

- COVID-19 vaccines are **not** interchangeable
  - No mixed-product safety or efficacy evaluations have been conducted
- If two-dose vaccine series is initiated, second dose should be with same product
- Strategies to ensure that patients receive the second dose with the appropriate product:
  - Provide COVID-19 vaccination record cards; encourage recipients to bring them to their second dose appointments
  - Record vaccine administration information in the Citywide Immunization Registry (and the patient's medical record, if applicable)
- In exceptional situations in which the first-dose mRNA vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the vaccination series
- If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time

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

Co-Administration of COVID-19 and Other Vaccines

- Vaccines may now be administered regardless of timing between COVID-19 and non-COVID-19 vaccines (including live vaccines)
  - Includes administration of COVID-19 and non-COVID-19 vaccines on same or different days
- Applies to all ages
- Many people have fallen behind on vaccination during the pandemic. Use the opportunity to administer other needed immunizations
  - For adolescents, consider need for school-required immunizations and to administer missed immunizations such as human papilloma virus (HPV) vaccine
  - When deciding whether to co-administer COVID-19 and other vaccines, considerations may include reactogenicity of other vaccines (e.g. reactogenic adjuvanted vaccines such as Shingrix)

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

Reported Anaphylaxis After COVID-19 Vaccination

Vaccine	Number of anaphylaxis cases*	Number of doses administered*	Rate of anaphylaxis per million doses*
Pfizer-BioNTech	47	9,943,247	4.7
Moderna	19	7,581,429	2.5

- There was one report of a serious hypersensitivity reaction, but no reports of anaphylaxis, during the Johnson & Johnson/Janssen clinical trial.** Data from post-authorization monitoring will be added when they become available.

* Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. *JAMA.* Published online February 12, 2021. doi:10.1001/jama.2021.1967

** https://www.fda.gov/media/146338/download

Contraindications & Precautions

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH 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†	**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.#	**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.†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

For complete footnotes and additional information: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B

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Observation Period After COVID-19 Vaccination

- 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
- 15 minutes: All other persons

Trained personnel qualified to recognize and treat anaphylaxis symptoms should be available at vaccination locations at all times

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

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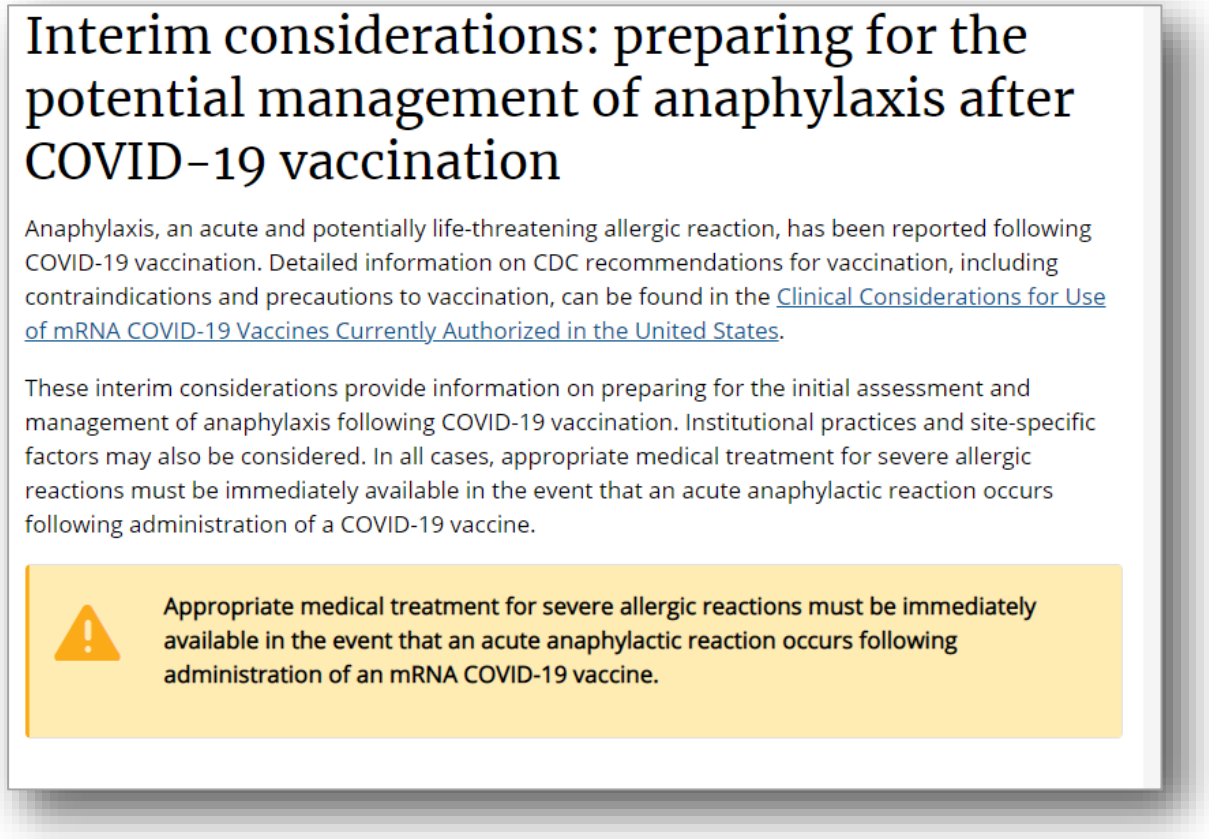
Preparing to Manage Anaphylaxis after COVID-19 Vaccination

- CDC provides guidance on:
  - Early recognition
  - Medication and supplies for assessing and managing
  - Steps to take if anaphylaxis is suspected
  - Considerations for management in older adults, pregnant people and homebound persons
  - Reporting



Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following COVID-19 vaccination. Detailed information on CDC recommendations for vaccination, including contraindications and precautions to vaccination, can be found in the Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

These interim considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination. Institutional practices and site-specific factors may also be considered. In all cases, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.

Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

Vaccination of Persons with Underlying Medical Conditions

- Clinical trials demonstrated similar safety and efficacy in persons with some underlying medical conditions, including those that place people at increased risk for severe COVID-19, compared to persons without comorbidities
- Individuals with any medical condition may receive COVID-19 vaccination, including:
  - Immunocompromised persons
  - Persons with autoimmune conditions
  - Persons with a history of Guillain-Barré syndrome
  - Persons with a history of Bell's palsy
- Individuals taking any type of prescription medication may receive COVID-19 vaccination

Persons with HIV or Immunosuppression

- May be at increased risk for severe COVID-19
- May receive COVID-19 vaccine
- None of the vaccines are live-virus vaccines
- Data not currently available to establish vaccine safety and efficacy in immunocompromised persons
- Persons with stable HIV infection were included in COVID-19 vaccine clinical trials, though data remain limited
- Counsel patients about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses

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

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#underlying-conditions

Persons with Autoimmune Conditions

- May receive COVID-19 vaccine
- Were eligible for enrollment in clinical trials
- Inform patients that no data are currently available on the safety of COVID-19 vaccines for people with autoimmune conditions
- No imbalances were observed in occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received vaccine compared to placebo

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

Persons with History of Guillain-Barré or Bell's Palsy

- May receive COVID-19 vaccine
- In clinical trials, there were no cases of Guillain-Barré syndrome (GBS) among participants who received mRNA vaccines; one recipient of the Johnson & Johnson/Janssen vaccine had GBS, but rate of GBS in vaccine recipients was not higher than expected in the general population
- Cases of Bell's palsy were reported following vaccination in participants in clinical trials for all three authorized vaccines, but FDA does not consider these above the frequency expected in the general population

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

Pregnant or Lactating People

- May choose to be vaccinated
- Pregnant people are at risk for severe illness due to COVID-19
- Data on vaccine safety and effectiveness in pregnant or lactating people are limited; however, based on current knowledge, vaccines unlikely to pose risk to pregnant person, fetus, or breastfed infant
- Consider level of COVID-19 community transmission and risk of COVID-19 to the patient and potential risk to the fetus
- Pregnant people who receive COVID-19 vaccine should take acetaminophen if they develop fever after vaccination, as fever during pregnancy can negatively affect a fetus (acetaminophen is safe in pregnancy)
- American College of Obstetricians and Gynecologists (ACOG) recommends COVID-19 vaccines:
  - Should not be withheld from pregnant people
  - Should be offered to lactating people
- Society for Maternal-Fetal Medicine strongly recommends that pregnant people have access to COVID-19 vaccines and that each person talk to their provider or midwife about their choice

https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM_Vaccine_Statement_12-1-20_(final).pdf

People with Prior Infection or Exposure to COVID-19

- People with a history of COVID-19 should be offered vaccination to reduce likelihood of reinfection
- Testing people without symptoms for evidence of current or past SARS-CoV-2 infection for the purpose of vaccine decision-making is not recommended
- Defer vaccination for people with acute infection or in quarantine to avoid potentially exposing healthcare personnel or patients to SARS-CoV-2 during the vaccination visit
  - People with acute infection should wait until isolation period has ended
  - Persons exposed to someone with COVID-19 should defer vaccination until after quarantine

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

People Who Received Monoclonal Antibody or Convalescent Plasma Treatment

- Currently, there are no data on the safety or efficacy of COVID-19 vaccines in people who received these treatments for COVID-19
- People who received either of these as treatment for COVID-19 should defer vaccination for at least 90 days
  - Precautionary measure until additional information becomes available to avoid interference of the antibody treatment with vaccine-induced immune response

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html#Contraindications

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
https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety

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Real-World Interim Estimates of Effectiveness* of mRNA Vaccines, U.S.

- Effectiveness* of mRNA vaccines among first responders, health care personnel and frontline workers against COVID-19 (regardless of symptoms):[1]
  - 90% after full immunization (≥14 days after second dose)
  - 80% after partial immunization (≥14 days after first dose, but before second dose) was 80%.
- Effectiveness against COVID-19-associated hospitalization among adults aged ≥ 65:[2]
  - 94% after full immunization
  - 64% after partial vaccination
- Neither study distinguished between effectiveness of Pfizer–BioNTech and Moderna products

*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. Teneforde MW et al. MMWR Morb Mortal Wkly Rep 2021; 70:674–679. DOI: http://dx.doi.org/10.15585/mmwr.mm7018e1external icon

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Additional Estimates of Real-World Effectiveness* of Pfizer-BioNTech Vaccine

- Israel:
  - Nationwide surveillance data following widespread introduction of the Pfizer–BioNTech vaccine were analyzed
  - Two-dose effectiveness:
    - 95.3% (CI, 94.9-95.7) against infection
    - 97.2% (95% CI, 96.8-97.5%) against hospitalization
    - 96.7% (CI, 96.0-97.3%) against COVID-19-associated death[1]
- England:
  - Public Health England reported a 42% reduction in hospitalization among persons aged ≥ 80 years who received their first dose of Pfizer-BioNTech vaccine at least 14 days prior vs. those who had not[2]
- For more information see CDC's summary of studies of effectiveness

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

1. Haas EJ et al. Impact and effectiveness of mRNA BNT162b2 vaccine in Israel. Lancet 2021 May 5. doi:https://doi.org/10.1016/S0140-6736(21)00947-8
2. 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

Guidance for Fully Vaccinated People

- Fully vaccinated* people without immunocompromising conditions** no longer need to:
  - Wear a face covering or stay 6 feet apart from others in most settings
  - Quarantine after an exposure to someone with COVID-19
  - Be tested for COVID-19 (unless they have COVID-19 symptoms or testing is required for work, school, travel, or other reasons)
- Fully vaccinated people should continue to:
  - Wear a face covering in schools, on public transportation, in health care or congregate settings (such as nursing homes or homeless shelters), or while near unvaccinated people at increased risk for severe COVID-19
  - Stay home if sick
  - Practice hand hygiene

https://www.cdc.gov/coronavirus/2019-ncov/index.html
https://www1.nyc.gov/site/doh/covid/covid-19-vaccines.page#bens

*At least 14 days have passed since completion of a COVID-19 vaccine series
** People with immunocompomising conditions should discuss the need for continuation of personal protective measures after vaccination with their health care provider because data on efficacy of COVID-19 vaccines among immunocompromised people are currently limited

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Non-FDA-Authorized COVID-19 Vaccines Received Outside the U.S.

Patient's Vaccination Status	Recommendation for COVID-19 Vaccination in U.S.
Fully vaccinated with COVID-19 vaccine authorized by World Health Organization	No further COVID-19 vaccination needed
Partially vaccinated with COVID-19 vaccine authorized by World Health Organization	Start new COVID-19 series with FDA-authorized vaccine*
Fully or partially vaccinated with COVID-19 vaccine not authorized by World Health Organization	Start new COVID-19 series with FDA-authorized vaccine*

*Start FDA-authorized COVID-19 vaccine series ≥ 28 days after the last dose of the non-FDA authorized COVID-19 vaccine
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#people-vaccinated-outside-us

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What is Not Yet Known About COVID-19 Vaccines?

- Duration of immunity provided by vaccination
- Whether additional doses will be needed in the future
- Safety and efficacy for children (clinical trials are ongoing)
- Efficacy in persons with immunosuppression

Safety Monitoring

Multiple COVID-19 Vaccine Post-Authorization Safety Monitoring Systems

Monitoring System	Population
Vaccine Adverse Event Reporting System (VAERS)	
• VAERS	All vaccine recipients in U.S.
• Veterans Affairs Adverse Drug Event Reporting System	VA patient populations
• Department of Defense Vaccine Adverse Event Clinical System	DoD patient populations
• CDC National Healthcare Safety Network	Acute care and long-term care facilities
V-Safe	All COVID-19 vaccine recipients eligible
Vaccine Safety Datalink (VSD)	Insured patients in VSD sites
Clinical Immunization Safety Assessment Project (CISA)	Referred cases from US population
Genesis Healthcare	Long-term care facility residents
FDA and Centers for Medicare and Medicaid Services	Medicare recipients
FDA BEST Initiative	Insured patients in BEST sites
FDA Post-licensure Immunization Safety Monitoring System	Insure patients in PRISM sites
Veterans Administration Data	Enrolled VA patients
Department of Defense Medical Surveillance System	Active duty military

Vaccine Adverse Event Reporting System (VAERS)

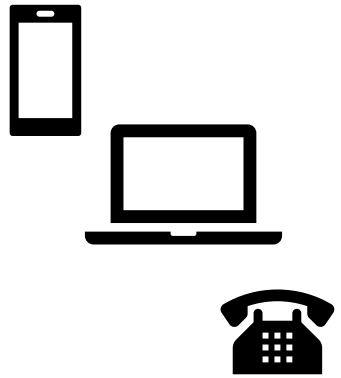
- Rapid, early warning system for safety signals
- Co-managed by the CDC and FDA
- Clinical review of individual reports received nationwide
- Statistical methods to detect disproportionate reporting of specific vaccine-adverse event

Reporting Adverse Events to VAERS

- Adverse events that occur following COVID-19 vaccination should be reported to VAERS
- Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:
  - Vaccine administration errors
  - Serious adverse events
  - Cases of Multisystem Inflammatory Syndrome
  - Cases of COVID-19 that result in hospitalization or death
- Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event
- Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967

V-Safe Tool for Patients

- CDC's new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines
- Health checks via text message
  - Daily for the first week after vaccination
  - Weekly thereafter for 6 weeks post-vaccination
  - Active telephone follow-up with people who report clinically important events*
- All COVID-19 vaccine recipients eligible
- Includes v-safe pregnancy registry to collect information on the health of pregnant people who get vaccinated
- Health care providers should encourage patient participation and provide patients with v-safe handout



*Symptoms or health conditions that cause one to miss work, forego normal daily activities, or seek health care
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Results of First Month of mRNA Vaccine Safety Monitoring, U.S.

- Descriptive analysis of VAERS and v-safe reports from December 14, 2020-January 13, 2021 (during which first and second Pfizer doses and first Moderna doses were administered)
- Most frequently reported symptoms after vaccination:
  - Headache (22%), fatigue (17%), dizziness (17%)
- Anaphylaxis was reported after both types of vaccine
  - 4.5 cases of anaphylaxis per million doses – a rate comparable to that associated with other widely used vaccines
- No unexpected patterns of reactions or safety concerns identified

Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021. MMWR Morb Mortal Wkly Rep. https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm

Reports of Rare Type of Blood Clot among Johnson & Johnson/Janssen COVID-19 Vaccine Recipients

- February 27, 2021: EUA issued, post-authorization use began soon after
- April 13, 2021:
  - CDC and FDA recommended a pause in use to investigate rare and severe type of blood clot in six Johnson & Johnson/Janssen COVID-19 vaccine recipients
  - Cases had been reported through VAERS in latter half of March through early April 2021
- April 23, 2021:
  - After active search for additional cases of thrombosis among Johnson & Johnson/Janssen COVID-19 vaccine recipients and careful risk benefit analysis, ACIP reaffirmed recommendation for use of the vaccine for all people aged ≥ 18 years
  - Warning regarding rare but potential risk for thrombotic thrombocytopenia syndrome (TTS) was added to EUA

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
Updated ACIP recommendations 4/27/2021: https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm

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Characteristics of U.S. TTS cases after Johnson & Johnson/Janssen COVID-19 Vaccination, N=28 (as of May 7, 2021)

- Median age: 40 years (range 18-59 years)
- Median time from vaccination to symptom onset: 9 days (range 3-15 days)
- All received Johnson & Johnson/Janssen vaccine before the pause on April 13, 2021
- Female (n=22), male (n=6)
- 19 had cerebral venous sinus thrombosis (CVST)
- None were pregnant or postpartum (defined as within 12 weeks of delivery)
- Past SARS-CoV-2 infection (n=5); 3 by history, 2 by nucleocapsid serology testing only
- Risk factors for thrombosis
  - Systemic estrogen (n=3)
  - Obesity (n=12)
  - Hypertension (n=7)
  - Hypothyroidism (n=3)
  - Diabetes (n=3)
  - Current cigarette smoking (n=2)
  - Malignancy (n=1)
  - Fertility treatment (n=1)
  - Coagulation disorders (n=0)

ACIP meeting presentation: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf

Rates of TTS after Johnson & Johnson/Janssen COVID-19 Vaccine by Sex and Age Group (as of May 7, 2021)

8.73 million total J&J/Janssen COVID-19 vaccines administered*

	Females			Males		
Age group	TTS cases	Doses admin	Reporting rate† (per million)	TTS cases	Doses admin	Reporting rate† (per million)
18-29 yrs old	**3**	641,510	4.7	**2**	714,458	2.8
30-39 yrs old	**8**	642,745	12.4	**1**	728,699	1.4
40-49 yrs old	**7**	743,256	9.4	**1**	775,390	1.3
50-64 yrs old	**4**	1,463,416	2.7	**2**	1,505,505	1.3
65+ yrs old	**0**	814,947	0	**0**	697,925	0

*Source of doses administered: https://covid.cdc.gov/covid-data-tracker/#vaccinations
†Reporting rate = TTS cases per 1 million Johnson & Johnson/Janssen COVID-19 vaccine doses administered
ACIP Meeting Presentation: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf

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ACIP Conclusions Regarding TTS after Johnson & Johnson/Janssen Vaccine

- After careful review of the current evidence, concluded that the benefits of vaccination outweigh the risks
- Limiting vaccine use to specific populations (i.e., by age or sex) could reduce numbers of TTS cases but could also:
  - Challenge public health implementation
  - Save fewer lives
  - Limit personal choice
  - Disproportionately affect populations with barriers to vaccine access or who have difficulty returning for a second dose
- Safety surveillance and research on TTS continues and evidence will be re-assessed as needed
  - Updates on confirmed TTS among Johnson & Johnson/Janssen vaccine recipients: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

CDC COCA presentation: https://emergency.cdc.gov/coca/ppt/2021/COCA-Call-4-27-2021-final.pdf

Revised CDC Clinical Considerations for Use Of Johnson & Johnson/Janssen COVID-19 Vaccine

- Women aged <50 years:
  - Can receive any FDA-authorized COVID-19 vaccine
  - Should be aware of the rare risk of TTS after receipt of the Johnson & Johnson/Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines)
- People with a history of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT):
  - Should not receive J&J vaccine if it has been ≤ 90 days since their illness resolved; offer another FDA-authorized COVID-19 vaccine instead
- People with risk factors for venous thromboembolism* or history of other types of thromboses not associated with thrombocytopenia:
  - Expert opinion to date is that they are unlikely to be at increased risk for TTS
  - Can receive any FDA-authorized COVID-19 vaccine, including the Johnson & Johnson/Janssen vaccine
- Use of aspirin or anticoagulants:
  - If part of routine medications, not necessary to stop before receipt of Johnson & Johnson/Janssen vaccine
  - NOT recommended before vaccination with the Johnson & Johnson/Janssen vaccine or mRNA vaccines

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#janssen-vaccine-certain-populations

*Including pregnancy, post-partum state, and use of hormonal contraceptives

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

- Education about TTS risk and availability of other COVID-19 vaccines is critical
  - Provide the EUA fact sheet to all vaccine recipients or their caregivers before vaccination
- Remain vigilant for symptoms of possible serious thrombotic events or thrombocytopenia in recent Johnson & Johnson/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
- If you identify a patient with TTS after Johnson & Johnson/Janssen COVID-19 vaccination:
  - Consult with hematologist and refer to American Society of Hematology treatment guidelines
  - Evaluate with screening platelet factor 4 enzyme-linked immunosorbent assay
  - 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
American Society of Hematology https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

NYC Health

Myocarditis and Pericarditis after mRNA COVID-19 Vaccines

- Rare cases of myocarditis and pericarditis have been reported after receipt of Moderna or Pfizer-BioNTech COVID-19 vaccines
- Cases have occurred
  - Mostly in male adolescents and young adults
  - Typically, within one week (mostly within 4 days) after mRNA COVID-19 vaccination
  - More frequently after the second vaccine dose than after the first dose
- Most cases have been mild and have responded to medical treatment and rest
- FDA will add a warning to the EUA fact sheets for health care providers and vaccine recipients
- Given the risks associated with COVID-19, CDC continues to strongly recommend COVID-19 vaccination for everyone 12 years of age or older

ACIP Vaccine Safety Technical Work Group report 5/17/2021: https://www.cdc.gov/vaccines/acip/work-groups-vast/technical-report-2021-05-17.html

CDC's Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

NYC Health

Myocarditis and Pericarditis after mRNA COVID-19 Vaccines: Key Messages for NYC Providers

- Consider myocarditis and pericarditis when evaluating chest pain, dyspnea, or palpitations
  - Ask about a history of COVID-19 vaccination
- Review CDC guidance for providers:
  - Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults
- Report cases of myocarditis, pericarditis and other serious events after vaccination to VAERS
- CDC continues to recommend COVID-19 vaccination for people ≥ 12 years
  - CDC information for patients: Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

COVID-19 Vaccine Distribution in NYC

Ensuring Equitable Vaccine Distribution in NYC

- Equity is at the core of all NYC Health Department planning, including vaccine operations
- The Health Department has developed a 3-part equity strategy:
  1. Equitable Access
     - Chose vaccine hub locations to eliminate physical, transportation and other barriers
     - Prioritize neighborhoods that have been disproportionately impacted by COVID-19
     - Ensure equitable access to information about vaccines so all New Yorkers can make informed decisions about COVID-19 vaccination

Ensuring Equitable Vaccine Distribution in NYC (continued)

2. Equitable Uptake

- Tailor approaches to individual communities' interests and needs
- Work with community-based organizations, faith-based organizations and trusted messengers to disseminate accurate and culturally sensitive information
- Engage community members that have experienced institutional betrayal and racism to guide community engagement

3. Equitable Outcomes

- Monitor vaccine safety trends and vaccination rates within each neighborhood
- Facilitate community feedback to identify barriers and solutions to vaccine distribution

COVID-19 Vaccine Campaign:

- Procure and distribute vaccine throughout NYC in accordance with federal and state guidance and help ensure equitable allocation
- Assist with Citywide Immunization Registry (CIR) registration, completion of COVID-19 vaccine agreement, and vaccine ordering and distribution
- Execute comprehensive community education and outreach
- Provide guidance to health care providers
  - Vaccine administration, storage and handling, best practices to increase uptake
- Administration of vaccine to eligible groups at NYC Health Department and Health + Hospitals vaccine sites
- Monitor key data points, track progress, and identify gaps in operations

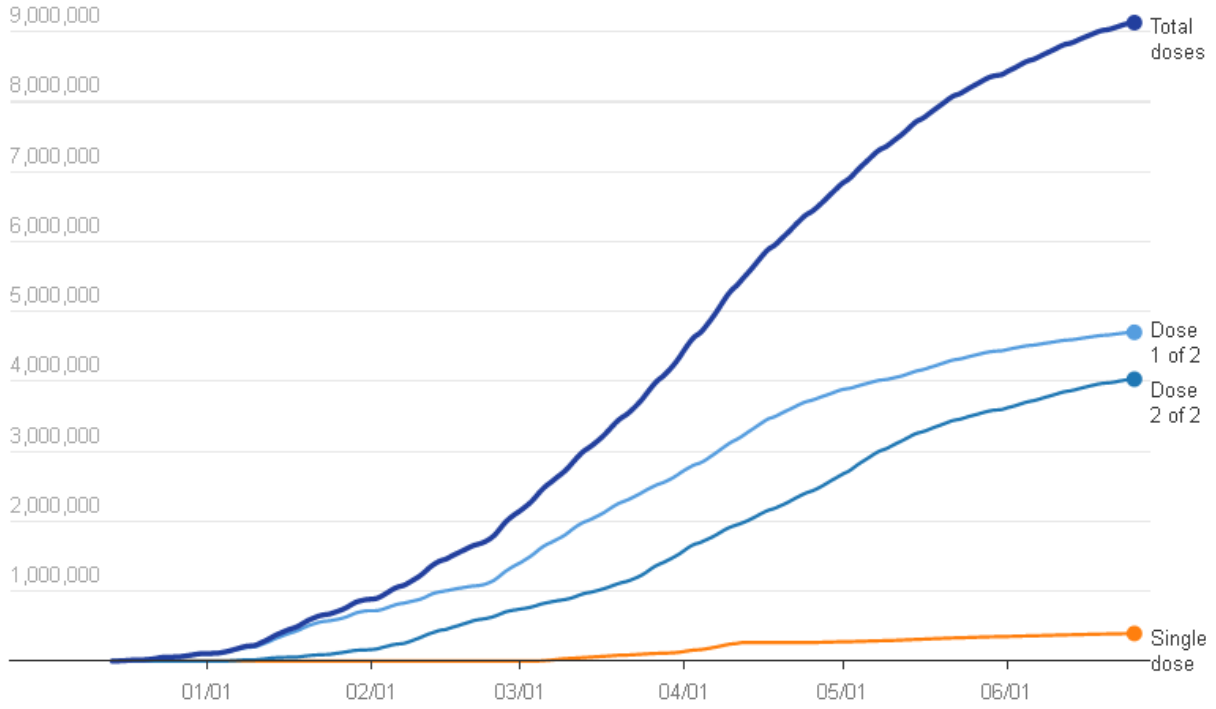
COVID-19 Vaccine Eligibility and Consent for Vaccination of Minors, NYS

- All people aged ≥ 12 years who live in the U.S. are now eligible
- For people aged 12 to 17 years:
  - Pfizer vaccine is the only currently approved product for this age group
  - Parent/guardian must provide consent
    - Not necessary to provide proof they are the child's parent/guardian
    - Some providers, including all City-run sites, accept proof of consent in writing; however, in-person or phone consent is preferred
  - Proof of age is required
    - If child does not have an ID or other document with date of birth, parent/guardian can accompany child to vaccination site to attest to their age
  - Minors ages 12 to 15 years must be accompanied to the vaccination site by a parent, guardian, or adult caregiver designated by parent/guardian

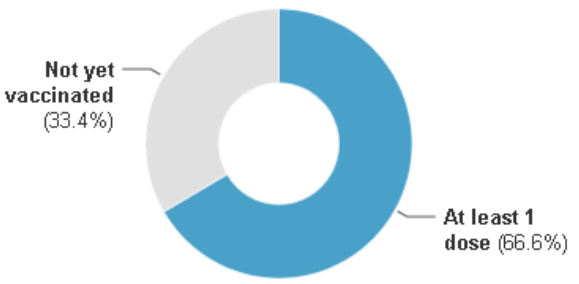
COVID-19 VACCINE ADMINISTRATION, NYC

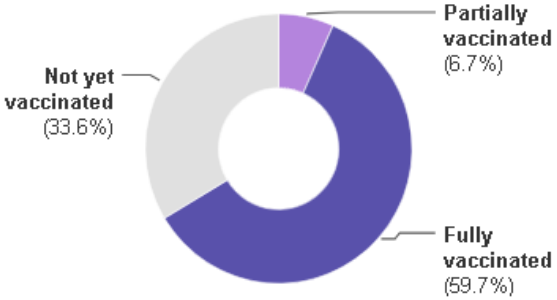
- Over 9.1 million doses administered
- Of NYC residents aged ≥ 18 years:
  - 67% received ≥ 1 dose
  - 60% fully vaccinated

DOSES ADMINISTERED



PERCENT OF ADULT RESIDENTS 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 6/25/2021

NYC Health

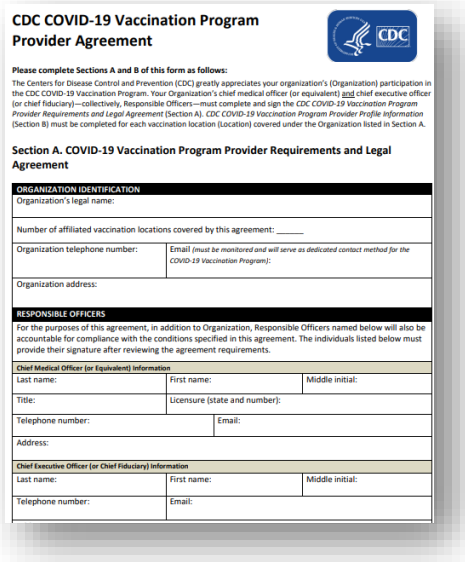
Preparing to Offer COVID-19 Vaccination

Review Background Information

- Review Preparing to Enroll in the COVID-19 Vaccination Program Guide to understand program requirements and enrollment process
- Review CDC guidance on preparing to administer COVID-19 vaccines:
  - COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf
  - COVID-19 Vaccine Training Modules https://www2.cdc.gov/vaccines/ed/covid19/
  - COVID-91 Vaccine Storage and Handling Tool Kits https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
  - Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Enroll in the NYC COVID-19 Vaccination Program

- Enrollment is now open for private practices, independent pharmacies and other facilities that intend to immunize adults in the NYC COVID-19 Vaccination Program
- Facilities choosing to participate must complete the CDC COVID-19 Vaccination Program Provider Agreement (Provider Agreement) in the online Citywide Immunization Registry (CIR)
- Facilities that are not already registered with the CIR or have not reported to the CIR in over a year should register now
- After registering, a CIR facility code is issued, which is used to set up an online CIR account and enroll in the COVID-19 Vaccination Program by completing the Provider Agreement in the provider's online account



CDC COVID-19 Vaccination Program Provider Agreement

Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* (Section A). *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination location (Location) covered under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

ORGANIZATION IDENTIFICATION

Organization's legal name:

Number of affiliated vaccination locations covered by this agreement: _____

Organization telephone number: | Email *(must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)*:

Organization address:

RESPONSIBLE OFFICERS

For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.

Chief Medical Officer (or Equivalent) Information

Last name: | First name: | Middle initial:

Title: | Licensure (state and number):

Telephone number: | Email:

Address:

Chief Executive Officer (or Chief Fiduciary) Information

Last name: | First name: | Middle initial:

Telephone number: | Email:

Enroll in the NYC COVID-19 Vaccination Program (continued)

- Only one enrollment form should be submitted per facility
- Facility groups or networks should complete a single Provider Agreement (Section A) **and**, for each vaccination site, a Provider Profile (Section B)
- The Provider Agreement must be signed by the Chief Medical Officer (or equivalent) and Chief Executive Officer (or Chief Fiduciary)
- The Provider Profile for each vaccination site must be signed by a designated COVID-19 Vaccine Coordinator or the Medical/Pharmacy Director
- Once a facility is approved to participate in the COVID-19 vaccination program and have proper vaccine storage they can order in the CIR Online Registry
  - Vaccine will ship directly from the manufacturer or CDC distributor to the vaccine provider

Prepare to Order, Track and Report Vaccination

- The CIR is the primary database for capturing vaccine data
- Become familiar with using the CIR to report administration of vaccine
- Three methods of reporting vaccination:
  - Preferred option is via direct connection from your electronic health record (EHR)
  - CIR Online Registry website
  - Flat file transfer
- All administered COVID-19 vaccine doses must be reported to the CIR within 24 hours*
- Patient's written consent not required
  - Authorizations include: NYS Executive Order 202.82**; NYC Commissioner's Order***
- Ensure race and ethnicity are populated in EHR – fields must be submitted to CIR when reporting COVID-19 vaccine doses administered
- CIR may also be used to provide reminders about second doses

* NY State EO No. 202.89. https://governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO_202_89.pdf
** NY State EO No. 202.82. https://governor.ny.gov/news/no-20282-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency
*** NYC Order of Commissioner of Health https://nyc.gov/assets/doh/downloads/pdf/covid/covid-19-vaccine-reporting-order.pdf

Prepare Your Facility or Practice

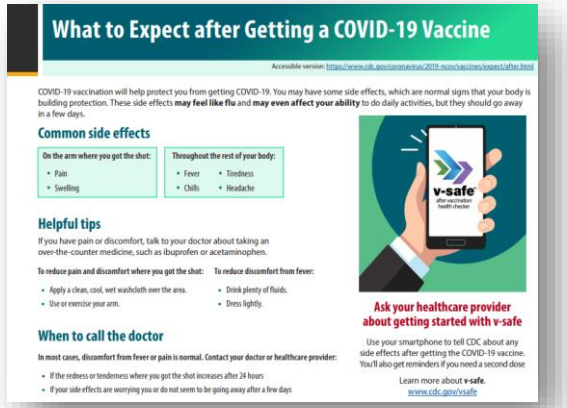
- Identify refrigerators and freezers to store vaccine
- Assess capacity to monitor vaccine, including continuous temperature monitoring
- Identify and order materials needed for vaccine administration
- Develop plans to safely vaccinate staff and patients by reducing crowding and following physical distancing recommendations
- Develop triage systems to screen patients for symptoms of COVID-19 in advance of vaccine administration

Prepare to Offer Vaccines to Staff and Patients

- Develop a plan to vaccinate staff
  - Consider staggered vaccination, especially of the second dose, after which systemic symptoms such as fever are more common
  - Consider vaccinating staff 1-2 days before scheduled time off
- Prepare staff and build confidence in COVID-19 vaccination
  - Provide education on the importance and safety of COVID-19 vaccination
  - Give staff tools they can use to educate patients and answer questions about COVID-19 vaccines
- Identify and estimate the number of patients you may vaccinate
- Use or adapt CDC's ready-made communication materials: https://cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

Review Vaccine Administration Fact Sheets

- Review vaccine-specific provider fact sheet
  - Pfizer-BioNTech: https://fda.gov/media/144413/download
  - Moderna: https://fda.gov/media/144637/download
  - Johnson & Johnson/Janssen: https://www.fda.gov/media/146304/download
- Written consent for adult vaccination is not required, but patients must be provided with a vaccine-specific fact sheet
- Prepare to distribute the patient fact sheet to vaccinated patients or their caregivers (available in multiple languages)
  - Pfizer-BioNTech: https://fda.gov/media/144414/download
  - Moderna: https://fda.gov/media/144638/download
  - Johnson & Johnson/Janssen: https://www.fda.gov/media/146305/download
- CDC guidance on what to expect during the vaccination visit and after getting vaccinated
  - https://cdc.gov/coronavirus/2019-ncov/vaccines/expect.html



COVID-19 Vaccine Reimbursement

- Providers are required to administer COVID-19 vaccines **at no cost to patients**, regardless of insurance status or ability to pay
- Providers may not bill for the cost of the vaccine, but they may bill the patient's health insurance for an administration fee
- If a person does not have health insurance, or their insurance does not cover the administration fee, providers can request reimbursement through the Provider Relief Fund
- For additional information: www.cms.gov/covidvax-provider
- Health and Human Services has also launched the new COVID-19 Coverage Assistance Fund, a reimbursement program for COVID-19 vaccine administration fees not covered by insurance

Take Every Opportunity to Vaccinate

- Use **every** opportunity to vaccinate every eligible person against COVID-19
- Updated CDC, New York State and New York City guidance: vaccinate even if this means you will not be able to use an entire multi-dose vial
  - New, more flexible policy will allow for broader administration
- Other recent changes that make providing COVID-19 vaccines easier:
  - Pfizer-BioNTech vaccine now available in 450 and 1170 dose orders
  - Moderna vaccine now available in 14 dose vials

https://coronavirus.health.ny.gov/system/files/documents/2021/05/guidance_for_facilities_receiving_vaccine_5.21.21.pdf
https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf
Updated Pfizer-BioNTech fact sheet for health care providers: https://www.fda.gov/media/144413/download

NYC Health

Resources for Counseling Patients

Discussing Vaccination with Patients

- A provider's recommendation is one of the strongest predictors of vaccine receipt
  - Make it clear to patients that you recommend COVID-19 vaccination for them
  - Even if you have only a few minutes with a patient, your recommendation can have a powerful influence
- Tell your patients about the benefits and safety of COVID-19 vaccines
- If a patient questions your recommendation, this does not necessarily mean they will not accept it; some questions are to be expected
  - Patients consider their providers the most trusted source of information on vaccines, and may simply want *your* answers
- NYC Health Department resources:
  - Addressing Patients' COVID-19 Vaccine Questions: a Guide for Health Care Providers
  - nyc.gov/VaccineTalks
- CDC resources:
  - https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions

Counseling Patients on Different COVID-19 Vaccine Products

- No product preference by ACIP
- All show high efficacy against severe disease, including COVID-19 hospitalizations and deaths
- No head-to-head comparisons have been conducted
- People, especially women aged < 50 years, should be counseled regarding the risk of TTS with the Johnson & Johnson/Janssen vaccine and the availability of other COVID-19 vaccines that are not associated with TTS

Addressing Concerns About Fetal Tissue

- None of the vaccines, including the Johnson & Johnson/Janssen vaccine, contain fetal tissue or human cells
- Johnson & Johnson/Janssen vaccine:
  - Fetal cell lines, cells that grow in a laboratory, were used in vaccine development to grow the adenovirus vector
  - The cell line originated 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

Counseling Patients who Express Concerns

- Start from a place of empathy and understanding
- Assume patients will want to be vaccinated but may have questions
- Give your strong recommendation
- Listen to and respond to questions in an understandable way
  - Resources: NYC Health Department nyc.gov/VaccineTalks, CDC, CHOP
- Wrap up the conversation
  - After answering questions, let patients know you are open to continuing discussion
  - Encourage them to consider scheduling a follow-up visit with you for this reason
  - Tell them where they can find additional information
  - Continue to remind them about the importance of vaccine in future visits

CDC. Making a strong recommendation for vaccine
Children's Hospital of Philadelphia, Vaccine Education Center. Evidence to Action Brief: Addressing Vaccine Hesitancy to Protect Children and Communities against Preventable Diseases.

COVID-19 Vaccine Resources in NYC

- COVID-19 vaccines are available at many NYC locations, including pharmacies, Federally Qualified Health Centers and hospitals
- Patients can find a vaccination site at nyc.gov/vaccinefinder
  - Searchable by vaccine brand, walk-in or ADA accessible
  - They can also call 877-VAX-4NYC (877-829-4692) for assistance making an appointment at a City-run site
  - NYC is now offering in-home COVID-19 vaccination to all City residents (Pfizer, Moderna, or Johnson & Johnson); visit: https://forms.cityofnewyork.us/f/home

NYC Health

COVID-19 Vaccine Resources in NYC for Providers

- Dedicated line for providers and staff to help patients make vaccine appointments:
  - 877-VAX-4NYC (877-829-4692); press 2 at the second prompt
- Providers can refer a patient to the Vaccine Appointment Hotline by filling out a short request form:
  - Patients referred through this form will receive a call within 48 hours

Additional Resources

COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccines:
  - Public: nyc.gov/covidvaccine
  - Providers: nyc.gov/health/covidvaccineprovider
  - Communication resources for providers: nyc.gov/VaccineTalks
  - Where to get vaccinated (vaccine finder): https://vaccinefinder.nyc.gov/
  - Latest data on vaccine distribution: https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page
  - Infographics:
    - mRNA vaccines: https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-mrna-vaccines-infographic.pdf
    - Johnson & Johnson/Janssen vaccine: https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-johnson-and-johnson-vaccine-infographic.pdf
- Direct line for providers and staff to schedule vaccine appointments for patients:
  - 877-VAX-4NYC (877-829-4692) – press 2 at second prompt
- 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**

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