

COVID-19
HEALTHCARE
PROVIDER UPDATE

DECEMBER 18, 2020

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*Our understanding of COVID-19 is evolving rapidly.
This presentation is based on our knowledge as of December 17, 2020, 5 PM.*

CONTINUING MEDICAL EDUCATION

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OUTLINE



WHERE WE ARE NOW



NEW GUIDANCE



RECENT EPIDEMIOLOGY OF COVID-19 IN NYC



VACCINE UPDATES AND STRATEGIES FOR NYC



QUESTIONS AND DISCUSSION

Mary Foote, MD, MPH

Health Systems Planning and Strategies Lead,
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HAN #39 PROPER USE AND INTERPRETATION OF SARS-COV-2 ANTIGEN TESTS

- Consider pretest probability before using SARS-CoV-2 antigen tests and when interpreting results, especially in the context of increasing community transmission
- Conduct confirmatory testing when someone who:
 - Has symptoms, tests negative
 - Has no symptoms, and no known exposure in the past 14 days, tests positive
- Confirmatory testing should be done using a nucleic acid amplification (NAA)- based test performed at a clinical laboratory on a specimen collected within 48 hours of the initial specimen
 - Individuals should isolate while awaiting confirmatory test results

NYC COMMISSIONER OF HEALTH ADVISORY

ADVISORY

FROM THE COMMISSIONER OF HEALTH & MENTAL HYGIENE
OF THE CITY OF NEW YORK

WHEREAS, on March 25, 2020, pursuant to Section 3.01 of the New York City Health Code ("Health Code"), the existence of a public health emergency within the City as a result of COVID-19, for which certain orders and actions are necessary to protect the health and safety of the City of New York and its residents, was declared;

WHEREAS, New York City is experiencing a rapid increase in COVID-19 cases and hospitalizations, and additional actions are warranted to protect public health, moderate case growth and preserve hospital capacity;

WHEREAS, older adults and people with certain underlying health conditions have an increased risk of severe COVID-19 that increases the risk of medical complications, hospitalization, and death;

The Commissioner of Health hereby issues an advisory for older adults (in particular, aged 65 and older), people with underlying health conditions that put them at increased risk of severe COVID-19, and household members and caregivers of these individuals.

THEREFORE, YOU ARE HEREBY PROVIDED NOTICE THAT:

To protect yourself, your household members and your communities against the spread of COVID-19, you are hereby advised to limit activities outside your home, except leaving home to travel to work or school, or for essential purposes including medical care, grocery shopping or pharmacy necessities.

Further, New Yorkers, especially those covered by this advisory, should, when possible, avoid public spaces and gatherings; wear a face covering at all times indoors and outdoors, including around household members, where such household members have symptoms of COVID-19, a known exposure to someone with COVID-19, or frequent interactions with the public; maintain at least 6 feet of distance from other individuals at all times outside of the home; stay home if you are sick except for essential medical care, including testing for COVID-19; follow good hand hygiene, including washing your hands often with soap and water for at least 20 seconds and avoiding touching your eyes, nose, and mouth with unwashed hands; and frequently clean high touch areas.

Additionally, to limit your interactions with other people as much as possible, you are advised not to have guests in your home except for necessary caregivers and to avoid travel within and outside of New York City.

Underlying health conditions that increase your risk for severe illness from COVID-19 include cancer, heart conditions, such as heart failure, coronary artery disease or cardiomyopathies, chronic kidney disease, type 2 diabetes, pregnancy, sickle cell disease, obesity, immunocompromised state (weakened immune system) from solid organ transplant, smoking, and chronic obstructive pulmonary disease. A full list of conditions that may increase the risk of severe illness can be found on the [CDC website](#).

You should maintain routine medical care for any chronic or other health conditions, and obtain any necessary vaccinations, under the consultation of your healthcare provider.

Contact your health care provider if you have symptoms of COVID-19. If you are experiencing a medical emergency, call 911.

For more information and guidance visit [nyc.gov/health/coronavirus](https://www1.nyc.gov/health/coronavirus)

- The NYC Commissioner of Health issued an advisory for:
 - Older adults (in particular, aged 65 and older)
 - People with underlying health conditions that put them at increased risk of severe COVID-19
 - Household members and caregivers of these individuals
- Advises that these groups take increased precautions as COVID-19 increases in NYC:
 - Avoid public spaces and gatherings and wear a face covering at all times outside the home, indoors and outdoors
 - Do not leave home, except for work, school or essential activities, including COVID-19 testing and other medical care, or to go to the grocery store or pharmacy
 - If you feel sick do not leave your home, except for COVID-19 testing or other essential medical care

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

CDC OPTIONS TO REDUCE QUARANTINE

- CDC Options to Reduce Quarantine
 - On December 2, the CDC released a [scientific brief](#) outlining options to shortening the period of quarantine
- Quarantine Period in NYC Remains 14 days
 - The quarantine period in NYC and NYS remains 14-days
 - The NYC Health Department will issue guidance if the current quarantine period is modified

FDA AUTHORIZES FIRST OVER-THE- COUNTER AT HOME COVID-19 DIAGNOSTIC TEST



<https://www.ellumehealth.com>

- Antigen-based test approved for use in symptomatic and asymptomatic individuals ≥ 2 years using nasal swab
- Bluetooth connected analyzer and a smartphone app used to perform the test with results within 20 minutes
- Requires zip code and date of birth, with optional fields for name and email address; app reports results to public health authorities
- In asymptomatic individuals, correctly identified 91% of those who were infected and 96% of those who were not infected
- In symptomatic individuals, correctly identified 96% of those who were infected and 100% of those who were not infected
- Costs approximately \$30

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-antigen-test-first-over-counter-fully-home-diagnostic>

EPIDEMIOLOGY
OF COVID-19
IN NYC

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DOHMH COVID-19
VACCINATION
PROGRAM

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NYC Department of Health and Mental Hygiene

OUTLINE

- I. Covid-19 Vaccine Overview and Planning
 - Vaccine Timelines
 - Availability and Prioritization
 - Participating in the NYC COVID-19 Vaccination Program

- II. Pfizer-BioNTech COVID-19 Vaccine
 - Results of Phase 2/3 Studies
 - Clinical Recommendations



COVID-19 VACCINATION OVERVIEW AND PLANNING

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 Emergency Use Authorization (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 and post vaccine monitoring

COVID-19 Vaccine Summary

Six vaccine manufacturers received funding from the federal program “Operation Warp Speed” to produce a COVID-19 vaccine

Company	Mechanism	Efficacy	Storage	Doses	Status
Pfizer-BioNTech	mRNA	95%	-70° C	2	Received EUA* and in use
Moderna	mRNA	94%	-20° C	2	Applied for EUA*
AstraZeneca	DNA	70%	2-8° C	2	Phase III trial
Janssen	DNA	Unk	-20° C	1	Phase III trial
Novavax	Protein subunit	Unk	2-8° C	2	Phase III trial
Sanofi; GlaxoSmithKline	Protein subunit	Unk	2-8° C	2	Phase II/III trial

*Emergency Use Authorization

COVID-19 VACCINE TIMELINES

PFIZER-BIONTECH & MODERNA

Pfizer-BioNTech COVID-19 Vaccine

- Pfizer application for Emergency Use Authorization (EUA) submitted 11/20/2020
- FDA issued EUA on 12/11/2020
- ACIP recommended use for individuals ages 16 and older on 12/12/2020

Moderna COVID-19 Vaccine

- Moderna EUA application submitted 11/30/2020
- Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended FDA authorize the use of the Moderna COVID-19 vaccine
- ACIP meeting planned for 12/19/2020

Expecting to have licensed products sometime in 2021

COVID-19 VACCINE AVAILABILITY

- Given limited supply of vaccine at this time, vaccine will be allocated in three Phases and subphases based on recommendations from [ACIP](#)
 - Phase Ia, Ib, Ic: Limited availability for highest priority groups
 - Phase II: Greater availability for general public
 - Phase III: Shift to routine vaccination

COVID-19 VACCINE AVAILABILITY

PHASE I

- Limited supply for the country
- Vaccine available under an FDA EUA and not yet a licensed product
- Vaccine to be offered at a limited number of sites that can reach the target populations
 - Hospitals
 - Large medical facilities
 - DOHMH-supported and DOHMH-run PODS for other high-risk healthcare personnel

COVID-19 VACCINE AVAILABILITY

PHASE II

- Greater availability to general public
- NYC Health Department would oversee vaccine distribution
- Broad distribution and availability
- Will expand on existing vaccination infrastructure:
 - Federally Qualified Health Centers
 - Independent health care providers
 - Pharmacies
 - Urgent care
 - Hospitals
 - H+H facilities
 - NYC Health Department COVID-19 testing sites
 - Community vaccinators
- DOHMH-run Points of Distribution (PODs) for the general public that fall into priority groups

COVID-19 VACCINE ALLOCATION

- ACIP principles include:
 - Reduce health impact of COVID-19
 - Reduce transmission
 - Vaccine safety and effectiveness
 - Equitable allocation and availability
- National Vaccine Allocation Framework*
 - Groups proposed for initial doses of vaccine include high risk health workers and first responders with high risk of exposure
 - Equity is a crosscutting consideration

* National Academy of Science, Engineering and Medicine. A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus.
<https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus>

COVID-19 VACCINE ALLOCATION

ACIP

ACIP Interim Recommendation – Phase 1a:

- Vaccination should be offered to:
 - 1) Health care personnel (HCP) and
 - 2) Staff and residents of long-term care facilities
- These considerations will be updated as additional information becomes available

Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html>

CDC definition of health care personnel: <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html>

COVID-19 VACCINE ALLOCATION

ACIP

ACIP recommendations for Phases 1b and 1c expected on 12/20/2020

- Additional target populations likely to include:
 - Persons with increased risk of exposure to COVID-19
 - Essential workers
 - Persons with increased risk of COVID-19 complications
 - Adults aged ≥ 65 years
 - Persons with high-risk medical conditions

See CDC for conditions associated with severe COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

NYC COVID-19 VACCINATION PROGRAM

- Stepwise approach to facility enrollment to reach priority populations
 - 55 acute care hospitals and specialty hospitals have enrolled
 - FQHC enrollment almost complete
 - Enrollment for remaining NYC vaccination providers opened 12/7
- Almost all nursing homes and adult care facilities in NYC are enrolled in CDC's Pharmacy Partnership for Long-term Care Program

NYC COVID-19 VACCINATION PROGRAM

- Medical facility networks and individual facilities are required to sign a federal provider agreement
 - Provider agreement must be completed and signed in the Citywide Immunization Registry (CIR)
- Once vaccine is available for your sector
 - Vaccine will be ordered via the CIR
 - Vaccine will ship directly from the manufacturer or CDC distributor to the vaccine provider

CIR REPORTING

- Required reporting of ALL administered COVID-19 vaccines doses to CIR within 24 hours of administration
- Patient consent not required
- Authorizations include:
 - NYS Emergency Order 12/13*
 - NYC Commissioner Order 12/14**
- CIR Reporting Assistance
 - <https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic>
 - BOI Hotline: 347-396-2400
- Ensure race and ethnicity are populated in electronic health records – fields must be submitted to CIR when reporting COVID-19 vaccine doses administered

*NY State. No. 202.82: Continuing Temporary Suspension and Modification of Laws Relating to the Disaster Emergency. Available at: <https://www.governor.ny.gov/news/no-20282-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency>

**NYC. Order of the Commissioner of Health and Mental Hygiene Regarding Reporting Vaccination Information. Available at: <https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-vaccine-reporting-order.pdf>

VACCINE ADVERSE EVENT REPORTING

- Adverse events that occur in a recipient 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.govexternal> or by calling 1-800-822-7967.

VACCINE MONITORING

- Vaccination coverage dashboards to track uptake and inform vaccination program decisions
- Monitor vaccination rates alongside COVID-19 positivity rates
- Monitor vaccine safety trends
- Ensure equitable distribution following utilization of racial equity and public health ethics tools and frameworks
- Post-incident response, learning, and improvement

PFIZER-BIONTECH COVID-19 VACCINE

PFIZER-BIONTECH COVID-19 VACCINE

ACIP RECOMMENDATIONS FOR USE

- December 12, 2020*
- ACIP recommended, as interim guidance, the use of the Pfizer-BioNTech COVID-19 vaccine for persons 16 years of age and older for the prevention of COVID-19

*CDC. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020. *MMWR* 69.

PFIZER-BIONTECH COVID-19 VACCINE
DEMOGRAPHICS – PHASE 2/3 STUDIES

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

Demographic Characteristics

Phase 2/3 (N=43,448)

		BNT162b2 (30 µg) N=21,720 n (%)	Placebo N=21,728 N (%)	Total N=43,448 n (%)
Sex	Male	11,183 (51.5)	10,942 (50.4)	22,125 (50.9)
	Female	10,537 (48.5)	10,786 (49.6)	21,323 (49.1)
Race	White	17,839 (82.1)	17,857 (82.2)	35,696 (82.2)
	Black or African American	2,091 (9.6)	2,107 (9.7)	4,198 (9.7)
	All others	1,790 (8.2)	1,764 (8.1)	3,554 (8.2)
Ethnicity	Hispanic/Latino	5,672 (26.1)	5,668 (26.1)	11,340 (26.1)
	Non-Hispanic/non-Latino	15,928 (73.3)	15,940 (73.4)	31,868 (73.3)
	Not reported	120 (0.6)	120 (0.6)	240 (0.6)
Age	16-55 Years	12,780 (58.8)	12,822 (59.0)	25,602 (58.9)
	>55 Years	8,940 (41.2)	8,906 (41.0)	17,846 (41.1)
	16-64 Years	17,176 (79.1)	17,190 (79.1)	34,366 (79.1)
	65-74 Years	3,620 (16.7)	3,646 (16.8)	7,266 (16.7)
	≥75 Years	924 (4.3)	892 (4.1)	1,816 (4.2)

>9000
(20.9%)

Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PFIZER-BIONTECH COVID-19 VACCINE
EFFICACY – PHASE 2/3

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

First COVID-19 Occurrence From 7 Days After Dose 2 Phase 2/3 Efficacy – Final Analysis

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

Efficacy Endpoint	BNT162b2 (30 µg) N=18,198		Placebo N=18,325		VE (%)	(95% CI)	Pr (VE >30%)
	n	Surveillance Time (n)	n	Surveillance Time (n)			
First COVID-19 occurrence ≥7 days after Dose 2	8	2.214 (17,411)	162	2.222 (17,511)	95.0	(90.3, 97.6)	>0.9999

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.
Pr=Posterior probability

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Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

First COVID-19 Occurrence From 7 Days After Dose 2 Phase 2/3 Efficacy – Final Analysis: Subgroups

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

		BNT162b2 N=18,198 n	Placebo N=18,325 n	VE (%)	(95% CI)
Overall		8	162	95.0	(90.0, 97.9)
Age	18-64 years	7	143	95.1	(89.6, 98.1)
	65-74 years	1	14	92.9	(53.1, 99.8)
	≥75 years	0	5	100.0	(-13.1, 100.0)
Sex	Male	3	81	96.4	(88.9, 99.3)
	Female	5	81	93.7	(84.7, 98.0)
Race	White	7	146	95.2	(89.8, 98.1)
	Black or African American	0	7	100.0	(31.2, 100.0)
	All Others	1	9	89.3	(22.6, 99.8)
Ethnicity	Hispanic/Latino	3	53	94.4	(82.7, 98.9)
	Non-Hispanic/Non-Latino	5	109	95.4	(88.9, 98.5)
Country	Argentina	1	35	97.2	(83.3, 99.9)
	Brazil	1	8	87.7	(8.1, 99.7)
	USA	6	119	94.9	(88.6, 98.2)

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Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

First COVID-19 Occurrence From 7 Days After Dose 2 by Comorbidity Status – Evaluable Efficacy (7 Days) Population

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

	BNT162b2 (30 µg) N=18,198		Placebo N=18,325		VE (%)	(95% CI)
	n	Surveillance Time (n)	n	Surveillance Time (n)		
Overall	8	2,214 (17,411)	162	2,222 (17,511)	95.0	(90.0, 97.9)
Comorbidity						
No comorbidity	4		76		94.7	(85.9, 98.6)
Any comorbidity	4		86		95.3	(87.7, 98.8)
Any malignancy	1		4		75.7	(-145.8, 99.5)
Cardiovascular	0		5		100.0	(-0.8, 100.0)
Chronic pulmonary disease	1		14		93.0	(54.1, 99.8)
Diabetes	1		19		94.7	(66.8, 99.9)
Obese (≥30.0 kg/m ²)	3		67		95.4	(86.0, 99.1)
Hypertension	2		44		95.4	(82.6, 99.5)
Diabetes (including gestational diabetes)	1		20		95.0	(68.7, 99.9)

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Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

BNT162b2 Protects Against Severe Disease Phase 2/3 Efficacy – Final Analysis (CDC definition)

Severe Disease Severe illness - CDC definition: hospitalization, admission to the ICU, intubation or mechanical ventilation, or death

Efficacy Endpoint	BNT162b2 (30 µg) N=18,198		Placebo N=18,325		VE (%)	(95% CI)
	n	Surveillance Time (n)	n	Surveillance Time (n)		
First Severe COVID-19 occurrence >7 days after Dose 2	0	2.215 (17,399)	5	2.229 (17,495)	100	(-9.9, 100)

Efficacy Endpoint	BNT162b2 (30 µg) N=21,669		Placebo N=21,686		VE (%)	(95% CI)
	n	Surveillance Time (n)	n	Surveillance Time (n)		
First Severe COVID-19 occurrence after Dose 1	1	4.018 (21,299)	14	4.001 (21,238)	92.9	(53.2, 99.8)

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint..

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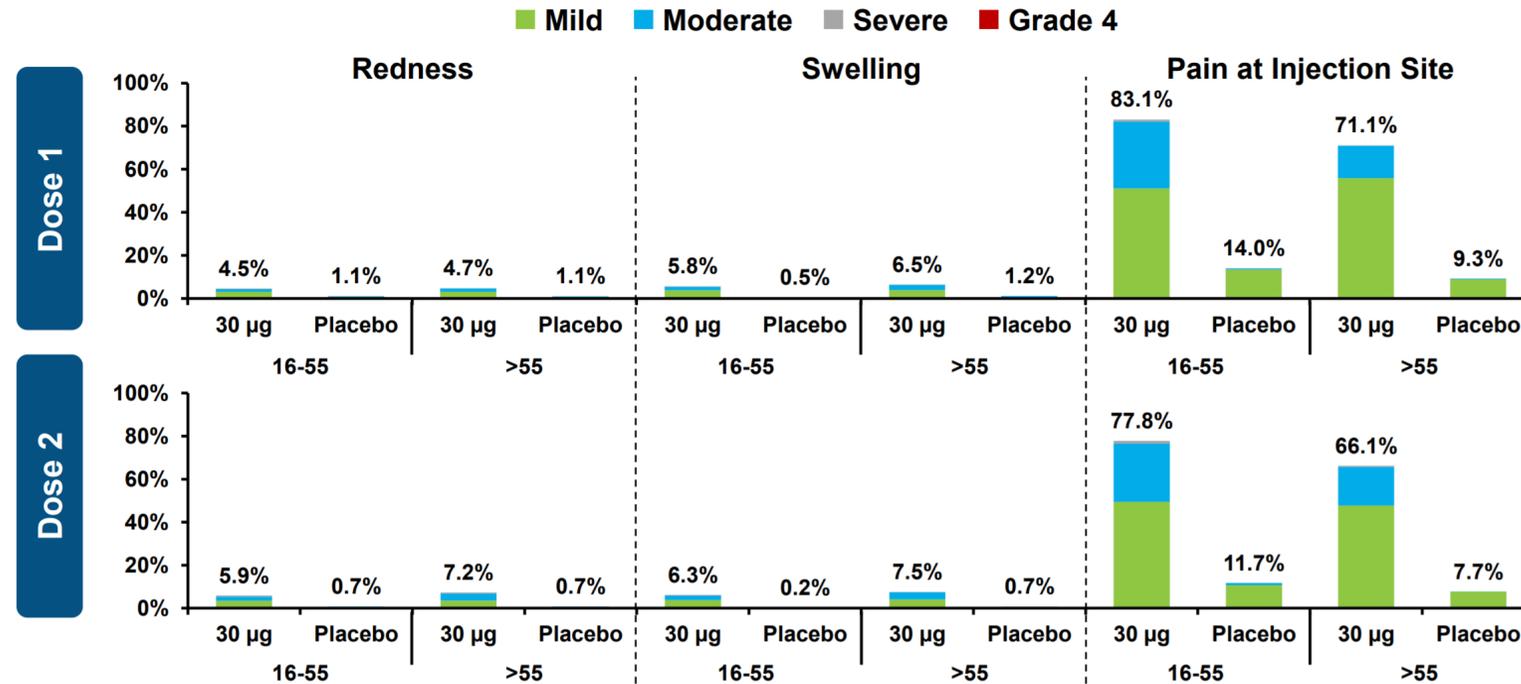
Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PFIZER-BIONTECH COVID-19 VACCINE
SAFETY – PHASE 2/3

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

eDiary: Local Events Within 7 Days From Dose 1 and 2 in 16-55 and >55 Year Olds (N=8,183)



Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 cm; Grade 4= necrosis
 Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Dose 1: 16-55 yrs N=4589; >55 yrs N=3594 Dose 2: 16-55 yrs N=4201 >55 yrs N=3306

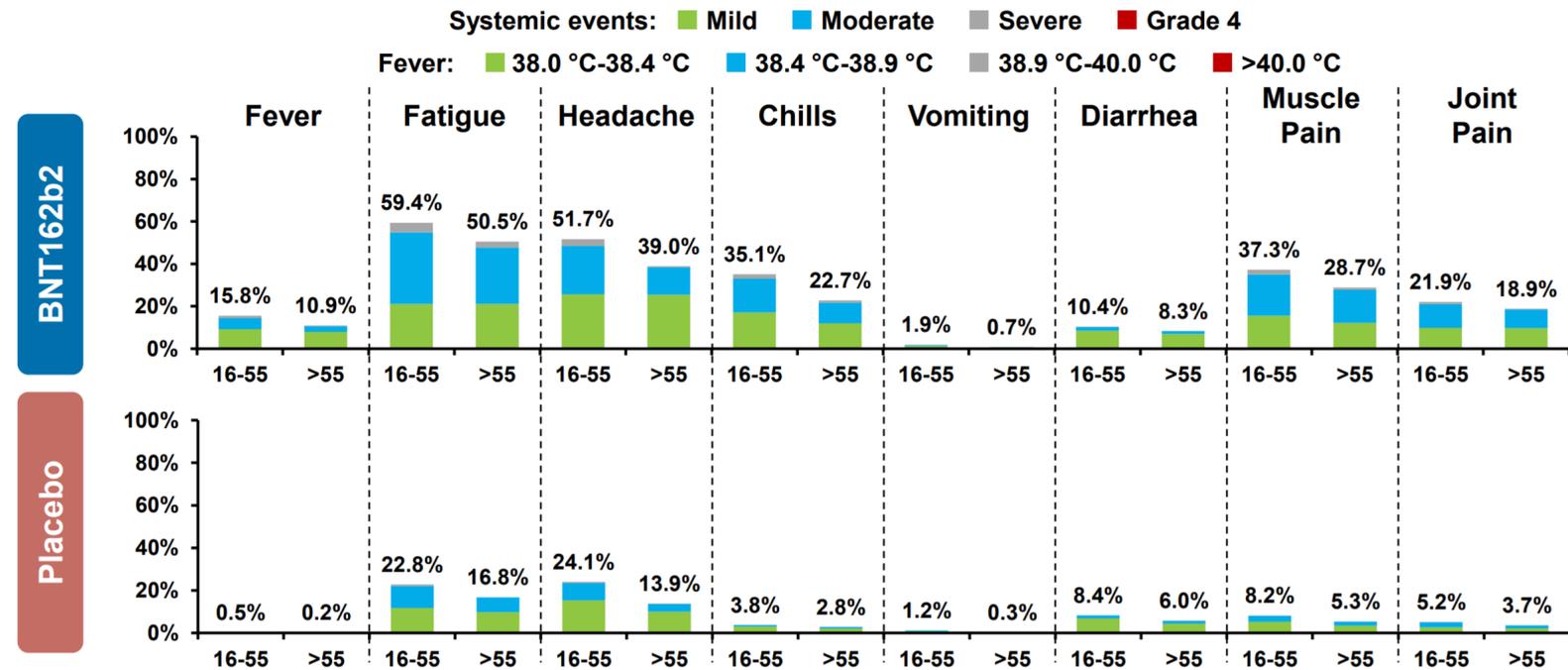
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Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

eDiary: Systemic Events Within 7 Days From Dose 2 in 16-55 and >55 Year Olds (N=8,183)



Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
 Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
 Dose 1: 18-55 yrs N=3529; 56-85 yrs N=3027 Dose 2: 18-55 yrs N=3345; 56-85 yrs N=2899

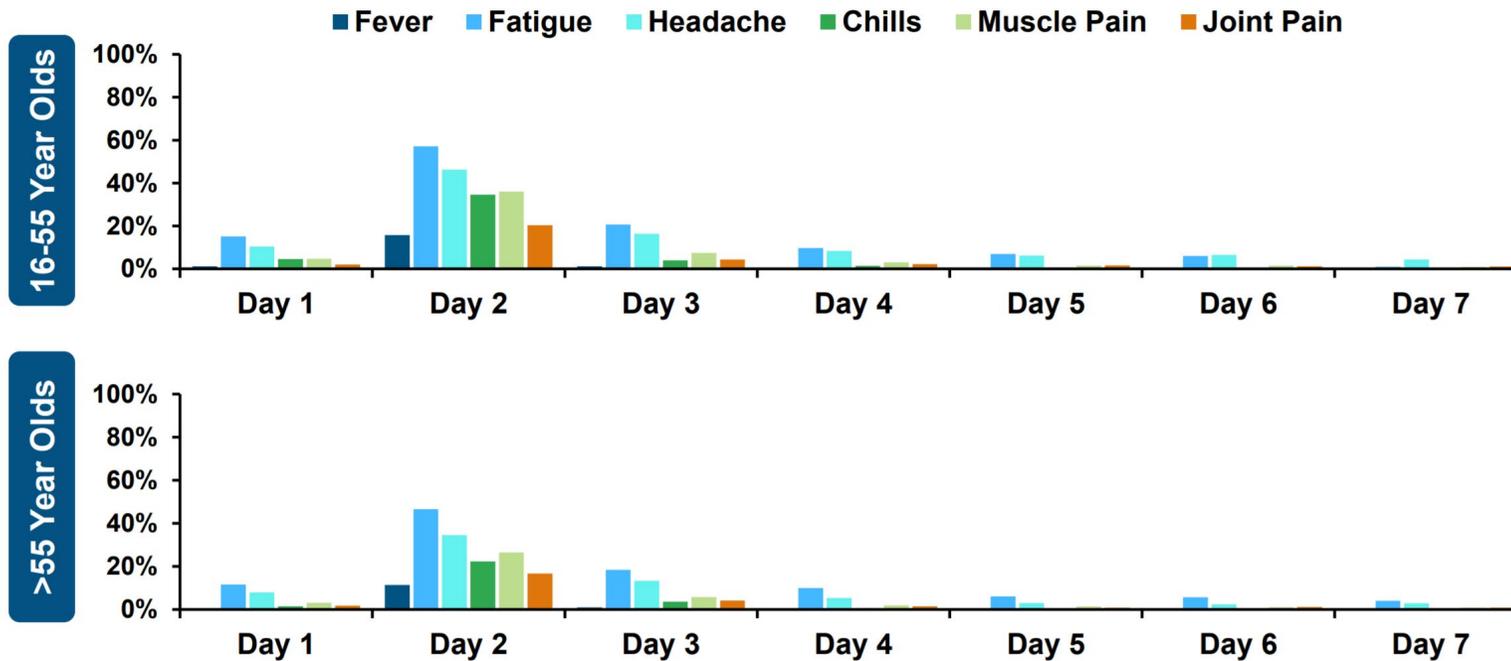
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Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>

PHASE 2/3 STUDIES: PFIZER-BIONTECH COVID-19 VACCINE

eDiary: Systemic Events Each Day From Dose 2 in 16-55 and >55 Year Olds (N=8,183) BNT162b2



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Gruber, William. BNT162b2 Vaccine Candidate Against COVID-19. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-11/COVID-02-Gruber.pdf>



CLINICAL RECOMMENDATIONS

PFIZER-BIONTECH COVID-19 VACCINE

ADMINISTRATION AND INTERVALS

- Intramuscular administration
- 1 dose = 0.3mL
- 2-dose series administered 3 weeks apart
- 4-day grace period (i.e., day 17-21 is valid)
- If > 21 days since 1st dose, administer 2nd dose at earliest opportunity (do not repeat 1st dose)
- Both doses necessary for protection

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

CO-ADMINISTRATION WITH OTHER VACCINES

- Do not co-administer with other vaccines
- Minimum 14 days before or after administration with any other vaccines
- If inadvertently administered within 14 days of another vaccine, do not repeat doses of either vaccine
 - The second dose of the Pfizer/BioNtech vaccine (if not already given) should still be administered 21 days after the first dose

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

HISTORY OF SARS- COV-2 INFECTION

- Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
- Viral testing for acute infection not recommended for vaccine decision-making
- Serologic testing for prior infection not recommended for vaccine decision-making
- Defer vaccination until recovery from acute illness (if person was symptomatic) and criteria for discontinuation of isolation met

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

KNOWN SARS-COV-2 EXPOSURE

- Community/outpatient:
 - Defer vaccination until end of quarantine period to avoid possible exposures
- Congregate healthcare settings
 - May be vaccinated (as it likely would not lead to additional/new exposures)
- Other congregate settings
 - May be vaccinated to avoid delays and missed opportunities to vaccinate
 - Take precautions to limit exposure to other residents or non-essential staff

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

IMMUNO- COMPROMISED PERSONS

- Individuals may be at increased risk for severe COVID-19
- No data to establish safety or efficacy
- May be vaccinated unless otherwise contraindicated
- Counseling:
 - Unknown safety/efficacy
 - Potential for reduced immune response
 - Continue to follow all guidance to protect against COVID-19

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

PREGNANT PERSONS

- No data on safety
- mRNA vaccines and pregnancy
 - Not live vaccines
 - Degraded quickly by normal cellular processes and do not enter nucleus of cell
- COVID-19 and pregnancy
 - Increased risk of severe illness
 - May be increased risk of adverse pregnancy outcomes (e.g., preterm birth)
- If a person is a part of a group (e.g., HCP) recommended to receive a COVID-19 vaccine and is pregnant, the individual may choose to be vaccinated
 - Encourage informed decision making in consultation with HC provider

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

BREASTFEEDING/ LACTATING PERSONS

- No data on safety in lactating persons or the effects of mRNA vaccines on breastfed infant or milk production/excretion
- mRNA vaccines not considered live virus vaccines – not thought to be a risk to the breastfeeding infant
- If a lactating person is part of a group (e.g., HCP) recommended to receive a COVID-19 vaccine, they may choose to be vaccinated

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

REACTOGENICITY

- Before vaccination, counsel recipients about expected local and systemic post-vaccination symptoms
 - Include fever, fatigue, headache, chills, myalgia, and arthralgia
- Unless individual develops a contraindication to vaccine, encourage them to complete the series
- Antipyretic or analgesic medication may be taken for treatment of symptoms following vaccination

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

PREVENTION OF COVID-19 POST- VACCINATION

- Protection is not immediate
- Takes 1-2 weeks following Dose #2 to be considered fully vaccinated
- No vaccine is 100% effective
- Continue to follow all guidance to protect themselves and others, including:
 - Stay home if sick
 - Keep physical distance
 - Wash hands frequently
 - Wear a face covering

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

CONTRAINDICATIONS

- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination
- Ensure appropriate medical treatment for managing immediate allergic reactions is immediately available

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

PFIZER-BIONTECH COVID-19 VACCINE

PRECAUTIONS

- Reports of anaphylactic reactions in persons vaccinated outside of clinical trials have occurred
- A severe allergic reaction to any vaccine or injectable therapy (IM, IV, SC) is a precaution to vaccination at this time
 - Seasonal allergies and allergies to foods, oral medications, and pets not included as precaution
 - Family history of anaphylaxis is not included as a precaution
- *Observe patients following vaccination*
 - Persons with history of anaphylaxis – observe 30 minutes
 - All other persons – observe 15 minutes

Cohn A, Mbaeyi S. What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>



KEY MATERIALS

COVID-19: Vaccine Information for Providers

Recent News and Recommendations

The COVID-19 vaccine developed by Pfizer-BioNTech has received an Emergency Use Authorization from the FDA for people 16 years and older. A vaccine from Moderna may receive similar authorization after a December 17 FDA advisory committee meeting. Both of the vaccines are [mRNA vaccines](#).

- [MMWR: The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine](#) (December 13)
- [CDC: Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine](#)
- [CDC: Pfizer-BioNTech COVID-19 Vaccine](#)

Webinars

Upcoming

- Tuesday, December 15, at 1 p.m.: [NYC Health Department: Enrollment in the NYC COVID-19 Vaccination Program](#)
- Thursday, December 17, at 3 p.m.: [ASCO/IDSA Webinar: The COVID-19 Vaccine & Patients with Cancer](#)
- Friday, December 18, at 1 p.m.: [NYC Health Department: Updates on the Epidemiology of COVID-19 in NYC; Updates on COVID-19 Vaccination and the NYC Campaign](#)

Recent

- [CDC: COVID-19 Vaccination Implementation and the "Vaccinate with Confidence Strategy"](#) (December 3)

For general information about the vaccine, including updates on development, approvals and distribution, see our main [COVID-19 Vaccines](#) page.

All COVID-19 vaccinations must be reported through the CIR within 24 hours of administration.

Required Factsheets

Health care providers administering the vaccine must review the following health care provider factsheet and distribute the patient fact sheet to patients receiving the vaccine or their caregivers.

- [Fact Sheet for Health Care Providers Administering Vaccine](#) (PDF, December)
- [Fact Sheet for Recipients and Caregivers](#) (PDF, December)

Nursing Homes and Assisted Living Facilities

The CDC is partnering with pharmacies to provide on-site vaccination services for residents of nursing homes and assisted living facilities.

- [CDC: Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination](#)

Additional Resources

Expand All

Collapse All

▶ Patient Communication

▶ Safety and Side Effects

▶ Costs and Reimbursements

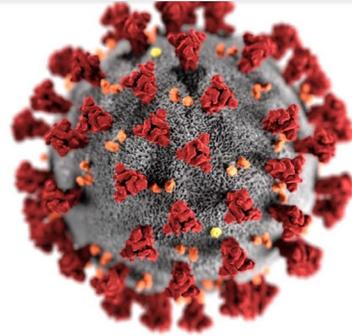
▶ Training

- [FDA: COVID-19 Vaccines](#)
- [FDA: Pfizer-BioNTech Vaccine Information](#)
- [New York State Department of Health: Vaccine Information for Providers](#)
- [New York State COVID-19 Vaccination Program](#) (PDF, October)

What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine

Amanda Cohn, MD
Sarah Mbaeyi, MD, MPH

December 13, 2020



<https://www.cdc.gov/vaccines/covid-19/downloads/pfizer-biontech-vaccine-what-Clinicians-need-to-know.pdf>

COVID-19 (Coronavirus Disease)

CASES ARE RISING.
ACT NOW!



Your Health ▾ Community, Work & School ▾ Healthcare Workers & Labs ▾ Health Depts ▾ Cases & Data ▾ More ▾

Home Healthcare Workers

HEALTHCARE WORKERS

Resources for Community Health Workers

Post Vaccine Considerations for Healthcare Personnel

Testing +

Updated Dec. 13, 2020 [Print](#)



Vaccination

Clinical Care +

Infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination

Infection Control -

Infection Control Guidance

Note: Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among healthcare personnel (HCP). The approach described in this document is intended to reduce the risks for disruptions in care and pathogen (e.g., SARS-

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html>

Home Vaccines and Immunizations Home

For Parents

For Adults

For Pregnant Women

For Healthcare Professionals

COVID-19 Vaccination -

For Healthcare Professionals +

COVID-19 Vaccination Planning +

Vaccination

COVID-19 Vaccination Communication Toolkit

For Medical Centers, Clinics, and Clinicians



On This Page

Getting Started [Slides](#)

Fact Sheets and FAQs [Social Media](#)

Posters [Video](#)

Stickers

<https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html>

Home Healthcare Workers

HEALTHCARE WORKERS

Resources for Community Health Workers

COVID-19 Vaccination

Testing +

Updated

Getting Vaccinated

How CDC is Making COVID-19 Vaccine Recommendations

Benefits of Getting a COVID-19 Vaccine

Ensuring the Safety of COVID-19 Vaccines in the United States

Preparing Your Patients

Answering Patients' Questions about COVID-19 Vaccination

Understanding and Explaining mRNA COVID-19 Vaccines

COVID-19 Vaccine Resources for Providers

What Clinicians Need to Know About the Vaccine [PDF - 36 pages]

Post Vaccine Considerations for Healthcare Personnel

Post Vaccine Considerations for Residents

COVID-19 Vaccination Training Programs and Reference Materials [PDF - 3 pages]

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<https://www.cdc.gov/coronavirus/2019-ncov/hcp/vaccination.html>

VACCINE PROVIDER ASSISTANCE

- NYC Health Department - COVID-19 Vaccine:
 - Public: nyc.gov/covidvaccine
 - Providers: nyc.gov/health/covidvaccineprovider
- Vaccine Provider Assistance:
 - Email
 - nycimmunize@health.nyc.gov
 - Bureau of Immunization Hotline:
 - 347-396-2400

COVID-19
VACCINE
NYS DOH
STANDING ORDER
TEMPLATE

- A New York [Executive Order](#) No. 202.82 issued earlier this week waives the requirement for a patient-specific physician order to administering vaccine.
- The CDC created a [non-patient-specific standing order template](#) for the administration of the Pfizer-BioNTech COVID-19 vaccine

HOLIDAY GUIDANCE: BE FESTIVE, STAY SAFE!

Be Festive, Stay Safe! Tips for a Safer Holiday Season

Make a plan to celebrate the holiday season safely. Be festive while protecting your loved ones and preventing the spread of COVID-19: Do not travel (rediscover holidays at home!); do not host or attend a holiday party (go virtual instead!); and do not gather in groups and only celebrate with household members (less is more!). Here are some tips on how to celebrate.

No matter how you celebrate, always practice these four key actions:

Stay home: Celebrate at home, especially if you aren't feeling well, tested positive for COVID-19, have been in close contact with someone who has COVID-19, or were recently traveling.

Stay apart: Keep at least 6 feet from others. Do not attend holiday parties or other gatherings, especially indoors.

Wear a face covering: Protect those around you. You can have COVID-19 and not know it.

Keep your hands clean: Wash your hands often or use alcohol-based hand sanitizer. Avoid touching your face with unwashed hands and cover your coughs and sneezes.

Safer holiday activities

• **Host a virtual party.** Celebrate with friends and family at a video dinner party. Kiss 2020 good-bye at a virtual New Year's ball or with a Tik-Tok dance.

• **Deck the halls.** Put up decorations such as a tree, menorah, kinarah, wreath, or lights. Walk around your neighborhood and enjoy the decorated homes and shops. Stop for a hot chocolate or cider to stay warm.

• **Spread the holiday cheer.** Surprise your neighbor by dropping off some holiday cookies. Send snail-mail holiday cards to your co-workers or call a friend you haven't spoken to in a while. Invite someone who may be alone to join your virtual Thanksgiving or holiday dinner.

• **Go caroling outdoors.** Give the gift of music. Wear a face covering and stay 12 feet from others (the virus can spread more easily when singing, so it is important to stand farther apart).

• **Let it snow.** Make a snowperson, go sledding or snow shoeing or have a snowball fight.

• **Holiday shopping.** Don't let Black Friday turn into COVID Monday! Shop online to avoid crowds (and a showdown over the last toy on the shelf) or call for curbside pick up at your favorite local store. If you shop in person, wear a face covering, use hand sanitizer, and go during off hours.

• **Have a feast.** Have a turkey with all the trimmings. Eat some kugel, latkes, or sugar cookies, and have an eggnog – you've earned it!

• **Watch football and the Grinch.** Enjoy your TV traditions and do your best touchdown dance when your team scores.



Religious Services

Attending indoor services can be risky since it often involves many people in a confined space. If you participate in religious services:

• **Go virtual or outside.** Join online services or worship outdoors.

• **Be prepared.** Bring and use hand sanitizer and make sure everyone over age 2 wears a face covering at all times.

• **Spread out.** Sit only with members of your household and keep at least 6 feet apart from others. Remember to stay 12 feet apart if there will be singing.

• **Bring your own (BYO).** Bring your own books of worship and ceremonial objects. Never drink from the same cup as others.



Travel

You should not travel this year. Traveling puts you, your family, and your community at risk. Returning travelers can be a source of community outbreaks. But if you cannot avoid travel over the holidays:

• **Stay local.** This is the perfect year to enjoy the best city and state in the country.

• **Travel safely.** Keep distance from others, bring and use hand sanitizer, and make sure everyone over age 2 wears a face covering. See the Health Department's [Commuting Safety guidance](#) for more traveling rules of the road.

• **Get a room.** Stay at a hotel rather than at someone's home. If you have out-of-town guests, suggest they do the same.

• **Don't drink and drive.** It's a good move to sleep in your own home, but do not drink and drive to get there. Designate a driver. And if you are the driver and you've had too much to drink, walk, take the subway or call a car service.

• **Get tested and quarantine after travel.** If you travel to most other states or another country, you will need to quarantine when you return home. See [New York State's travel quarantine requirements](#) for more information.



Activities you definitely should not do:

• **Mistletoe:** Unless it's with your live-in partner, keep kissing to a minimum this year.

• **Use your neighbor's blow up snowperson for a dart board.** I know, it's tempting.

• **Have a snowball fight with a pitcher from the Yankees.** Snow is not soft at 95 miles per hour.

If you are overwhelmed, anxious or depressed, contact NYC Well, a free and confidential mental health support service available 24/7.

Call 888-NYCWELL (888-692-9355), text "WELL" to 65173, or visit nyc.gov/nycwell.

- Available in multiple languages at nyc.gov/health/safeholidays
- Discourages gatherings and traveling (except for household gatherings) but provides tips on how to do so safely
- Provides idea for safe holiday activities

TRAVELING DURING COVID-19: DON'T DO IT



**DO NOT TRAVEL THIS HOLIDAY SEASON.
BE PREPARED TO QUARANTINE IF YOU DO.**

WHAT YOU NEED TO KNOW ABOUT TRAVELING DURING COVID-19

There is widespread transmission of COVID-19 across the United States (U.S.) and in many other countries. Traveling right now puts you, your family and your community at risk of getting sick and spreading the virus to others. If you must travel, plan ahead, take precautions and be prepared to quarantine when you return.

New York State (NYS) has strict quarantine requirements for visitors and returning New Yorkers. These requirements help us reduce the spread of COVID-19. People returning from areas with a large number of COVID-19 cases are more likely to have been exposed to the virus and get COVID-19 themselves. Quarantine is particularly important for reducing the spread of COVID-19 since it is possible to have COVID-19 and not know it. People without symptoms can spread the virus.

When on the road or at home, always practice these four key COVID-19 prevention actions:

- **Stay home:** Stay home if you aren't feeling well, tested positive for COVID-19 or have been in close contact with someone who has COVID-19.
- **Stay apart:** Keep at least 6 feet from others.
- **Wear a face covering:** Protect those around you by wearing a face covering at all times outside your own home. Face coverings are required in New York State on all public transportation (including car services) and by air, train and bus carriers.
- **Keep your hands clean:** Wash your hands often and carry alcohol-based hand sanitizer to use while traveling. Avoid touching your face with unwashed hands and cover your coughs and sneezes.

What You Need to Know About NYS Travel Quarantine

Returning travelers and visitors arriving from the following places must fill out the [NYS Travel Health Form](#) (click the link or scan the QR code to access) and quarantine upon arrival:

- Another U.S. state **except** Connecticut, Massachusetts, New Jersey, Pennsylvania or Vermont
- A country or territory with a [Centers for Disease Control and Prevention Level 2 or 3 health alert](#)



...ve in NYS. However, testing may shorten quarantine. If you receive two negative COVID-19 tests, as follows: ...to New York, and

...that use saliva or nose or throat swab), and not ...te near you, visit [here](#). Many sites offer no-cost testing. ...iving their day 4 diagnostic test and while waiting ...se not to get tested must quarantine for 14 days.

...ours, you do not need to get tested before arrival or ...eed to fill out the NYS Travel Health Form and get

...u are staying; do not go in public. As best as possible, ...and wear a face covering when in the same room with ...be delivered, or other arrangements made so that ...only leave home for essential medical care, including

...me, you may be eligible to quarantine at an NYC ...68-4319) or visit [here](#) for more information.

Quarantine?

...fined by NYS. If so, you must take the following steps: ...er arriving. ...k.

...onitor for COVID-19 symptoms, wear a face covering ...d distancing.

...in group settings.

...ct requirements. For example, school staff and child ...ng exception to be able to return to work. Consult with ...nce that may apply to you and about sick leave policies.

What are the NYS travel quarantine requirements?

...violates a quarantine order may be subject to a civil ...ailing to complete the NYS Travel Health Form prior to ...fine and the person may be ordered to quarantine.

...for more information about travel quarantine.

The NYC Health Department may change recommendations as the situation evolves. 11.13.20

- Available in multiple languages at nyc.gov/health/covidtravel
- Discourages traveling
- Provides a summary of NYS travel quarantine requirements

RETRIEVING CME CREDITS

- Log onto the CPE website - <http://cme.nychhc.org>
- Look for the login section (on the right side)
- Create a profile if you have not logged in before
- Enter your username (email address) and password. Click on the **Go** button.
- The Welcome Screen will appear. Click on the **Go** button.
- The next screen will display three tabs. “**My Programs**”, “**CPE Tracker**” and “**My Account Info.**”
- Click the tab “**CPE Tracker**”
- On the same row look to your right. Locate the ‘**Select Year**’ section. Click on the **down arrow and select the year** to view. Certificates will be listed by program name.
- View credits or print certificates by clicking on the certificate located under the **view/print** column.
- Note: It may take up to 8 weeks for H+H to process credits

ADDITIONAL RESOURCES ON COVID-19

NYC Health Department

- Provider page: <https://www1.nyc.gov/site/doh/covid/covid-19-providers.page>
- Provider COVID-19 Vaccine page: [nyc.gov/health/covidvaccineprovider](https://www1.nyc.gov/site/doh/covid/covid-19-vaccine-provider.page)
- Data page: <https://www1.nyc.gov/site/doh/covid/covid-19-data.page>
- Next provider webinar: Friday, January 15, 1 p.m. (sign up on provider page)
- Dear Colleague COVID-19 newsletters (sign up for *City Health Information* subscription at: [nyc.gov/health/register](https://www1.nyc.gov/site/doh/covid/covid-19-newsletters/register))
- 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**
- Neighborhood resource snapshots: <https://www1.nyc.gov/site/doh/covid/covid-19-communities.page>

NYC COVID-19 Citywide Information Portal

- Includes information on >150 testing sites in NYC: [NYC.gov/covidtest](https://www1.nyc.gov/site/doh/covid/covid-19-testing-sites)

Learn more below about zone restrictions

- <https://www1.nyc.gov/site/doh/covid/covid-19-main.page>

Other sources

- CDC: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>