

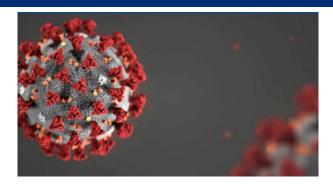
An Update for NYS Healthcare Providers on COVID-19

November 19, 2020

Elizabeth Dufort, MD, FAAP Medical Director, Division of Epidemiology New York State Department of Health

Agenda

- Global, National, New York State Updates
- Testing Updates
- Community Mitigation, Clusters, and Containment
- NYSDOH COVID-19 Vaccination Program Updates
- Travel Advisory
- PPE
- School testing in yellow zone updates
- Bamlanivimab
- Resources
- Q&A





• Recordings will be available immediately: <u>NYSDOH COVID-</u>

19 Healthcare Provider website

 In addition to YouTube, an on-demand version of our weekly sessions for healthcare providers in NYS is now available as a podcast – search NYSDOH



Disclaimer

• The situation is rapidly evolving, as is our understanding of this new virus.

 All of the information presented is based on our best knowledge as of <u>today</u>.



Situation Summary: COVID-19 Global, 11/15/2020

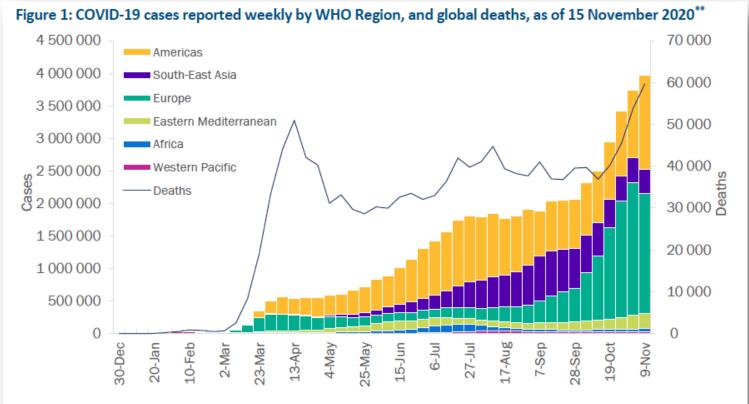
Department of Health

www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

Region	Confirmed Cases	Deaths
Global	53,766,728	1,308,975
Western Pacific	798,170	16,377
Europe	15,047,248	341,488
South-East Asia	10,015,731	153,860
Eastern Mediterranean	3,545,801	90,052
Africa	1,398,935	31,450
Americas	22,960,102	675,735

Situation Summary: COVID-19 Global, 11/15/2020

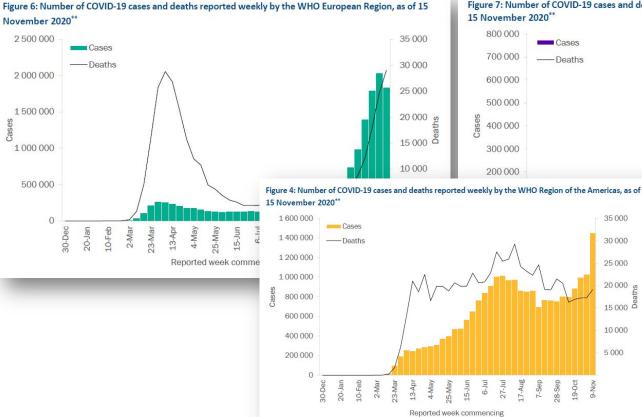
www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports



Reported week commencing



Situation Summary: COVID-19 Global, 11/15/2020 www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports



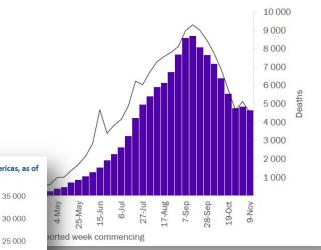
Cases

Figure 7: Number of COVID-19 cases and deaths reported weekly by the WHO South-East Asia Region, as of

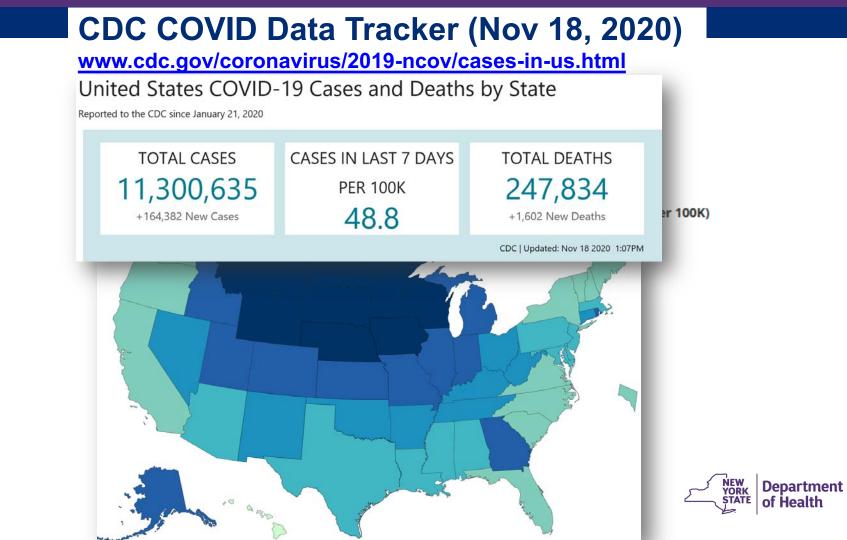
10,000

5 000

Vov-6







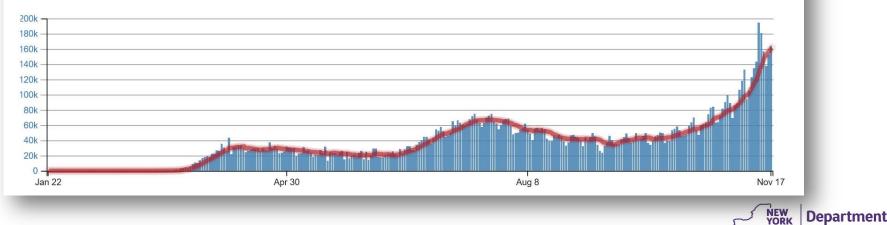
Situation Summary: COVID-19 U.S. (Nov 18, 2020)

www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html

Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory

Reported to the CDC by State or Territory

Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC



of Health

CDC COVID Data Tracker Case Rate Last 7 Days (Nov 18, 2020)

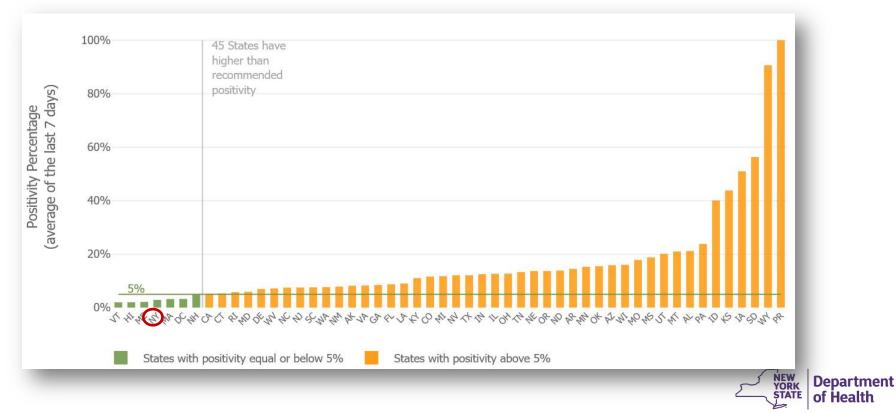
www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html

State/Territory 🖨	Cases in Last 7 Days per 100K	Maryland	31.7
North Dakota	185.3	Florida	29.5
South Dakota	161.1	South Carolina	28.6
owa	134	North Carolina	27.6
Vyoming	128.9	New York*	26.9
/innesota	120.3	Washington	26.8
lebraska	119	New Hampshire	25.1
Visconsin	118.8	Guam	23.3
Iontana	110.9	District of Columbia	23.1
Itah	97.5	Oregon	22.7
linois	97.2	California	21.9
ansas	94.2	Puerto Rico	21.4
ndiana	91.5	Virginia	20.7
olorado	84.3	New York City*	20
laska	80.6	Vermont	14.6
daho	79	Maine	14.1
hode Island	77.4	Virgin Islands	6.8
1issouri	75.1	Hawaii	5.6
eorgia	74	Northern Mariana Islands	0.8
1ichigan	73.8	Republic at Marshall Islands	0.7
oklahoma	69.5	American Samoa	
lew Mexico	68.3	Federated States of Micronesia	0 5 4
ennessee	65.4	Palau	
Thio	62.3	Palau	0

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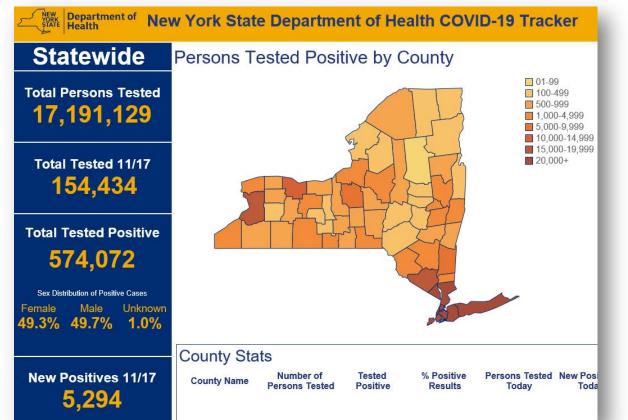
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Johns Hopkins Coronavirus Resource Center



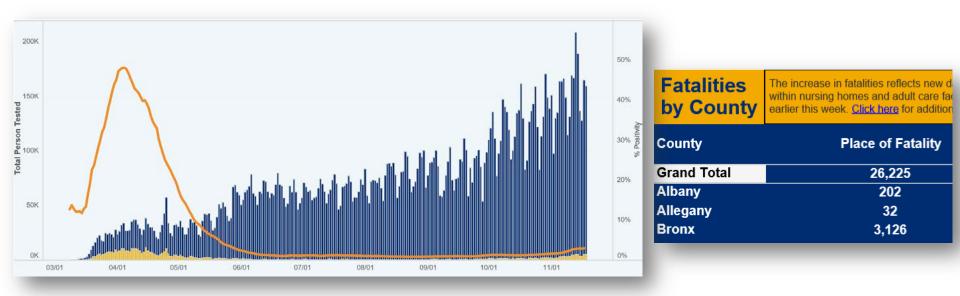
NYSDOH COVID-19 Tracker (Nov 17, 2020)

Found at: NYSDOH COVID-19 website





Percentage Positive Results By Region Dashboard





NYS Percentage Positive Results by Region or County Dashboard

Percentage Positive Results By Region Dashboard

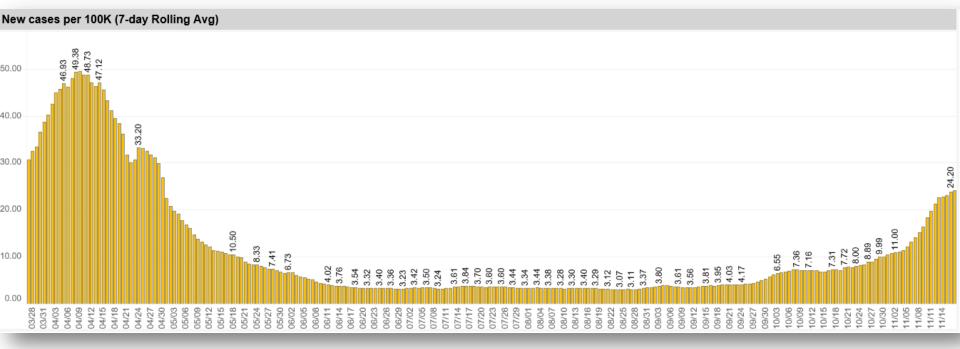
Test Results - Yesterday

	Total Persons Tested	Total Tested Positive	% Positive, Yesterday	% Positive, 7-day Avg
Capital Region	5,390	177	3.3%	2.3%
Central New York	8,285	310	3.7%	3.7%
Finger Lakes	9,345	360	3.9%	4.3%
Long Island	23,280	827	3.6%	3.3%
Mid-Hudson	16,574	770	4.6%	3.8%
Mohawk Valley	5,323	139	2.6%	2.5%
New York City	58,371	1,747	3.0%	2.5%
North Country	2,630	49	1.9%	1.8%
Southern Tier	11,693	163	1.4%	1.2%
Western New York	13,543	752	5.6%	5.1%



NYS Percentage Positive Results by Region Dashboard

Early Warning Monitoring Dashboard



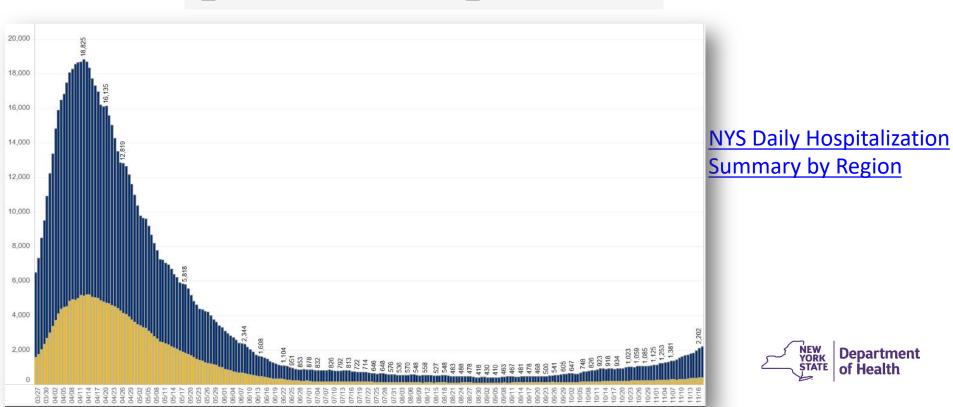
NYS Early Warning Monitoring Dashboard



Daily Hospitalization Summary by Region

Total COVID-19 Patients Hospitalized

Total COVID-19 Patients in ICU



NYS COVID-19 Healthcare Utilization (Nov 17, 2020)

- Increases in COVID-associated hospitalizations, ICU admissions, intubations, and fatalities
- Currently hospitalized for COVID-19: 2,202 (*increased by 78*)
- Current ICU: 423 (increased by 15)
 - Current Intubation: 192 (increased by 16)
- Cumulative discharges: 82,261
- Deaths: 35



Testing Updates



Lucira COVID-19 All-in One TEST Kit

(versus previously authorized at home specimen collection kits)

- Utilizes reverse transcription loop-mediated isothermal amplification (RT-LAMP) technology to detect RNA of the N gene for SARS-CoV-2
 - Faster and less cumbersome than traditional PCR test
 - Generally less accurate
- Reported as a battery powered test
- Single-use, disposable vial containing an elution buffer to release and lyse virions from a nasal swab sample
- Single use disposable test unit with lyophilized reagents for amplification and detection of SARS-CoV-2 RNA



Lucira COVID-19 All-in One TEST Kit

- Vial is placed into the testing unit; swab is place into the vial; mixed the swab removed, and test started
- Swirl the swab in both nostrils → into the vial → cartridge → 30 minutes → results as 'positive' or 'negative'.
- Expected to cost \$50 or less
- Expected to be available California and Florida in the near future and nationally by spring 2021
- Notably: small study by company and only included those with symptoms
 - It has not been evaluated in those who are asymptomatic



Lucira COVID-19 All-in One Test Kit

Authorization

- For home use with a provider prescription with self-collected nasal swab samples in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider
- For use by laboratories, including those doing waived testing, for individuals suspected of COVID-19 by their healthcare provider who are aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC



Lucira COVID-19 All-in One Test Kit

Performance

- Lucira COVID-19 All-in One Test Kit
 - Positive percent agreement (PPA)/sensitivity: 94.1%
 - Negative percent agreement (PPA)/specificity: 98.0%
- Abbott ID Now
 - Positive percent agreement (PPA)/sensitivity: 93.3%
 - Negative percent agreement (PPA)/specificity: 98.4%



Reporting

- Providers ask patients to report their test results to their prescribing physician

COVID-19 Testing updates

Remember to tell your patients to stay in ISOLATION while awaiting test results!!

- Then, once resulted:
- If positive (or if concern for COVID-19 persists) isolate x 10 days from symptom onset (or specimen collection date if asymptomatic) AND 72 hours fever-free (without use of fever reducing medicines) AND symptoms improving
 - Advise contacts to quarantine
- If negative, BUT, had contact to a known case, STILL NEED TO QUARANTINE for 14 days from last exposure!
 - Testing is still valuable to expand contact tracing to try to contain the virus' spread!

COVID-19 Testing **Next Steps**

You are being tested for a virus that causes COVID-19. If you have symptoms of the disease, or if you have been in contact with someone who is infected. you will be asked to stay apart from others. This is also called isolation or guarantine. COVID-19 spreads easily. Staying apart helps stop the disease from spreading.

Symptoms Include:

Fever, cough, difficulty breathing

Other symptoms may include: Chills muscle aches, headache, sore throat, abdominal pain, vomiting, diarrhea, runny nose, fatigue, wheezing, or new loss of taste or smell

You Should Be Isolated If:

· You have symptoms and think you may have been infected with the virus.

You Should Be Quarantined If:

· You have been in close contact with someone known to have COVID-19, even if you don't have symptoms. Close contact means sharing the same household, direct physical contact, or being within six feet for more than 10 minutes.

See back for more information.



If You are an **Essential Worker:**

You can ONLY return to work while you wait for your test results if:

- · You have your employer's permission to do so.
- You DO NOT have symptoms.
- · And you have NOT had contact with a person known to have COVID-19.

In addition, you must continue to:

- Practice social distancing (stay more than 6 feet from others).
- Use appropriate personal protective equipment (PPE).
- · Wear a mask when less than 6 feet away from others in public.
- Take your temperature and monitor your symptoms daily.

5/20

Over ----





Stay home, except to visit a doctor.

If you must see a doctor, call ahead and avoid using public transport such as subways, buses, taxis.



Separate yourself in a room that is not shared with others. Stay at least 6 feet away from others at all times.

Use a separate bathroom, if possible, and disinfect after each use.



Cover your coughs and sneezes. Throw away used tissues. Bag your trash and

Don't touch pets.

Arrange for others to care for your children, if possible.

Wear a face mask if you must be around others.

60% alcohol.

13112

Wash your hands often with soap and water for 20 seconds each time, or if unavailable, use hand sanitizer with at least

Stay apart now. Be together later.

New York State Department of Health

Test Results

You will be contacted with your results

If you test positive on a diagnostic test for the virus, you must continue isolation. You will get a call from a public health representative to identify any contacts you have had.

If you test negative, but you have been in close contact with a person known to have been infected, you must still continue guarantine until 14 days have passed from your last contact with a person known to have COVID-19. Even though you may feel well now, you are at risk of getting the disease and you may get sick. It can take up to 14 days to get the disease.

Your local health department can help you determine when it is safe to stop isolation or guarantine. Find them at www.nysacho.org/directory

Learn more at coronavirus.health.ny.gov

Support and Job Assistance

Any New Yorker under a mandatory or precautionary order to stay home may be eligible for job-protected sick leave and compensation. Learn more at https://coronavirus.health.nv.gov/protecting -public-health-all-new-vorkers#employee

If you need help caring for yourself or your children while in isolation or guarantine, call your local health department. Find them at www.nysacho.org/directory

To order materials from NYSDOH:

bmcc@health.ny.gov



Department of Health

Available in Spanish

NYSDOH COVID-19 Testing Next Steps

Arrange for food, medicine, and other supplies to be left

leave outside your door.

Contact Tracing Tool for People Being Tested for COVID-19

If you test positive for COVID-19, you will get a call from a public health representative to identify any contacts you have had. This form can help you identify your contacts so you will be ready for the call.

SU	JBTRACT 2 DAYS	5:///	= YOUR CONTACT TRACING	DATE
EP Who has b	een in your hou	se with you since v	our contact tracing date?	
Include pe	ople who live in	your home, and peo	ple who may have visited like friend	ds, a babysitter or anyone else
providing i	n-home services	i.		
Na	me of Person		Date Last in	Home Their Phone Numbe
1				
2				
3				
4				
5				
			going to work, running errands, appo blic transportation to get there. Use	
activities o	utside the house	, and if you used put	bic transportation to get there. Use	another piece of paper if neede
-				
ay One:	·		People you were with Address	Phone Number
Activity	Location	Name	Address	Phone Number
ay Two:	//		People you were with	
ay Two:	// Location	Name	People you were with Address	1 Phone Number
	Location	Name		
	Location	Name		
	Location	Name		
Activity	// Location	Name	Address	Phone Number
Activity	// Location	Name		Phone Number
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Activity ay Three:			Address People you were with	Phone Number
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Activity			Address People you were with Address	Phone Number Phone Number
Activity ay Three: Activity ay Four:	// Location	Name	Address People you were with Address People you were with	Phone Number Phone Number

To order materials from NYSDOH:

bmcc@health.ny.gov





For Their Contacts

To order materials from NYSDOH:

bmcc@health.ny.gov

You're a part of the solution... now answer the phone!



As we battle coronavirus together, tracing exposures to COVID is important to stop the spread.

The NYS Contact Tracing Program works with confirmed positive COVID-19 people to determine who they have been in contact with. Trained specialists reach out to those contacts about possible exposure. If you have been identified as a contact you will get a call from "NYS Contact Tracing."

Because the disease can be transmitted without symptoms, notifying people about a possible exposure is critical to stop the spread.

So, if you get a call from "NYS Contact Tracing" please answer. It is confidential and private.

Please Answer the Phone so we can keep NY moving forward and stop the spread of COVID-19.

health.ny.gov/coronavirus

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NYS Contact Tracing Answer the Phone

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Community Mitigation Strategies



NYS Cluster Action Initiative

- The positivity rate among those tested in the "micro-cluster" focus areas was 4.7% percent yesterday
 - Range of percent positivity in red/orange/yellow zones from 11/17:
 3.5% (Rockland yellow zone) to 8.3% (Erie yellow zone)
- The statewide positivity rate excluding these areas was 3.1%
- The statewide positivity rate including the focus areas was 3.4%



NYS Cluster Action Initiative

COVID-19 Micro-Cluster Strategy

New rules and restrictions directly target areas with the highest transmission of COVID-19 cases & surrounding communities.

Type of Activity	Red	Orange	Yellow	
Non-Essential Gatherings	Prohibited	10 people maximum, indoors and outdoors	25 people maximum, indoors and outdoors	
House of Worship	Lesser of: 25% of maximum capacity 10 people	Lesser of: 33% of maximum capacity 25 people	50% of maximum capacity	COVID-19 HOT SPOTS Find COVID-19 Hot Spot Zones by Address
Businesses	Non-essential businesses are closed	Certain high-risk non-essential businesses (eg., gyms, fitness centers and classes, barber shops, hair salons, personal care services) are closed.	Open	CHECK YOUR ADDRESS
Dining	Takeout or delivery only	Outdoor dining, takeout or delivery only, 4 person maximum per table	Indoor and outdoor dining permitted, 4 person maximum per table	
Schools	Closed* Remote-only	Closed* Remote-only	Open Mandatory weekly testing of students and school personnel, in accordance with DOH guidance to be issued by October 9, 2020.	

Schools may reopen if they follow new guidelines that require mass testing in schools before they reopen followed by vigilant symptom and exposure screening conducted daily. See new guidelines.

NYS Micro-Cluster Strategy



Community Mitigation Measures

- Gathering at private residences limited to 10 people
- Urging caution over the holidays
- In order to mitigate the threat of college students returning home for the holidays importing COVID-19 into their communities, a consortium of NE Governors asked Northeastern colleges to:
 - Provide testing for students before they leave for Thanksgiving break
 - Any student who tests positive will be encouraged to isolate on campus before they can travel or detail safe travel arrangements home with the local department of health
 - Use remote instruction to end the Fall semester, reducing the need for students to travel back-and-forth between campus and home multiple times
 - If colleges/universities do reopen for in-person instruction, all returning students should receive COVID-19 tests and comply with relevant isolation and quarantine protocols
- NYC closed schools today for in-person instruction and transitioned to full remote learning after reaching 3% positivity of tests in the NYC

COVID-19 Vaccine



COVID-19 Vaccine Updates – <u>Pfizer/BioNTech</u>

- Last week preliminary analyses revealed 90% vaccine efficacy based interim analyses of the first 94 cases of COVID-19 among all study participants
- Yesterday, final Phase 3 study results were publicly announced based on 170 cases revealing a vaccine efficacy of 95% beginning 28 days after the first dose
 - 162 confirmed cases of COVID-19 in the placebo group and 8 in the vaccine group
 - Vaccine efficacy rate of 95% (p<0.0001) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose
 - Among those over 65 years, Pfizer reported 94% vaccine efficacy
- This is the first set of complete results from a phase 3 vaccine trial
- Over 43,000 participants enrolled
- No serious side effects were identified and the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2%
 - Older adults tended to report fewer and milder solicited adverse events following vaccination.
- Reported that the vaccine prevented mild and severe forms of the disease
- Efficacy was consistent across age, gender, race and ethnicity demographics

Interim Analysis Press Release

Pfizer/BioNTech PHase 3 Study Press Release



COVID-19 Vaccine Updates - Pfizer/BioNTech

- Pfizer reports publicly that they are applying to the FDA for EUA 'within days'
- Pfizer reports up to 50 million doses will be available by the end of the year
 - However, only about ½ of the supply would go to the U.S. this year (25M doses for 12.5M people)
- Must be stored at -94 degrees F ('ultra-cold')
- Ship in special boxes of 1,000-5,000 doses with dry ice and GPS enabled sensors
- US government did not support the vaccine development
- Americans will receive the vaccine free of charge under a 1.9 billion dollar deal the federal government reached with Pfizer for 100M doses
- Received FDA approval in October to start including children 12 years and over in clinical trials



COVID-19 Vaccine Updates – <u>Moderna/NIAID</u>

- Early this week (November 16th), Moderna/NIAID provided public updates on early analyses which revealed a 94.5% vaccine efficacy based on 95 study participants becoming ill with COVID-19
- Among these 95 participants who developed COVID-19
 - 90 had received placebo and 5 had received vaccine
- Also, the vaccine appeared to protect from severe disease
 - Of the 11 volunteers who developed severed disease, none were vaccinated
- Reporting they will submit an EUA in the next few weeks
- U.S. government provided \$1 billion in funding support for vaccine development
- U.S. government provided an additional \$1.5 billion, in August, in exchange for 100M doses

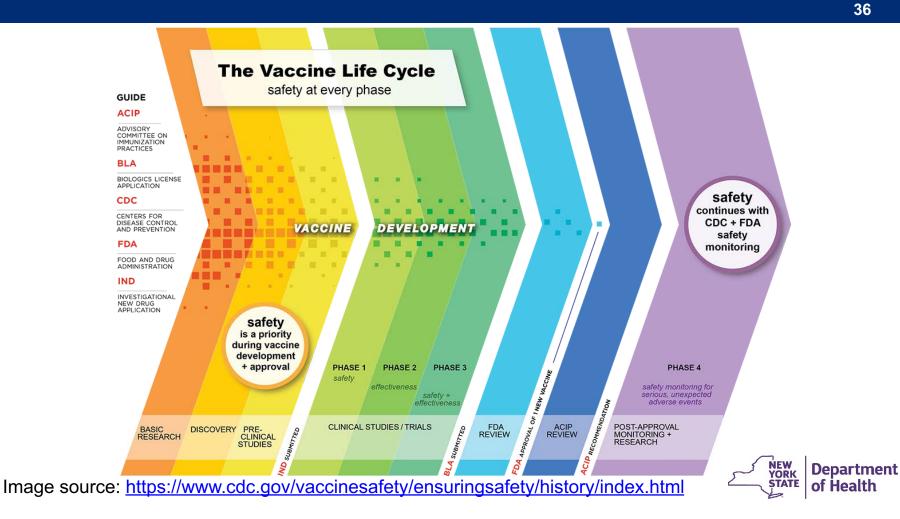


Press Release: Moderna's COVID-19 vaccine candidate

COVID-19 Vaccine Updates

- Given rapid COVID-19 vaccine development and progress
- Health care providers should remain aware of updates in COVID-19 vaccine development to begin the vaccine education process among health care staff and with patients and communities
- It is essential to begin COVID-19 vaccine education with transparency, sharing the processes, and discussing what we know, and what we do not know
- In preparation for COVID-19 vaccine:
 - Health care providers located in NYS, outside of NYC, should register with the <u>New York State Immunization Information System (NYSIIS)</u>
 - Health care providers located in NYC should register with the <u>Citywide</u> <u>Immunization Registry (CIR)</u>





How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

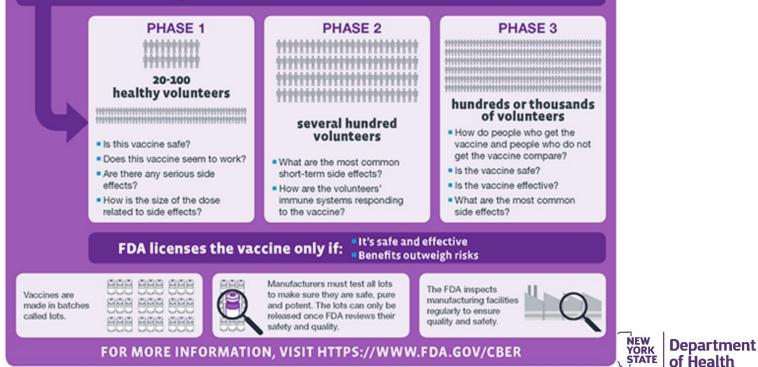


Image source: https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html

How are COVID-19 Vaccines Developed So Quickly?

- Not starting from scratch: Vaccine candidates were previously developed and studied against SARS-CoV-1 (which caused the 2003 SARS outbreak), MERS-CoV (which caused the 2013 Middle Eastern Respiratory Syndrome outbreak), and other viruses
- **Data transparency**: The SARS-CoV-2 genetic code was rapidly shared with scientists across the globe in early 2020
- High rates of COVID-19 infections: Researchers study vaccine effectiveness by comparing the number of infections in people who got the vaccine versus people who did not. Vaccines against rare diseases need to be studied for many years before there are enough infections to measure effectiveness. Right now, COVID-19 is not rare, so researchers will probably have enough data sooner.

How are COVID-19 Vaccines Developed So Quickly? 2/2

- Up-front investment in manufacturing: Operation Warp Speed invested in factories and supplies to make and distribute vaccines before the clinical trials were even done.
 - This step usually isn't done until after a vaccine has been approved.
- **Combined phases of clinical trials**: Some vaccines have done combined Phase 1/2 studies; others combined Phases 2 and 3.
 - Combined phases are done simultaneously but include all of the steps of solo phases.



FDA COVID-19 Vaccine Approval/Authorization Criteria

- The U.S. Food and Drug Administration (FDA) issued guidance for industry on development and licensure of vaccines to prevent COVID-19 in June 2020 and updated in October 2020
- Any authorized or approved COVID-19 vaccine would need to show that it is at least 50% effective
- Sample size for Phase 3 clinical trials: approximately 30,000 volunteers, including racial and ethnic minorities, older adults and other high-risk groups
- Must follow up vaccinated people for at least 2 months following the final dose to monitor adverse events and occurrence of COVID-19
- An Emergency Use Authorization (EUA) may be appropriate once studies have demonstrated the safety and effectiveness of a vaccine but before the manufacturer has submitted and/or FDA has completed its formal review of the biologics license application

Sources: https://www.fda.gov/media/139638/download, https://www.fda.gov/media/142749/download

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- Independent advisory group that reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products and provides input upon request of the FDA
- VRBPAC recommendations are not binding, but are usually followed by the FDA
- Met publicly on October 22, 2020 to discuss COVID-19 vaccines
- Will re-convene a public meeting before any FDA action regarding COVID-19 vaccines, evaluate and discuss safety and effectiveness data, and issue recommendations to the FDA



Emergency Use Authorization (EUA)

- An EUA for a COVID-19 vaccine may be requested to allow for the vaccine's rapid and widespread deployment following a planned interim analysis in an ongoing Phase 3 clinical trial
- Would need to demonstrate at least 50% efficacy and safety data from throughout all stages of clinical development
- If an EUA were issued before a Phase 3 clinical trial were completed, then researchers would be required to complete the trial
- VRBPAC members broadly agreed that data to support an EUA should not be less than data needed for FDA approval
- The manufacturing process must ensure product quality and consistency.
- Safety and effectiveness data from at least one well designed clinical Phase 3 trial is needed to determine that the benefits of the vaccine outweigh the risks

Advisory Committee on Immunization Practices (ACIP)

- Independent advisory group to the CDC
- Medical and public health experts who review and summarize data submitted to the FDA as well as post-licensure data and other available data to develop recommendations for the use of vaccines in the U.S. civilian population
- Annually establishes and updates vaccination schedules for children, adolescents and adults
- ACIP recommendations are not binding, however the CDC usually follows them
- The ACIP may modify or rescind previous recommendations if/when new data becomes available

Factors that Go into an ACIP Recommendation

- Vaccine safety and efficacy in various age groups and highrisk populations
- Severity of the disease
- Frequency of the disease
- How practical the recommendations are to put into practice
 - o Cost and insurance coverage
 - Health disparities, justice and accessibility
 - Acceptability to recommended populations and their healthcare providers



Vaccine Licensure vs. Vaccine Recommendation

- The FDA licenses a vaccine to be used under certain circumstances
- The ACIP recommends use in specific age groups
- ACIP recommendations are typically more detailed then FDA licensure
- The ACIP does not always recommend that a vaccine be given to every population covered by an FDA licensure
- On occasion, the ACIP might recommend a vaccine be used in groups not addressed by the FDA licensure



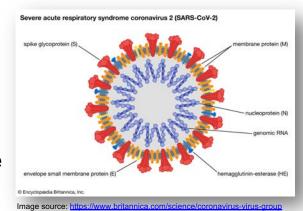
ACIP and COVID-19 Vaccines

- The ACIP has been holding monthly public special meetings since June 2020 to discuss the COVID-19 pandemic, COVID-19 vaccine development, priority groups for COVID-19 vaccine and vaccine distribution and allocation plans
- The ACIP has committed to convening a public meeting to issue recommendations for any FDA-licensed or – authorized COVID-19 vaccine within 24 hours of licensure or EUA authorization



COVID-19 Messenger RNA (mRNA)-Based Vaccines

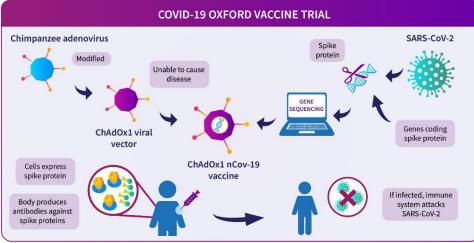
- Deliver genetic "code" to teach human cells to build the SARS-CoV-2 spike protein
- Vaccinated individuals develop immune responses to the spike protein (supported by Phase 1 and 2 studies to date)
- Hopefully, when vaccinated individuals are exposed to SARS-CoV-2 they will have an immune response and be protected from infection (being studied during Phase 3)
- mRNA is broken down and naturally cleared by the human body
- U.S. COVID-19 mRNA vaccine candidates
 - o Moderna in Phase 3
 - BioNTech/Pfizer in Phase 3





COVID-19 Adenovirus-Vectored Vaccines

- Use a genetically modified and weakened adenovirus to carry the genes encoding the SARS-CoV-2 spike protein
- Similar to the mRNA vaccines, vaccinated individuals develop immune responses to the spike protein
- U.S. COVID-19 vaccine candidates
 - University of Oxford/AstraZeneca in Phase 3
 - o Johnson & Johnson in Phase 3





COVID-19 Protein Subunit Vaccines

- Contain the SARS-CoV-2 spike protein and a plant-based adjuvant to stimulate the immune response
- Similar technology to hepatitis B and HPV vaccines
- U.S. COVID-19 protein subunit vaccines
 - Novavax expected to begin Phase 3 in November 2020
 - o GSK/Sanofi in Phase 2



COVID-19 Vaccine Assumptions

- Vaccine will initially only be available through CDC or NYSDOH
- Distribution will be limited by vaccine storage and handling requirements
- Two doses will be required
 - Except: Johnson & Johnson vaccine might only need 1 dose
 - Interval is either 21 days (Pfizer) or 28 days (Moderna)
- Intramuscular administration
- Products will not be interchangeable
- Shipped with vaccination supplies



COVID-19 Vaccine Distribution Phases

- Phase I: Limited availability for priority groups
 - Depending on the speed at which vaccine is produced and distributed, may be several sub-phases, e.g., Phase 1A, Phase 1B, etc.
- Phase II: Widespread availability for the general public



Priority Groups for COVID-19 Vaccine – NOT RANKED

- Healthcare personnel
- Other essential workers
- Residents of long-term care facilities
- Adults age \geq 65 years

- Adults with high-risk medical conditions
 - \circ Cancer
 - o Chronic kidney disease
 - COPD (chronic obstructive pulmonary disease)
 - Immunocompromised state (weakened immune system)
 - Obesity (body mass index [BMI] of 30 or higher)
 - o Serious heart conditions
 - o Sickle cell disease
 - Diabetes mellitus



Vaccines

- Pfizer/BioNTech:
 - ultra-cold storage (dry ice)
 - minimum 975 doses
- Moderna/NIAID:
 - frozen storage, 7-30* days refrigerated
 - minimum 100 doses
- 3 other vaccines likely to come available, in the following months



COVID-19 Vaccine

- Before NYSDOH will recommend a COVID-19 vaccine, the DOH and an expert independent advisory group will be reviewing the vaccine studies and other information related to the vaccine(s) from the FDA, CDC, ACIP, and other independent entities
- Clinical Advisory Task Force comprised of leading medical and science experts to review every vaccine authorized by Federal Government for distribution
- Vaccine Distribution and Implementation Task Force charged with preparing for administration of approved COVID-19 vaccine in New York State



Step 1: Register for the Immunization Information System

Step One - Register for the Immunization Information System:

- Healthcare providers are strongly recommended to register in <u>NYSIIS</u> for providers outside of NYC and with <u>CIR for providers located in NYC</u>
- This is because all COVID-19 Vaccination Program providers (each location submitting a profile) will need a NYSIIS account for providers outside of NYC or CIR account for providers located in NYC
- Your organization may currently have a NYSIIS or CIR account, but it is important to ensure that the appropriate staff have access

For health care providers located in NYS outside of NYC, take the following steps for

new users in <u>NYSIIS - see the Checklist to Go Live with NYSIIS:</u>

- 1. NYSIIS is located on the Health Commerce System. If responsible staff do not yet have an HCS account, they must apply for one
- 2. Take the <u>NYSIIS Administrative User Training</u>

Health care providers located in NYC, register your practice online in CIR



Step 2: Enroll in the COVID-19 Vaccination Program

- In addition to registering with NYSIIS or CIR (Step 1), providers will then need to enroll in the COVID-19 Vaccine Program (Step 2).
- NYSDOH and NYC DOHMH are implementing a phased approach to provider enrollment and will notify healthcare facilities, providers and professional groups as each new group is opened for enrollment.
- Providers in NYS, outside of NYC, will enroll in the NYS COVID-19 Vaccination Program through the Health Commerce System.
- Providers in NYC will enroll in the NYC COVID-19 Vaccination Program through the CIR.
- Networks with facilities or providers in both NYS and NYC should enroll their facilities or providers outside of NYC in the NYS Covid-19 Vaccination Program through the Health Commerce System and enroll their facilities or providers in NYC in the NYC Covid-19 Vaccination Program through the CIR.



COVID-19 Vaccine – Step 3: Ordering, Receiving, and Administering Vaccine

- When COVID-19 vaccine is available, providers in NYS, outside of NYC will order COVID-19 vaccine through NYSIIS and providers in NYC will order COVID-19 vaccine through the CIR. Orders will be approved by NYS DOH and shipped directly from the vaccine manufacturer or CDC distributor.
- When vaccine is available, functions staff perform in NYSIIS or CIR will also include monitoring vaccine inventory; entering doses administered and/or performing data exchange (uploading and downloading data) between the provider's electronic health system and NYSIIS/CIR; entering vaccine returns and wastage; and generating reports for internal review (e.g. doses administered).



COVID-19 Webinars



Steps to Physician Wellness & Resiliency



Supported by MLMIC

Sponsored by MSSNY's Committees on Physician Wellness and Resiliency & Quality Improvement and Patient Safety

Live Webinar

Thursday December 10, 2020 @ 7:30-8:30am

Faculty: Frank Dowling, MD Educational Objectives:

- Review the warning signs that stress, depression, anxiety or substance use may impact work or personal life
- Identify strategies to increase personal empowerment towards making positive change, including self-assessment tools
- Recognize self-monitoring strategies for stress related problems and know when to seek professional assistance

Click here to register

For more information, contact: Cayla Lauder at <u>clauder@mssny.org</u> or call (518) 465-8085

The Medical Society of the State of New York is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Medical Society of the State of New York designates this live activity for a maximum of 1.0 AMA PRA Category 1 creditsTM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.







Click here for MSSNY webinar registration





Medical Matters 2021 🛞

Sponsored by the Medical Society of the State of New York

COVID-19 From a Physician-Patient Perspective

Live Webinar

Wednesday December 16, 2020 @ 7:30am

Faculty: Lorraine Giordano, MD & Parag Mehta, MD Educational Objectives:

- Describe COVID-19 from the perspective of both patient and physician
- Examine insights gained from experiencing SARS-CoV-2 firsthand
- Identify chronic and acute symptoms that are prominent as a result of experiencing COVID-19 as a patient

Click here to register

For more information, contact:

Vielissa Hoffman at mhoffman@mssny.org or call (518) 465-8085

Funding provided by the New York State Department of Health

The Medical Society of the State of New York is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Medical Society of the State of New York designates this live activity for a maximum of 1.0 AMA PRA Category 1 creditsTM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Click here for MSSNY registration





Click here to register

For more information, contact:

Melissa Hoffman at mhoffman@mssny.org or call (518) 465-8085

Funding provided by the New York State Department of Health

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The Medical Society of the State of New York designates this live activity for a maximum of 1.0 AMA PRA Category 1 credits". Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ARCHIVED:

Dr. Erick Eiting an Emergency Department physician at Mt. Sinai Downtown will share his experience from the first days of the COVID-19 pandemic.

Registration Link:

https://mssny.zoom.us/webinar/register/WN_Yf0UnVLvTmyed7PiJsvTpA

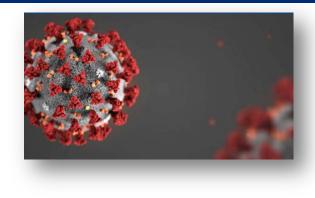


Marcus Friedrich, MD, MHCM, MBA, FACP Chief Medical Officer, Office of Quality and Patient Safety NYSDOH



COVID-19 Healthcare Capacity and Response

• Updated Travel Advisory



- PPE
- Bamlanivimab
- School testing in yellow zone updates
- NYS DOH Vaccination Program Updates
 New York State's COVID-19 Vaccination Program



COVID-19 Resources



COVID Alert NY

Add Your Phone. Stop the Spread.

Download the app to get COVID-19 exposure alerts and help protect your community while maintaining your privacy.

- COVID Alert NY is a voluntary, anonymous, exposurenotification smartphone app.
- You will get an alert if you were in close contact with someone who tests positive for COVID-19.
- Knowing about a potential exposure allows you to selfquarantine immediately, get tested and reduce the potential exposure risk to your family, friends, neighbors, co-workers and others.
- The more people who download COVID Alert NY, the more effective it will be.
- Help protect your community while maintaining your privacy.
- The free mobile apps–available to anyone 18 or older who lives, works, or attends college in New York or New Jersey–are available for download from the Google Play Store or Apple App Store. COVID Alert NY is available in English, Spanish, Chinese, Bengali, Korean, Russian and Haitian Creole.
- Download the free app to your smartphone to receive an alert if you have been in close contact with someone who has tested positive for COVID-19.





Are you struggling with everyday life stressors? MSSNY's P2P Supporters are here to help

Any physician, resident or medical student who wishes to relate to a peer supporter may contact the Medical Society of the State of New York in the following ways:

- Email: <u>P2P@mssny.org</u>
- Phone 1-844-P2P-PEER (1-844-727-7337)

Support, Empathy & Perspective









Healthcare Provider/Physician Wellness

- The state is partnering with the Kate Spade New York Foundation and Crisis Text Line to provide a 24/7 emotional support service for frontline healthcare workers
- Text NYFRONTLINE to 741-741 to access these emotional support services
- New York State-regulated health insurers will be required to waive costsharing, including deductibles, copayments and coinsurance, for innetwork mental health services for frontline essential workers during COVID-19



Mental Health Resources

NYS Mental Health Helpline 1-844-863-9314

 The helpline is staffed by specially trained volunteers, including mental health professionals, who have received training in crisis counseling related to mental health consequences of infectious disease outbreaks, typical stress reactions, anxiety management, coping skills, and telephonic counseling



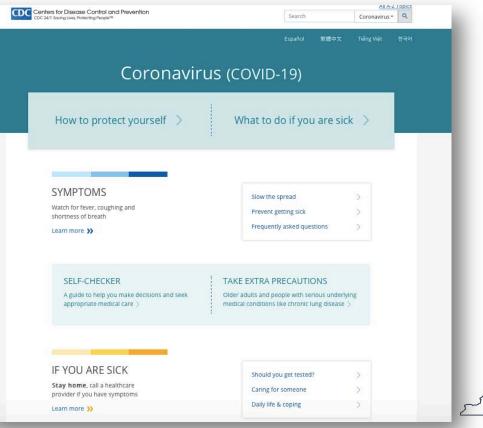
Healthcare Provider Well-being Resources

<u>MSSNY</u>	AAFP
<u>ACP</u>	AAP
NAM	AHRQ well-being AHRQ burnout
<u>AMA</u>	<u>NIH</u>
IHI	<u>Stanford</u>



November 20, 2020

CDC COVID Website





70

www.cdc.gov/coronavirus/2019-ncov/index.html

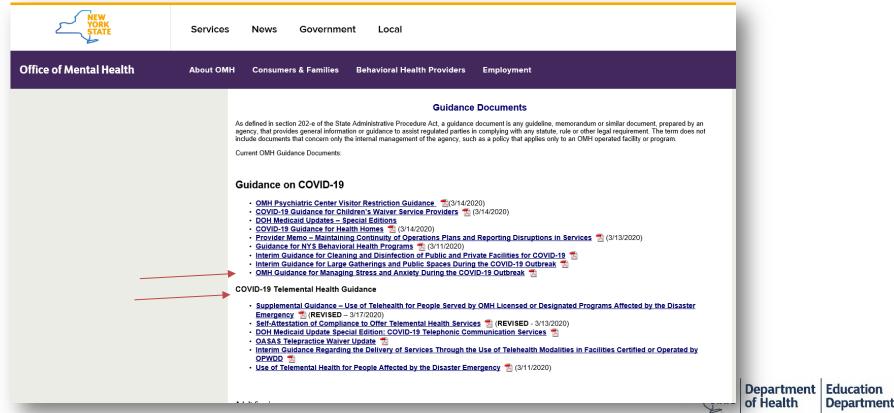
NYC DOHMH COVD-19 Webpage

Promoting and Protecti	ing the City's Hea	lth	Healt	C		한국어 ▶ Translate ▼ Text-Size
About	Our Health	Services	Providers	Data	Business	Search Q
Reporting and Se	ervices	Health To	opics Resourc		esources	Emergency Prep
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November 20, 2020

Mental Health Resources



- For everyone
- For individuals receiving mental health services
- For parents
- For caregivers of older adults
- For mental health providers

March 16, 2020



Feeling Stressed About Coronavirus (COVID-19)?

Managing Anxiety in an Anxiety-Provoking Situation

The outbreak of COVID-19 around the world has led to the spread of fear and panic for individuals and communities. In addition to following physical precautions guidelines, individuals should be taking care of their psychological well-being.

This guide includes tips for the following populations:

- For Everyone
- For Individuals Receiving Mental Health Services
- For Parents, Including Parents of Children with Pre-Existing Anxiety Disorders
- For Caregivers of Older Adults
- For Mental Health Providers

For Everyone:

Reduce anxiety by reducing risk. Ways to reduce risk include practicing good hygiene (e.g.



NYS Medicaid Telehealth Updates and Guidance

NYSDOH COVID-19 Guidance for Medicaid Providers website

- **Webinar:** New York State Medicaid Guidance Regarding Telehealth, Including Telehonic, Services During the COVID-19 Emergency **5.5.2020**
 - <u>Slides</u> (PDF)
 - Recording Coming Soon
- Frequently Asked Questions (FAQs) on Medicaid Telehealth Guidance during the Coronavirus Disease 2019 (COVID-19) State of Emergency - (Web) -(PDF) - Updated 5.1.2020



Telehealth Guidance

• American College of Physicians Telehealth Resource:

www.acponline.org/practice-resources/business-resources/health-information-technology/telehealth

• CDC Outpatient and Ambulatory Care Setting Guidance:

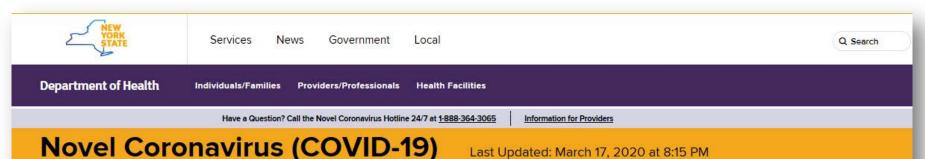
www.cdc.gov/coronavirus/2019-ncov/hcp/ambulatory-care-settings.html

• Medicaid:

www.health.ny.gov/health care/medicaid/program/update/2020/



NYSDOH COVID-19 Website



Protect Yourself and Your Family

Stay home and Keep a Safe Distance from others in public. It's the only way to help slow the spread of Coronavirus.

► WATCH VIDEO

SYMPTOMS

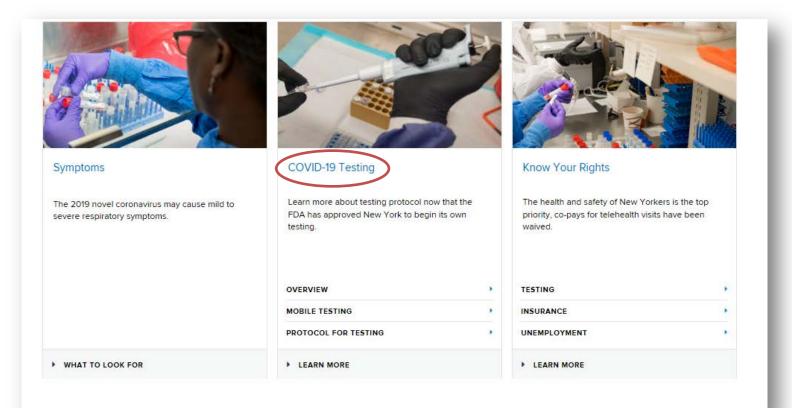
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Department

PROTECTING THE PUBLIC HEALTH OF ALL NEW YORKERS

Mandatory and Precautionary Quarantine	Mass Gatherings	Healthcare Providers	Nursing Homes
Schools	Childcare Providers	Employees & Employers	Insurance
Voting	International Travel	Cyber Security	Price Gouging

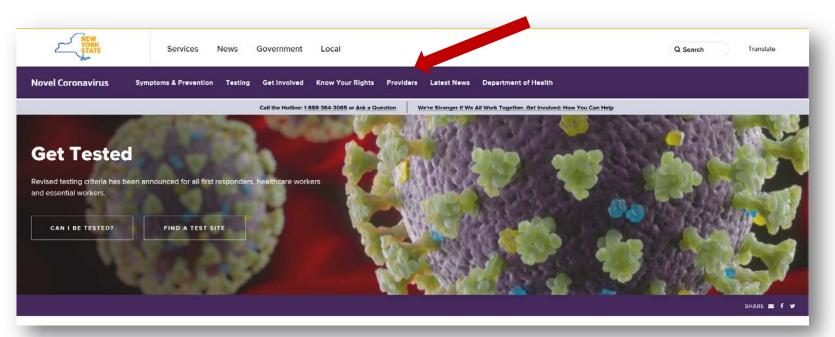






Department of Health

NYSDOH COVID-19 Website





COVID-19 Weekly Healthcare Provider Update Compilation: As of October 1, 2020, 11:00 AM

The information in this compilation is current only as of the above date and time.

Purpose: The purpose of this weekly publication is to provide healthcare providers in New York State with a consolidated update of guidance released by the New York State Department of Health (NYSDOH) related to the COVID-19 pandemic response. This will show only current guidance for any given topic and will be updated to reflect new guidance.

As a reminder, all advisories and informational messages (including webinar invitations) are distributed through the Integrated Health Alerting Network System (IHANS), an application housed on the <u>Health Commerce</u> <u>System (HCS)</u>. If you are not receiving IHANS notifications, please work with your site's HCS coordinator. Additional CCVID-19 resources may be found on the NYSDOH webpage under <u>Information for Healthcare</u> <u>Providers</u>.

Recordings of COVID-19 Weekly Healthcare Provider Updates are also available on the NYSDOH webpage.

Guidance/Health Advisory Topic	Link(s)	Date
Advisory Topic Testing/ Specimen Collection	Additional Capacity Guidance (Collection, triage, treatment)	3/19/2
	Specimen Collection and Handling to Allow NP and Saliva Specimen	4/01/2
	Wadsworth Specimen Collection, Handling and Transport	4/01/2
	Updated Infectious Disease Requisition Form	4/09/2
	Updated Infectious Disease Requisition Guidance	4/09/2
	Private Practice Collection Guidance	4/19/2
	The NYSDOH Wadsworth Center's Assay for SARS-CoV-2 IgG FAQ	4/20/2
	Serology Testing	4/30/2
	Specimen Collection Training for Unlicensed Individuals	5/15/2
	Authorization of Licensed Pharmacists to Order COVID-19 Tests	5/15/2
	SARS-CoV-2 Diagnostic Testing FAQ	5/15/2
	COVID-19 Testing Next Steps	5/12/2
	Revised Interim Guidance: Protocol for COVID-19 Testing Applicable to All Health Care Providers and Local Health Departments	7/2/20
nfection Control	Requests for PPE should go through your county OEM	3/23/2
and PPE	Requests for FFE should go through your county OEM	312312
	PPE Shortage Guidance	4/02/2
	Optimizing PPE (CDC)	4/22/2
	Infection Control Guidance (CDC)	4/24/2
Quarantine/ Isolation	Guidance for Local Health Departments highlighting definitions and situations for quarantine and isolation.	4/07/2
	Precautionary Quarantine, Mandatory Quarantine, and Isolation	4/16/2
	Discontinuation of Isolation for Patients with COVID-19 who are Hospitalized, in Nursing Homes, or in Other Congregate Settings	4/19/2

HCP Compilation

For questions, contact <u>covidproviderinfo@health.ny.gov</u>

NYSDOH COVID-19 Weekly HCP Update Compilation



Mirror Clings

13068

Protect Yourself from Coronavirus (COVID-19)

WASH

YOUR

HANDS with soap and water for 20 seconds.

ny.gov/coronavirus

VORK YORK STATE of Health 3/20



To order mirror clings for public use email the NYSDOH:

bmcc@health.ny.gov





Mirror Clings

To order mirror clings for public use email the NYSDOH:

bmcc@health.ny.gov



Face Masks and Coverings for COVID-19



- You must wear a face mask or face covering in public when social distancing (staying at least 6 feet apart) is not possible, unless a face covering is not medically tolerated. This includes on public transport, in stores and on crowded sidewalks.
- Children over 2 years of age should wear a face mask in public, too. Children under 2 years of age should NOT wear face coverings for safety reasons.
- Cloth face coverings should be made from fabric you can't see through when held up to the light. They must be cleaned before reusing.
- · Disposable paper face masks should be used for one outing outside the home. They cannot be properly cleaned.

 The best way to prevent COVID-19 is to continue social distancing (staying at least 6 feet away from others), even when wearing a face covering.

Putting On Face Covering

 DO clean your hands with soap and water or if that's not available, alcohol-based hand sanitizer, before putting on your face covering.

 Make sure the face covering covers both your nose and mouth.

 DON'T wear your mask hanging under your nose or mouth or around your neck. You won't get the protection you need.

 DON'T wear the face covering on top of your head, or take it off and on repeatedly. Once it is in place, leave the covering in place until you are no longer in public.

13105

Taking Off Face Covering

 DO clean your hands with soap and water or if that's not available, alcohol-based hand sanitizer, before taking off your face covering.

Remove your mask only touching the straps.

 Discard the face covering if it is disposable. If you are reusing (cloth), place it in a paper bag or plastic bag for later.

· Wash your hands again.

 When cleaning a cloth face covering, DO put in the washer (preferably on the hot water setting).

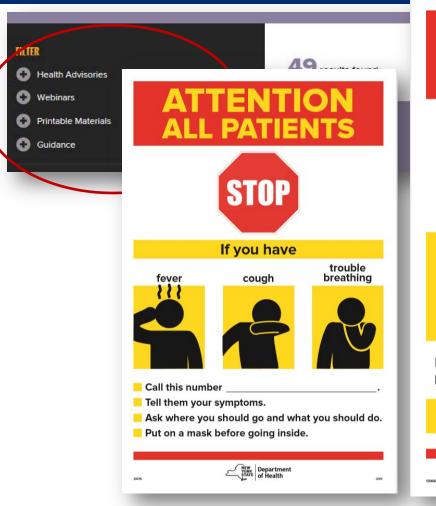
 Dry in dryer at high heat. When it is clean and dry, place in a clean paper or plastic bag for later use. If you live in a household with many people, you might want to label the bags with names so the face coverings are not mixed up.



5/20











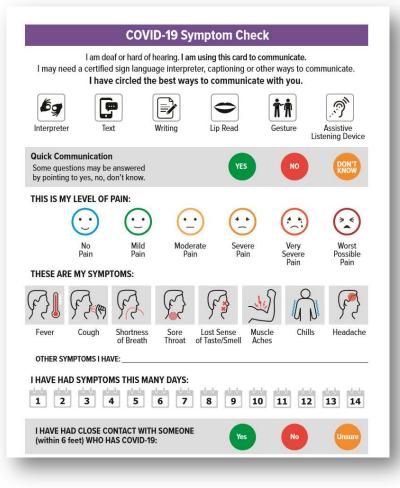
NO VISITORS ARE ALLOWED AT THIS TIME

If you feel there is an urgent need for visitation, please contact ______.

DO NOT VISIT

NEW YORK STATE of Health







Questions or Concerns

- Call the local health department <u>www.health.ny.gov/contact/contact_information/</u>
- In New York City: Notify the NYC DOHMH provider access line (PAL)
 - 1-866-NYC-DOH1 or 1-866-692-3641 (works 24 hours/day x 7 days/week)
- Providers who are unable to reach the LHD can contact the NYSDOH Bureau of Communicable Disease Control at 518-473-4439 during business hours or the NYSDOH Public Health Duty Officer at 1-866-881-2809 evenings, weekends, and holidays



QUESTIONS?

TO NYS HEALTHCARE PROVIDERS THANK YOU!

