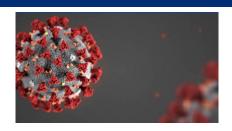


An Update for NYS Healthcare Providers on COVID-19

March 18th, 2021

Agenda

- Global, National, New York State Updates
- COVID-19 Variants Update
- Janssen (Johnson & Johnson) COVID-19 Vaccine
- COVID-19 Vaccine Updates
- COVID-19 FDA Testing Update
- Updated COVID-19 Guidance
- Monoclonal Antibody Update
- Clinician Well-Being





Recordings will be available immediately:

NYSDOH COVID-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.

 All of the information presented is based on our best knowledge as of today.



COVID-19 Global Update

Bryon Backenson
Acting Director
Division of Bureau of Communicable Diseases



Situation Summary: COVID-19 Global, 3/14/2021

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

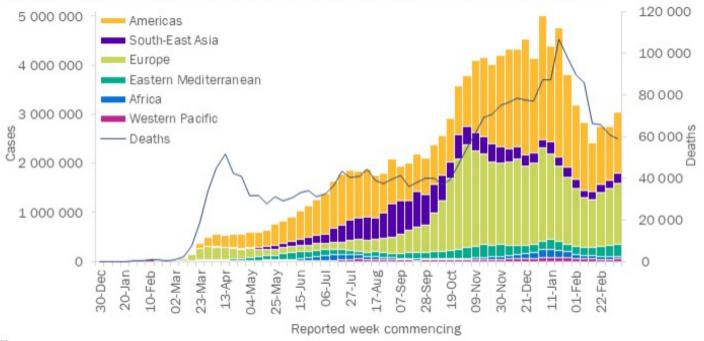
Region	Confirmed Cases	Deaths
Global	119,212,530	2,642,612
Western Pacific	1,711,830	30,357
Europe	41,043,949	903,843
South-East Asia	13,884,294	212,355
Eastern Mediterranean	6,860,070	150,173
Africa	2,948,236	74,685
Americas	52,763,406	1,268,186



Situation Summary: COVID-19 Global, 3/14/2021

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

Figure 1. COVID-19 cases reported weekly by WHO Region, and global deaths, as of 14 March 2021**





CDC COVID Data Tracker (Mar 17, 2021)

TOTAL CASES

29,374,758

+51,954 New Cases

7-DAY CASE RATE PER

100,000

114.8

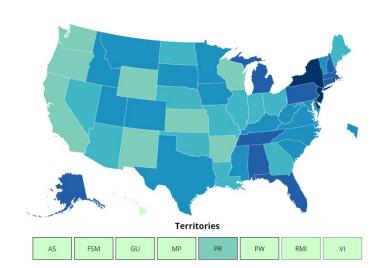
TOTAL DEATHS

534,099

+995 New Deaths

CDC | Updated: Mar 17 2021 1:37PM

US COVID-19 7-Day Case Rate per 100,000, by State/Territory

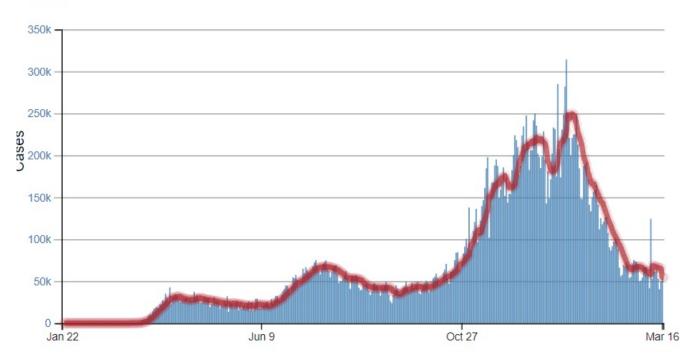




Situation Summary: COVID-19 U.S. (Mar 16, 2021)

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

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

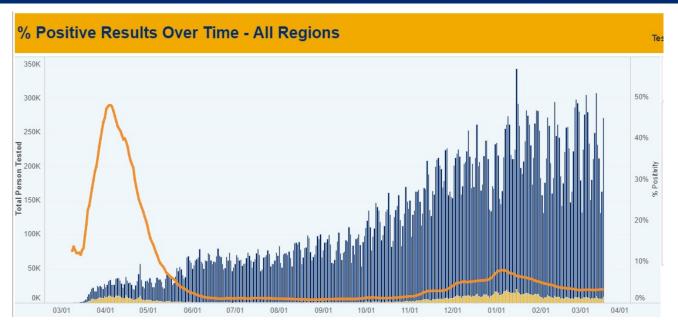




NYSDOH COVID-19 Tracker (Mar 17, 2021)

Found at: NYSDOH COVID-19 website

	Total Persons Tested	Total Tested Positive	% Positive Results	New Positives Today	Persons Tested Today
Grand Total	41,744,092	1,749,697	4.2%	8,976	263,401
ALL NYC	17,859,103	775,990	4.3%	5,389	135,895
NYS Excluding NYC	23,884,989	973,707	4.1%	3,587	127,506





COVID-19 Variants Update



"Variants of interest"

- A variant with specific genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity.
- Possible attributes of a variant of interest:
 - Specific genetic markers that are predicted to affect transmission, diagnostics, therapeutics, or immune escape
 - Evidence that demonstrates it is the cause of an increased proportion of cases or unique outbreak clusters
 - Limited prevalence or expansion in the US or in other countries
- A variant of interest might require one or more appropriate public health actions, including
 enhanced sequence surveillance, enhanced laboratory characterization, or epidemiological
 investigations to assess how easily the virus spreads to others, the severity of disease, the risk of
 reinfection, and whether currently authorized vaccines offer protection.
- Current variants of interest include B.1.526, B.1.525 and P.2



"Variants of Concern"

- A variant for which there is evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures.
- Possible attributes of a variant of concern:
 - In addition to the possible attributes of a variant of interest
 - Evidence of impact on diagnostics, treatments, and vaccines
 - » Widespread interference with diagnostic test targets
 - » Evidence of substantially increased resistance to one or more class of therapies
 - » Evidence of significant decreased neutralization by antibodies generated during previous infection or vaccination
 - » Evidence of reduced vaccine-induced protection from severe disease
 - Evidence of increased transmissibility
 - Evidence of increased disease severity
- Variants of concern might require one or more appropriate public health actions, such as the reporting
 to CDC, local or regional efforts to control spread, increased testing, or research to determine the
 effectiveness of vaccines and treatments against the variant. Based on the characteristics of the
 variant, additional considerations may include the development of new diagnostics or the modification
 of vaccines or treatments.
- Current variants of concern are B.1.1.7, B.1.351, P.1, B.1.429, and B.1.427



		8.1.17	81.351	P1	8.1.427	8.1.429	B.1.526 E484K/5477N	
Gene	Mutation	defining mutations	defining mutations	defining mutations	defining mutations	defining mutations	Defining mutations	Potential impact of the mutation
SUTR	REIC	denning metacons	Genning motorcom	centring in Disserting	RB1C	RB1C	Defining measures	Political impact of the inductor
orflab	T265I				T265I	T2651		
orfiab	T1001I	T1001i			1201	12004		
		11001		20100				
orflab	S1188L			\$1188L				
orflab	K1655N		K1655N					
orflab	A1708D	A1708D						
orflab	K1795Q			K1795Q				
orflab	12230T	12230T			Caracterist .			
orflab	\$3158T				\$3158T			
orflab	SGF3675-3677del	SGF3675-3677del		SGF3675-3677dul	1505000	200 MARCO 1		
orflab	14205V				14205V	14205V		
orfib	P976L				P976L			
orfib	D1183Y				D1183Y			
S	LSF						LSF	
S	\$13				S13I	\$13		
S	LLEF			LIBF				
S	T20N			T20N				
S	P265			P265				
S	HV69-70del	HV69-70del						The HE9-1/70 after the shape of the spike and may help it evade some antibodies.
S	DBCA		DBOA					
S	T95i						T95i	T95 is a buried residue in the NTD, and thus T95I would not seem to affect antigenicity
S	01381			D138Y				
S	Y144del	Y144del						Y144/345 deletions after the shape of the spike and may help it evade some antibodies.
S	WISX	1			W152C	W152C		
S	81906			R1906				
5	D215G		0215G					
S	D253G						0253G	located in the REO, at the interface with the ACE2 receptor. Located in a short, disordened region of the "superatio" loop of the NTD, near the interface with the neutral ising antibody 444. Hypothesized to reduce efficacy of neutral ising antibodies.
S	K417N		K417N	K417N				The mutation appears on the tip of the coronavirus spike, and may help the virus bind more tightly to human cells.
S	L452R				LAS2R	L452R		The L452R mutation is not common in the United States, but it has recently spread in California, especially in the Los Angeles area. The mutation appears in several lineages, and was first observed in Denmark in March. It's possible that the L452R mutation gives the coronavirus an advantage at spreading over other varients, but the results of experiments that will demonstrate that have yet to come.
S	\$477N	-					\$477N	
s	E484K		E484K	E484K			E484K	The mutation occurs near the top of the coronavirus spike, where it afters the shape of the protein. This change may help the spikes evade some types of coronavirus antibodies, as at least one trial has shown.
S	NS01Y	N501Y	NS01Y	NSOIY				The mutation is near the tip of the coronavirus spike, where it seems to change the shape of the protein to be a tighter fit with human cells.

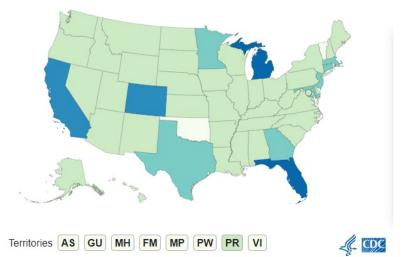
Department of Health

Currently 3 main variants of public health interest:

UK variant: B.1.1.7

- 118 countries, 50 US states (4686 detections), 455 detections in NY
- Increased transmissibility (36-75%), mixed evidence on increased severity, slight reduction in neutralization capacity
- No significant impact on Moderna, Pfizer, AstraZeneca vaccines





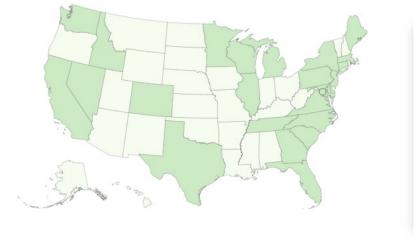


Currently 3 main variants of interest:

South African variant: B.1.351

- 64 countries, 25 US states (142 detections), 5 detected in NY
- Increased transmissibility (approx. 1.5x), no impact on severity reported, decrease in neutralization capacity—potential risk of reinfection
- Reduction of neutralization in neutralizing activity of Moderna, Pfizer vaccines, but practical impact unknown; lower vaccine efficacy in Novavax and J&J vaccines compared to other regions; minimal efficacy of AstraZeneca vaccine





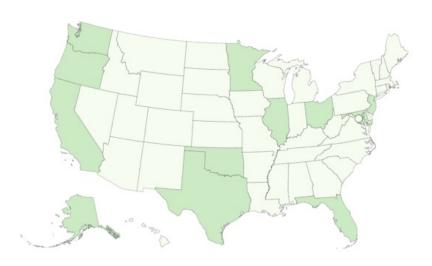


Currently 3 main variants of interest:

Brazil variant: P.1

- 38 countries, 12 US states (27 detections), none detected in NY
- Suggested increase in transmissibility, no evidence on increased severity, reduction in neutralization capacity still being determined
- Impacts on vaccine protection still being evaluated

















SARS-CoV-2 Variants Circulating in the United States



 State/Territory
 B.1.1.7
 B.1.351
 B.1.427/B.1.429
 P.1
 All Other Lineages

 New York
 3.4%
 0.1%
 5.7%
 90.7%

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 Of Health

Janssen (Johnson & Johnson) COVID-19 vaccine

Elizabeth Rausch-Phung, M.D., M.P.H. NYSDOH Bureau of Immunization



What is the Janssen COVID-19 Vaccine?

- Also referred to as the Johnson & Johnson (J&J) COVID-19 vaccine
- Received emergency use authorization from the FDA on February 27, 2021
- A viral-vector vaccine for individuals 18 years of age and older
- Uses a genetically modified and weakened adenovirus to carry the genes encoding the SARS-CoV-2 spike protein to a cell
 - The vaccine does not cause infection with either COVID-19 or the adenovirus used as the vector
- Similar to the mRNA vaccines, vaccinated individuals develop immune responses to the spike protein
- Single dose



Comparison of COVID-19 vaccines

	Pfizer/BioNTech COVID-19 Vaccine (mRNA vaccine)	Moderna COVID-19 Vaccine (mRNA vaccine)	Janssen COVID-19 Vaccine (adenovirus vector vaccine)
Doses per vial	5 or more doses per vial	10 or more doses per vial	5 doses per vial
Reconstitution required	Yes, requires diluent for reconstitution just prior to administration	No	No
Route of administration	Intramuscular (IM)	Intramuscular (IM)	Intramuscular (IM)
Dose (ml)	0.3 ml	0.5 ml	0.5 ml
Doses required	2 dose series	2 dose series	1 dose series
Interval between doses	21 days (3 weeks)	28 days	Not applicable
Vaccine contents	Preservative free, latex free (no latex stopper)	Preservative free, latex free (no latex stopper)	Preservative free, latex free (no latex stopper)
Indication (yrs)	16 years of age and older	18 years and older	18 years and older

Janssen COVID-19 Vaccine - Receipt

Vaccine

- The vaccine will arrive refrigerated between 2°C and 8°C (36°F and 46°F).
- 2. Examine the shipment for signs of damage.
- Open the box and remove the TagAlert Temperature Monitor (placed in the inner box next to vaccine).
- Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
 - Left arrow points to a green check mark: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
 - Right arrow points to a red X: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label "DO NOT USE!". Call the phone number indicated in the instructions or your jurisdiction's immunization program IMMEDIATELY!
- 5. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
 - . Scan the QR code on the outer carton, or
 - · Call 1-800-565-4008, or
 - Visit www.vaxcheck.jnj.

Write the expiration date on the carton.

Ancillary Supply Kit

- An ancillary supply kit will be provided and includes enough supplies to administer 100 doses of vaccine.
- Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPE.
- The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.



- The Janssen COVID-19 vaccine comes in a multiple-dose vial that is stored in a frozen state at the manufacturer but is shipped at 2° to 8°C (36° to 46°F)
 - If the vaccine is frozen upon receipt, thaw at 2° to 8°C (36° to 46°F)
 - o If the vaccine is needed immediately, thaw at room temperature (maximum of 25°C/77°F). At room temperature, a tray of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw
- Do not re-freeze once thawed

Information from CDC Janssen COVID-19 Vaccine Storage and Handling Summary, and EUA Fact Sheet for Healthcare Providers Administering Janssen COVID-19 Vaccine

| New York | Department | D

Janssen COVID-19 Vaccine Storage PRIOR to First Puncture

- Store <u>unpunctured vials</u> at 2° to 8°C (36° to 46°F) and protect from light. **Do not store frozen.** May be stored at these refrigerated temperatures for up to 3 months.
 - Unpunctured vials may be stored at 9° to 25°C (47° to 77°F) for up to 12 hours



Janssen COVID-19 Storage AFTER First Puncture

- After the first dose has been withdrawn, punctured vials can be stored:
 - o At 2° to 8°C (36° to 46°F) for up to 6 hours
 - At 9° to 25°C (47° to 77°F) for up to 2 hours
 - Discard the vial if vaccine is not used within these times
- The two-hour unrefrigerated time limit is not in addition to the 6-hour refrigerated time (i.e., you may not hold the vaccine at room temperature for 2 hours and then hold refrigerated for another 6 hours)
- If you do not reach the 2-hour time limit at room temperature, you may transfer the punctured vial to a refrigerated storage unit between 2°C and 8°C for the remaining time, up to 2 hours.
 - For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (between 2°C and 8°C) for no more than 1 hour before using or discarding. If the 2-hour time limit at room temperature has been met, it must be discarded and cannot be transferred to the refrigerator.

Janssen COVID-19 Vaccine Dose Preparation

- Perform hand hygiene before vaccine preparation
- The Janssen COVID-19 vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension that does not contain a preservative
- Visually inspect the vaccine vial for particulate matter and discoloration prior to administration. <u>If either of these conditions exist, do not</u> administer the vaccine.
- Before withdrawing each dose, carefully mix the contents by swirling gently in an upright position for 10 seconds. Do not shake.



Janssen COVID-19 Vaccine Dose Preparation cont

- Using aseptic technique, cleanse the vial stopper with a single-use, sterile alcohol prep pad
- Choose the correct equipment, including the correct needle size. Using a new, sterile needle and syringe, withdraw 0.5 mL of vaccine into the syringe
 - Each vial contains 5 doses. Do not pool excess vaccine from multiple vials.
- Record the date and time of the first use on the vaccine vial label
- Use a new, sterile needle and syringe, and aseptic technique, to draw up each subsequent dose. Remember to gently swirl vaccine for 10 seconds before withdrawing subsequent doses.



Janssen COVID-19 Vaccine Dose Preparation cont

Once vaccine is in syringe:

- Visually inspect each dose of the Janssen COVID-19 vaccine in the dosing syringe prior to administration. The vaccine is a colorless to slightly yellow suspension. During the visual inspection:
 - verify the final dosing volume of 0.5 mL
 - confirm there are no particulates, and that no discoloration is observed
 - do not administer if vaccine is discolored or contains any particulate matter
- Use the same needle to withdraw and administer the vaccine, unless the needle is damaged or contaminated



Contraindications

Do not administer Janssen COVID-19 vaccine to anyone with a known history of

- A severe allergic reaction (e.g., anaphylaxis) to any of the Janssen COVID-19 vaccine's components (including polysorbate) listed in the prescribing information at https://www.fda.gov/media/146304/download,
- An immediate allergic reaction of any severity (defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress, or anaphylaxis within 4 hours of exposure to a vaccine or mediation) to any of the Janssen COVID-19 vaccine's components (including polysorbate), or
- A known (diagnosed) allergy to any of the Janssen COVID-19 vaccine's components (including polysorbate)



Components of Janssen COVID-19 vaccine

Recombinant, replication-Citric acid monohydrate incompetent Ad26 vector, encoding a stabilized variant of Trisodium citrate dihydrate the SARS-CoV-2 Spike (S) protein Polysorbate-80 Sodium chloride 2-hydroxypropyl-β-cyclodextrin Ethanol

Polysorbate is an ingredient in many vaccines, including the Janssen COVID-19 vaccine. It is also an ingredient in several other vaccines.



Precautions

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots")
 - These individuals should be counseled about the unknown risks of developing a severe allergic reaction and the risks and benefits of COVID-19 vaccination. Consider deferral of vaccination until further information on risk of anaphylaxis is available and/or consultation with an allergist-immunologist. If the benefit of the vaccine outweighs the risk of an adverse reaction, the vaccine may be given.
- Individuals with a severe or immediate allergic reaction to a previous dose of mRNA vaccine or a component of an mRNA vaccine including polyethylene glycol (PEG)
 - Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Inactive ingredients	2[(polyethylene glycol (PEG))-2000] -N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl- rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3- phosphocholine	1,2-distearoyl-sn-glycero-3- phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis (hexane-6,1-diyl)bis (2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo- 6-(undecyloxy) hexyl) amino) octanoate
	Sodium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Potassium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

Components of Pfizer and Moderna COVID-19 vaccines

Polyethylene glycol (PEG) is an ingredient in both Pfizer and Moderna vaccines. It is a primary ingredient in certain laxatives and in bowel preparation prior to colonoscopy, and an inactive ingredient in many medications. It is chemically similar to PEG, and cross-reactive hypersensitivity reactions can occur between both ingredients



Other Medications and Vaccines Containing Polysorbate and PEG

- The National Institutes of Health DailyMed database (https://dailymed.nlm.nih.gov/dailymed/index.cfm) may be used to determine whether medications contain PEG, PEG derivatives or polysorbates
- No other vaccines contain PEG, but several vaccines contain polysorbates. A list of vaccine excipients is available at https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf



Resources

- NYSDOH COVID-19 Vaccine Information for Providers: https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers
- CDC COVID-19 Vaccine: https://www.cdc.gov/vaccines/covid-19
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- NYSDOH COVID-19 Immunization Screening and Consent Form (optional): https://coronavirus.health.ny.gov/system/files/documents/2021/02/vaccine-consent-form-2.12.21-0917.pdf
- Information for Healthcare Professionals about the Screening and Consent Form: https://coronavirus.health.ny.gov/system/files/documents/2021/03/information-for-health-care-providers-covid-19-screening-checklist-3.5.21.pdf



COVID-19 Update

Jessica Kumar MPH, DO
Medical Director
Division of Bureau of Communicable Diseases



Updates on AstraZenca

- Reports from multiple countries in Europe like Italy, Germany, France, Spain, etc have suspended its use due to side effects consisting of blood clots
- AstraZeneca has <u>reported</u> 15 events of deep vein thrombosis and 22 events of pulmonary embolism in vaccinated individuals as of March 8 and he European Medicines Agency (EMA) and World Health Organization (WHO) are reviewing data and meeting 3/18
- Causes a challenge as Europe faces a third surge
- Two doses of the AstraZeneca-Oxford University COVID-19 vaccine were ineffective against mild-to-moderate infections with the B1351 variant first identified in South Africa, according to a phase 1b-2 clinical trial published today in the New England Journal of Medicine and use was paused in South Africa favoring J&J

Moderna Pediatric Trial: KidCOVE Study

- Candidate: mRNA-1273 vs placebo (Link) for ages 6mo to 12 yrs
- Two injections 28 days apart of either the Moderna vaccine or a saline placebo to children
- Kids who get the vaccine will receive one of three possible doses, from 25 micrograms up to 100 micrograms the same dose that received an emergency authorization for use in adults from the Food and Drug Administration
- 6,750 children in the U.S. and Canada for the study, which is taking place at sites in at least eight states, from Arizona and California to South Carolina and Texas
- To join the pediatric trial for ages of 6 months and 11 years from getting sick if
 they come in contact with SARS-COV-2 Link for the closest study site of Health

Pfizer Pediatric Studies

- Pfizer is also testing its vaccine in young people. The company will study its vaccine's effects on kids who are 12 to 15 years old
- This study is fully enrolled with 2,259 participants.
- Pfizer plans to share data from that study in the first half of 2021
- Pfizer has not yet begun a separate pediatric study for its vaccine that would focus on children under 12 years old
- <u>Link</u> to pediatrics studies with Pfizer
- Find a trial near you <u>Link</u>



Moderna: first patients dosed for their next version of the COVID-19 vaccine and more stable storage and transport conditions being tested

- Moderna on March 15th has announced that the first participants have been dosed in the Phase 1 study of mRNA-1283, their next generation COVID-19 vaccine candidate Link
- Moderna starts a trial to look at storage/shipment in refrigerators instead of freezers
- They will assess the safety and immunogenicity of the next-generation vaccine, designated as mRNA-1283, at three dose levels, and will be given to healthy adults either as a single dose or in two doses 28 days apart



Updates for Vaccine Providers

- Effective immediately, providers in receipt of COVID-19 vaccine, irrespective as
 to whether such doses are via a direct State or federal allocation or a
 redistribution, will now be required to report to the
 vaccine tracker on Mondays and Thursdays by 10am
- All providers with COVID-19 vaccine doses on hand or that depleted their allocation since their last report are required to fill out the vaccine tracker both days
- This reporting will continue to be used for allocation determinations and is still required
- If you have any questions regarding this change or the vaccine tracker in general, please email: VaccineTracker@health.ny.gov.



Breastfeeding/protection and the COVID vaccine

- First case of an infant with SARS-CoV-2 IgG antibodies detectable in cord blood after a single dose of an mRNA (Moderna) vaccine to a Covid naïve mother three weeks before delivery
- Cord blood antibodies (IgG) were detected to the S-protein of SARS-CoV-2 at time of delivery (<u>link</u> to pre-print)
- New prospective cohort study (<u>link</u> to pre-print) of six lactating women who
 planned to receive both doses of the Pfizer-BioNTech or Moderna vaccine
 between December 2020 and January 2021
- Breast milk samples were collected pre-vaccination and at 11 additional timepoints, with last sample at 14 days post 2nd dose of vaccine
- Significantly elevated levels of SARS-CoV-2 specific IgG and IgA antibodies in breast milk beginning at Day 7 after the initial vaccine dose, with an IgGdominant response

Testing Updates: NY Forward Rapid Test Program

- 26 sites will open in New York City, Hudson Valley, Capital Region, Western New York and on Long Island for a total of 38 active sites statewide
- Plan to increase vaccination and testing to ensure public events re-opening such as catered events (3/15) and arts/entertainment venues (4/2)
- Efforts through a public-private partnership to provide low-cost rapid testing to support efforts to increase economic activity
- The rapid testing program \$30 dollars in 30 mins
- New York Forward Rapid Test Program <u>Here</u>
- Find A Test Site Near You Here



State of Vaccination in NY

- 22.5% of New Yorkers have received at least one vaccine dose
- Over the past 24 hours, 122,778 total doses have been administered. To date, New York administered 7,000,000 total doses with 11.6 percent of New Yorkers completing their vaccine series.
- Approx. 2 million fully vaccinated
- See data by region and county on the State's Vaccine Tracker: ny.gov/vaccinetracker
- NYS legislation was signed granting employees time off to get the COVID vaccine. Under this new law, public and private employees will be granted up to four hours of excused leave per shot that will not be charged against any other leave the employee has earned or accrued

Vaccine Finder

- https://vaccinefinder.org/search/
- <u>Link</u> for provider enrollment in vaccine finder
- Appointments become available for booking Wednesday, March 17, at 8:00am and can be made through the Am I Eligible Tool or by calling the NYS COVID-19 Vaccine Hotline at 1-833-NYS-4-VAX (1-833-697-4829)
- Three new mass vaccination sites are coming to Long Island in Brentwood, Old Westbury and Southampton opening this Friday, March 19
- All three sites will plan to vaccinate more than one thousand New Yorkers daily dependent on supply from the federal government
- Biden's federal plan link





Do's and Don't after vaccine from the CDC

- You can gather indoors with fully vaccinated people without wearing a mask.
- You can gather indoors with unvaccinated people from one other household without masks, unless any of those people or anyone they live with has increased risk for severe disease
- If you've been around someone who has COVID-19, you do not need to stay away from others or get tested unless you have symptoms, except in congregate settings
- You should not gather with unvaccinated people from more than one other household
- You should not visit with an unvaccinated person who is at <u>increased risk of severe illness or death from COVID-19</u> or who lives with a person at increased risk
- You should still avoid medium or large-sized gatherings.
- You should still delay domestic and international travel and if you do travel, you'll still need to follow state regulations
- You should still watch out for <u>symptoms of COVID-19</u>, especially if you've been around someone who is sick and if you have symptoms of COVID-19, you should get tested and stay home and away from others.
- You will still need to follow guidance at your workplace.
- CDC <u>Link</u> for patients



Clinical Real Time Resource

 https://www.idsociety.org/covid-19real-time-learning-network/

Call Center:

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form
- https://www.idsociety.org/cliniciancalls
- @RealTimeCOVID19
- #RealTimeCOVID19

FOR WHOM?

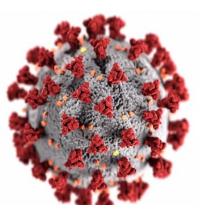
 Clinicians who have questions about the clinical management of COVID-19

WHAT?

 Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form







Side by Side comparison of available vaccines

Source:

https://www.medpagetoda y.com/special-

reports/exclusives/91489?x id=nl_covidupdate_2021-03-

16&eun=g1667471d0r&ut m_source=Sailthru&utm_m edium=email&utm_campai gn=DailyUpdate_031621&u tm_term=NL_Gen_Int_Dail

y_News_Update_active



Other COVID -19 Updates

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



FDA COVID-19 Testing Updates



FDA COVID-19 Testing Updates

- FDA issued a Letter to Clinical Laboratory Staff, Point-of-Care Facility Staff and Health Care Providers to alert them that false positive results can occur with the Roche Molecular Systems, Inc. cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System.
- FDA issued an Emergency Use Authorization (EUA) to Cue Health Inc. for its over-the-counter at-home diagnostic test for COVID-19. The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is a molecular test that can be used completely at home without a prescription by people with or without COVID-19 symptoms. It requires the use of a compatible smartphone and a downloadable app. Results are available in about 20 minutes.

https://www.fda.gov/news-events/fda-newsroom/press-announcements



FDA COVID-19 Testing Updates cont.

FDA issued an EUA to Adaptive Biotechnologies for its T-Detect COVID Test.

The T-Detect COVID Test analyzes DNA from a patient's T cells (white blood cells) to aid in identifying people with an adaptive T cell immune response to SARS-CoV-2, indicating recent or previous SARS-CoV-2 infection. The test should be used together with a clinical examination and a patient's medical history. Negative results do not rule out acute or current SARS-CoV-2 infection.

NEW YORK STATE of Health

Guidance Updates



Guidance Update

Guidance for The New York State COVID-19 Vaccination Program Effective March 17, 2021:

- Enrolled providers other than pharmacies, may vaccinate any eligible individual.
- Pharmacies must continue to vaccinate individuals age 60 and older, and prioritize P-12 school faculty and staff, and childcare worker per federal guidance, however, are now authorized to vaccinate individuals with comorbidities or underlying conditions.
- All providers must make efforts to vaccinate the most vulnerable New Yorkers, including those with comorbidities or underlying conditions, and individuals 60+.

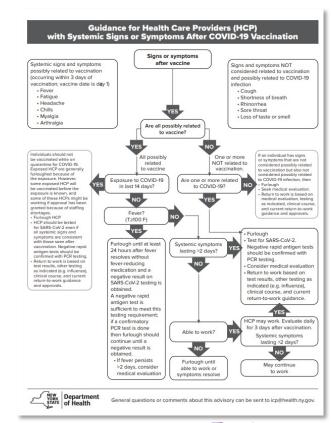
https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers



Guidance for The New York State COVID-19 Vaccination Program Effective March 17, 2021:

- Public-facing government and public employees, not-for-profit workers who
 provide public-facing services to New Yorkers in need, and essential in-person
 public-facing building service workers and providers of essential building
 services are eligible to be vaccinated.
- New York is mandating social equity and fair distribution among the priority groups eligible to ensure fair treatment and proportionate allocations both by eligibility group and by region.
- All vaccine providers in New York State must follow New York State
 Department of Health (NYSDOH) guidance regarding vaccine prioritization, as
 well as any other relevant directives, including reporting to the NYS Vaccine
 Tracker.

- Guidance for Health Care Providers (HCP) with systemic signs of symptoms after COVID-19 Vaccination
- Guidance for workers who have signs or symptoms after COVID-19 Vaccination





March 10, 2021: UPDATE to Interim Health Advisory:

Revised protocols for personnel in healthcare and other direct care settings to return to work following COVID-19 exposure – including quarantine and furlough requirements for different healthcare settings

This update aligns with the February 14, 2021 CDC update to "<u>Testing Healthcare</u> Personnel for SARS-CoV-2."

In general, asymptomatic HCP who have been fully vaccinated against COVID-19 do not need to quarantine or furlough during the first 3 months after full vaccination if: fully vaccinated, within 3 months following receipt of the last dose in the series and remained asymptomatic since the last COVID-19 exposure.*

NEW YORK STATE of Health

^{*} Please review the health advisory here:

March 10, 2021: Interim Guidance for Quarantine Restrictions on Travelers Arriving in New York State Following Out of State Travel

All individuals coming into New York, whether or not such person is a New York resident, are required to complete the traveler health form upon entering New York. Significant penalties may be imposed on any individual who fails to complete the <u>traveler health form</u>.

Consistent with recent CDC guidance, asymptomatic individuals who have been vaccinated against COVID-19 do not need to quarantine during the first 3 months after full vaccination if such travelers:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine);
- Are within 3 months following receipt of the last dose in the series; AND
- Have remained asymptomatic since last COVID-19 exposure.*



^{*} Please review the health advisory here: https://coronavirus.health.ny.gov/system/files/documents/2021/03/update-interim-travel-advisory-march-10-2021 0.pdf

Other Updates

Governor Cuomo announced that beginning March 22:

- Residential gatherings of up to 25 people can be held outdoors.
- Indoor residential gatherings remain capped at 10 people to reduce the continued risk of spread.
- Non-residential social gatherings of up to 100 people can occur indoors and up to 200 people can occur outdoors.

Monoclonal AB Update



Monoclonal Antibody update

- Monoclonal antibody treatments for Covid19 are no longer being distributed through a state allocation system.
- Therapies are now available through direct ordering only. All treatment sites
 meeting EUA requirements must now order Covid-19 monoclonal antibody
 therapies directly from AmerisourceBergen Corporation (ABC), the drugs' sole
 distributor. The products remain free of charge to requesting sites.
- HHS will continue to monitor all direct orders and retains the capacity to resume allocation of these and future therapies if needed. Treatment sites should review the <u>direct ordering process guide</u> and place orders directly with ABC at this <u>site</u>

Link to: Direct Order Process



Monoclonal Antibody Update

- Treatment sites wishing to place direct orders will be required to provide ABC with a board of pharmacy license or physician letter of authorization, attest to their designated class of trade, and ensure that product administration will be conducted according to the drugs' EUAs.
- Should you have any questions or concerns regarding the direct order process for COVID-19 monoclonal antibodies, you may contact HHS/ASPR at COVID19Therapeutics@hhs.gov or ABC at C19therapies@amerisourcebergen.com.

Link to: Direct Order Process



Other COVID -19 Updates



Building Confidence in COVID-19 Vaccines

Six Ways to Help Build COVID-19 Vaccine Confidence

- 1. Encourage leaders in your family, community, or organizations to be vaccine champions.
- 2. Have discussions about COVID-19 vaccines where people can openly discuss their views and ask questions.
- 3. Share key messages through multiple channels that people trust and that promote action.
- 4. Help educate people about <u>COVID-19 vaccines</u>, how they are developed and monitored for safety, and how individuals can talk to others about the vaccines.
- 5. Learn more about <u>finding credible vaccine information</u>. When you come across COVID-19 information, cross-check with CDC.gov and learn how to respond to misinformation you encounter.
- 6. When vaccine is offered to you, make visible your decision to get vaccinated and celebrate it!



COVID-19 Vaccine Second-Dose Completion

New York State COVID-19 vaccination program guidance: Those who receive the vaccine must return to the **same**location to receive the second dose, unless NYSDOH approves an alternative due to extenuating circumstances.*

CDC MMWR: 95.6% received the second dose within the recommended interval.

CDC: Identifying and addressing possible barriers to completing the COVID-19 vaccination series can help ensure equitable coverage across communities and optimal health benefits for recipients.



Morbidity and Mortality Weekly Report

COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020–February 14, 2021

Jennifer L. Kriss, PhD¹; Laura E. Reynolds, MPH¹; Alice Wang, PhD¹; Shannon Stokley, DrPH¹; Matthew M. Cole, MPH¹; La Treace Q. Harris, MPH¹ Lauren K. Shaw, MS¹; Carla L. Black, PhD¹; James A. Singleton, PhD¹; David L. Fitter, MD¹; Dale A. Rose, PhD¹; Matthew D. Ritchey, DPT¹; Robin L. Toklin, PhD¹; CDC COVID-19 Vaccine Task Force

In December 2020, two COVID-19 vaccines (Pfizer-Bio NTech and Moderna) received Emergency Use Authorization from the Food and Drug Administration.*,† Both vaccines require 2 doses for a completed series. The recommended interval between doses is 21 days for Pfizer-BioNTech and 28 days for Moderna; however, up to 42 days between doses is permissible when a delay is unavoidable. Two analyses of COVID-19 vaccine administration data were conducted among persons who initiated the vaccination series during December 14, 2020-February 14, 2021, and whose doses were reported to CDC through February 20, 2021. The first analysis was conducted to determine whether persons who received a first dose and had sufficient time to receive the second dose (i.e., as of February 14, 2021, >25 days from receipt of Pfizer-BioNTech vaccine or >32 days from receipt of Moderna vaccine had elapsed) had received the second dose. A second analysis was conducted among persons who received a second COVID-19 dose by February 14, 2021, to determine whether the dose was received during the recommended dosing interval, which in this study was defined as 17-25 days (Pfizer-BioNTech) and 24-32 days (Moderna) after the first dose. Analyses were stratified by jurisdiction and by demographic characteristics. In the first analysis, among 12,496,258 persons who received the first vaccine dose and for whom sufficient time had elapsed to receive the second dose, 88.0% had completed the series,

* https://www.fda.gov/emergency-preparedness-and-response/coronavirusdisease-2019-covid-19/pfizer-biontech-covid-19-vaccine

8.6% had not received the second dose but remained within the allowable interval (<42 days since the first dose), and 3.4% had missed the second dose (outside the allowable interval, >42 days since the first dose). The percentage of persons who missed the second dose varied by jurisdiction (range = 0.0%-9.1%) and among demographic groups was highest among non-Hispanic American Indian/Alaska Native (AI/AN) persons (5.1%) and persons aged 16-44 years (4.0%). In the second analysis, among 14,205,768 persons who received a second dose, 95.6% received the dose within the recommended interval, although percentages varied by jurisdiction (range = 79.0%-99.9%), Public health officials should identify and address possible barriers to completing the COVID-19 vaccination series to ensure equitable coverage across communities and maximum health benefits for recipients. Strategies to ensure series completion could include scheduling second-dose appointments at the first-dose administration and sending reminders for second-dose visits.

During December 14, 2020–February 14, 2021, a total of 40,517,900 persons initiated the COVID-19 vaccination series and had vaccine administration data reported to CDC by February 20, 2021. Providers submitted COVID-19 vaccine administration data to CDC via immunization information systems (IIS), the Vaccine Administration Management System (VAMS), or direct data submission. First and second doses were linked based on a recipient ID assigned by the reporting entity (e.g., jurisdictions, territories, and federal entities) and

* https://coronavirus.health.ny.gov/system/files/documents/2021/03/guidance for facilities receiving vaccine.pdf CDC MMWR report: https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7011e2-H.pdf

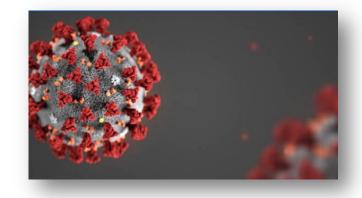


Clinician Well-being

Louis S. Snitkoff, MD, MACP
Immediate Past-President
American College of Physicians, NY Chapter







Clinician Well-being

Louis S. Snitkoff, MD, MACP Immediate Past-President American College of Physicians, NY Chapter

COVID-19 Resources



COVID-19 Healthcare Provider Compilation

What is the Provider Compilation Document?

- Contains links to the most recently available COVID-19 guidance for healthcare providers
- Includes links and guidance for:
 - Vaccinations, testing, quarantine, infection control and other relevant information for outpatient healthcare providers
- Updated weekly or as new guidance is released



NYSDOH COVID-19 Healthcare Provider Compilation As of January 5, 2021, 9:00 AM

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

Purpose: The purpose of this publication is to provide healthcare providers in New York State with a consolidated reference document of guidance released by the New York State Department of Health (NYSDOH) related to the COVID-19 pandemic response. This document displays hyperlinks to the current guidance documents. Additional COVID-19 resources may be found on the NYSDOH <u>Information for Healthcare Providers</u> webpage. Recordings of COVID-19 <u>Weekly Healthcare Provider Updates</u> are also available on the NYSDOH webpage.

COVID-19 Vaccine Information for Providers

Link to Guidance

NYSDOH COVID-19 Vaccine Webpage

- How to Order COVID-19 Vaccine
- Documents and Guidance on Administering the COVID-19 Vaccine and Vaccine Prioritization
- Provider Training

Determine Eliqibility for a Vaccine and Find a Local Vaccination Site to Make an Appointment

Testing and Specimen Collection

Link to Guidance

NYSDOH COVID-19 Testing Webpage

- Antigen Testing
- Antibody Testing
- Molecular Testing
- Protocols for Drive-Through Testing

DOH Wadsworth Center Coronavirus Testing Guidance Webpage

- Specimen Collection, Handling and Transport
- Guidance on Pooling
- Test Results Reporting
- Infectious Disease Requisition

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COVID-19 Healthcare Provider Compilation

• Link on NYSDOH web page: https://coronavirus.health.ny.gov/information-healthcare-providers

Information for Healthcare Providers

COVID-19 INFORMATION FOR PROVIDERS

Providing up-to-date information about the COVID-19 outbreak for NYS healthcare providers, including:

- COVID-19 Vaccine Information for Providers
- · Weekly health care provider updates
- COVID-19 webinars, health advisories, printable materials and guidance
- COVID-19 Testing Information
- Joining the NYS health care provider reserve workforce
- Creating a Health Commerce Account



WEEKLY HEALTHCARE PROVIDER UPDATE COMPILATION



NY State DOH COVID-19 Hotline

Call the Hotline: 1-888-364-3065 or Ask a Question

New Yorkers Can Now Report Vaccine-Related Fraud by Calling 833-VAX-SCAM (833-829-7226) or Emailing STOPVAXFRAUD@health.ny.gov





GET COVID-19 EXPOSURE ALERTS

Add Your Phone. Stop the Spread.





- 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.

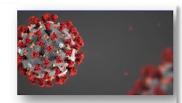


Healthcare Provider Well-Being



Healthcare Provider/Physician Wellness





Supporting Healthcare Provider Well-Being in COVID & Beyond

July 9, 2020

Howard Zucker, MD, JD Commissioner of Health, New York State

https://www.youtube.com/watch?v=B9PRLV- XQE



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/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

Office of Mental Health

About OMH

Consumers & Families

Behavioral Health Providers

Employment

COVID-19 Resources

The COVID-19 pandemic has left many New Yorkers feeling anxious and stressed

Learn more about:

- · The COVID-19 Vaccine
- · Managing anxiety in difficult times
- · Coronavirus-related guidance for healthcare providers
- · How you can help

VACCINATION INFORMATION

New York State COVID-19 Vaccine webpage

Learn more about the State's distribution plan and if you're eligible for the vaccine.

OMH COVID-19 Vaccine Fact Sheet 7

Get answers to common questions about the COVID-19 Vaccine.

PUBLIC RESOURCES

NY Project Hope Emotional Support Helpline: 1-844-863-9314 *

New York has a free, confidential helpline as part of the FEMA response to COVID-19. Call 1-844-863-9314 or visit nyprojecthope.org.

Tips for Mental Wellness 秀 (Español 秀 | 本) 비수文 秀 | P YC C K N Й 秀 | Kreyòl Ayisyen 秀 | 한국어를 秀) How to manage COVID related stress and anxiety

Mental Health in the Next Phase of Coronavirus 🔁 (Español 📆 | বাংলা 🟂 | 中文 📆 | Р УС С К И Й 🟂 | Kreyòl Ayisyen 💆 | ייִדיש 📆) A guide of coping tips and resources to help with the ongoing mental health impact of the pandemic.

Mental Health Resources During an Emergency

People often experience anxiety, fear, and helplessness during an emergency. Know the signs and get help.





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: P2P@mssny.org
- Phone 1-844-P2P-PEER (1-844-727-7337)

Support, Empathy & Perspective







CDC COVID-19 Website



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



Additional COVID-19 Resources



NYS resources

 https://forward.ny.gov/early-warningmonitoring-dashboard

COVID-19 Early Warning Monitoring System Dashboard

- Testing/tracing
- New infections/severity hospitalization
- Hospital capacity





Helpful Links

- HERO Together: COVID vaccine effects study
- New York State vaccine tracker
- NY Times vaccine tracker



Highlighted CDC resources

- Update to COVID-19 clinical considerations: <u>www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u>
- Nursing Home COVID-19 Data Dashboard: CDC's National Healthcare Safety Network (NHSN) is supporting the nation's COVID-19 response by providing a <u>Long-term Care Facilities (LTCFs) COVID-19 Module</u>, <u>NHSN Nursing Home COVID-19 Data Dashboard</u>
- Estimated Disease Burden of COVID-19: estimates of COVID-19 infections, symptomatic illnesses, and hospitalizations using a statistical model to adjust for cases that national surveillance networks are unable to capture for a number of reasons.
- These estimates and methodology used to calculate them are published in Clinical Infectious Diseases and available online. To learn more, please visit: Estimated COVID-19 Burden



CDC Upcoming Pending Topics

- 2/08/2021: Tools for Essential Workers
- 2/22/2021: Finding the Silver Lining: Advancing Smoke-Free Protections During the COVID-19 Pandemic



NYS Medicaid Telehealth Updates and Guidance

NYSDOH COVID-19 Guidance for Medicaid Providers website

- Webinar: New York State Medicaid Guidance Regarding Telehealth, Including Telephonic, Services During the COVID-19 Emergency - 5.5.2020
 - Slides (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

LAST UPDATED: JANUARY 13, 2021 AT 2:30 PM

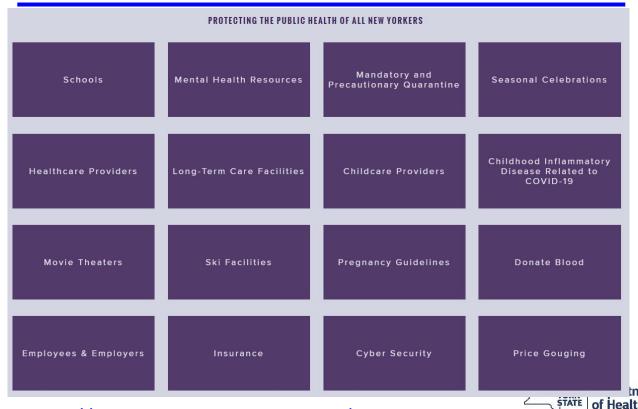
What You Need to Know

- . Visit ny.gov/vaccine to get the facts on the COVID-19 Vaccine in New York.
- The COVID-19 Emergency Eviction and Foreclosure Prevention Act places a moratorium on residential evictions until May 1, 2021 for tenants who have endured COVID-related hardship.
- · A new Micro-Cluster Strategy is addressing COVID-19 hot spots that have cropped up across the state.
- Look up an address to see if falls into a Red, Orange, or Yellow Zone
- · See the restrictions that correspond to each color-coded level of cluster zone
- Indoor and outdoor gatherings at private residences are limited to no more than 10 people.
- · Read New York's COVID-19 Winter Plan to mitigate the spread of the virus and bolster New York's hospital's preparedness.
- New travel guidelines are in effect that allow out-of-state travelers to "test out" of the mandatory 10-day quarantine.
- To report violations of health and safety restrictions and requirements for businesses, gatherings and individuals, please choose the appropriate link below:
- File a complaint about a business, location or incident in your community.
- · File a complaint against your employer or place of work.
- Health care workers can text NYFRONTLINE to 741-741 to access 24/7 emotional support services. Any New Yorker can call the COVID-19 Emotional Support Hotline at 1-844-863-9314 for mental health counseling.

https://coronavirus.health.ny.gov/home



NYSDOH COVID-19 Website



Education Department

https://coronavirus.health.ny.gov/home

NYSDOH COVID-19 Testing Website



Mirror Clings



To order mirror clings for public use email the NYSDOH:

bmcc@health.ny.gov





QUESTIONS?

TO NYS HEALTHCARE PROVIDERS THANK YOU!

