

COVID-19  
HEALTHCARE  
PROVIDER  
UPDATE

OCTOBER 2, 2020

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COVID-19 Vaccines: Updates and Planning Considerations

New York City Department of Health and Mental Hygiene

*Our understanding of COVID-19 is evolving rapidly.  
This presentation is based on our knowledge as of October 1, 2020, 5 PM.*

# OUTLINE



WHERE WE ARE NOW



RECENT EPIDEMIOLOGY OF COVID-19 IN NYC



UPDATED GUIDANCE



COVID-19 VACCINATION



QUESTIONS AND DISCUSSION

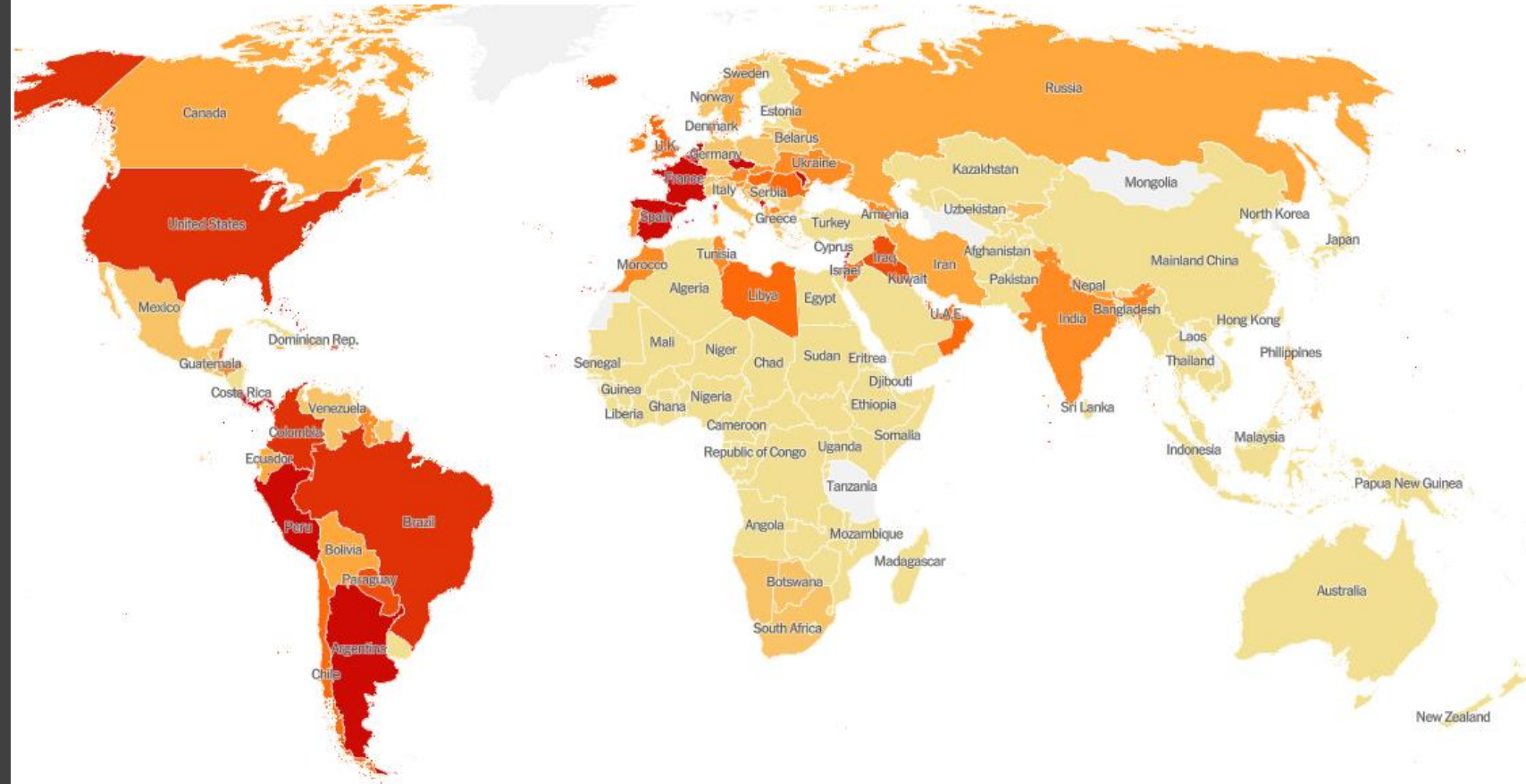
# WHERE WE ARE NOW

- Over 1 million deaths due to COVID-19 have been reported worldwide
- Highest recent burden of disease has been in the Americas and Southeast Asia
- Resurgences are occurring in several European countries
- Cases are on the rise in the United States
- New York City (NYC) public schools have resumed in-person classes, and indoor dining at 25% capacity started September 30<sup>th</sup>
- A concerning increase in case counts and hospitalizations has been observed in certain NYC areas, though citywide test positivity remains <2%
- NYC Health Department issued a Commissioner's Order to reduce risk at nonpublic schools in certain ZIP codes with increased transmission and is working with partners in affected communities to reinforce COVID-19 guidance and precautions

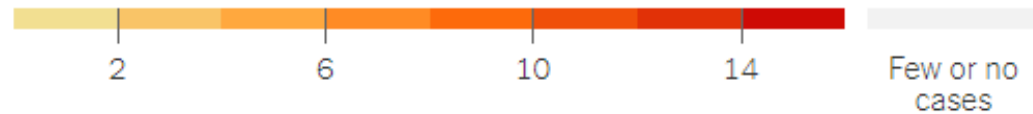
# COVID-19 WORLDWIDE

Cumulative:  
>34 million cases  
>1 million deaths

10/1/20



Average daily cases per 100,000 people in the past week



New York Times. Coronavirus map: tracking the global outbreak.

<https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>

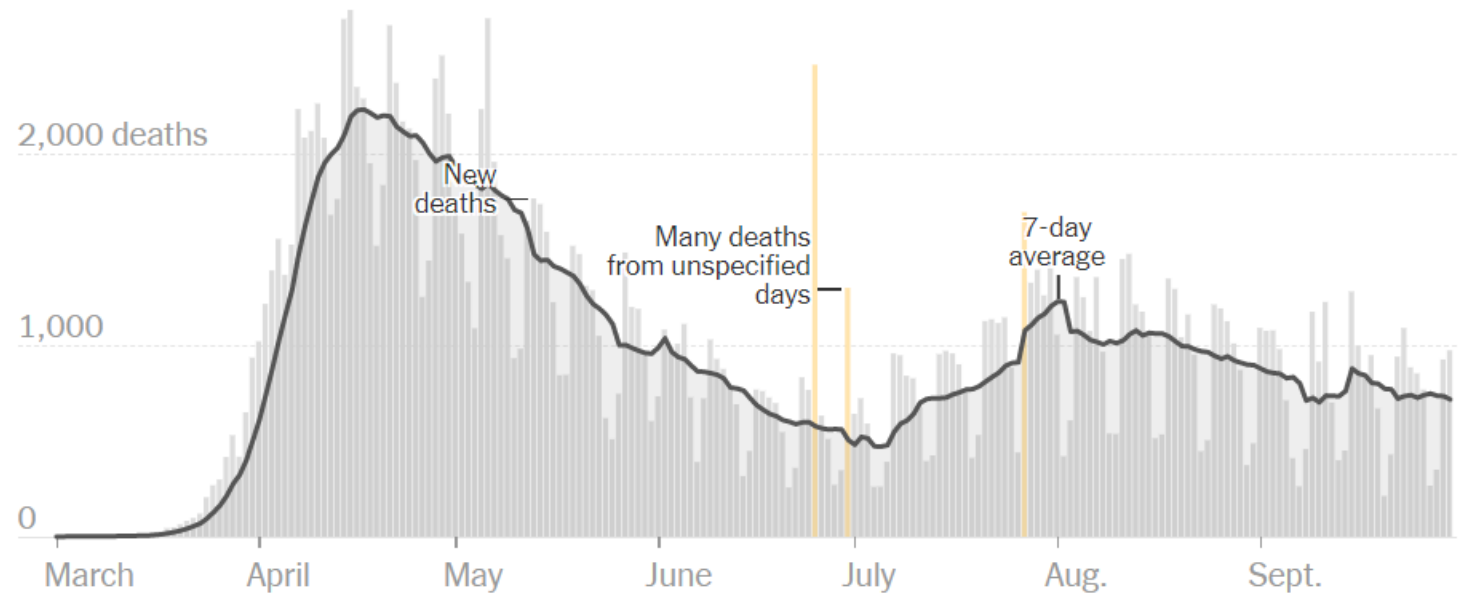
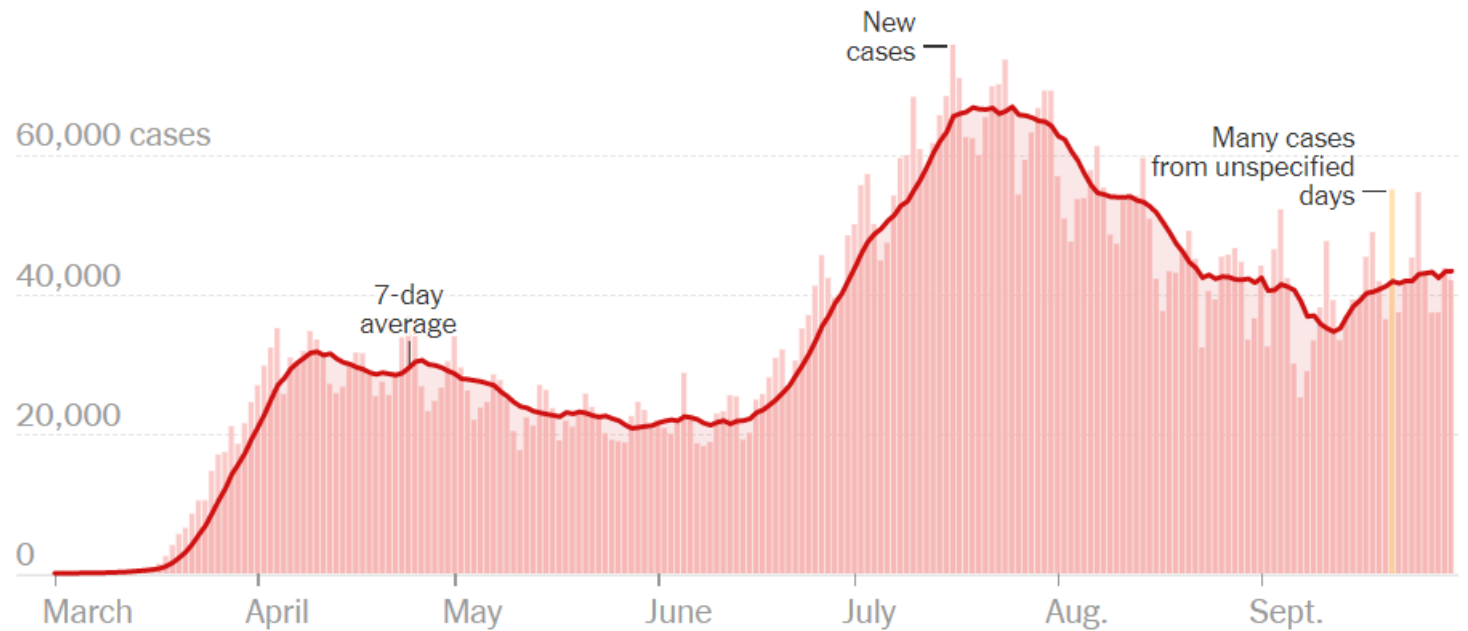
# COVID-19, U.S.

Cumulative:

>7.2 million cases

>207 thousand deaths

10/1/20

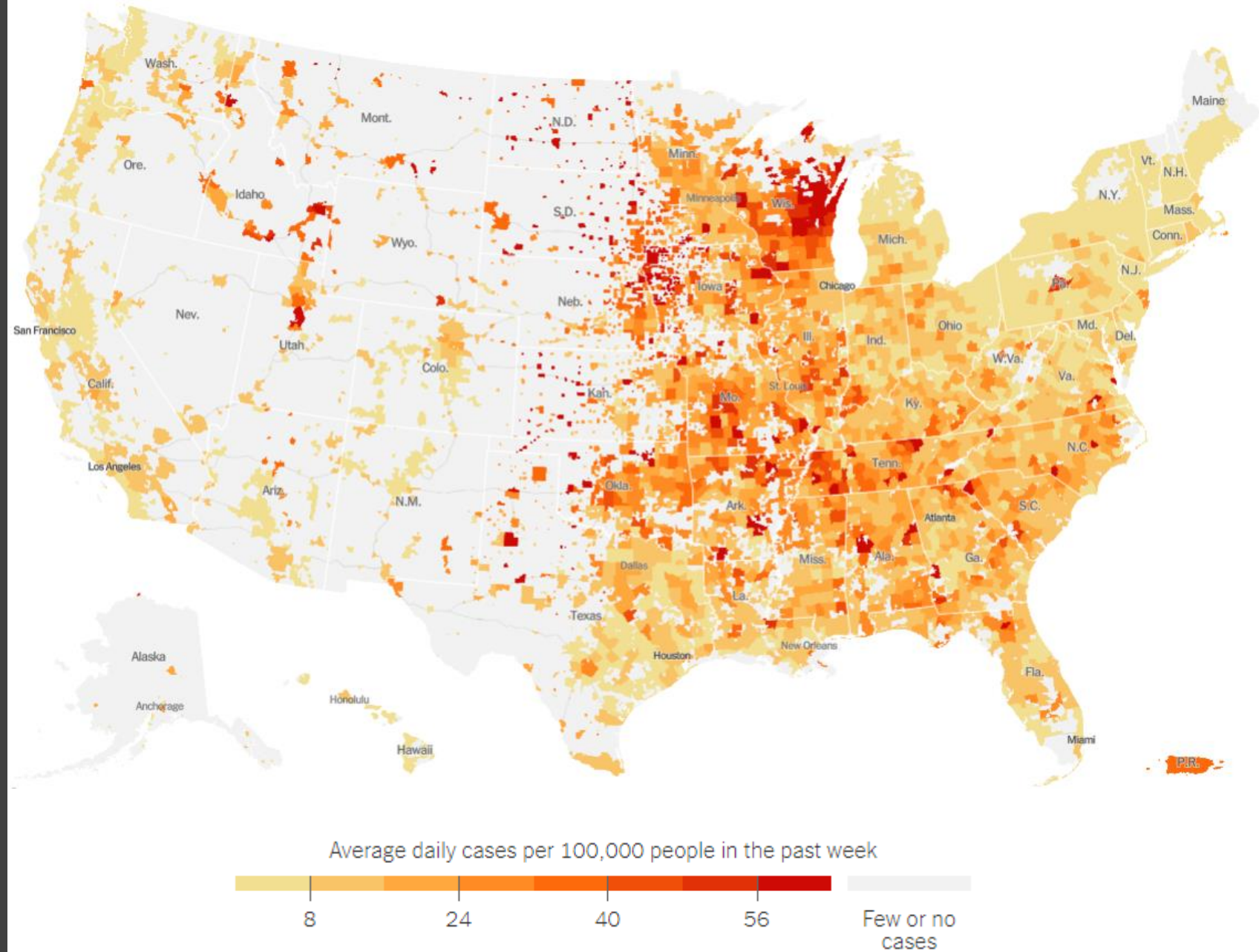


New York Times. Coronavirus in the U.S.: new reported cases and deaths.

<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>

# NEW CASES IN THE PAST WEEK, U.S.

10/1/20



New York Times. Coronavirus in the U.S.: latest map and case count.  
<https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>

EPIDEMIOLOGY  
OF COVID-19  
IN NYC

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UPDATED  
GUIDANCE

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POINT-OF-CARE  
TEST RESULTS  
MUST BE  
REPORTED  
ELECTRONICALLY

NEW YORK STATE  
EXECUTIVE ORDER  
202.61

- New York State (NYS) requires that all SARS-CoV-2 test results be reported via its Electronic Clinical Laboratory Reporting System (ECLRS)
- Includes point-of-care (POC) tests performed at clinics or other patient care sites
  - Nucleic acid amplification, antigen, and antibody tests
  - All results (positive, negative, indeterminate)
  - Report results within 3 hours of receipt
- Contact NYC Health Department's ECLRS team ([nyceclrs@health.nyc.gov](mailto:nyceclrs@health.nyc.gov)) and NYS ECLRS Help Desk (866-325-7743 or [eclrs@health.ny.gov](mailto:eclrs@health.ny.gov)) for assistance
- Providers may use the NYC Health Department's Reporting Central online portal **until ECLRS is established**
  - Providers without access to Reporting Central must fax a completed Universal Reporting form to 347-396-8991 **until they gain ECLRS capacity**

NYC Health Advisory #37. All Point-of-Care COVID-19 Test Results Must be Reported Electronically:

<https://www1.nyc.gov/assets/doh/downloads/pdf/han/advisory/2020/covid-19-point-of-care-test-results.pdf>

NYS Executive Order 202.61:

[https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO\\_202.61.pdf](https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO_202.61.pdf)

NYS Health Alert on Executive Order 202.61:

[https://oasas.ny.gov/system/files/documents/2020/09/doh\\_health\\_advisory\\_testing.pdf](https://oasas.ny.gov/system/files/documents/2020/09/doh_health_advisory_testing.pdf)

**POINT-OF-CARE  
TEST RESULTS  
MUST BE  
REPORTED  
ELECTRONICALLY**

**NEW YORK STATE  
EXECUTIVE ORDER  
202.61**

**Additional NYS Executive Order 202.61 requirements**

- When testing for SARS-CoV-2, providers must ask for and include the following information on the ECLRS report or laboratory requisition form:
  - Whether individual attends, works, or volunteers at a school; if so, name and address (enter school information in “occupation” field)
  - Place and address of employment, employer phone number
  - Full residential address and phone number
  - Local address, if different from permanent address
  - Race and ethnicity
- Licensed professionals authorized by NYS Department of Health Physician Office Laboratory Evaluation Program who administer influenza testing must report results via ECLRS within 3 hours of receipt

NYC Health Advisory #37. All Point-of-Care COVID-19 Test Results Must be Reported Electronically:

<https://www1.nyc.gov/assets/doh/downloads/pdf/han/advisory/2020/covid-19-point-of-care-test-results.pdf>

NYS Executive Order 202.61:

[https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO\\_202.61.pdf](https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/EO_202.61.pdf)

NYS Health Alert on Executive Order 202.61:

[https://oasas.ny.gov/system/files/documents/2020/09/doh\\_health\\_advisory\\_testing.pdf](https://oasas.ny.gov/system/files/documents/2020/09/doh_health_advisory_testing.pdf)

NYC HEALTH  
DEPARTMENT  
COMMISSIONER'S  
ORDER TO  
NONPUBLIC  
SCHOOLS IN  
DESIGNATED ZIP  
CODES

- Issued September 25, 2020, amended September 28, 2020
- Applies to non-public schools in 6 Brooklyn and 2 Queens ZIP codes where >25% of new cases in past two weeks occurred (despite accounting for <7% of NYC's population)
- Based on a 14-day average (as of September 29):

Neighborhood(s)	Zip Code	% Positivity
Gravesend/Homecrest	11223	6.92
Midwood	11230	5.64
Kew Gardens	11415	3.31
Edgemere/Far Rockaway	11691	4.91
Borough Park	11219	6.23
Bensonhurst/Mapleton	11204	6.05
Gerritsen Beach/Homecrest/Sheepshead Bay	11229	4.05
Flatlands/Midwood	11210	4.73

- Other ZIP codes will be added as necessary

NYC Order of the Commissioner: <https://www1.nyc.gov/assets/doh/downloads/pdf/covid/covid-19-non-public-schools-order.pdf>

NYC HEALTH  
DEPARTMENT  
COMMISSIONER'S  
ORDER TO  
NONPUBLIC  
SCHOOLS IN  
DESIGNATED ZIP  
CODES

- Requirements for nonpublic schools in designated ZIP codes:
  - Remain  $\geq 6$  feet apart while on premises except in emergencies or when doing so would create a safety hazard, or when physical barriers are put in place between individuals in accordance with New York State guidance
  - Face coverings are required in school buildings at all times, except for individuals who cannot wear one (medical, developmental, age)
  - Coordinate with Health Department and Test & Trace Corps to identify, isolate and prevent spread of COVID-19
  - Follow established protocols for opening and closing schools if a student or staff is confirmed to have COVID-19
  - Follow Health Department protocols for opening and closing if a student or staff member is confirmed to have COVID-19; exclude students and staff who have symptoms of or are confirmed to have COVID-19 or have been identified as a close contact of someone with COVID-19

CONSIDERATIONS  
FOR COVID-19  
VACCINE  
PLANNING AND  
DISTRIBUTION

**Jane R. Zucker, MD, MSc, FIDSA**

Branch Director, Vaccine Task Force  
Assistant Commissioner, Bureau of Immunization  
NYC Department of Health and Mental Hygiene

## OUTLINE

- I. Status of COVID-19 vaccine development
- II. Vaccine characteristics
- III. Planning assumptions
- IV. Vaccine allocation
- V. Key steps for providers

# COVID-19 VACCINE DEVELOPMENT

- Six vaccine manufacturers have received funding from the federal program “Operation Warp Speed” to produce a COVID-19 vaccine to be available in early 2021
- Four vaccines are in phase III trials in the U.S. to assess safety and whether the vaccine can prevent COVID-19
  - Moderna mRNA vaccine
  - Pfizer mRNA vaccine
  - Oxford/AstraZeneca DNA vaccine – trial on hold
  - Johnson & Johnson Janssen DNA vaccine
- Phase I/II trials and animal challenge studies have demonstrated good humoral and cellular immune responses
  - Safety profile is acceptable though these vaccines are reactogenic

## COVID-19 VACCINE PHASE III TRIALS

- Designed to address vaccine safety and effectiveness
- Randomized, blinded, placebo-controlled trials
- Enrolling participants aged  $\geq 18$  years
- Do not include immunocompromised persons, pregnant persons or children
- FDA has issued guidance for licensure outlining regulatory data expected to be submitted, including effectiveness information



COVID-19  
VACCINES  
EXPECTED TO  
BECOME  
AVAILABLE FIRST

- Pfizer mRNA vaccine
  - Shipped at -70°C
  - Can be stored in shipping container with replenishment of dry ice
  - Can be stored for up to 5 days at -20°C
  - 1000 dose order minimum
  - 10 dose vials
  - Requires reconstitution
- Moderna mRNA vaccine
  - Shipped and stored at -20°C
  - Can be stored at 2-8°C for up to 14 days
  - Minimum 100 dose orders
  - 5 dose vials
  - No preservative or reconstitution needed

## VACCINE ASSUMPTIONS

- Vaccine will only be available through CDC or NYC Health Department initially
- Distribution will be limited by vaccine storage and handling requirements
- Two doses will be required
- Intramuscular administration
- Products will not be interchangeable
- Shipped with vaccination supplies

## COVID-19 VACCINE AVAILABILITY

- Expect vaccine to become available in two phases
  - I: Limited availability for highest priority groups, as early as November 2020
  - II: Greater availability for general public, early 2021

COVID-19  
VACCINE  
AVAILABILITY  
PHASE I

- Limited supply for the country, November 2020
  - Initially, 3 million doses in early November
  - Approximately 20 million doses by end of the month
- Vaccine would likely be available under an FDA Emergency Use Authorization and not be a licensed product
- CDC will likely distribute vaccine to
  - Federal locations (e.g., Veterans Health Administration sites)
  - Other national entities (e.g., chain pharmacies)
- Vaccine is likely to be offered at a smaller number of sites that can reach the target populations (e.g., hospitals and large medical facilities for administration to health care personnel)
- NYC allocation is not known

# COVID-19 VACCINE AVAILABILITY PHASE II

- A licensed vaccine is expected as early as 2021
- This will mean greater availability to general public
- Production expected to start before vaccine is licensed
- NYC Health Department would oversee vaccine distribution
- Broad distribution and availability
- Will expand on existing vaccination infrastructure:
  - Federally Qualified Health Centers
  - Independent health care providers
  - Pharmacies
  - Urgent care
  - Hospitals
  - H+H facilities
  - NYC Health Department COVID-19 testing sites
  - Community vaccinators

# COVID-19 VACCINE ALLOCATION

- Principles include:
  - Reduce health impact of COVID-19
  - Reduce transmission
  - Vaccine safety and effectiveness
  - Equitable allocation and availability
- National Vaccine Allocation Framework\*
  - Recommendations are evolving
  - Groups proposed for initial doses of vaccine include workers in health care facilities and first responders with high risk of exposure
- Advisory Committee on Immunization Practices (ACIP)
  - Recommendations are in development
  - Priority groups will likely include health care personnel, adults aged ≥65 years, persons with high-risk medical conditions, long-term care facility residents and/or staff, and essential workers
- Recommendations not expected to be finalized until last week of October 2020

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

# COVID-19 VACCINE PRIORITIZATION

Initial target expected to be:

- Health care personnel<sup>1</sup> with high risk of exposure
- Persons with increased risk of COVID-19 complications
  - Adults aged  $\geq 65$  years
  - Persons with certain underlying health conditions<sup>2</sup>
  - Essential workers
    - To be defined; may include transportation, food services

1. See CDC for conditions associated with severe COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>
2. CDC definition of health care personnel: <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html>

## COVID-19 VACCINE DISTRIBUTION

- Medical facility networks and individual facilities will be required to sign a federal provider agreement
  - Each administration site needs to be identified
- Expect vaccine to be sent to facility's main pharmacy
  - Not ordered by separate facilities, clinics, practices
  - Includes Emergency Medical Services



# PROVIDER AGREEMENT: SECTION A

- Signed by Chief Medical Officer or equivalent
- Requirements:
  - Administer vaccine in accordance with ACIP guidance
  - Report administered doses within 24 hours
  - Adhere to vaccine storage and handling requirements
  - Inventory management
  - Billing
  - Report vaccine adverse events

## CDC COVID-19 Vaccination Program Provider Agreement



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

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

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

ORGANIZATION IDENTIFICATION		
Organization's legal name:		
Number of affiliated vaccination locations covered by this agreement: _____		
Organization telephone number:	Email ( <i>must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program</i> ):	
Organization address:		
RESPONSIBLE OFFICERS		
For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.		
Chief Medical Officer (or Equivalent) Information		
Last name	First name	Middle initial
Title	Licensure (state and number)	
Telephone number:	Email:	
Address:		
Chief Executive Officer (or Chief Fiduciary) Information		
Last name	First name	Middle initial
Telephone number:	Email:	
Address:		

# PROVIDER AGREEMENT: SECTION B

- Provider profile
  - Contact information
  - Shipping location and hours
  - Size and type of population served
  - Type of facility
  - Vaccine storage capacity
  - Provider information

**Section B. CDC COVID-19 Vaccination Program Provider Profile Information**  
 Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

ORGANIZATION IDENTIFICATION FOR INDIVIDUAL LOCATIONS				
Organization location name:			Will another Organization location order COVID-19 vaccine for this site?	
			<input type="checkbox"/> Yes; provide Organization name: _____ <input type="checkbox"/> No	
CONTACT INFORMATION FOR LOCATION'S PRIMARY COVID-19 VACCINE COORDINATOR				
Last name:		First name:	Middle initial:	
Telephone:		Email:		
CONTACT INFORMATION FOR LOCATION'S BACK-UP COVID-19 VACCINE COORDINATOR				
Last name:		First name:	Middle initial:	
Telephone:		Email:		
ORGANIZATION LOCATION ADDRESS FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS				
Street address 1:		Street address 2:		
City:	County:	State:	ZIP:	
Telephone:		Fax:		
ORGANIZATION ADDRESS OF LOCATION WHERE COVID-19 VACCINE WILL BE ADMINISTERED (IF DIFFERENT FROM RECEIVING LOCATION)				
Street address 1:		Street address 2:		
City:	County:	State:	ZIP:	
Telephone:		Fax:		
DAYS AND TIMES VACCINE COORDINATORS ARE AVAILABLE FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS				
Monday	Tuesday	Wednesday	Thursday	Friday
AM:	AM:	AM:	AM:	AM:
PM:	PM:	PM:	PM:	PM:
<i>For official use only:</i>				
VTrckS ID for this location, if applicable: _____			Vaccines for Children (VFC) PIN, if applicable: _____	
IIS ID, if applicable: _____		Unique COVID-19 Organization ID (from Section A): _____	Unique Location ID**:	
<p>**The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number will include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A), has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3.</p>				

## ROLE OF NYC CITYWIDE IMMUNIZATION REGISTRY (CIR)

- Provider agreement will be available, completed and signed in the CIR
- Vaccine can be ordered via an online system
  - System is a part of the CIR
  - Currently used by all providers enrolled in the Vaccines for Children Program
- Orders will be reviewed and approved by NYC Health Department
- Initially, shipments will likely be partial
- Orders will be sent to CDC by NYC Health Department using VTrkS, a CDC application used for pediatric vaccine
- Vaccine will be shipped directly to the facility from the vaccine manufacturer or CDC distributor
- Reporting of all administered COVID vaccine doses is expected to be required

## START PLANNING NOW

- How will your facility allocate initial doses of vaccine?
- Initial target should be healthcare personnel at high risk or exposure
- Those at higher risk of severe COVID-19 illness
- Consider how you would vaccinate your patients
- Is your facility registered with the CIR?
- Is your facility reporting adult vaccine doses to CIR?
  - <http://www.nyc.gov/health/cir>
  - [cir@health.nyc.gov](mailto:cir@health.nyc.gov)

# ADDITIONAL RESOURCES ON COVID-19

## NYC Health Department

- Provider page: <https://www1.nyc.gov/site/doh/covid/covid-19-providers.page>
- Data page: <https://www1.nyc.gov/site/doh/covid/covid-19-data.page>
- Weekly webinars: Every other Friday, 1 p.m. (sign up on provider page)
- Dear Colleague COVID-19 newsletters (sign up for *City Health Information* subscription at: [nyc.gov/health/register](https://www1.nyc.gov/site/doh/covid/covid-19-providers.page))
- NYC Health Alert Network (sign up at <https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page>)
- Provider Access Line: **866-692-3641**
- Neighborhood resource snapshots: <https://www1.nyc.gov/site/doh/covid/covid-19-communities.page>

## NYC COVID-19 Citywide Information Portal

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

## Other sources

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

## RETRIEVING CME CREDITS

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