



COVID-19 VACCINE PLAN



Webinar
11/19/2020

Stephen J. Acquario
Executive Director



NYSAC Thanks Our Webinar Sponsor:



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“The world is preparing to deliver one of the largest mass vaccination campaigns in human history, managing the process of safely distributing effective COVID-19 vaccines to potentially billions of people will be extremely challenging, but is of critical importance to the health of our population. Salesforce understands the need for a carefully managed process that is scalable, mobile and cloud-based.”



Hon. Jack Marren

NYSAC President

Ontario County Board of Supervisors





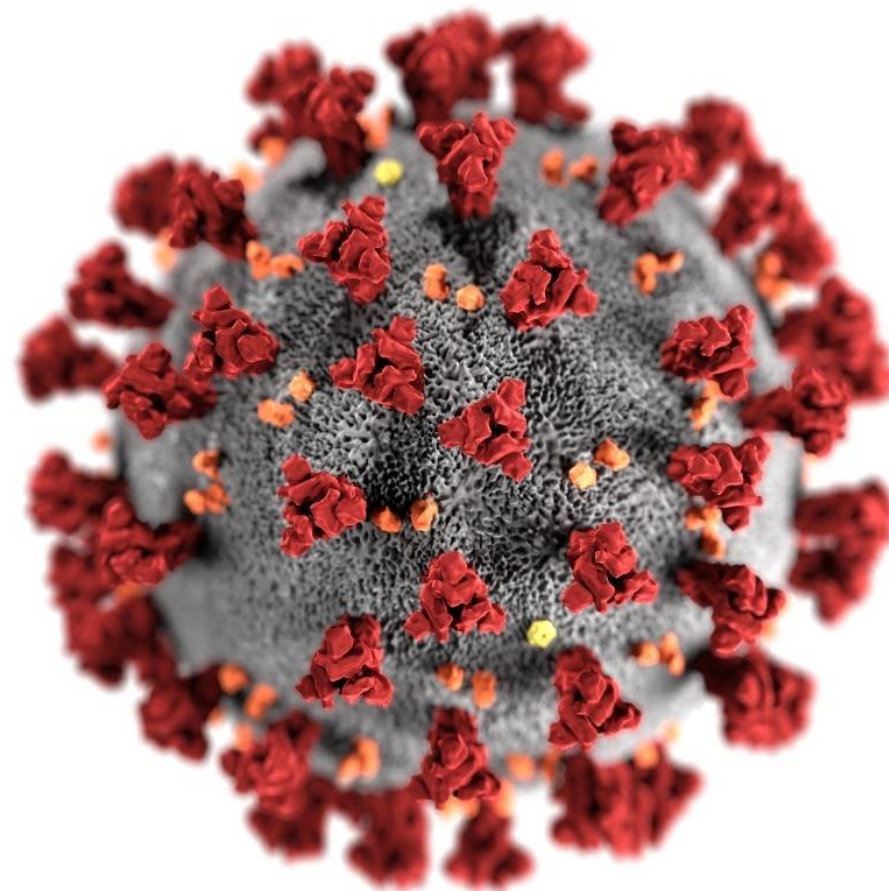
Dr. Nancy Messonnier

Director of the National Center for Immunization and
Respiratory Diseases (NCIRD)

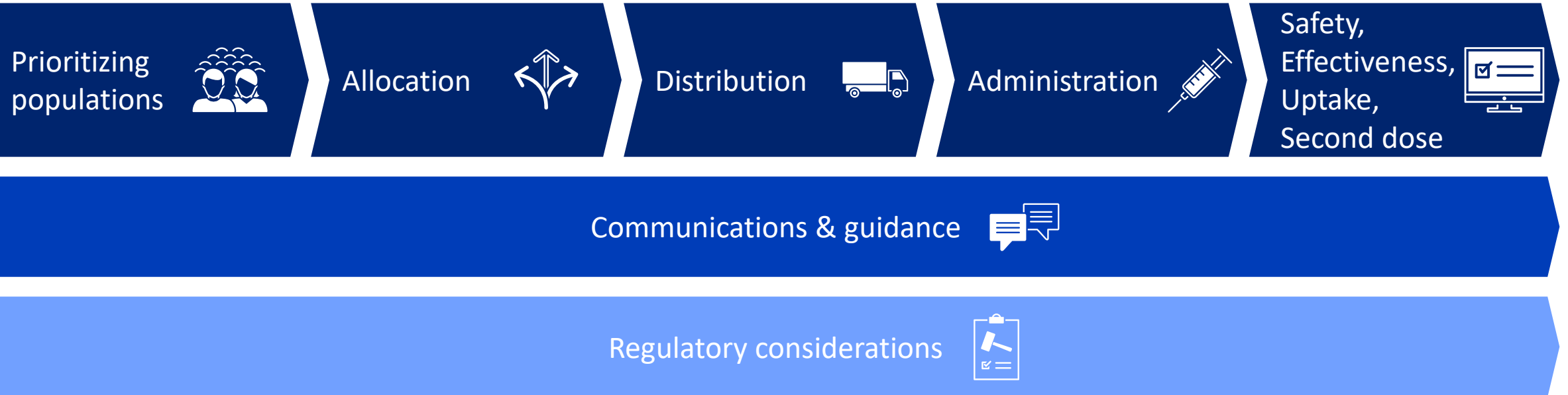


COVID-19 Vaccine Planning

Nancy Messonnier, MD

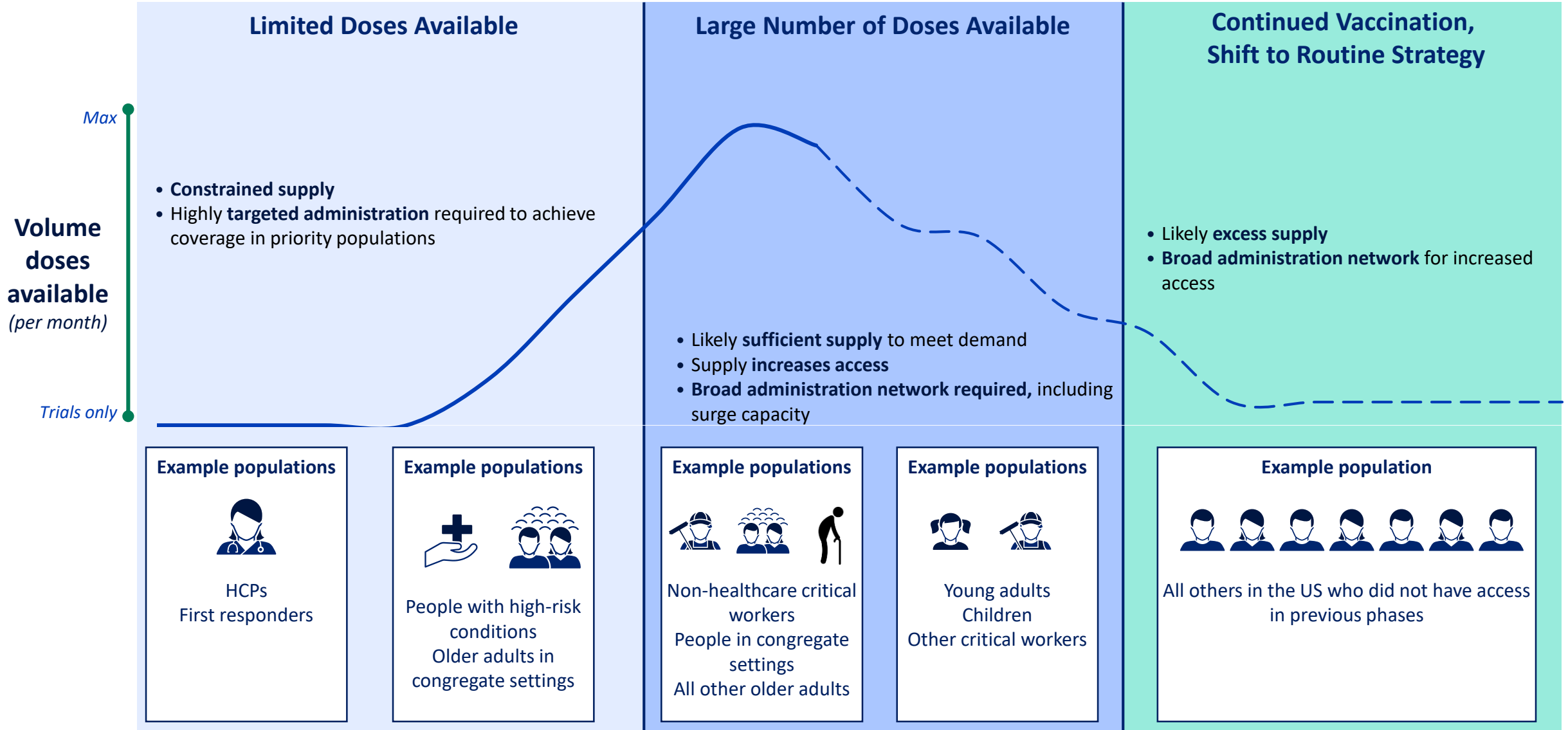


Multiple components to vaccine implementation



Public health impact relies on rapid, efficient, and high uptake of complete vaccine series, with particular focus on those at increased risk for severe COVID-19 illness

Distribution will adjust as volume of vaccine doses increases



Critical Populations to Ensure Access

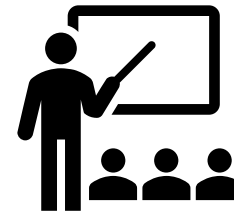
Critical infrastructure



People at increased risk for severe illness



People at increased risk for COVID-19



People with limited access to vaccinations



Vaccine Safety COVID-19 Strategy

- 1. Use established systems** to implement heightened safety monitoring for COVID-19 vaccines
- 2. Develop new platforms** and leverage other federal data sources to complement existing systems (V-SAFE)
- 3. Communicate clearly** on the vaccine safety process and systems now; provide COVID-19 vaccine safety data and monitoring results once available



11/19/20

DO NOT DISTRIBUTE



Vaccinate with **Confidence**

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

Reinforce Trust

Objective: Regularly share clear and accurate COVID-19 vaccine information and take visible actions to build trust in the vaccine, the vaccinator, and the system.

Empower Healthcare Providers

Objective: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

Engage Communities & Individuals

Objective: Engage communities in a sustainable, equitable and inclusive way—using two-way communication to listen, increase collaboration and build trust in COVID-19 vaccine.

What You Need to Know

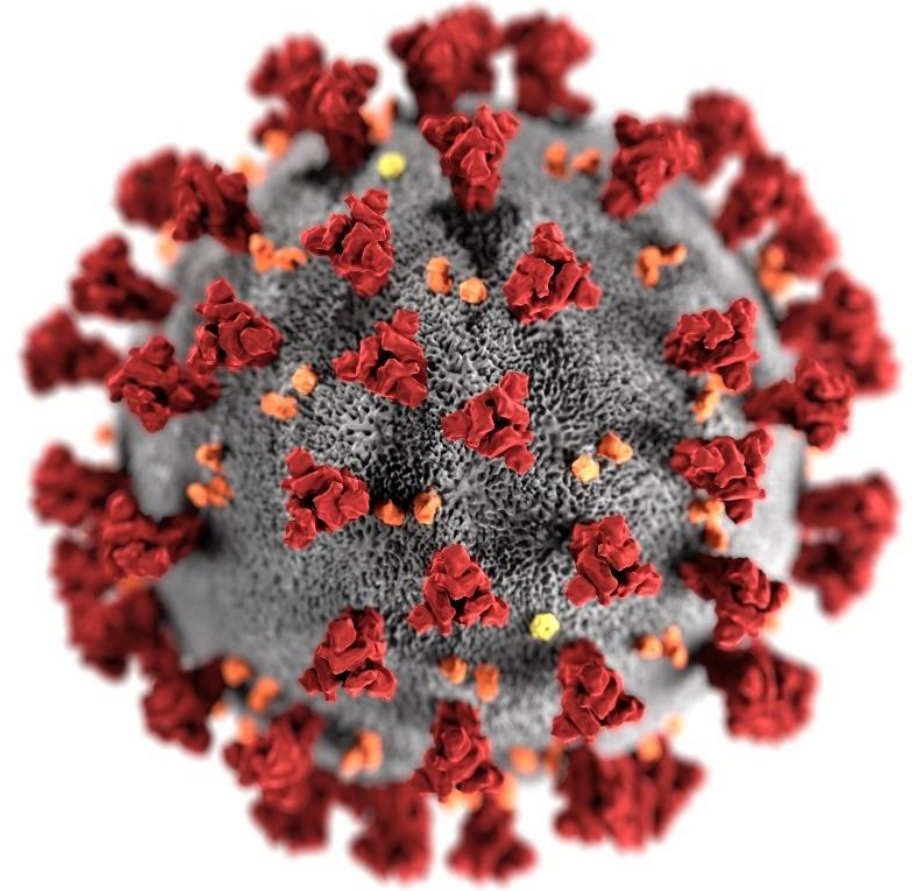
- We are in a **complicated vaccine landscape**, with many types of vaccines in development that could possibly be authorized by FDA.
- CDC and FDA will deploy their routine procedures and systems **to ensure vaccines are safe and effective**.
- Vaccination populations will evolve over time.
 - Limited vaccine doses may be available in 2020, but supply will increase over time.
 - Initially, vaccines will only be authorized and recommended for adults.
- COVID-19 vaccine planning is changing rapidly, and new information will be available soon.
- **You can play a critical role in helping build confidence in COVID-19 vaccination.**

For up-to-date COVID-19 vaccine information visit:

www.cdc.gov/coronavirus/2019-ncov/vaccines

The image shows a screenshot of the CDC website's COVID-19 vaccine page. At the top, the CDC logo and name are visible, along with a search bar and a "COVID-19" dropdown menu. Below the header, there is a banner for "Coronavirus Disease 2019 (COVID-19)" with a "WEAR A MASK, PROTECT OTHERS" message and images of people wearing masks. The main navigation bar includes "Your Health", "Community, Work & School", "Healthcare Workers & Labs", "Health Dept", "Cases & Data", and "More". The "Your Health" section is active, showing a "Vaccines" sub-section. The page content includes a "YOUR HEALTH Vaccines" heading, a date "Updated Oct. 14, 2020", and a "Vaccines" menu with options like "8 Things to Know", "How CDC is Making Vaccine Recommendations", and "Ensuring the Safety of Vaccines". A large image shows a healthcare worker administering a vaccine to a patient, with a text overlay: "Safety Is a Top Priority. The U.S. vaccine safety system ensures that all vaccines are as safe as possible. [Learn more](#)". Below this, there are sections for "Vaccine Information for You & Your Family" and "8 Things to Know about Vaccination Planning". The "Vaccine Information for You & Your Family" section lists links for "8 Things to Know about U.S. COVID-19 Vaccination Plans", "How CDC is Making COVID-19 Vaccine Recommendations", "Ensuring the Safety of COVID-19 Vaccines", and "Frequently Asked Questions about COVID-19 Vaccination". The "8 Things to Know about Vaccination Planning" section includes a link for "Vaccination Plans". At the bottom, there is a "Get Email Updates" form with a text input field for an email address and a "Submit" button. The footer contains the text "Last Updated Oct. 14, 2020" and "Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Field Operations".

Thank you



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

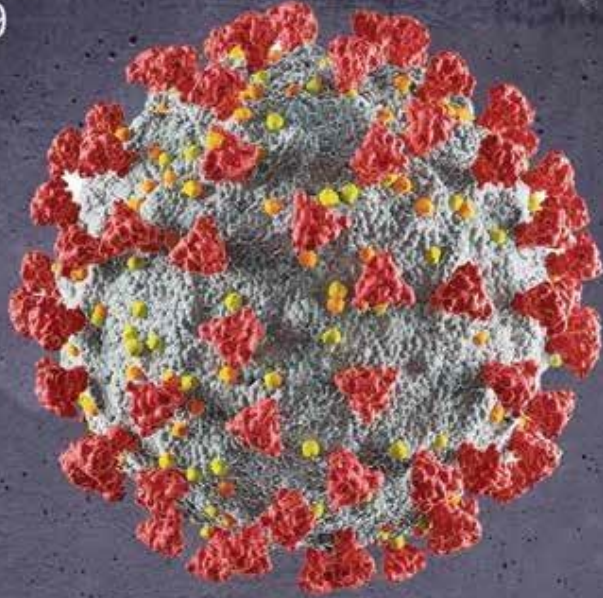
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.





Loretta Santilli, MPH

Director, Office of Public Health Practice



New York State COVID-19 Vaccination Program

**Presentation to the
NYS Association of Counties (NYSAC)**

November 19, 2020

NYS Vaccine Administration Program (VAP)

Executive Summary

To ensure the safe and efficient distribution and administration of vaccine to New York residents, the plan outlines:

- ❖ **Guiding principles** to be adhered to throughout the process
- ❖ **Key assumptions** and variables that may impact planning
- ❖ Measures to ensure vaccine **safety** and **effectiveness** (pre and post administration)
- ❖ **Expertise** to guide vaccine distribution and **implementation**
- ❖ A **vaccine prioritization** matrix based on clinical guidance and equity principles
- ❖ A process for efficient **vaccine distribution**
- ❖ A NYS directed process to **identify, enroll, train, and support providers and sites** to administer the vaccine
- ❖ A **data and IT infrastructure** to coordinate and monitor all aspects of the vaccine program
- ❖ A **public outreach and communication** campaign to build trust and inform the public
- ❖ A **leadership structure** to manage the entire vaccine program
- ❖ A **budget and procurement process** to obtain necessary supplies and equipment

Guiding Principles



Safety | Effectiveness | Expert approved

Only endorse and distribute a COVID-19 vaccine if it is determined to be *safe* and demonstrated to be appropriately *effective* in the populations intended for use. Rely on the advice and counsel of the Governor's Clinical Advisory Task Force to review and approve every vaccine that is authorized by the federal government for distribution and ensure it will only be used according to the indication under which it received its authorization or license.

Equitable & clinically driven distribution Approach will be based solely on clinical and equitable standards that prioritize access to persons at higher risk of exposure, illness and/or poor outcome.

Transparency All aspects of the COVID-19 vaccine distribution, administration, and monitoring process will be transparent.

Guiding Principles - 2

Data Driven Use robust data systems to guide all parts of the COVID-19 vaccine distribution and administration process to maximize safety, accuracy, and efficiency and meet all Federal reporting requirements.

Safety | Privacy Demand compliance with social distancing, mask wearing, hand washing, and other COVID-19 safety measures. Ensure all vaccination processes prioritize patient safety, and all information systems guarantee patient privacy.

Coordination | Public Outreach Coordinate and direct all local resources and assets from regional and local health agencies, providers and community organizations to ensure safe and successful distribution and administration of the COVID-19 vaccine. Outreach efforts must focus on underserved, hard to reach, vulnerable, less accessible and vaccine hesitant populations.

State Leadership | New York Tough NYS will undertake all preparations necessary to ensure an efficient and organized vaccine distribution using the COVID-19 response approach - tough, strong, united, disciplined, and loving.

Assumptions



- COVID-19 vaccines are expected to be approved for use by the FDA under an **Emergency Use Authorization (EUA)**. Vaccines are expected to be recommended for use by the CDC's Advisory Committee on Immunization Practices (ACIP).
- **COVID-19 vaccine supply will initially be limited** in the first months after approval and allocation will be made based on **priority populations**.
- **Most COVID-19 vaccines are expected to require two doses about one month apart.** Doses must be from the same vaccine manufacturer and cannot be interchanged from one product to another.
- **Varied cold chain requirements** for the vaccines (from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold freezers (-60°C to -80°C) may pose unique challenges to storage, handling, and distribution.
- **Public opinion will be mixed** on the safety and efficacy of any vaccine. We can expect that misinformation will be disseminated on social media and other sources.

Executive Organizational Leadership

NYS will design and manage all aspects of the COVID-19 vaccine administration program. Executive Leadership will direct state agencies, local public health, health care agencies, and community based partners in the implementation of the program using all resources necessary.



"What do we want to accomplish in New York? We should have the best vaccination program in the United States of America. I think the way we have handled COVID has been a model for this country. I want New Yorkers to do the same thing with vaccines."

Governor Andrew M. Cuomo
September 2020



NYS Task Forces



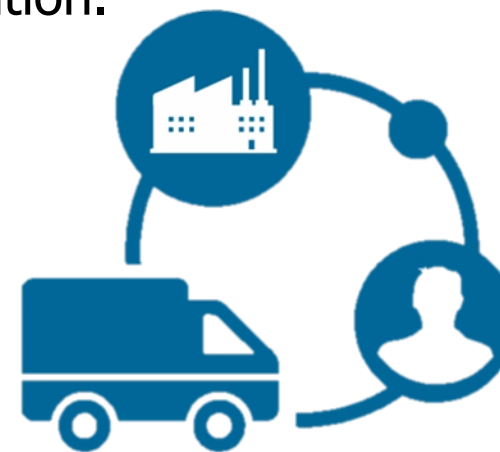
Clinical Advisory Task Force (CATF)

formed to establish and build public trust. Comprised of seven independent, leading scientists, doctors, health and legal experts.

Vaccine Distribution and Implementation Task Force (VDITF)

comprised of experts in public health, immunizations, government operations, data and other fields relevant to vaccine distribution and administration.

Members reflect the racial, socio-economic and geographic diversity and unique characteristics of the local communities that will be served by this Vaccination Program.



Logistics



➤ Supply Chain

Procuring critical supplies (sharps containers, bandages, additional PPE) and equipment necessary to conduct state, regional and local operations including cold-chain storage and transit such as dry ice, transportation vehicles, storage sites, etc.

➤ Call Center

Fully staffed and operationalized call centers with FAQs, scripted messaging and relevant information to address PUBLIC and PROVIDER questions, concerns and comments.

➤ Budget

Funding for supplies, equipment, critical operations and other expenses.

➤ Legal Considerations

Executive Orders, Liability, Reimbursement for Vaccine Administration, Worker's Compensation, Consent

Public Outreach and Communication

With more than half of Americans expressing skepticism of a COVID-19 vaccine, effective communication will be a critical element of New York State's vaccination program.



- Dedicated communications effort to **promote vaccine confidence** and quickly **address misinformation** that may spread on social media and in other media forms
 - Special attention and resources will be dedicated to outreach to Black and Brown communities at high-risk of COVID-19.
- **Dedicated public relations team and targeted paid media campaign across all platforms** (digital, social, print, broadcast, website, etc.)
- **Promotion of user-friendly tools (Vaccine Finder)** for determining vaccine eligibility, location of vaccine providers, and appointment scheduling
- **Public events and media campaigns** with trusted health care experts to build public confidence

Data Systems

Establish or enhance the data and analytics infrastructure to support all aspects of the vaccination program.

- **Provider profile and enrollment** as a vaccination administration site
 - Documentation of **statistics on priority groups** in order to properly match vaccine allotment amounts with populations
 - **Vaccine ordering** and **distribution** and **inventory/supply chain management**
 - Support for first and second dose **appointment scheduling, registration** and **appointment reminders**
 - Documentation of all aspects of **vaccine administration** including patient consent
 - **Record and track doses** administered by priority groups
 - Documentation of **patient demographics** and dose-level vaccination information adhering to national standards
 - Documentation of a **second dose** and related reminder-recall communications with patients
 - Documentation of **adverse reactions** and events
 - **Interoperability** with provider electronic health records
 - Support for analytics and required **reporting**
- **Vaccine Tracking System (VTrckS)**
 - **New York State Immunization Information System (NYSIIS) and Citywide Immunization Registry (CIR)**
 - **Countermeasure Data Management System (CDMS)**
 - **Analytics and Visualization Dashboard (including Tiberius)**



Operations



➤ Regional and Local PODs

Identify and operationalize point of dispensing vaccine administration sites

- Plan for quick activation and mobilization of MASS vaccination point of dispensing (POD) sites, designed to be operationalized once vaccine availability increases and outpaces provider administration capacity.
- Designate mobile vaccination units, similar to the rapid response team testing efforts that have been deployed statewide to help control viral spread and outbreaks, to ensure access to underserved areas

➤ Training, Competencies and Exercises

Identify, train, and deploy qualified staff for vaccine administration and site support including expanding the network of authorized health providers who can administer the vaccine.

- pharmacists, dentists, veterinarians, paramedics and EMTs, physician assistants, student nurses; professionals who are currently licensed in other states to vaccinate.

➤ Provider Support and Enrollment

Identify, enroll and train all eligible providers capable of providing COVID-19 vaccination

- Hospitals, LHDs, LTCFs, FQHCs, CHCs, RHCs, urgent care centers, private provider offices, pharmacies, shelters and other congregate living facilities, schools/colleges and universities, correction facilities, etc.

Clinical Operations



➤ Vaccine Safety & Efficacy

Close monitoring of evolving surveillance data and the clinical efficacy of the vaccination program.

Post vaccine administration safety monitoring including the Vaccine Adverse Event Reporting System (VAERS).

➤ Prioritization

Critical populations identified and recommended by the Advisory Committee on Immunization Practices (ACIP) with input from the National Academies of Sciences, Engineering, and Medicine (NASEM).

Detailed, flexible planning to quickly adjust given changes in the supply of vaccine and the number of New Yorkers seeking vaccination.

➤ Clinical Training & Competency Assessments

➤ Special Populations

Comprehensive effort that demands **health equity** and access to healthcare and vaccine.

Update on Federal Approval Process

FDA COVID-19 Vaccine Approval 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 it in October 2020

Criteria for approval:

- Vaccine candidate would need to be at least 50% effective
- Phase 3 clinical trial must include at least 30,000 volunteers
- Trials must include racial and ethnic minorities and other special populations
- Participants must be monitored for at least 2 months after the last dose

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. Recommendations are not binding, but are usually followed by the FDA.

Advisory Committee on Immunization Practices (ACIP)

- Independent advisory group to the CDC comprised of 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. Recommendations are not binding, however the CDC usually follows them.
- Annually establishes and updates vaccination schedules for children, adolescents and adults. 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 high-risk populations
- Severity of the disease
- Frequency of the disease
- How practical the recommendations are to put into practice
 - Cost and insurance coverage
 - Complexity/ease of use
 - Health disparities, justice and accessibility
 - Acceptability to recommended populations and their healthcare providers

The ACIP has committed to convening to issue recommendations for any FDA-licensed or -authorized COVID-19 vaccine within 24 hours of licensure or authorization.

Vaccine EUA vs. Licensure vs. Vaccine Recommendation

- An Emergency Use Authorization (EUA) may be appropriate once studies demonstrate safety and efficacy, before a full formal FDA review
- The FDA **licenses** a vaccine to be used under certain circumstances
 - e.g. “2 doses, separated by at least 12 months, in persons aged 18 years or older; contraindicated in pregnancy”
- The ACIP **recommends** use in specific age groups
 - e.g. “2 doses, separated by 12-18 months, recommended for persons aged 65 years or older, and 1 dose in persons aged 18-64 years who have chronic heart or lung disease; give booster dose during an outbreak”
- ACIP recommendations are typically more detailed than FDA licensure
- There may be differences between the groups for whom a vaccine is licensed vs. recommended.



Sarah Ravenhall

Executive Director
NYSACHO



**County
Health Officials
of New York**

Leading the way to healthier communities

The Local Health Department's Role in COVID-19 Vaccine Distribution

Sarah Ravenhall, MHA, CHES

Executive Director

The New York State Association of County Health
Officials



Representing the 58 LHDs in NYS

- Technical assistance
- Inform public health policy
- Advocacy
- Regulatory review
- Bipartisan voice for LHDs
- Training
- Workgroup structure for policy review
- Liaison between state and County Health Officials



Public Health At the Helm of Disease Outbreak for Decades

- Surveillance
- Contact tracing/Case Investigation
- Quarantine/Isolation
- Informing the public and providing education
- Issuing and enforcing orders when needed
- MCM/PODs-vaccine distribution



Citizens in Laredo, Texas, receive typhoid vaccinations in 1954.
© CDC

Applicable NYS Public Health Legal References Related to Immunization

- Public Health Law Article Six
 - 602 1. (b) Communicable disease control, which shall include activities to control and mitigate the extent of infectious diseases.
 - 602 1. (f) Public health emergency preparedness and response, including planning, training, and maintaining readiness for public health emergencies.
 - 602 2. (a-d) d: (d) actions to assure that services necessary to achieve agreed upon goals are provided.
 - 613 – municipality local programs of immunization
- Public Health Law Section 2168 Entry into NYSIIS



Counties and LHDs are Prepared

- PHEP and CRI Activities (Annual)
 - POD plans revised 11/20 to specify COVID-19
 - Emergency Drills, exercises, tabletops
 - Training and working with partner organizations
 - Incorporating vulnerable populations in planning efforts
- Preparation for Distribution of COVID-19 Vaccine
 - Enrolled as NYS Provider Distribution Sites
 - Assessed cold storage capability
 - Enlisting volunteers for POD activities SERV NY, Medical and non-medical reserve corps





Medical Countermeasures (MCM)

- Vaccines, antiviral drugs, antibiotics, antitoxins, chemical antidotes
- Function to mitigate or treat adverse health effects during public health emergency
- Delivered via Strategic National Stockpile (SNS) which manages MCMs at the federal level
- LHDs dispense MCMs to partners and the public through a coordinated system using PODs



Fact Sheet: Medical Countermeasures (MCM) and Points of Dispensing (POD) Basics www.cdc.gov/cpr/readiness

What are Points of Dispensing (PODs)?

- Run by Local Health Department Staff and Volunteers (Serv NY, Medical and Non-Medical Reserve Corps)
- Community locations in which state and local agencies dispense MCMs to the public during a public health emergency
 - Open: public-facing; community setting
 - Closed: agency-managed; in tandem with open PODs



Who are our Community Partners in Vaccine Distribution?

- Long-Term Care Facilities (nursing homes, adult care facilities, assisted living)
- Congregate settings (OPWDD, camps, farm-workers)
- Federally Qualified Health Centers
- Community Health Centers
- Rural Health Clinics
- Private Providers
- Schools, colleges and universities
- Businesses
- Volunteers
- Religious Leaders



Incorporating Elements of Health Equity

- States and localities know their vulnerable populations best
- Black and Hispanic communities due to increased COVID-19 mortality
- Request for federal flexibility allowing states and locals to prioritize vaccine distribution based on high-risk populations and localize information



Local Health Department Role as Outlined in New York State Plan

- Support state-identified priorities and initiatives
- Storage/administration of product
- Implement local mass vaccination plans
- Develop protocols for building public trust in the vaccine
- Work with community providers and partners to ensure availability of supplies and product



Legal Considerations and Resources

- Public Readiness and Emergency Preparedness (PREP) Act
- CDC Website: *Fact Sheet: Legal Issues for Health Care Providers and Their Attorneys*
- Review your County Plans for health, safety and security protocols

Legal Issues Fact Sheet for Health Care Providers and Their Attorneys

| | |
|--|--|
| What is the Public Readiness and Emergency Preparedness? | <p>The PREP Act authorizes the Secretary of the U.S. Department of Health and Human Services (HHS) to issue a "PREP Act Declaration" that provides immunity from tort liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of disaster countermeasures.</p> <p>A list of standing and past PREP Act declarations can be found at http://www.phe.gov/preparedness/legal/prepact/pages/default.aspx.</p> |
| What is the Stafford Act? | <p>On request by any state governor, The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) authorizes the President of the United States to declare a state of emergency. Declarations under the Stafford Act activate response by federal emergency management agencies.</p> |
| What is the National Emergencies Act (NEA)? | <p>The NEA authorizes the President to declare a national emergency. A declaration under the NEA does not give any specific emergency authority. However, it does allow other federal statutory emergency authorities to be activated.</p> |
| What is the Public Health Service Act (PHSA)? ¹ | <p>The PHSA gives legal authority to HHS in responding to emergencies. Specifically, PHSA Section 319 authorizes the HHS secretary to determine that a public health emergency exists. Similar to the NEA, this determination triggers other emergency powers that permit federal governments to address the public health emergency.</p> |
| What is the Social Security Act (SSA) Section 1135 waiver? | <p>When authorized, Section 1135 waivers ensure that sufficient health care services are available to meet the needs of individuals enrolled in SSA programs when and where a public health emergency occurs. The HHS secretary is authorized to waive or modify a number of reimbursement requirements including, but not limited to, licensure, sanctions under Emergency Medical Treatment and Active Labor Act (EMTALA), and sanctions regarding Health Insurance Portability and Accountability Act (HIPAA) privacy regulations.</p> |
| How do they all work together? | <p>The PREP Act <u>does not</u> require a public health emergency determination for the secretary to make a PREP Act declaration. The Stafford Act, NEA, and PHSA <u>all require</u> a declaration or determination to take effect. Section 1135 waivers are only authorized after a Stafford Act or NEA declaration <u>and</u> a PHSA determination have been made.</p> |

¹ <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/Public-Health-Service-Act%2c-Section-319-Fact-Sheet/>



What funding is available to support these activities?

- PHEP Contract
- Immunization Action Plan Funding (ELC Supplemental)
- Article 6 (ITPH set at 50% reimbursement)
- Federal Funding

FOR IMMEDIATE RELEASE

September 23, 2020

Contact: HHS Press Office

202-690-6343

media@hhs.gov

Administration Announces \$200 million from CDC to Jurisdictions for COVID-19 Vaccine Preparedness

The Department of Health and Human Services (HHS) is announcing upcoming action by the Centers for Disease Control and Prevention (CDC) to provide \$200 million to jurisdictions for COVID-19 vaccine preparedness.

Potential Challenges to Prepare For

- Funding availability, parameters, restrictions
- Drained and stretched thin public health workforce
- Vaccine hesitancy
- Groups opposing vaccine and potential security concerns
- Product challenges (ultra-cold storage; two-dose vaccines, etc.)
- ***KEY: Federal-State-Local partnership; Supportive Local Elected Officials; Protecting Public Health***

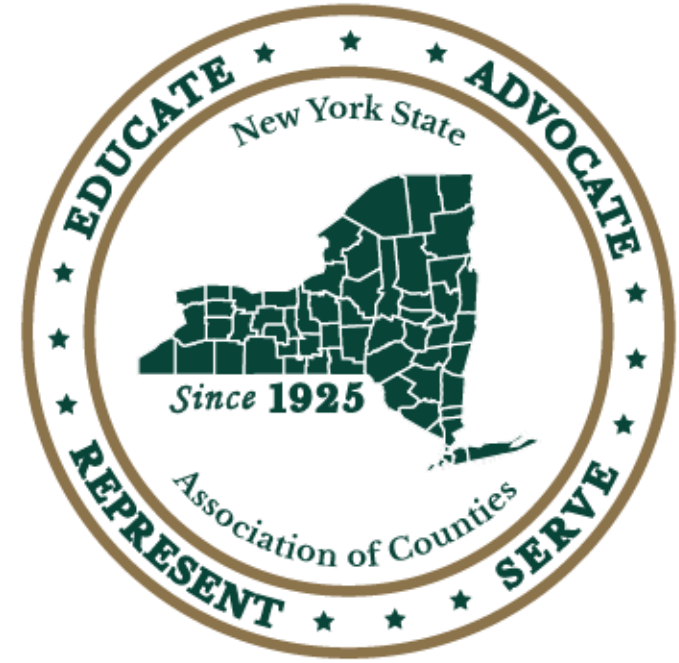


County Government and Local Health Departments are Heroes!

- Thank you to county elected officials and leadership for your relentless commitment to serving the public during this pandemic.
- Thank you to our State and Federal partners!



QA



NYSAC Thanks Our Webinar Sponsor:



Maureen Hagen, Regional Vice President

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“The world is preparing to deliver one of the largest mass vaccination campaigns in human history, managing the process of safely distributing effective COVID-19 vaccines to potentially billions of people will be extremely challenging, but is of critical importance to the health of our population. Salesforce understands the need for a carefully managed process that is scalable, mobile and cloud-based.”