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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

**Limited Doses Available**
- Constrained supply
- Highly targeted administration required to achieve coverage in priority populations

**Large Number of Doses Available**
- Likely sufficient supply to meet demand
- Supply increases access
- Broad administration network required, including surge capacity

**Continued Vaccination, Shift to Routine Strategy**
- Likely excess supply
- Broad administration network for increased access

**Example populations**
- HCPs
- First responders
- People with high-risk conditions
- Older adults in congregate settings
- Non-healthcare critical workers
- People in congregate settings
- All other older adults
- Young adults
- Children
- Other critical workers
- All others in the US who did not have access in previous phases

Illustrative scenario for planning purposes; will be adapted based on clinical / manufacturing information on all OWS candidates & vaccine prioritization
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

11/19/20
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
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
Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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)
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

Sources: https://www.fda.gov/media/139638/download, https://www.fda.gov/media/142749/download
Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- Independent advisory group that reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products and provides input upon request of the FDA. 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
  o Cost and insurance coverage
  o Complexity/ease of use
  o Health disparities, justice and accessibility
  o 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
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, table tops
  • 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
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
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
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!
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.”