



**NYC Health Care Coalition (NYCHCC) Leadership Council
Meeting co-hosted with Borough of Queens Emergency
Preparedness Coalition**

**NYC DOHMH Office of Emergency Preparedness and Response
Bureau of Healthcare and Community Readiness**

Thursday, January 21, 2021



Welcome!

Agenda

AM

- | | |
|----------------------|--|
| 10:00 – 10:03 | <i>Arrivals / Welcome</i>
Taina Lopez , Sr. Manager Planning and Strategy, Healthcare System Readiness, OEPR, Bureau of Healthcare and Community Readiness, NYC DOHMH |
| 10:03 – 11:00 | <i>Vaccine Distribution- BQEPC</i>
Greg Wayrich , Emergency Preparedness Coordinator/Borough Coalition Lead, New York Presbyterian/Queens
Borough of Queens Emergency Preparedness Coalition Partners |
| 11:00 – 11:03 | <i>DOHMH Session Remarks</i>
David J. Miller, Jr. , Executive Director, Healthcare System Readiness, OEPR, Bureau of Healthcare and Community Readiness, NYC DOHMH |

Agenda...cont.

AM	
11:03 – 11:30	COVID-19 Vaccine: New York City Jennifer Rosen , MD, Director Epidemiology and Surveillance, Bureau of Immunization/ Director, Vaccine Hesitancy Branch, COVID-19 Response, NYC DOHMH
11:30 – 12:00	NYCPDC: Pediatric Response to COVID-19 Michael Frogel , MD, Co-Principal Investigator, New York City Pediatric Disaster Coalition Chairman, National Pediatric Disaster Coalition Steven G. Kernie M.D., Chief, Pediatric Critical Care and Hospital Medicine, Acting Chief, Pediatric Cardiology Morgan Stanley Children's Hospital Dr. Bruce Greenwald , Chief of the Division of Pediatric Critical Care Medicine, Executive Vice-Chairman of the Department of Pediatrics, Weill Cornell Medicine
12:00	Adjournment



Vaccine Distribution- BQEPC

Greg Wayrich, Emergency Preparedness Coordinator/Borough Coalition Lead, New York Presbyterian/Queens

Borough of Queens Emergency Preparedness Coalition Partners

The Borough of Queens Emergency Preparedness Coalition



COVID-19 Vaccine Distribution

JANUARY 21, 2021

Agenda

- ▶ Planning
- ▶ Space
- ▶ Staffing
- ▶ Supplies & Equipment
- ▶ Vaccine Storage & Transport
- ▶ Staff Education & Communication
- ▶ Scheduling & Tracking
- ▶ Public Relation
- ▶ NYS & NYC Reporting
- ▶ Long Term Care



Salsman, S. (2020). Retrieved from <https://abcnews.go.com/Health/pfizer-moderna-companies-developed-covid-vaccine/story?id=74291125>

Planning

- ▶ Identify Space, Staff, Stuff
- ▶ Staff Prioritization
- ▶ Hours of Operation
- ▶ Emergency Code Team Involvement

▶ **Challenges**

- ▶ Little information provided from external agencies until a few days prior to vaccine delivery
- ▶ Rapidly changing information

▶ **Opportunities**

- ▶ Collaborative efforts between departments
- ▶ Leadership very involved

Space

- ▶ Unidirectional Flow; 1 Room Per Function
 - ▶ **Triage** → **Vaccination** → **Evaluation**
 - ▶ Triage: X2 personnel w/ seated waiting area
 - ▶ Vaccination: X4 stations w/ supply cart and X1 station for Pharmacist
 - ▶ Evaluation: X2 observers w/ X4 recliner seats w/ station numbers, crash cart, and stretcher
- ▶ Ventilation
 - ▶ X1 HEPA filter per room
- ▶ Pharmacy
 - ▶ Room nearby for reconstitution and prep

▶ Challenges

- ▶ Finding a space large enough for operations that allow social distancing and meet room ventilation requirements
- ▶ Unable to acquire stretcher chairs for the evaluation area

▶ Opportunities

- ▶ Smooth operation and no line formation
- ▶ Effective communication b/t Pharmacist in vaccination area and prep

Staffing

- ▶ Utilized Flex Staffing Within Institutions/Systems
- ▶ In-House Volunteers to Support Future Vaccinations
- ▶ Traveler resources, though onboarding can be long process

▶ Challenges

- ▶ New personnel on-site frequently that is not familiar w/ site
- ▶ Access to correct area of EMR for both new and in house staff
- ▶ Facilities with limited resources shifting between COVID surge and vaccine PODs
- ▶ Smaller sites have challenges with manpower/space constraints

▶ Opportunities

- ▶ In-house staff able to support hospital operations without causing impact at some sites
- ▶ Many staff members volunteered to assist in the vaccine operation
- ▶ OR/PACU/Med staff reassigned as load changes

Supplies & Equipment

It's Not Just the Vials!



Supplies

- ▶ Syringes
- ▶ Needles (2 per injection)
- ▶ Alcohol prep pads (for vial and skin)
- ▶ Exam gloves in all sizes
- ▶ Blue underpads
- ▶ Alcohol-based hand sanitizer
- ▶ Surface disinfectant wipes
- ▶ Adhesive bandages
- ▶ Forms and handouts
- ▶ Stationery
- ▶ Buttons, lollipops, etc.

Equipment

- ▶ ULT freezer (and PPE)
- ▶ Freezer, refrigerator
- ▶ Work stations for pharmacists
- ▶ Work stations for intake
- ▶ Work stations for injection
- ▶ PCs/LTs, scanners, printers, copiers
- ▶ Waste containers: trash, confidential, sharps
- ▶ Barricades, stanchions, etc.
- ▶ Resuscitation: EpiPen, O₂, BVM, AED *crash cart (?)*
- ▶ Stretcher, wheelchair

Supplies & Equipment

▶ Challenges

- ▶ Vaccination / Testing / Patient care
 - ▶ Personnel
 - ▶ Materiel
 - ▶ Space
- ▶ Quantities – a moving target
 - ▶ Eligibility?
 - ▶ Demand?

▶ Opportunities

- ▶ Protect our people
- ▶ Protect the public
- ▶ **Crush the curve!**

Vaccine Storage & Transport

- ▶ Frozen Vaccine Stored in Pharmacy
- ▶ Transport Request
- ▶ Transport Logistics
- ▶ Emergency Management Concerns

▶ **Challenges**

- ▶ Pfizer / BioNTech COVID-19 Vaccine – Stored in ULTF at -80°C
- ▶ Moderna COVID-19 Vaccine – Stored in standard freezer
- ▶ Freezer temperature monitoring
- ▶ Vaccine security oversight

▶ **Opportunities**

- ▶ Identify and implement safeguards sooner
- ▶ Equipment tested and ready

Security

- ▶ Preplanning for vaccine
- ▶ Internal security measures
 - ▶ Access control
 - ▶ Temp warning
 - ▶ Video cameras
 - ▶ Security Present 24/7
- ▶ Arrival and escorting delivery
- ▶ Transport
- ▶ Pharmacy during transports
- ▶ Outside people coming for vaccination

▶ **Challenges**

- ▶ Designing an appropriate storage and delivery system
- ▶ Access control including people coming for vaccine
- ▶ Multitude of guidance and needs to support program

▶ **Opportunities**

- ▶ Interagency contact
- ▶ “Get it done”
- ▶ Review of POD plans

Staff Prioritization

- ▶ NYS “Guiding Principles” Excerpts
 - ▶ Equitable and clinically driven distribution
 - ▶ Transparency
 - ▶ Use of data
 - ▶ Partnership, coordination, and public outreach
 - ▶ NEW YORK TOUGH

Staff Prioritization

- ▶ ED's and ICU's ≥ 60 y/o (any function)
- ▶ ED's and ICU's (any age, any function)
- ▶ Other high risk areas or activities
- ▶ All med/surg units
- ▶ All patient-facing personnel
- ▶ All personnel
- ▶ Dynamic, controlled, **communicated**

▶ **Challenges**

- ▶ Perceptions of "fairness"
- ▶ Clarity
- ▶ Transients / floaters / cross-covering

▶ **Opportunities**

- ▶ Promote vaccine campaign

Staff Education & Communication

- ▶ Direct Messaging
 - ▶ Text messaging (Intrado)
 - ▶ Blast email (HR/OHS)
 - ▶ Link pointing to information
 - ▶ Department Leadership
 - ▶ Q&A sessions
 - ▶ Virtual Meetings
 - ▶ Unit Based
 - ▶ In-direct messaging
 - ▶ Screen savers
 - ▶ Signage
 - ▶ Encouraged word-of-mouth
- ▶ **Challenges**
 - ▶ Employee prioritization
 - ▶ Keeping messaging consistent with current guidance
 - ▶ Competing with social media myths
 - ▶ Ensuring leadership support
 - ▶ **Opportunities**
 - ▶ Setting up a hotline to allow for anonymous Q&A session
 - ▶ Working with union representatives to encourage the vaccine

Scheduling & Tracking

- ▶ Evolving process
 - ▶ Contact staff through System Employee Health Portal/Emails
 - ▶ Creating records for staff not in EMR
 - ▶ Amount of POD staff & space directly related to schedule availability, especially in light of social distancing requirements
 - ▶ Appointment time greatly shortened over time
 - ▶ Lengthy registration process
 - ▶ NYS form electronically completed
- ▶ **Challenges**
 - ▶ Appointments filled up quickly and booked a month ahead, or conversely mistrust of vaccine meant low demand in beginning
 - ▶ Eligibility-uneven demand
 - ▶ Appointments in 5s then 6s
 - ▶ Walk-ins
 - ▶ No shows
 - ▶ **Opportunities**
 - ▶ Ability to schedule at other system hospitals
 - ▶ Automated e-mail and text reminders
 - ▶ Low-tech scheduling options for elderly population

Public Relations

- ▶ Press Conference
- ▶ Social Media
 - ▶ Employee Vaccine photos
 - ▶ Facebook/Twitter
 - ▶ #COVIDVaccine
 - ▶ Buttons/Stickers
- ▶ Employee Video
 - “I got mine you should to”
- ▶ Employee Newsletter
- ▶ Non-Affiliated Community Physician Partners
- ▶ Challenges
 - ▶ Consistent message
 - ▶ Keeping with the guidance
 - ▶ Employee Prioritization

External Reporting

- ▶ System/network HQ
 - ▶ NYCDoHMH
 - ▶ NYSDoH HERDS
 - ▶ COVID-19 Patient / Bed / Vaccine
 - ▶ MIS-C
 - ▶ Remdesivir
 - ▶ Influenza
 - ▶ CIR or NYSIS
 - ▶ NHSN (LTC, ESRD)
 - ▶ GNYHA SitStat 2.0
 - ▶ OCME
 - ▶ HHS
- ▶ **Challenges**
 - ▶ Updated information requirements made without advance notice
 - ▶ Short turnaround times
 - ▶ **Opportunities**
 - ▶ ESSENTIAL for regional decision-making, planning, resource allocation, risk communication, etc.
 - ▶ Collaborative effort among agencies
 - ▶ Standardized definitions, timeframes
 - ▶ Periodic review of the need for data elements, reporting frequency, etc.
 - ▶ Share best/promising practices, lessons learned
 - ▶ **Crush the curve!**

Long Term Care- Hospital Affiliated

- ▶ Initial Plan CVS to do staff & residents
 - ▶ CVS first session scheduled for 12/29
 - ▶ Opted to do staff ourselves
 - ▶ LTC staff earlier
 - ▶ OHS Record Keeping
 - ▶ Perception of treating LTC staff differently than hospital staff
- ▶ CVS for residents
- ▶ 1st Session 12/29/2020
 - ▶ **Very good experience!!**
 - ▶ Vaccinated 123 of 183 residents
- ▶ 2nd session scheduled for 1/19
 - ▶ 1st Shot-
 - ▶ New Admits/Changed Mind
 - ▶ 2nd Shot
- ▶ 3rd session scheduled for 2/9
 - ▶ 2nd Shot Only
- ▶ Challenges
 - ▶ Initial communication
 - ▶ Very long telephone wait times
 - ▶ Dedicated CVS POC
 - ▶ Frontend work prior to CVS arrival
 - ▶ Consents
 - ▶ Insurance information

Stand alone Long-Term Care NYCH+H/Coler

- ▶ All of the long term care facilities follow the same protocol for the COVID - 19 vaccine distribution.
- ▶ Partnered with its pharmacy vendor PharmScripts to provide the vaccinations to staff and residents.
- ▶ Pharmscript responsible for storage, transportation, administration of the vaccine, and federal and state reporting requirements.
- ▶ Coler responsible for overall coordination of the on-site vaccine clinic; to include, consents, scheduling, education, notification and tracking

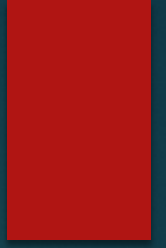
▶ **Challenges:**

- ▶ The vaccine is not mandatory for residents and staff.
- ▶ Continuous education and engagement is necessary to enable staff and residents to agree to the vaccine.
- ▶ Pfizer vaccine needs special freezer requirements and this affects flexibility of scheduling vaccine clinics.
- ▶ At this point the vaccine is only available on scheduled days rather than a daily basis which prolongs the process.

▶ **Opportunities:**

- ▶ Smooth implementation of the administration of the vaccine
- ▶ Staff and resident excitement was apparent and grew throughout the day.
- ▶ More residents and staff members are interested in receiving the vaccine now that others have already received it.

Thank You





DOHMH Session Remarks

David J. Miller, Jr., Executive Director, Healthcare System Readiness, OEPR,
Bureau of Healthcare and Community Readiness, NYC DOHMH



COVID-19 Vaccine: New York City

Jennifer Rosen, MD, Director Epidemiology and Surveillance, Bureau of Immunization/ Director, Vaccine Hesitancy Branch, COVID-19 Response, NYC DOHMH

COVID-19 VACCINES AND VACCINATION PROGRAM IN NYC

AN OVERVIEW FOR HEALTH CARE PROVIDERS

Jennifer Rosen, MD

Director, Epidemiology & Surveillance, Bureau of Immunization

Director, Vaccine Hesitancy Branch, COVID-19 Response

New York City Department of Health and Mental Hygiene

*Information on COVID-19 vaccines is evolving rapidly.
This presentation was last updated January 14, 2021.*

COVID-19 Vaccine Development

COVID-19 Vaccine Development Process

- Same process that has been used for previous vaccines, but expedited because:
 - Built on years of research on related coronaviruses, including research on vaccines for other coronaviruses
 - Substantial funding allowed multiple trials to be run in parallel
 - Funding also allowed companies to begin manufacturing vaccines early, enabling immediate distribution upon approval
- Safety was monitored closely during every phase of development
 - Tens of thousands of clinical trial participants received vaccines safely
- Federal government, state and local health departments, and health care providers have spent months planning for storage, distribution, supplies, and other logistics

Emergency Use Authorization vs. Licensure or Approval

- During a public health emergency, the Food and Drug Administration (FDA) can use Emergency Use Authorization (EUA) to allow use of vaccines before they are officially licensed so that they can be used sooner
- Certain criteria must be met, including that there are no adequate, approved, and available alternatives and that evidence strongly suggests that benefits outweigh any risks to patients
- Vaccines issued an EUA must go through the same clinical trials as all other licensed vaccines
- To support licensure of a vaccine, FDA generally requires at least 6 months of safety follow-up for serious and other medically attended adverse events

<https://fda.gov/news-events/fda-brief/fda-brief-fda-issues-guidance-emergency-use-authorization-covid-19-vaccines>

<https://fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

<https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>

COVID-19 VACCINE DEVELOPMENT AND APPROVAL PROCESS

- Vaccine discovery and development by manufacturers
- Clinical trial Phases I, II, III by manufacturer to assess safety and efficacy
- Manufacturer submits EUA request
- Advisory Committee for FDA votes whether to recommend EUA
- FDA decides whether to issue EUA
- ACIP reviews data and votes to recommend vaccine and appropriate use
- Vaccine shipped for use in phases; post-vaccination monitoring begins

First U.S. COVID-19 Vaccines Authorized and Recommended for Emergency Use

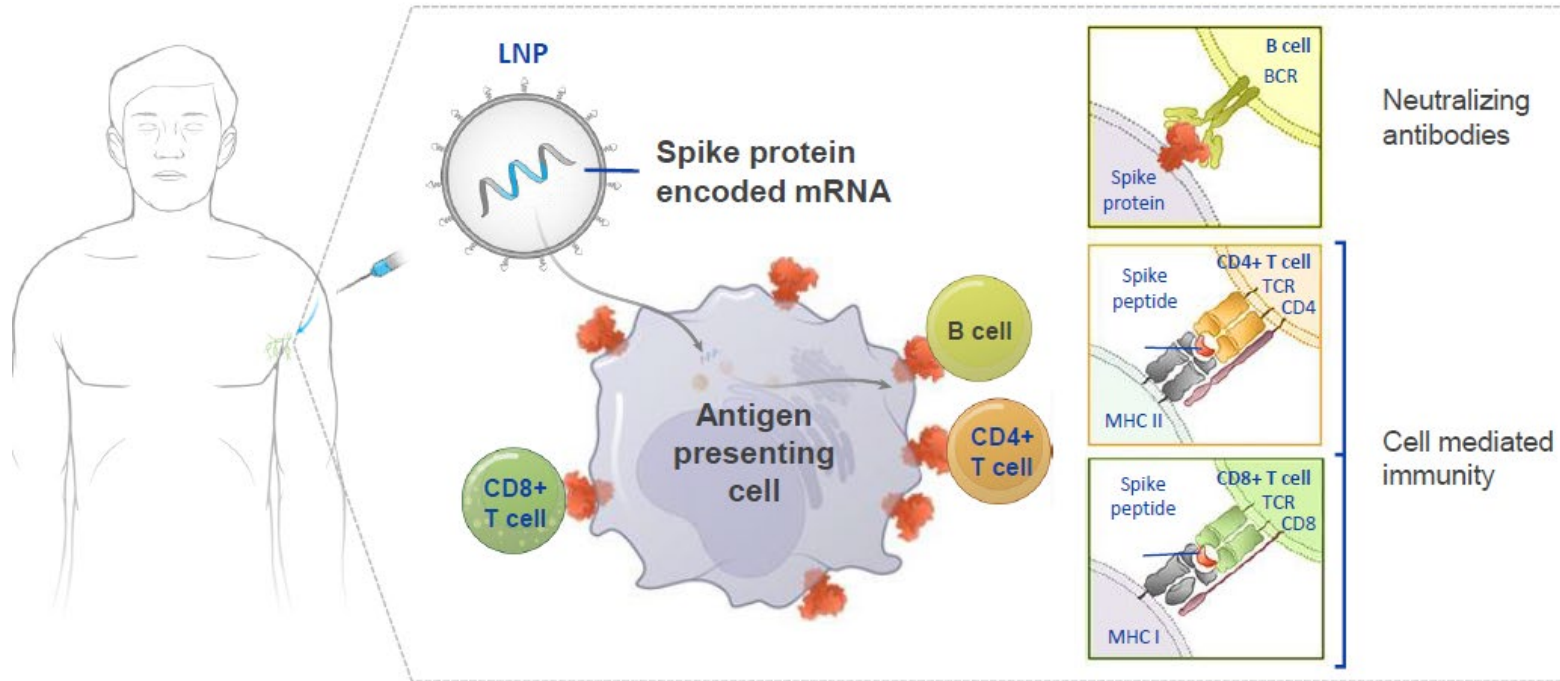
- Emergency Use Authorizations issued for two vaccines
 - Pfizer-BioNTech - 12/11/2020
 - Moderna - 12/18/2020
- Both are mRNA vaccines

The image displays two screenshots of the CDC's 'Vaccines & Immunizations' website. The top screenshot shows the 'Pfizer-BioNTech COVID-19 Vaccine' page. It features a navigation menu on the left with categories like 'For Parents', 'For Adults', and 'COVID-19 Vaccination'. The main content area includes a header for the vaccine, a photograph of vials, and detailed information: General Information (Diluent: 0.9% sodium chloride, Mix before using, Multi-dose vial: 5 doses per vial, Dosage: 0.3 mL), Schedule (2 doses series separated by 21 days), Age Indications (16 years of age and older), and Administration (Intramuscular (IM) injection in the deltoid muscle). Below this are links for 'EUA' and 'Interim Clinical Considerations'.

The bottom screenshot shows the 'Moderna COVID-19 Vaccine' page. It has a similar layout. The main content area includes a header, a photograph of vials, and detailed information: General Information (Multidose vial: 10 doses per vial, Dosage: 0.5 mL), Schedule (2-dose series separated by 28 days), Age Indications (18 years of age and older), and Administration (Intramuscular (IM) injection in the deltoid muscle). Below this are links for 'EUA', 'Interim Clinical Considerations', 'Moderna Covid-19 Vaccine FAQs', and 'ACIP Recommendations'. At the bottom, there is a section for 'Administration Overview' with a link to 'How to Thaw, Prepare, and Administer the Moderna Vaccine'.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

mRNA Vaccines



- Contain genetic material from SARS-CoV-2 but not the actual virus
- mRNA provides instruction directly to the immune system
- Creates specific immune memory in a natural context
- mRNA never enters nucleus of cell; it can neither interact with nor integrate into the cell's DNA and is broken down quickly
- Although this is a new type of vaccine, mRNA vaccines have been studied for over 30 years

Image: <https://www.fda.gov/media/144583/download>

Pfizer-BioNTech and Moderna Vaccine Clinical Trial Findings

	Pfizer-BioNTech	Moderna
Phase III study population	<ul style="list-style-type: none">• > 44,000 volunteers in U.S. and other countries• 26.2% of participants were Hispanic/Latino, 9.8% Black/African-American, and 4.4% Asian• 21.4% of participants were age 65 and older	<ul style="list-style-type: none">• > 30,000 volunteers in U.S.• 20% of participants were Latino, 9.7% Black/African-American, and 4.7% Asian• 25.3% of participants were age 65 and older
Efficacy	<ul style="list-style-type: none">• Overall: 95%• High efficacy maintained across age, gender, race and ethnicity	<ul style="list-style-type: none">• Overall: 94.1%• High efficacy maintained across age, gender, race and ethnicity
Safety	<ul style="list-style-type: none">• No serious safety concerns found	<ul style="list-style-type: none">• No serious safety concerns found

Pfizer-BioNTech vs. Moderna Vaccine: Similarities

- Lipid nanoparticle-formulated mRNA vaccines that encode the perfusion spike glycoprotein (S protein) of SARS-CoV-2
- Require two doses
- Are administered by intramuscular injection
- Cause local and systemic reactogenicity, particularly after second dose
- Are highly effective
- No serious safety concerns identified during Phase III clinical trials

Pfizer-BioNTech vs. Moderna Vaccine: Differences

	Pfizer-BioNTech	Moderna
VIALS*	5 doses per vial	10 doses per vial
DOSAGE	0.3 mL	0.5 mL
STORAGE	Ultracold (-70°C)	-20°C
AGE INDICATIONS	≥ 16 years	≥ 18 years
SCHEDULE	2 doses separated by 21 days	2 doses separated by 28 days

*Additional doses have been reported for Pfizer and occasionally Moderna vials; use these doses to vaccinate

Other COVID-19 Vaccine Candidates in Development

Company	Mechanism	Storage	Doses	Status
AstraZeneca	Viral vector	2-8° C	2	Phase III trial
Janssen	Viral vector	-20° C	1	Phase III trial
Novavax	Protein subunit	2-8° C	2	Phase III trial
Sanofi; GlaxoSmithKline	Protein subunit	2-8° C	2	Phase I/II trial

Clinical Considerations

Expected Reactions After COVID-19 Vaccination

- Clinical trials suggest COVID-19 vaccines often elicit mild to moderate reactions, especially after second dose
- More common in younger compared to older age groups
- Usually occur within the first 3 days of vaccination and resolve within 1-3 days of onset

	Moderna vaccine ¹	Pfizer vaccine ²
Pain at injection site	100%	83%
Fatigue	80%	75%
Headache	60%	67%
Myalgia	53%	58%
Fever	40%	17%

¹Jackson et al. An mRNA Vaccine against SARS-CoV-2-Preliminary report. NEJM 2020;20:1920-1931.

²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.

Prepare Patients for Reactions Expected After COVID-19 Vaccination

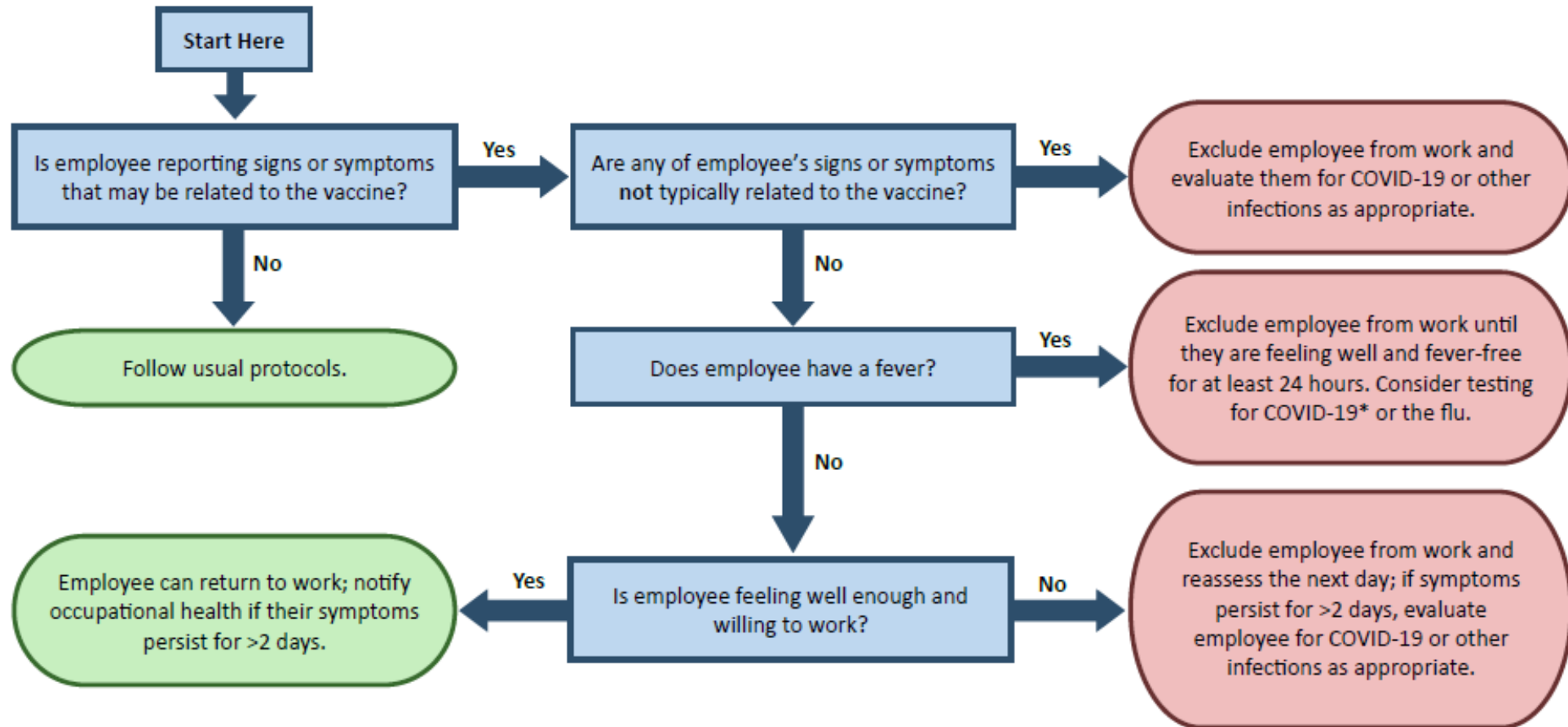
- Before vaccination, counsel patients on expected post-vaccination symptoms
- Unless a person develops a contraindication* to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms, to optimize protection against COVID-19
- Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms
- Routine prophylaxis to prevent symptoms is not recommended due to lack of information on impact of use on vaccine-induced antibody responses

Contraindications to COVID-19 mRNA vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html#Patient-counseling

Post Vaccine Considerations for Health Care Workers



*A nucleic acid amplification (NAA) test is preferred. If an antigen test is used, negative results should be confirmed with an NAA.

Timing of Second Vaccine Dose

- Recommended schedule
 - Pfizer-BioNTech: 3 weeks (21 days) apart
 - Moderna: 1 month (28 days) apart
- Second doses administered within 4 days before the recommended date will be considered valid
 - Grace period for Pfizer: day 17-21; for Moderna: day 24-28
 - However, grace period should not be used routinely to schedule second dose
 - Doses inadvertently administered earlier than the grace period do not need to be repeated
- There is no maximum interval between the first and second dose
- Currently, there are no circumstances under which restarting a COVID-19 vaccine series or giving an extra dose are recommended

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Administration>

Co-Administration with Other Vaccines

- There are no data on safety and efficacy of COVID-19 vaccines when administered simultaneously with other vaccines
 - Ideally, administer COVID-19 vaccines a least 14 days before or after any other vaccine
- However, COVID-19 and other vaccines may be administered within a shorter period if:
 - Benefits of vaccination outweigh potential risks (e.g., tetanus vaccine for wound management) or
 - To avoid potential barriers or delays to COVID-19 vaccination (e.g., long-term care facility residents who received influenza vaccine prior to COVID-19 vaccine availability)
- If inadvertently administered within 14 days of another vaccine, do not repeat doses of either vaccine

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html#Coadministration

Anaphylaxis Following COVID-19 Vaccination

- Anaphylactic reactions after mRNA COVID-19 vaccines have been reported, though uncommon
- 21 reports (11.1 per million doses) detected by the Vaccine Adverse Event Reporting System, Dec 14-23, 2020
- Time from vaccination to onset: median 13 min (range 2-150 min); 71% <15 min
- Age: median 40 years (range 27-60 years)
- Outcomes: 19% hospitalized (3 ICU); 81% treated in EDs; 95% discharged home or recovered at time of VAERS report; no deaths
- Allergy history: 17 (81%) had documented history of allergies or allergic reactions, including to drugs, medical products, food, insect bites; 7 (33%) had past anaphylaxis (including after rabies and flu vaccine)
- No geographic clustering; occurred after doses from multiple vaccine lots

Contraindications to COVID-19 Vaccination

- Contraindications and precautions are updated as experience with the Pfizer and Moderna vaccines increases
- A history of the following is currently considered a contraindication:
 - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
 - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
 - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

*Unless allergist-immunologist determined they can safely receive vaccine (e.g., under observation, in a setting with advanced medical care)

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Precautions to COVID-19 Vaccination

- A history of any immediate allergic reaction to any other vaccine or injectable therapy (IM, IV, SC) is considered a precaution (not a contraindication)
 - Counsel persons with such a history regarding unknown risk for severe reaction and balance this against benefits of vaccination
 - Consider consultation with an allergist-immunologist
- Allergic reactions not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines, or polysorbates are **not** a contraindication or precaution

Observation Period After COVID-19 Vaccination

- 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
- 15 minutes: All other persons

Preparing to Manage Anaphylaxis after COVID-19 Vaccination

- CDC provides guidance on:
 - Early recognition
 - Medication and supplies for assessing and managing
 - Steps to take if anaphylaxis is suspected
 - Considerations for management in older adults and pregnant people
 - Reporting

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following COVID-19 vaccination. Detailed information on CDC recommendations for vaccination, including contraindications and precautions to vaccination, can be found in the [Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](#).

These interim considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination. Institutional practices and site-specific factors may also be considered. In all cases, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.



Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.

Vaccination of Persons with Underlying Medical Conditions

- Clinical trials demonstrated similar safety and efficacy in persons with some underlying medical conditions, including those that place people at [increased risk for severe COVID-19](#), compared to persons without comorbidities
- Individuals in all the following groups may receive COVID-19 vaccination (unless they have a contraindications to vaccination):
 - Immunocompromised persons
 - Persons with autoimmune conditions
 - Persons with a history of Guillain-Barré syndrome
 - Persons with a history of Bell's palsy

Persons with HIV or Immunosuppression

- May be at increased risk for severe COVID-19
- May receive COVID-19 vaccine if they have no vaccine contraindications*
- Data not currently available to establish vaccine safety and efficacy in immunocompromised persons
- Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited
- Counsel patients about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses

*Contraindications to COVID-19 mRNA vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

Persons with Autoimmune Conditions

- May receive COVID-19 vaccine if they have no vaccine contraindications
- Were eligible for enrollment in clinical trials
- Inform patients that no data are currently available on the safety of mRNA COVID-19 vaccines for people with autoimmune conditions
- No imbalances were observed in occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received vaccine compared to placebo

Persons with History of Guillain-Barré or Bell's Palsy

- May receive COVID-19 vaccine if they have no vaccine contraindications
- No cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the vaccine clinical trials
- Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 clinical trials
 - FDA does not consider these above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination

Pregnant or Lactating People

- May choose to be vaccinated
- Pregnant people are at risk for severe illness due to COVID-19
- Limited or no data on safety and effectiveness of vaccines in pregnant and lactating people; however, based on current knowledge, vaccines unlikely to pose risk to pregnant person, fetus, or breastfed infant
- Consider level of COVID-19 community transmission and risk of COVID-19 to the patient and potential risk to the fetus
- Pregnant people who receive COVID-19 vaccine should take acetaminophen if they develop a fever after vaccination, as fever during pregnancy can negatively affect a fetus (acetaminophen is safe in pregnancy)
- American College of Obstetricians and Gynecologists (ACOG) recommends COVID-19 vaccines:
 - Should not be withheld from pregnant people
 - Should be offered to lactating people

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>

People with Prior Infection or Exposure to COVID-19

- People with a history of COVID-19 should be offered vaccination to reduce likelihood of reinfection
 - Since reinfection is uncommon in the 90 days after initial infection, people with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired
- Testing asymptomatic persons for evidence of current or past SARS-CoV-2 infection for the purpose of vaccine decision-making is not recommended
- Defer vaccination for people with acute infection or in quarantine to avoid potentially exposing healthcare personnel and patients to SARS-CoV-2 during the vaccination visit
 - People with acute infection should wait until isolation period has ended
 - Persons exposed to someone with COVID-19 should defer vaccination until completion quarantine

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

People Who Received Monoclonal Antibody or Convalescent Plasma Treatment

- Currently, there are no data on the safety or efficacy of mRNA COVID-19 vaccines in people who received these treatments for COVID-19
- People who received either of these as treatment for COVID-19 should defer vaccination for at least 90 days
 - Precautionary measure until additional information becomes available to avoid interference of the antibody treatment with vaccine-induced immune response

COVID-19 Prevention for Vaccinated Persons

- Protection afforded by vaccine is not optimal until 1-2 weeks after 2nd dose
- No vaccine is 100% effective
- Information is limited on:
 - Vaccine effectiveness in the general population
 - Extent to which vaccination reduces ability to transmit infection
 - Duration of vaccine-related immunity
- Vaccinated persons should continue to:
 - Stay home if sick
 - Wear a face covering
 - Stay at least 6 feet from others whenever possible
 - Practice hand hygiene

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

What is Not Yet Known About COVID-19 Vaccines?

- Duration of immunity provided by vaccination
- Whether vaccination prevents transmission of the virus to others
- Whether additional doses will be needed in the future
- Safety and efficacy for children (clinical trials are ongoing)
- Efficacy in persons with immunosuppression

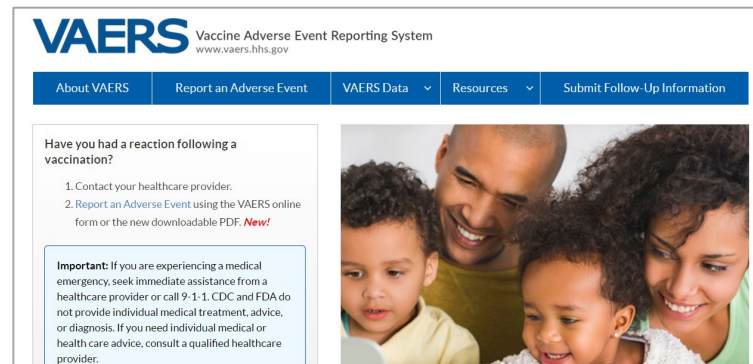
Safety Monitoring

Multiple COVID-19 Vaccine Post-Authorization Safety Monitoring Systems

Monitoring System	Population
Vaccine Adverse Event Reporting System (VAERS)	
<ul style="list-style-type: none"> • VAERS 	All vaccine recipients in U.S.
<ul style="list-style-type: none"> • Veterans Affairs Adverse Drug Event Reporting System 	VA patient populations
<ul style="list-style-type: none"> • Department of Defense Vaccine Adverse Event Clinical System 	DoD patient populations
<ul style="list-style-type: none"> • CDC National Healthcare Safety Network 	Acute care and long-term care facilities
V-Safe	All COVID-19 vaccine recipients eligible
Vaccine Safety Datalink (VSD)	Insured patients in VSD sites
Clinical Immunization Safety Assessment Project (CISA)	Referred cases from US population
Genesis Healthcare	Long-term care facility residents
FDA and Centers for Medicare and Medicaid Services	Medicare recipients
FDA BEST Initiative	Insured patients in BEST sites
FDA Post-licensure Immunization Safety Monitoring System	Insure patients in PRISM sites
Veterans Administration Data	Enrolled VA patients
Department of Defense Medical Surveillance System	Active duty military

Vaccine Adverse Event Reporting System (VAERS)

- Rapid, early warning system for safety signals
- Co-managed by the CDC and FDA
- Clinical review of individual reports received nationwide
- Statistical methods to detect disproportionate reporting of specific vaccine-adverse event



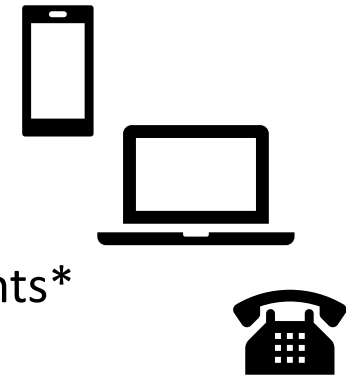
Reporting Adverse Events to VAERS

- Adverse events that occur following COVID-19 vaccination should be reported to VAERS
- Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:
 - Vaccine administration errors
 - Serious adverse events
 - Cases of Multisystem Inflammatory Syndrome
 - Cases of COVID-19 that result in hospitalization or death
- Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event
- Information on how to submit a report to VAERS is available at <https://vaers.hhs.gov> or by calling 1-800-822-7967

V-Safe Tool for Patients



- CDC's new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines
- Health checks via text messages and email
 - Daily for the first week after vaccination
 - Weekly thereafter for 6 weeks post-vaccination
 - Active telephone follow-up with people who report clinically important events*
- All COVID-19 vaccine recipients eligible
- Health care providers should encourage patient participation and provide patients with v-safe enrollment form



*Symptoms or health conditions that cause one to miss work, do normal daily activities, or seek health care
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

COVID-19 Vaccine Distribution in NYC

COVID-19 Vaccine Eligibility, NYS

- Groups eligible as of January 11, 2021 include:
 - Healthcare workers
 - People 65 and older
 - Residents and staff in nursing homes and certain other group living facilities
 - Certain frontline essential workers, such as first responders, teachers and school staff, day care workers, transit workers, and grocery store workers
- Eligibility for COVID-19 vaccination is being expanded rapidly even though supply of vaccine remains very limited
- A detailed, up-to-date list of currently eligible groups and anticipated future availability may be found at: nyc.gov/covidvaccinedistribution



885,325

Doses reserved for NYC



524,425

Doses delivered to NYC



194,501

Received dose 1



18,295

Received dose 2

COVID-19 Vaccine Tracker

1/11/2021, 12 a.m.

Data on doses administered are reported by providers to the Citywide Immunization Registry and may be delayed. Data updated daily:

<https://nyc.gov/site/doh/covid/covid-19-data-vaccines.page>

Begin Discussing Vaccination with Patients

- Even if a patient is not yet eligible to be vaccinated, lay the groundwork for when vaccine becomes more available
- Let patients know that you plan to recommend the vaccine for them
 - Provide information on the benefits and safety of vaccination
- If a patient questions your recommendation, this does not necessarily mean they will not accept it; some questions are to be expected
- Patients consider their providers the most trusted source of information on vaccines, and may simply want *your* answers

CDC. <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html#>

Counseling Patients who Express Concerns

- Start from a place of empathy and understanding
- Assume patients will want to be vaccinated but may have questions
- Give your strong recommendation
 - A provider recommendation is one of the strongest predictors of vaccine receipt
- Listen to and respond to questions in an understandable way
 - Resources: [CDC](#), [CHOP](#), NYC Health Department website and materials
- Wrap up the conversation
 - After answering questions, let patients know you are open to continuing discussion
 - Encourage them to consider scheduling a follow-up visit with you for this reason
 - Tell them where they can find additional information
 - Continue to remind them about the importance of vaccine in future visits

CDC. [Making a strong recommendation for vaccine](#)

Children's Hospital of Philadelphia, Vaccine Education Center. [Evidence to Action Brief: Addressing Vaccine Hesitancy to Protect Children and Communities against Preventable Diseases.](#)

Additional Resources

COVID-19 Vaccines

- NYC Health Department - COVID-19 Vaccine:
 - Public: [nyc.gov/covidvaccine](https://www.nyc.gov/covidvaccine)
 - Providers: [nyc.gov/health/covidvaccineprovider](https://www.nyc.gov/health/covidvaccineprovider)
- Citywide Immunization Registry Reporting Assistance
 - <https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic>
- Vaccine Provider Assistance:
 - Email nycimmunize@health.nyc.gov

General COVID-19 Resources

- 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>
- Dear Colleague COVID-19 newsletters (sign up for *City Health Information* subscription at: [nyc.gov/health/register](https://www.nyc.gov/health/register))
- 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**



NYCPDC: Pediatric Response to COVID-19

Michael Frogel, MD, Co-Principal Investigator, New York City Pediatric Disaster Coalition Chairman, National Pediatric Disaster Coalition

Steven G. Kernie M.D., Chief, Pediatric Critical Care and Hospital Medicine, Acting Chief, Pediatric Cardiology
Morgan Stanley Children's Hospital

Dr. Bruce Greenwald, Chief of the Division of Pediatric Critical Care Medicine, Executive Vice-Chairman of the
Department of Pediatrics, Weill Cornell Medicine



NYCPDC: Pediatric Response to COVID-19

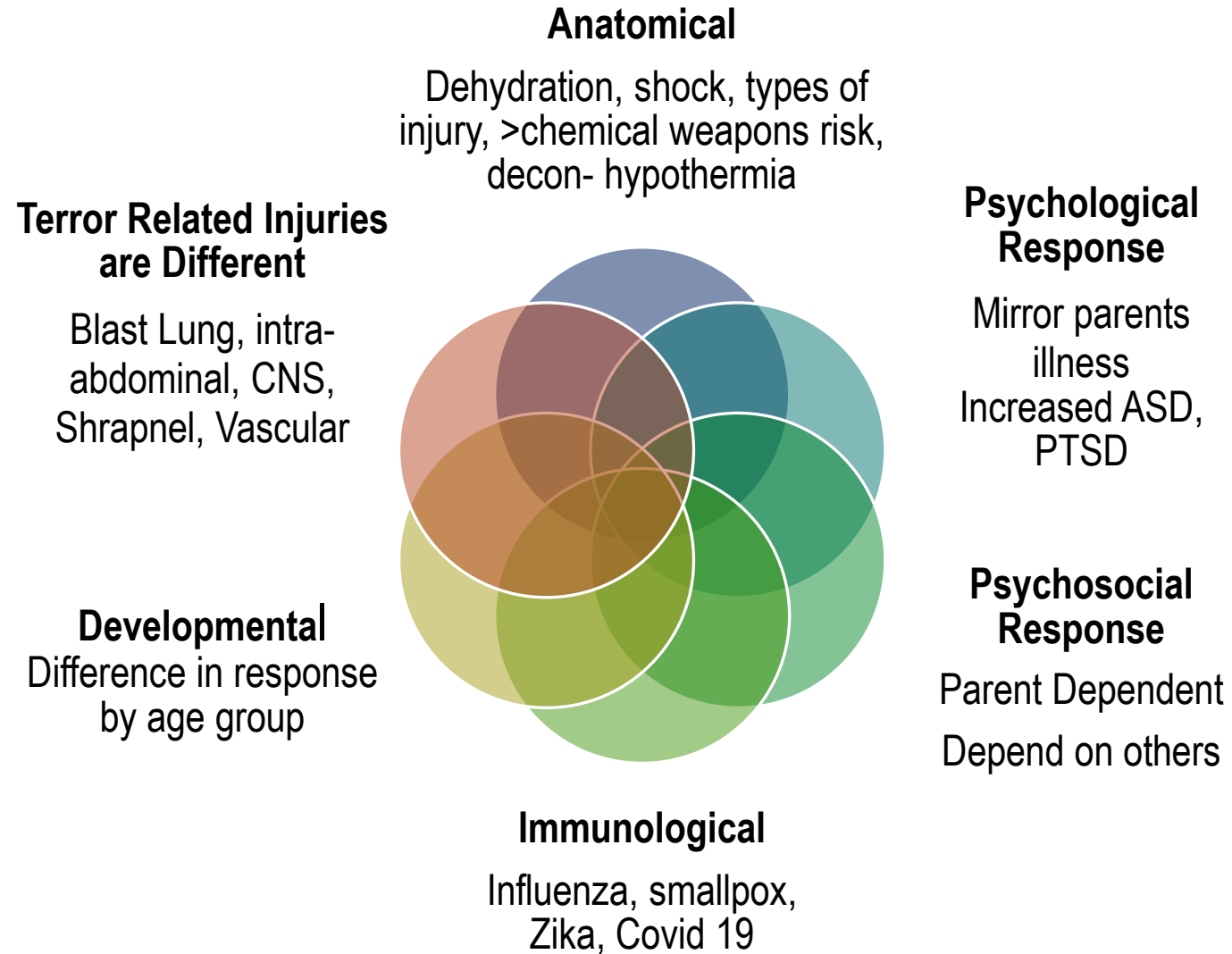
JANUARY 21, 2021 LEADERSHIP COUNCIL MEETING PRESENTATION
NEW YORK CITY PEDIATRIC DISASTER COALITION

Special MCI Considerations: Children Today (United States)

- Estimated 78 million people less than 18 years of age
- Roughly 25% of the population
- Largest vulnerable population
- Disabled children
- Tech dependent children
- >10% living at or near the poverty level
- Environment and Response provided by adults



Children are different!



Therefore, the pediatric plan and response to disasters must be tailored to the special needs of children.



Tsunami, Indonesia



Superstorm Sandy



Tornado, Oklahoma City



Bus crash, Michigan



Moscow theater siege



Beslan school siege



OKC Bombing

Chemical MCI Children more likely to be victims (closer to ground, higher respiratory rate)



Example children have special needs

Pediatric Generic Decon Issues

- Avoid Separation of Families
- Cannot assume parents can decon child plus self
- Older children may resist due to fear, peer pressure, modesty issues
- Risk of Hypothermia if temp $<98^{\circ}$
- Large volume low pressure hand-held hoses
- Beware airway management throughout
- Soap and water only



Pediatric MCI Disaster Planning Considerations

Peds Annex to Overall CEMP

Special Needs of Children

Surge

Evacuation

Transportation (Newborns/Neonates)

Sheltering in Place

Communications (Child/Parent)

Supply Chain (pharmacy, food, shelter, equipment especially for vertical evacuation, Decon, PPE)

Age Specific Disaster Behavioral/Mental Health

Need for Caretakers

Reunification

Resiliency Building

NYC PDC Coalition based Regional Planning and Response



- Established in 2008 to prepare NYC for a catastrophic MCI involving children and their families
- **Multidisciplinary Coalition Membership:** Pediatric disaster medicine experts, NYC hospitals, Outpatient/Urgent care facilities, FDNY/EMS, NYC Emergency Management, DOHMH, Pediatric Long Term Care Facilities, MRC, ASPR/TRACIE - working with an iterative process and literature review
- **Developing Citywide planning and response from:** incident scene triage, to primary transport to tiered pediatric receiving locations, secondary transport, surge and evacuation that are part of the Draft Citywide Pediatric Disaster Plan
- **Creating site specific Guidelines and Template Plans for Surge and Evacuation of:** Pediatric PICUs, NICUs, Obstetric and Newborn Services, and Pediatric Long-term Care, and Outpatient Urgent Care facilities.
- **Creating self use tools and conducting Functional, Tabletop and Full-Scale Exercises to operationalize plans**
- **Increasing pediatric critical care resources through Pediatric Fundamentals of Critical Care Support Courses**
- **Presenting at local, national and international conferences to:** promote pediatric disaster preparedness
- **Responding to real disasters:** H1N1, Superstorm Sandy, Ebola, Haitian earthquake, Covid 19 and creating lessons learned and revision of pediatric disaster planning/response

Demonstrating Success: The PDC NYC 28 Hospital Pediatric Exercise



Exercise included all 28 hospitals that care for pediatric patients in NYC and the following agencies: FDNY/EMS, NYCEM, DOHMH, MRC and the Pediatric Intensivist Response Team (PIRT)

Scope: Hospital surge, communications, activation of the NYC Pediatric Disaster Plan and secondary transport.

Scenario: Explosions on arrival of school buses citywide. 70 patients with critical/non-critical injuries and mental health problems arrive at individual hospitals with/without EMS transport

Selected Outcomes/Lessons Learned:

- 1105 Pediatric inpatient Surge Beds (baseline 1039) – capacity doubled
- 254 PICU Surge Beds (baseline 224 beds) – more than double capacity
- NICU surge beds available after rapid patient discharge: 247
- 304 ED Critical Care Surge Beds/312 ED Non-Critical Care Surge Beds
- 203 OR Surge beds
- 268 Adult Medical ICU Surge Beds/120 Additional Adult Surgical ICU Surge Beds
- 342 Pediatric Ventilator capable surge beds

PDC COVID-19 Related Activities

- Member of NYC HCC Governance Board Representing Pediatric Population
- Participated in daily ESF8 calls to receive and provide situational awareness updates and SME input
- Provided updates on the pediatric response in regard to utilization of Pediatric assets (Space, Staff, Equipment) to provide care for adult patients as well as consolidating pediatric care at selected sites

PDC COVID-19 Related Activities Cont.

- Maintained up to date information on MIS-C and potential ramifications of drug shortages especially IVIG
- Participated in conference with GNYHA, drug providers and distributors to develop response process to potential IVIG shortages.
- Provided ASPR with current information re; NYC pediatric status and contacts with pharmaceutical providers

NYP Pediatric Experience with COVID-19: ICU Adaptations to Multi-system Inflammatory Syndrome in Children (MIS-C)

Bruce Greenwald, MD
Steve Kernie, MD

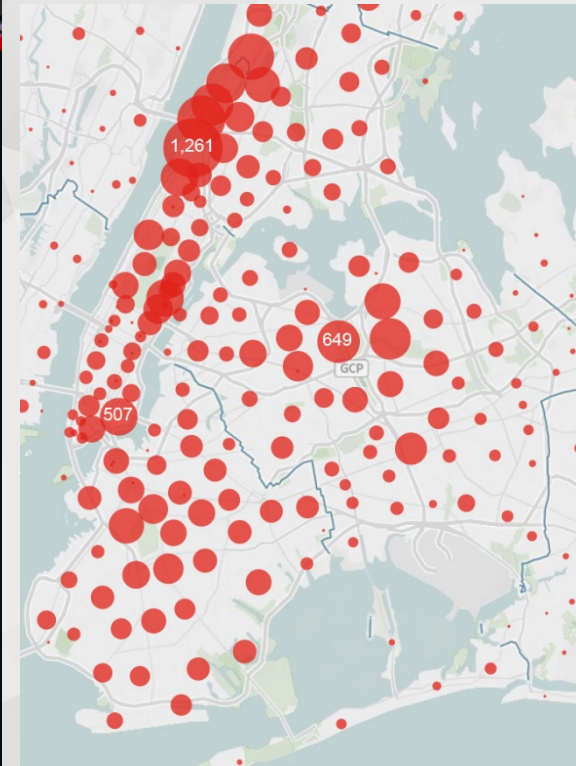
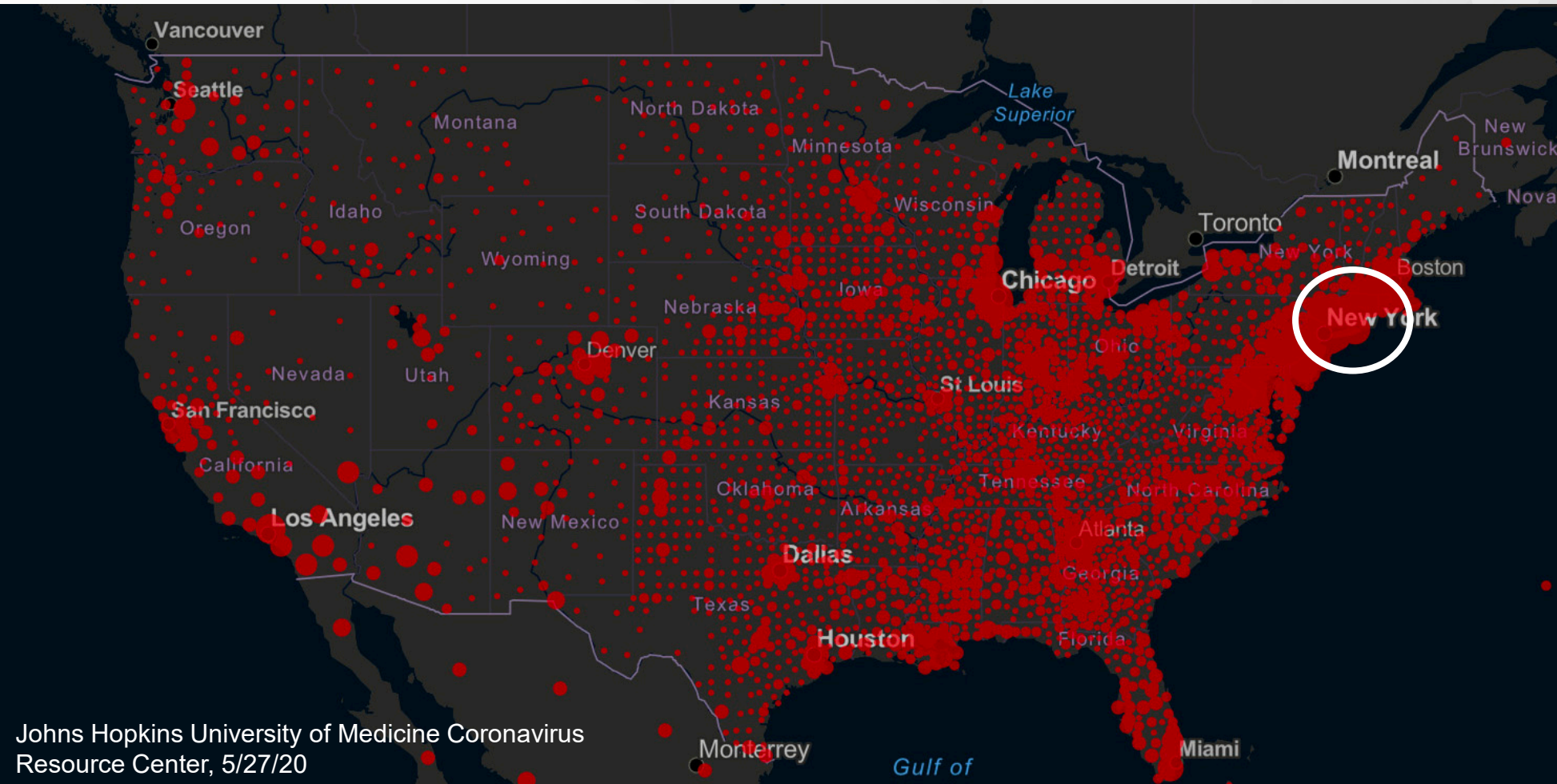


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Timeline for COVID patients at NYP/MSCH

- March 13 Admitted first pediatric COVID-19 patient
- March 20 Ceased all elective surgical cases; surgeries limited to emergent cases only
- March 25 Regionalized all pediatric care in the New York Presbyterian enterprise (9 hospitals) to the Morgan Stanley Children's Hospital
- March 25 Admitted first adult COVID-19 patient to PICU
- April 18 Admitted first Multisystem Inflammatory Syndrome pediatric patient
- May 11 Resumed limited urgent surgeries/procedures
- May 14 Transferred last adult patient to the MICU



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NYP Pediatric Intensive Care Unit Restructuring

Capacity:

- Increased ICU bed capacity by incorporating ~20 beds from step-down unit

Staffing:

- Increased ICU faculty/fellow coverage
- Deployed nursing and respiratory teams to adult care
- Designated triage roles to facilitate system-wide coordination

Bedside Care:

- Positioned IV pumps and ventilator consoles outside of rooms
- Coordinated bedside care with ICU nurses, respiratory therapists, PT/OT
- Balanced optimal patient care and safety of healthcare workers



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NYPH - Weill Cornell Experience

- March 25- Decision to close NYP-Weill Cornell PICU
- March 26- All patients discharged/ transferred to NYP-Morgan Stanley PICU
- March 27-29- Physical transformation
 - Multi-bed neutral pressure rooms outfitted w/ floor to ceiling barriers and HEPA filters
 - Medical supplies transitioned to adult CVLs, A-lines, chest tubes, NG tubes, Foleys, etc.
 - Automated medication dispenser reconfigured, and restocked
 - Physiologic monitors alarms reset to adult parameters
- March 30- First adult admission (COVID respiratory failure)
- April 2- Unit at capacity with 20 intubated COVID patients
- May 15- Unit closed in preparation for return of pediatric patients



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Weill Cornell Staff Transformation

- PICU attendings
 - 1 hour Zoom orientation
 - Initial pairing with adult intensivist or hospitalist and IM residents (2 weeks)
 - Subsequent pairing with MICU fellow and IM or pediatric residents, with available in-house adult intensivist (primarily covering other units)
- PICU nurses and PAs - 3-day 'just-in-time' training included:
 - 2 MICU shifts paired with experienced adult practitioners
 - Orientation to adult ventilator management
 - Standardized (non-weight based) medication/continuous infusion dosing
 - MICU documentation
 - No ACLS training
 - Didactics – Donning and doffing, ARDS, proning



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Weill Cornell Outcomes

- 60 patients with COVID-19 related critical illness admitted to PICU over 7 weeks-
 - Median age 67 years (interquartile range: 53-72 years)
 - 53 (88%) Intubated/ received mechanical ventilation for median of 18 days
 - 18 (30%) required renal replacement therapy (CVVH or peritoneal dialysis)
 - 17 (28%) expired
 - Mortality rates did not differ from those cared for in adult units



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SARS-CoV-2 Testing During Pandemic

SARS-CoV-2 Nasopharyngeal PCR testing (nasal swab)

- Shortage of nasopharyngeal swabs and testing media – at first only symptomatic/suspected cases (ER and ICU only) → ALL hospital admissions (ED and Transfers) → pre-procedural testing (inpatient AND outpatient)

SARS-CoV-2 Serology testing (blood)

- First tested with patients late April 2020
- Currently testing all pediatric patients suspected to have multisystem inflammatory syndrome related to COVID-19



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15 Children Are Hospitalized With Mysterious Illness Possibly Tied to Covid-19

The health authorities in New York City issued an alert saying that the children had a syndrome that doctors do not yet fully understand.

The New York Times Published May 5, 2020



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

May 6, 2020

TO: Hospital Operators, Health Care Providers, Health Care Facilities, Clinical Laboratories, and Local Health Departments
FROM: New York State Department of Health (NYS DOH) Bureau of Communicable Disease Control (BCDC)

**HEALTH ADVISORY: PEDIATRIC MULTI-SYSTEM INFLAMMATORY SYNDROME
POTENTIALLY ASSOCIATED WITH CORONAVIRUS DISEASE (COVID-19)
IN CHILDREN**



"All the News
That's Fit to Print"

The New York Times

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NEW YORK, MONDAY, MAY 18, 2020

\$3.00

Late Edition

Today: periodic clouds and sunshine, high 61. Tonight: plenty of clouds, breezy, low 53. Tomorrow, mostly cloudy, breezy, cooler, high 60. Weather map appears on Page A24.



An incident at the Marathon Petroleum plant in River Rouge, Mich., last year released a pungent gas and spurred a stay-at-home order.

Virus Is Yet Another Deadly Risk In Shadows of U.S. Smokestacks

By HIROKO TABUCHI

This isn't the first time Vicki Dobbins's town has been forced to shelter in place. Last year, the Marathon Petroleum refinery that looms over her neighborhood near Detroit emitted a pungent gas, causing nausea and dizziness among neighbors and prompting health officials to warn people to stay inside. When a stay-at-home advisory returned in March, this time for the coronavirus, "it was just devastating," Ms. Dobbins said. Ms. Dobbins, who is 76, later contracted Covid-19, and spent two weeks on oxygen in intensive care. Now she has a question. "Do the polluters in our area make us more susceptible to asthma, bronchitis, heart failure, cancers?" she asked. "Is the virus just going to be one of the ones added to that list?" Nationwide, low-income com-

Continued on Page A8

Biden Pursues Ideas to Match Scale of Crisis

Left Senses an Opening
for a Bolder Agenda

By ALEXANDER BURNS

More than 36 million Americans are suddenly unemployed. Congress has allocated \$2.2 trillion in aid, with more likely to be on the way as a fight looms over government debt. Millions more people are losing their health insurance and struggling to take care of their children and aging relatives. And nearly 90,000 are dead in a continuing public health catastrophe.

This was not the scenario Joseph R. Biden Jr. anticipated confronting when he accepted the Democratic nomination on a conventional left-of-center platform. Now, with Mr. Biden leading President Trump in the polls, the former vice president and other Democratic leaders are racing to assemble a new governing agenda that meets the extraordinary times — and they agree it must be far bolder than anything the party establishment has embraced before.

So far, neither Mr. Biden nor Mr. Trump has defined in itemized terms what an agenda for the first 100 days of a new presidency in the coronavirus era might look like. But on the Democratic side, far more than within the Republican Party, there is an increasingly clear sense of the nature and scale of the goals a new administration would pursue.

Mr. Biden's campaign has been rapidly expanding its policy-drafting apparatus, with the former vice president promising on Monday to detail plans for "the right kind of economic recovery" within weeks. He has already effectively shed his primary-season theme of restoring political normalcy to the country, replacing it with promises of sweeping economic change.

On Wednesday, Mr. Biden signaled anew that he was willing to reopen his policy platform, announcing six policy task forces — severe inflammatory syndrome and the coronavirus that has already been identified in about 200 children in the United States and Europe and killed several.

The condition, which the Centers for Disease Control and Prevention are calling Multisystem

Continued on Page A11

POMPEO IS FACING FRESH QUESTIONS ON USE OF ASSETS

FIRING RAISES RED FLAG

Democrats See a Pattern
of Abuse by a Shrewd
Trump Loyalist

By EDWARD WONG

WASHINGTON — Secretary of State Mike Pompeo swatted away questions about his use of government resources again and again last year.

In January, news reports cited unnamed diplomats complaining about his wife, Susan, traveling with him across the Middle East during a partial government shutdown.

In the summer, members of Congress began examining a whistle-blower complaint accusing Mr. Pompeo of asking diplomatic security agents to run errands like picking up restaurant takeout meals and retrieving the family dog from a groomer.

And in October, a Democratic senator called for a special counsel to investigate his use of State Department aircraft and funds for frequent visits to Kansas, where he was reported to be considering a Senate run.

In each case, Mr. Pompeo or other department officials denied wrongdoing, and the secretary moved on unscathed. But his record is now coming under fresh scrutiny after President Trump told Congress on Friday night that he was firing the State Department inspector general — at Mr. Pompeo's private urging, a White House official said.

The inspector general, Steve A. Linick, who leads hundreds of employees in investigating fraud and waste at the State Department, had begun an inquiry into Mr. Pompeo's possible misuse of a political appointee to perform personal jobs for him and his wife, according to Democratic aides.

That included walking the dog, picking up dry-cleaning and making restaurant reservations, one said — an echo of the whistle-blower complaint from last year.

The details of Mr. Linick's investigation are not clear, and it may be related to the previous allegations. But Democrats and other

Continued on Page A19

Tracking an Outbreak Medical Mysteries

YOUTH AFFLICTION

'Straight-Up Fire' in His Veins: Teen Battles New Syndrome

From Page A1

Inflammatory Syndrome in Children, has shaken widespread confidence that children were largely spared from the pandemic. Instead of targeting lungs as the primary coronavirus infection does, it causes inflammation throughout the body and can cripple the heart. It has been compared to a rare childhood inflammatory illness called Kawasaki disease, but doctors have learned that the new syndrome affects the heart differently and erupts mostly in school-age children, rather than infants and toddlers. The syndrome often appears weeks after infection in children who did not experience first-phase coronavirus symptoms.

At a Senate hearing last week, Dr. Anthony S. Fauci, a leader of the government's coronavirus response, warned that because of the syndrome, "we've got to be careful that we are not cavalier and thinking that children are completely immune to the deleterious effects."

Jack's recovery and the experience of other survivors are Rosetta stones for doctors, health officials and parents anxious to understand the mysterious condition.



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Signs and Symptoms of MIS-C Related to COVID-19

Most Common Symptoms

- Fever – high for many days
- Gastrointestinal Symptoms (85%)
 - Abdominal Pain and Guarding
 - Nausea/Vomiting
 - Diarrhea
- Rash (75%)
- Conjunctivitis (68%)
- Lip Redness/Swelling (40%)
- Neuro: Lethargy and Headaches (40%)

Less Common Symptoms

- Myalgias (35%)
- Respiratory Symptoms (30%)
- Lymphadenopathy (30%)
- Skin Desquamation (8%)
- Neuro: focal deficits, seizures (5%)



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MIS-C at NYP Morgan Stanley Children's Hospital

- First case on April 18, 2020
- As of 5/31/20, 52 cases admitted
 - ~54% admitted to the PICU for shock and vasoactive support
 - PICU admission before 5/5/20 = 84%, after 5/5/20 = 31%
- Majority with no prior co-morbidities (>90%)
- Male 48%, Female 52%
- Caucasian 30%, Black 28%, Hispanic 30%, Unknown 12%



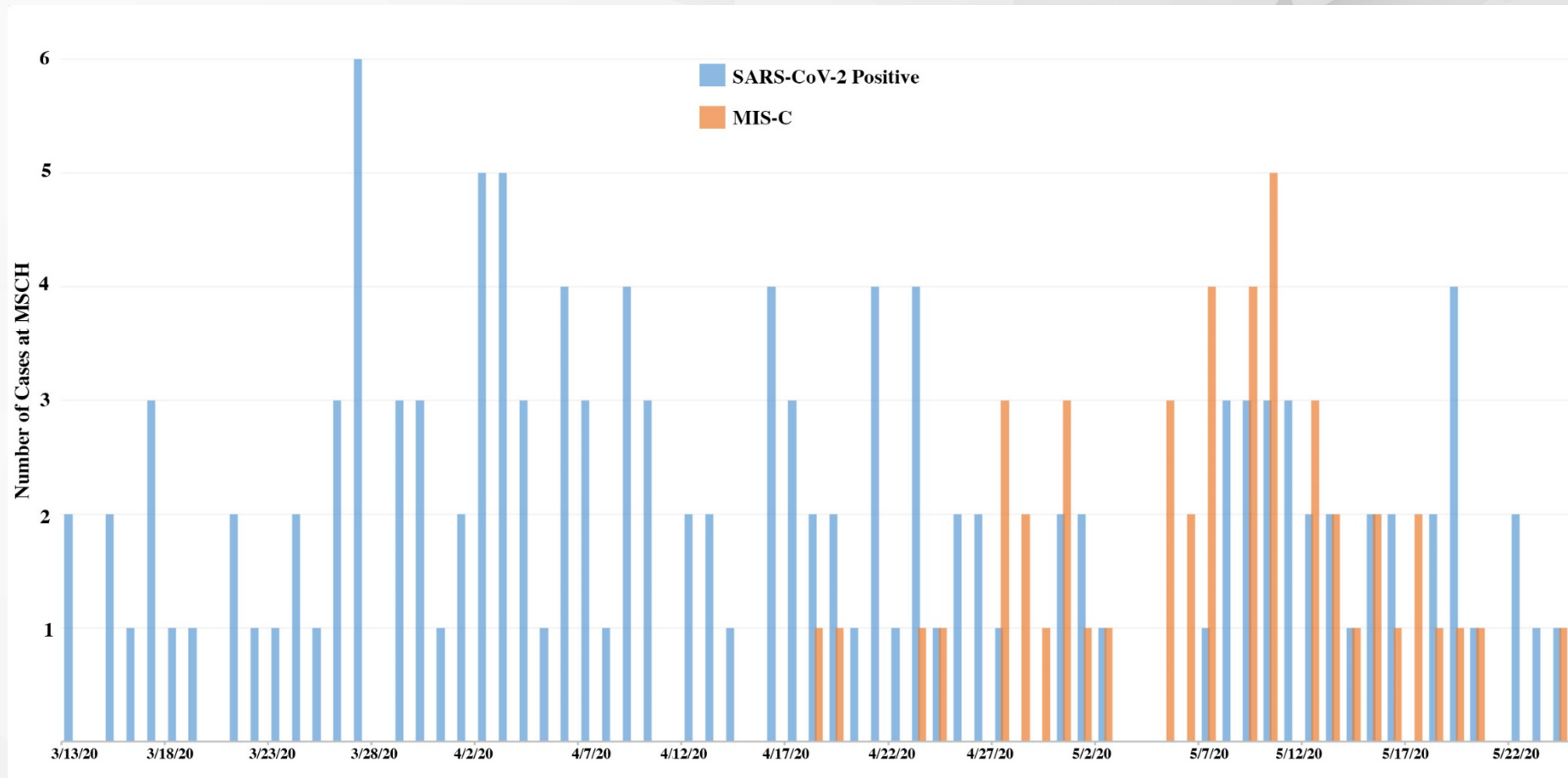
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Epidemiology of SARS-CoV-2 Positive Testing and MIS-C



Outcomes in Children with MIS-C at New York Presbyterian

Over 300 total COVID-19 patients treated at MSCH (two deaths)

- 29 adults with COVID-19 in the PICU at MSCH (one death*)
- 70 children with MIS-C (no deaths)
 - All children currently home and healthy
 - One child developed a coronary artery aneurysm which resolved with treatment
 - Decreased ICU admissions from 80% to <50%
 - Decreased length of stay from 8 days to 4 days
 - Disseminated treatment guidelines around the world
 - Experience published in JAMA, Pediatric Critical Care Medicine



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Lingering Questions about MIS-C

- Pathophysiology of disease – infectious vs post-infectious?
- Immunologic profile of patients – to understand disease and target therapy
- Genetic sequencing – why is this affecting some children but not others?
- Regional differences – differences in the host vs virus?
- Long-term sequelae – on-going surveillance

For Additional Reading...

Rapid Transition of a PICU Space and Staff to Adult Coronavirus Disease 2019 ICU Care

Wasserman, Emily MD; Toal, Megan MD; Nellis, Marianne E. MD, MS; Traube, Chani MD; Joyce, Christine MD; Finkelstein, Robert MD, CM; Killinger, James S. MD; Joashi, Umesh MBBS; Harrington, John S. MD; Torres, Lisa K. MD; Greenwald, Bruce M. MD; Howell, Joy MD

https://journals.lww.com/pccmjournal/Abstract/9000/Rapid_Transition_of_a_PICU_Space_and_Staff_to.97919.aspx

Critical Care for Coronavirus Disease 2019: Perspectives From the PICU to the Medical ICU

Joyce, Christine L. MD; Howell, Joy D. MD; Toal, Megan MD; Wasserman, Emily MD; Finkelstein, Robert A. MDCM; Traube, Chani MD; Killinger, James S. MD; Joashi, Umesh MBBS; Greenwald, Bruce M. MD; Nellis, Marianne E. MD, MS

https://journals.lww.com/ccmjournal/fulltext/2020/11000/critical_care_for_coronavirus_disease_2019_.1.aspx

Future Considerations

Monitor ongoing pediatric epidemiology surveillance

Consider surge activities needed, in-regard to, utilization of pediatric resources

- ED
- Inpatient
- PICU

Pediatric Disaster Mental Health (Developing PICU and Overall Guidance for patients, parents and providers)

Therapeutics and Vaccine availability to the Pediatric population (Currently Monoclonals 12>, Pfizer 16 and >).

Consider overall situational awareness, centralized control and command citywide to best match pediatric resources to needs.

Comments and Questions?



Thank you for you time!

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Adjournment



Thank you!