## THE COVID-19 VACCINES AN UPDATE FOR HEALTHCARE WORKERS

A Three-hour Interprofessional Symposium Sponsored by the 1199SEIU Training and Employment Funds



# Sandi Vito

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Newark, NJ

### The Development of COVID-19 Vaccines: A "Pandemic Speed"

1199SEIU Training and Employment Funds January 24, 2021

Chris T. Pernell, MD, MPH, FACPM Chief Strategic Integration and Health Equity Officer









- First confirmed case in the US reported on January 20, 2020<sup>1</sup>
- Record number of cases confirmed in one day: 314K on January 8, 2021<sup>2</sup> and over 24.5M+ US cases to date<sup>3</sup>
- ~116,000+ current hospitalizations in the US<sup>4</sup>
- 410,000+ deaths in the US and rising<sup>3</sup>; tracking to be the 3<sup>rd</sup> leading cause of death in the US in 2020<sup>5</sup>
- CDC estimates there have been ~376,000+ cases among healthcare workers and ~1275 deaths<sup>6</sup>

### Fast and Slow Pandemics: COVID-19 and Earthquakes of Devastation in Black and Brown Communities

# According to the most recent data compiled by the Color of Coronavirus project:

- 1 in 595 Indigenous Americans has died
- ✤ 1 in 735 Black Americans has died
- 1 in 895 Pacific Islander Americans has died
- 1 in 1,000 Latino Americans has died
- ✤ 1 in 1,030 White Americans has died
- ✤ 1 in 1,670 Asian Americans has died





#### Adjusted for age, other racial groups are this many times more likely to have died of COVID-19 than White Americans

Reflects mortality rates calculated through Jan. 5, 2021.



Indirect age-adjustment has been used.

Source: APM Research Lab + Get the data - Created with Datawrapper



### **COVID-19 Hospitalization and Death by Race/Ethnicity: Racism as a Pre-existing Condition**

"Race and ethnicity are risk markers for other underlying conditions that impact health including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers." (CDC, November 30, 2020)

Rate ratios compared to White, Non- Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non- Hispanic persons	Black or African American, Non- Hispanic persons	Hispanic or Latino persons
Cases <sup>1</sup>	1.8x	0.6x	1.4x	1.7x
Hospitalization <sup>2</sup>	4.0x	1.2x	3.7x	4.1x
Death <sup>3</sup>	2.6x	1.1x	2.8x	2.8x

### How Did We Get Here: A Pandemic Speed

#### COVID-19 Vaccinations in the United States

Overall US COVID-19 Vaccine Distribution and Administration

Total Doses Distributed	Total Doses Administered	Number of People Receiving 1 or More Doses	Number of People Receiving 2 Dos
41,411,550	20,537,990	17,390,345	3,027,865

#### U.S. COVID-19 Vaccine Administration by Vaccine Type





View: Total Doses Administered People Receiving 1 or More Doses People Receiving 2 Doses Total Doses Distributed

Metric: O Count Rate per 100,000

Total Doses Administered Reported to the CDC by State/Territory and for Selected Federal Entities per 100,000





### Key Steps Along the Pathway to Vaccine Emergency Use Authorization (EUA) and Phased Distribution: Health Equity Implications

FDA has established several criteria for the COVID vaccine approval process

- Vaccine trials must be large enough to demonstrate safety and efficacy (i.e. many thousands)<sup>1</sup>
- FDA expects the vaccine would prevent disease or decrease its severity in at least 50%<sup>1</sup> of people who are vaccinated
- Must include diverse populations<sup>2</sup> in all phases of clinical development, including populations most affected by COVID-19, specifically communities of color, as well as adequate representation in late phase trials of elderly individuals and those with medical comorbidities





### Steckelberg, A., Johnson, C.Y., Florit, G., Alcantara, C. (2020, November 23). These are the top coronavirus vaccines to watch. *Washington Post.* https://www.washingtonpost.com

How long it took to develop other notable vaccines

Polio: 7 years (1948-1955) Measles: 9 years (1954-1963) Chickenpox: 34 years (1954-1988) Mumps: 4 years (1963-1967) HPV: 15 years (1991-2006) Coronavirus Average vascu development 10.7 year Iniversity SPITAL Newark, NJ

DATE	MILESTONE
December 1	Covid-19 illness documented (unpublicized Nov 17 <sup>th</sup> )
January 10	SARS-CoV-2 virus sequenced
January 15	NIH designs mRNA vaccine in collaboration with Moderna
March 16	Moderna Phase 1 2 trial begins
May 2	Pfizer/BioNTech Phase 1 2 trial begins
July 14	Moderna Phase 1 2 trial published in NEJM
July 27, 28	Moderna and Pfizer/BioNTech Phase 3 trials begin
August 12	Pfizer/BioNTech Phase 1 2 trial published in Nature
October 22, 27	Enrollment in both Phase 3 trials complete; >74,000
November 9	Pfizer/BioNTech reports interim analysis efficacy > 90%
November 16	Moderna announces interim analysis efficacy > 94.5%
November 18	Pfizer/BioNTech announces 95% efficacy as final result
November 20	1 <sup>st</sup> EUA submitted by Pfizer/BioNTech
December 11; December 12	FDA granted Emergency Use Authorization of Pfizer/BioNTech; CDC approved use in persons <a> 16</a>
December 14	Phase 1a Vaccination begins for health care workers
December 18; December 19	FDA granted EUA of Moderna; CDC approved use in persons $\geq$ 18

# How Is the Coronavirus Vaccine Development Different?

- Government has taken on the financial risk of COVID vaccine development
  - ✓ The US gov't invested \$9.5B+ to speed up development and jumpstart manufacturing before testing is finished
  - Removed the financial disincentives to manufacture vaccines before a drugmaker knows they will work
  - ✓ NIH entered into public-private-partnerships with drug companies where hundreds of millions of dollars in funding have allowed specific companies to expedite the process and raise large-scale nationwide trials (e.g., Moderna, J&J, AstraZeneca)



# How Is the Coronavirus Vaccine Development Different?

- New technologies have given researchers new tools
  - ✓ Synthetic genetic material can be delivered into the body's cells, making them into factories to produce specific proteins, which then trigger a robust immune response
  - ✓ Skipping otherwise time-consuming steps such as manufacturing viral proteins or growing the whole virus in chicken eggs
- Pfizer and Moderna are the only two vaccine candidates that specifically use mRNA technologies
  - $\checkmark$  Have the advantage of speed can be designed and manufactured quickly
  - $\checkmark$  RNA vaccine research made significant advances over the last 10-15 years
  - ✓ In particular, research on past outbreaks (MERS and SARS) gave scientists key insights on the approach



### Black Americans Significantly Trail in Covid Vaccinations

The percentage of those vaccinated who are Black is far lower than their share of both the general population and the health care workforce. Most people who have been vaccinated are health workers.



NOTE: The 12 states shown are those that report race separately from ethnicity; four other states with incomparable data were excluded. Covid vaccinations for which the race of the recipient is unknown were excluded.

CREDIT: Hannah Recht/KHN

SOURCE: Data from state health departments as of Jan. 14, 2021; American Community Survey 2019; Integrated Public Use Microdata Series





### **Demonstrating Trustworthiness and Building Trust**



#### Perspective

**Jniversitv** SPITA

Newark, NJ

#### Trustworthiness before Trust — Covid-19 Vaccine Trials and the Black Community

Rueben C. Warren, D.D.S., Dr.P.H., M.Div., Lachlan Forrow, M.D., David Augustin Hodge, Sr., D.Min., Ph.D., and Robert D. Truog, M.D.







University HOSPITAL

Newark, NJ





## Dr. Shobha Swaminathan, MD

Director of HIV Programs University Hospital, Newark, NJ Associate Professor of Medicine Rutgers New Jersey Medical School



# COVID-19 Vaccine Update

## Shobha Swaminathan, MD Director of HIV Programs Associate Professor of Medicine Rutgers New Jersey Medical School





Severe Acute Respiratory Syndrome Coronavirus-2 (SARS CoV-2)

- 85.6 million cases worldwide
- 1.85 million deaths worldwide
- 23 million cases in the US
- >390,000 deaths in the US
- Finding a safe and effective vaccine is critical

## Why is this important in Minority Communities

Rate ratios compared to White, Non- Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non- Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases <sup>1</sup>	1.8x	0.6x	1.4x	1.7x
Hospitalization <sup><math>2</math></sup>	4.0x	1.2x	3.7x	4.1x
$Death^{\frac{3}{2}}$	2.6x	1.1x	2.8x	2.8x



https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html; Accessed January 16, 2021



Company	Platform	Dosing	Phase 3	Sample size
Moderna	mRNA	2 doses (0,28)	Published	30,000
Pfizer/ Biontech		2 doses (0,21)	Published	44,000
Astra Zeneca	Adeno- virus vector	2 doses (0,28)	Published	30,000
Janssen		1 dose	Enrolled	45,000
Novavax	Recombin ant protein	2 doses (0,21)	Started enrollment	30,000
Sanofi/GSK		2 doses (0,21)	Starting soon	30,000

Current Phase 3 Vaccine Studies in US

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## mRNA Approaches

- Eliminates need to work with the virus directly
- Facilitated early vaccine development
- mRNA with lipid nanoparticle
- <u>Does not integrate with host</u> <u>genome</u>
- Disintegrates after a short time in the body





#### Phase 1 and 2 studies showed that it was Moderna safe and possibly effective Second dose showed better neutralizing mRNA-1273 antibody titers Vaccine Safety and efficacy supporting Phase 3 study

- Established safety and effectiveness in animal models

KS Corbett et al. N Engl J Med 2020;383:1544-1555.; Widge, A. T., et al. (2020). New England Journal of Medicine

100 mcg, 2 doses28 days apart

# Moderna **mRNA-1273** Vaccine Phase 3 **COVE** Study

- 30,420 enrolled
- 1:1 Phase 3 randomized, stratified, observer-blinded, placebo-controlled trial
- Symptomatic COVID-19 14 days after second dose of vaccine among seronegative participants
  - Two designated symptoms AND one sample PCR positive for SARS-CoV-2

## **COVE Study Demographics**

Comorbidities



https://www.modernatx.com/sites/default/files/content\_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.p.,

Solicited Local and **Systemic Adverse Events** 

- Slightly worse after second dose but generally got better within 48 hours
- Local
  - Pain, redness or swelling
- Systemic
  - Headache and fatigue commonest
  - Muscle and joint pains
- Older people tolerated it better

## Vaccine Efficacy

- 94 % effective in preventing symptomatic COVID-19
- Effective in all age groups, sex, racial groups and underlying risk factors
- 93.2% effective in Whites and 97.5% effective in communities of color


# Other Key Points

- <u>100% effective</u> in preventing severe COVID-19
- Received EUA approval Dec 18, 2020
- Approved for ALL ADULTS >18 years
- Pediatric study to start soon

# Pfizer/ BionTech BNT162b2

 Animal models and Phase I/II studies showed that vaccine safe and likely effective

• 30 mcg, 21 days apart used for phase 3



Pfizer/ Biontech Phase 3 Study

- N=44,820 screened
- 49% female
- 83% White, 9% Black, 28% were Latinx
- 21% had at least one coexisting condition
- Median age was 52 years, and 42% of participants were >55 years old



## Local and Systemic Reactions

- Participants >55 years had fewer adverse events
- No increase after the 2nd dose
- Local
  - Pain, Redness and swelling
- Systemic
  - Fatigue and headache (approx. 50%)
  - Chills and muscle pain (approx. 35%)
  - Fever was reported in 11%-16% after second dose
- 28% and 45% reported use of anti-pyretic medications after first and second dose respectively



# Vaccine Efficacy

- Vaccine was 95% effective in preventing COVID-19
- Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group
- No difference in effectiveness by age, sex, race or underlying health conditions
- Received EUA Dec 11, 2020
- Approved for >16 years of age

## Allergic Reactions

- Likely related to lipid nano-particle
- No anaphylaxis reported in either study
- Few cases of allergic reactions to mRNA vaccines have been reported
- EXTREMELY RARE and ALL PERSONS RECOVERED

## Allergic Reactions

- Persons who have experienced mild or moderate allergic reaction (hives, swelling) to first dose should <u>not</u> receive second dose
- Allergies to food and medications is not a contraindication to mRNA vaccines
- Persons allergic to PEG or polysorbate should <u>not</u> receive mRNA COVID-19 vaccine

# Other Key Points



## Pregnant and Breast Feeding Women

- 13 pregnancies occurred in the mRNA-1273 study
- 23 pregnancies in the BNT162b2
- mRNA are not live vaccines
- Consider vaccination based on risk group
- Pregnancy test prior to vaccination is not recommended



https://www.fda.gov/media/144434/download; https://www.fda.gov/media/144246/download; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html;

Oliver, S. E., et al. (2021). ACIP, December 2020." MMWR Morb Mortal Wkly Rep 69(5152): 1653-1656

## Myths about COVID Vaccines

- Vaccines were developed too quickly so they are not safe
- Vaccines will cause long term side effects
- The vaccine will give you COVID-19
- If you had COVID-19, you don't need to get vaccinated
- If you have underlying health problems or suppressed immune system, you should not take the vaccine
- Vaccines will alter your DNA
- You can stop wearing masks etc. after vaccination

## **Ongoing Monitoring**

- Study participants followed for 12-25 months
- http://vsafe.cdc.gov
- Vaccine Adverse Event Reporting System or VAERS
- Almost 38 million vaccinated worldwide
- 13 M people vaccinated in the US



# Vaccines are coming but.....

- <u>W</u>ear a mask
- Watch your distance
- <u>W</u>ash your hands

- As of January 21, 2021
- Over 16 million vaccinations in the US
- 54 million worldwide

Vaccines don't prevent disease VACCINATIONS prevent disease



#### COVPN

#### **Research Team**

Participants

RCAB

Community Partners

844 782 6765 researchwithaheart@njms.rutgers.edu







## **Zeynep Sumer-King**

#### **Vice President**

Regulatory and Professional Affairs Greater New York Hospital Association



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## **NYS Vaccination Plan**

Zeynep Sumer King GNYHA



### <sup>52</sup> NYS COVID-19 Vaccine Plan

#### Framework

- Goal: Vaccinate all NYers that wish to be vaccinated as quickly as possible.
   NYS-NYC Integration
  - New York City is receiving a direct allocation from CDC
- Regional hubs to act as coordinating entities – NYC is a hub

#### Phases

Phase 0. No vaccine. Planning period.

Phase 1. Limited supply of vaccine doses available.

Phase 2. Large number of vaccine doses available.

Phase 3. Sufficient supply of vaccine for entire population.



## <sup>53</sup> Vaccine Distribution Phases





## <sup>54</sup> Currently Eligible Populations: 1A

Clinical and non-clinical health care
 Long-term care
 Congregate care settings





## <sup>55</sup> Currently Eligible Populations: 1B

Phase 1b: As of Monday,

January 11

#### **Older Adults**

• People ages 65 and older

#### **Grocery Workers**

• Public-facing grocery store workers



## **Currently Eligible Populations: 1B**

#### First Responders and Support Staff for First

#### **Responder Agencies**

• Fire Service

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- State Fire Service, including firefighters and investigators (professional and volunteer)
- Local Fire Services, including firefighters and investigators (professional and volunteer)
- Police and Investigations
  - State Police, including Troopers
  - State Park Police, DEC Police, Forest Rangers
  - SUNY Police
  - Sheriffs' Offices
  - County Police Departments and Police Districts
  - City, Town and Village Police Departments
  - Transit of other Public Authority Police Departments
  - State Field Investigations, including Department of Motor Vehicles, State Commission of Correction, Justice Center, Department of Financial Services, Inspector General, Department of Tax and Finance, Office of Children and Family Services and State Liquor Authority

- Public Safety Communications
  - Emergency Communication and Public Safety Answering Point Personnel, including dispatchers and technicians
- Other Sworn and Civilian Personnel
  - Court Officers
  - Other Police or Peace Officers
  - Support of Civilian Staff for any of the above services, agencies or facilities

#### Corrections

- State Department of Corrections and Community Supervision
   Personnel, including correction and parole officers
- Local Correctional Facilities, including correction officers
- Local Probation Departments, including probation officers
- State Juvenile Detention and Rehabilitation Facilities
- Local Juvenile Detention and Rehabilitation Facilities



## <sup>57</sup> Currently Eligible Populations: 1B

#### P-12 Schools, College and Child Care

- P-12 school or school district faculty or staff (includes all teachers, substitute teachers, student teachers, school administrators, paraprofessional staff and support staff including bus drivers)
- Contractors working in a P-12 school or school district (including contracted bus drivers)
- In-person college instructors
- Licensed, registered, approved or legally exempt group child care
- Licensed, registered, approved or legally exempt group child care providers
- Employees or support staff of licensed or registered child care setting
- Licensed, registered, approved or legally exempt child care providers
- State Office of Children and Family Services:
  - State operated staff
  - Licensed or certified residential programs staff and eligible residents

#### **Public Transit**

- · Airline and airport employees
- Passenger railroad employees
- Subway and mass transit employees (MTA, LIRR, Metro North, NYC Transit, Upstate Transit)
- Ferry employees
- Port Authority employees
- Public bus employees

#### **Homeless Shelters**

- People living in a homeless shelter where sleeping, bathing or eating accommodations must be shared with people who are not part of their household
- People working (paid or unpaid) in a homeless shelter where sleeping, bathing or eating accommodations must be shared by people who are not part of the same household, in a position where there is potential for interaction with shelter residents

#### **Other Residential Programs and Supportive Housing**

- Staff and residents of residential programs for victims of domestic violence and family type home for adults
- Staff and residents of unlicensed congregate supportive housing



## 58 Future Eligibility

Phase	Eligible Groups
Phase 1b: Likely starting February 2021	<ul> <li>Other frontline essential workers (to be determined by New York State)</li> <li>Other at-risk groups (to be determined by New York State)</li> </ul>
Phase 1c: Likely starting March- April 2021 Likely includes:	<ul> <li>People with certain underlying health conditions (to be determined by New York State)</li> <li>All other essential workers (to be determined by New York State)</li> </ul>
Phase 2: Likely starting Summer 2021	All other people



## <sup>59</sup> The Evolving NYS COVID-19 Vaccine Plan

#### Evolving NYS strategy

- NYS-operated mass vaccination sites
  - 20 planned; 13 currently operational
  - " "High Demand-High Output"
- Expanded provider network
- Expanded priority groups
  - □ 1A, 1B, 65+
  - 7 million vaccine-eligible NYers

#### Factors driving these changes

- Limited vaccine supply
  - 250,000 doses/week statewide
- Sluggish start to vaccinations
  - Holidays, hesitancy, overly prescriptive guidance
- IT/Scheduling issues



### <sup>60</sup> Where to get vaccinated

### Where you work—you will be prioritized.

Another health care provider (e.g., hospital, FQHC, pharmacy)

In NYC: https://vaccinefinder.nyc.gov/

In NYS: https://am-ieligible.covid19vaccine.health .ny.gov/





## Kevin Cranston, MDiv

Assistant Commissioner and Director Bureau of Infectious Diseases and Laboratory Sciences, Massachusetts Department of Public Health



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#### Vaccine information for the general public

#### When can I get a COVID-19 vaccine in MA?



#### COVID-19 Vaccine Plan >

Massachusetts is preparing for the safe, equitable, and effective delivery of an FDA-approved COVID-19 vaccine. The state's planning is based on guidance from the CDC and the MA COVID-19 Advisory Group. It includes logistics, distribution, staff recruitment, and more.

For more information on vaccine distribution visit Mass.gov/COVIDvaccine



https://www.mass.gov/covid-19-vaccine-in-massachusetts



**≡** Menu

#### COVID-19 Vaccine in Massachusetts

🔄 🌐 Select Language 🗸

a State Organizations

🛃 Log In to...

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Massachusetts is preparing for the safe, equitable, and effective delivery of an FDA-approved COVID-19 vaccine. Learn about the approach and when you can expect to get vaccinated.

WHEN CAN I GET THE VACCINE?

https://www.mass.gov/covid-19-vaccine-in-massachusetts



THE INTERPROFESSIONAL VACCINE SYMPOSIUM WILL RESUME IN

## **5 MINUTES**





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## Dr. Magdalena Sobieszczyk MD, MPH

#### Associate Professor of Medicine Columbia

University Vagelos College of Physicians and Surgeons **Chief of Infectious Diseases** NY-Presbyterian/Columbia University Irving Medical Center, NYC



### **COVID-19** Vaccines in the pipeline

Magda Sobieszczyk, MD, MPH Chief of Infectious Diseases NY-Presbyterian/Columbia University Irving Medical Center, NYC







### Virus Vector vaccines AstraZeneca AZD122 vaccine & J&J/Janssen vaccine

- AZD1222: developed by AstraZeneca and their partners at the University of Oxford (England).
- AZD1222 vaccine uses the Chimpanzee version of a common cold virus called Adenovirus as the vector (carrier).
- The Adenovirus is inactivated and "silent"→ cannot cause common cold.
- Virus vector carries a copy of the spike protein found on the surface of the SARS-CoV-2 virus
- Virus Vector vaccines can be stored in refrigerators
  - Both Janssen/J&J and AZ vaccines

Genetic information about Spike protein



Immune system reacts and makes antibodies and activates T-cells to destroy cells infected with coronavirus





#### Global Clinical Development of AZD122 Vaccine



#### Phase 3 study of AZD vaccine in the United States, Peru, and Chile

- Conducted at >90 sites
- 2 doses: 28 days





# What do we know about AZD1222 vaccines from studies outside of United States

- Combined analyses from UK/Brazil showed that 2 doses of AZD1222 given at least 4 weeks apart decreased symptomatic COVID-19 disease by 70.42% (90% CI 58.84, 80.63)
  - Highly effective in preventing severe COVID and death
  - Remaining questions about intervals (#weeks between doses) and dose level (amount per dose)
- Authorization for emergency supply/use in selected countries
  - United Kingdom ,India, Argentina, Mexico
- What does this mean for the United states
  - awaiting results of the phase 3 study and full review by the FDA





Voysey et al Lancet 2020; (397); p 99-111



#### Mobile Unit

NYC\_based Sites conducting Different Phase 3 Vaccine Efficacy studies:

Moderna Janssen/J&J AstraZeneca Pfizer/BioNTech







## Thank you!



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Columbiaresearchunit.org



Masks are the best way to stop the spread of droplets from your mouth and nose to others.



COVID-19 PreventCOVID.org



# **Panel Discussion**

Dr. Magdalena Sobieszczyk, MD, MPH Dr. Chris T. Pernell, MD, MPH, FACPM Dr. Shobha Swaminathan, MD Zeynep Sumer-King Kevin Cranston, MDiv




# **Questions?**

Raise Hand

Chat

Q&A

#### **IF YOU HAVE A QUESTION FOR A PANELIST**

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• use "Q&A" or "Raise Hand"





### George Gresham

**President** 1199SEIU United Healthcare Workers East

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## COVID-19 Vaccines: Healthcare Workers Experience

#### THE COVID-19 VACCINES AN UPDATE FOR HEALTHCARE WORKERS

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