COVID-19 Vaccine update

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Financial Disclosure

I am a full time Pfizer Inc. employee

Forward Looking Statements

- Our discussions during this presentation may include forward-looking statements about, among other things, our efforts to respond to COVID-19, that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These statements are subject to risks, uncertainties and other factors that may cause actual results to differ materially from past results, future plans and projected future results.

- Additional information regarding these and other factors can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in our subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in our subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

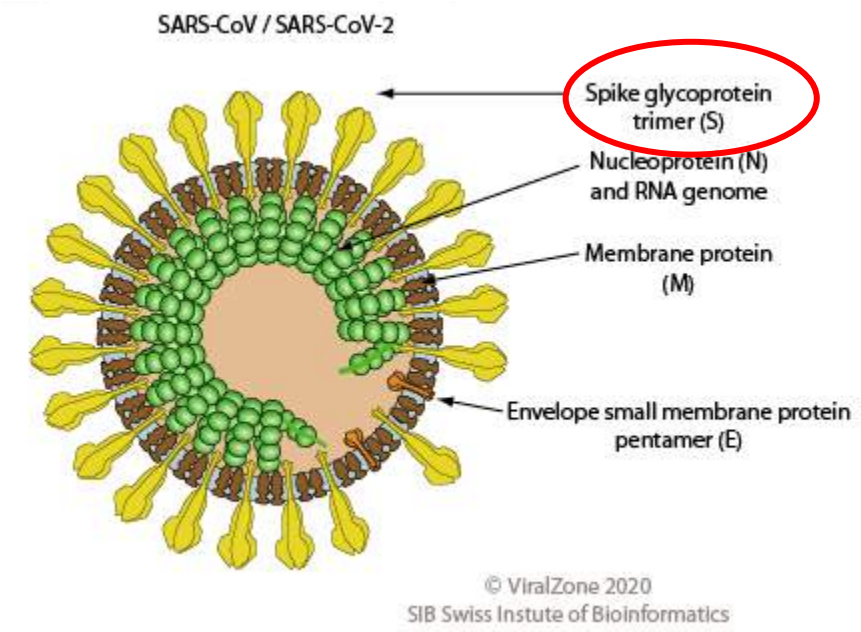
- The forward-looking statements in this presentation speak only as of the original date of this presentation and we undertake no obligation to update or revise any of these statements.

SARS-CoV-2 and Approaches to Vaccine Development

a. **The pathogen and its global impact**
b. **Vaccine Platforms**
c. **mRNA Vaccines and Mechanism of Action**
d. **Clinical Trials**
e. **Regulatory requirements**
f. **Allocations, Distribution and Recommendations**
g. **Vaccine Confidence**

SARS-CoV-2: General Characteristics

Single-stranded RNA viruses



odes **four major structural proteins** (all are lly complete viral particle)

nthesis

on/assembly

/assembly

members of the Coronavirus family such as, **-CoV** (2012) are the causative agents of outbreaks.

Su, S. et al. Epidemiology, Genetic Recombination, and Pathogenesis of Coronaviruses. Trends Microbiol. 24, 490–502 (2016)
Rasmussen SA, Watson AK, Swerdlow DL. 2016. Microbiol Spectrum 4(3):EI10-0020-2016

The COVID-19 global pandemic represents an unparalleled moment in the history of modern science

COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University

Source: Johns Hopkins University

As October 26, 2020

43.399.252

Confirmed Cases

1.157.802

Deaths

189

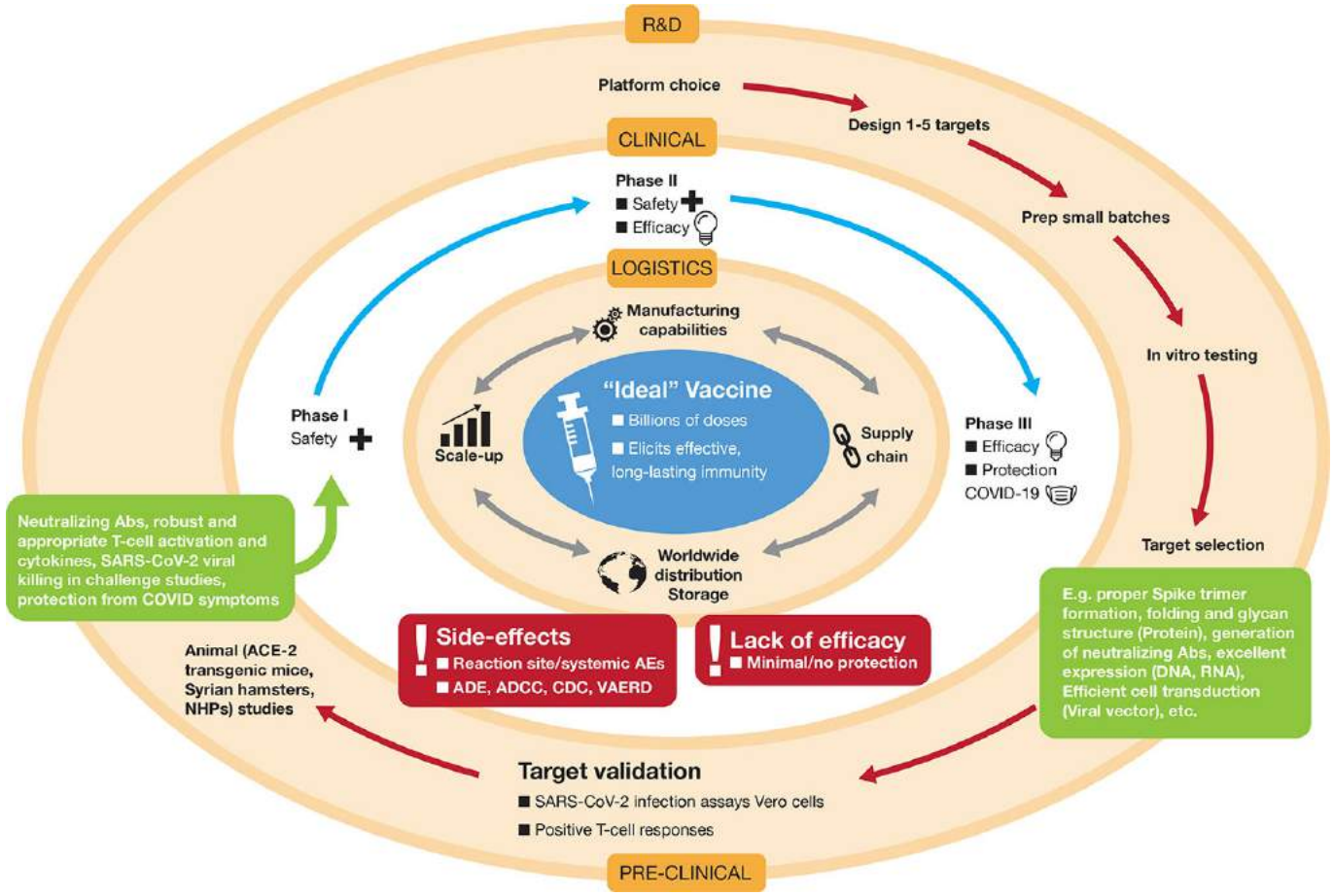
Countries

Rapid development, manufacturing scale-up, and delivery of a vaccine is an essential part of the long-term solution for ending this pandemic

NHIA COVID-19 Education Series

Source: COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU); https://coronavirus.jhu.edu/map.html]

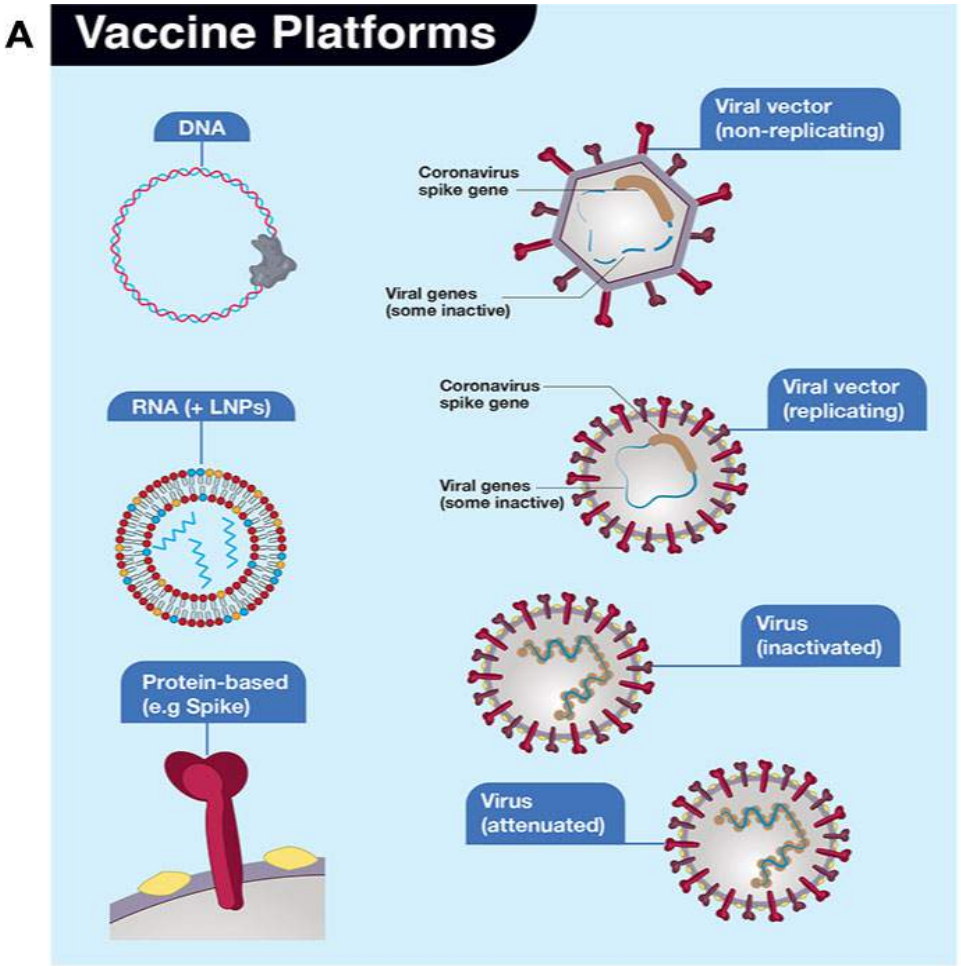
Roadmap to a COVID 19 Vaccine

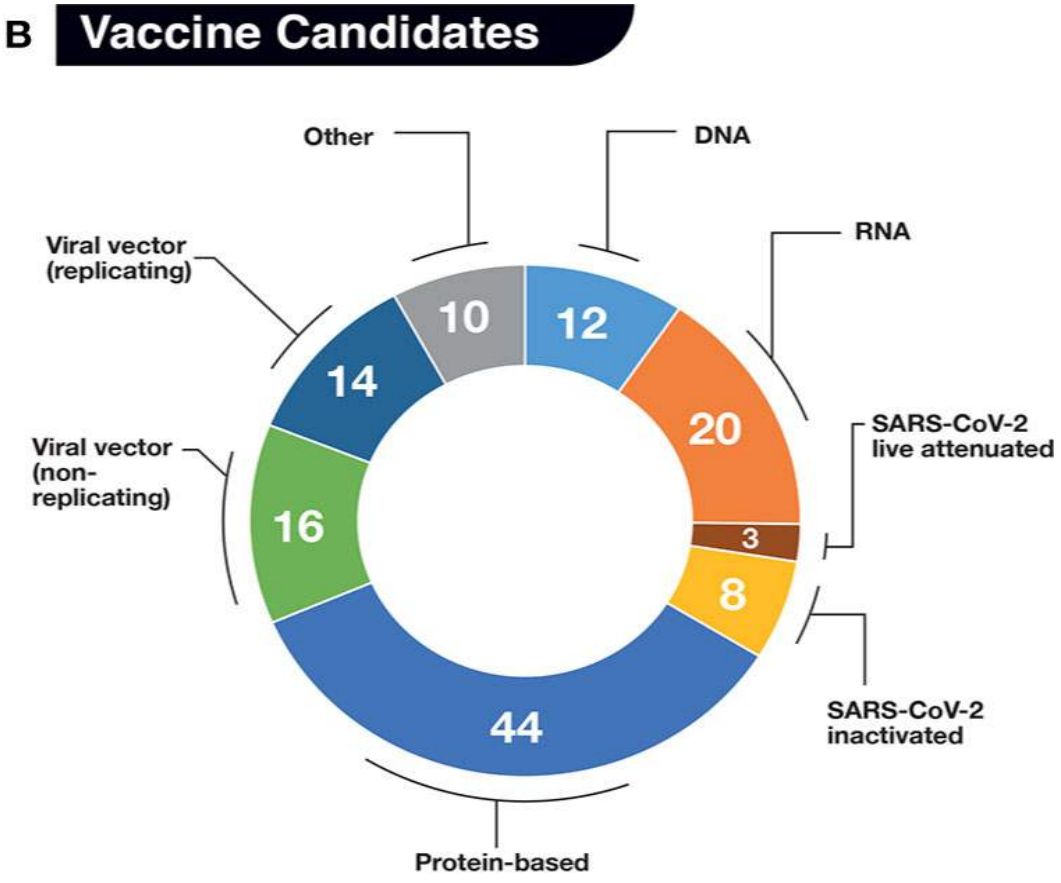


NHIA COVID-19 Education Series

- Funk, C. D., et al. (2020). "A Snapshot of the Global Race for Vaccines Targeting SARS-CoV-2 and the COVID-19 Pandemic." Frontiers in Pharmacology 11(937) https://doi.org/10.3389/fphar.2020.00937

Approaches to COVID-19 Vaccine Development





Funk, C. D., et al. (2020). "A Snapshot of the Global Race for Vaccines Targeting SARS-CoV-2 and the COVID-19 Pandemic." Frontiers in Pharmacology 11(937) https://doi.org/10.3389/fphar.2020.00937

U.S. Government / BARDA Vaccine Programs

ModernaTX, Inc.

SARS-CoV-2 mRNA-1273 vaccine

Phase 3

Learn More

Janssen Pharmaceuticals, Inc.

AD26.COV2.S - Viral Vector Vaccine for COVID-19

Phase 3

Learn More

Sanofi Pasteur and GSK

Recombinant SARS-CoV-2 Protein Antigen + AS03 Adjuvant

Phase 1/2

Learn More

Pfizer Inc.

BNT162, a prototype COVID-19 mRNA vaccine

Phase 2/3

Learn More

Novavax Inc.

NVX-CoV-2373 Vaccine for SARS-CoV-2

Phase 1

Learn More

AstraZeneca

AZD1222 (formerly ChAdOx1 nCoV-19 vaccine)

Phase 3

Learn More

Source: https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine

Pfizer – BioNTech Collaboration

Initially partnered with BioNTech in 2018 to research and develop a vaccine for influenza and have now extended that partnership with the BNT162 program.

The vaccine candidates are based on BioNTech's proprietary mRNA vaccine platforms.

The collaboration leverages Pfizer's broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network.

mRNA Vaccines: A novel approach with promising vaccine characteristics

mRNA vaccine technology uses the cell's own machinery to stimulate an innate immune response through T cells and neutralizing antibodies

Safety: RNA vaccines are non-infectious and pose no risk of insertional mutagenesis

Efficacy: RNA vaccines pose minimal risk of anti-vector immunity which permits potent boosting of immune responses.. It may contribute to strong antibody responses, as well as expansion of multifunctional CD8 and T_H1-type CD4 T cells.

Speed: BioNTech's mRNA vaccine technology is designed to enable rapid development and quick production scaling

1. Holtkamp S, et al. Modification of antigen-encoding RNA increases stability, translational efficacy, and T-cell stimulatory capacity of dendritic cells. *Blood* 2006; 108 (13): 4009–4017.
2. Orlandini von Niessen A, et al. Improving mRNA-based therapeutic gene delivery by expression-augmenting 3' UTRs identified by cellular library screening. *Molecular Therapy* 2019; 27 (4): 824-836.

Responding to the current global health crisis with a potential COVID-19 mRNA Vaccine

SARS-CoV-2 Genetic Sequence

Public January 12, 2020

China

COVID-19 mRNA Vaccine Animal Studies

Started March, 11, 2020

BioNTech

PFE/BNT Letter of Intent

Signed March 17, 2020

Pfizer-BioNTech

Phase 1 / 2 Trial

Germany Started April 23, 2020

- Up to 200 subjects aged 18 – 55

US Started May 4, 2020

- Up to 360 subjects aged 18 – 85

Candidate/Dose Selection

BNT162**b2** July 24, 2020

Pivotal Phase 2b / 3 Trial

July 27, 2020 Start

Up to 48,400 subjects

Potential Regulatory Approval or Authorization

Goal: 4Q 2020

Note: All future dates represented in graphic reflect anticipated timelines and are subject to clinical, technical, and regulatory success

Phase 3 Efficacy Trial: 42,113 Participants are Currently Enrolled Across More Than 150 Sites in 6 Countries

Primary Efficacy Objectives	Endpoints
Efficacy against confirmed COVID-19 in participants without evidence of infection before vaccination	COVID-19 incidence based on confirmed NAAT in participants with no serological or virological evidence of past SARS-CoV-2 infection
Efficacy against confirmed COVID-19 in participants with and without evidence of infection before vaccination	COVID-19 incidence based on confirmed NAAT

Clinical Sites Across The Globe

US | Brazil | Argentina | South Africa | Germany | Turkey

Enrollment On Track

42,113 participants enrolled and 35,771 participants have received their second vaccination

Diverse Study Population

	%US	%Global
Black or African American	10%	10%
Hispanic	13%	27%
Native American/Alaska Native	0.9%	0.6%
Asian	6%	5%
Total Diverse Enrollment	**30%**	**43%**
Enrollment Age 56-85	**47%**	**42%**

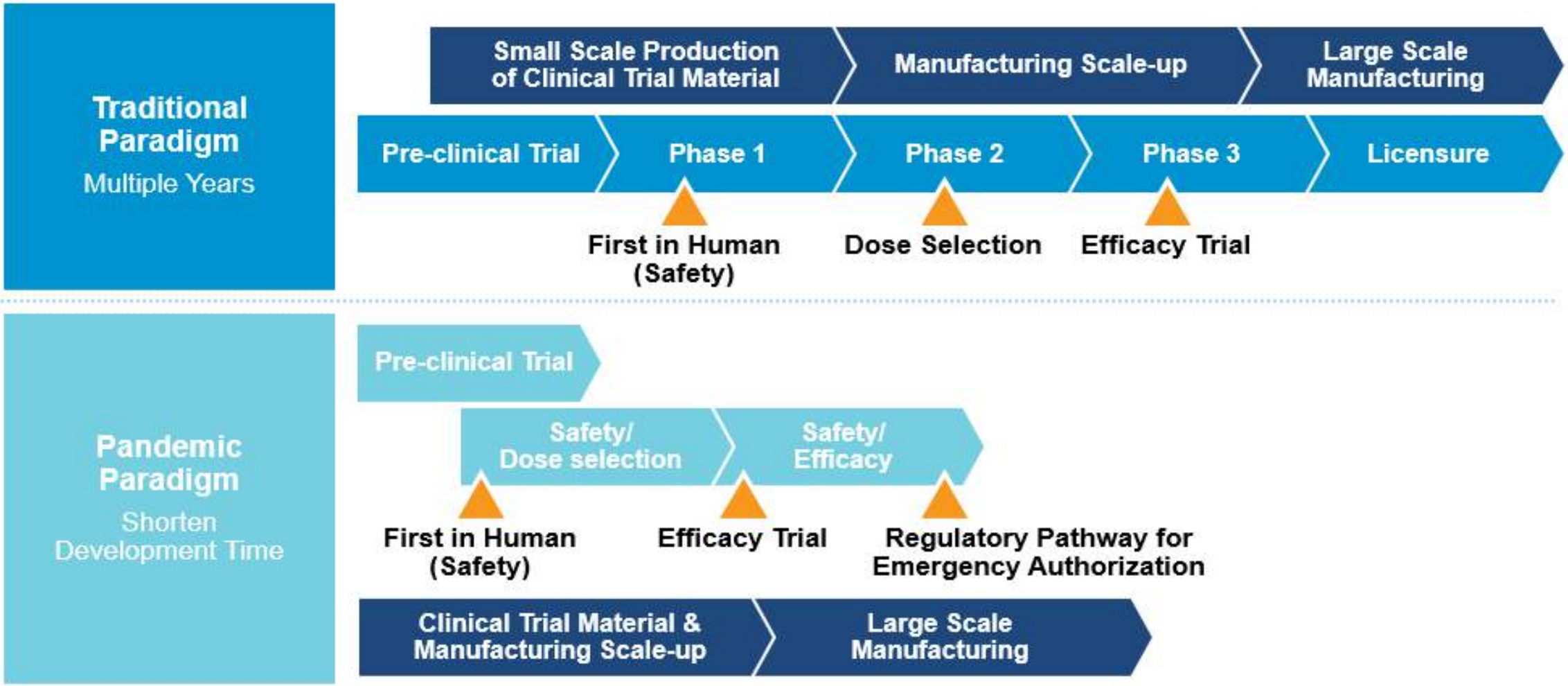
Data as of October 26th, 2020

NAAT: Nucleic acid amplification tests

Pfizer & BioNTech
COVID-19 Vaccine Program

- *Entered into supply agreement with U.S. government for 100 million doses, with option to supply additional 500 million doses, subject to regulatory approval*
- *Supply agreements executed with UK, Japan & Canada, subject to regulatory approval*
- *U.S. government announced it will supply COVID-19 vaccines for free and are developing distribution plans to provide vaccines to individuals according to prioritized allocations, including critical infrastructure workers*

Vaccine Development Timelines



Adapted from Lurie N. et al. *NEJM.* 2020 May 21;382(21):1969-1973

FDA plays a critical role in the current situation

Development and Licensure of Vaccines to Prevent COVID-19

Guidance for Industry

Table of Contents

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
June 2020

Contains Nonbinding Recommendations

Emergency Use Authorization for Vaccines to Prevent COVID-19

Guidance for Industry

October 2020

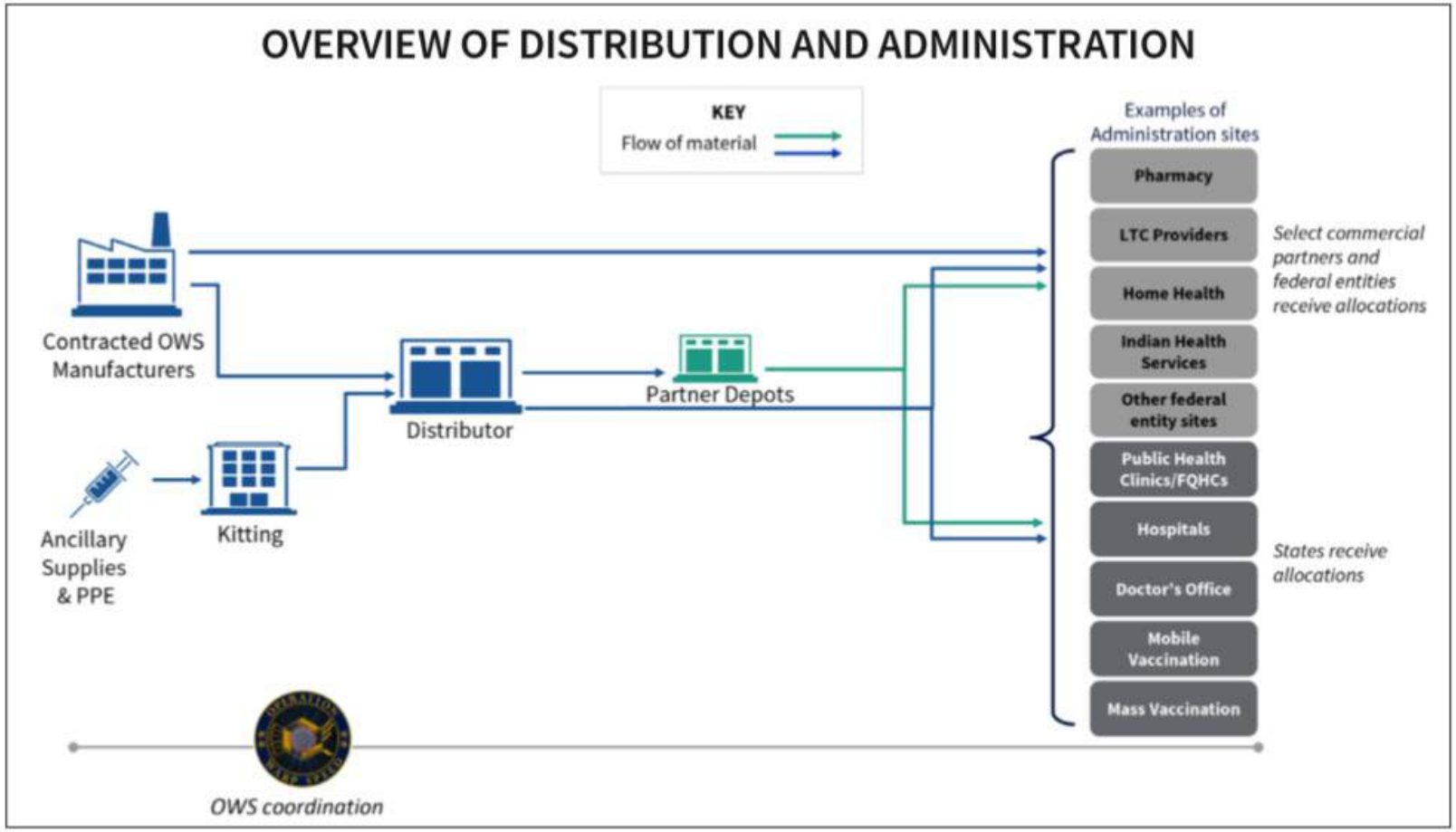
Contains Nonbinding Recommendations

Table of Contents

NHIA COVID-19 Education Series

1- Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry, June 2020, https://www.fda.gov/media/139638/download.
2- EUA for Vaccines to Prevent COVID-19 Guidance for Industry, October 2020, https://www.fda.gov/media/139638/download

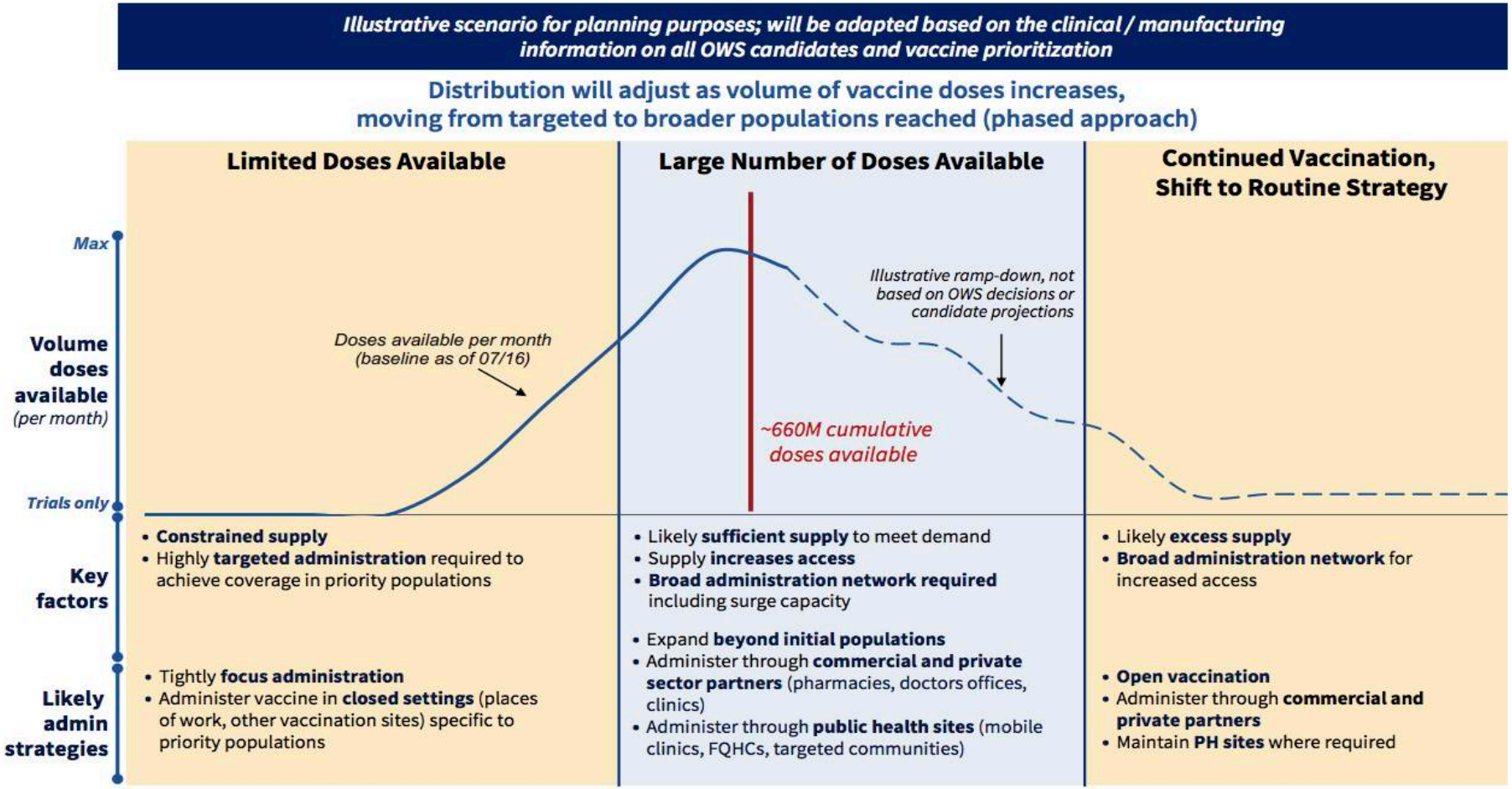
USG is developing vaccine distribution in coordination with the States through direct and centralized models



Source: https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

OWS: Operation Warp Speed; CDC: Centers for Disease Control and Prevention; IT: Information Technology; DoD: Department of Defense; USG: US Government; LTC: Long-Term Care; IHS: Indian Health Service; PHC: Public Health Clinic; FQHC: Federally-Qualified Health Center; Vx: Vaccination; PPE: Personal Protective Equipment

U.S. Government COVID-19 vaccine supply overview



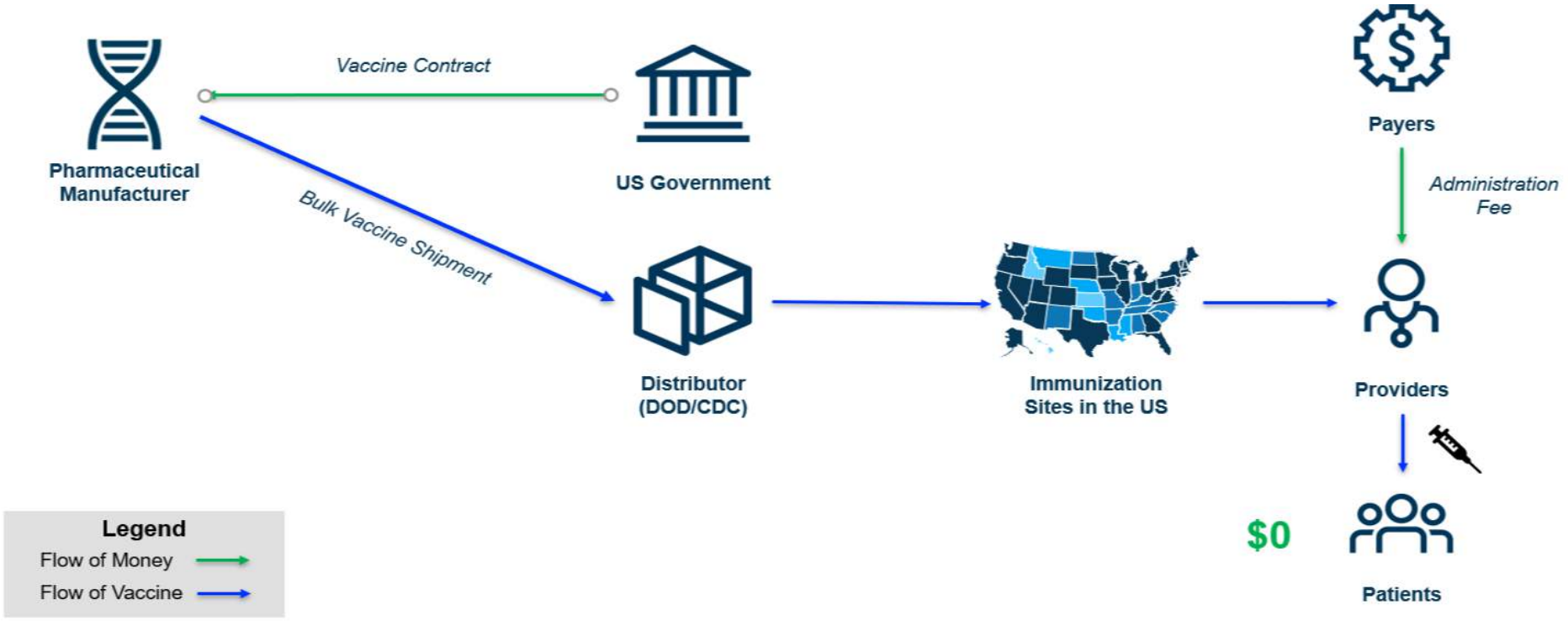
NHIA COVID-19 Education Series

Source: https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

COVID-19 Vaccines Anticipated Coverage & Cost

- **During the pandemic, the U.S. government announced it will purchase and distribute COVID-19 vaccines**

- Vaccines will be free of charge and providers – physicians, pharmacists, nurses – will be paid a fee for each vaccine administered (U.S. government is reviewing potential cost to patients for administration fees)
- The U.S. Government is actively planning vaccine allocation & distribution for pandemic doses:



NOTE: The above is based on US government announcements thus far and remains subject to change based on future government decisions, product development, regulatory and manufacturing assumptions and timelines

Source: https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

Principles for Prioritization, Allocation and Recommendation

WHO SAGE:
Values Framework for the Allocation and Prioritization of COVID-19 Vaccination

- Both national and global considerations
- Six core values principles
  - Human well-being
  - Equal respect
  - Global equity
  - Reciprocity
  - Legitimacy
  - National equity

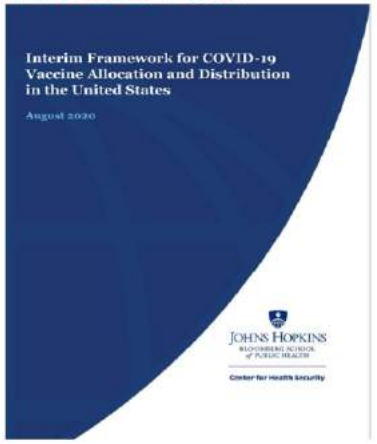

WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020

World Health Organization

Johns Hopkins Bloomberg School of Public Health:
Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

- Purpose
  - Identify candidate groups for serious consideration as priority groups
  - Demonstrate how ethical principles and objectives can be integrated to produce an ethically defensible list of candidate groups
- Authors note importance of:
  - Transparency and a fair process
  - Equity, including access to healthcare
  - Community outreach and engagement


Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

August 2020

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Center for Health Security

National Academies of Medicine
Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

- Purpose
  - Develop an overarching framework for vaccine allocation to assist policy makers in domestic and global health communities in planning for equitable allocation of vaccines against SARS-CoV-2
  - Expectation that framework will inform decisions by health authorities, including the ACIP, as they create and implement national/local guidelines for vaccine allocation
- Asked to consider
  - Criteria for setting priorities for equitable allocation
  - How to apply criteria to determine 1st tier of recipients

The National Academies of SCIENCES ENGINEERING MEDICINE


Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Committee on Equitable Allocation of Vaccine for the New Coronavirus

DISCLAIMER: This discussion draft is not intended to be the final framework recommended by the committee, and the information contained herein is subject to change based on public comments and further committee deliberations. The committee's final report and recommended framework is forthcoming.

NATIONAL ACADEMY OF MEDICINE

The National Academies of SCIENCES · ENGINEERING · MEDICINE

DISCUSSION DRAFT FOR PUBLIC COMMENT

NHIA COVID-19 Education Series

https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf
https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-covid-19-vaccine-allocation-and-distribution-in-the-us
https://www.nap.edu/catalog/25914/discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine

ACIP ethical principles proposed

- Maximize benefits and minimize harms:
  - Minimize death and serious disease
  - Addresses our obligation to promote public health and promote the common good
  - Balanced with our obligation to respect and care for persons
  - Based on best available science
- Equity
  - Vaccine allocation reduces rather than increases health disparities
  - Ensure that everyone has a fair and just opportunity to be as healthy as possible
- Justice
  - Commitment to remove unfair, unjust, and avoidable barriers to good health and well- being that disproportionately affect the most disadvantaged populations
  - Interventions must intentionally ensure that groups, populations, and communities affected by a policy are being treated fairly
- Fairness
  - Commitment to fair stewardship in the distribution of a scarce resource
    - Not exacerbate existing disparities in health outcomes
    - Equal opportunity to access vaccine to those within the agreed groups of early recipients
    - Consistency in implementation

TRANSPARENCY and EVIDENCE BASED

Source: https://www.cdcgov/sites/default/files/ACIP September 2020 -covid-19-vaccine.

ACIP ongoing discussions

Possible groups for Phase 1 vaccination

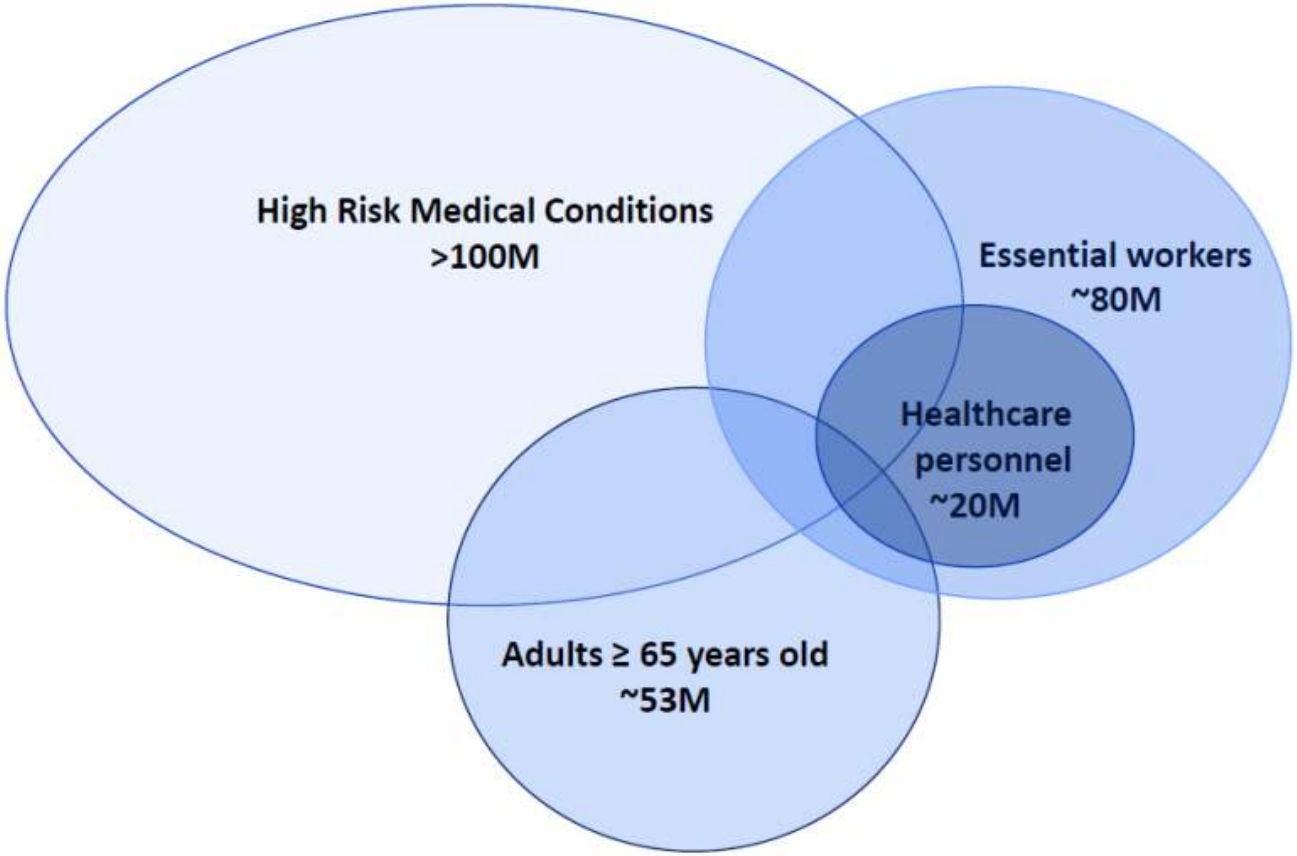
August ACIP meeting

Phase 1a:
-HCP

Phase 1b:
-Essential Workers
-High Risk Med Conditions
-Adults ≥ 65 years old

September ACIP meeting

-Explore groups for phase 1b
  -risk for COVID-19
  -overlap between groups
  -racial and ethnic composition
-Summary of Work Group considerations



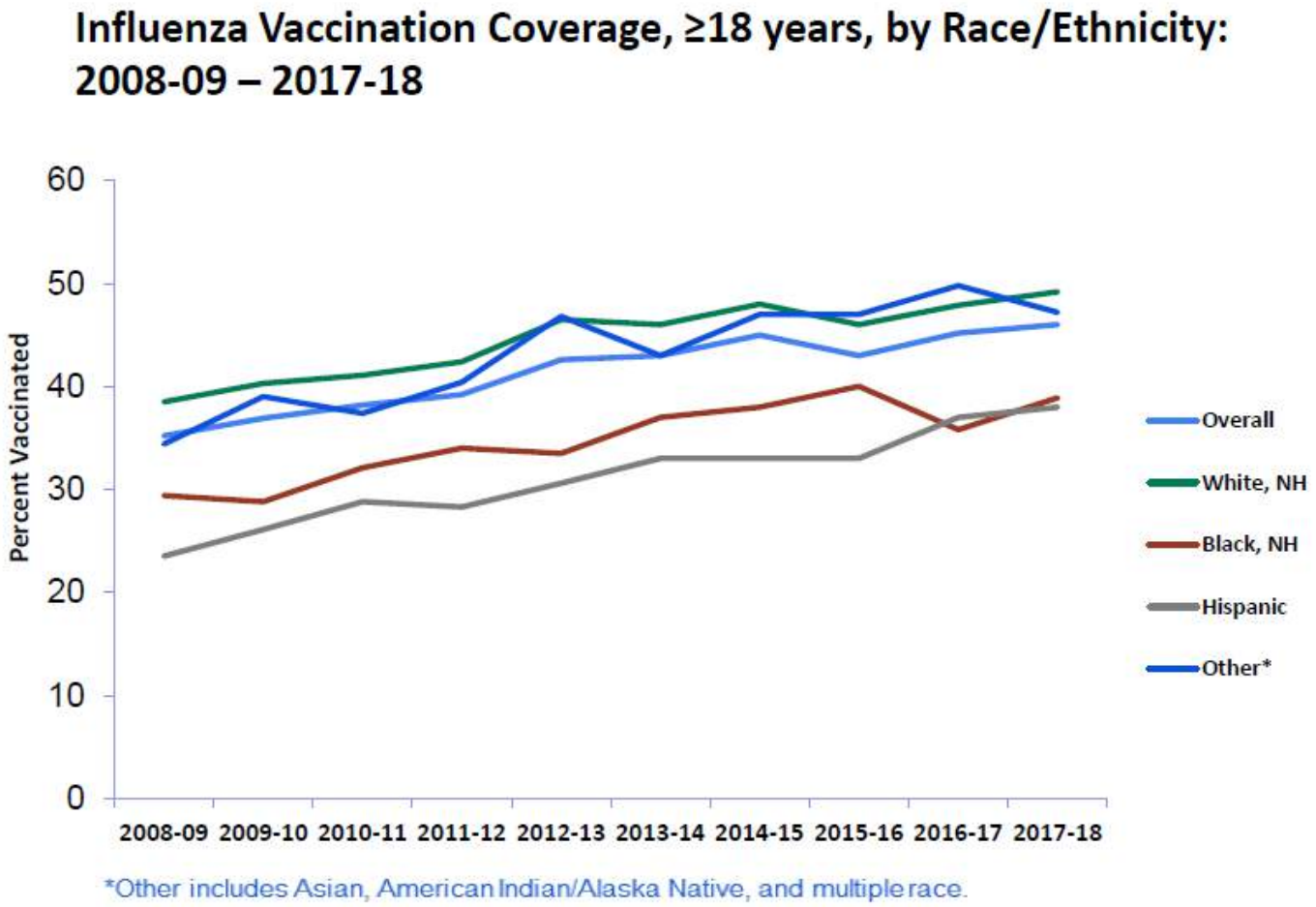
Source: https://www.cdcgov/sites/default/files/ACIP September 2020 -covid-19-vaccine.

Vaccine Confidence

- Vaccine confidence refers to the trust that parents or healthcare providers have in:
  - recommended immunizations
  - in the provider(s) who administers vaccines
  - in the process and policies that lead to vaccine development, licensure, manufacturing, and recommendations for use

- Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee June 2015

Rising to the challenge to achieve high coverage with COVID 19 Vaccines



- Vaccination coverage of racial and ethnic minorities is consistently lower than that of white populations
- **We need novel and more robust strategies to increase uptake of COVID-19 vaccine, once one becomes available**

Source: Vaccination Coverage among Adults in the United States, National Health Interview Survey, CDC, 2017. NH = Non-Hispanic

State of Confidence in Potential COVID-19 Vaccine

Editorials
nature

Vaccine confidence needs radical transparency

Public trust in a potential COVID-19 vaccine is low. Drug companies and their academic partners must disclose protocols and results.

"Trial participants put their health at risk to help further research that can benefit society at large."

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Evaluating and Deploying Covid-19 Vaccines — The Importance of Transparency, Scientific Integrity, and Public Trust

Jason L. Schwartz, Ph.D.

CNN Opinion Political Op-Eds Social Commentary

Will the public trust a Covid-19 vaccine?

Opinion by Edgar K. Marcuse

Updated 4:05 PM ET, Thu September 24, 2020

Regulatory Focus™ > News Articles > 2020 > 9 > COVID-19 vaccine: Experts warn of waning public confidence

COVID-19 vaccine: Experts warn of waning public confidence

Posted 22 September 2020 | By Denise Fulton

European Journal of Epidemiology

ESSAY

Vaccine confidence in the time of COVID-19

Emily A. Harrison · Julia W. Wu

Abstract

THE VACCINE CONFIDENCE PROJECT

Vaccine confidence in the time of COVID-19

22 JULY 2020

The Vaccine Confidence Project™
London School of Hygiene & Tropical Medicine

#vaccineconfidence

News > Medscape Medical News

COVID-19 Vaccines Face Hesitancy, Fair Distribution Issues

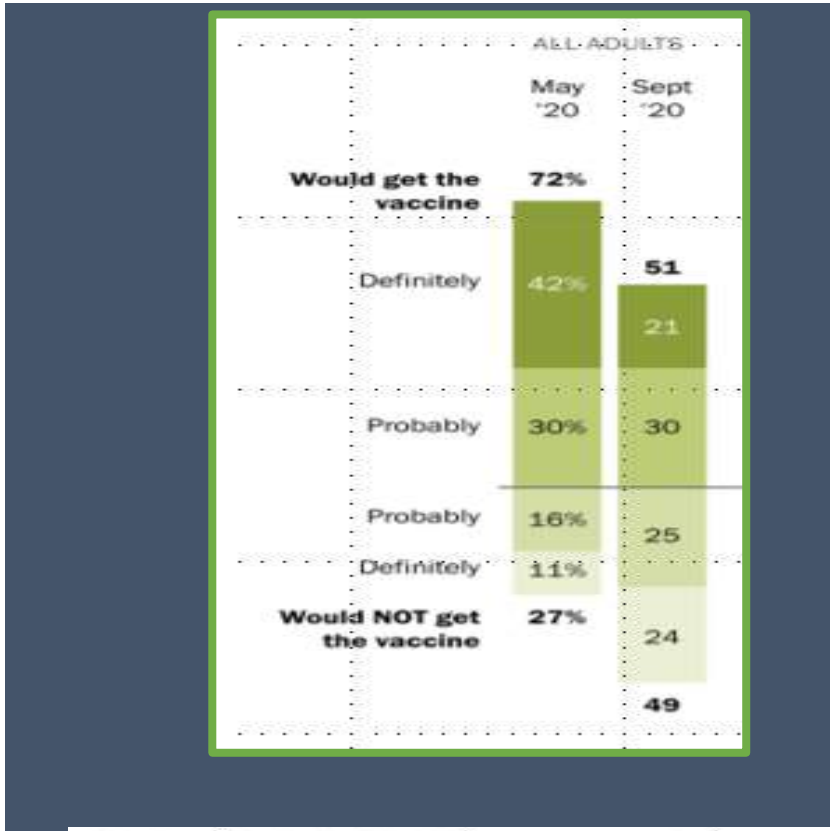
Alicia Ault

June 15, 2020

Poll: Most Americans Worry Political Pressure Will Lead to Premature Approval of a COVID-19 Vaccine; Half Say They Would Not Get a Free Vaccine Approved Before Election Day

Drop in share of Americans who say they would get a COVID-19 vaccine if it were available to them today

% of U.S. adults who say if a vaccine to prevent COVID-19 were available today, they ...



Note: Respondents who did not give an answer are not shown.
Source: Survey conducted Sept. 8-13, 2020.
"U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine"

PEW RESEARCH CENTER

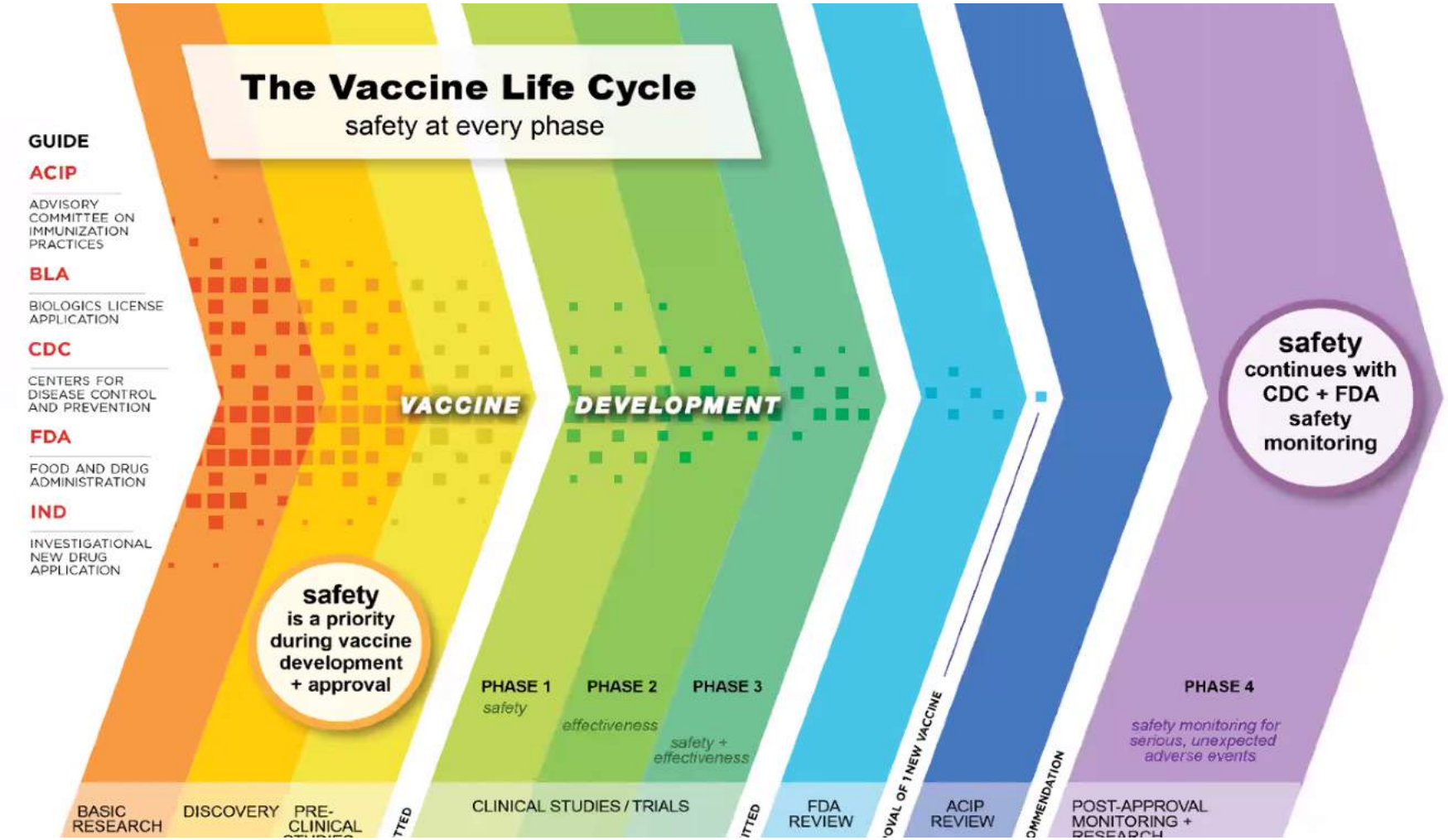
Building Trust in the Process of Pandemic Vaccine Development

- Trust is one of the most important factors associated with vaccine confidence, which extends to the HCPs, systems, policies and belief that the system has adequately evaluated the safety and effectiveness of the recommended vaccines.[1]
- Transparency about potential vaccine risks and benefits is necessary to develop trust.
- The process of pandemic vaccine development and approval is designed to allow safe and effective vaccines to be available to the public.
- Educating about the clinical trial process during the pandemic is important.

We cannot increase trust and confidence in safety and effectiveness for a new vaccine without data confirming such.

- [1]Badur S et al. Human Vaccines & Immunotherapeutics, 2020. 16:5, 1007-1017

COVID-19 Vaccines: Safety and Efficacy are prioritized



- Safety is a priority during all phases of vaccine development, approval, and use
- Post-licensure (post-authorization) safety monitoring is an established part of the vaccine life cycle
- Monitoring COVID-19 vaccine safety will be a coordinated effort by multiple federal agencies

- 1. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html Accessed 6/17/2019

Vaccine Safety Monitoring

CDC Monitors the Safety of Vaccines by:[1]

- Performing high-quality vaccine safety research
- Making determinations about whether vaccines caused reactions in certain cases and helping to learn about preventable risk factors
- Identifying vaccine adverse events through public health surveillance

CDC's Immunization Safety Office Conducts Four Primary Vaccine Safety Activities:[1]

1 — Vaccine Adverse Event Reporting System (VAERS)

An early warning system that helps CDC and FDA monitor problems following vaccination. Anyone can report suspected vaccine reactions and issues to VAERS

2 — Vaccine Safety Datalink (VSD)

A collaboration between CDC and several health care organizations that allows ongoing monitoring and proactive searches of vaccine related data.

3 — Clinical Immunization Safety Assessment (CISA) Project

A partnership between CDC and several medical centers that conduct clinical research on vaccine-associated health risks in certain groups of people.

4 — Emergency Preparedness for Vaccine Safety

In the event of a disease outbreak in which a mass vaccination campaign is needed, CDC activates emergency preparedness activities to ensure that vaccines remain safe.

1. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html Accessed 6/17/2019

During health crises, communication, community engagement and cultural competency are critical

Targeted Messaging

Epidemics do not increase vaccine acceptance in racial or ethnic minorities, meaning targeted communication from trusted messengers remains necessary—especially when a vaccine is new, data on safety or risks is limited, and negative informal messaging occurs (CDC, 2015).

Community Engagement

Sustained community engagement is key in identifying the education and support required to implement health efforts—especially in communities that face instability with basic needs, such as employment, food, shelter, and clean water (Hutchins, 2009).

Cultural Competency

Health care staff and first responders should provide culturally competent messaging and care—and include minority groups in planning—to encourage equitable engagement and outcomes in a pandemic response (Hutchins, 2009).

- 1. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html Accessed 6/17/2019

Thank You