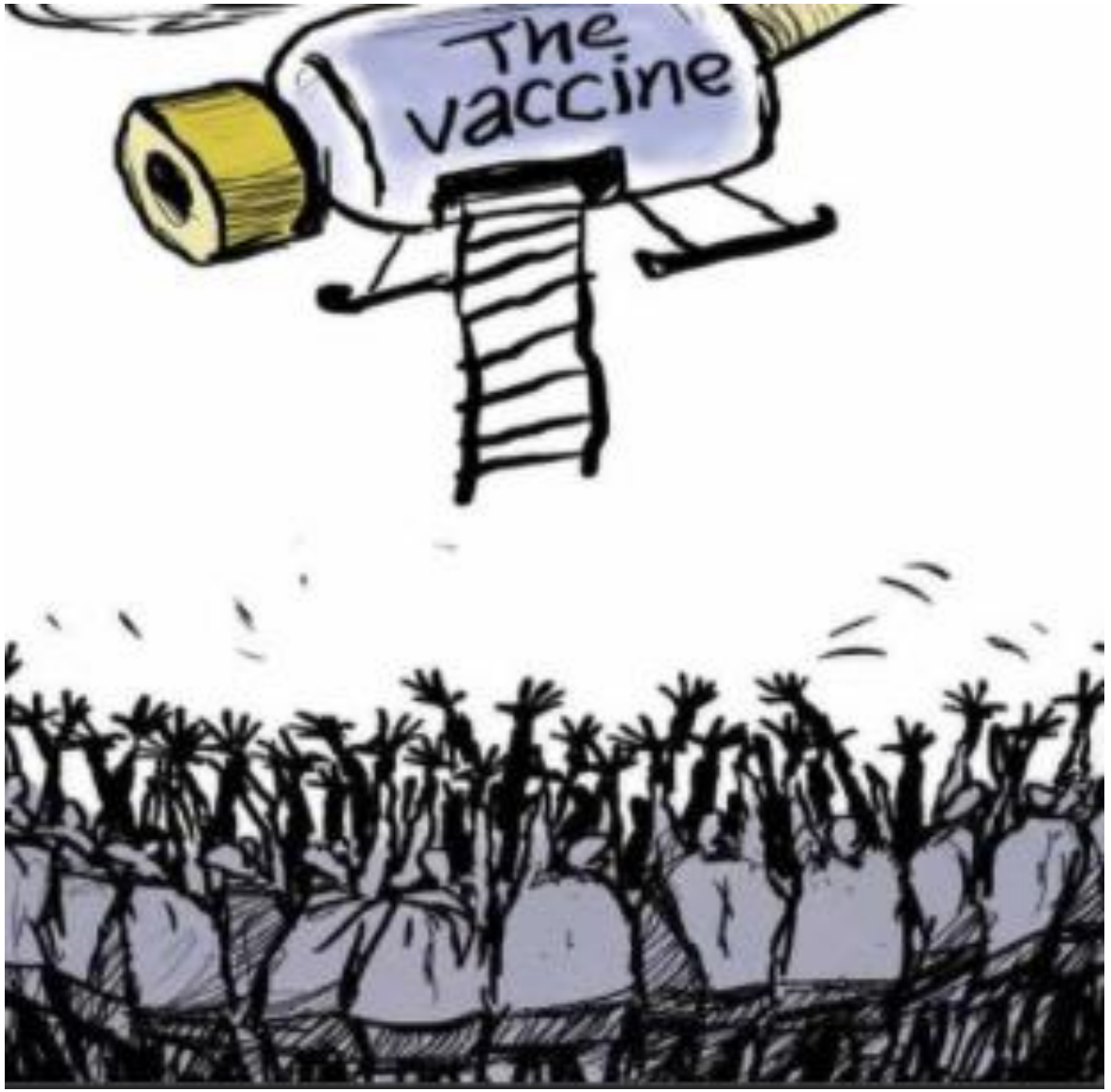
COVID-19 VACCINE PLANNING
PUERTO RICO

Iris Cardona, MD

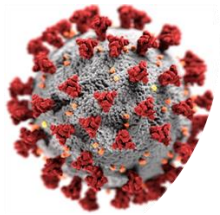
SARS CoV-2 and COVID-19

- This coronavirus has challenged all of us.
- It has taught us that life can change in ways we aren’t prepared for.
- This a time to have more compassion.
- This is a time for science and solidarity.



We Need A Vaccine

“When Will We Have a Vaccine?”



- “When a candidate vaccine is demonstrated to be safe, effective, and available. That can be determined only by scientific data…
- Food and Drug Administration (FDA) guidelines on testing of Covid-19 vaccine candidates are scientifically sound and indicate that no compromises will be made when it comes to evaluating safety and efficacy.
- Surveys suggest that physicians, nurses, and pharmacists remain the most highly trusted professionals.
- Extensive, active, and ongoing involvement by clinicians is essential to attaining the high uptake of Covid-19 vaccines that will be needed for society to return to prepandemic conditions.
- Throughout the world, health care professionals will need to be well-informed and strong endorsers of Covid-19 vaccination.

CNN health Food Fitness Wellness Parenting Vital Signs

FDA wants two months of safety data before considering Covid-19 vaccine

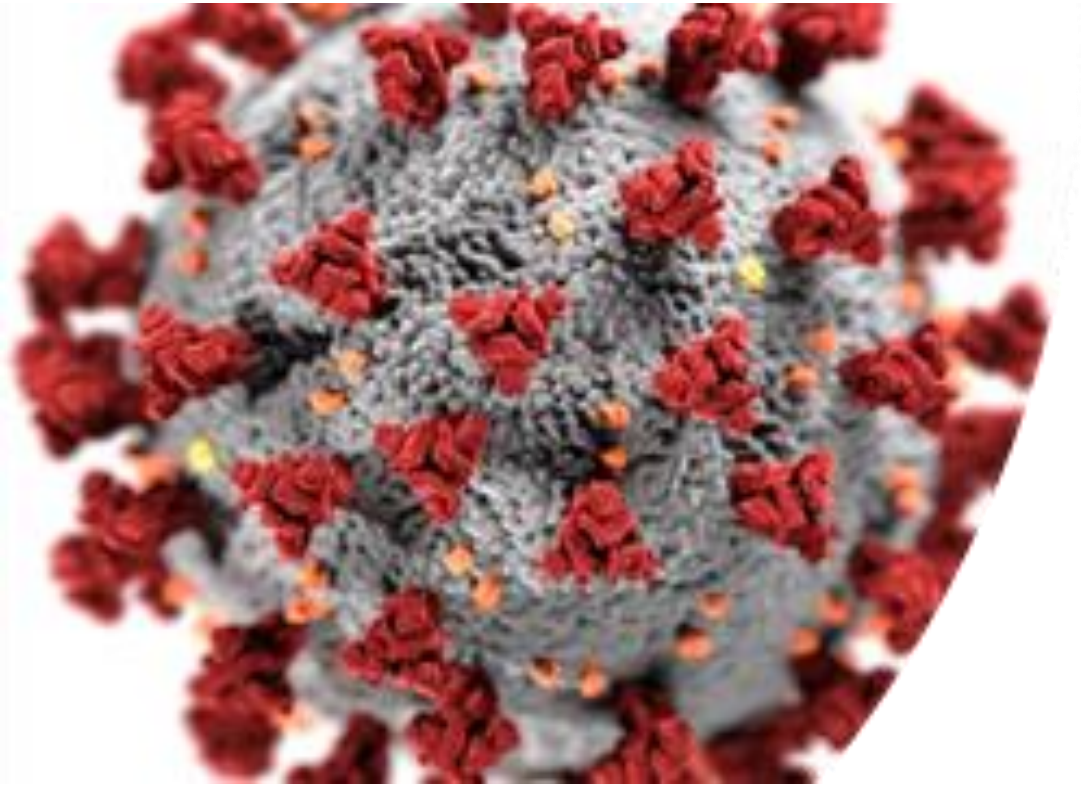
By Jacqueline Howard and Maggie Fox, CNN

Updated 9:14 PM ET, Tue October 6, 2020

90% of serious adverse events are detected in 1st 6 weeks after vaccination

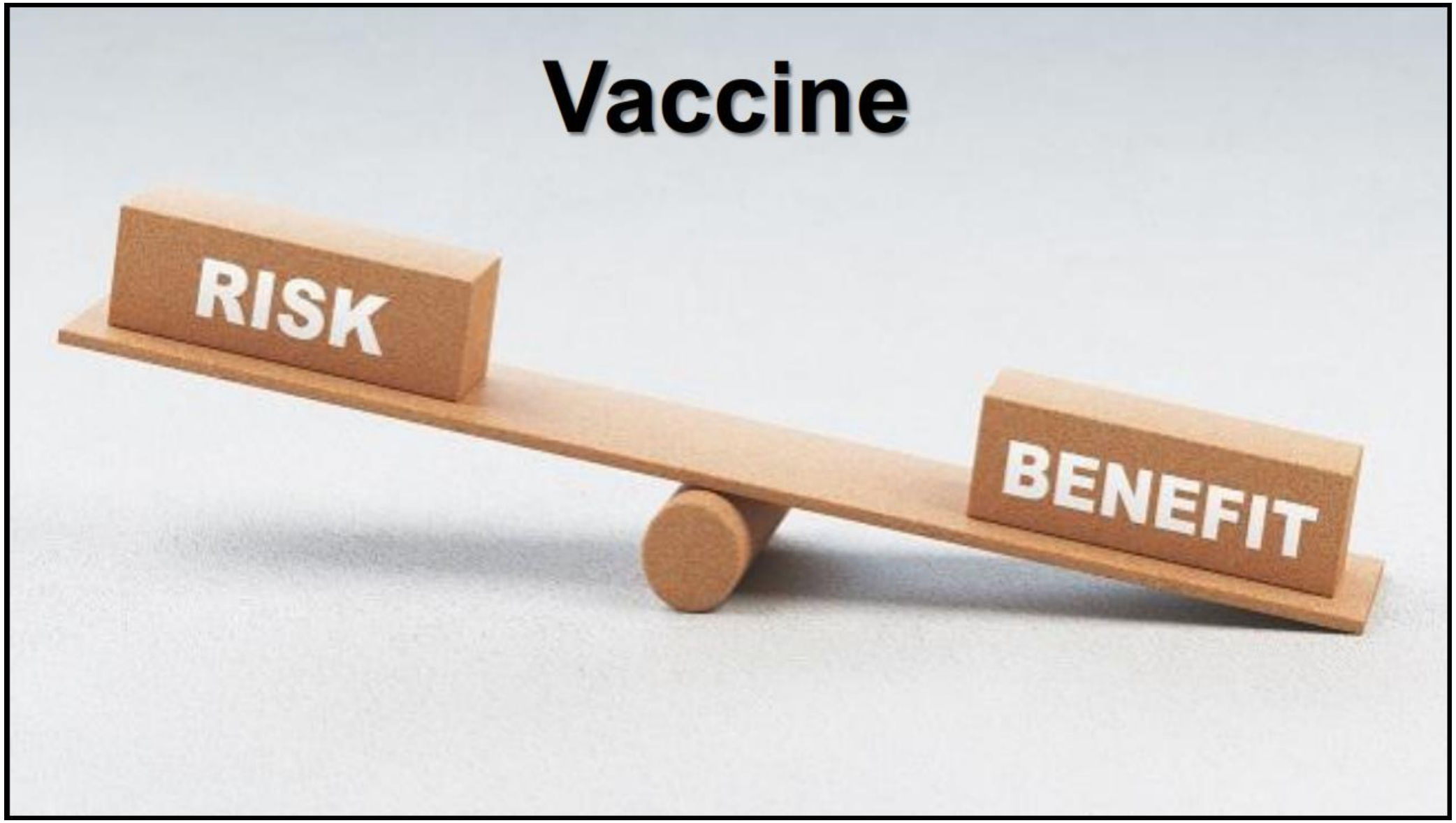
“When Will *We* Have a Vaccine?”

- “We will have a safe and effective Covid-19 vaccine when the research studies, engagement processes, communication, and education efforts undertaken have built trust and result in vaccination recommendations being understood, supported, and accepted by the vast majority of the public, priority and nonpriority groups alike.”

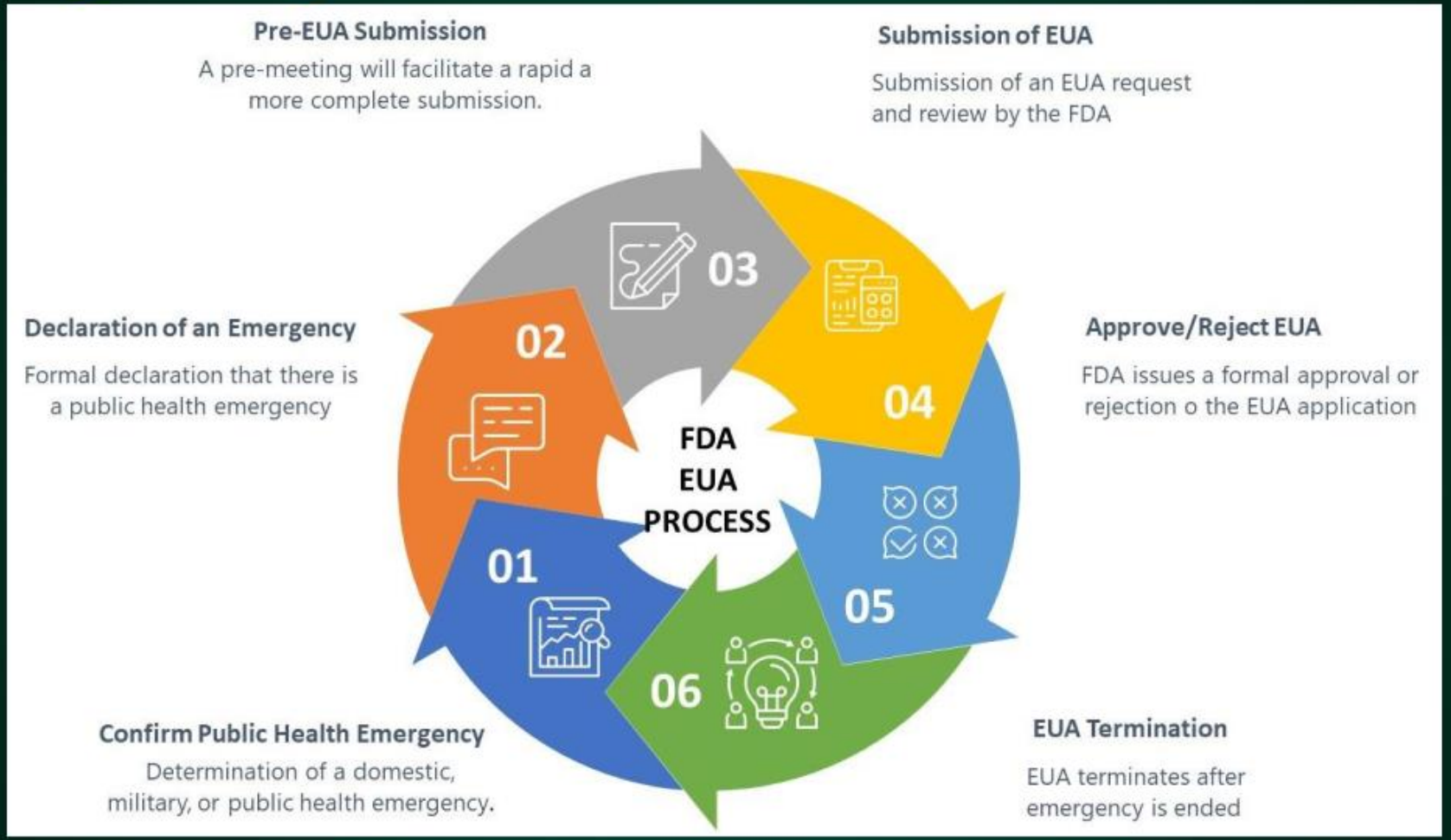


Barry R. Bloom, Ph.D., Glen J. Nowak, Ph.D., and Walter Orenstein, M.D.

September 8, 2020 DOI: 10.1056/NEJMp202533

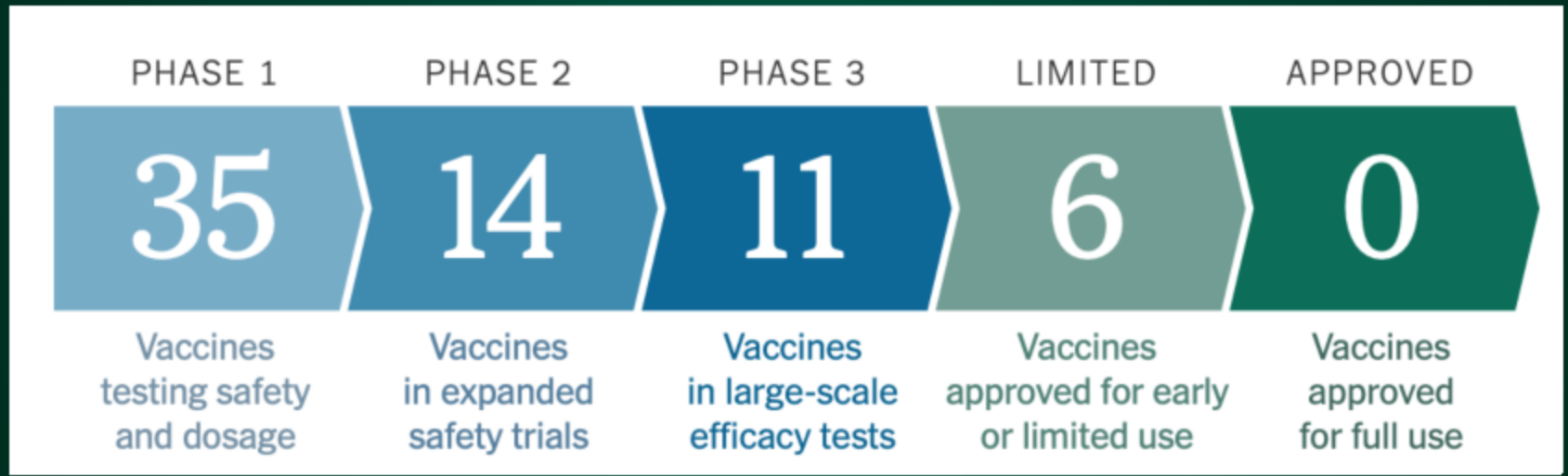

Vaccine
RISK
BENEFIT

Emergency Use Authorization Process



The New York Times

Coronavirus Vaccine Tracker



https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

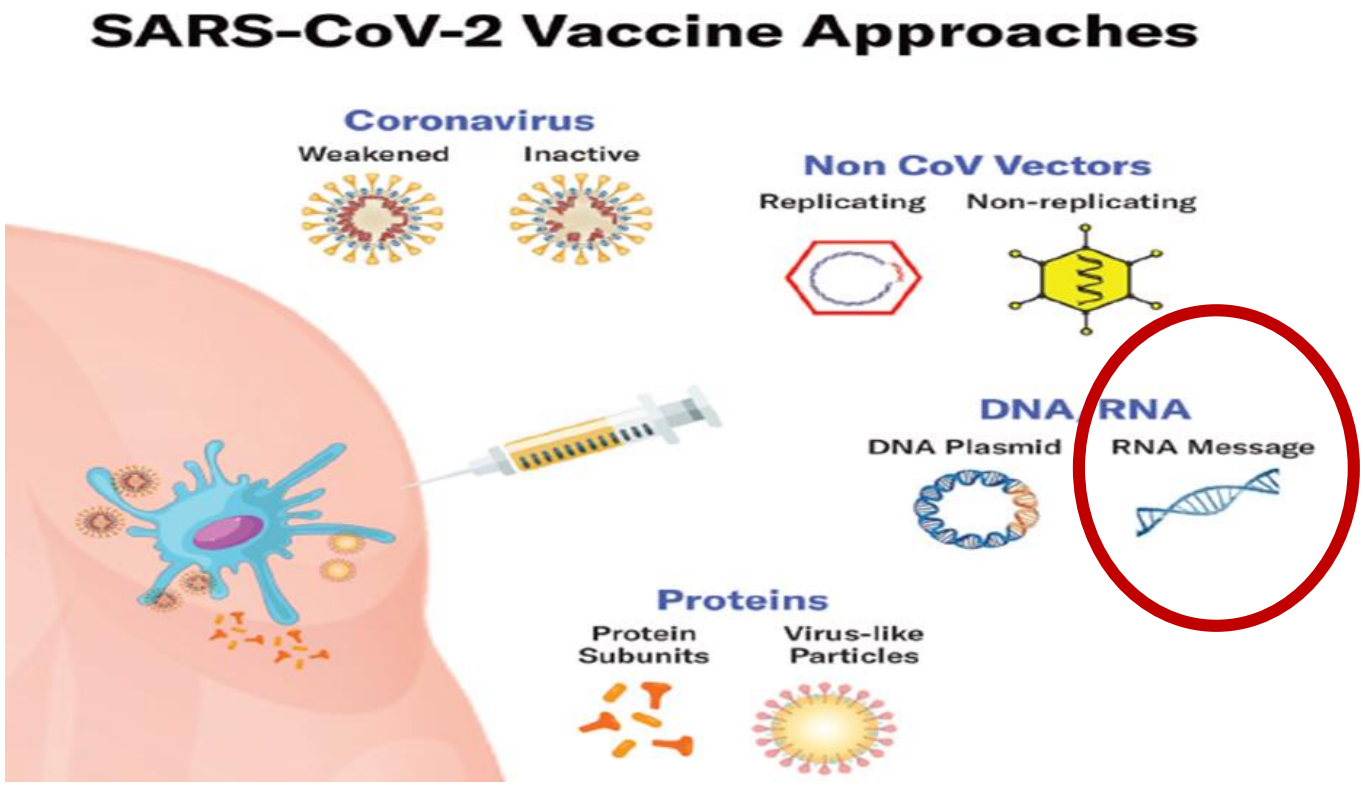
Comparing Clinical Trial Sizes of Vaccine Series

Vaccine or Developer	Type of Vaccine	Protects Against	Approval Year	Doses	Phase II n	Phase III n
IPOL	Inactivated	Polio	2000	4	361	2,358
Daptacel	Combination	Diphtheria, Tetanus, Pertussis	2002	5	7,471	10,575
Gardasil	Subunit	HPV	2006	3	4,047	22,938
Prevnar 13	Inactivated	Pneumococcal disease	2010	4	1,478	49,296
Moderna/NIH	mRNA	COVID-19	-	2	600*	30,000
Johnson & Johnson	Viral vector	COVID-19	-	2	394*	60,000
BioNTech/ Pfizer	mRNA	COVID-19	-	2	-	43,000†

*combined phase I and phase II trial
†combined phase II and phase III trial

Reference:
Weinberg SH, et al. Size of clinical trials and introductory prices of prophylactic vaccine series. *Human Vaccines & Immunotherapeutic*. 2012;8(8):1066-70.
WHO. Draft landscape of COVID-19 candidate vaccines. Available at: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

SARS-CoV-2 VACCINE APPROACHES



From: Update on COVID-19 Vaccine Development
ASA Monitor. 2020;84(8):17-18. doi:10.1097/01.M99.0000695144.71454.73

The vaccine presents the spike protein to the dendritic cells, which trigger the adaptive immune response to SARS-CoV-2.

The spike protein

1) can be expressed on the surface of a weakened or inactive coronavirus,
2) delivered as RNA by a non-coronavirus viral vector and manufactured in host cells,
3) delivered as either a DNA plasmid or an RNA message and manufactured in the host cells, or
4) injected directly either as immunogenic protein subunits or attached to a particle that looks like a virus to the immune system but lacks genetic material.

All of these approaches are being explored in an effort to develop an effective vaccine.

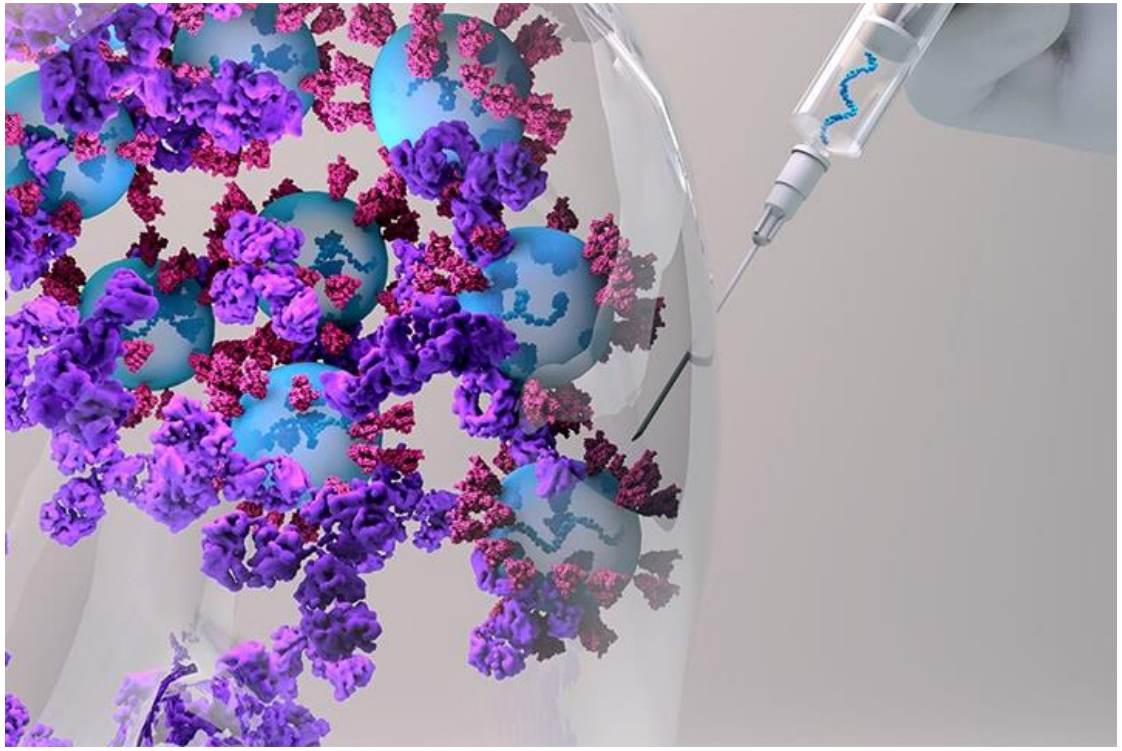
mRNA Vaccines in Phase III

PharmaLive.com

MODERNA COMPLETES ENROLLMENT IN LARGE COVID-19 VACCINE STUDY

PHASE 2 | PHASE 3 | COMBINED PHASES

BIONTECH Pfizer FOSUN PHARMA



THE POTENTIAL OF MRNA VACCINE

Safety

Non-infectious and chemically defined, contains no viral foreign proteins;
spike antigen encoded in mRNA vaccine produced by the participants' human cells

Efficacy

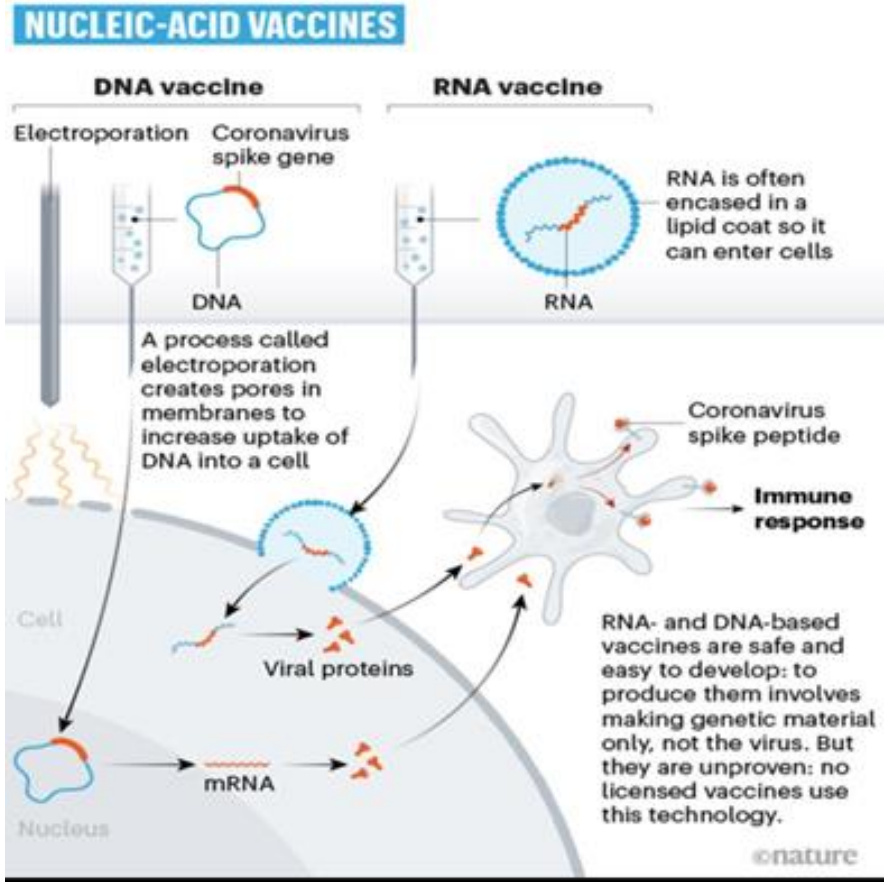
Broad immune responses based on early data, minimal risk of anti-vector immunity, and permits **frequent boosting**

Speed

Technology enables **rapid development** and **quick production scaling**

Mechanism for Action

- mRNA vaccines have strands of genetic material (mRNA) inside a special coating. That coating protects the mRNA from enzymes in the body that would otherwise break it down. It also helps the mRNA enter the muscle cells near the vaccination site.
- mRNA can most easily be described as instructions for the cell on how to make a piece of the "spike protein" that is unique to SARS-CoV-2. Since only part of the protein is made, it does not do any harm to the person vaccinated but it is antigenic.
- After the piece of the spike protein is made, the cell breaks down the mRNA strand and disposes of them using enzymes in the cell.
- It is important to note that the mRNA strand never enters the cell's nucleus or affects genetic material. This information helps counter misinformation about how mRNA vaccines alter or modify someone's genetic makeup.
- Once displayed on the cell surface, the protein or antigen causes the immune system to begin producing antibodies and activating T-cells to fight off what it thinks is an infection. These antibodies are specific to the SARS-CoV-2 virus, which means the immune system is primed to protect against future infection.



Essentially, instead of pharma producing the proteins via an expensive and difficult process, mRNA enlists the body to do the work. The capability to produce mRNA so rapidly is one reason these vaccines are out front in the global race for a COVID-19 vaccine.

A Closer Look at How COVID-19 mRNA Vaccines Work

- RNA vaccines are faster and cheaper to produce than traditional vaccines, and a RNA based vaccine is also safer for the patient, as they are not produced using infectious elements
- The use of mRNA is attractive because of the following:
  - (1) The expression of antigen can be robust and transient.
  - (2) mRNA is noninfectious, and no problems would be expected owing to genomic integration.
  - (3) There is no potential risk of infection or insertional mutagenesis.
  - (4)Additionally, mRNA is degraded by normal cellular processes, and its *in vivo* half-life can be regulated through the use of various base modifications and delivery methods.

A Closer Look at How COVID-19 mRNA Vaccines

- Facts about COVID-19 mRNA Vaccines
  - **They cannot give someone COVID-19.**
  - mRNA vaccines do not use the live virus that causes COVID-19.
  - **They do not affect or interact with our DNA in any way.**
  - mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept.
  - The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

Pros and Cons of mRNA Vaccine Platform

Advantages	Disadvantages
• Can be produced quickly • Low production cost (vs. protein vaccines) • No adjuvants • Non-Infectious • Synthesize by in vitro transcription • Free of microbial molecules • Non-integrating (vs. DNA vaccines) • Induction of T and B cell immune response	• Novel – no approved RNA vaccines, but some clinical testing for other viruses (rabies and influenza) • Instability of single stranded mRNA • Inflammatory reaction possible • Potential difficulty of intracellular delivery • Development of additional technologies for storage and administration • Most formulations require deep cold chain for longevity and stability • Low immunogenicity – require multiple doses

PFIZER PHASE 2/3 TRIAL UPDATE

Trial Locations

Approximately **150 clinical trial sites** in **6 countries,** including **39 U.S. states**

Trial Progress

The Phase 2/3 clinical trial **has enrolled 43,661 participants** and **41,135 participants** have received their **second vaccination**

Participant Diversity

Approximately **42%** of overall and **30%** of U.S. participants have diverse backgrounds

Participants	Overall Study	U.S. Only
Asian	4.5%	5.5%
Black	10.0%	10.1%
Hispanic/Latinx	26.1%	13.1%
Native American	0.8%	1.0%
Ages 56 to 85	40.9%	45.4%

Updated as of Monday, November 16, 2020

PFIZER AND BIONTECH TO SUBMIT EMERGENCY USE AUTHORIZATION REQUEST THE U.S. FDA FOR COVID-19 VACCINE

Friday, November 20, 2020 - 06:45am

- The Phase 3 clinical trial began on July 27 and has enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 13, 2020.
- Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose;
    - 170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group
- Efficacy was consistent across age, gender, race and ethnicity demographics;
    - observed efficacy in adults over 65 years of age was over 94%
- Safety data milestone required by U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved
    - Data demonstrate vaccine was well tolerated across all populations with over 43,000 participants enrolled; no serious safety concerns observed; the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%
- The companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021

Systemic effects

- Systemic effects have definitely been seen with the two mRNA COVID vaccines
- Pfizer/BioNTech reported no serious safety concerns with their COVID-19 vaccine, patients did experience grade 3 fatigue and headache at rates of 3.8% and 2%, respectively.
- Moderna: Interim data from phase III trial did include adverse event rates: fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%), and erythema/redness at the injection site (2.0%).

Product Packaging Overview

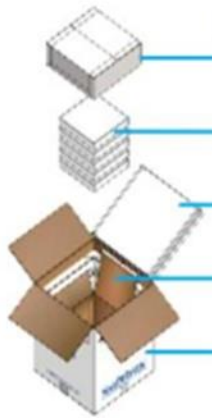
1 Primary Packaging

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

2 Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

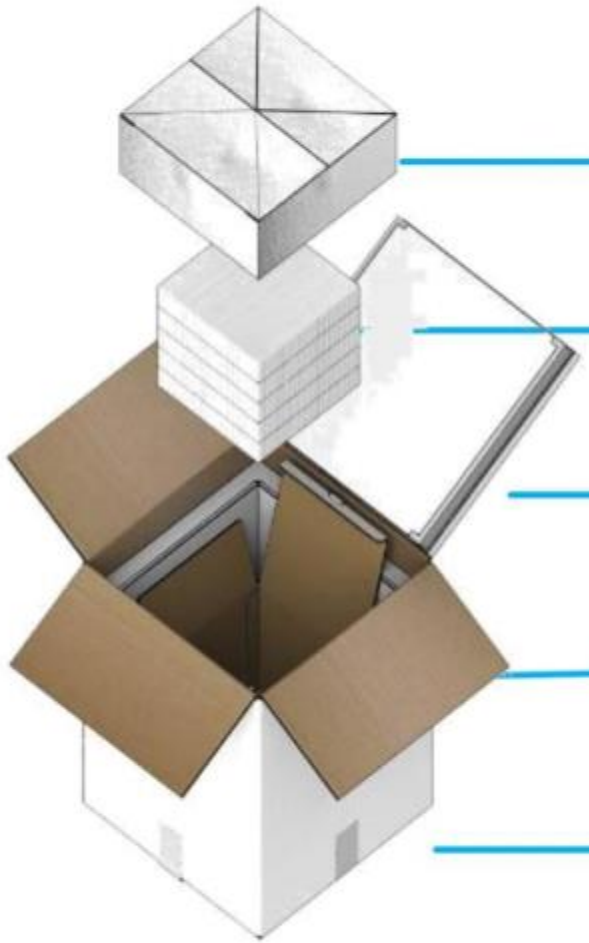
3 Tertiary Container: Thermal Shipper



Item	Description
1	Dry Ice Pod
2	Payload (Vial Trays)
3	Inner Lid
4	Payload Sleeve
5	Outer Carton

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT (-75±15°C) up to 10 days if stored at 15°C to 25°C temperatures without opening.
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice

Ultra Low Temperature Thermal Shipper – Overview of Pack Out



ITEM	DESCRIPTION
1	DRY ICE POD
2	PAYLOAD (VIAL TRAYS)
3	INNER LID
4	PAYLOAD SLEEVE
5	OUTER CARTON

Weights and Dimensions	
Tare Weight (Inc. Dry-Ice)	8.5kg (31.5kg)
Volumetric Weight	15.0kg
Payload Space L x W x H	245x245x241mm
Shipper Dimensions L x W x H	400x400x560mm


PfizerThermalShipper_9_23
Proprietary, scaffold design
Play (k)

Vaccine Storage Options* At the Point of Vaccination

1 Ultra-Low Temperature Freezer

- Store as frozen liquid at -75°C±15°C for long term storage.
  - Emergency Use vials are labeled as -70°C±10°C, however they can be safely stored in a freezer set to the USP condition of -75°C±15°C
- Frozen vials at have a 6 month expiry from the date of manufacture
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

2 Thermal Shipper Designed for Temporary Storage

- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper should be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice temperature monitor

3 2 to 8°C Refrigerator

- Can be stored at 2 to 8°C up to 5 days
- Room temperature storage is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Pfizer | BIONTECH

Please see slide 2 for important limitations with respect to this presentation.

World

Moderna's Covid Vaccine Found 94.5% Effective in Early Analysis

By Robert Langreth

November 16, 2020, 5:58 AM CST *Updated on November 16, 2020, 10:30 AM CST*

- Fast-paced hunt for prevention is paying off with new tools
- Interim results suggest vaccine may block severe cases

Coming Soon…

COVID-19 vaccine (mRNA-1273) poised to deliver safety & efficacy readouts

Preclinical and clinical data show consistent and robust immune responses

Nonhuman primate data publication showed mRNA-1273 led to a robust immune response and protection against SARS-CoV-2 infection[1]

- Two-dose vaccination schedule rapid protection against SARS-CoV-2 infection in both the lungs and nose of non-human primates

Phase 1 clinical data showed mRNA-1273 has consistent immunogenicity across all age cohorts[2,3]

- Neutralizing antibody titers were observed in 100% of evaluated participants across all age groups
- In the pseudovirus (ID50) neutralization assay, at the 100 µg dose, mRNA-1273 induced consistently high levels of neutralizing antibody titers in all participants in the young adult and older adult cohorts
- In the live SARS-CoV-2 (PRNT80) neutralization assay in the younger adult cohort, the Day 43 geometric mean titer levels at the Phase 3 selected dose of 100 µg were above those seen in reference convalescent sera

Phase 3 COVE study fully enrolled with diversity and of major risk factors representative of the U.S.[4]

- COVE study fully enrolled on October 22nd with 37% of participants coming from communities of color
- 25% of participants over 65 years old; 17% with comorbidities

1. Corbett K, Flynn B, Foulds L, et al. Evaluation of the mRNA-1273 vaccine against SARS-CoV-2 in nonhuman primates. N Engl J. Med. 28 Jul 2020; DOI: 10.1056/NEJMoa2024671
2. Jackson L, Anderson EJ, Rouphael NG, et al. An mRNA vaccine against SARS-CoV-2- preliminary report. N Engl J Med. 14 Jul 2020; DOI: 10.1056/NEJMoa2022483
3. Jackson L, Anderson EJ, Rouphael NG, et al. Safety and immunogenicity of SARS-CoV-2 mRNA-1273 vaccine in older adults. N Engl J Med. 29 Sept 2020; DOI: 10.1056/NEJMoa2028436
4. Moderna COVE study: https://www.modernatx.com/cove-study

Pivotal Phase 3 efficacy, safety and immunogenicity study

Fully enrolled (N=30,000) on October 22nd

Phase 3 trial overview (NCT04470427)

Protocol Title	A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older			
Study Groups	**Strata**	**Dosage IM (D1, D29) 1:1**	**Sample Size**	**Enrollment status**
	≥ 65 years	100 µg, placebo	42%	Enrollment completed October 22
	< 65 years at increased risk for complication of COVID-19 ("at risk")	100 µg, placebo		
	< 65 years and not at risk	100 µg, placebo	58%	Enrollment completed October 22
Participant Population	Approximately 30,000 participants (case driven) whose locations or circumstances put them at appreciable risk of acquiring COVID-19 and/or SARS-CoV-2 infection "All-comers" with regard to SARS-CoV-2 serostatus (baseline serology will be collected)			
Study Objectives	To demonstrate the efficacy of mRNA-1273 to prevent COVID-19 To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart			
Study Duration	Approximately 25 months for each participant corresponding to a 24-month follow up after the last vaccine administration			


USS ENTERPRISE
NCC-1701

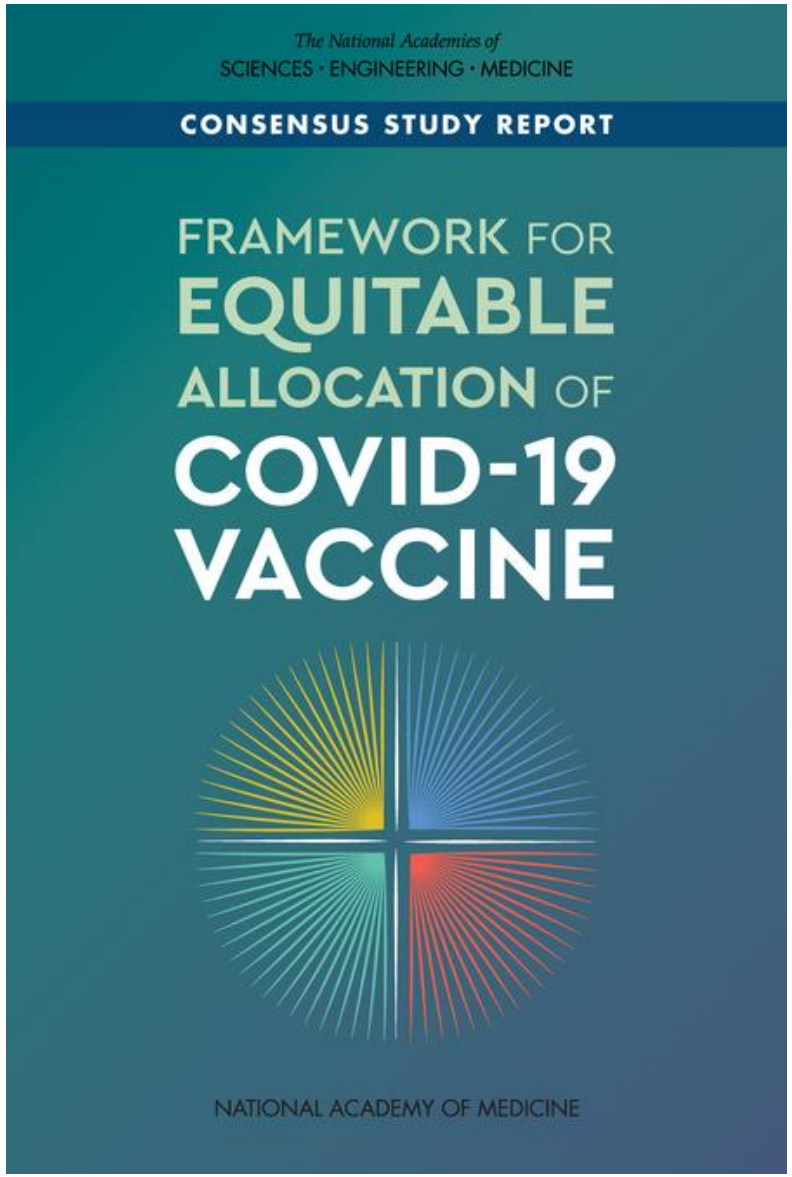

OPERATION
WARP SPEED
40 mg/mL
VACCINE
SARS-CoV-2
COVID-19
10mL Multi Dose Via
Injectable Suspension

Operation Warp Speed

- Key players: CDC, HHS, FDA, NIH, DoD, BARDA
- Aimed at accelerating the production of COVID-19 vaccine(s) while maintaining proper safety and efficacy measures
- Developing details around vaccine distribution and priority groups

COVID-19 VACCINE PLANNING

- At least at first, COVID-19 vaccines might be used under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).
- There may **be a limited supply of COVID-19** vaccines before the end of 2020, but supply will continually increase in the weeks and months that follow.
- If there is limited supply, some groups may be recommended to get a COVID-19 vaccine first.
- COVID-19 vaccines will be **allocated pro rata by population** to ensure fair and equitable distribution across the U.S.
- Primary goals of ongoing planning efforts are to ensure high-priority groups are vaccinated early and to establish a foundation to ensure vaccine access to larger groups by working at the community level.



The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Nancy McClung, PhD[1]; Mary Chamberland, MD[1,2]; Kathy Kinlaw, MDiv[3]; Dayna Bowen Matthew, JD, PhD[4]; Megan Wallace, DrPH[1,5]; Beth P. Bell, MD[6]; Grace M. Lee, MD[7]; H. Keipp Talbot, MD[8]; José R. Romero, MD[9]; Sara E. Oliver, MD[1]; Kathleen Dooling, MD[1]

On November 23, 2020, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

To reduce the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) and its associated impacts on health and society, COVID-19 vaccines are essential. The U.S. government is working to produce and deliver safe and effective COVID-19 vaccines for the entire U.S. population. The Advisory Committee on Immunization Practices (ACIP)* has broadly outlined its approach for developing recommendations for the use of each COVID-19 vaccine authorized or approved by the Food and Drug Administration (FDA) for Emergency Use Authorization or licensure (*1*). ACIP's recommendation process includes an explicit and transparent evidence-based method for assessing a vaccine's safety and efficacy as well as consideration of other factors, including implementation (*2*). Because the initial supply of vaccine will likely be limited, ACIP will also recommend which groups should receive the earliest allocations of vaccine. The ACIP COVID-19 Vaccines Work Group and consultants with expertise in ethics and health equity considered external expert committee reports and published literature and deliberated the ethical issues associated with COVID-19 vaccine allocation decisions. The purpose of this report is to describe the four ethical principles that will assist ACIP in formulating recommendations for the allocation of COVID-19 vaccine while supply is limited, in addition to scientific data and implementation feasibility: 1) maximize benefits and minimize harms; 2) promote justice; 3) mitigate health inequities; and 4) promote transparency. These principles can also aid state, tribal, local, and territorial public health authorities as they develop vaccine implementation strategies within their own communities based on ACIP recommendations.

The ACIP COVID-19 Vaccines Work Group has met several times per month (approximately 25 meetings) since its establishment in April 2020. Work Group discussions included review of the epidemiology of COVID-19 and consultation with experts in ethics and health equity to inform the development of an ethically principled decision-making process. The Work Group reviewed the relevant literature, including frameworks for pandemic influenza planning and COVID-19 vaccine allocation (*3*–*8*); summarized this information; and presented it to ACIP. ACIP supported four fundamental ethical principles to guide COVID-19 vaccine allocation decisions in the setting of a constrained supply. Essential questions that derive from these principles can assist in vaccine allocation planning (Table 1).

Maximize benefits and minimize harms. Allocation of COVID-19 vaccine should maximize the benefits of vaccination to both individual recipients and the population overall. These benefits include the reduction of SARS-CoV-2 infections and COVID-19–associated morbidity and mortality, which in turn reduces the burden on strained health care capacity and facilities; preservation of services essential to the COVID-19 response; and maintenance of overall societal functioning. Identification of groups whose receipt of the vaccine would lead to the greatest benefit should be based on scientific evidence, accounting for those at highest risk for SARS-CoV-2 infection or severe COVID-19–related disease or death, and the essential role of certain workers. The ability of essential workers, including health care workers and non–health care workers, to remain healthy has a multiplier effect (i.e., their ability to remain healthy helps to protect the health of others or to minimize societal and economic disruption). Some of these workers are at increased risk for SARS-CoV-2 infection because of their limited ability to maintain physical distance in the workplace or because they do not have consistent access to recommended personal protective equipment.

Promote justice. Inherent in the principle of justice is an obligation to protect and advance equal opportunity for all persons to enjoy the maximal health and well-being possible. Justice rests on the belief in the fundamental value and dignity of all persons. Allocation of COVID-19 vaccine should promote justice by intentionally ensuring that all persons have equal opportunity to be vaccinated, both within the groups recommended for initial vaccination, and as vaccine becomes more widely available. This includes a commitment to removing unfair, unjust, and avoidable barriers to vaccination that disproportionately affect groups that have been economically or

* The ACIP includes 15 voting members responsible for making vaccine recommendations. Fourteen of the members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine; one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. In addition to the 15 voting members, ACIP includes eight ex officio members who represent other federal agencies with responsibility for immunization programs in the United States, and 30 nonvoting representatives of liaison organizations that bring related immunization expertise. https://www.cdc.gov/vaccines/acip/members/index.html.

Foundational principles for allocation

Ethical Principles

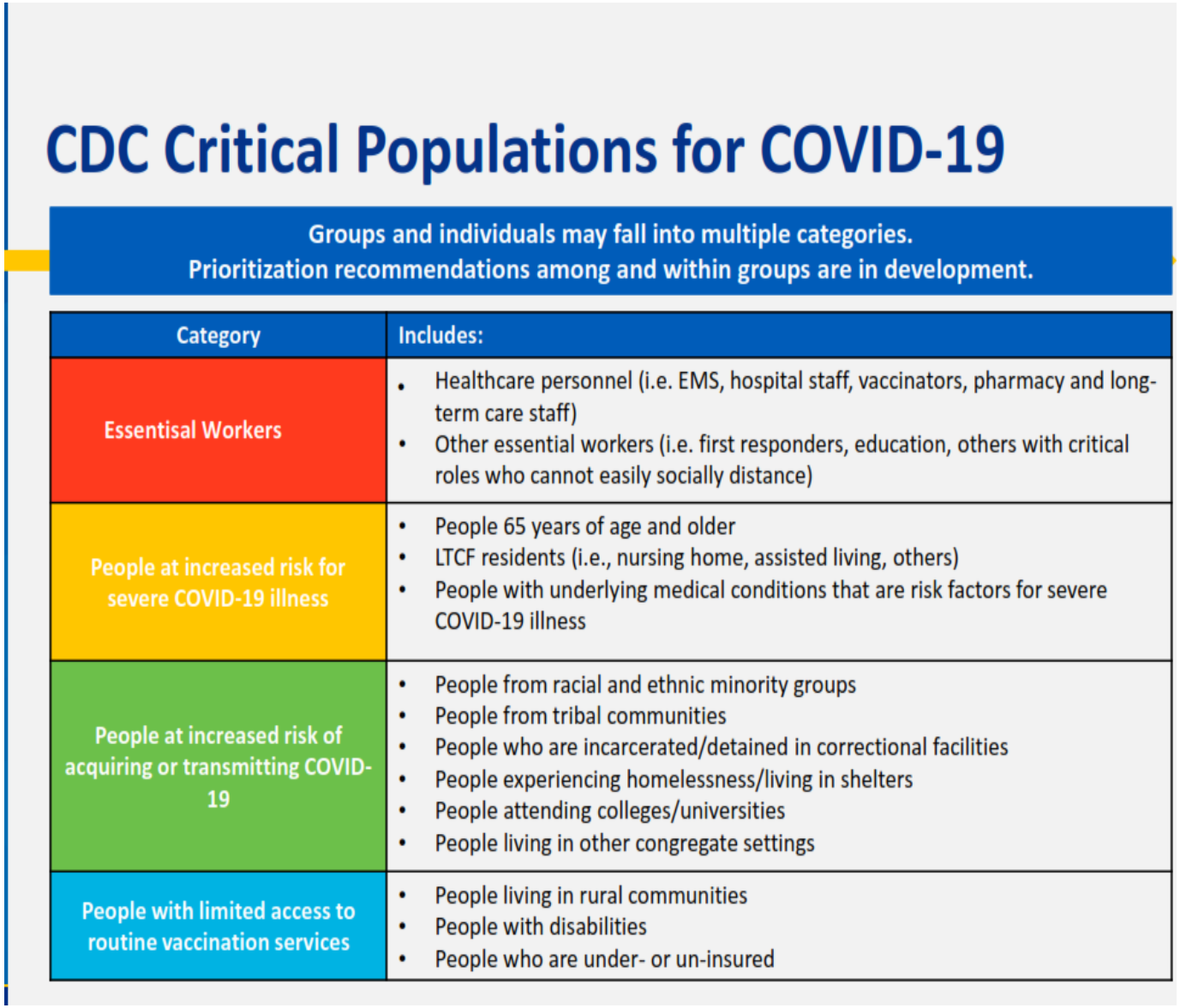
- **Maximum benefit** encompasses the obligation to protect and promote the public's health and socioeconomic well-being in the short and long term.
- **Equal concern** requires that every person be considered and treated as having equal dignity, worth, and value.
- **Mitigation of health inequities** includes the obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and health inequities.

Procedural Principles

- **Fairness** requires engagement with the public, particularly those most affected by the pandemic, and impartial decision-making about and evenhanded application of allocation criteria.
- **Transparency** includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the allocation framework as it is being developed, deployed, and modified.
- **Evidence-based** expresses the requirement to base the allocation framework on the best available and constantly updated scientific information and data.

(National Academy of Medicine, 2020)

Plans to ensure equitable access to vaccination for each of the critical population



CDC Critical Populations for COVID-19

Groups and individuals may fall into multiple categories.
Prioritization recommendations among and within groups are in development.

Category	Includes:
Essentisal Workers	• Healthcare personnel (i.e. EMS, hospital staff, vaccinators, pharmacy and long-term care staff) • Other essential workers (i.e. first responders, education, others with critical roles who cannot easily socially distance)
People at increased risk for severe COVID-19 illness	• People 65 years of age and older • LTCF residents (i.e., nursing home, assisted living, others) • People with underlying medical conditions that are risk factors for severe COVID-19 illness
People at increased risk of acquiring or transmitting COVID-19	• People from racial and ethnic minority groups • People from tribal communities • People who are incarcerated/detained in correctional facilities • People experiencing homelessness/living in shelters • People attending colleges/universities • People living in other congregate settings
People with limited access to routine vaccination services	• People living in rural communities • People with disabilities • People who are under- or un-insured

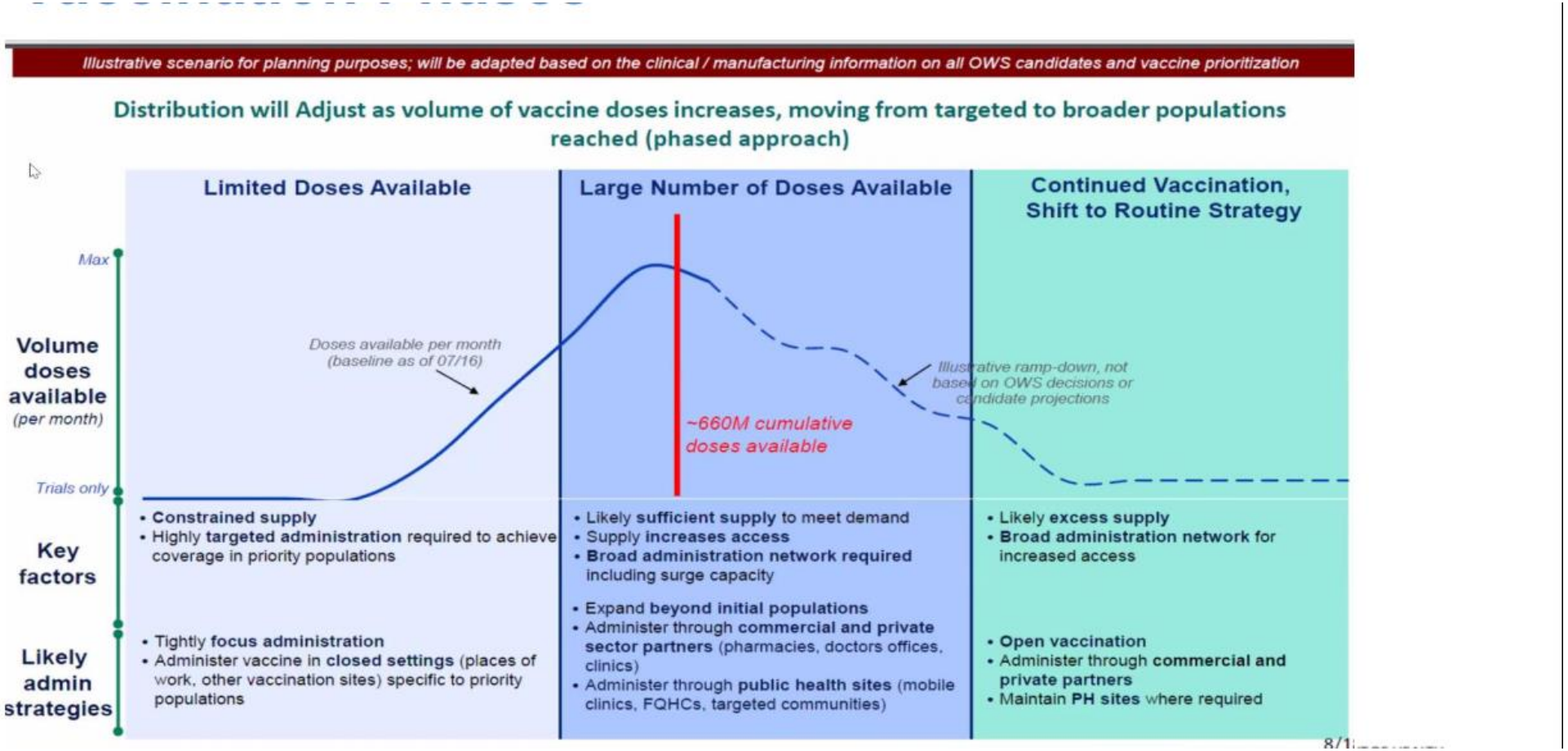
Healthcare Personnel (HCP):

- HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances; contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air.
- HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, home healthcare personnel, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

Phased Approach

- Phase 1: Potentially limited supply of COVID-19 vaccine doses available
  - **Focus initial efforts on reaching the critical populations**
- Phase 2: Larger number of vaccine doses available
  - **Focus on ensuring vaccination Phase 1 critical populations who were not yet vaccinated as well as for the general population**
- Phase 3: Sufficient supply of vaccine doses for entire population
  - **Focus on ensuring equitable vaccination access across the entire population.** Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

Phased Approach



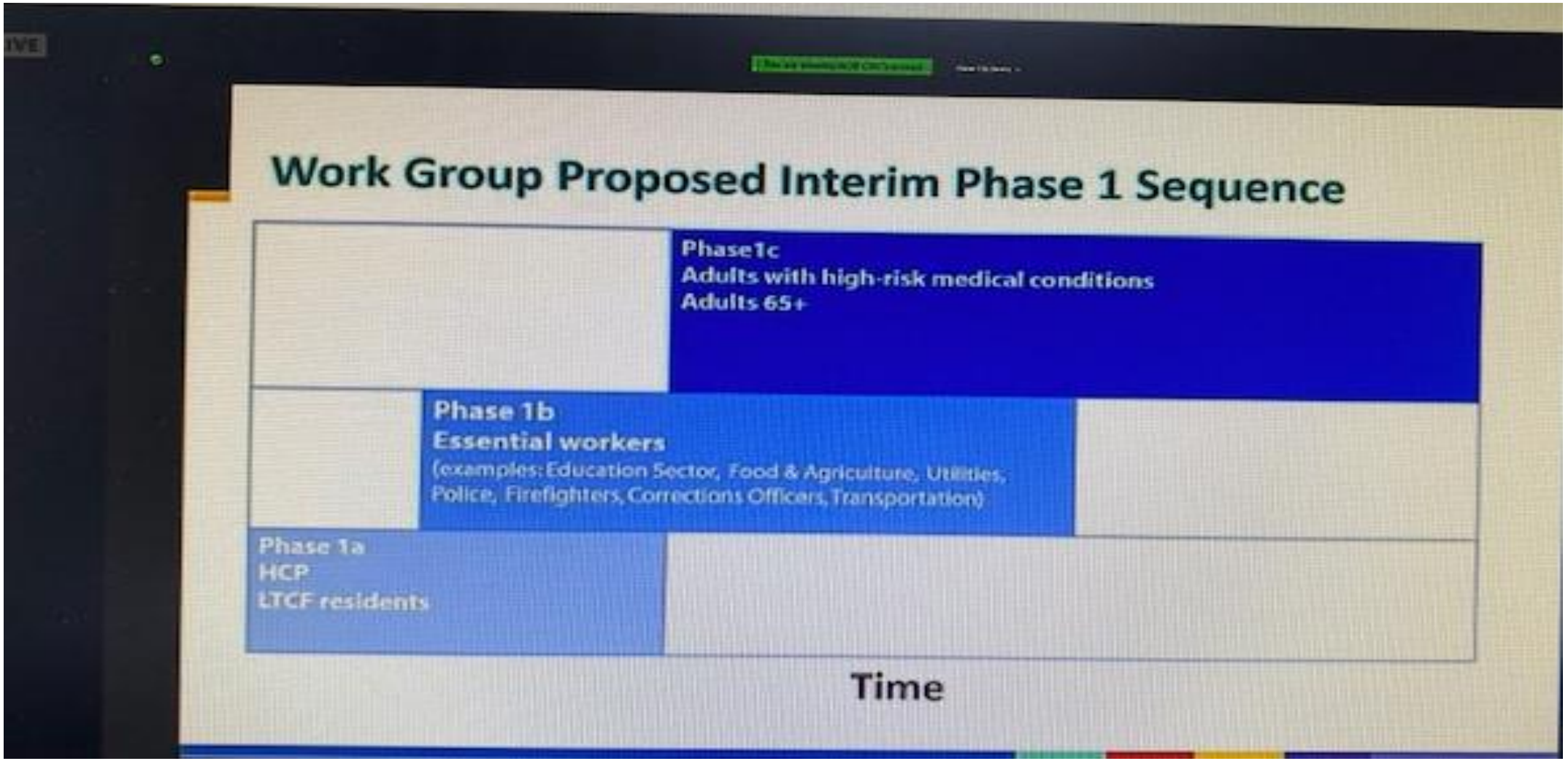
Vaccine Allocation Phases

Equity is a crosscutting consideration: In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.

12/2020

Adapted from https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES



Should Docs Who Had COVID Still Get the Vaccine?

Healthcare workers consider giving up their spot in line considering limited supply

Given that at the very beginning, we are really expecting demand to far outpace supply, it does make some sense to prioritize people who have not been infected already

Pharmacy Partnership for Long-term Care Program

End-to-end management of the COVID-19 vaccination process for LTCFs nationwide

- Cold chain management
- On-site vaccinations for all residents and any staff not already vaccinated
- Fulfillment of reporting requirements to jurisdictions and CDC

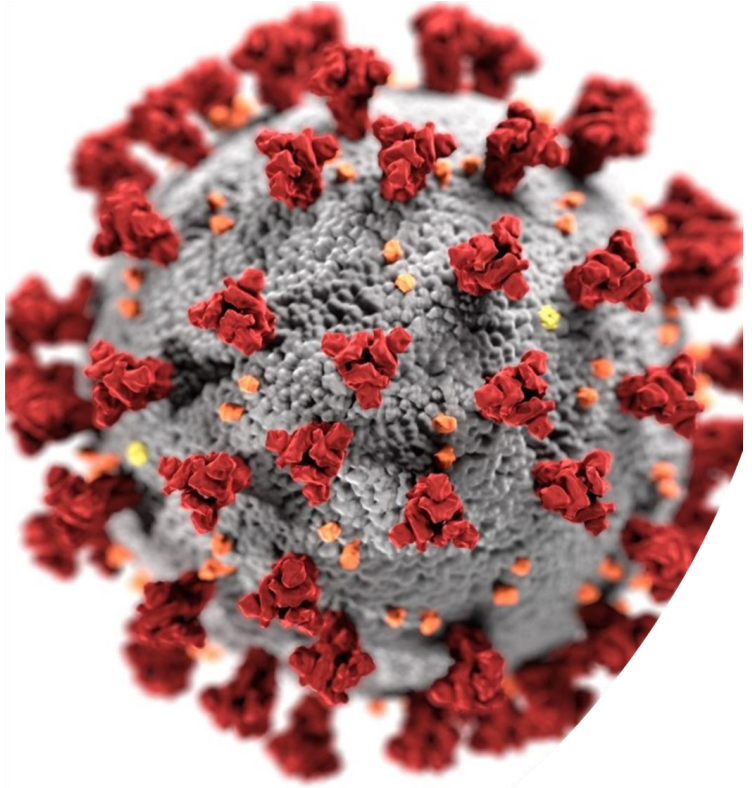
As part of this program, which is free of charge to facilities, the pharmacy will:

- Schedule and coordinate on-site clinic date(s) directly with each facility.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data to the local, state/territorial, and federal jurisdictions within 72 hours of administering each dose.
- Adhere to all applicable Centers for Medicare & Medicaid (CMS) COVID-19 testing requirements for LTCF staff.

https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html

PUBLIC HEALTH PREPAREDNESS PLANNING

- **Emphasis in collaboration:**
  - Immunization Program
  - Health emergency preparedness program
  - Emergency management agency
  - Health care coalitions
  - Industry groups
  - Community vaccination providers
- Leverage seasonal influenza and routine vaccination program
- COVID-19 vaccination response will be more complex



COVID-19 Vaccination Provider Requirements

All COVID-19 vaccination providers participating in the U.S. COVID-19 Vaccination Program are required to sign a COVID-19 Vaccination Program Provider Agreement to receive delivery of any COVID-19 vaccine from CDC's distributor or a COVID-19 vaccine manufacturer.

The agreement must be completed by all public and private providers, provider organizations, and government-affiliated federal, state, territorial, and local providers.

As part of the agreement, providers are required to:

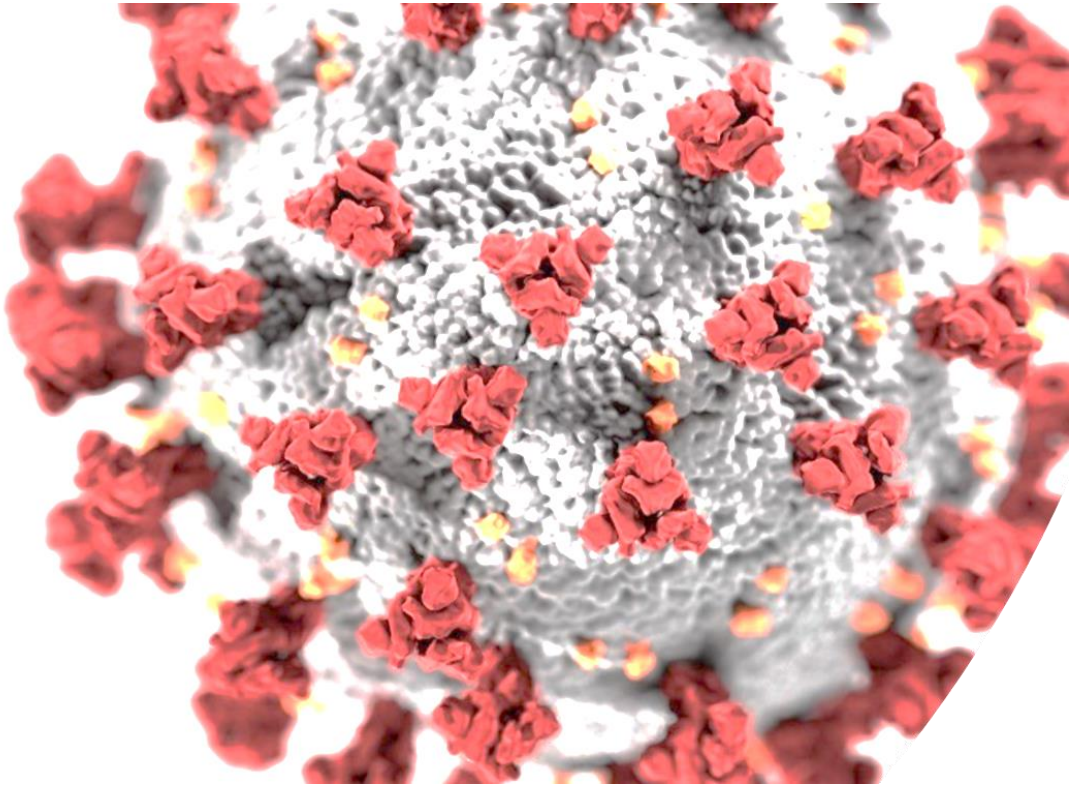
- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in this toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in this toolkit.
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

CDC Requirements for COVID-19 Vaccination Providers

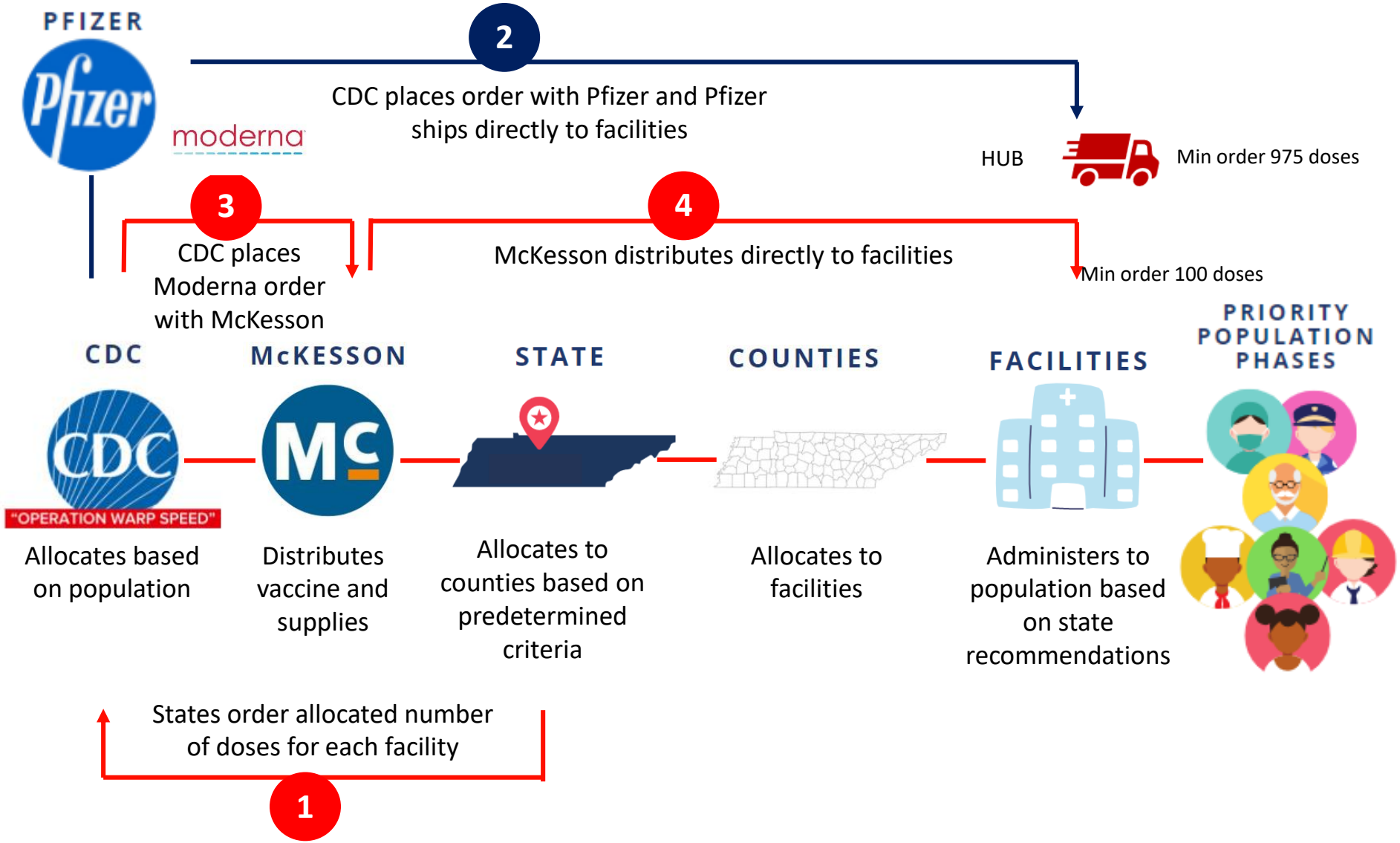
- Must have an active NPI/TPI number.
- Must follow ACIP requirements and recommendations.
- Must comply CDC requirements for COVID-19 vaccine management and maintain adequate storage capacities to maintain integrity of the vaccine cold-chain requirements
- Must report dose usage within 24 hours to the state immunization registry,
- Must report of all doses received including those administered, lost, wasted, etc.
- Must report of any adverse event related to receiving the vaccine.

PROVIDER ASSESMENT

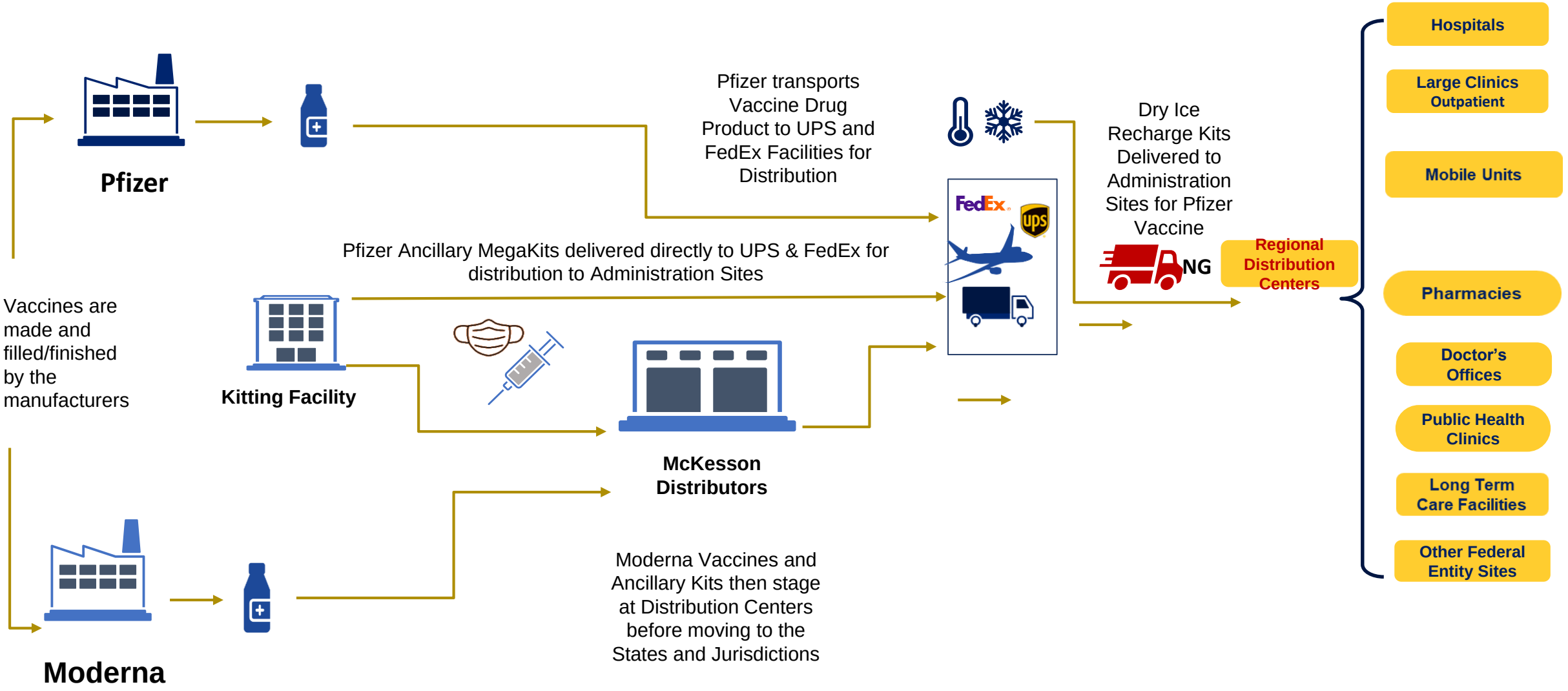
- Hospitals
- VFC/VFA Providers
- Private centers
- FQCHC
- PHARMACIES
- Brand Pharmacies
- Mobile Units



Vaccine Allocation and Distribution



Vaccine Distribution Process



Distribution Plan Includes Options for Points of Use (POUs) to Store COVID Vaccine Up To 6 Months

Direct Shipment to Point of Vaccination

Each thermal shipper arrives with a reusable GPS temperature monitoring device

Vaccine Storage

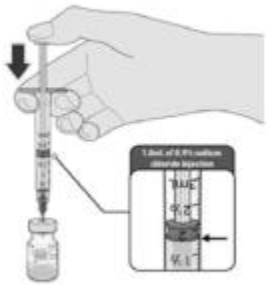
Ultra-Low Temperature Freezer (6 Months)
Commercially available for POUs from suppliers

Dry Ice Thermal Shippers (15 Days*)

2-8°C Refrigerator Storage (5 Days)

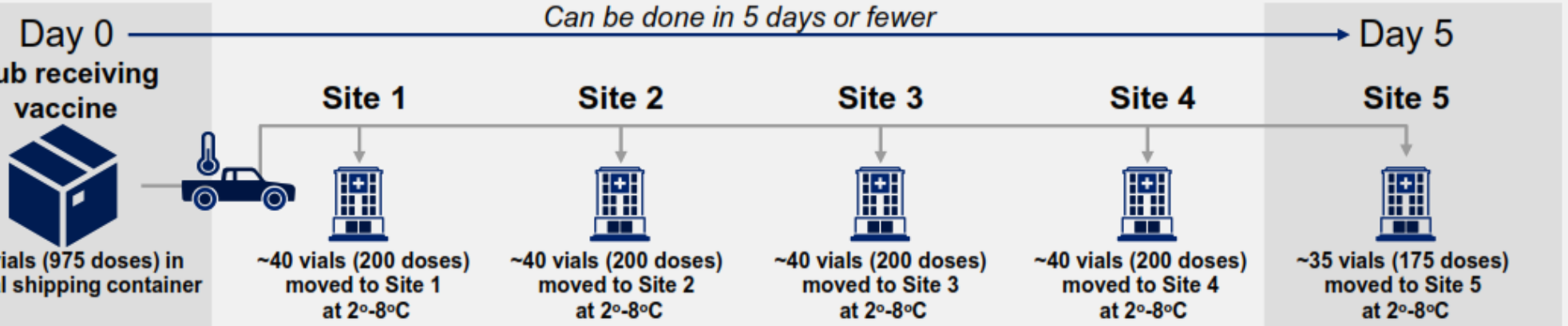
Vaccine Preparation

From storage 1 vial used for every 5 patients



Vaccine A Example: Hub and Spoke Model, Delivery at 2-8C

Illustrative example, using one-time re-ice of thermal shipping container



Logistics

- Receive product
- Re-ice thermal shipping container (provides 5 days for vaccine storage at ultra low temperature)
- Thermal shipper may be opened twice a day.

For delivery to each site:

- At hub: Remove ~40 vials (200 doses) from thermal shipping container and thaw
- Transport thawed vials at 2°-8°C (e.g. mobile refrigerator) to site

Either:

- Remove ~35 vials (175 doses) from thermal shipping container, thaw, and move at 2°-8°C to Site 5

OR

- Re-ice thermal shipping container for another 5 days at -60°C to -80°C and repeat cycle

Admin-istration

- *Hub may also be a point of vaccine administration*

At each site:

- Site stores doses at 2°-8°C in refrigerator
- Site has 5 days (incl. day of delivery) to administer 200 doses (40 doses / day)
- **If needed**, site has 5 days to administer remaining 175 doses (35 doses / day)

Hub & spoke model would be the recommended transfer model for Phase 1a

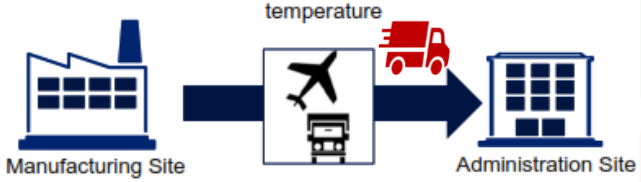
- **Phase 1A: hospitals, CDT, FQHC**
- **Phase 1B: first responder sites, occ health clinics, correctional facilities, etc.**
- **Phase 1C: 700+ public & private providers**

Vaccine A

Vaccine Storage

Shipped CONUS < 24 hours

Thermal shipping container maintains -60° C to -80° C up to 10 days without opening at room temperature



- Thermal shipping container must be opened and inspected upon receipt
- Initial inspection must be completed in less than 5 minutes
- The thermal shipping container can only be opened twice per day for 2 minutes during each opening

24 hours

If the thermal shipping container will be used for storage, it must be re-iced within 24 hours of initial inspection and then every 5 days thereafter. Up to 3 re-icings are authorized.

Option 1
Placed in ultra-cold temperature freezer

Product stable for ~6 months → **6 Months**

Option 2
Maximize use of thermal shipping container

Re-ice → 5 Days → Re-ice → 5 Days → Re-ice → 5 Days → Refrigeration 2°-8° C → 5 Days → **20 Days**

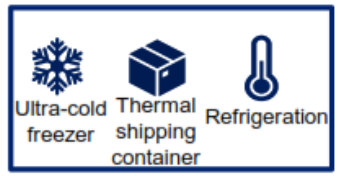
Option 3
One-time re-ice of thermal shipping container

Re-ice → 5 Days → Refrigeration 2°-8° C → 5 Days → **10 Days**

Option 4
Immediately placed in refrigerator

Refrigeration 2°-8° C → 5 Days → **5 Days (120 Hours)**

Vaccine Thawing



Thermal shipping container

Minimum shipper quantity: 1 tray (**195 vials, 975 doses**)
Maximum shipper quantity: 5 trays (**975 vials, 4875 doses**)

If removed directly from ultra-cold temperatures, thaw vial at room temperature 30 minutes to 2 hours before dilution

Once vaccine is thawed, it must be diluted within 2 hours; if unable to dilute within 2 hours, store at 2°– 8°C

Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours)

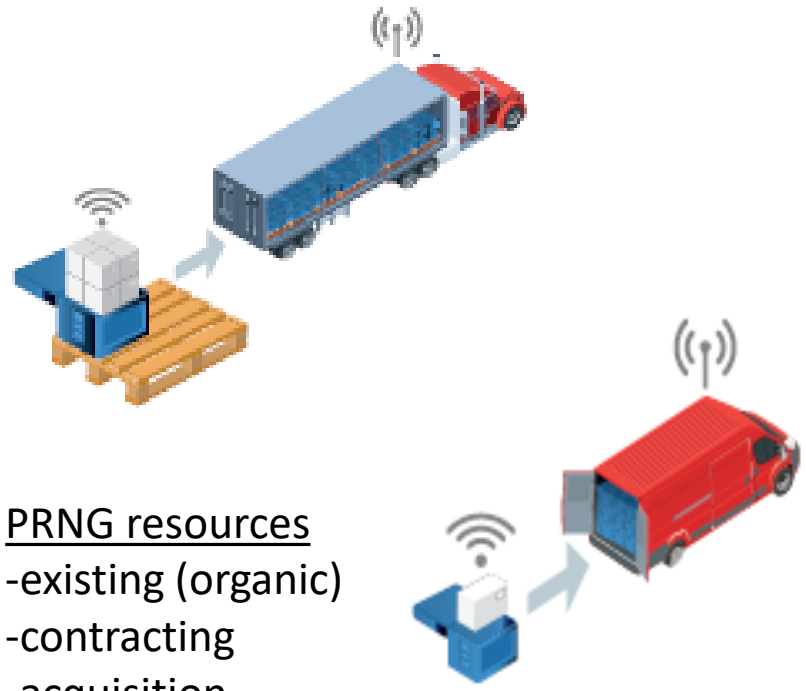
Moderna (mRNA)

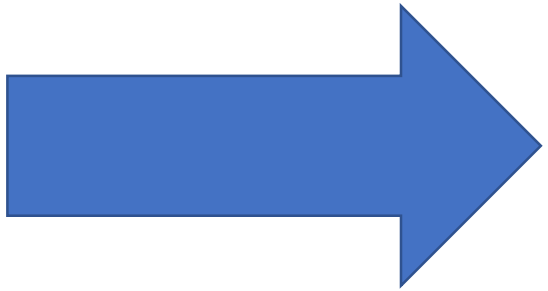
- Anticipating late December/early January
- Shipped from McKesson warehouse
- Frozen storage, -20^{o}C; Fridge stable for 30 days
- 94.5% effective in preventing COVID-19 7d after dose 2
- 28 days between doses
- Minimum quantity 100 doses

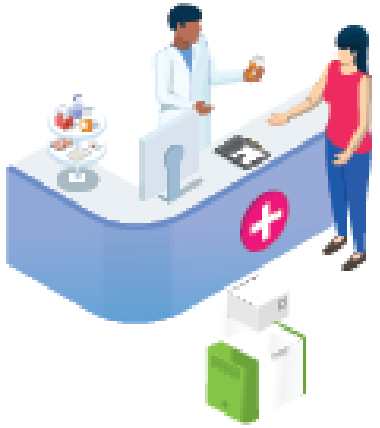
Shipping to Local Points of Care

Three main Lines of Effort (local points of care):

- Phase 1a:Hospitals throughout PR (65) + 10 CDT ER
- Phase 1b: First Responder vaccination sites, + 1 mobile team, CDTs, FQCHCOCC Health Clinics, Correctional Facilities
- Phase 1c: 700+public and private providers







PRNG resources
-existing (organic)
-contracting
-acquisition

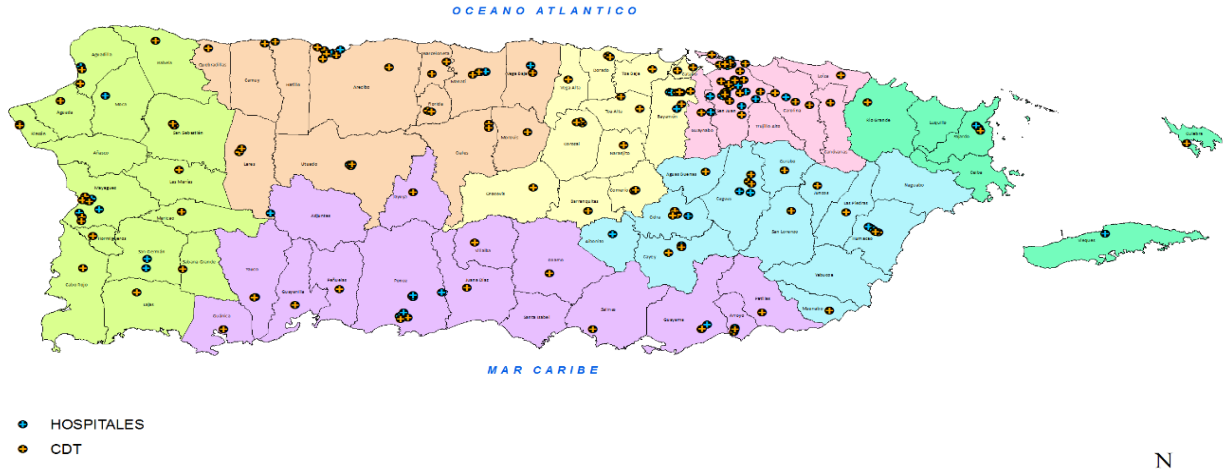
Local points of care

Local Points of Care/Vaccination

Local points of care

- Hospitals
- Regional Distribution Center
- First Responder vaccination sites

FACILIDADES DE SALUD



Mobile Team

Possible Timeline (Assumptions)

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
NOVEMBER						
15	16 CDC ACIP	17	18	19	20 Doses Allocated; EUA Submitted	21
22	23 CDC ACIP	24	25	26	27 Doses Allocated; EUA Submission	28
29	30	DECEMBER				
	State Microplans Locked	1	2	3	4	5
6	7	8	9	10 FDA VRBPAC	11 Window for EUA Decision / ACIP Review	12
13 Window for EUA Decision / ACIP Review	14	15 Vx Distribution	16	17 FDA VRBPAC	18 Window for EUA Decision / ACIP Review	19
20 Window for EUA Decision / ACIP Review	21	22 Vx Distribution	23	24	25	26
27	28	29	30	31		

Source: OWS Gen Perna Governor's call

Vaccine Safety

All adverse events that occur will need to be reported online at VAERS

CDC and HHS are in the process of improving the system to handle the vaccine

Once vaccine is deployed:

- VAERS will start collecting reports of adverse events for COVID-19 vaccine
- All health care providers will need to report online at https://vaers.hhs.gov/

So How Is This Going to Work?

- Communication in advance of vaccine is critical
  - Health care buy-in, uptake and recommendations
  - Expectations for who gets vaccine when
  - Vaccine confidence
- **Vaccinating facilities need to complete the CDC Provider Agreement and Profile, onboard to report all administered doses to IIS, and have their vaccine storage and handling vaccine capability approved**
- Vaccine will be offered to all of Phase 1a until demand diminishes and then facilities will begin vaccinating Phase 1b
- Facilities within will be in different phases at different times
  - And that's ok
  - We want shots in arms

Can I Choose My COVID-19 Vaccine?

COVID-19 Final Though

- This COVID-19 ---is the moral test of our time, assessing our ability to think about others before ourselves and to act for the greater good.
- Recommendation
  - Trust science.
  - Trust our institutions — grounded in responsive, responsible, evidence-based governance and leadership.
  - Trust in each other. Mutual respect and upholding human rights must be our compass in navigating this crisis.
- It is a test, not the final exam.
  - We are still learning

REMINDER

The information presented today is based on CDC’s recent guidance and MAY change.

Questions?

Thank you for your partnership!