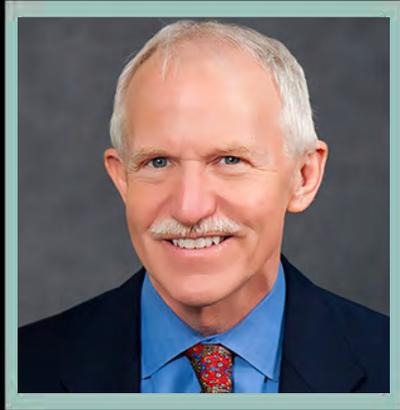
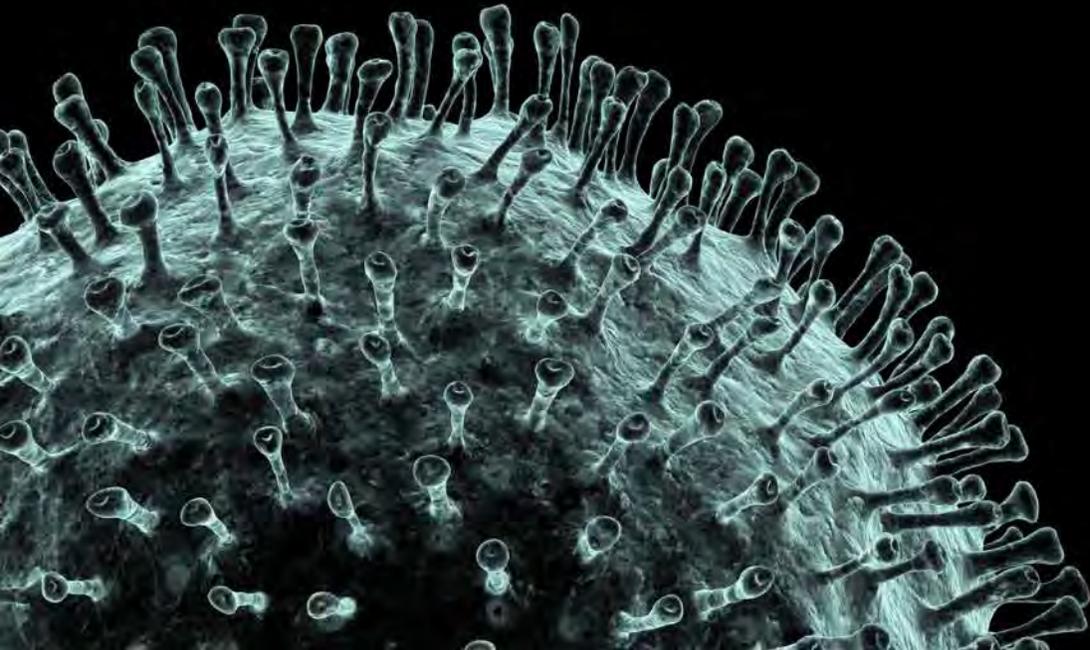


COVID-19 Conversations



Jay Butler

Deputy Director for Infectious Diseases
Centers for Disease Control and Prevention



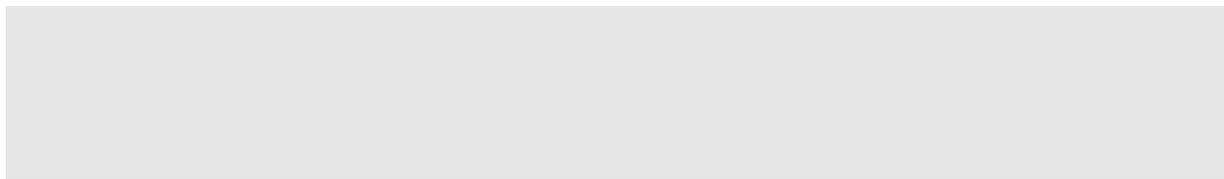
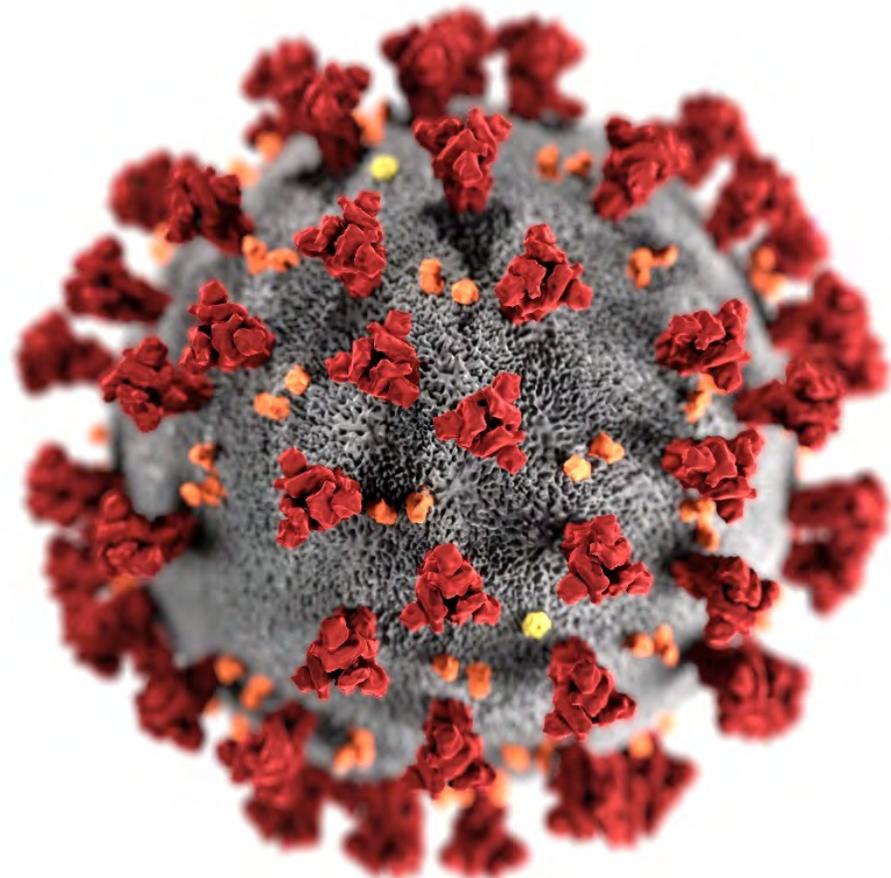
COVID19Conversations.org

[#COVID19Conversations](https://twitter.com/COVID19Conversations)



COVID-19 Vaccine Distribution and Administration

Jay C. Butler, MD
Deputy Director for Infectious Diseases
November 18, 2020



COVID-19 vaccines in human clinical trials – United States*

| Candidate | Manufacturer | Type | Phase | Trial characteristics | Trial # | Recruiting |
|-------------|---|-------------------|--------|---|-------------|---------------------|
| mRNA-1273 | Moderna TX, Inc. | mRNA | III | <ul style="list-style-type: none"> • 2 doses (0, 28d) • IM administration • 18-55, 56+ years | NCT04470427 | Enrollment complete |
| mRNA-BNT162 | Pfizer, Inc./BioNTech | mRNA | II/III | <ul style="list-style-type: none"> • 2 doses (0, 21d) • IM administration • 18-85 years | NCT04368728 | ✓ |
| AZD1222 | University of Oxford/AstraZeneca consortium** | Viral vector (NR) | III | <ul style="list-style-type: none"> • 2 doses (0, 28d) • IM administration • ≥18 years | NCT04516746 | ✓ |
| Ad26COVS1 | Janssen Pharmaceutical Companies | Viral vector (NR) | III | <ul style="list-style-type: none"> • 1 dose • IM administration • 18-55, 65+ | NCT04436276 | ✓ |
| -- | Sanofi/GSK | Protein Subunit | I/II | <ul style="list-style-type: none"> • Single or 2 doses • IM administration • 18-49, 50+ | NCT04537208 | ✓ |
| NVX-CoV2373 | Novavax | Protein Subunit | I/II | <ul style="list-style-type: none"> • 2 doses (0, 21d) • IM administration • 18-84 | NCT04368988 | Enrollment complete |
| V591 | Merck | Viral Vector | I/II | <ul style="list-style-type: none"> • 2 doses (1, 57d) • IM administration • 18-55 | NCT04498247 | ✓ |

*As of October 27, 2020

**Currently on hold in US

Sources: <https://millkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccineshinyapps.io/ncov_vaccine_landscape/; <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



Overarching objectives for COVID-19 vaccination program



Ensure safety and effectiveness of COVID-19 vaccines



Reduce mortality, morbidity, and incidence of COVID-19 disease

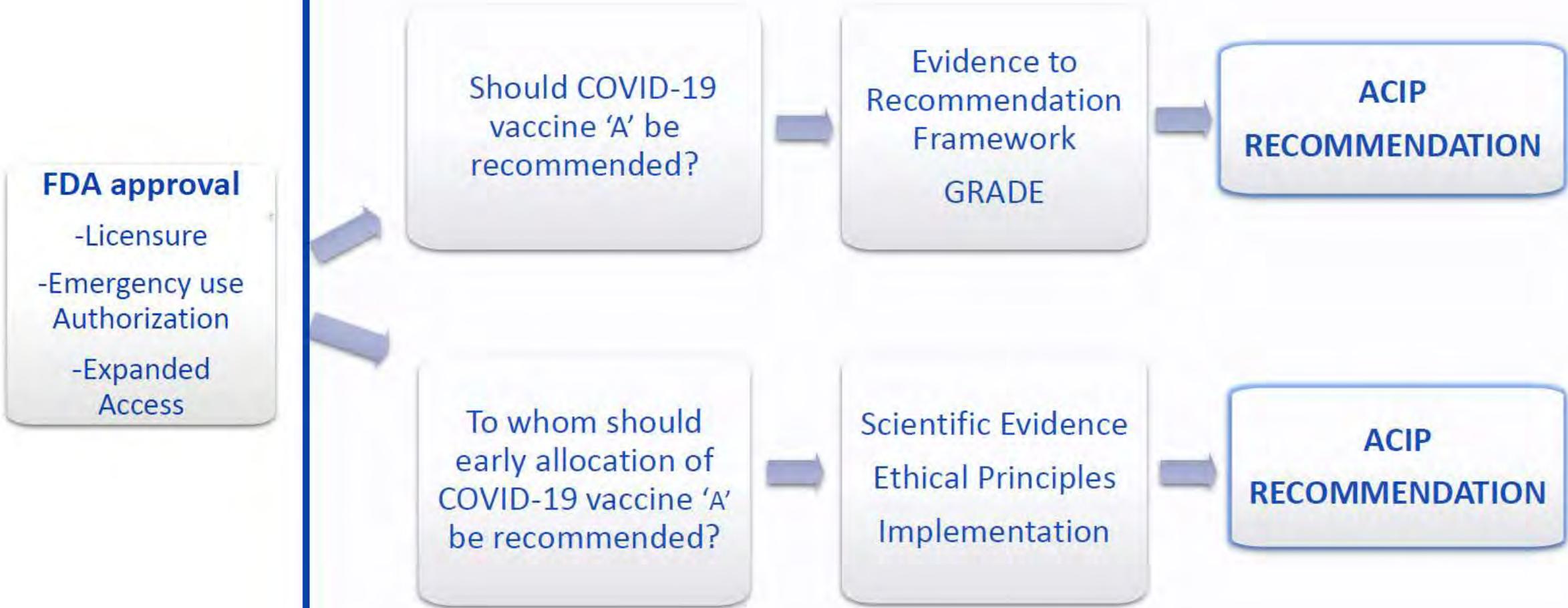


Help minimize disruption to society and economy, including maintaining healthcare capacity

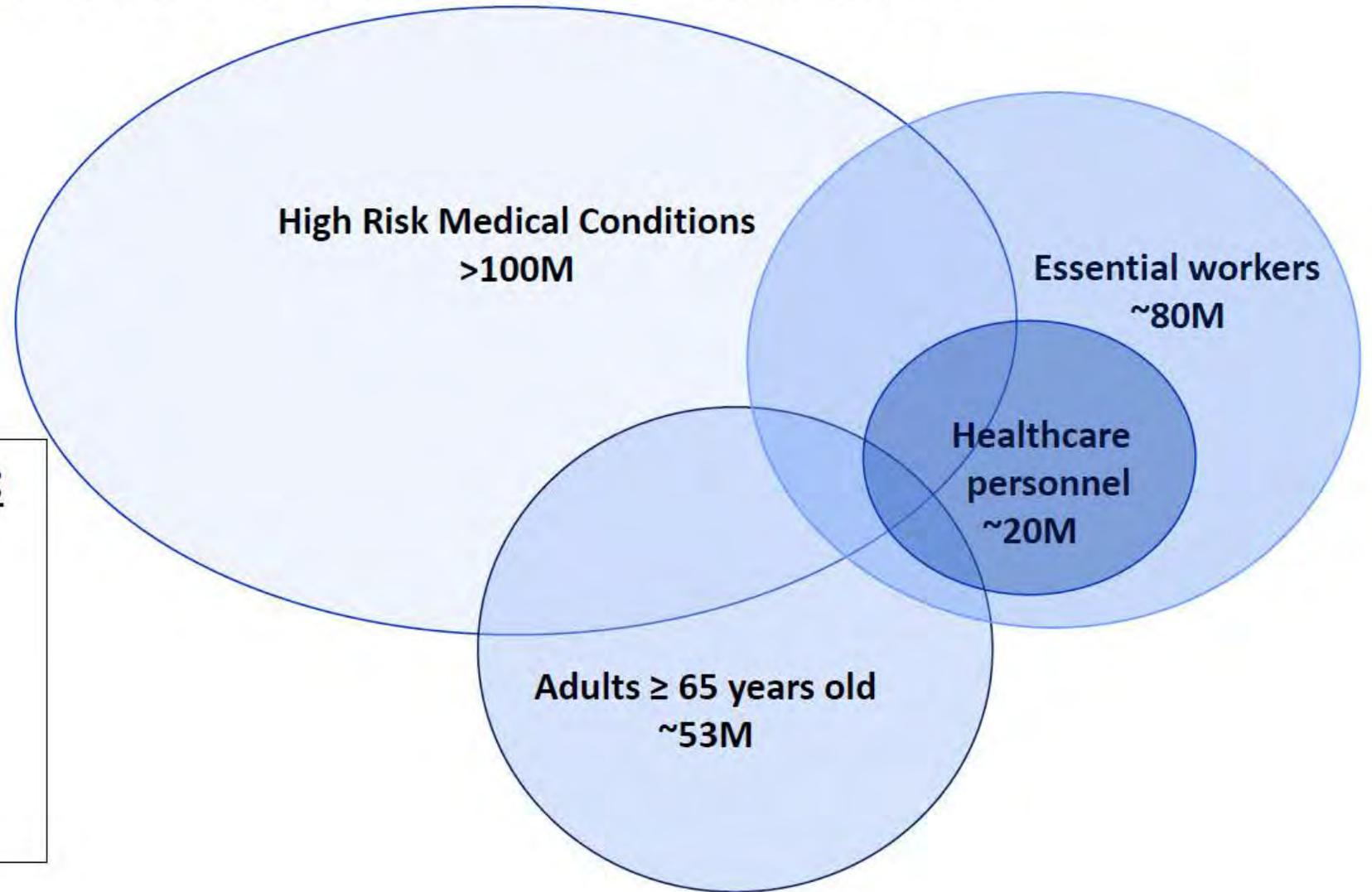


Ensure equity in vaccine allocation and distribution

ACIP Pathway to Recommendation



Possible groups for Phase 1 vaccination



From prior ACIP Discussions:

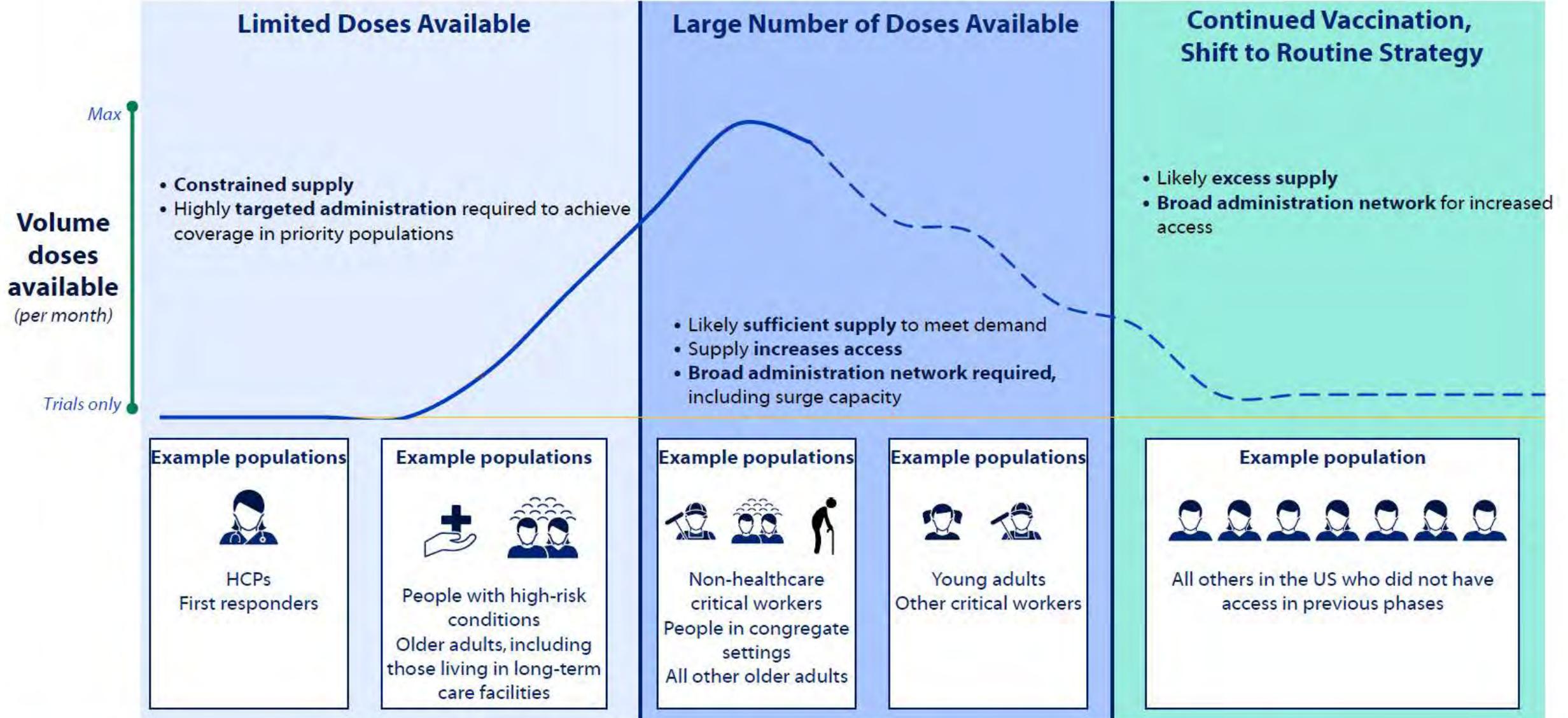
Phase 1a:

-HCP

Phase 1b:

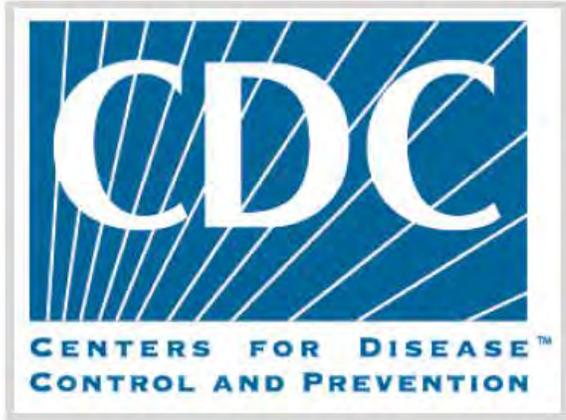
- Essential Workers
- High Risk Med Conditions
- Adults ≥ 65 years old

Distribution will adjust as volume of vaccine doses increases



Vaccine Safety Monitoring

- The Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA) Project, and other planned projects are key components of COVID-19 vaccine safety monitoring and adverse event assessment
- VAERS is the U.S. frontline vaccine safety monitoring system
 - VAERS traditionally has provided the initial data on the safety profile of new vaccines when they are introduced for use in the population
 - Healthcare providers (HCPs) can play an important role in identifying and reporting potential AEs to VAERS: **HCPs are partners in safety monitoring**
- **V-safe** is a new smart-phone based active surveillance program
 - HCPs can play an important role in helping CDC enroll patients in **v-safe** at the time of vaccination: **HCPs are partners in safety monitoring**



1. Text message check-in or email from CDC (daily 1st week post-vaccination and weekly thereafter until 6 weeks post-vaccination)

Vaccine recipient completes web survey



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Vaccine recipient

2. Clinically important event(s) reported

- ✓ Missed work
- ✓ Unable to do normal daily activities
- ✓ Received medical care

v-safe
after vaccination
health checker



VAERS call center



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3. A VAERS customer service representative conducts active telephone follow-up on a clinically important event and completes a VAERS report if appropriate

