

DEPARTMENT OF GLOBAL HEALTH

UNIVERSITY *of* WASHINGTON



# COVID-19 VACCINES: EVALUATION AND DISTRIBUTION

Beth P Bell MD, MPH

Clinical Professor

University of Washington

Member, Advisory Committee on Immunization Practices

**UW Medicine**  
SCHOOL OF MEDICINE



SCHOOL OF PUBLIC HEALTH  
UNIVERSITY *of* WASHINGTON

# Talk Outline



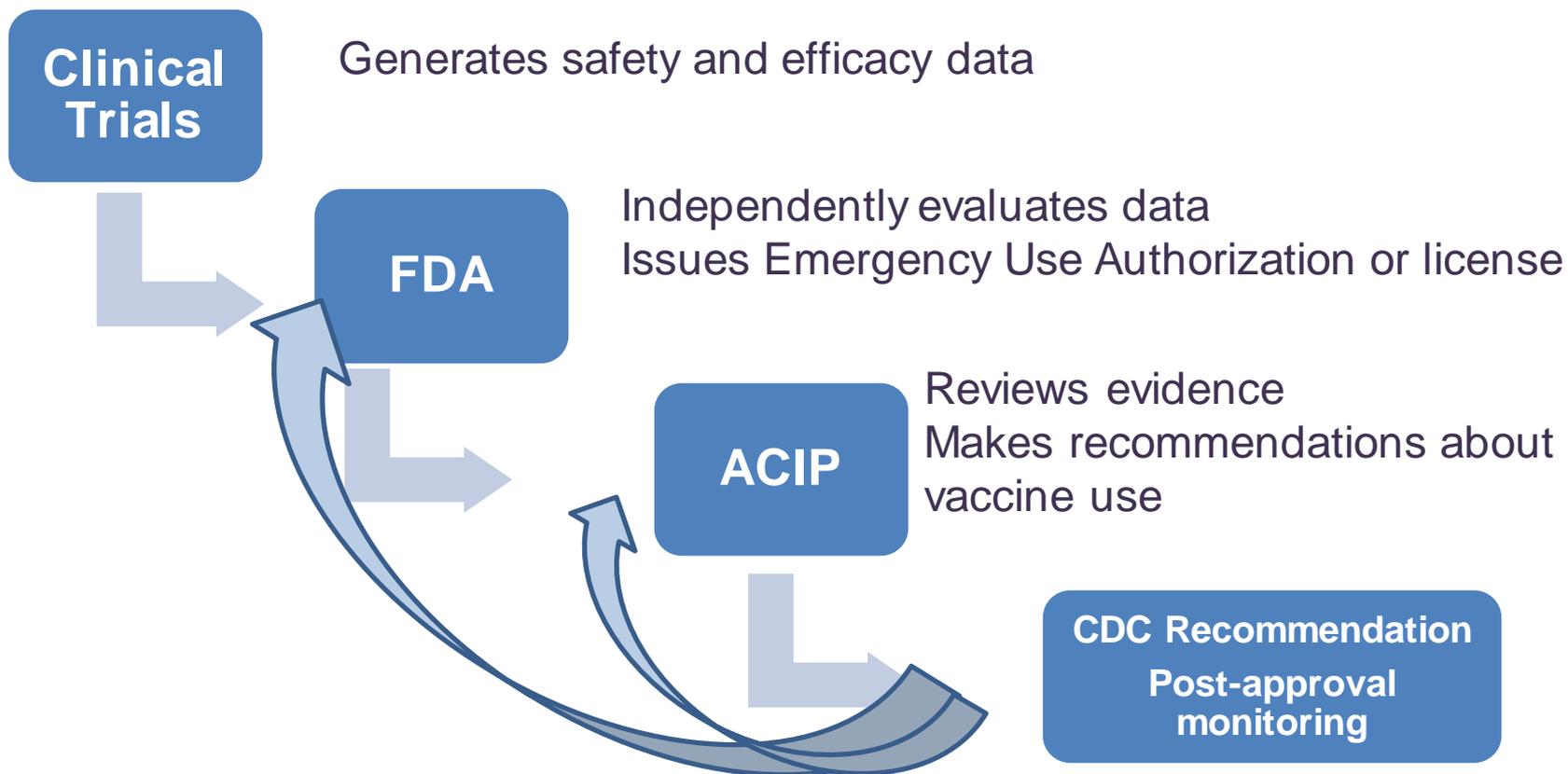
- About COVID-19 vaccines
- How do we figure out if a vaccine works?
- What's the process for approving and licensing vaccines?
- What's the process for deciding who should get them?
- What happens next?

# COVID-19 Vaccines



- Vaccines prevent diseases
  - Vaccines stimulate your immune system to produce antibodies, protecting you against the disease
- mRNA vaccines, a new vaccine type, will be the first COVID-19 vaccines to become available in the US
  - They teach your body to make a harmless protein that tells the immune system to make antibodies
  - **They do not use the live virus that causes COVID-19**

# Path from clinical development to recommendation



# Vaccine Clinical Trials



- Provide information about how well a vaccine prevents a disease and how safe it is
- Volunteers test the vaccine
  - Representative of the population that will be offered vaccine
  - Randomly divided into two similar groups
  - One group receives the vaccine, the other receives a placebo
- Scientists and participants are “blinded” to who is receiving vaccine or placebo
- Participants go about their lives and are monitored over time to see who gets COVID-19
- **No one is deliberately given the virus**

5

# Vaccine Clinical Trials (2)



- As information is collected from a trial, an independent group of experts, the *Data and Safety Monitoring Board*, reviews the data to evaluate if the vaccine is safe and to track if it is working
  - If a safety concern is noted they can recommend pausing the trial
- When sufficient information has been collected the manufacturers submit all data to the FDA and ask them to license or authorize the vaccine under Emergency Use (EUA)
  - An EUA is pending from Pfizer and Moderna, manufacturers of mRNA vaccines, to the FDA

6

# FDA Approval Process



- Manufacturers submit all data from all clinical trials and manufacturing information
- FDA scientists review these data; may do their own analyses
  - Evaluating safety and efficacy
- FDA's advisory committee of external experts – *Vaccines and Related Biologics Advisory Committee* (VRPAC) - holds a public meeting to review the data and advise on if the vaccine should be licensed or receive an EUA
  - VRPAC meetings scheduled for Dec 10 (Pfizer) and Dec 17 (Moderna) mRNA vaccines
- FDA decides whether to issue an EUA or license
  - Typically follow the advice of VRPAC

# Next: The Advisory Committee on Immunization Practices (ACIP)



- Provides advice and guidance to the CDC Director on the most effective means to prevent vaccine-preventable diseases in the U.S. civilian population
- 15 voting members (including Chair and Vice Chair)
  - One consumer representative, and 14 members with diverse expertise
  - External to the federal government
  - Screened for conflicts of interest
    - Includes scrutiny of personal and professional finances and research funding

8

# ACIP Recommendations Process



- Uses a rigorous and transparent process to develop recommendations that are evidence-based and implementable
  - Standardized approach to evaluating scientific evidence
  - Also considers factors such as feasibility and acceptability
- Recommendations become Department of Health and Human Services policy once approved by CDC and published in the MMWR
- ACIP's approved routine immunization schedule determines which vaccines are covered by insurance
  - Everyone will receive COVID-19 vaccines at no cost

9

# ACIP deliberations about COVID-19 vaccines



- Monthly meetings, open to the public, beginning in June
- All meeting materials (i.e., slides, live webcast archive, minutes) posted on ACIP website after each meeting
- Topics covered:
  - COVID-19 disease, immunology, epidemiology
  - COVID-19 vaccines in development: how they work, safety, effectiveness
  - Ethics and equity
  - Recommendations for distribution when available vaccine doses are limited

# ACIP's guiding principles for COVID-19 vaccination recommendations



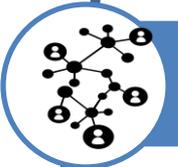
E  
Q  
U  
I  
T  
Y



**Safety is paramount.** Vaccine safety standards should not be compromised in efforts to accelerate COVID-19 vaccine development



**Inclusive clinical trials.** Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable

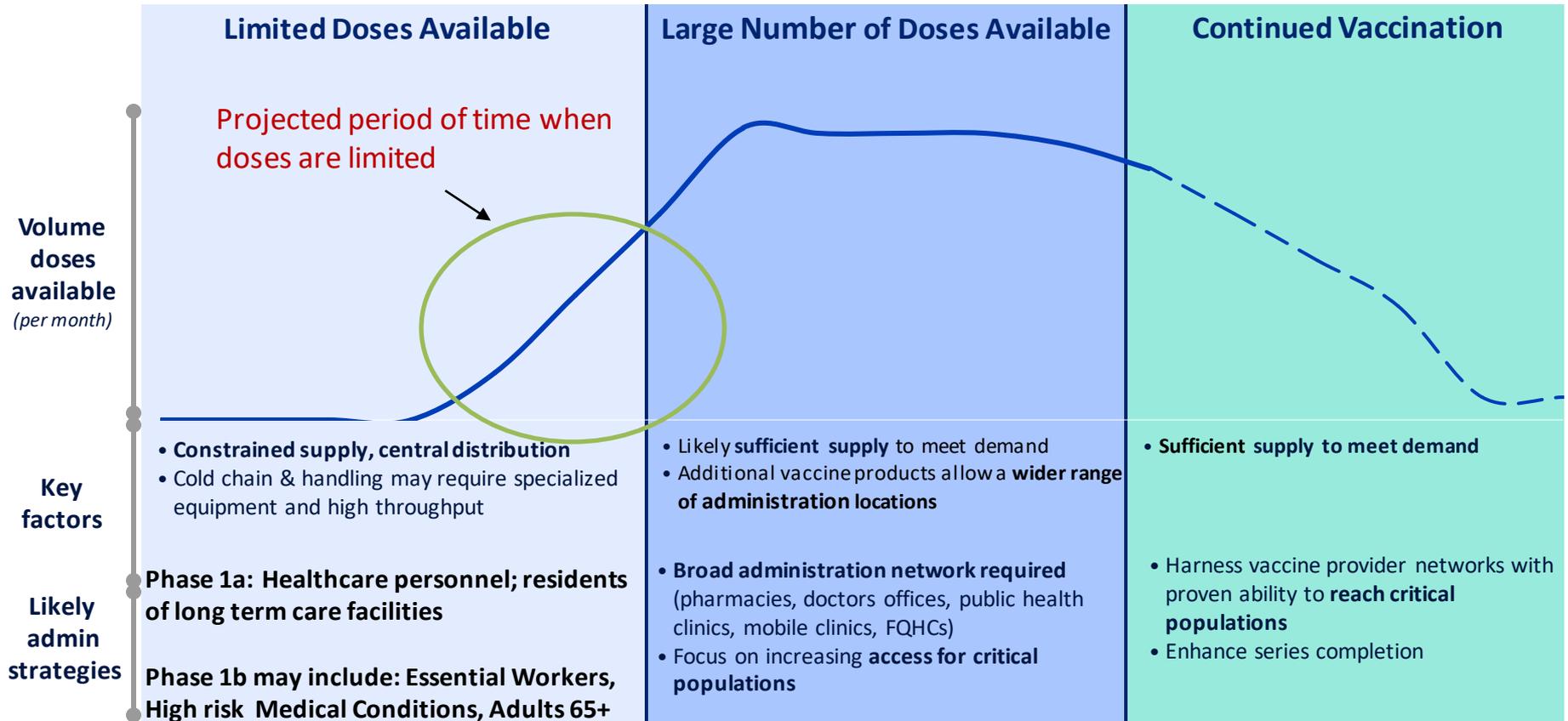


**Efficient Distribution.** During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical



**Flexibility.** Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand

# Administration of COVID-19 Vaccine: *A phased implementation is needed*



# ACIP's Ethical Principles for Phased Implementation



Centers for Disease Control and Prevention

**MMWR**

Early Release / Vol. 69

Morbidity and Mortality Weekly Report

November 23, 2020

- Maximize benefits and minimize harms
- Promote justice
- Mitigate health inequities
- Promote transparency

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

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

# Groups Recommended for Phase 1a Vaccination



**Health care Personnel<sup>1,2</sup>  
(HCP)  
(~21 million)**

**Long-Term Care Facility (LTCF)  
Residents<sup>3</sup>  
(~3M)**

## Examples

- Hospitals
- Long-term care facilities
- Outpatient clinics
- Home health care
- Pharmacies
- Emergency medical services
- Public health

- Skilled nursing facilities (~1.3 M beds)
- Assisted living facilities (~0.8 M beds)
- Other residential care (~0.9 M beds)

1. <https://www.cdc.gov/infectioncontrol/guidelines/healthcare>

2. [personnel/index.htmlhttps://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce](https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce)

3. <https://www.cdc.gov/longtermcare/index.html>



Morbidity and Mortality Weekly Report

Early Release / Vol. 69

December 3, 2020

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

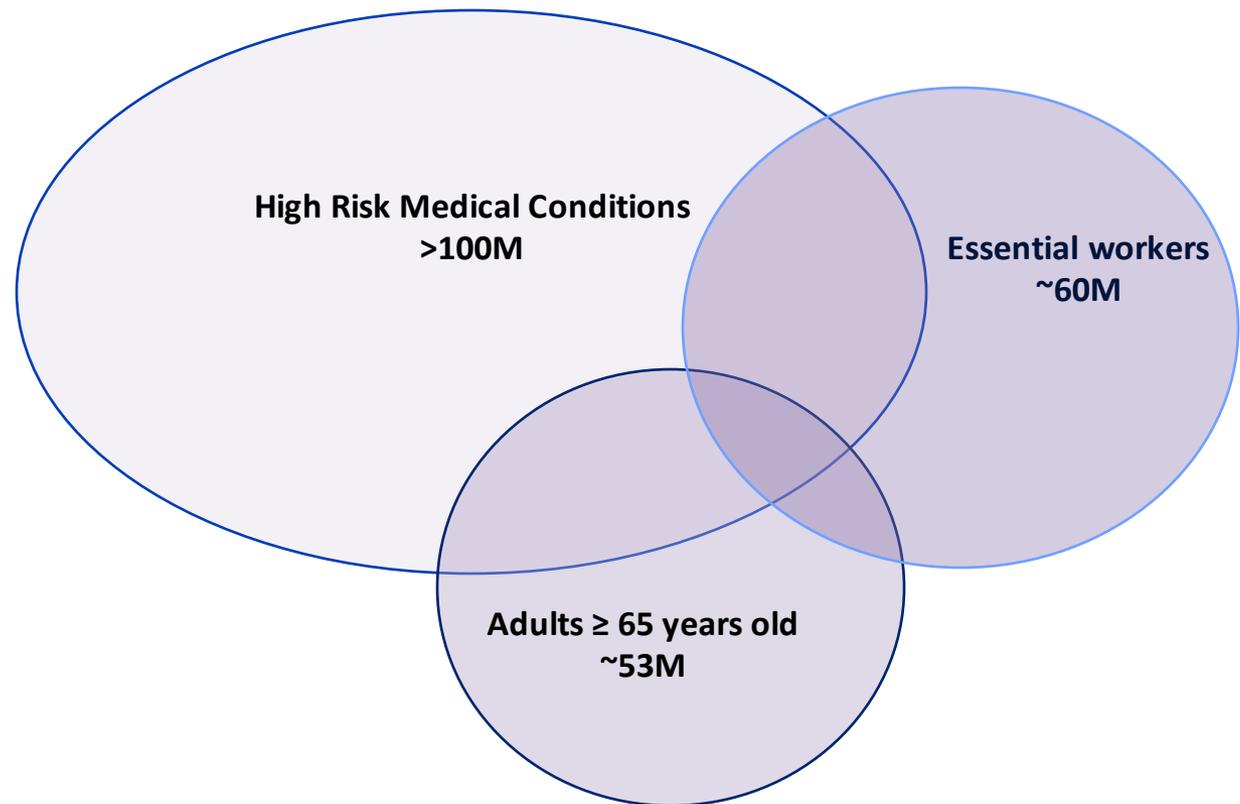
Kathleen Dooling, MD<sup>1</sup>; Nancy McClung, PhD<sup>1</sup>; Mary Chamberland, MD<sup>1,2</sup>; Mona Marin, MD<sup>1</sup>; Megan Wallace, DrPH<sup>1,3</sup>; Beth P. Bell, MD<sup>4</sup>; Grace M. Lee, MD<sup>5</sup>; H. Keipp Talbot, MD<sup>6</sup>; José R. Romero, MD<sup>7</sup>; Sara E. Oliver, MD<sup>1</sup>

# Candidate groups for next phases



## Considerations:

- How to prevent the most illness and death
- Balance of potential benefits and harms
- Feasibility
- Acceptability
- Ethical considerations



# What happens next?



- If/when FDA issues EUAs for the Pfizer and/or Moderna vaccines, ACIP will meet to consider and vote on recommendations for each of the vaccines
- Next, state and local health departments will begin offering vaccine to health care personnel and residents of long term care facilities
- ACIP is in the process of considering allocation recommendations for additional groups to be offered vaccine while supplies remain constrained
- As vaccines are distributed, FDA and CDC closely monitor safety
  - As with all vaccines, there will likely be events that need to be investigated and that will get done!



# Thank You



For more information on COVID-19 and the approval process:

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

ACIP: <https://www.cdc.gov/vaccines/acip/index.html>

FDA: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

VRPAC: <https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/2020-meeting-materials-vaccines-and-related-biological-products-advisory-committee>