COVID-19 VACCINES: EVALUATION AND DISTRIBUTION

Beth P Bell MD, MPH
Clinical Professor
University of Washington
Member, Advisory Committee on Immunization Practices
• 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

- Clinical Trials
  - Generates safety and efficacy data

- FDA
  - Independently evaluates data
  - Issues Emergency Use Authorization or license

- ACIP
  - Reviews evidence
  - Makes recommendations about vaccine use

- CDC Recommendation
  - Post-approval monitoring
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**
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
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 and 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
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
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
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
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*

- **Limited Doses Available**
  - Projected period of time when doses are limited
  - Constrained supply, central distribution
  - Cold chain & handling may require specialized equipment and high throughput

- **Large Number of Doses Available**
  - Likely sufficient supply to meet demand
  - Additional vaccine products allow a wider range of administration locations
  - Broad administration network required (pharmacies, doctors offices, public health clinics, mobile clinics, FQHCs)
  - Focus on increasing access for critical populations

- **Continued Vaccination**
  - Sufficient supply to meet demand
  - Harness vaccine provider networks with proven ability to reach critical populations
  - Enhance series completion

---

**Likely admin strategies**

- **Phase 1a:** Healthcare personnel; residents of long term care facilities
- **Phase 1b** may include: Essential Workers, High risk Medical Conditions, Adults 65+
ACIP’s Ethical Principles for Phased Implementation

- Maximize benefits and minimize harms
- Promote justice
- Mitigate health inequities
- Promote transparency
Groups Recommended for Phase 1a Vaccination

<table>
<thead>
<tr>
<th>Health care Personnel(^1,^2) (HCP) (~21 million)</th>
<th>Long-Term Care Facility (LTCF) Residents(^3) (~3M)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examples</strong></td>
<td><strong>Examples</strong></td>
</tr>
<tr>
<td>Hospitals</td>
<td>Skilled nursing facilities (~1.3 M beds)</td>
</tr>
<tr>
<td>Long-term care facilities</td>
<td>Assisted living facilities (~0.8 M beds)</td>
</tr>
<tr>
<td>Outpatient clinics</td>
<td>Other residential care (~0.9 M beds)</td>
</tr>
<tr>
<td>Home health care</td>
<td></td>
</tr>
<tr>
<td>Pharmacies</td>
<td></td>
</tr>
<tr>
<td>Emergency medical services</td>
<td></td>
</tr>
<tr>
<td>Public health</td>
<td></td>
</tr>
</tbody>
</table>

1. [https://www.cdc.gov/infectioncontrol/guidelines/healthcare](https://www.cdc.gov/infectioncontrol/guidelines/healthcare)
3. [https://www.cdc.gov/longtermcare/index.html](https://www.cdc.gov/longtermcare/index.html)
The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Kathleen Dooling, MD¹; Nancy McClung, PhD¹; Mary Chamberland, MD¹,²; Mona Marin, MD¹; Megan Wallace, DrPH¹,³; Beth P. Bell, MD⁴; Grace M. Lee, MD⁵; H. Keipp Talbot, MD⁶; José R. Romero, MD⁷; Sara E. Oliver, MD³
Candidate groups for next phases

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

- Essential workers: ~60M
- High Risk Medical Conditions: >100M
- Adults ≥ 65 years old: ~53M
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!
For more information on COVID-19 and the approval process:


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