

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

COVID-19 VACCINE PRESS BRIEFING

December 11, 2020



BOB SWANSON

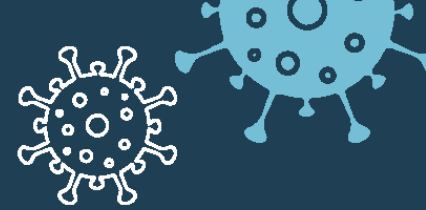
Director, Division of Immunizations

**Michigan Department of Health
and Human Services**

CDC Vaccination Approval Process

- Vaccine moves through a three-phase process of development and human trials.
- FDA authorizes or approves the vaccine (Emergency Use Authorization).
- Advisory Committee on Immunization Practices (ACIP) holds public meeting to review data and vote on whether to recommend use, and if so, for who.

How a new vaccine is developed, approved and manufactured



The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

Phase 1

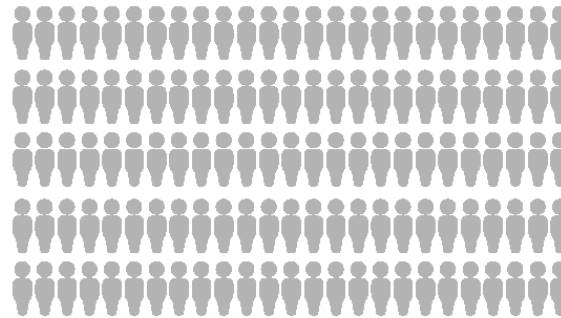


20-100
healthy volunteers



- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to the side effects?

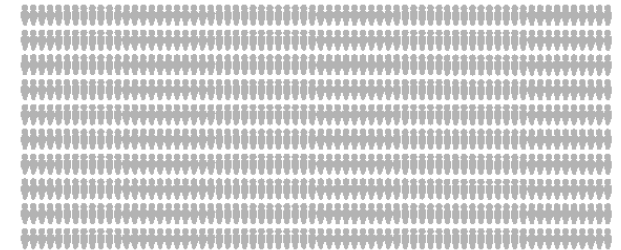
Phase 2



Several hundred
volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

Phase 3



Hundreds of thousands
of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

FDA licenses the vaccine only if:

- It's safe and effective
- Benefits outweigh risks

CDC Vaccination Approval Process

- Vaccines are approved only after they have been held to the highest safety standards.
- By the time a vaccine is approved, that data has been reviewed by the country's top public health, medical and immunizations experts.
- The COVID-19 vaccines have been developed faster than any vaccine before thanks to unprecedented, worldwide collaboration among scientists, medical doctors, health and government officials, and manufacturers.
- This collective effort has allowed researchers to shorten the typical vaccine timeline without sacrificing safety or quality.

Vaccine Administration

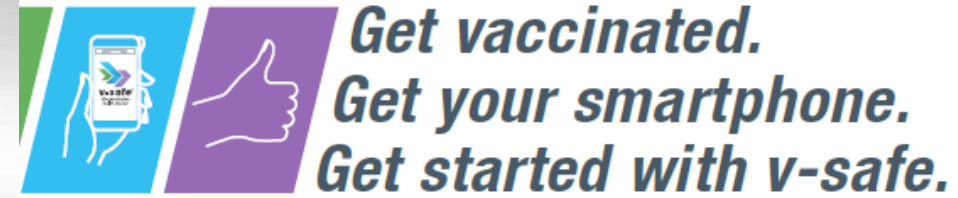
Side Effects

- As with many vaccines, there are the potential for mild side effects such as redness and soreness at the inject site, fatigue, and mild fever.
- These **side effects are normal** and represent the body's immune response to the vaccine.
- Potential serious side effects, if they were to occur, would likely happen within 30 days of receiving a vaccination.

Vaccine Safety Monitoring

VAERS – Vaccine Adverse Events Reporting System, passive surveillance system monitor adverse events.

V-Safe – Active Surveillance System to monitor possible adverse events.



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

When you get your COVID-19 vaccination, ask your healthcare provider about getting started with **v-safe**

Learn more about **v-safe**
www.cdc.gov/vsafe



Vaccine allocations within Michigan

- **Pfizer Vaccine**

- EUA submitted on (11/20/20).
- FDA panel recommended approval on 12/10/20. Final review by FDA expected soon.
- ACIP meeting 12/11/20 and 12/13/20 for final recommendations to CDC, expect vaccinations to begin shortly after.
- Initial allocation of 84,825 to hospitals and LHDs with ultra cold freezer.
- Future allocations to Federal Long Term Care-Pharmacy partnership.

- **Moderna Vaccine**

- EUA submitted on (11/30/20).
- Expect vaccination before the end of the year.
- Broader distribution, less complex storage requirements.
- Initial allocations of 173,600 to LHDs for use in first priority populations and smaller hospitals.

Initial Vaccine Distribution Plan

- Initially there will be a limited number of doses available.
- ACIP provides guidance on priority groups to be vaccinated first.
- Initial distribution will go to health care providers who can administer the initial doses to the priority groups:
 - Hospitals
 - Local Health Departments

Initial Allocations of Pfizer Vaccine

Region	Number of Hospitals	Number of Health Departments
1	3	1
2N	11	2
2S	15	2
3	5	3
5	3	3
6	7	2
7	4	2
8	8	1
Total	56	16

Moderna vaccine will be distributed to the remainder of the hospitals and local health departments after FDA/ACIP approval.

Expect ongoing weekly allocations of both vaccines.

Michigan Care Improvement Registry (“MCIR”)

- Providers will record all COVID vaccine dosages given, including demographic data.
- Allows for collecting and transmitting required data to CDC.
- Contains 11.6 million person records.
- Contains 156 million shot records.
- 16,150 active users of the system.



DR. JONEIGH KHALDUN

**Chief Medical Executive &
Chief Deputy Director for Health**

**Michigan Department of Health
and Human Services**

GOAL:

**70% OF MICHIGAN ADULTS WILL BE
VACCINATED BY THE END OF 2021
(5.4 MILLION PEOPLE)**

ACIP's Goals for Prioritization if Vaccine Limited

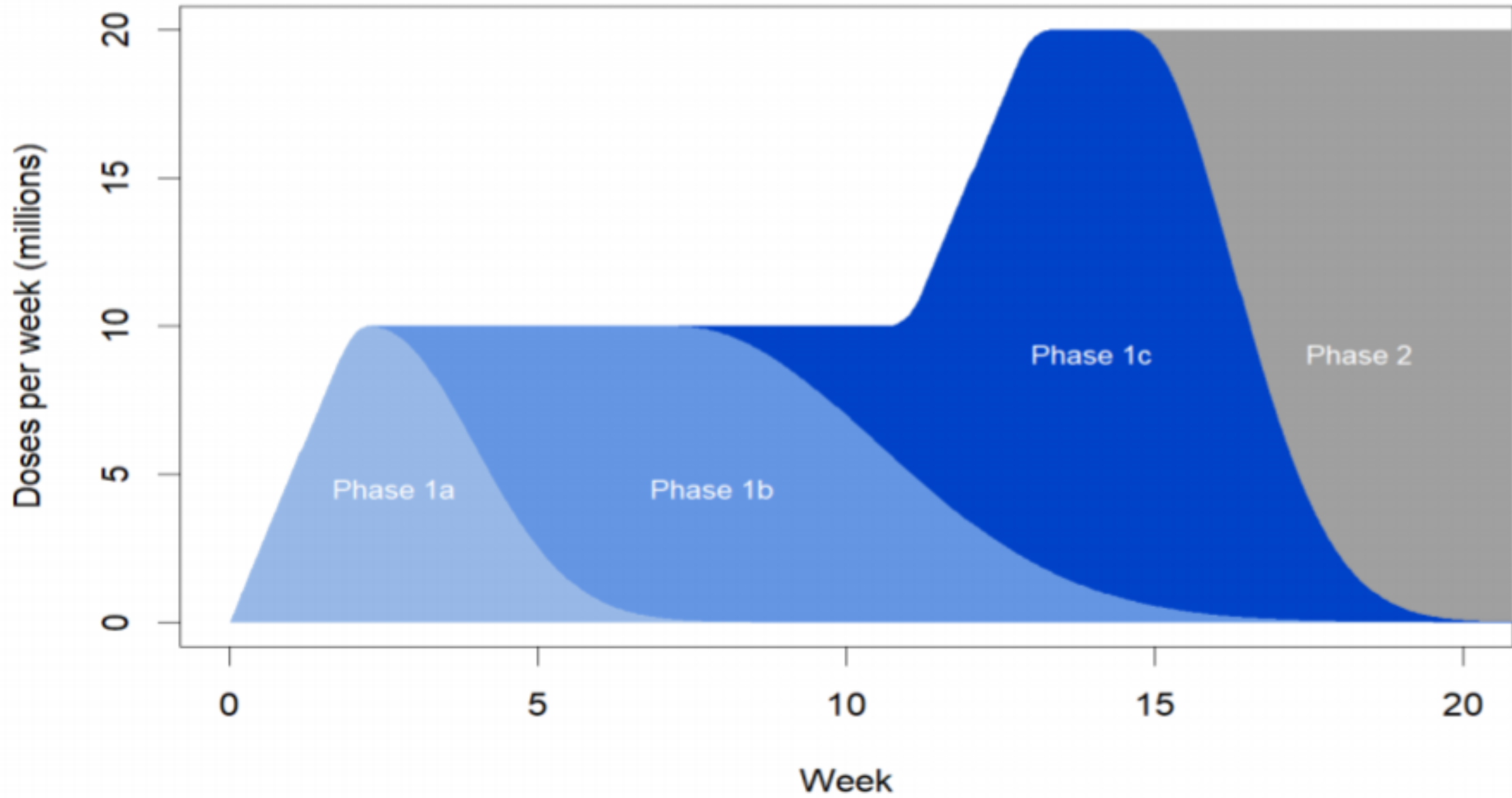
- Decrease death and serious disease as much as possible.
- Preserve functioning of society.
- Reduce the extra burden the disease is having on people already facing disparities.
- Increase the chance for everyone to enjoy health and well-being.

ACIP's ethical principles to guide decision-making process if supply is limited:

- **Maximize benefits and minimize harms:** Respect and care for people using the best available data to promote public health and minimize death and severe illness.
- **Mitigate health inequities:** Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
- **Promote justice:** Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.
- **Promote transparency:** Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.

CDC Social Vulnerability Index

- Used to target timing and distribution of supplies by geography.
- Ranks each community on 15 social factors, including poverty, lack of vehicle access, and crowded housing.
- The status in Michigan communities correlates with the communities hardest hit by COVID-19 this spring, as well as areas of that state with high rates of risk factors for severe COVID-19 outcomes.



Phase 1A includes paid and unpaid persons serving in health care settings who have direct or indirect exposure to patients or infectious materials and are unable to work from home, as well as residents of long-term care facilities.

Phase 1B includes some workers in essential and critical industries, including workers with unique skill sets such as non-hospital or non-public health laboratories and mortuary services.

Phase 1C includes people at high risk for severe COVID-19 illness due to underlying medical conditions, and people 65 years and older.

Phase 2 is a mass vaccination campaign for all adults.

1A Priority One: Keep critical health care infrastructure open and functioning (i.e., hospitals, critical care units, and emergency medical response systems) through vaccination of staff who perform direct patient care and work in critical areas.

- **Group A.** Emergency medical service providers, including medical first responders
- **Group B.** General medical floor
- **Group C.** Emergency department
- **Group D.** Intensive care units

1A Priority Two: Prevent outbreaks in long-term care facilities.

Group A: Vaccinate workers who have direct contact with large number of vulnerable residents, including staff who come in and out of the buildings.

1. Skilled nursing facility staff
2. Psychiatric hospital staff
3. Homes for aged staff
4. Adult foster care centers staff
5. Assisted living facility staff
6. Home health care workers caring for high risk clients with large patient loads (e.g. people with a tracheostomy/ventilator at home)

Group B: Vaccinate vulnerable residents in long term care facilities

1. Skilled nursing facility residents
2. Psychiatric hospital patients
3. Homes for aged residents
4. Adult foster care centers residents
5. Assisted living facility residents

1A Priority Three: Keep necessary health care infrastructure functioning.

Group A: Vaccinate workers with direct patient contact who conduct high risk procedures (e.g. dentists, endoscopy).

Group B: Vaccinate other workers who have direct patient contact (including outpatient, urgent care, ambulatory care, home health care).

Group C: Vaccinate workers who have indirect patient contact with specialized skills critical to health care system functioning (e.g. hospital and public health laboratories, pharmacy).

PHASE 1B: Other essential workers

Keep critical infrastructure open and functioning. Use the Critical Infrastructure Protection Program as well as continuity of operations plans in this allocation.

- K-12 school and child-care staff with direct contact with children
- Some workers in 16 sectors of Critical Infrastructure Protection Program, including Chemical; Communications; Dams; Emergency Services; Financial Services; Government Facilities; Information Technology; Transportation Systems; Energy; Food and Agriculture; Healthcare and Public Health; Nuclear Reactors, Materials and Waste; and Water and Wastewater Systems
- Staff in homeless shelters, corrections facilities (prisons, jails, juvenile justice facilities), congregate childcare institutions, and adult and child protective services
- Workers with unique skill sets not covered above, such as non-hospital laboratories and mortuary services

PHASE 1C: Individuals with high risk of severe illness due to COVID-19 infection, including people 65 years of age and older.

Group A: Individuals age 65 years and older

Group B: Individuals over age 18 with COPD, hypertension, chronic kidney disease, heart disease, diabetes, obesity or other [conditions that puts them at high risk of negative COVID-19 outcome](#)

NOTE: Pregnant women are currently not recommended to receive the COVID-19 vaccine.

PHASE 2: Individuals 18 years of age or older

All individuals who did not otherwise fit into the earlier groups for whom the vaccine is recommended.

Vaccine Administration

Who will administer the vaccine?

- Hospitals
- Pharmacies
- Local Health Departments
- Emergency Medical Services
- Michigan National Guard
- Outpatient Clinics

Learn more at
[Michigan.gov/COVIDVaccine](https://michigan.gov/COVIDVaccine)