

COVID-19 Mass Vaccination

Preliminary Guidance for Local Government Leaders and Managers

Today's Presenters



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ICMA



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Association for Immunization Managers

The background of the slide is a blurred image of laboratory glassware, including two vials with black caps and a pipette, set against a blue gradient. The text is overlaid on this background.

ICMA and COVID-19

www.icma.org/coronavirus

Moving with the Crisis

A horizontal sequence of four dark blue chevron-shaped boxes pointing to the right. The third box, labeled "Response + Initial Recovery", is highlighted with a thick green border. The other three boxes have a thin blue border.

Planning/
Preparation

Initial
Response

Response
+ Initial
Recovery

Future
Recovery/
Restoration

Areas of Action

Research and
Content

Events and
Learning

Policy and
Advocacy

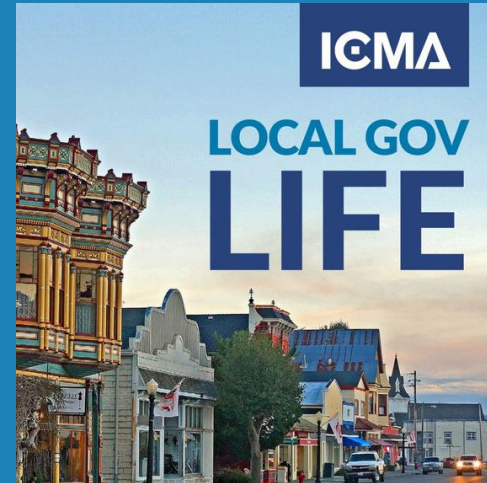
Member
Outreach &
Engagement

Research & Content

- 140 blog posts and articles since early March
- Additional fact sheets, documents, templates
- Two COVID impacts surveys



Events & Learning Opportunities



Policy & Advocacy

- Big 7 coordination
- Letters to White House & Congress
- Legislative updates, guidance from federal agencies



Member Outreach & Engagement



2020: The Year of What Could Possibly Be Next

www.icma.org/coronavirus



ASSOCIATION OF IMMUNIZATION MANAGERS



ICMA: COVID-19 Vaccine Preparation

CLAIRE HANNAN, MPH
EXECUTIVE DIRECTOR, ASSOC OF IZ
MANAGERS

OCTOBER 14, 2020

Agenda

- Introduction to AIM
- COVID-19 vaccine development
- COVID-19 vaccine distribution plan
- CDC's Interim Playbook for Jurisdictional Operations and state COVID-19 vaccine planning

Association of Immunization Managers (AIM)

AIM represents the 64 immunization programs who receive funding from CDC's National Center for Immunization and Respiratory Diseases (NCIRD). These 64 immunization programs are in 50 states, 5 major cities + DC, the territories, and Pacific Islands

These 64 immunization programs are tasked with COVID-19 vaccine planning: distribution, administration, and tracking.



Operation Warp Speed

May 15, 2020



Explaining Operation Warp Speed

What's the goal?

Operation Warp Speed's goal is to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).

How will the goal be accomplished?

By investing in and coordinating countermeasure development, OWS will allow countermeasures such as a vaccine to be delivered to patients more rapidly while adhering to standards for safety and efficacy.

Who's working on Operation Warp Speed?

OWS is a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). OWS engages with private firms and other federal agencies, including the Department of

The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY
COMMITTEE ON
IMMUNIZATION
PRACTICES

BLA

BIOLOGICS LICENSE
APPLICATION

CDC

CENTERS FOR
DISEASE CONTROL
AND PREVENTION

FDA

FOOD AND DRUG
ADMINISTRATION

IND

INVESTIGATIONAL
NEW DRUG
APPLICATION

**safety
is a priority
during vaccine
development
+ approval**

VACCINE

DEVELOPMENT

PHASE 1
safety

PHASE 2
effectiveness

PHASE 3
safety +
effectiveness

CLINICAL STUDIES / TRIALS

FDA REVIEW

FDA APPROVAL OF 1 NEW VACCINE

ACIP REVIEW

ACIP RECOMMENDATION

POST-APPROVAL
MONITORING +
RESEARCH

PHASE 4

safety monitoring for
serious, unexpected
adverse events

**safety
continues with
CDC + FDA
safety
monitoring**



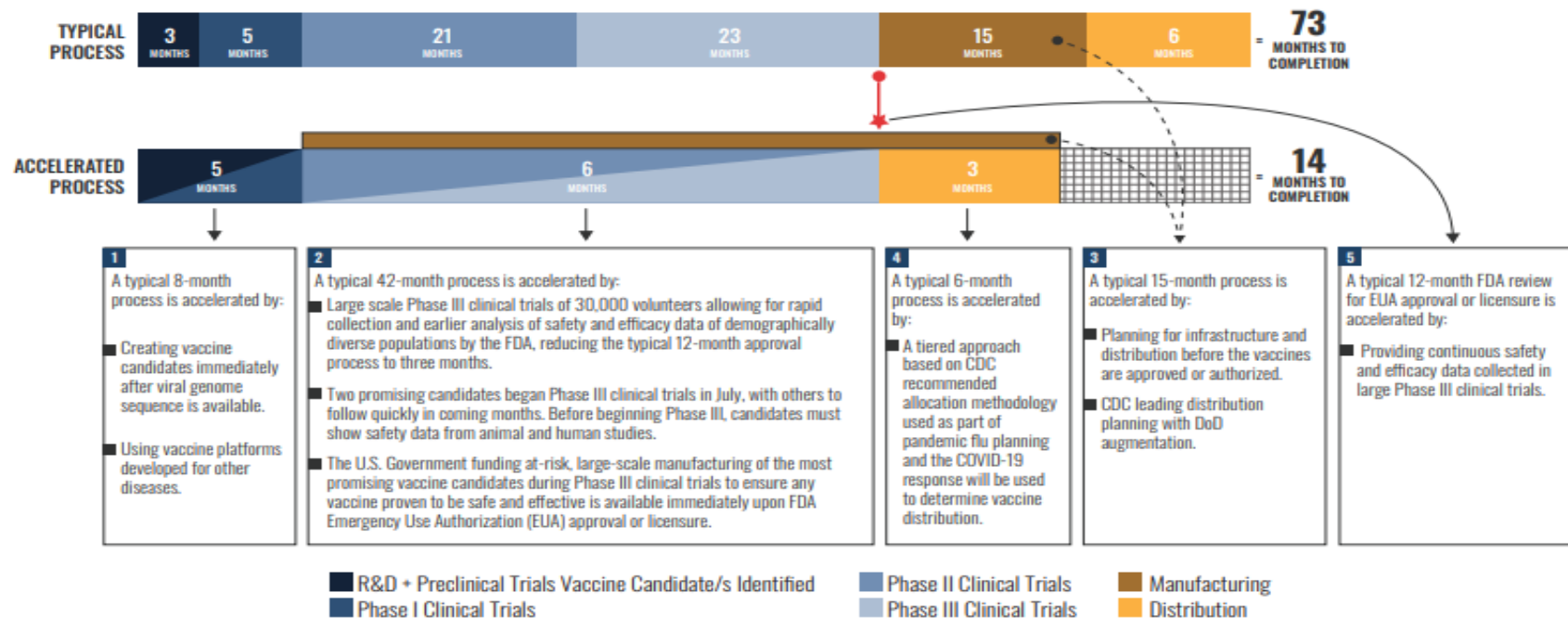
**LEARN
MORE**

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS <http://go.usa.gov/xvvNd>
CDC VACCINE SAFETY MONITORING + RESEARCH <http://go.usa.gov/xvvNe>



OPERATION WARP SPEED ACCELERATED VACCINE PROCESS

MISSION: Deliver 300 million doses of safe and effective vaccine by 1 January 2021.



FDA COVID-19 Vaccine Guidance for Industry

- Development and Licensure of Vaccines to Prevent COVID-19, June 2020
 - Demonstrate 50% effectiveness
- Emergency Use Authorization for Vaccines to Prevent COVID-19, October 2020
 - Follow-up duration of at least two months after completion of the full vaccination regimen to help provide adequate information to assess a vaccine's benefit-risk profile
- EUA:
 - Declared HHS emergency
 - Evidence of effectiveness
 - Known and potential benefits outweigh known and potential risk
 - No adequate, approved and available alternative



U.S. FDA safety guidelines likely to push COVID-19 vaccine authorization past election

A senior administration official confirmed the White House had approved the plan, which undercuts...

Reuters via Yahoo News
6 days ago

COVID-19 Vaccine Approval and Recommendation Process

- FDA approves vaccine licensure request or authorizes its use under Emergency Use Authorization (regulatory authority)
- CDC makes recommendations on the *use* of vaccine once it is authorized or licensed (CDC/ACIP recommendations are covered by health insurance)
- Two independent advisory committees: Vaccines and Related Biological Products Advisory Committee (VRBPAC) advises FDA; Advisory Committee on Immunization Practices (ACIP) advises CDC

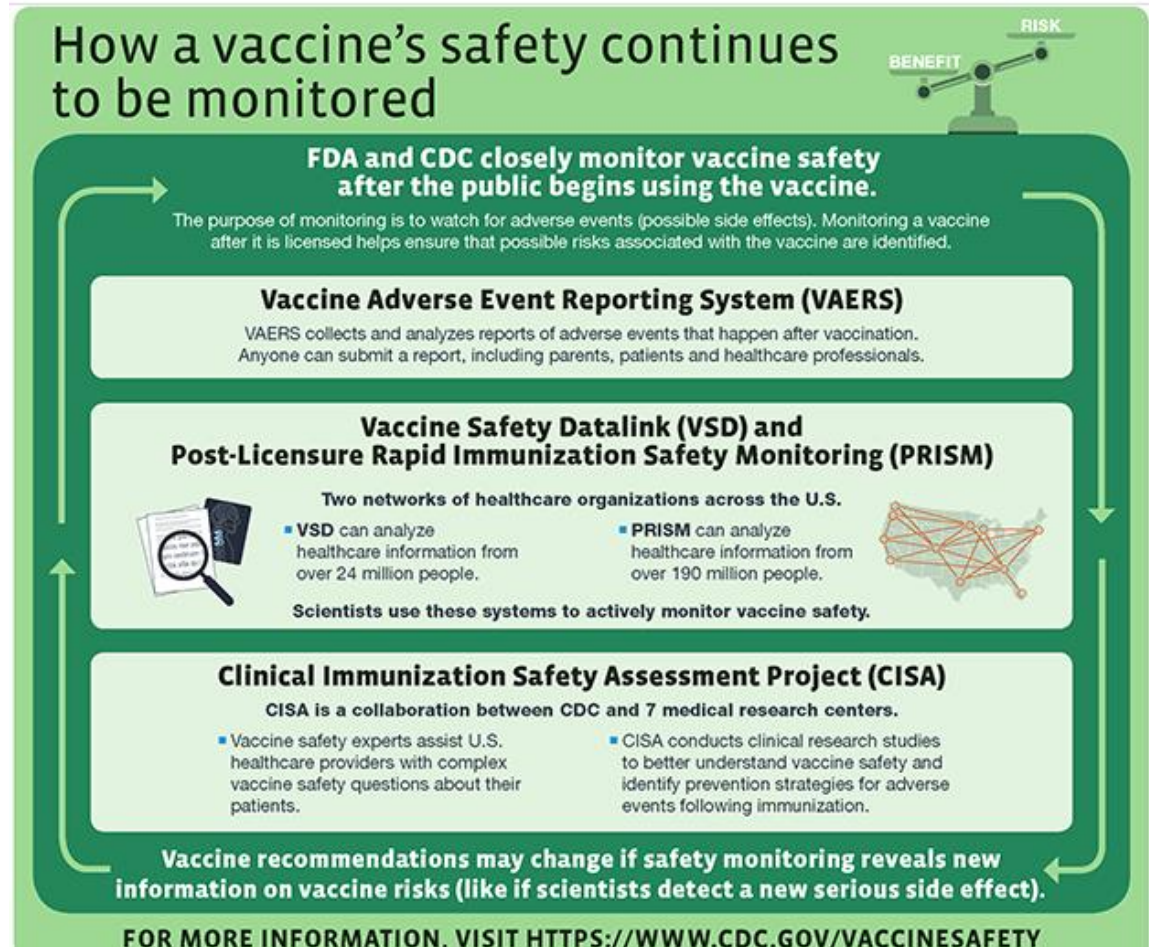
"We are committed to expediting the development of COVID-19 vaccines, but not at the expense of sound science and decision making. We will not jeopardize the public's trust in our science-based, independent review of these or any vaccines. There's too much at stake."

— Stephen M. Hahn, M.D., FDA Commissioner, and Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research

FDA and CDC continue to monitor vaccine safety after it is licensed or approved for use

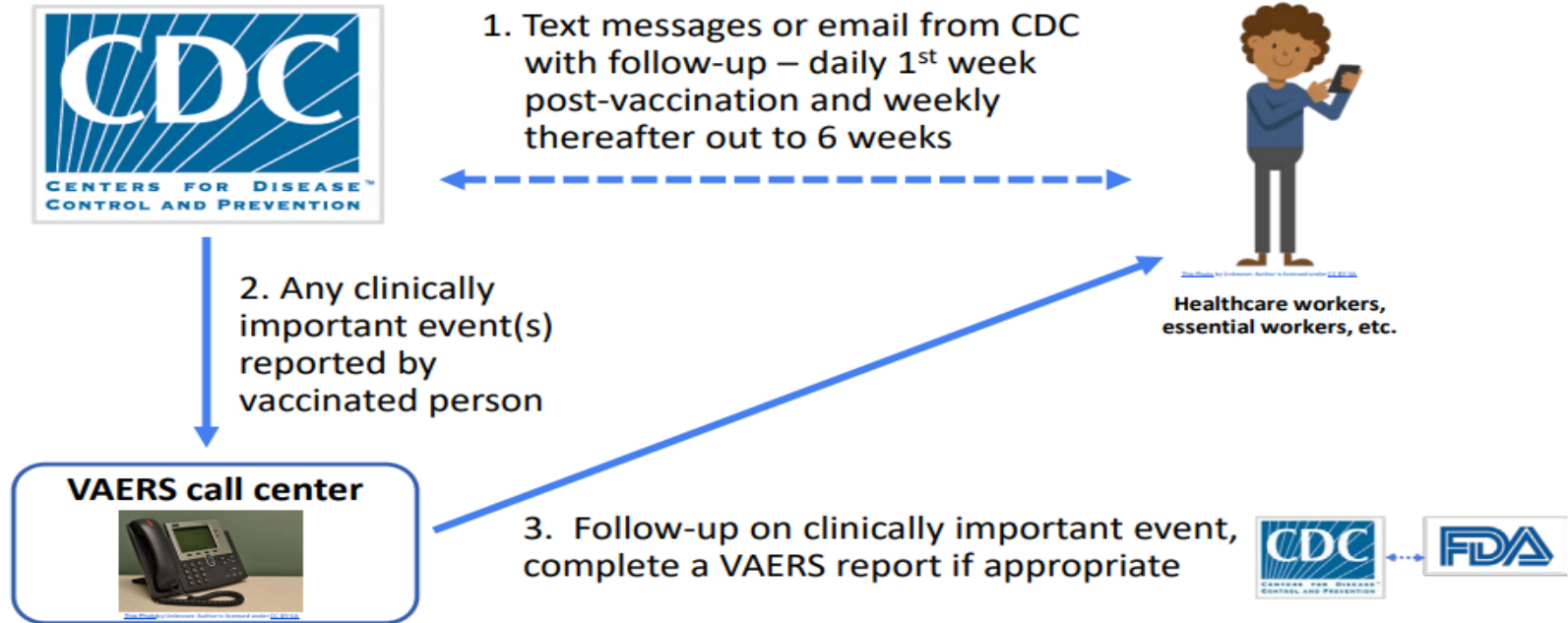
Multiple surveillance systems are used to track adverse events following vaccination

Any adverse events occurring more frequently in vaccinated persons than in non-vaccinated persons will be investigated as a potential safety signal



V-SAFE Safety Surveillance

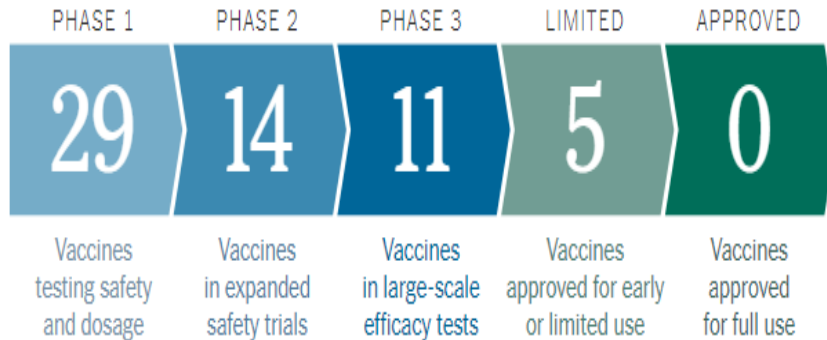
Vaccine safety assessment for essential workers (V-SAFE)



COVID-19 Vaccine Development

Coronavirus Vaccine Tracker

By Jonathan Corum, Sui-Lee Wee and Carl Zimmer Updated October 12, 2020



Third COVID vaccine candidate starts phase 3 trial in US

Filed Under: COVID-19

Stephanie Southeray | News Reporter | CIDRAP News | Sep 01, 2020

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Today the United States has three COVID-19 vaccine candidates in phase 3 trials, as **AstraZeneca** launched the final stage of a trial of its vaccine candidate, which it plans to test in 30,000 healthy adults.

The AstraZeneca vaccine, developed at Oxford University, is already in a phase 3 trial in the United Kingdom. The first US volunteers were inoculated today at the University of Wisconsin School of Medicine and Public Health in Madison, and AstraZeneca plans to add 50 participants each day after Sep 7.



Pornpak Khunatorn / iStock

In addition to the AstraZeneca vaccine, Moderna's vaccine candidate is already in phase 3 trials in the United States, as is Pfizer and BioNTech's. If any of the vaccines succeed, they will mark the fastest development timeline in history.

The phase 3 trials occur as the United States reported 33,888 new COVID-19 cases on Monday and 594 deaths, according to the Johns Hopkins **COVID-19 tracker**. According to the *Wall Street Journal*, this is the **lowest national daily high since Jun 22**. In total, the United States has 6,055,569 COVID-19 cases and 184,114 fatalities.

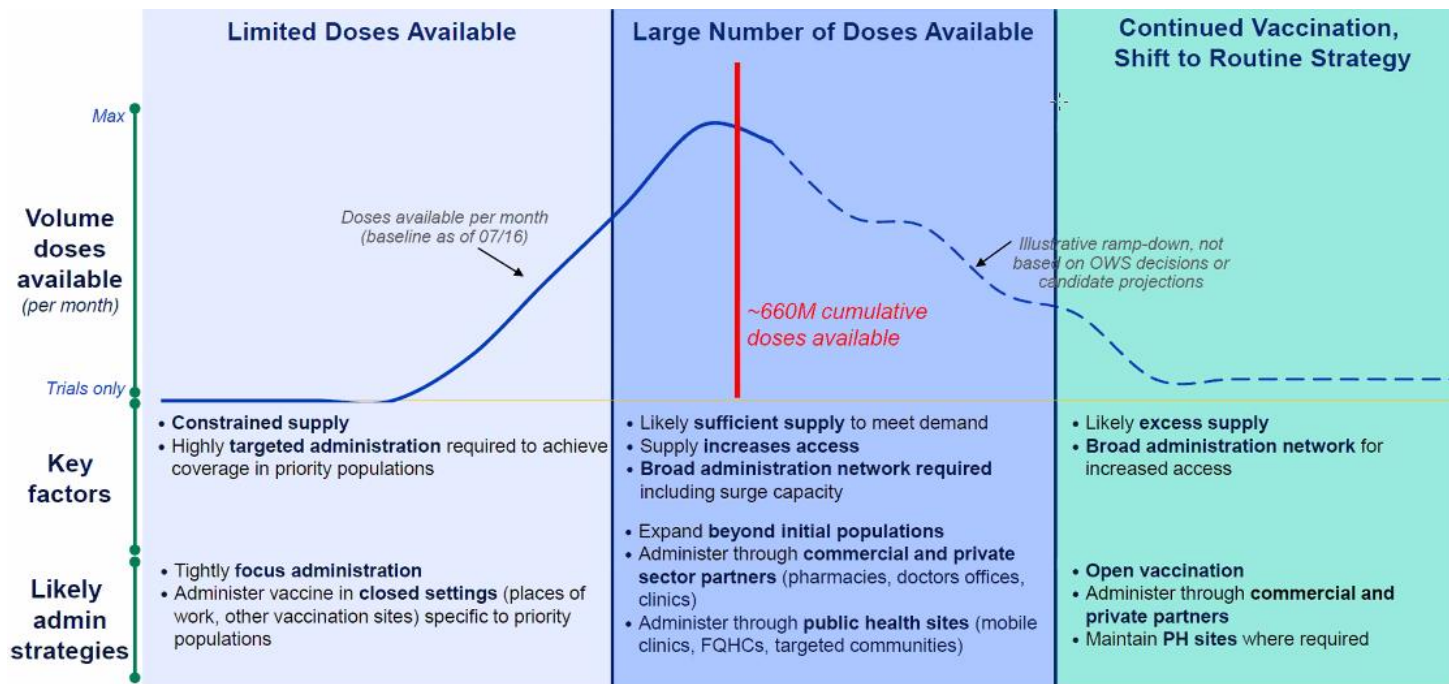
Promising Vaccine Candidates

Operation Warp Speed has invested in research and development of 14 promising vaccine candidates and contracted for manufacture of 6 vaccine candidates:

1. **Pfizer** (100 million doses, late 2020/early 2021) [2 dose series, 21 days apart, ultra cold, pkg in 975 dose increments, requires diluent]
2. **Moderna** (100 million doses, early 2021) [2 dose series, 28 days apart, frozen, 100 dose pkg]
3. **Johnson & Johnson** (100 million doses, Spring 2021) [1 dose, refrigerator stable, 100 dose pkg]
4. **Astra Zeneca** (300 million doses)
5. **GSK/Sanofi** (100 million doses)
6. **Novavax** (100 million doses)



COVID-19 Vaccine Phased Approach



National Academy of Science *Framework for Equitable Distribution*

3-20

FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE

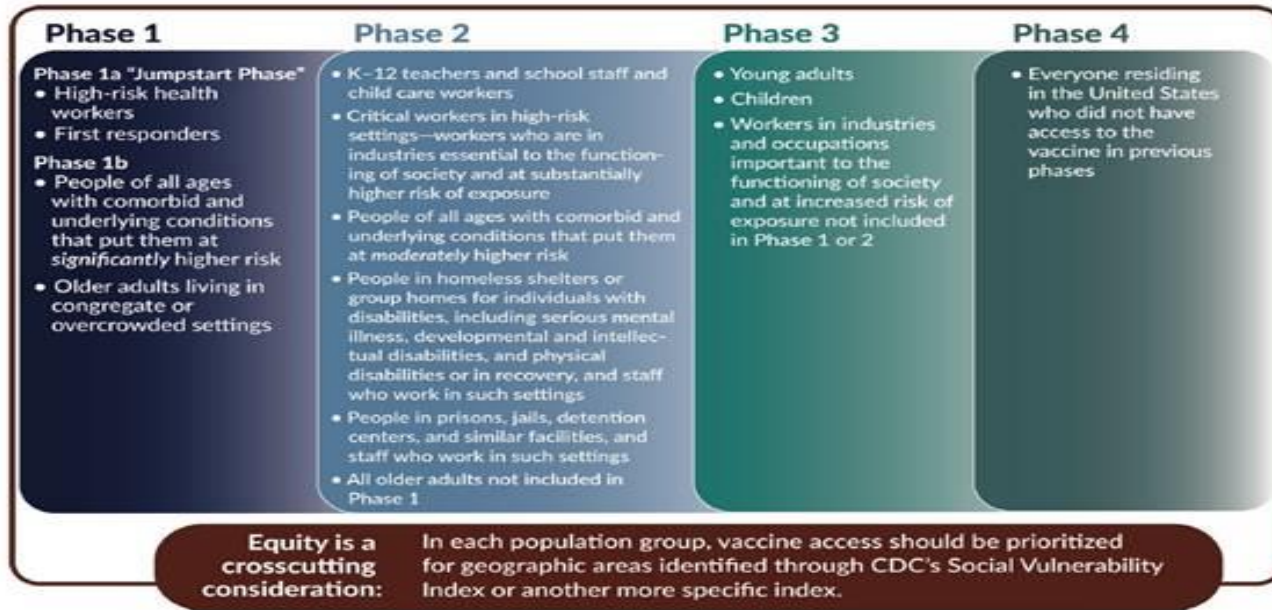


FIGURE 3-2 A phased approach to vaccine allocation for COVID-19.

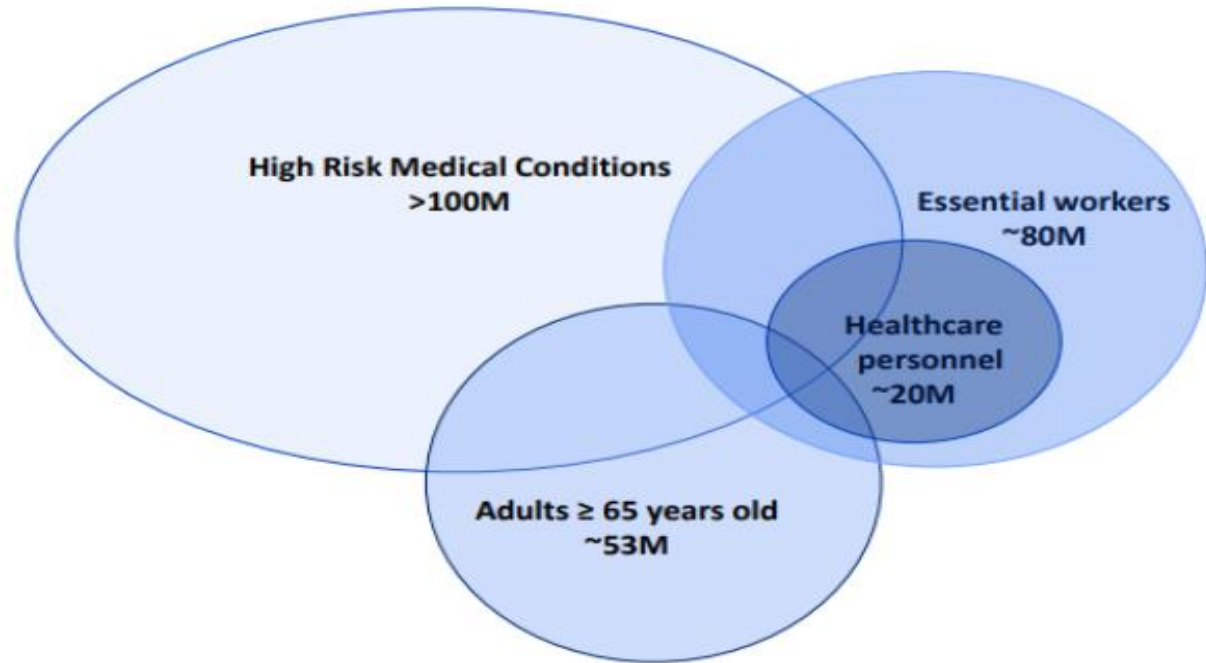
Possible Groups for Phase 1 Vaccination

Phase 1a

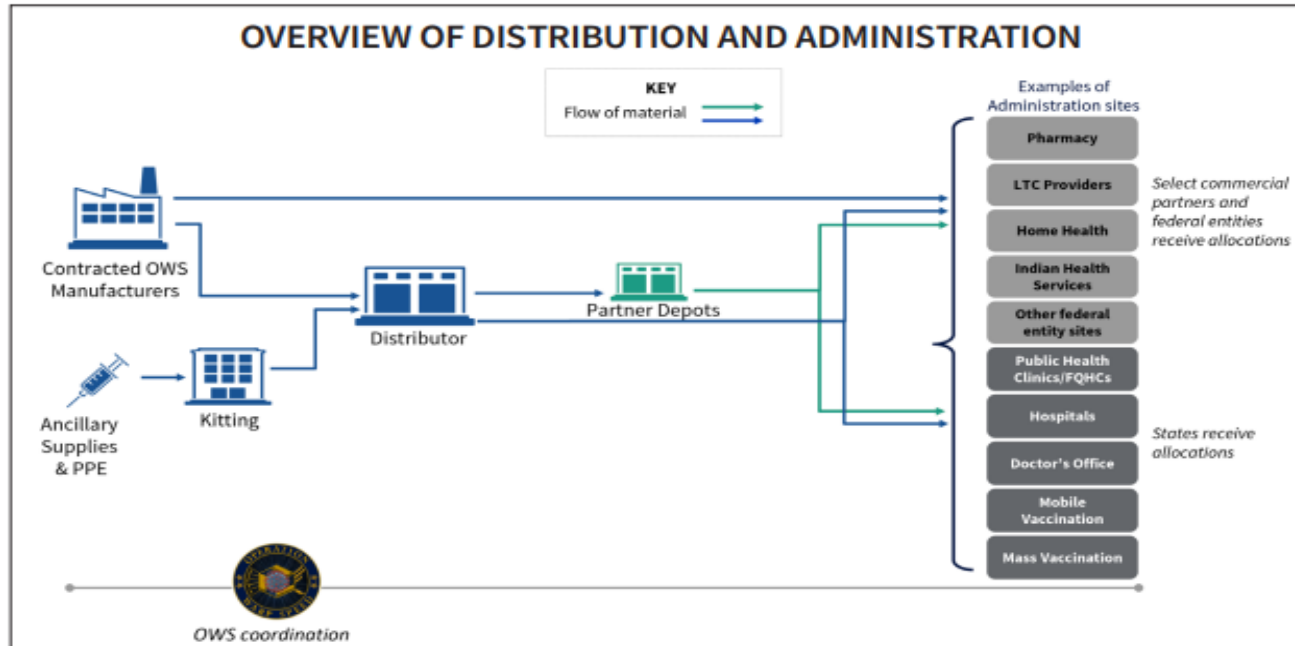
- health care personnel

Phase 1b

- essential workers
- high risk medical conditions
- adults \geq 65 years old



COVID-19 Distribution Plan

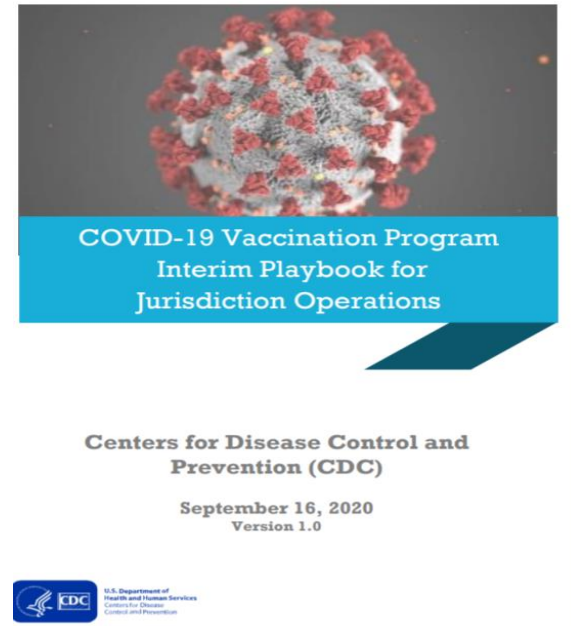


COVID-19 Interim Playbook for Jurisdictional Operations

Guidance released September 16, 2020; State written plans due October 16, 2020

Guidance for planning in 15 sections, including:

1. Provider enrollment and training
2. Vaccine allocation, ordering and distribution
3. Defining and estimating critical populations
4. Vaccine storage and handling (preliminary)
5. Communications
6. Required data collection and reporting



State Planning Activities



Identifying and enrolling providers

Estimating priority populations

Determining allocation/prioritization process

Establishing data expectations and IT capacity

Identifying ultra cold storage capacity and high throughput clinic capacity

Preparing communication plans

Vaccine Distribution: Planning Assumptions

- Limited doses may be available Nov/Dec 2020
- Phase 1: Critical workforce, health care personnel, high-risk
- Multiple presentations with different protocols; some requiring 2 doses

Vaccine Distribution: Planning Assumptions

- Cold chain storage and handling requirements for vaccine presentations will vary from refrigerator stable to frozen to ultra cold
- Early vaccine logistical challenges (ultra cold storage, 975 dose minimum, dry ice pkg)
- Vaccine will be provided at no cost to providers; no out-of-pocket costs for consumers

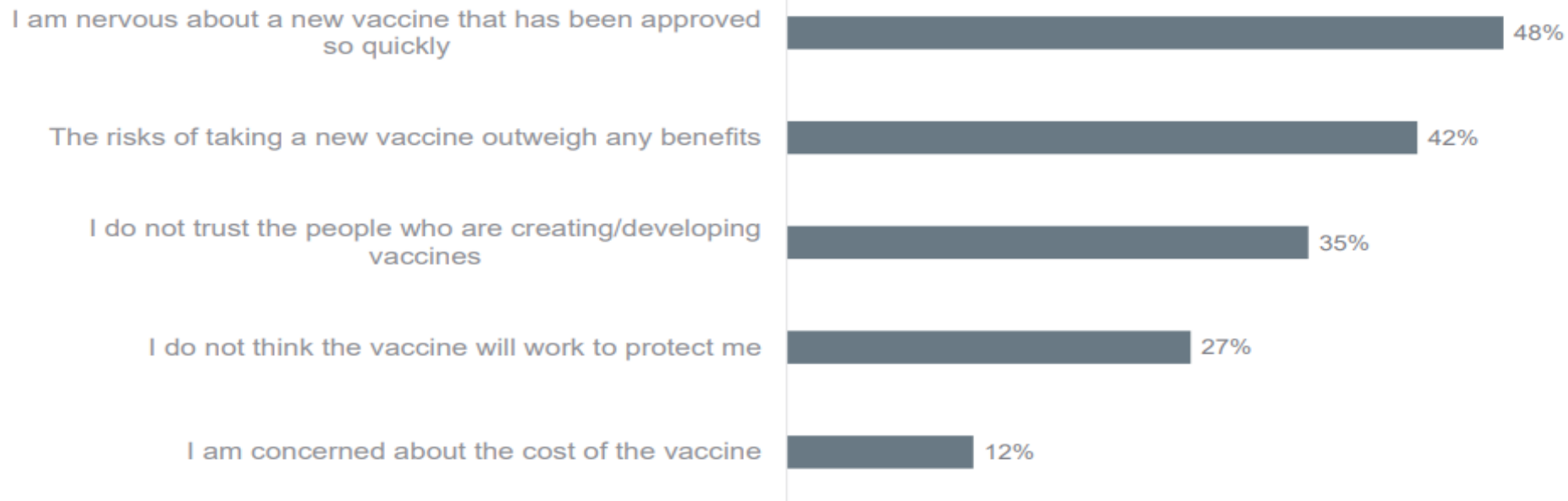
Vaccine Distribution: Planning Assumptions

- Supply kits containing needles, syringes, alcohol prep pads, vaccination record cards, and personal protective equipment (PPE) will be provided (not including gloves, sharps containers and band aids)
- Redistribution will be allowed but with the challenge of maintaining cold chain redistribution is not a best practice

Communication

- Training for providers on proper storage and handling, dose reporting, and vaccine administration
- Educational materials for consumers and providers, tailored to each audience
- Vaccine confidence and trust, particularly among groups anticipated to receive early vaccination and groups at highest risk
- Dispelling misinformation

Why are people not interested in the vaccine?



Reuters/Ipsos, Base= 1,048 U.S. adults who indicated they would not get a COVID-19 vaccine

VYF Has Responses to Common Concerns

<https://www.vaccinateyourfamily.org/vaccine-safety/>

Aren't vaccines just a way for pharmaceutical companies (Big Pharma) to make money?

If I'm breastfeeding my baby, why do I need to vaccinate him or her?

If some vaccines are grown in human fetal cells, is it against Christian religions to be vaccinated?

Who monitors the safety of vaccines in the United States?

How can I be confident that vaccines don't cause autism?



Funding

- Supplemental funding \$200 million for immunization program awardees (Sept 2020)
- Must be spent by June 30, 2021
- No specific funding appropriated by Congress for COVID-19 vaccine planning or implementation
- State and local health departments need additional funding

Key Considerations

- Familiarize yourself with your state plan
- Build relationships with local and state health department immunization and preparedness staff
- Pay special attention to communications planning. Where will you direct providers who want to enroll? Employers who want to provide vaccine for employees? Consumers with questions about vaccine safety?
- What is expected of local government? Volunteers? Large clinic locations? Security? Traffic flow?

Mass Vaccination Clinics



Mass Vaccination Resources

Resources for Developing Mass Vaccination Clinics

Mass vaccination clinics involve the administration of vaccine(s) to a large number of people over a relatively short period of time, allowing providers to rapidly and efficiently immunize communities. Due to the unique nature of mass vaccination clinics, they frequently are held in non-traditional or temporary settings, such as in parking lots or large indoor spaces. Patient flow may be managed through a variety of venues, such as walk-through, drive-through, and curbside clinics, or by using mobile medical units.

This listing from the [Immunization Action Coalition](#) offers access to guidance

Webinar

Related Resources

About

Home

09/15/20 127	Back to School Vaccine Clinic Operations	Immunize NV	Toolkit	Not specified	I, C, T, A	S, WT
09/15/20 124	How to Open a Drive Thru Flu Clinic at a Pediatric Practice	PCC	Article	Flu	I, C	DT
09/06/20 125	Drive Thru, Stop the Flu - What You Need to Know Before Coming to Flu Clinic!	E. Portland Peds	Video	Flu	I, C, T, A	DT
08/28/20 102	Resources for Hosting a Vaccination Clinic	CDC	Guidance	Not specified	I, C, T, A	CS, DT, WT
08/20/20 120	Back to School Immunization Toolkit	CO DPHE	Toolkit	Not specified	C, T	NS
08/05/20 115	Recommendations for Mass Immunization Events during Pandemic Conditions	DOD	Guidance	Flu	I, C, T, A	WT, DT, M, P
08/01/20 116	General Immunization Clinic Tools	Sanofi	Guidance	Not specified	I, C, T, A	NS
07/28/20 113	Guidance for Hosting Socially Distanced Vaccine Clinics	Immunize CO	Webinar	Not specified	I, C, T, A	S, DT, WT
07/27/20 100	Considerations for Planning Curbside/Drive-Through Vaccination Clinics	CDC	Guidance	Not specified	I, C, T, A	CS, DT
07/23/20 101	Guidance for Planning Vaccination Clinics Held at Temporary, Satellite, or Off-Site Locations	CDC	Guidance	Not specified	I, C, T, A	CS, DT, WT
07/01/20 104	Influenza Walk-thru Clinic	Sanofi	Toolkit	Flu	I, C, T, A	WT
07/01/20 103	Influenza Drive-thru Clinic	Sanofi	Toolkit	Flu	I, C, T, A	DT
06/17/20 108	Recommendations for Pharmacy-based Immunization Services during COVID-19	CA Pharm Assoc	Guidance	Not specified	I, C, T, A	P

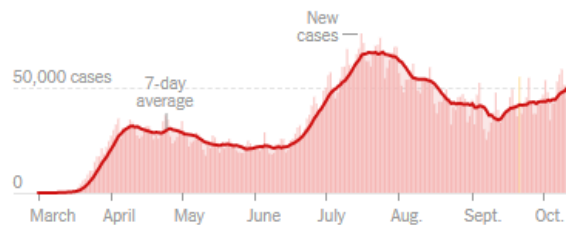
Flu Vaccination Activities

- Communication and outreach campaigns
- School located and mass vaccination clinics
- Late-season flu vaccine
- Involvement with FQHCs, CHCs
- Partnerships with pharmacies, doctors, insurers, hospitals, community leaders...
- More effort and involvement by public health than ever before!

Covid in the U.S.: Latest Map and Case Count

By The New York Times Updated October 12, 2020, 12:24 P.M. E.T.

[Leer en español](#)



	TOTAL REPORTED	ON OCT. 11	14-DAY CHANGE
Cases	7.8 million+	44,333	+15% →
Deaths	214,711	419	-5% →

■ Day with data reporting anomaly.

Includes confirmed and probable cases where available. 14-day change trends use 7-day averages.

Map

Cases by state

Hot spots

Clusters

Key COVID Vaccine Planning Resources



- [CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#)
- [IAC's Mass Vaccination Resources](#)
- [AIM's COVID-19 Vaccination Preparation Tips for Immunization Program Managers](#)
- [AIM / ASTHO / NACCHO / AIRA Recommendations to OWS Leaders](#)
- [ASTHO – AIM Immunization Campaign Policy Principles](#)
- [HHS Operation Warp Speed Fact Sheet](#)
- [ASTHO Report Assessing Policy Barriers To Effective Public Health Response In The H1N1 Influenza Pandemic](#)
- [GAO Report INFLUENZA PANDEMIC Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning](#)
- [CDC Pandemic Vaccine Program Distribution, Tracking, and Monitoring](#)
- [CDC Interim Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine during an Influenza Pandemic](#)
- [CDC Pandemic Influenza Vaccine Targeting Checklist](#)
- [CDC Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce](#)
- [CDC Checklist of Best Practices for Vaccination Clinics Held at Temporary, or Off-site, Satellite Clinics](#)
- [CDC Guideline for Large-Scale Influenza Vaccination Clinic Planning](#)

Questions?

ICMA

INTERNATIONAL CITY/COUNTY
MANAGEMENT ASSOCIATION