

# COVID-19 Vaccine Planning

Interim Joint Committee on Health,  
Welfare, and Family Services  
October 28, 2020

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Commissioner for Public Health



**Kentucky Public Health**  
Prevent. Promote. Protect.

# LRC HWFS Testimony Request

## COVID-19 Vaccine

### Rollout Plan:

- Distribution
- Priority populations
- CDC guidelines
- FDA approval process and where the vaccine is in the process so far

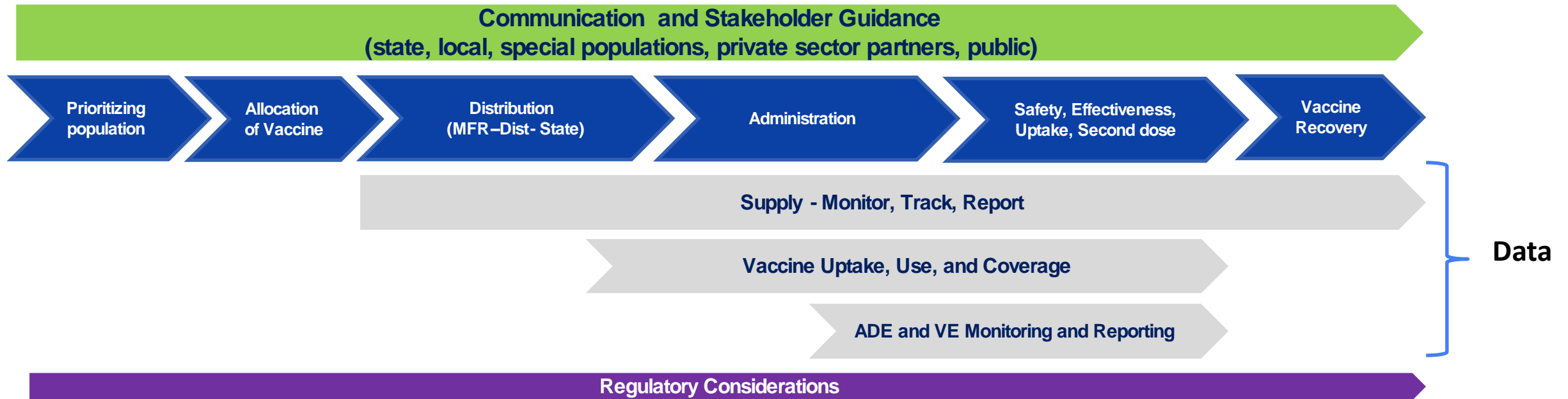
# State COVID-19 Vaccination Planning

- McKesson announced as federal COVID-19 vaccine distributor on Aug. 14, 2020
- CDC Vaccination Program Interim Playbook for Jurisdiction Operations Interim Playbook released Sept. 16, 2020
- First draft Kentucky vaccination plan submitted to CDC Oct. 16, 2020
- CVS and Walgreens partnerships for LTCFs announced Oct. 16, 2020
- Limited initial doses not before Dec. 2020 with escalating availability
- Unprecedented new challenges, particularly storage & handling

# Logistics

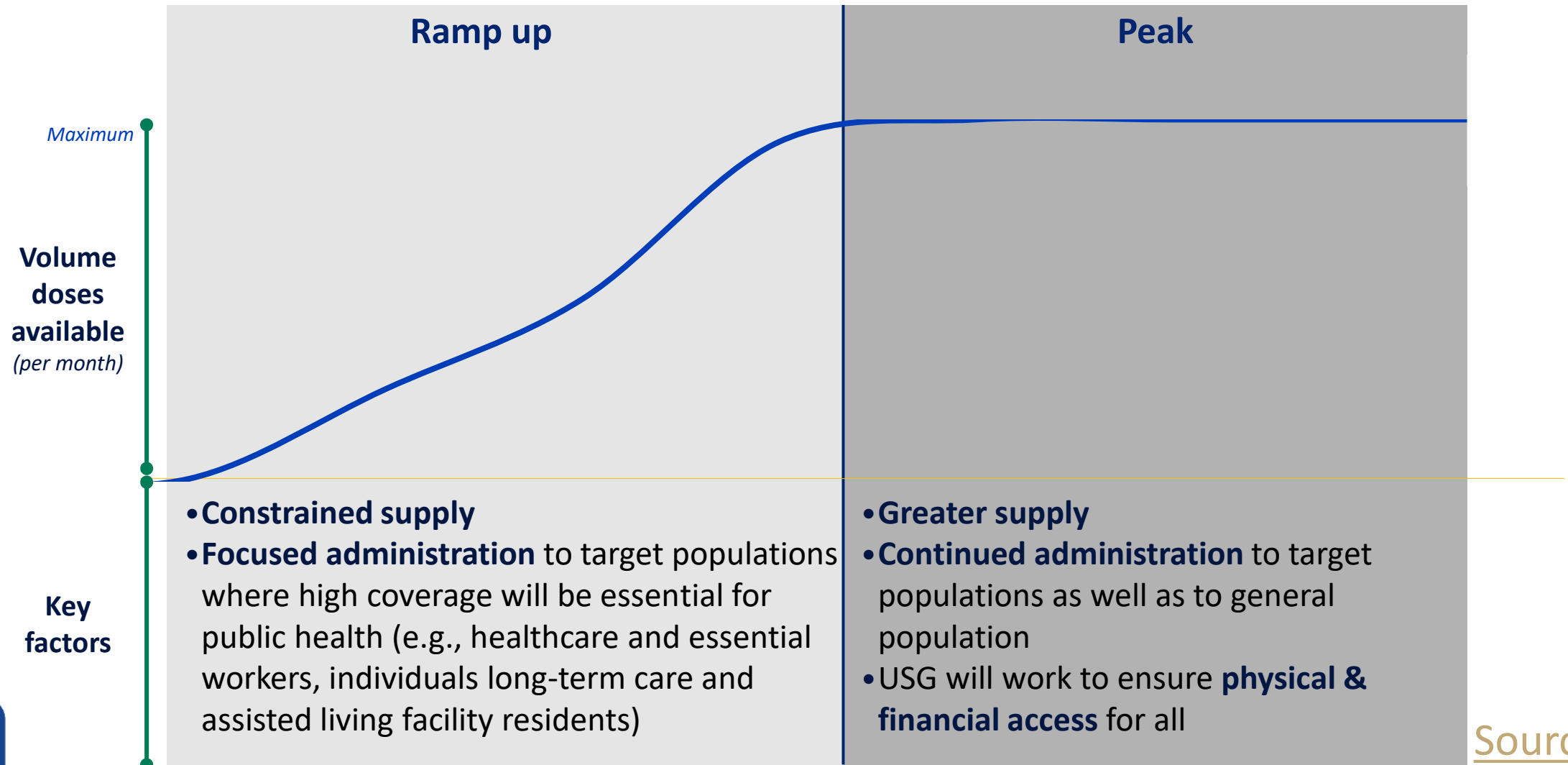
- Providers (hospitals, pharmacies, clinics) must sign a COVID-19 provider agreement.
- Providers must be connected to KY Immunization Registry (KYIR) and Kentucky Health Information Exchange (KHIE) to order, receive, and document administration of vaccine.
- KYIR is connected to the CDC software platform for ordering, tracking, and documenting doses.
- McKesson will direct ship vaccines to enrolled vaccinators.

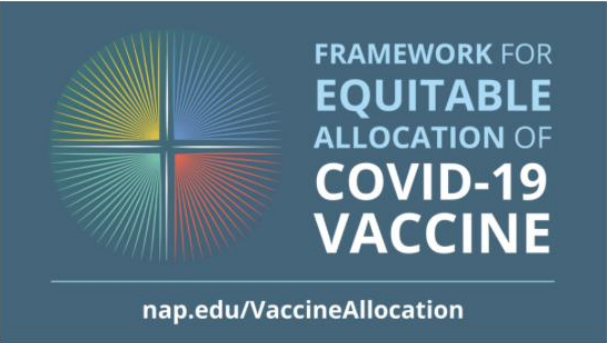
# Multiple Critical Components to Vaccine Implementation



Source

# As volume of doses available increases, we will be able to vaccinate broader populations





Framework for Equitable Allocation of COVID-19 Vaccine

Read the full report and the committee’s recommendations

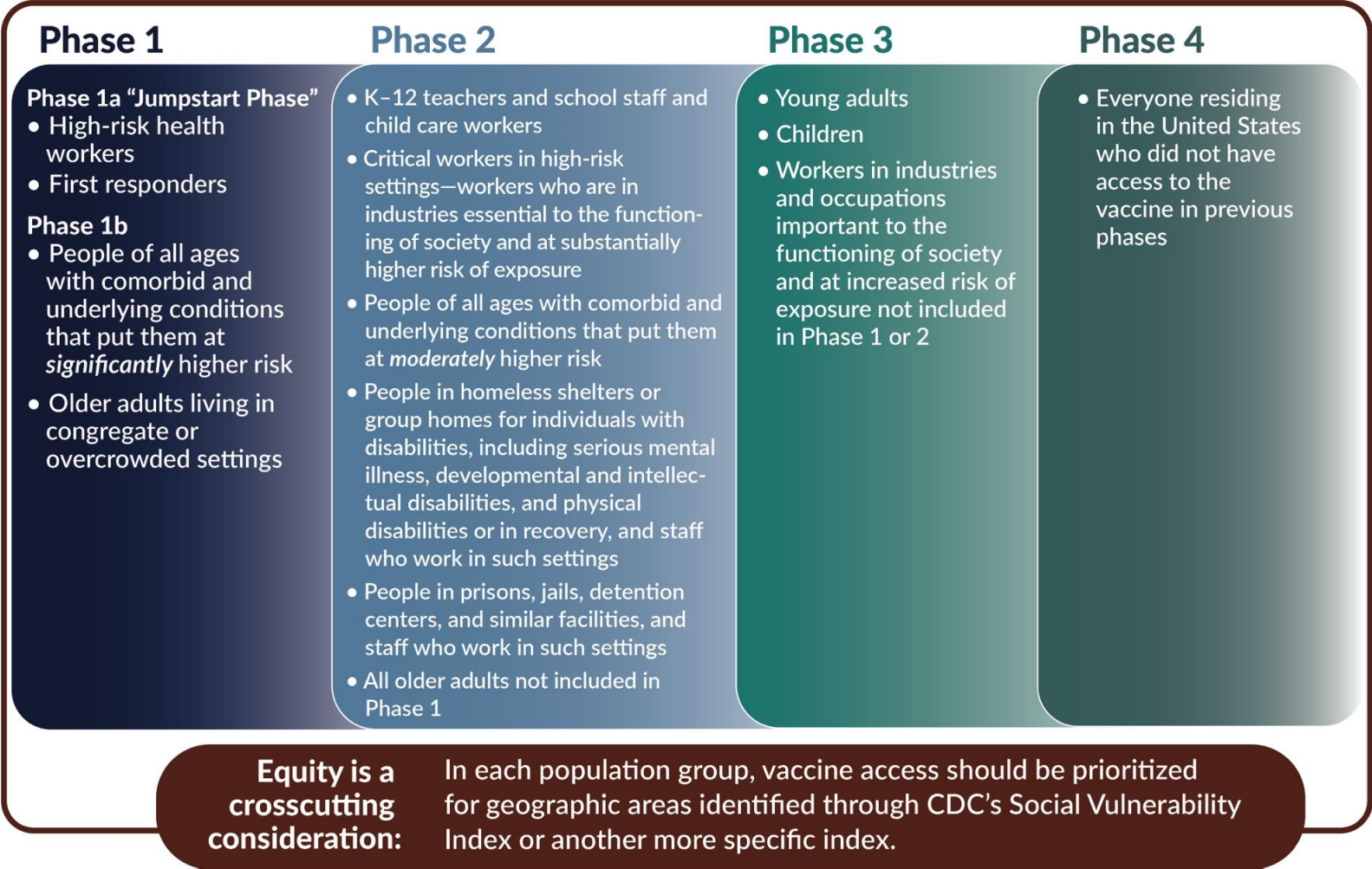


FIGURE S-2 A phased approach to vaccine allocation for COVID-19.

Source

## Coronavirus Disease 2019 (COVID-19)

MENU >



### YOUR HEALTH

# How CDC Is Making COVID-19 Vaccine Recommendations

Updated Oct. 13, 2020

Languages ▾ [Print](#)



CDC is making coronavirus disease 2019 (COVID-19) vaccination recommendations for the United States based on input from the Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee made up of medical and public health experts who develop recommendations on the use of vaccines in the U.S. public. ACIP holds regular meetings, which are open to the public and provide opportunity for public comment.

### ACIP's role

[CDC's vaccine recommendation process](#) >



**ACIP Resources:** [Meeting agendas, minutes, live meetings, and presentation slides](#)

Source



# 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

**VACCINE**

**DEVELOPMENT**

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

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

PHASE 4

safety monitoring for  
serious, unexpected  
adverse events

POST-APPROVAL  
MONITORING +  
RESEARCH

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



**LEARN  
MORE**

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

# U.S. Food & Drug Administration (FDA)

- Vaccine manufacturers will submit Emergency Use Authorization (EUA) applications when they have sufficient data
- Multiple vaccine candidates are in phase 3 trials (see next slide)
- Visit [FDA COVID-19 vaccine website](#) for current status

# 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"> <li>2 doses (0, 28d)</li> <li>IM administration</li> <li>18-55, 56+ years</li> </ul>	NCT04470427	✓
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	<ul style="list-style-type: none"> <li>Single or 2 doses</li> <li>IM administration</li> <li>18-85 years</li> </ul>	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	<ul style="list-style-type: none"> <li>2 doses (0, 28d)</li> <li>IM administration</li> <li>≥18 years</li> </ul>	NCT04516746	On Hold
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	I/II	<ul style="list-style-type: none"> <li>2 doses (0, 56d)</li> <li>IM administration</li> <li>18-55, 65+</li> </ul>	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	<ul style="list-style-type: none"> <li>Single or 2 doses</li> <li>18-49, 50+</li> </ul>	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II		NCT04368988	✓
AV-COVID-19	Aivita	AuDendritic cell	I/II		NCT04386252	
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	<ul style="list-style-type: none"> <li>2 doses (0, 4w)</li> <li>SC administration/ electroporation</li> <li>≥18 years</li> </ul>	NCT04336410	



\*As of September 14, 2020

\*\*Currently on hold in US

Sources: <https://milkeninstitute.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://vaccineshinyapps.io/nCoV_vaccine_landscape/); <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

Source

# Thank you!

Steven J. Stack, MD, MBA

Commissioner

Kentucky Department for Public Health

**[kycovid19.ky.gov](https://kycovid19.ky.gov)**



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