



CDC/IDSA COVID-19 Clinician Call

December 5, 2020

Welcome & Introductions

Dana Wollins, DrPH, MGC

Vice President, Clinical Affairs & Guidelines

IDSA

- 46th in a series of weekly calls, initiated in January by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Vaccine Update and Q&A



Carol J. Baker, MD

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Division of Infectious Diseases
University of Texas Health Science Center
McGovern Medical School, Houston
IDSA Liaison Representative
Advisory Committee on Immunization Practices



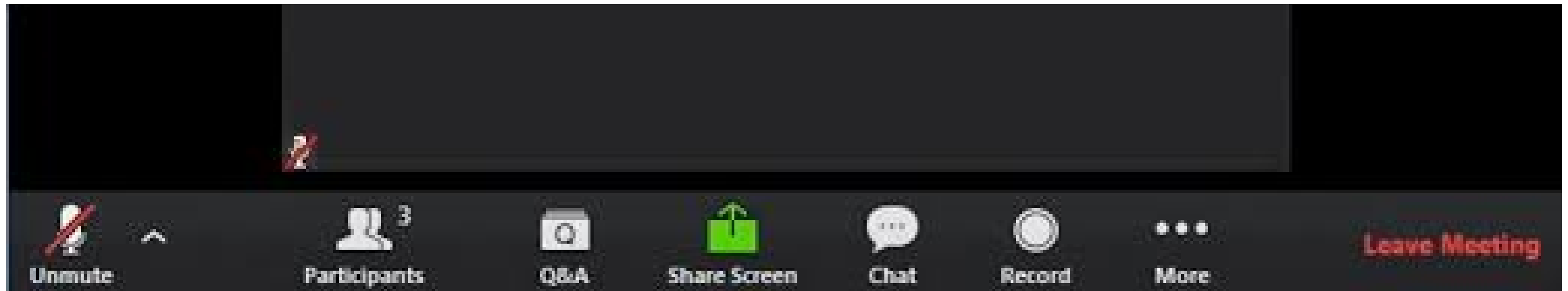
Amanda Cohn, MD

Chief Medical Officer, COVID-19 Vaccine Task Force
Chief Medical Officer, National Center for
Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Question?
Use the "Q&A" Button

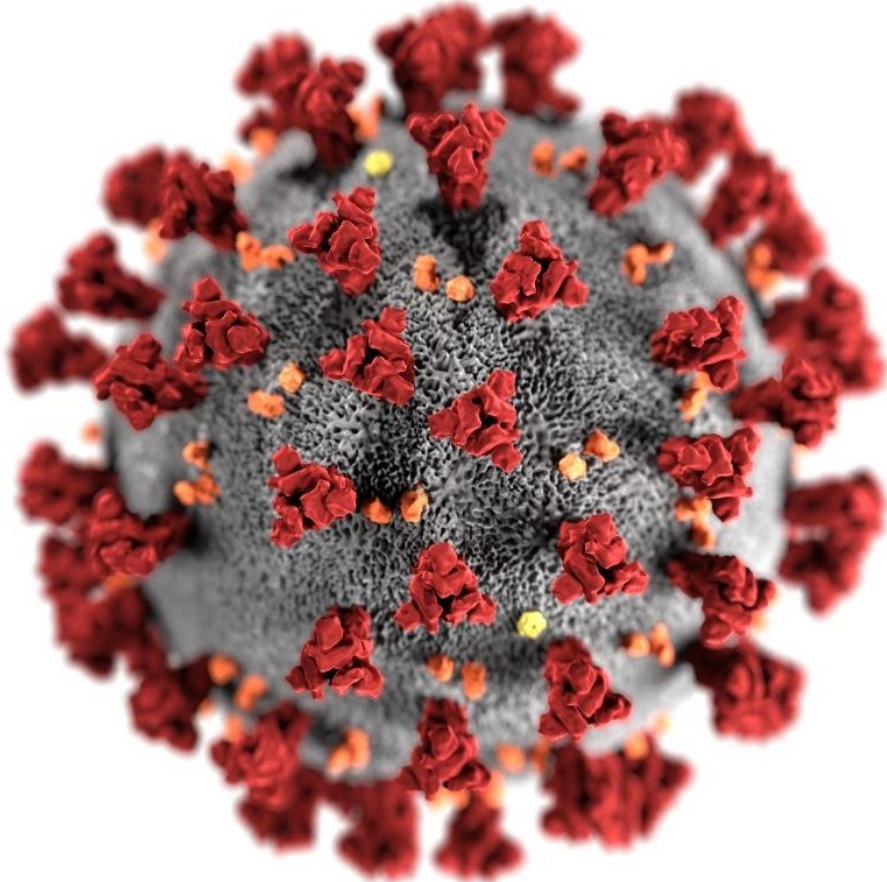


Comment?
Use the "Chat" Button



COVID-19 Vaccine Update

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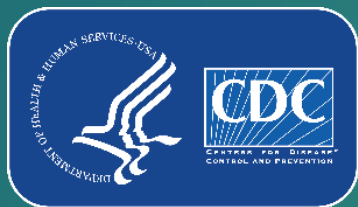
Disclosures

**Carol J. Baker, M.D. is a consultant to Pfizer, Inc.
for maternal group B streptococcal (GBS)
vaccine development**

Amanda Cohn, M.D. nothing to disclose



FDA Emergency Use Authorization (EUA)



Role of VBRPAC and ACIP

- VBRPAC and ACIP are U.S. federal advisory committees charged with reviewing evidence for authorizing (FDA) and recommending (ACIP) vaccines for use
- For Covid-19 vaccines requesting EUA, the evidence will be reviewed at relatively the same time by VBRPAC and ACIP, but FDA and VBRPAC 1st then ACIP
- **1st ACIP vote:** 12-1-2020 phase 1a implementation (HCP and LTCF residents)
- **1st VBRPAC Meeting:** Pfizer mRNA vaccine review on 12-10-2020 with possible EUA sent for approval and signature by FDA commissioner
- **2nd ACIP vote:** recommendation for use of Pfizer vaccine in adults 12-11 or 12-13
- **2nd VBRPAC Meeting:** Moderna mRNA vaccine review on 12-17-2020



mRNA Vaccines



mRNA COVID-19 Vaccines

- **Discovered in the 1990's; studied for more than a decade (eg, CMV, Zika)**
- **mRNA vaccines take advantage of the process that human cells use to make proteins to trigger an immune response**
 - **Enter muscle cells, mRNA instructs them to make “spike” protein**
 - **“Spike” protein displayed on cell surface then immune response**
 - **cell gets rid of the mRNA soon after it is finished using the instructions**
- **Fully synthetic thus fast production, stability, low cost**
- **COVID-19 mRNA vaccines have been rigorously tested for safety**
- **Despite some rumors, mRNA vaccines do not contain live virus and do not alter a person's DNA as they don't enter cell nucleus)**

Reactogenicity of mRNA Vaccines

Data from published Phase I/II trials

Moderna¹

Adults 18–55 years of age

100µg	Post-dose 1			Post-dose 2		
N=15	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	—	—	—	5 (33%)	1 (7%)	—
Headache	4 (27%)	—	—	5 (33%)	4 (27%)	—
Myalgia	1 (7%)	—	—	2 (13%)	6 (40%)	—

Pfizer²

30µg	Post-dose 1			Post-dose 2		
N=12	Mild	Moderate	Severe	Mild	Moderate	Severe
Fever	1 (8%)	1 (8%)	—	—	2 (17%)	—
Headache	3 (25%)	1 (8%)	2 (17%)	6 (50%)	2 (17%)	—
Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

Systemic symptoms more common after the second dose

¹Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.

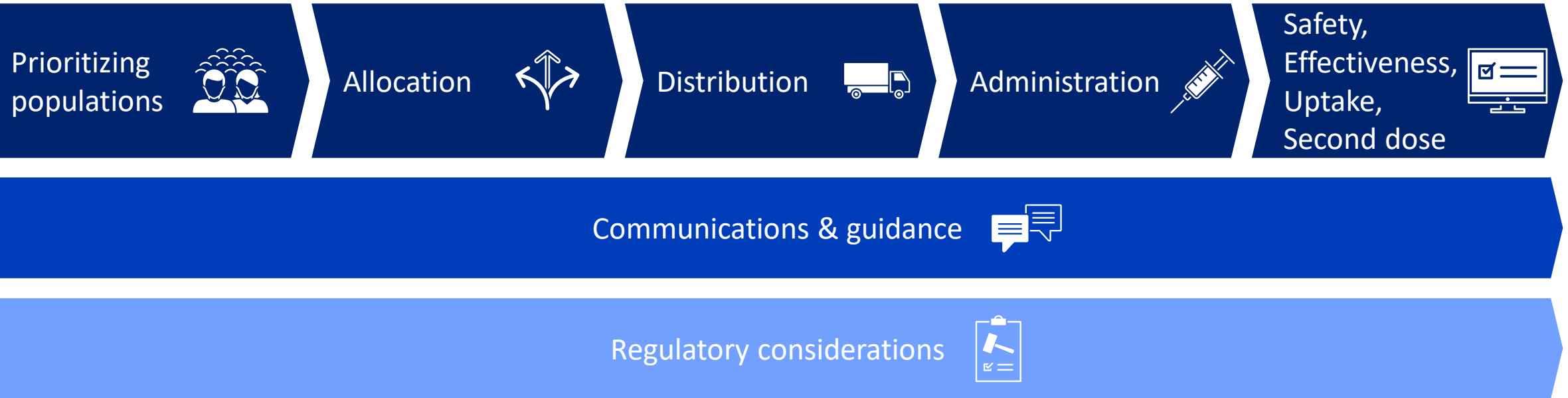
²Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.



Prioritization Planning Update from ACIP

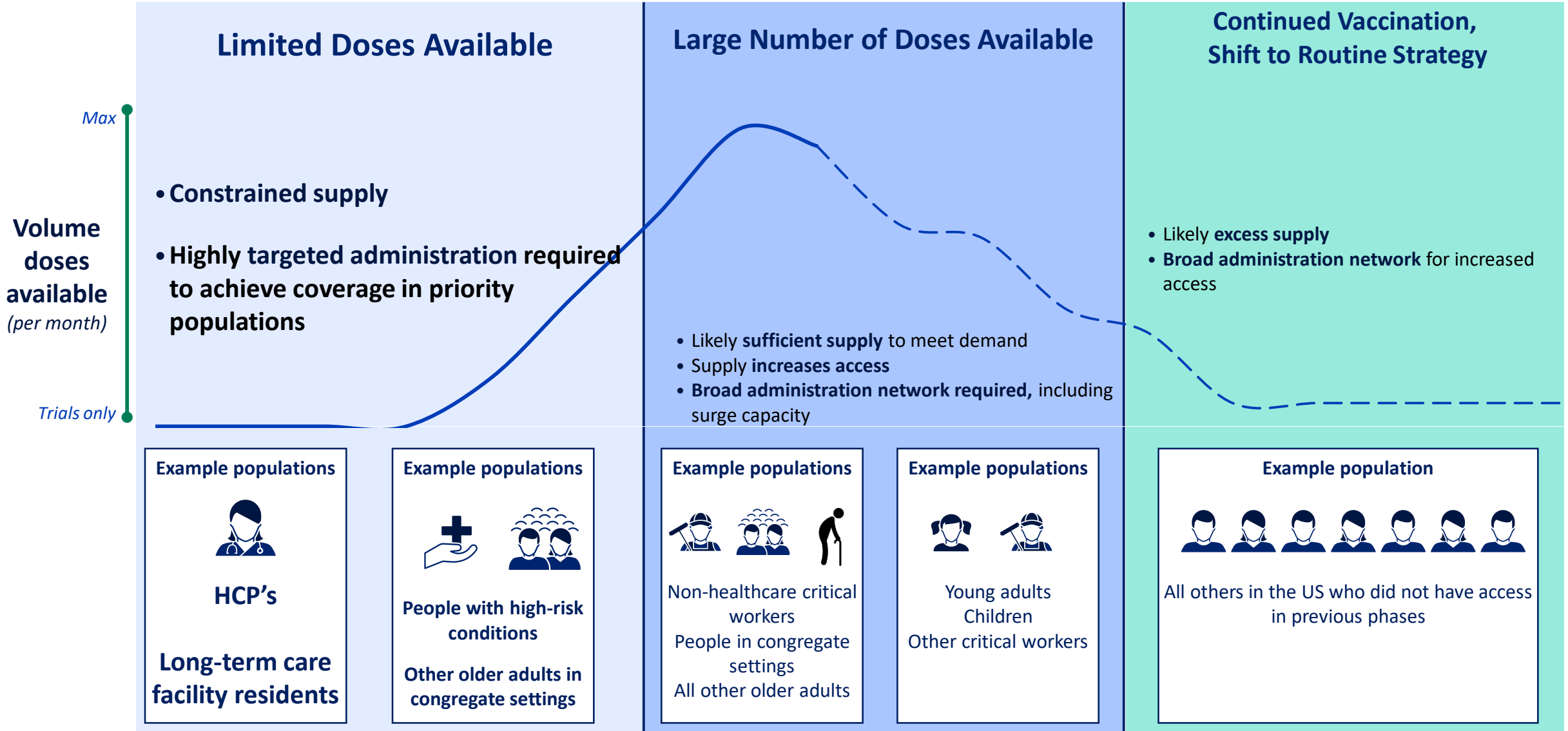


Multiple components to vaccine implementation



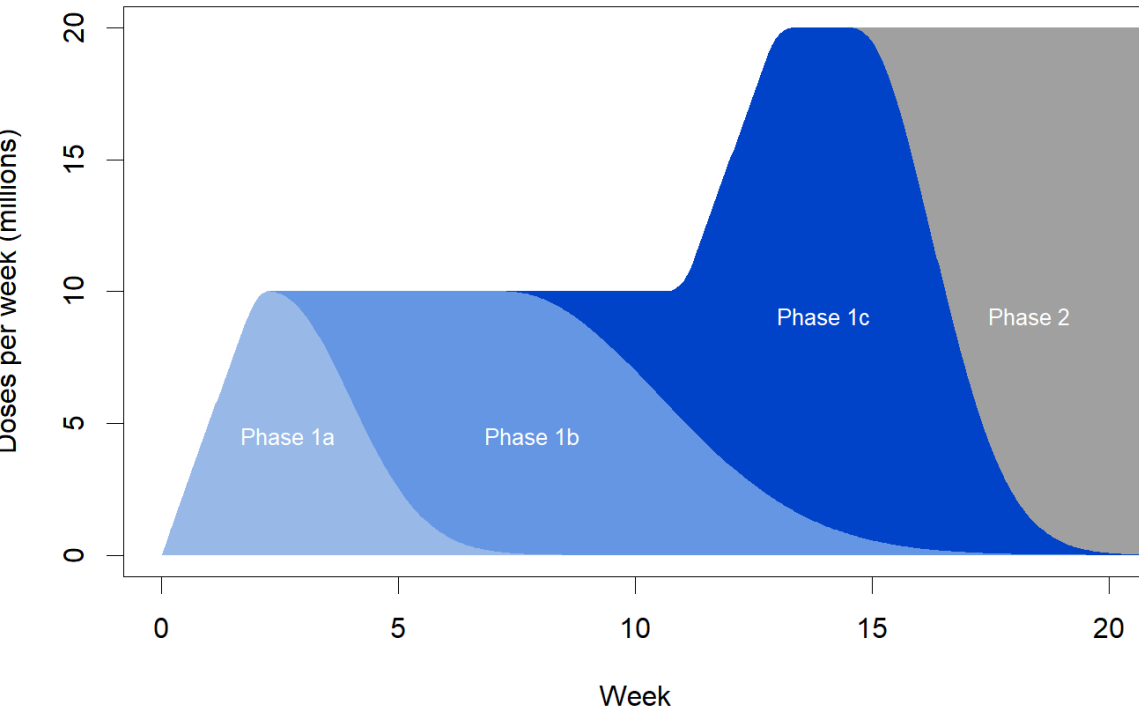
Public health impact relies on rapid, efficient, and high uptake of complete vaccine series, with particular focus on those at increased risk for severe COVID-19 illness

Distribution will adjust as volume of vaccine doses increases



Illustrative example populations; final prioritization to be decided by ACIP

Example of a possible Phase 1 sequence



1a- HCW and LTCF residents

Followed by:

Essential workers (examples include Education Sector, Food & Agriculture, Utilities, Police, Firefighters, Corrections Officers, Transportation)

Adults with high-risk medical conditions

Adults 65+

Persons living in congregate settings

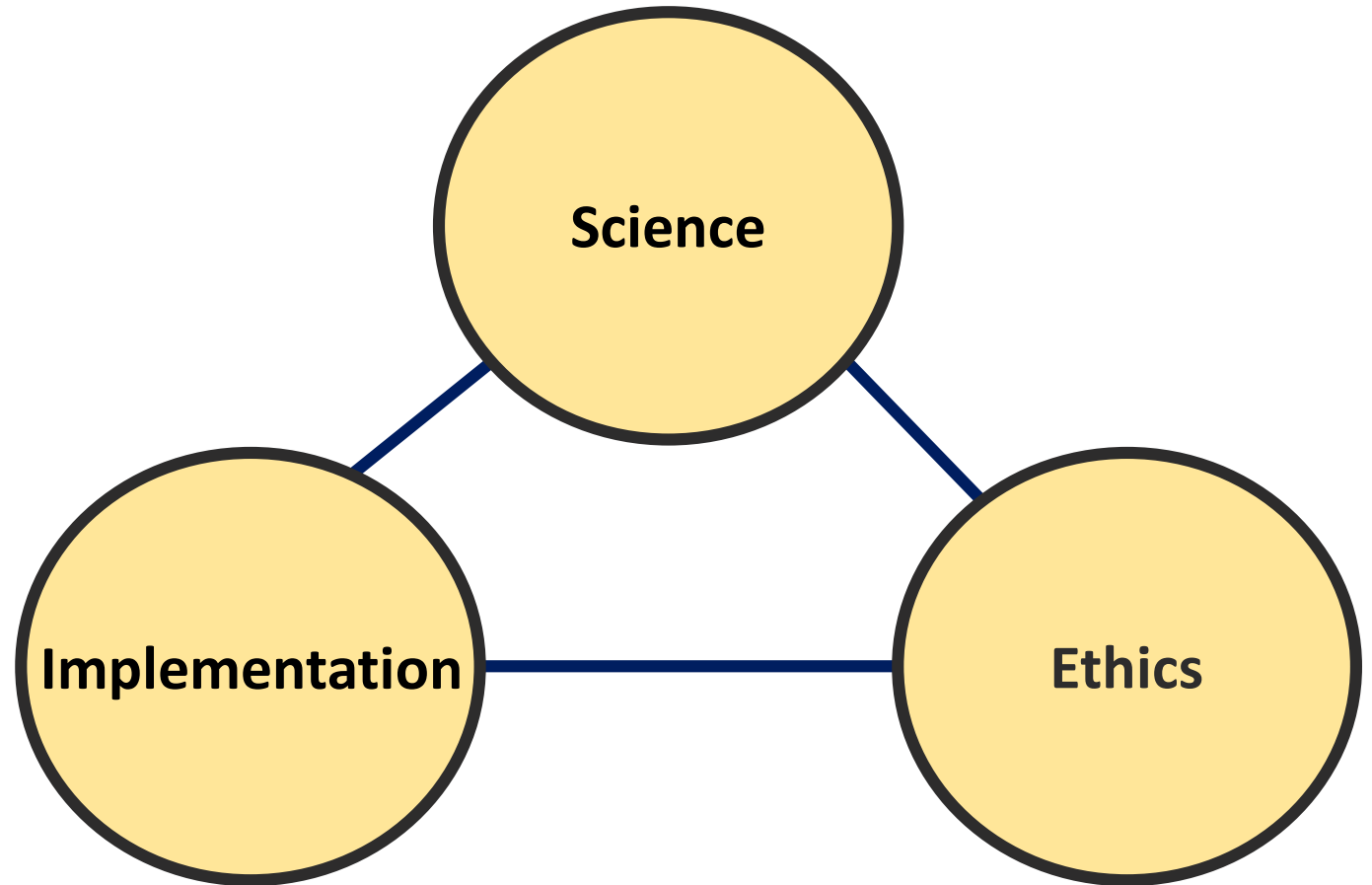


ACIP Allocation of COVID-19 Vaccine

Which groups should be recommended to receive COVID-19 vaccine 'X' during Phase 1a?

Ethical Principles:

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



ACIP Recommendations for Use of Vaccine Against COVID-19

When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, ACIP recommends that 1) health care personnel and 2) residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a).

Goals for vaccination if supply is limited

ACIP has set the following goals for recommending which groups should receive COVID-19 vaccines when supply is 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

Groups for Phase 1a Vaccination

Health Care Personnel^{1,2} (HCP) (~21 million)	Long-Term Care Facility (LTCF) Residents³ (~3 million)
Examples	
<ul style="list-style-type: none">■ Hospitals■ Long-term care facilities■ Outpatient clinics■ Home health care■ Pharmacies■ Emergency medical services■ Public health	<ul style="list-style-type: none">■ 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. <https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce>

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

Proposed Clinical Considerations: ACIP, Nov 2020

- **Pregnancy:**

- Pregnancy is *not* a contraindication to receiving a COVID-19 vaccine (no data yet on safety of these vaccines in pregnant women)

- **Breastfeeding:**

- Lactating women can continue to breast feed

- **Prior SARS-CoV-2 infection:**

- Vaccination is recommended regardless of prior infection
- Testing for SARS-CoV-2 antibodies is *not* recommended prior to vaccination
- While vaccine supplies are limited, vaccination of persons with *recent* prior infection may be delayed (90 days; duration of protection after infection unknown)

- **Vaccine dosing schedules; testing for prior infection; dosing intervals?**

- **Co-administration with other vaccines (no data yet)**

Pfizer & Moderna | Specifications impact planning (as of 11/30/2020)

	Pfizer	Moderna
Long term storage	<ul style="list-style-type: none">• -60C to -80C	<ul style="list-style-type: none">• -20C
Storage container	<ul style="list-style-type: none">• ULT freezer, thermal shipper	<ul style="list-style-type: none">• Freezer
Short term storage	<ul style="list-style-type: none">• 2C-8C, 5 days	<ul style="list-style-type: none">• 2C-8C, 30 days, don't shake
Dose separation	<ul style="list-style-type: none">• 21 days• Unknown: window, what if you miss the window?	<ul style="list-style-type: none">• 28 days• Unknown: window, what if you miss the window?
Mixing	<ul style="list-style-type: none">• Yes, diluent	<ul style="list-style-type: none">• No



Healthcare Personnel: Considerations for Implementation

- Healthcare systems and public health should work together to ensure vaccine **access** to healthcare personnel who are not affiliated with hospitals
- Consider **staggering** vaccination of personnel from similar units or positions
- Planning for personnel to have **time away** from clinical care if HCP experience systemic symptoms post-vaccination
- Additional CDC guidance forthcoming:
 - Approach to systemic symptoms in HCP after COVID-19 vaccination

COVID-19 Vaccination Provider Enrollment

- States working with healthcare and hospital systems, local health departments, and federal pharmacy program for Phase 1a
 - Closed pods and open pods
- Need to expand broadly to ensure access in provider's offices, pharmacies, and in underserved communities
- Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 Vaccination Program
- Training and clinical materials include:
 - Toolkits for health systems and clinics, long-term care facilities, and health departments
 - Training materials on vaccine administration, storage and handling, vaccine products, etc.



Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
- Uses text messaging and web surveys to check-in with vaccine recipients after vaccination
- Participants can report any side effects or health problems after COVID-19 vaccination
- Includes active telephone follow-up by CDC for reports of significant health impact



Your role

COVID-19 vaccine safety gets stronger with your participation

Public health partners

- promote participation in **v-safe** ✓
- promote reporting to **VAERS** ✓
- communicate with your partners on vaccine safety ✓

Healthcare providers

- encourage patient participation in **v-safe** ✓
- report adverse events to **VAERS** ✓
- communicate with patients on vaccine safety ✓

Thank you



Q&A and Discussion

Questions to be Addressed during the Q&A

Safety

- **What are the long-term safety data—and potential safety concerns—about mRNA vaccines? What types of post-market monitoring will be in place to assess long-term sequelae?**

Efficacy

- How will the efficacy of COVID vaccine be measured in terms of lab findings (i.e., IgG or Nab)?
- Please comment on the [Gifford article](#) from earlier this week suggesting the vaccines currently in phase III trials may not be as effective in individuals of Black or Asian genetic ancestry.
- For whom will COVID-19 vaccine be contraindicated? (children, pregnant women, active chemo, HIV, CD4 cut-off, etc.)?

Vaccination in Previously Infected Individuals

- What will be the guidance to patients who have already had the disease this year?
 - Are there data from study participants who were IgG positive at baseline and received the vaccines?
 - Are there data on individuals who received the vaccine after positive RT-PCR testing and symptoms but did not develop IgG antibodies?

Distribution

- What is the distribution strategy for rural and underserved areas (i.e., what is the IHS going to do for Native American communities?)
- How can I find out what's happening in my state regarding distribution plans? Whom do I contact?

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Continue the
conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19



We want to hear from you! Please complete
the post-call survey.

Next Call: **Saturday, December 12th**

Topic: IDSA Testing Guidelines Updates

A recording of this call will be posted on
Monday at **www.idsociety.org/cliniciancalls**

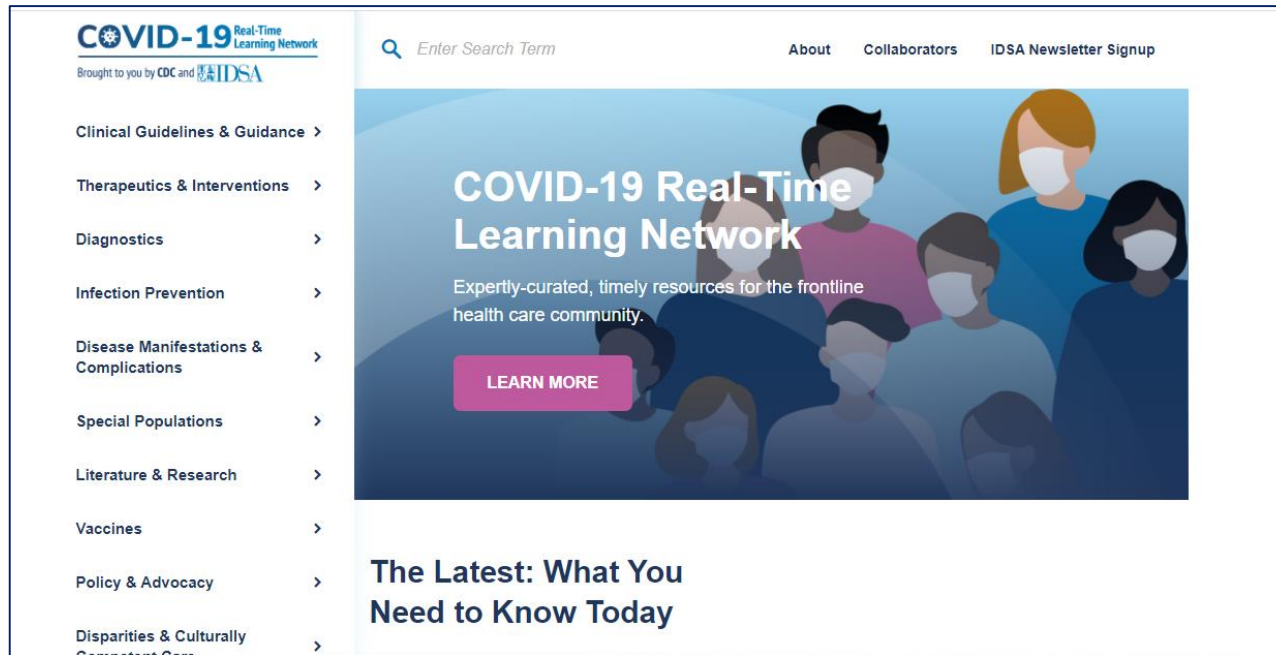
-- library of all past calls now available --

Contact Us:

Dana Wollins (dwillins@idsociety.org)

Deirdre Lewis (dlewis@idsociety.org)

COVID-19 Real-Time Learning Network



Specialty Society Collaborators:

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Emergency Physicians
- American College of Physicians
- American Geriatrics Society
- American Thoracic Society
- Pediatric Infectious Diseases Society
- Society for Critical Care Medicine
- Society for Healthcare Epidemiology of America
- Society of Hospital Medicine
- Society of Infectious Diseases Pharmacists

With funding from the Centers for Disease Control and Prevention, IDSA has launched the COVID-19 Real Time Learning Network, an online community that brings together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

www.COVID19LearningNetwork.org

@RealTimeCOVID19

#RealTimeCOVID19

CDC-IDSA Partnership: Clinical Management Call Support

Announcing a new service for clinicians:

FOR WHOM?

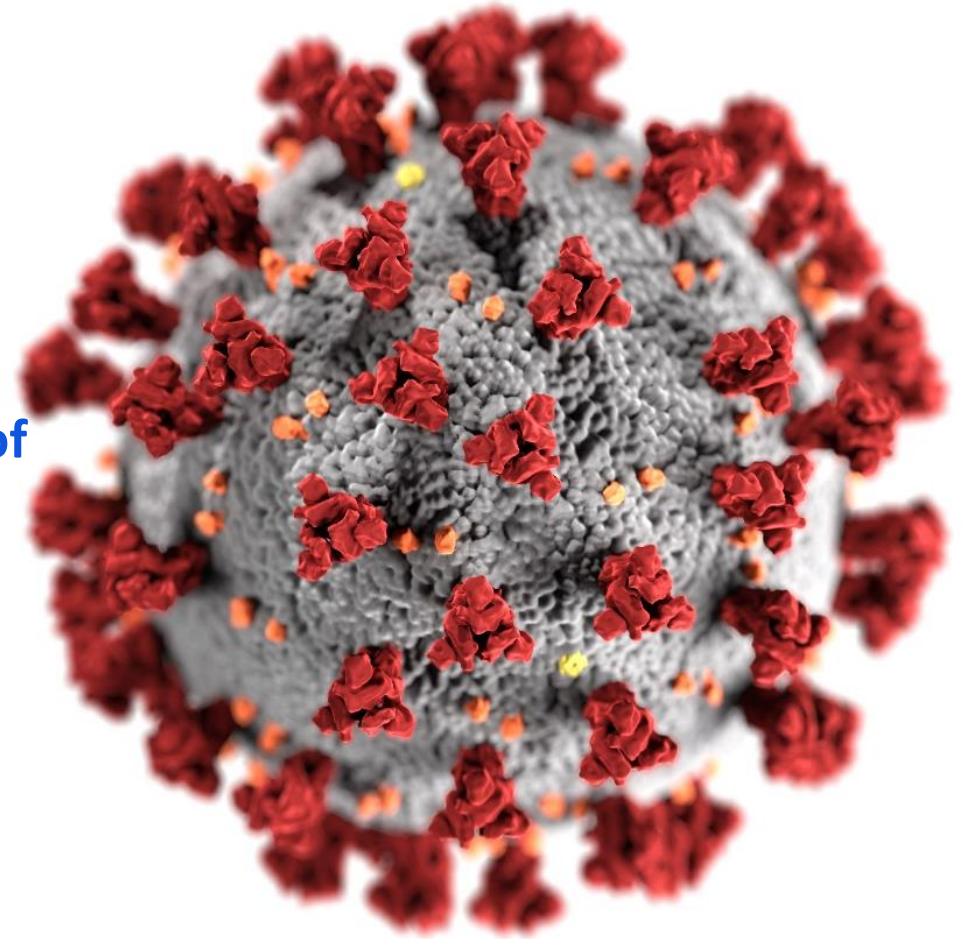
- Clinicians who have questions about the clinical management of COVID-19

WHAT?

- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form



IDSA
Infectious Diseases Society of America

cdc.gov/coronavirus