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.id society.org/cliniciancalls.
Vaccine Update and Q&A

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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
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

#### Adults 18–55 years of age

<table>
<thead>
<tr>
<th>Moderna(^1)</th>
<th>100µg</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=15</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Fever</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Headache</td>
<td>4 (27%)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Myalgia</td>
<td>1 (7%)</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pfizer(^2)</th>
<th>30µg</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=12</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Fever</td>
<td>1 (8%)</td>
<td>1 (8%)</td>
<td>—</td>
</tr>
<tr>
<td>Headache</td>
<td>3 (25%)</td>
<td>1 (8%)</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>1 (8%)</td>
<td>1 (8%)</td>
<td>1 (8%)</td>
</tr>
</tbody>
</table>

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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.

Prioritizing populations

Allocation

Distribution

Administration

Safety, Effectiveness, Uptake, Second dose

Communications & guidance

Regulatory considerations
Distribution will adjust as volume of vaccine doses increases

**Limited Doses Available**
- Constrained supply
- Highly targeted administration required to achieve coverage in priority populations

**Large Number of Doses Available**
- Likely sufficient supply to meet demand
- Supply increases access
- Broad administration network required, including surge capacity

**Continued Vaccination, Shift to Routine Strategy**
- Likely excess supply
- Broad administration network for increased access

**Example populations**
- **HCP’s**
- Long-term care facility residents
- People with high-risk conditions
- Other older adults in congregate settings
- Non-healthcare critical workers
- People in congregate settings
- All other older adults
- Young adults
- Children
- Other critical workers
- All others in the US who did not have access in previous phases

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

<table>
<thead>
<tr>
<th>Health Care Personnel(^1,)(^2) (HCP) (~21 million)</th>
<th>Long-Term Care Facility (LTCF) Residents(^3) (~3 million)</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)
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)
<table>
<thead>
<tr>
<th>Specifications impact planning (as of 11/30/2020)</th>
<th>Pfizer</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Long term storage</strong></td>
<td>-60C to -80C</td>
<td>-20C</td>
</tr>
<tr>
<td><strong>Storage container</strong></td>
<td>ULT freezer, thermal shipper</td>
<td>Freezer</td>
</tr>
<tr>
<td><strong>Short term storage</strong></td>
<td>2C-8C, 5 days</td>
<td>2C-8C, 30 days, don’t shake</td>
</tr>
<tr>
<td><strong>Dose separation</strong></td>
<td>21 days</td>
<td>28 days</td>
</tr>
<tr>
<td>• Unknown: window, what if you miss the window?</td>
<td></td>
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<tr>
<td><strong>Mixing</strong></td>
<td>Yes, diluent</td>
<td>No</td>
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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
COVID-19 vaccine safety gets stronger with your participation

Your role

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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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](http://www.idsociety.org/cliniciancalls) -- *library of all past calls now available* --

**Contact Us:**
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Deirdre Lewis ([dlewis@idsociety.org](mailto:dlewis@idsociety.org))

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Continue the conversation on Twitter

@RealTimeCOVID19 #RealTimeCOVID19
COVID-19 Real-Time Learning Network

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.

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

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

cdc.gov/coronavirus