Addressing the COVID-19 Crisis: An Open Forum Webinar Series for Pharmacists

December 10, 2020
Michael D. Hogue, PharmD, FAPhA, FNAP  
Dean and Professor  
Loma Linda University School of Pharmacy  
President, APhA  

Host and Moderator
Today’s Focus:

Discuss breaking information about COVID-19 vaccines, including the latest in the development, approval, allocation, and distribution, as well as vaccine hesitancy.
Angela Guo, MPH
Epidemiologist
Centers for Disease Control and Prevention

Guest Speaker
Colonel (Ret.) John Grabenstein, RPh, PhD, FAPhA
Editor, Immunization Action Coalition
President, Vaccine Dynamics

Guest Speaker
Steve Foster, PharmD, FAPhA
APhA Liaison to ACIP
CAPT (Ret.), U.S.P.H.S.

Guest Speaker
Mitchel Rothholz, RPh, MBA
Chief of Governance & State Affiliates
American Pharmacists Association

Executive Director
American Pharmacists Association
Foundation

Speaker
Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President
Pharmacy Practice and Government Affairs
American Pharmacists Association

Subject Matter Expert: Q&A
Daniel Zlott, PharmD, BCOP
Senior Vice President
Education and Business Development
American Pharmacists Association

Subject Matter Expert: Q&A
Disclosures

Stephan Foster, PharmD, FAPhA, FNAP, has served as a speaker for Merck Vaccines, Pfizer and Seqirus. He has served on advisory boards for Pfizer and Seqirus.

John Grabenstein, RPh, PhD, FAPhA, serves an advisory board member for Janssen, VBI Vaccines and Bavarian Nordic. He is a consultant at Valneva. He has stock in Merck.

Mitchel C. Rothholz, RPh, MBA, declares that his spouse is an employee of Merck and that he has served on advisory boards for Merck and Pfizer.

All other speakers and individuals involved in the development of this material declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria. APhA’s editorial staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria. For a complete list of APhA staff disclosures, please visit the APhA website at www.pharmacist.com/apha-disclosures.
CPE Information

Target Audience: Pharmacists
ACPE#: 0202-0000-20-390-L01-P
Activity Type: Knowledge-based
Learning Objectives

1. Discuss the latest updates on the various COVID-19 vaccines.
2. Describe emerging processes for approval, allocation, and distribution.
3. Review vaccine safety information and strategies to overcome vaccine hesitancy.
Which of the following serious adverse events were seen in the Pfizer clinical trials?

a. Anaphylaxis
b. Cardiac arrest
c. Guillain-Barre syndrome
d. None of the above
What is the name of the new CDC smartphone-based, after vaccination health checker for people who receive the COVID-19 vaccines?

a. COVID-19 Vaccine Safety Monitor
b. Vaccine Safety Datalink (VSD)
c. V-SAFE
d. Clinical Immunization Safety Assessment (CISA) Project
Which of the following should a pharmacist NOT do when preparing to administer COVID-19 vaccination?

a) Communicate with local health department colleagues  
b) Order product from vaccine manufacturers directly  
c) Enroll with state or metropolitan immunization information system (registry)  
d) Discuss with staff how to identify and report adverse events
Format for Today’s Webinar

1:00 pm: Introductions
1:05 pm: Interview with Angela Guo, John Grabenstein, Steve Foster, and Mitch Rothholz
1:25 pm: Open Forum: A Minute for Your Thoughts
1:50 pm: Wrap Up: Review of APhA’s Resources and Assessment Questions
Open Forum Ground Rules

- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- Individuals whose submissions are selected will be asked by the moderator to state the comment or question for the audience. The line for the individual will be unmuted to read their comment or question.
- To maximize the number of questions/comments addressed, a **60-second time limit** will be in effect for everyone to state their question or comment.
- We will try to get to as many comments and questions as possible. We have created a new forum for COVID-19 discussions where further discussion post-webinar. Information on participating in this forum will be provided at the end of the open forum.
Discussion with Angela Guo, John Grabenstein, Steve Foster, and Mitch Rothholz

Discuss breaking information about COVID-19 vaccines, including the latest in the development, approval, allocation, and distribution, as well as vaccine hesitancy.
COVID-19 Vaccination

Protect Yourself, Your Patients, and Family
Getting vaccinated against COVID-19 and maintaining other prevention measures are essential for you, your patients, and your family to stay healthy.

Prepare for COVID-19 Vaccination
Resources for the planning, allocation, distribution, administration, storage & handling, patient education, and more for COVID-19 vaccine.

Getting Vaccinated
How CDC Is Making COVID-19 Vaccine Recommendations
Benefits of Getting a COVID-19 Vaccine
Ensuring the Safety of COVID-19 Vaccines in the United States

Preparing Your Patients
Answering Patients’ Questions about COVID-19 Vaccination
Understanding and Explaining mRNA COVID-19 Vaccines

COVID-19 Vaccine Resources for Providers
Vaccines Storage and Handling Toolkit
COVID-19 Vaccination Training Programs and Reference Materials
The Advisory Committee on Immunization Practices’ Interim

CDC recommends the COVID-19 vaccine for healthcare workers.

Healthcare Professionals: Preparing for COVID-19 Vaccination

Training and Educational Materials

- Vaccine Storage and Handling Toolkit
- COVID-19 Vaccine Training Module For Healthcare Professionals
- COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals

Preparing to Provide COVID-19 Vaccines
Making a Strong Recommendation for COVID-19 Vaccination
Talking to Patients about COVID-19 Vaccines
Answering Patients’ Questions
Understanding and Explaining mRNA COVID-19 Vaccines

State Immunization Plans
Find out what your state’s immunization plans are. COVID-19 Vaccination Program Operational Guidance

What Healthcare Professionals Need to Know
For the top 10 things you need to know about U.S. COVID-19 vaccine planning, visit the COVID-19 website.

https://www.cdc.gov/vaccines/covid-19/hcp/index.html
Training and Clinical Materials for COVID-19 Vaccine Providers

• Storage and Handling Toolkit: Updated with COVID-19 Addendum

• COVID-19 Vaccine Training Module
  • Web-based, on-demand training for HCPs outlining best practices when preparing to administer COVID-19 vaccine

• Comprehensive list of COVID-19 vaccine clinical trainings and materials

• Upcoming: Clinical materials for specific COVID-19 vaccine products (after EUAs issued)
Resources to Help Explain COVID-19 Vaccination Data Reporting Systems

- COVID-19 Vaccine Data Reporting Systems Website

- COVID-19 Vaccine IT Overview: Vaccine Allocation, Distribution, Administration, Data, and Reporting

- Data Reporting Requirements and Instructions for Pharmacies
Resources to Help Guide Discussions With COVID-19 Vaccine Recipients

• COVID-19 Vaccination Communication Toolkit

• Talking to Patients About COVID-19 Vaccines

• Answering Patients Questions about COVID-19 Vaccines

• Making a Strong Recommendation for COVID-19 Vaccination
How to report an AE to VAERS

• Go to vaers.hhs.gov
• Submit a report online
• For help:
  • Call 1-800-822-7967
  • Email info@VAERS.org
  • Video instructions https://www.youtube.com/watch?v=sbCWhcQADFE

General safety information

• https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
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 side effects and health impact events after COVID-19 vaccination

• includes active telephone follow-up by CDC for reports of significant health impact

• captures information on pregnancy status and enables follow-up on pregnant women
1. Text message check-ins from CDC (daily 1<sup>st</sup> week; weekly thru 6 weeks; then 3, 6, and 12 mo.)
   
vaccine recipient completes web survey

2. Clinically important health impact reported
   - missed work
   - unable to do normal daily activities
   - received medical care

Vaccine recipient

3. A CDC representative conducts active telephone follow-up on a clinically important health impact event and takes a report if appropriate
Federal Pharmacy Partners for COVID-19 Vaccination

- Albertsons Companies, Inc.
- Costco Wholesale Corp.
- CPESN USA, LLC
- CVS Pharmacy, Inc.
- Good Neighbor Pharmacy and AmerisourceBergen Drug Corporation’s PSAO, Elevate Provider
- Gerimed
- Health Mart Systems, Inc.
- H-E-B, LP
- Hy-Vee, Inc.
- LeaderNET and Medicine Shoppe, Cardinal Health’s PSAOs
- Managed Health Care Associates (MHA)
- Meijer Inc.
- Premier/Innovatix
- Publix Super Markets, Inc.
- Retail Business Services
- Rite Aid Corp.
- Southeastern Grocers
- The Kroger Co.
- Topco Associates, LLC
- Walgreens
- Walmart, Inc.

## SARS-CoV-2 Vaccine Candidates

<table>
<thead>
<tr>
<th>Vaccine Sponsor [w/ Major Partners]</th>
<th>ModernaTX USA</th>
<th>BioNTech with Pfizer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Designator</td>
<td>mRNA-1273</td>
<td>BNT162b2</td>
</tr>
<tr>
<td>Vaccine Type</td>
<td>mRNA</td>
<td>mRNA</td>
</tr>
<tr>
<td>Dosing Regimen</td>
<td>Days 0 + 28</td>
<td>Days 0 + 21</td>
</tr>
<tr>
<td># of Volunteers</td>
<td>&gt; 30,000</td>
<td>40,277</td>
</tr>
<tr>
<td>Efficacy, overall</td>
<td>94.1% (CI: _____)</td>
<td>95.0% (CI: 90.0, 97.9%) after 2 doses</td>
</tr>
<tr>
<td>Efficacy, stratified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56+ y/o:</td>
<td>93.7%</td>
<td></td>
</tr>
<tr>
<td>16 to 55:</td>
<td>95.6%</td>
<td></td>
</tr>
<tr>
<td>Secondary analyses</td>
<td>Severe disease: 1 vs 9 cases</td>
<td>After Dose 1: 41 vs 103 cases</td>
</tr>
<tr>
<td></td>
<td>All volunteers: 50 vs 275 cases</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td>16-17 y/o: 153 volunteers</td>
<td></td>
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9 Dec 20

[https://www.fda.gov/advisory-committees/advisory-committee-calendar](https://www.fda.gov/advisory-committees/advisory-committee-calendar) (Dec 10th & 17th)
# SARS-CoV-2 Vaccine Candidates

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## Safety

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<th></th>
<th>Most AEs mild or moderate.</th>
<th>Common AEs: injection-site reactions (84%), fatigue (63%), headache (55%), muscle pain (38%), chills (32%), joint pain (24%), fever (14%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3:</td>
<td>Fatigue 9.7%, muscle ache 8.9%, joint pain 5.2%, headache 4.5%, pain 4.1%</td>
<td>Serious AEs: 0.0% to 4.6%. Post-Dose 2 more than Dose 1. Less if 56+ (≤ 2.8%) vs &lt;=55 (≤4.6%). No meaningful imbalances between study arms.</td>
</tr>
</tbody>
</table>

## Deaths

For discussion

<table>
<thead>
<tr>
<th></th>
<th>2 vaccine vs 4 control arm</th>
<th>Bell’s palsy: 4 vs 0</th>
</tr>
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Product Quality:

Chemistry-manufacturing-control (CMC) data

Adequate information to ensure quality and consistency

[https://www.fda.gov/advisory-committees/advisory-committee-calendar](https://www.fda.gov/advisory-committees/advisory-committee-calendar) (Dec 10th & 17th)
Listen to Your Patients. Help Teach Them.

How do we know if these vaccines are safe?

• ... large studies, > 30,000 volunteers, various ages—races—ethnicities—underlying diseases ...
• ... this is about same # of volunteers as in studies of Shingrix® ...
• ... no safety steps were skipped ... thorough review by career scientists at FDA ...

I heard COVID-19 vaccines cause a lot of side effects.

• ... the most common side effects are ___ ... About 1 in 10 or 20 people develop ___ ...
• ... most people do not have serious problems after being vaccinated ...
• ... your arm may be sore, red, warm to the touch ... symptoms usually last a few days ...
• ... these reactions are a sign your immune system is doing what it is supposed to do ...

Nobody knows whether these vaccines have long-term side effects.

• ... it does take time to accumulate a lot of safety experience ...
• ... common side effects are pretty well understood ...
• ... FDA and CDC use multiple programs to monitor safety ... independent experts review these data ...

www.cdc.gov/vaccines/covid-19/index.html
Listen to Your Patients. Help Teach Them.

mRNA is brand new stuff – never used in a vaccine before – too risky – messes with your DNA (genes).

- ... your cells use mRNA every day to make all kinds of proteins that enable you to live ...
- ... mRNA technology has been studied for more than a decade ... rigorous clinical trials ...
- ... mRNA vaccines cannot cause COVID-19 ...
- ... mRNA vaccines do not enter the cell nucleus – cannot change your DNA (genes) ...

Wouldn’t surviving COVID give you better, more natural immunity?

- ... COVID-19 is a lethal disease caused by a lethal virus ...
- ... you could infect others ...
- ... getting vaccinated is a safer choice ... vaccines tap a body’s natural abilities ...

www.cdc.gov/vaccines/covid-19/index.html
COVID-19 AND YOU

Information to help you make decisions about your health and what you can do to join the fight against COVID-19.

INTRODUCTION

Every day, we learn more about the coronavirus that causes COVID-19.

https://combatcovid.hhs.gov/
Find answers to your questions about COVID-19 vaccines.

Top Questions

- What is a vaccine?
- How are vaccines developed?
- How will we know a Covid-19 vaccine is safe and effective?

https://www.covidvaccinefacts.org/
COVID-19 Vaccination Program: Interim Playbook for Jurisdiction Operations

Open Forum Discussion: A Minute for Your Thoughts
Comments, Questions, Feedback
Review of APhA’s Resources and What’s Coming
Exclusive Member Benefit: APhA breaks down the latest, most important Legislative & Regulatory Updates for pharmacists in yesterday’s email newsletter!

Check your inbox!
HHS Amends PREP Act

What was modified/clarified?
- Pharmacist Training Requirement
- CPR Requirement (Pharmacists, pharmacy interns, and pharmacy technicians)

**UPDATED:** View the full list of requirements as amended.

COVID-19 Vaccine Resources:

• Vaccine Hesitancy

• Frequently Asked Questions About COVID-19 Vaccines

• Reimbursement for Administration of COVID-19 Vaccine(s) – What We Know

Check out the library of [practice resources here](#)
Weekly Open Forum Webinars

Join Us!

Thursday, December 17, 1pm ET

Today’s webinar recording and slides will be available within 24hrs

https://www.pharmacist.com/coronavirus/weekly-webinars
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How to Claim CE Credit

*CE is only available to those who attended the live webinar

1. After the webinar ends, return to the “My Training” page on pharmacist.com (http://elearning.pharmacist.com/my-training)
2. Log in using your pharmacist.com username and password
3. Click on the “Breaking News: COVID-19 Vaccines – Part 2” session listed in your enrollments
4. Click on “Breaking News: COVID-19 Vaccines – Part 2” under the “Activities” heading
5. Enter the attendance code
6. Complete the evaluation
7. Claim credit