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

December 17, 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.
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
Michael Baxter
Senior Director, Regulatory Policy
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
Format for Today’s Webinar

1:00 pm: Introductions

1:05 pm: Interview with John Grabenstein, Steve Foster, and Mitch Rothholz

1:25 pm: Open Forum: A Minute for Your Thoughts

2:20 pm: Wrap Up: Review of APhA’s Ongoing Activities and What’s Coming
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 John Grabenstein, Steve Foster, and Mitch Rothholz

Discuss breaking information about COVID-19 vaccines.
Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine (ACIP, 12 Dec 20)

- mRNA vaccines are not live vaccines

**Dosing:**
- Dose 2: Days 17-21 considered valid.
- Dose 2: If delayed, give ASAP, do not restart series

- Other vaccines: Separate by 14 days (for AE attribution) until additional data gathered

- If two different mRNAs given inadvertently (take efforts to avoid this), give no further doses

- COVID mAbs: Defer vaccination > 90 d to avoid interference

https://www.pharmacist.com/sites/default/files/audience/APhACOVIDPfizerAtAGlance_121620_web.pdf
Clinical Considerations

COVID-19 Status:
• Prior COVID-19: Offer vaccine
• Current COVID-19 infection: Postpone vaccination until recover from acute illness. No minimum interval.
• Pretesting before vaccination: None recommended

Persons with Known COVID-19 Exposure:
• Defer vaccination during quarantine period, to avoid exposing HCPs during vaccination visit
• Residents of LTCFs: May be vaccinated, unlikely to result in additional exposures.
• Residents of correctional facilities, homeless shelters: May be vaccinated to avoid missed opportunities.

SARS-CoV-2 Tests:
• Vaccination does not affect tests nucleic acid amplification or antigen tests
• A positive test for spike protein IgM/IgG could indicate either prior infection or vaccination.
• To evaluate infection in a vaccinee, use a test evaluating IgM/IgG to nucleocapsid protein
Clinical Considerations

Special Populations:

• Underlying medical conditions: Vaccinate if no contraindication

• Immunocompromised persons: Risk of COVID-19 elevated.
  • HIV-infected people included in clinical trials.
  • No data on other groups. May be vaccinated unless contraindicated. Prevaccination counseling warranted.
  • Considerations for COVID-19 Vaccination in Immunocompromised Patients

• Pregnant women: Risk of COVID-19 elevated.
  • No data on vaccine safety. mRNAs degraded quickly, do not enter cell nucleus.
  • Pregnant women may choose to be vaccinated. Fever associated with adverse pregnancy outcomes, so acetaminophen warranted.

• Breastfeeding: No data on vaccine safety. mRNA not considered a risk to infant. Lactating women may choose to be vaccinated.

• Considerations for COVID-19 Vaccination During Pregnancy and Lactation
Clinical Considerations

**Contraindications and Precautions:**

- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.
- Reports of anaphylactoid reactions: __________
# SARS-CoV-2 Vaccine Candidates

<table>
<thead>
<tr>
<th>Vaccine Sponsors</th>
<th>ModernaTX USA</th>
<th>BioNTech with Pfizer</th>
</tr>
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<tbody>
<tr>
<td>Product Designator</td>
<td>mRNA-1273</td>
<td>BNT162b2, tozinameran</td>
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<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>30,351</td>
<td>40,277</td>
</tr>
<tr>
<td>Efficacy, overall</td>
<td>94.1% (CI: 89.3, 96.8%), starting 14 d after Dose 2</td>
<td>95.0% (CI: 90.0, 97.9%), starting 7 d after Dose 2</td>
</tr>
<tr>
<td>Efficacy, stratified</td>
<td>65+ y/o: 86.4% (61.4, 95.5%), 18 to 64: 95.6% (90.6, 97.9%)</td>
<td>56+ y/o: 93.7% (80.6, 98.8%), 16 to 55: 95.6% (89.4, 98.6%)</td>
</tr>
<tr>
<td>Secondary analyses (vaccinated vs control arms)</td>
<td>Severe disease: 100% (CI not described), Between Doses 1-2: 80% (55, 92%), No conclusion on prior infection</td>
<td>Severe disease: 89% (20%, 99%), Between Doses 1-2: 52% (30%, 68%), No effect among those w/prior infection</td>
</tr>
<tr>
<td>Notes</td>
<td>Adequate information to ensure product quality and consistency</td>
<td>16-17 y/o: 283 for safety</td>
</tr>
<tr>
<td>Chemistry-manufacturing-control (CMC) data</td>
<td>Adequate information to ensure product quality and consistency</td>
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*Source: FDA Briefing (Dec 17)*
*Source: FDA EUA Fact Sheet*
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<tr>
<td>Common: inj-site pain (92%), fatigue (69%), headache (63%), muscle pain (60%), joint pain (45%), chills (43%)</td>
<td>Common: inj-site rxns (84%), fatigue (63%), headache (55%), muscle pain (38%), chills (32%), joint pain (24%), fever (14%)</td>
<td></td>
</tr>
<tr>
<td>Grade 3 Events</td>
<td>Fatigue 9.7%, muscle ache 8.9%, joint pain 5.2%, headache 4.5%, pain 4.1%</td>
<td>Fatigue 3.8%, headache 2.0%</td>
</tr>
<tr>
<td>Serious Adverse Events (AEs)</td>
<td>Severe AEs: 0.2% to 9.7%. More frequent after Dose 2 than Dose 1. Fewer SAEs if 65+ y/o No meaningful imbalances</td>
<td>Serious AEs: 0.0% to 4.6%. More frequent after Dose 2 than Dose 1. Fewer SAEs if 56+ (≤2.8%) vs ≤55 (≤4.6%). No meaningful imbalances</td>
</tr>
<tr>
<td>Deaths</td>
<td>6 vaccine arm vs 7 control arm</td>
<td>2 vaccine vs 4 control arm</td>
</tr>
<tr>
<td>For discussion</td>
<td>Bell’s palsy: 3 vs 1, 22-32 d post vax Hypersensitivity: 1.5% vaccine, 1.1% control, none severe</td>
<td>Bell’s palsy: 4 vs 0, not clustered in time Anaphylactoid reactions from UK</td>
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Sources:
- FDA Briefing (Dec 17)
- FDA EUA Fact Sheet
Discussion with John Grabenstein, Steve Foster, and Mitch Rothholz

Discuss breaking information about COVID-19 vaccines.
CDC smart-phone based monitoring program for COVID-19 vaccine safety

For patients and caregivers

Uses text messaging and web surveys to check-in with vaccine recipients after 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

Hear from Tanya Myers, PhD, MSc, the v-safe team lead for the CDC, as she provides a brief overview of VAERS & V-safe. (Video - Slides)
Polling Question

Have you received the COVID-19 vaccine?

A. Yes
B. No
Polling Question

Have you given a COVID-19 vaccine?

A. Yes
B. No
Open Forum Discussion: A Minute for Your Thoughts

Comments, Questions, Feedback
Review of APhA’s Ongoing Activities and What’s Coming
What Does this Mean?

“First, it brings transparency to the business practices of PBMs and holds them more accountable for their actions. Second, it sets a clear blueprint for states to follow as they pursue oversight and regulation of PBMs. If states follow, pharmacy wins across the country, not just in Arkansas.

Third, it’s a ray of hope for community pharmacies, which have long been struggling to remain viable while PBMs did their damage almost wholly unchecked.”

–APhA CEO Scott Knoer
Looking to 2021

The fight against COVID-19 has demanded the federal government take action to allow pharmacists and other health care professionals to do more of what they are trained to do.

The problem is many of these flexibilities and authorities are not considered permanent (temporary) and further action is needed to expand access to pharmacist provided services.

Visit Understanding Policy Priorities and Advocacy Opportunities During COVID-19 at: https://www.pharmacist.com/coronavirus/advocacy-opportunities?

"Agencies have likewise been called on to assess the various temporary deregulatory actions they have taken to fight COVID-19 and its impact on our economy to determine which temporary regulatory actions should be made permanent."

COVID-19 Advocacy Wins:

- Testing
- Immunizations
- Removal of Operational Barriers
- Compounding/Track and Trace
- Telehealth
Locked on Pharmacy: Pfizer-BioNTech Vaccine: What Pharmacists Need to Know | Locked on Pharmacy

https://www.pharmacist.com/locked-pharmacy-podcast
Immunizations During COVID-19

Featured Updates

**Authority to Immunize Resource**
The most important thing you can do right now is review the requirements and ensure you meet the requirements.

**APhA Immunization Education Library**
A collection of CE to help pharmacists meet requirements under the new authorities to provide immunizations.

**CDC: Preparing for COVID-19 Vaccination**
Find training and educational materials for healthcare professionals, links to state vaccination plans, vaccine storage and handling information and more.

**COVID-19 Vaccines**

*APhA Know the Facts: Key Points About COVID-19 Vaccines (December 11)*
This resource summarizes key information to help pharmacists and their team address common questions. Hang up this handout in the pharmacy or give it to patients! (PDF)

*APhA Know the Facts: COVID-19 Vaccine Development and Approval (December 11)*
This resource outlines how the COVID-19 vaccines have been developed and approved at unprecedented speeds without compromising safety. (PDF)

Hear from CDC representatives about the latest information about how to prepare for COVID-19 vaccination and vaccine safety monitoring. (Video - Slides)

*APhA Weekly Open Forum Webinar (Excerpt): Monitoring COVID-19 Vaccine Safety: VAERS and V-SAFE (December 19)*
Hear from Tanya Myers, PhD, MSc, the v-safe team lead for the CDC, as she provides a brief overview of two vaccine safety monitoring platforms pharmacists should be aware of. (Video - Slides)

*APhA Know the Facts: Frequently Asked Questions About COVID-19 Vaccines (December 9)*
This FAQ guide compares dosing, efficacy, and safety data for the Pfizer/BioNTech and Moderna COVID-19 vaccine candidates and answers questions about immunity. (PDF)

https://www.pharmacist.com/coronavirus/immunizations
NEW COVID-19 Vaccine Resources:

- Key Points About COVID-19 Vaccines
- COVID-19 Vaccine Development and Approval

Check out the library of practice resources here
COVID-19 Education Opportunities – CE Available

New Free 1 hr CE Program:
Pfizer/BioNTech COVID-19 Vaccine Overview

• A comprehensive overview of the information that pharmacists need about the Pfizer/BioNTech COVID-19 vaccine
  • Mechanism of action
  • Review of efficacy & safety data
  • Storage
  • Handling
  • Dose preparation/administration
  • EUA Authorization requirements for vaccine providers
  • Tips to address vaccine hesitancy

• More info & Registration available here
  • https://elearning.pharmacist.com/products/5993/pfizer-biontech-covid-19-vaccine-bnt162b2?sectionId=3cde3e7b-3de6-42a5-a542-8ebeb50fd43e
Post on **ENGAGE**

*Pharmacy’s Response to COVID-19*

**POST** your questions

**SHARE** your lessons learned

**SUPPORT** your colleagues

**ACCESS** the latest information

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What are you doing to prepare your practice for the COVID-19 vaccines?

What barriers do you anticipate or face currently?
Join Us In 2021!

Thursday, January 7, 1pm ET

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

https://www.pharmacist.com/coronavirus/weekly-webinars