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

February 11, 2021
Michael D. Hogue, PharmD, FAPhA, FNAP
Dean and Professor
Loma Linda University School of Pharmacy
President, APhA

Host and Moderator
Today’s Focus:

Discuss the latest updates on COVID-19 vaccines, including clinical considerations for special populations and emerging processes for vaccine approval, allocation, and distribution.
Daniel Zlott, PharmD, BCOP
Senior Vice President
Education and Business Development
American Pharmacists Association

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

Executive Director
American Pharmacists Association
Foundation

Speaker
Claire Hannan, MPH
Executive Director
Association of Immunization Managers

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

Subject Matter Expert: Q&A
Disclosures

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 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#: 0202-0000-21-126-L06-P
Activity Type: Knowledge-based
Learning Objectives

1. Discuss the latest updates on the various COVID-19 vaccines.
2. Discuss clinical considerations for COVID-19 vaccinations for special populations.
What type of vaccine is the Johnson & Johnson COVID-19 vaccine?

a. mRNA vaccine
b. Protein-based vaccine
c. Inactivated vaccine
d. Viral vector vaccine
Immunocompromised persons should be counseled on which of the following?

a. COVID-19 vaccines are not recommended due to increased safety risks.

b. Revaccination is necessary after immune competence is regained.

c. Due to the potential for reduced immune response, all current guidance for protection from COVID-19 should be followed closely.

d. Antibody testing is needed after vaccination to ensure a proper immune response occurred.
Which of the following is true regarding the initial activation of the Federal Retail Pharmacy Program as of February 11, 2021?

a. Select pharmacies will be allocated vaccine supplies directly from the federal government.

b. Pharmacies will be contacted by the government to become enrolled in the program.

c. All pharmacies will be allocated vaccine supplies directly from the federal government.

d. Pharmacies participating in the federal program can only receive vaccine supplies directly from the federal government.
Format for Today’s Webinar

1:00 pm: Introductions
1:05 pm: Interview with Dan Zlott and Mitch Rothholz
1:20 pm: Interview with Claire Hannan
1:30 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.

• We will try to get to as many comments and questions as possible!

• Refer to the Handout in the GoToWebinar toolbar to access today’s slides.
Discussion with Mitch Rothholz and Dan Zlott

Discuss breaking news, clinical considerations for special populations and emerging processes for approval, allocation, and distribution.
COVID-19 Variants

To understand potential impact of variants, we need to understand how antibodies work

- **Antibodies have 2 main parts**:¹
  - **Variable domain (Fv)**
    - This is the portion of the antibody which binds to antigens
  - **Constant domain (Fc)**
    - This portion of the antibody provides the structural backbone, and may serve as a signal for other components of the immune system

---

COVID-19 Variants

This portion of the key determines whether or not the key unlocks the lock.

This portion of the key determines whether or not the key will fit into the lock.
COVID-19 Variants

Variant: B.1.1.7: Identified in the UK – Spreads more quickly and easily than other variants.
• Multiple mutations, including some which affect spike protein receptor binding domain and potentially change the conformation of the spike protein

Variant: B.1.351: Identified in South Africa – Shares many mutations with the B.1.1.7 variant.
• Multiple mutations, including some which affect spike protein receptor binding domain
• Predominant variant in South Africa (95% of cases, according to J&J trial)²

Variant P.1: Identified in travelers from Brazil
• Contains multiple mutations, including some which may affect the ability of antibodies to recognize the variant

Johnson & Johnson Vaccine Update

• Still waiting for FDA summary of data to be released
• J&J Vaccine Platform is a genetically modified, replication incompetent adenovirus vector that codes for the SARS-CoV-2 spike protein\(^1\)
• Single dose
• According to Johnson & Johnson Press Release\(^2\):
  • \(n = 43,783\)
  • 66% effective at preventing moderate to severe COVID-19 disease 28 days after vaccination (72% effective in the U.S.)
  • 85% effective at preventing severe disease
  • 100% effective at preventing COVID-19 related hospitalization and death
  • Demonstrated efficacy against the B.1.351 COVID-19 variant

---

Currently, there are no data available examining how taking NSAIDs prior to receiving a COVID-19 vaccine might affect the efficacy of the vaccine.

Why is this being raised as a concern?

• Systematic review looking at the effect of prophylactic antipyretics on pediatric immunizations demonstrated decreased antibody levels in pts who took NSAIDs\(^1\)
  • Even though antibody levels were lower, pts still achieved a sufficient level of antibodies to provide protection against infection

• Mouse model of COVID-19 demonstrated that NSAIDs might blunt the antibody response to COVID-19 infection\(^2\)
  • Humans aren’t mice
  • The immune response to the SARS-CoV-2 virus and the COVID-19 vaccine are different. It is not appropriate to conclude that NSAIDs would have the same impact on antibody levels from vaccine without additional study
  • As noted above, decreased antibody levels don’t always result in loss of protection against infection


Special Populations

- **HIV Patients**: Patients with controlled HIV were included in the Pfizer, Moderna, and J&J trials\(^1\-^3\), and should receive the vaccine when available.

- **Patients receiving chemotherapy**: Patients were excluded from clinical trials, so no data is available.
  - Patients may not mount an immune response, however, current recommendations are that patients receiving chemotherapy should receive the vaccine when available.
  - General practice is to avoid live vaccines in this patient population (if/when live COVID-19 vaccines become available).

Special Populations

• Patients receiving immunosuppressant therapies: Patients were excluded from clinical trials, so no data is available\(^1,2\)
  • Patients may not mount an immune response, however, current recommendations are that patients receiving immunosuppressive therapies should receive the vaccine when available
  • General practice is to avoid live vaccines in this patient population (if/when live COVID-19 vaccines become available)

• Pregnant & Breastfeeding women: Pregnant and breastfeeding women were excluded from clinical trials, however, there were a small number of pregnancies which occurred during clinical trials\(^1,2\)
  • Although data is very limited, available data suggest that it is safe for pregnant and breastfeeding women to receive mRNA-based COVID-19 vaccines
  • General practice is to avoid live vaccines in this patient population (if/when live COVID-19 vaccines become available)

Immunocompromised Individuals

• Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19.

• Data are not currently available to establish vaccine safety and efficacy in these groups.

• Immunocompromised individuals can receive COVID-19 vaccination if they have no contraindications to vaccination.
  • counsel about the unknown vaccine safety profile and effectiveness in immunocompromised populations, and the potential for reduced immune responses
    - need to continue to follow all current guidance to protect themselves against COVID-19
    - antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination.

• At this time, re-vaccination is not recommended after immune competence is regained
  • Patients still need to complete the 2-dose series recommended for all individuals

• Recommendations on re-vaccination or additional doses of mRNA COVID-19 vaccines may be updated when additional information is available.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
Pregnant Patients

• Pregnant people with COVID-19 have an increased risk of severe illness.

• Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus because mRNA vaccines are not live vaccines.

• Pregnant patients may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine - conversation with a healthcare provider is not required prior to vaccination.
  • consider the level of COVID-19 community transmission
  • patient’s personal risk of contracting COVID-19,
  • risks of COVID-19 to the patient and potential risks to the fetus,
  • efficacy of the vaccine
  • side effects of the vaccine, and
  • lack of data about the vaccine during pregnancy.

• If experience fever or other symptoms following vaccination can take acetaminophen because fever has been associated with adverse pregnancy outcomes.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
Discussion with Claire Hannan

Discuss breaking news, clinical considerations for special populations and emerging processes for approval, allocation, and distribution.
Plans, Progress and Challenges

- Efficiency has improved
- FEMA support available for states/jurisdictions
- Productions/allocations increasing – outlook not crystal clear
- States still struggling to manage demand; communication improving
- Focus on efficiency creating concern for equity
- Federal retail pharmacy program beginning (week of 2/8/2021)
- FQHCs/CHCs receiving federally-allocated vaccine (week of 2/15/2021)
- Supply is limiting factor right now
Race and Ethnicity

Race/Ethnicity of People with 1 or More Doses Administered:

Data from 33,783,384 people with 1 or more doses administered. Race/Ethnicity was available for 18,398,606 (54.4%) people with 1 or more doses administered.

Race/Ethnicity of People with 2 Doses Administered:

Data from 10,469,514 people with 2 doses administered. Race/Ethnicity was available for 5,458,719 (52.1%) people with 2 doses administered.
Federal Retail Pharmacy Program

• Federal govt partnership with 21 national pharmacy chains
• Pharmacies enroll at federal level, not state, and receive allocation separate from states
• Will begin this week, 1 million doses per week initially
• States chose pharmacy chains initially, but not specific locations
• Will take some time work through collaboration at state and local level, but goal is to have in place to be ready for supply ramp up
• As supply increases, all 21 federal pharmacy partners will receive vaccine

https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/participating-pharmacies.html
"Have you held discussions with the retail pharmacy chains who will be distributing vaccine in your jurisdiction?" (n=12)
AIM Situational Awareness Survey (2/5/2021) – Preliminary Results

"On a scale of 1-5, how do you rate your satisfaction regarding the partnership and collaboration with the pharmacy chains of the Federal Retail Pharmacy Partnership?" (n=13)
Second Dose Supply/Ordering

• Federal government will add second dose allocation for pharmacy partners 2-3 weeks after first doses are allocated.
• Pharmacy partners are encouraged to utilize reminder systems to reach out to individuals to return for second doses.
• Pharmacists should encourage enrollment into V-SAFE, VaxText, or the after-vaccination health checker.
  ▪ Will remind individual of when to return for second dose.
Looking Ahead....

• Pfizer – 100 million doses by end of March, another 100 million by end of July
• Moderna – 100 million doses by end of March, another 100 million by end of July
• Janssen/Johnson & Johnson– 100 million doses by end of June
What’s working? Best Practices from Jurisdictions

- **New Mexico**: NMDOH Pre-Registration System
  - Provides NMDOH visibility into vaccination demand, priority groups/occupations, and locations to best hold vaccination clinics

- **West Virginia**: Vaccinate long-term care facility (LTCF) residents and staff by partnering with rural, independent pharmacies and pharmacy chains
  - Distributed vaccine allocation to LTCFs immediately
  - Incredible collaborative approach with state public health, WV National Guard, and other associations
  - On January 29, 2021, WV announced that it’s the first state to complete vaccinations at all nursing homes, assisted living facilities

- **North Dakota**: Clear and transparent communication between state/local health departments and vaccine providers

- **Vermont**: Partner with vendors and large provider groups to assist with large-scale vaccination
Open Forum Discussion:
A Minute for Your Thoughts
Comments, Questions, Feedback
Review of APhA’s Ongoing Activities and What’s Coming
“American Rescue Plan” Highlights

• Vaccines and Therapeutics ($8.5 Billion-New Funding)
  • $7.5 billion for CDC to prepare, promote, administer, monitor, and track COVID-19 vaccines
  • $1 billion for CDC to strengthen vaccine confidence, further information and education with respect to authorized or licensed vaccines, and improve vaccination rates

• Testing ($46 Billion-New Funding)
  • For HHS to detect, diagnose, trace, and monitor COVID-19 infections, and for other activities necessary to mitigate the spread of COVID-19
  • National strategy for testing, contact tracing, surveillance, mitigation of COVID-19; and developing, manufacturing, procuring, distributing, and administering tests, personal protective equipment (PPE), etc.

• Public Health Workforce ($7.6 Billion-New Funding)
  • For HHS to make awards to State, local and public health departments
NEW RESOURCE:
• Reimbursement for Administration of COVID-19 Vaccine(s) – What We Know

Check out the library of practice resources here
Maximize the Doses in Each Vial

15 on 19: Understanding Dead Space
0.25 hrs CPE

• A quick, but in depth, review of the concept of dead space & why it matters
• Tips on techniques to get as many doses out of each vial of COVID-19 vaccine as possible
COVID-19 Education Opportunities – CE Available

Moderna Vaccine Overview
1 hr CPE

- Review everything that you need to know for the Moderna vaccine
- Mechanism of action
- Safety info
- Updated storage and handling recommendations
- Tips on overcoming vaccine hesitancy
APhA2021 Virtual
March 12-15, 2021

Scheduled COVID-19 Programs

• Ingredients of a Successful Vaccination Program
• Colleagues in Research: Pharmacy Practice & Research Implications of COVID-19
• Pharmacists as First Responders: Clarifying COVID-19 Testing Facts
• APRS Keynote: Healthy Coping During COVID-19: Why Self-Care is Vital for Healthcare Professionals
• The Psychological Toll of COVID-19 and Systemic Racism: Trauma Care for Patients
• The Psychological Toll of COVID-19 and Systemic Racism: Who Is Caring for the Pharmacists?
• Paid In Full: How to Get Reimbursed for Vaccines
• Pharmacists Out Front: Examining the Middle East COVID-19 Response

Register by February 28 for early bird rates.
https://apha2021.pharmacist.com/
Post on **ENGAGE**

*Pharmacy’s Response to COVID-19*

**POST** your questions

**SHARE** your lessons learned

**SUPPORT** your colleagues

**ACCESS** the latest information

Tell us how your pharmacy setting has been prioritizing who receives COVID-19 vaccines!

What sources do you rely on for updates on the various COVID-19 vaccines?
Weekly Open Forum Webinars

Join Us!

Thursday, February 25, 1-2pm ET

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

https://www.pharmacist.com/coronavirus/weekly-webinars
What type of vaccine is the Johnson & Johnson COVID-19 vaccine?

a. mRNA vaccine  
b. Protein-based vaccine  
c. Inactivated vaccine  
d. Viral vector vaccine
a. COVID-19 vaccines are not recommended due to increased safety risks.
b. Revaccination is necessary after immune competence is regained.
c. Due to the potential for reduced immune response, all current guidance for protection from COVID-19 should be followed closely.
d. Antibody testing is needed after vaccination to ensure a proper immune response occurred.
Which of the following is true regarding the initial activation of the Federal Retail Pharmacy Program as of February 11, 2021?

a. Select pharmacies will be allocated vaccine supplies directly from the federal government.
b. Pharmacies will be contacted by the government to become enrolled in the program.
c. All pharmacies will be allocated vaccine supplies directly from the federal government.
d. Pharmacies participating in the federal program can only receive vaccine supplies directly from the federal government.
How to Claim CE
(Only available live)

• Be prepared to record the code when it appears
• To Claim CPE Credit:
  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 “COVID-19 Vaccines Update” session listed in your enrollments
  4. Click on “COVID-19 Vaccine Update” under the “Activities” heading
  5. Enter the attendance code
  6. Complete the evaluation
  7. Claim credit
February 2, 2021
President Biden Announces
• Increased Vaccine Supply
• Initial Launch of the Federal Retail Pharmacy Program
• Expansion of FEMA Reimbursement to States

List of Federal Pharmacy Partners

<table>
<thead>
<tr>
<th>Chain Partners</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walgreens (incl. Duane Reade)</td>
<td>Topco Associates, LLC (incl. Acme Fresh Markets, Associated Food Stores, Big-Y Pharmacy and Wellness Center, Brookshire’s Pharmacy, Super One Pharmacy, FRESH by Brookshire’s Pharmacy, Cobom’s Pharmacy, Cash Wise Pharmacy, MarketPlace Pharmacy, Giant Eagle, Hartig Drug Company, King Kullen, Food City Pharmacy, Ingles Pharmacy, Raley’s, Bel Air, Nob Hill Pharmacies, Save Mart Pharmacies, Lucky Pharmacies, SpartanNash, Price Chopper, Market 32, Tops Friendly Markets, ShopRite, Wegmans, Weis Markets, Inc.)</td>
</tr>
<tr>
<td>CVS Pharmacy, Inc. (incl. Long’s)</td>
<td>CPESN USA, LLC</td>
</tr>
<tr>
<td>Walmart, Inc. (incl. Sam’s Club)</td>
<td>Good Neighbor Pharmacy and AmerisourceBergen Drug Corporation’s pharmacy services administrative organization (PSAO), Elevate Provider</td>
</tr>
<tr>
<td>Rite Aid Corp.</td>
<td>Health Mart Systems, Inc.</td>
</tr>
<tr>
<td>Kroger Co. (incl. Kroger, Harris Teeter, Fred Meyer, Fry’s, Ralphs, King Soopers, Smiths, City Market, Dillons, Marianos, Pick-n-Save, Copps, Metro Market)</td>
<td>LeaderNet and Medicine Shoppe, Cardinal Health’s PSAOs</td>
</tr>
<tr>
<td>Publix Super Markets, Inc.</td>
<td>Managed Health Care Associates** (long-term care and retail)</td>
</tr>
<tr>
<td>Costco Wholesale Corp.</td>
<td>GeriMed** (long-term care and retail)</td>
</tr>
<tr>
<td>Hy-Vee, Inc.</td>
<td></td>
</tr>
<tr>
<td>Meijer Inc.</td>
<td></td>
</tr>
<tr>
<td>H-E-B, LP</td>
<td></td>
</tr>
<tr>
<td>Retail Business Services, LLC (incl. Food Lion, Giant Food, The Giant Company, Hannaford Bros Co, Stop &amp; Shop)</td>
<td></td>
</tr>
<tr>
<td>Winn-Dixie Stores Inc. (incl. Winn-Dixie, Harveys, Fresco Y Mas)</td>
<td></td>
</tr>
</tbody>
</table>

*Pharmacy networks represent independent pharmacies and smaller regional chains
**Long-term care pharmacy partners will be added as supply allows once the program launches
What have we accomplished so far?

• According to CDC COVID Data Tracker, as on February 10, 2021:
  ◦ 44.7 million COVID-19 vaccine doses have been administered
  ◦ 10.4 million people have completed their COVID-19 vaccination series

• Infrastructure in place to carry out COVID-19 vaccination campaign
  ◦ Enrolled tens of thousands of private providers/pharmacies as vaccine administrators
  ◦ Educated and trained private providers to communicate about and administer COVID-19 vaccine
  ◦ Connected 64 data systems to federal “cloud”

• Vaccine safety monitoring, flexibility, lessons learned

Overall US COVID-19 Vaccine Delivery and Administration; Maps, charts, and data provided by the CDC, updated daily by 8 pm ET†

<table>
<thead>
<tr>
<th>Total Doses Delivered</th>
<th>Total Doses Administered</th>
<th>Number of People Receiving 1 or More Doses</th>
<th>Number of People Receiving 2 Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>65,972,575</td>
<td>44,769,970</td>
<td>33,783,384</td>
<td>10,469,514</td>
</tr>
</tbody>
</table>
Plans, Progress and Challenges

- **Phase 1A: Healthcare Workers and LTCF**
  - Plan: Ship vaccine to hospitals; vaccinate healthcare workers where they work
  - Plan: Federal Partnership with CVS/Walgreens; “strike team” approach to vaccinate residents and staff in LTCF; set aside of doses from state allocations
  - Lessons learned:
    - Prioritization is not efficient
    - Hospitals are spread thin: throughput and data reporting challenging
Plans, Progress and Challenges

- **Phase 1B: Essential Workers and Persons Age 75 and Older**
  - Plan: Ship vaccine to wide array of providers; use scheduling software to manage demand; expand providers as supply ramps up
  - Adjustments in reaction to Phase 1A lessons learned:
    - Prioritization is not efficient = Open up to larger populations
    - Hospitals are spread thin: throughput and data reporting challenging = more large-scale clinics, increased throughput, centralized inventory management
    - LTCF: Local, independent pharmacies partnered to vaccinate some LTCFs in partnership with states.
Jurisdiction Activities

- Ohio-
- “Governor DeWine announced that Ohio's maintenance COVID-19 vaccine program plan to ensure residents and staff within nursing homes and assisted living facilities have continuing access to the life-saving vaccine is nearly complete. The plan will outline how nursing homes and assisted living facilities will move forward to vaccinate new residents, new workers, and workers who initially declined the vaccine but are now willing to be vaccinated. The plan will leverage existing relationships between nursing homes, assisted living facilities, and the pharmacies that regularly provide them with prescription drugs.”
What’s working? Best Practices from Jurisdictions

• Collaboration
  • at state and local level: one vision, one goal
  • Vaccine shipments are for community, not inventory

• Communication

• Data