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

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*Host and Moderator*
Today’s Focus:

Discuss the “then and now” of COVID-19 and ongoing opportunities and challenges for pharmacists’ on the frontlines.
Daniel Zlott, PharmD, BCOP
Senior Vice President
Education and Business Development
American Pharmacists Association

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

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

Executive Director
American Pharmacists Association
Foundation

Speaker
Anne Burns, RPh
Vice President, Professional Affairs
American Pharmacists Association

Subject Matter Expert: Q&A
Subject Matter Expert: Q&A
Format for Today’s Webinar

1:00 pm: Introductions
1:05 pm: Epidemiology & Treatment
1:15 pm: Advocacy & Patient Care Service Developments
1:25 pm: Well-being
1:30 pm: Open Forum Q&A
1:55 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 Dan Zlott

Discuss the “then and now” of COVID-19 epidemiology and treatment.
COVID-19 Epidemiology – Cumulative Cases

Image source: Johns Hopkins Coronavirus Resource Center. Cumulative Cases by Date

COVID-19 Epidemiology – Cumulative Deaths

Image source: Johns Hopkins Coronavirus Resource Center. Cumulative Cases by Date¹

COVID-19 Epidemiology – Cases/100K Population

Image source: Johns Hopkins Coronavirus Resource Center. Cumulative Cases by Date¹

COVID-19 Epidemiology – Deaths/100K Population

Image source: Johns Hopkins Coronavirus Resource Center. Cumulative Cases by Date

COVID-19 Epidemiology – Daily New Cases

COVID-19 Therapies: Remdesivir

The Adaptive COVID-19 Treatment Trial (ACTT-1) was a multicenter, multinational, randomized, double blind, placebo-controlled trial\(^1\)

- **60 trial sites**
  - US, Denmark, UK, Greece, Germany, Korea, Mexico, Spain, Japan, Singapore

Enrollment began 2/21/20 and ended 4/19/20

Data based on interim analysis conducted 4/27/20

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COVID-19 Therapies: Remdesivir

Results

• **Time to recovery:**
  - Overall: 11 days in remdesivir arm vs 15 days in the placebo arm (p<0.001)

• **Clinical improvement (reduction of ordinal score):**
  - Odds ratio for improvement at day 15: 1.5 (95% CI: 1.18 - 1.91; p=0.001)

• **Mortality:**
  - Hazard ratio for death: 0.7 (95% CI: 0.47 – 1.04)
  - Mortality rates at day 14: 7.1% in the remdesivir arm vs 11.9% in the placebo arm

COVID-19 Therapies: Dexamethasone

• RECOVERY trial\(^1\): Randomized, controlled, open-label trial in 6425 pts (for dexamethasone arm) from 176 hospitals in the UK
  • Intervention: Dexamethasone 6mg PO/IV q day x 10 days vs standard of care (SOC)
  • 2104 pts dexamethasone arm; 4321 pts SOC arm

COVID-19 Therapies: Dexamethasone

• Results:
  
  • 28-day Mortality: 21.6% in the dexamethasone arm vs 24.6% in the SOC arm (RR: 0.83; 95%CI: 0.74 -0.92; p<0.001)
  
  • In pts who required invasive mechanical ventilation:
    ❑ 28 day mortality: Dexamethasone reduced mortality by 35% (RR: 0.65; 95%CI: 0.51 – 0.82; p<0.001)
  
  • In pts who required O2 support but not mechanical ventilation:
    ❑ 28 day mortality: Dexamethasone reduced mortality by 20% (RR: 0.8; 95%CI: 0.7-0.92; p=0.002)
  
  • No mortality benefit in pts who did not require respiratory support

COVID-19 Therapies: Dexamethasone

1. Figure 2 from: Horby, et al. Horby, et al. NEJM. 2020; DOI: https://doi.org/10.1056/NEJMoa2021436
COVID-19 Therapies: Convalescent Plasma

• Convalescent plasma Expanded Access Program (EAP):
  • Multi-center, open label, non-randomized, uncontrolled trial
  • 35,322 pts from 2,807 centers
  • Convalescent plasma donated by recently-recovered COVID-19 patients
  • Antibody levels in the plasma units unknown at the time of transfusion
  • Intervention: Transfusion of at least 1 unit of convalescent plasma

COVID-19 Therapies: Convalescent Plasma

- **Results**: 
  - Patients who were transfused within 3 days of COVID-19 diagnosis had a lower 7-day mortality rate than pts who were transfused 4 or more days after diagnosis:
    - 8.7% (95% CI: 8.3%-9.2%) vs 11.9% (95% CI: 11.4%-12.2%) \[p<0.001\]
    - Difference remained statistically significant at 30 days:
      - 21.6% vs 25.7% \(p<0.0001\)
  - Higher anti-COVID-19 IgG levels in plasma units was associated with lower 7-day mortality rates \(p=0.048\)
    - High IgG: 8.9%
    - Medium IgG: 11.6%
    - Low IgG: 13.7%
    - Dose-response relationship remained at 30 days \(p=0.021\)

Hydroxychloroquine

• On June 15\textsuperscript{th}, the FDA revoked the Emergency Use Authorization for Chloroquine and Hydroxychloroquine (HCQ) for COVID-19\textsuperscript{1}

  • The FDA cited multiple reasons for the revocation:
    - The dosing regimens proposed were unlikely to produce an antiviral effect
    - Contrary to earlier reports, HCQ has not been consistently shown to reduce viral shedding
    - Current treatment guidelines, including the NIH guidelines do not recommend the use of HCQ outside the setting of a clinical trial
    - Recent data from a large randomized controlled trial did not show a benefit to HCQ use

Hydroxychloroquine

• Data comes from the same RECOVERY trial discussed previously:
  • Randomized, controlled, open-label trial in 4674 pts (for HCQ arm) from 176 hospitals in the UK\(^1\)
    • Intervention: 2400mg HCQ day 1, followed by 800mg HCQ q day on days 2-10 vs SOC\(^2\)
    • 1542 pts HCQ arm; 3132 pts SOC arm\(^1\)
    • Pts: Hospitalized pts with clinically suspected or confirmed COVID-19\(^2\)
      ❑ Included pts <18 yo and pregnant/breastfeeding women
    • Exclusion criteria: Medical history that might put the patient at significant risk if they were to participate in the trial\(^2\)

Hydroxychloroquine

• Results:\(^1\):
  • Mortality: 25.7% in the HCQ arm vs 23.5% in the SOC arm (Hazard ratio: 1.11; 95%CI: 0.98-1.26; p=0.1)
  • No evidence that HCQ provided benefit with regard to:
    - Length of hospital stay
    - Need for mechanical ventilation

Discussion with Ilisa Bernstein

Discuss the “then and now” of COVID-19 scope of practice changes, advocacy priorities, and patient care service developments.
Testing

THEN

• Allowed in a limited number of states
• Limited tests
• Variable coverage

NOW

• Pharmacies are patient care settings for CLIA-waived tests
• All pharmacists can order and administer
• All States
• COVID, Flu, RSV
• Lack of clear billing pathway for services

But... limited to public health emergency period
Immunizations
(Childhood vaccines)

THEN

• Age and scope varies among states

NOW

• Pharmacists/interns can order and administer ACIP-recommended vaccines for children ages 3-18
  • All States
  • Certain requirements
  • No guidance yet re: COVID-19 vaccines

But... limited to public health emergency period
Compounding

THEN

• No flexibility for 503A
• Limited enforcement discretion.

NOW

• Broader use of enforcement discretion
• 503A and 503B compounding of certain medications for hospitalized patients without patient specific prescriptions, in specific situations
• FDA will not enforce 5% rule until MOU finalized

But… limited to public health emergency period
Telehealth

THEN

• Limited opportunities

NOW

• Certain flexibilities for outpatient services
• Supervision for pharmacists providing evaluation/management via telehealth using real-time audio and video
• DSMT (Diabetes self-management training) – DSMT accredited pharmacies enrolled in Medicare can deliver services via telehealth

But... limited to public health emergency period
Regulatory Collaboration

THEN

• Stakeholder outreach on case by case basis and annual listening sessions
• Snails pace

NOW

• Frequent stakeholder outreach and meetings
• Listens
• Open to new and innovative approaches
• Rapid turn around
Practice-level

THEN

• Pharmacist safety
  • PPE - severe shortages
  • Distancing issues
  • Barriers lacking

• Operational
  • Staffing
  • Refills
  • Substitution
  • Shortages
  • Inappropriate prescribing

NOW

• Pharmacist safety
  • PPE – some problems
  • Distancing measures
  • Protective barriers

• Operational
  • Staffing – more guidance
  • Refills
  • Substitution
  • Shortages - variable
  • Inappropriate prescribing
Pharmacy Community Collaboration -- NOW

Pharmacists Call for New Action to Enhance COVID-19 Patient Care

Authorize Test-Treat-Immunize
- Allow pharmacists to order, collect specimens, conduct and interpret tests and, when appropriate, initiate treatment for infectious diseases including COVID-19, flu, strep, and interpret and discuss with patients. Expand current state pharmacists immunization authority to include all FDA-approved vaccines, including the forthcoming novel vaccine for COVID-19, for all indicated populations.

Ease Operational Barriers to Address Workforce and Workflow Issues
- Allow pharmacists and pharmacy technicians with valid licenses to operate across state lines, including telehealth. Authorize pharmacists and pharmacy staff to conduct routine pharmacy tasks remotely as necessary (e.g., prescription data entry and script verification), including those licensed outside the state.

Address Shortages and Continuity of Care
- Authorize pharmacists to conduct therapeutic interchange and substitution without physician authorization when product shortages arise. The FDA should identify drugs that are in, or at risk of shortage and work with firms to extend expiration dates. Require manufacturers to provide the FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information.

Reimburse for Services by Removing Barriers
- Remove the specific-day’s supply requirement from co-pay waivers for essential, life-sustaining medications to ensure continuous access when medication in shortage or needed to be rationed. Remove restrictions and cover home or mail delivery. Assist access to testing, treatment, and pharmacists services for patients without adequate access to services.

Joint Statement: APhA, ASCP, ASHP, AACP, NASPA, ACCP, NACDS, NASP, HOPA, CPNP, NCPA, ACPE
March 20, 2020
State Efforts, Orders, Waivers.....
Discussion with Mitch Rothholz

Discuss resources available for addressing well-being.
Well Being

Assess Your Level of Stress

Well-Being index

Burnout is real. Now APhA has an online screening tool, invented by the Mayo Clinic, to evaluate fatigue, depression, burnout, anxiety/stress, and mental/physical quality of life to assess your well-being. It’s 100% anonymous and evaluates distress in just 9 questions.

Take The Wellness Survey

Beat Burnout/Build Resiliency

We’ve been with you from the start, and we’re here for you now. APhA is a dependable ally through every phase of your pharmacy career and that includes times of stress and uncertainty. From work-life balance to managing stress we have resources to help.

Well-Being Resources

Consensus Recommendations

Enhance Well-being and Resilience Among the Pharmacist Workforce:
A National Consensus Conference

We’re all-in on your well-being. That’s why APhA, along with four national pharmacy organizations, held a national consensus conference, to develop strategies that address pharmacists’ well-being and resiliency and design a path forward. The conference hosted multiple stakeholders from diverse practice perspectives.

Learn More

www.pharmacist.com/well-being
Your Report with overall score, comparison to all pharmacists and where you fall on each of the dimensions

Available Resources after you assess
Burnout is real.

Take advantage of APhA’s online screening tool, invented by the Mayo Clinic, to evaluate your fatigue, depression, burnout, anxiety, and stress and assess your well-being.

It takes less than 5 minutes to answer 9 short questions.

It’s 100% anonymous, free, and you do not need to be an APhA member.

Resources are available once you submit your assessment.

Pharmacists Well-being Index
https://app.mywellbeingindex.org/signup

Invitation Code: APhA
Polling Question

Since the beginning of the COVID-19 pandemic, the conditions in my practice have:

A. Significantly improved
B. Improved
C. Remained the same
D. Worsened
E. Significantly worsened
Polling Question

Since the beginning of the COVID-19 pandemic, my personal well-being has:

A. Significantly improved  
B. Improved  
C. Remained the same  
D. Worsened  
E. Significantly worsened
Open Forum Discussion: Audience Reflections

Successes, Barriers, Opportunities
Review of APhA’s Ongoing Activities and What’s Coming
Check out the practice resources here

Recently Updated:

• COVID-19 Fraudulent Medical Products and Scams
• Pharmacists’ Authority to Test for COVID-19
Contact Congress Today! Authorize Provider Status for COVID-19 and Influenza Testing and Vaccinations!

APhA members are urged to #BringCOVIDCareCloser by contacting Congress today to authorize pharmacist provider status for COVID-19 and influenza testing and vaccinations:
https://actioncenter.pharmacist.com/campaign/coronavirus/

A coalition of over 30 patient, physician, and diverse health care groups appealed to Congress to support provider status, we need you to act as well!!

APhA Urges Administration to Expand and Make Pharmacy Flexibilities Permanent to Reopen the Economy

On August 7, APhA and other pharmacy groups urged the Administration to take action under a recent Executive Order to make permanent the regulatory flexibilities surrounding pharmacists' ability to test and treat patients for COVID-19 and influenza; remove operational barriers that have addressed workforce and workflow issues that have previously prevented pharmacists from engaging in patient care, and maintain compounding flexibilities to address current and future drug shortages.

HHS Allows Laboratory Developed Tests on the Market Without FDA Review

On August 19, HHS announced, effective immediately, that FDA will no longer require premarket review of laboratory developed tests (LDTs) until FDA goes through a lengthy rulemaking process. LDTs can still voluntarily request FDA reviews. As a result, substandard COVID-19 tests could be in the marketplace. The action appears to revolve previous FDA guidance used to remove 27 faulty COVID-19 serology tests from the marketplace and require testing manufacturers to submit applications for Emergency Use Authorization (EUA) in 10 days. LDTs that have not been approved or authorized by the FDA do not have federal liability immunity protections. Pharmacists should know they may not be covered under federal liability protections if they provide specimen collection for a lab that uses LDTs that have not been approved or authorized. APhA recommends pharmacists inform patients of the risks involved with using LDTs.

For APhA members only
Check your INBOX to keep up-to-date on the latest regulatory and legislative news and how APhA is advocating for you
Take Action Now!

It’s Game Time! Tell Congress Pharmacists Can Help Fight COVID-19 and Influenza!

- Your immediate participation will help spur conversation within Congress about the need for pharmacists’ provider status during the public health emergency.
- We need ALL of our representatives to advocate to Congressional leadership in both parties to ensure this receives the attention it – and our patients – deserve so it is included in the next legislative package!

To take action now, go to: https://actioncenter.pharmacist.com/campaign/coronavirus/
To learn about how you can call your representatives, contact Mary-Ryan Douglass at mrdouglass@aphanet.org
APhA's 15 on COVID-19 Series is designed to help you separate fact from fiction, and rumor from hypothesis, so that you will have the answers you need to educate yourself, your colleagues, and your patients about COVID-19. Each episode is 15–20 minutes long and is approved for CPE for pharmacists and pharmacy technicians.

**APhA 15 on COVID-19: Dexamethasone (July 31)**
Finally there is a drug that has demonstrated improved survival outcomes in COVID-19. Fortunately for everyone, that drug is a widely available, inexpensive drug that we are all familiar with: dexamethasone. Join us for today's 15 on COVID-19 episode as we review the dexamethasone data in COVID-19. *(CPE Video)*

**APhA 15 on COVID-19: mRNA Vaccines (July 24)**
As the number of COVID-19 cases has started to spike again in the U.S., there is an increased focus on COVID-19 vaccines. Join us for today's 15 on COVID-19 episode as we look at the new mRNA vaccine technology, and look at the early data to see if they are a viable option for preventing COVID-19. *(CPE Video)*

**APhA 15 on COVID-19: Telehealth (June 12)**
COVID-19 has resulted in a major shift in the health care landscape, particularly the telehealth landscape. Join us as our guest host, APhA President-elect Sandra Leal, takes us through some of these recent changes and what we can do to retain the advances that pharmacy has made in the telehealth arena. *(CPE Video)*

https://www.pharmacist.com/coronavirus/training
Post on **ENGAGE**

*Pharmacy’s Response to COVID-19*

**POST** your questions

**SHARE** your lessons learned

**SUPPORT** your colleagues

**ACCESS** the latest information

What practice changes have surprised you most?

What challenges do you foresee for pharmacists in the next six months?
Join Us

• No weekly webinar next week – September 3
• Next Weekly webinar will be on Thursday, September 10th, from 1-2pm ET
• Topic: Phall, Phlu & Pharmacy Amidst COVID-19 – CPE Available!
• Today’s webinar recording and slides will be available within 24hrs

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