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

COVID-19 Therapeutics: Evidence-based Care and Practice Opportunities

October 14, 2021

For Every Pharmacist. For All of Pharmacy.

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Dan Zlott, PharmD, BCOP
Senior Vice President
Education and Business Development
American Pharmacists Association

Host, Moderator & Speaker

Today's Webinar

Discuss medications being studied with a focus on ivermectin and available outcomes data, as well as COVID-19 therapeutics, including monoclonal antibody therapies and opportunities for pharmacists.

Randy McDonough, PharmD, MS, BCGP, BCPS, FAPhA

Co-owner of Towncrest Pharmacy, Solon Towncrest Pharmacy, Towncrest Compounding Pharmacy, Towncrest LTC, and Innovative Pharmacy Solutions

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Executive Director
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Subject Matter Expert: Q&A

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Subject Matter Expert: Q&A

Disclosures

Mitchel C. Rothholz, RPh, MBA, has provided the following disclosures:

- Merck: Advisory board member, Spouse employer
- Pfizer: Advisory board member

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.

Learning Objectives

1. Discuss research methodology and how evidence is evaluated to support recommendations for use of COVID-19 therapeutics.
2. Review the evidence base and debate on the use of ivermectin for the prevention and treatment of COVID-19.
3. Discuss pharmacist authority to order and administer monoclonal antibody therapies and recommendations for their use to prevent and treat COVID-19.
4. Describe pharmacy practice models that can be implemented to increase access to evidence-based monoclonal antibody therapies.

Which of the following is an appropriate interpretation of outcomes from a study that are not pre-specified?

a) They should be considered hypothesis generating only
b) They should only be considered clinically relevant if the p-value is highly significant (i.e., <0.001)
c) They should always be ignored, since they weren't pre-specified
d) They can be used for clinical decision making without further study as long as they demonstrate statistical significance

Which declaration provided pharmacists with the authority to order and administer COVID 19 therapeutics?

a) Federal Support Act, 1st amendment
b) PREP Act, 9th amendment
c) PREP Act, 5th amendment
d) DSHEA Act, 4th amendment

To implement a successful monoclonal antibody (mAb) therapy program (using sub-Q injections), the following steps should be taken, EXCEPT:

a) Determine which mAb product you will provide
b) Identify a safe and secure area to provide the mAb for treatment
c) Review how the product will be prepared for administration
d) Determine what documentation and/or reporting is needed

Format for Today's Webinar

1:00pm: Introductions

1:05pm: Presentation from Dan Zlott

1:20pm: Presentation from Randy McDonough

1:35pm: Open Forum Discussion: Share Your Questions & Thoughts

1:50pm: Review of APhA's Ongoing Activities & What's Coming

Open Forum Ground Rules

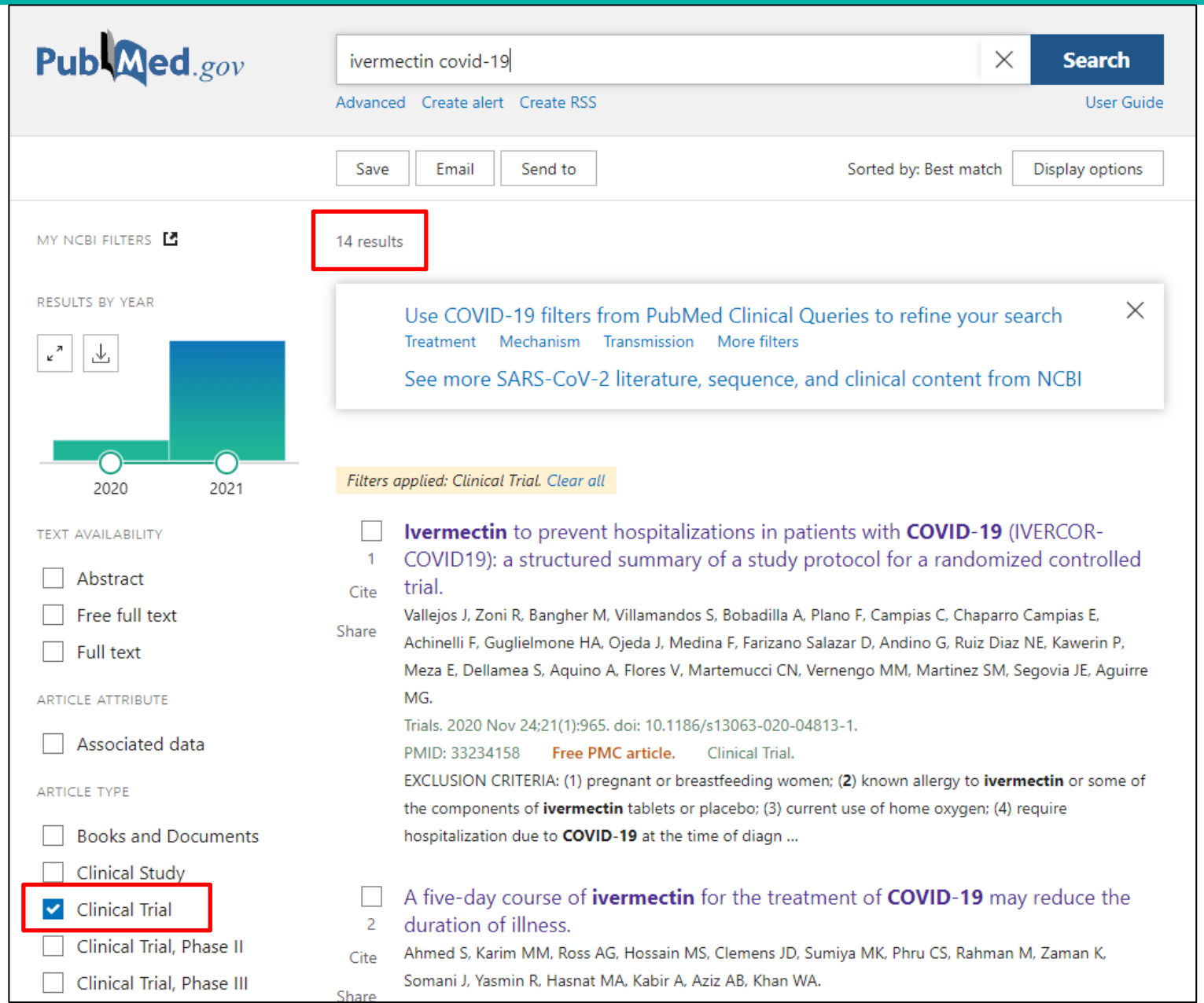
- Use the **Questions** field on the GoToWebinar toolbar to submit comments and questions related to the topic discussion.
- We will try to get to as many comments and questions as possible!
- Refer to the **Handout** in the GoToWebinar toolbar to access today's slides and links to resources.
- This webinar recording will be made available.
- CE is only available during the live webinar.

Presentation with Dan Zlott

Discuss the controversy around ivermectin, the outcomes reported in clinical trials to date, and review how studies inform evidence-based decision making.

Ivermectin – A Closer Look at the Data

What's on PubMed?



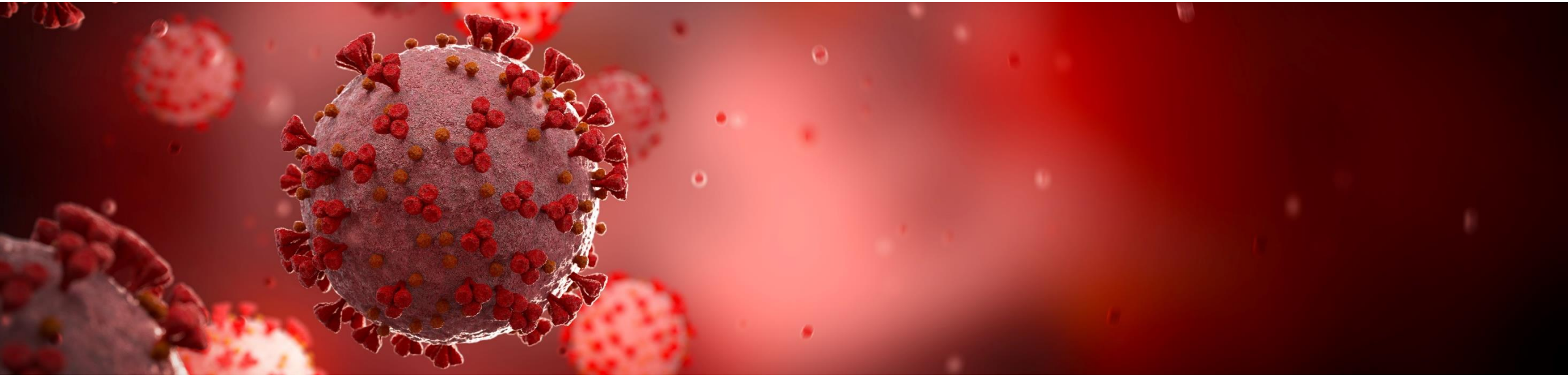
Ivermectin – A Closer Look at the Data

High-Level Overview

- 1 article describing a proposed study design (no actual study data)
- 7 articles describing systemic ivermectin used as a single agent
- 4 articles describing systemic ivermectin used in combination with other investigational agents
- 1 article describing systemic ivermectin vs systemic ivermectin in combination with other investigational agents
- 1 article describing ivermectin administered as a nasal spray

Single-Dose Ivermectin in Asymptomatic Pts[1]

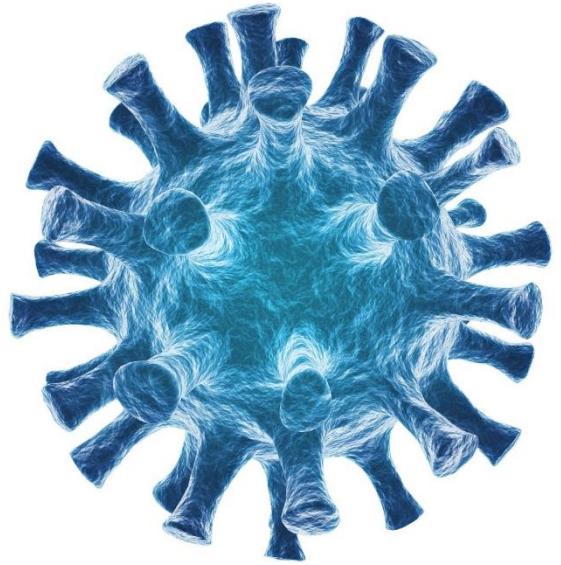
- Design
  - Randomized, open-label, controlled trial
  - Interventions:
    - Ivermectin 9mg, 12mg, or 150mcg/kg (depending on weight) PO x1 vs
    - SoC



1. Samaha, et al. *Viruses*, 2021; 13:989. DOI: https://doi.org/10.3390/v13060989

Single-Dose Ivermectin in Asymptomatic Pts[1]

- Strengths:
  - Randomized, controlled trial
- Weaknesses:
  - Open label
  - Small N (50 pts per arm)
  - Endpoints (primary and secondary) not pre-specified
    - Any results from this study should be considered hypothesis generating, only!!!
    - No corrections applied for multiple comparisons
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine impact of dosage on efficacy



1. Samaha, et al. *Viruses*, 2021; 13:989. DOI: https://doi.org/10.3390/v13060989

Single-Dose Ivermectin in Asymptomatic Pts[1]

- Results:
  - N=100
    - 50 ivermectin, 50 SoC
  - Outcomes of interest not pre-specified

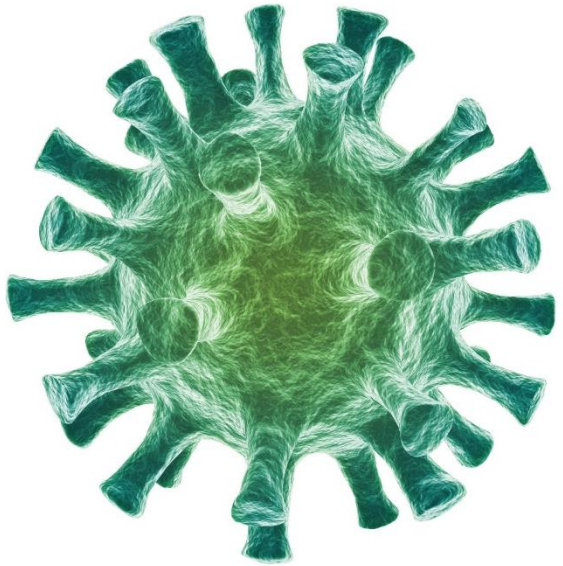
Outcome	SoC	Ivermectin	p-value
Fever	22%	2%	0.002
Anosmia	32%	6%	0.001
Myalgia	18%	0%	0.002
Loss of Taste	24%	6%	0.012
Hospitalization	6%	0%	0.079

  - Other outcomes which did not demonstrate statistical significance: Cough, runny nose, headache, fatigue, dizziness

1. Samaha, et al. *Viruses*, 2021; 13:989. DOI: https://doi.org/10.3390/v13060989

Single-Dose Ivermectin in Asymptomatic Pts[1]

- Pts:
  - Inclusion:
    - Asymptomatic adult pts with COVID-19 PCR+ test
    - Weight ≥ 45kg
  - Exclusion:
    - Allergy to ivermectin
    - Pregnant or lactating pts
    - End-stage kidney or liver disease
    - Pulmonary fibrosis
    - Advanced COPD
    - Heart Failure (NYHA class IV)
    - Cardiac intervention within prior 2 months



1. Samaha, et al. *Viruses*, 2021; 13:989. DOI: https://doi.org/10.3390/v13060989

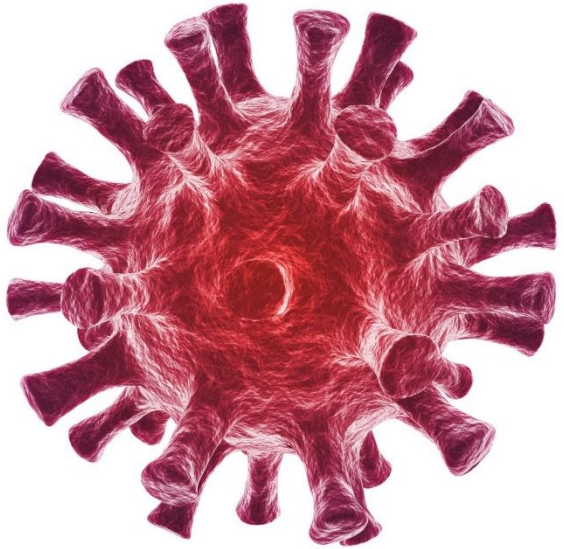
IVERCOR-COVID19 Trial[1]

- Design: Randomized, double-blind, placebo-controlled trial
- Intervention: Ivermectin + Standard of Care (SoC) vs Placebo + SoC
  - Ivermectin Dose: 12-18mg/dose x 2 doses, 24 hours apart

1. Vallejos, et al. *BmC Infectious Diseases*, 2021; 21:635. DOI: https://doi.org/10.1186/s12879-021-06348-5

IVERCOR-COVID19 Trial[1]

- Strengths:
  - Solid trial design
  - Relatively large N (for an ivermectin trial)
  - Clinically relevant outcomes
  - Appropriate statistical methodology (intention to treat analysis)
- Weaknesses:
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine impact of dosage on efficacy



1. Vallejos, et al. *BmC Infectious Diseases*, 2021; 21:635. DOI: https://doi.org/10.1186/s12879-021-06348-5

IVERCOR-COVID19 Trial[1]

- Results:
  - N=501
    - 250 ivermectin, 251 placebo
  - Primary Outcome:
    - 14 pts hospitalized in ivermectin group vs 21 pts in placebo group
      - Odds ratio: 0.65, 95%CI: 0.32 – 1.31, p = 0.227
  - Secondary Outcomes
    - No statistically significant differences in:
      - Time from enrollment to hospitalization
      - Mechanical ventilation rates
      - Time to viral clearance
      - All-cause mortality

1. Vallejos, et al. *BmC Infectious Diseases*, 2021; 21:635. DOI: https://doi.org/10.1186/s12879-021-06348-5

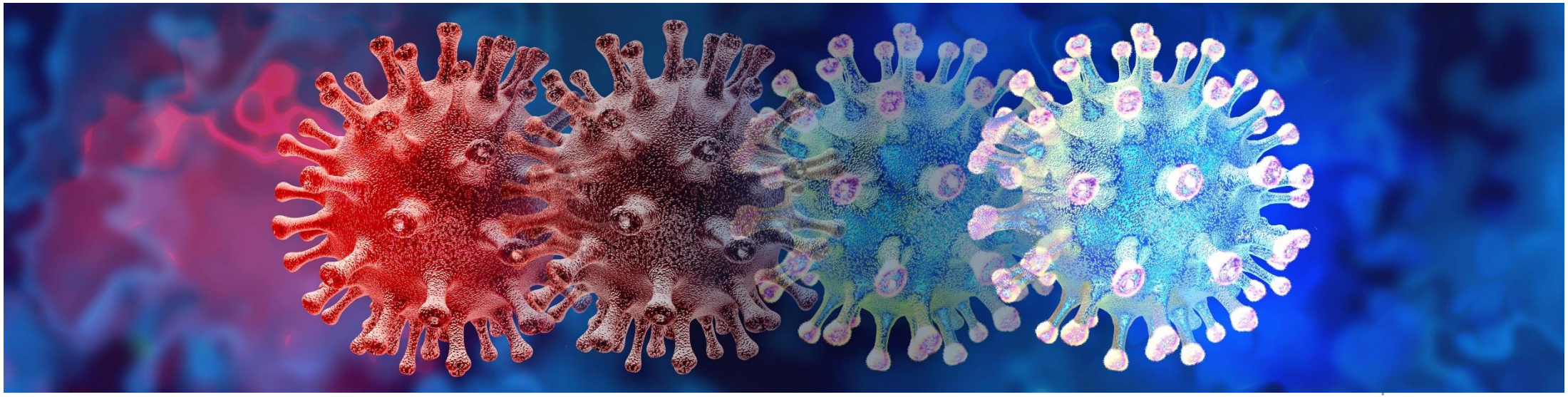
IVERCOR-COVID19 Trial[1]

- Pts:
  - Inclusion:
    - COVID-19 PCR+ within 48hrs
  - Exclusion:
    - Pts < 48kg
    - Use of O_2
    - COVID-19 hospitalization
    - Pregnant or breastfeeding pts
    - Allergies to ivermectin
    - Known severe liver disease
    - Dialysis

1. Vallejos, et al. *BMC Infectious Diseases*, 2021; 21:635. DOI: https://doi.org/10.1186/s12879-021-06348-5

5 Day Course of Ivermectin

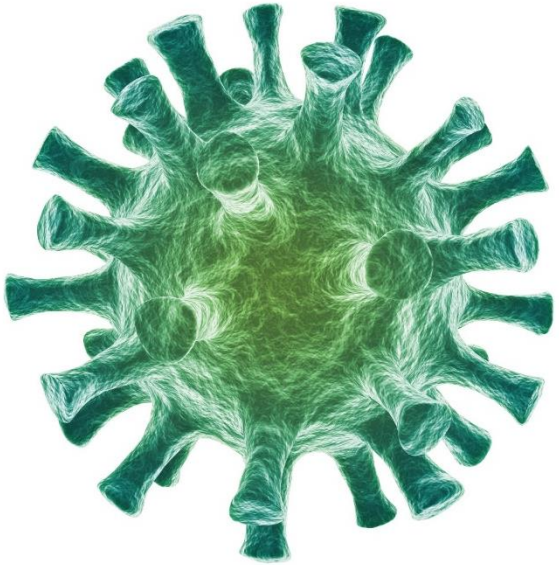
- Design
  - Randomized, double-blind, placebo-controlled trial
  - Interventions:
    - Ivermectin 12mg PO q day x 5 days vs
    - Ivermectin 12mg PO x1 on day 1 + Doxycycline 200mg PO on day 1 + Doxycycline 100mg PO q 12hrs x 4 days vs
    - Placebo



1. Ahmed, et al. *International Journal of Infectious Diseases*, 2021; 103:214. DOI: https://doi.org/10.1016/j.ijid.2020.11.191

5 Day Course of Ivermectin[1]

- Strengths:
  - Solid trial design
  - Appropriate statistical methodology
- Weaknesses:
  - Small N (only 24 pts per arm)
  - Primary outcome = viral clearance (no clinical outcomes discussed)
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine if dosage impacts efficacy
  - Combination of ivermectin + doxycycline confounds impact of ivermectin in this arm



1. Ahmed, et al. *International Journal of Infectious Diseases*, 2021; 103:214. DOI: https://doi.org/10.1016/j.ijid.2020.11.191

5 Day Course of Ivermectin[1]

- Results:
  - N=72
    - 24 ivermectin, 24 ivermectin + doxycycline, 24 placebo
  - Primary Outcome:
    - Mean time to viral clearance:
      - Ivermectin: 9.7 days (p=0.02 compared to placebo)
      - Ivermectin + Doxycycline: 11.5 days (p=0.27 compared to placebo)
      - Placebo: 12.7 days
  - Secondary Outcomes
    - N/A

1. Ahmed, et al. *International Journal of Infectious Diseases*, 2021; 103:214. DOI: https://doi.org/10.1016/j.ijid.2020.11.191

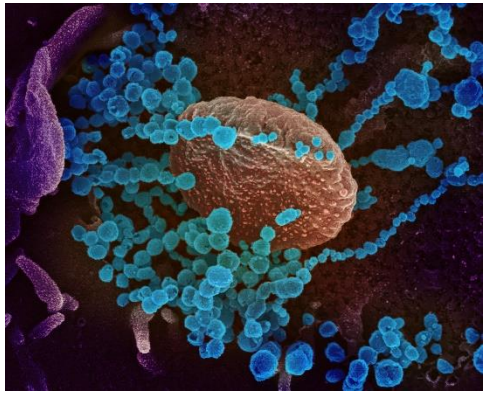
5 Day Course of Ivermectin[1]

- Pts:
  - Inclusion:
    - Age 18-65
    - Admitted to hospital within past 7 days
    - Sx consistent w/ COVID-19
    - COVID-19 PCR+
  - Exclusion:
    - Allergies to ivermectin or doxycycline
    - Drug-drug interactions with ivermectin or doxycycline
    - Chronic illness
    - Receipt of ivermectin or doxycycline within past 7 days
    - Pregnant or lactating patients
    - Participation in a clinical trial within previous month

1. Ahmed, et al. *International Journal of Infectious Diseases*, 2021; 103:214. DOI: https://doi.org/10.1016/j.ijid.2020.11.191

Ivermectin in Mild COVID-19[1]

- Design
  - Randomized, double-blind, placebo-controlled trial
  - Interventions:
    - Ivermectin 300mcg/kg PO (oral solution) q day x 5 days vs
    - Placebo
      - Different placebo formulations were used at different timepoints in the study
        - 5% Dextrose in saline or 5% dextrose in distilled water used until drug-free placebo was available from manufacturer
        - To prevent compromise of blinding, only 1 patient per household was included in the study until manufacturer's placebo was available



1. Lopez-Medina, et al. *JAMA*, 2021; 325:1426. DOI: https://doi.org/10.1001/jama.2021.3071

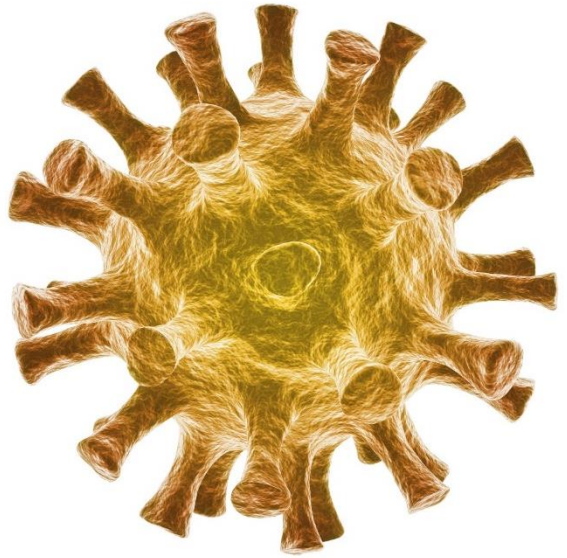
Ivermectin in Mild COVID-19[1]

- Strengths:
  - Double-blind, placebo-controlled, randomized
  - Relatively large N (for an ivermectin trial)
  - Appropriate statistical methodology (intention to treat analysis)
- Weaknesses:
  - Potential issues with maintaining blinding due to placebo formulations
  - Changed primary outcome 6 weeks into study
  - Labelling issue resulted in pts not receiving treatments as randomized, which resulted in pts needed to be replaced
    - Replaced pts not included in primary analysis
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine impact of dosage on efficacy

1. Lopez-Medina, et al. *JAMA*, 2021; 325:1426. DOI: https://doi.org/10.1001/jama.2021.3071

Ivermectin in Mild COVID-19[1]

- Results:
  - N=476
    - 238 ivermectin, 238 placebo
  - Primary Outcome:
    - Time to resolution of symptoms:
      - Ivermectin: 10 days
      - Placebo: 12 days
      - HR: 1.07 (95% CI: 0.87 – 1.32; p = 0.53)
  - Secondary Outcomes
    - No statistically significant differences in:
      - Clinical deterioration
      - Escalation of care
      - Development of fever or duration of fever



1. Lopez-Medina, et al. *JAMA*, 2021; 325:1426. DOI: https://doi.org/10.1001/jama.2021.3071

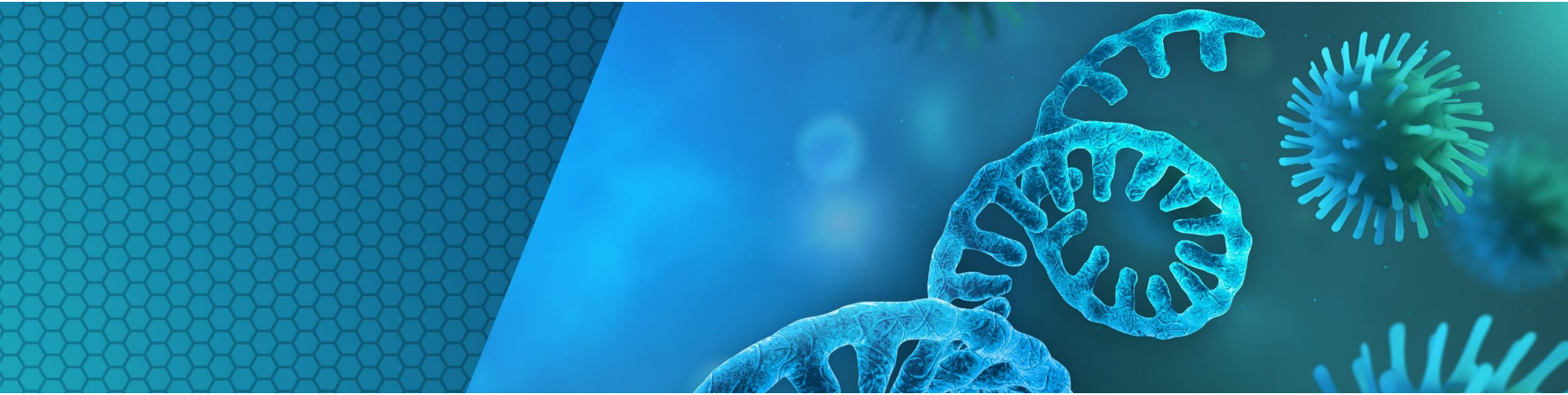
Ivermectin in Mild COVID-19[1]

- Pts:
  - Inclusion:
    - Mild COVID-19 disease with symptoms beginning within previous 7 days
    - COVID-19 PCR+
  - Exclusion:
    - Asymptomatic pts
    - Severe pneumonia
    - Receipt of ivermectin within previous 5 days
    - LFTs > 1.5x ULN

1. Lopez-Medina, et al. *JAMA*, 2021; 325:1426. DOI: https://doi.org/10.1001/jama.2021.3071

Ivermectin in Severe COVID-19[1]

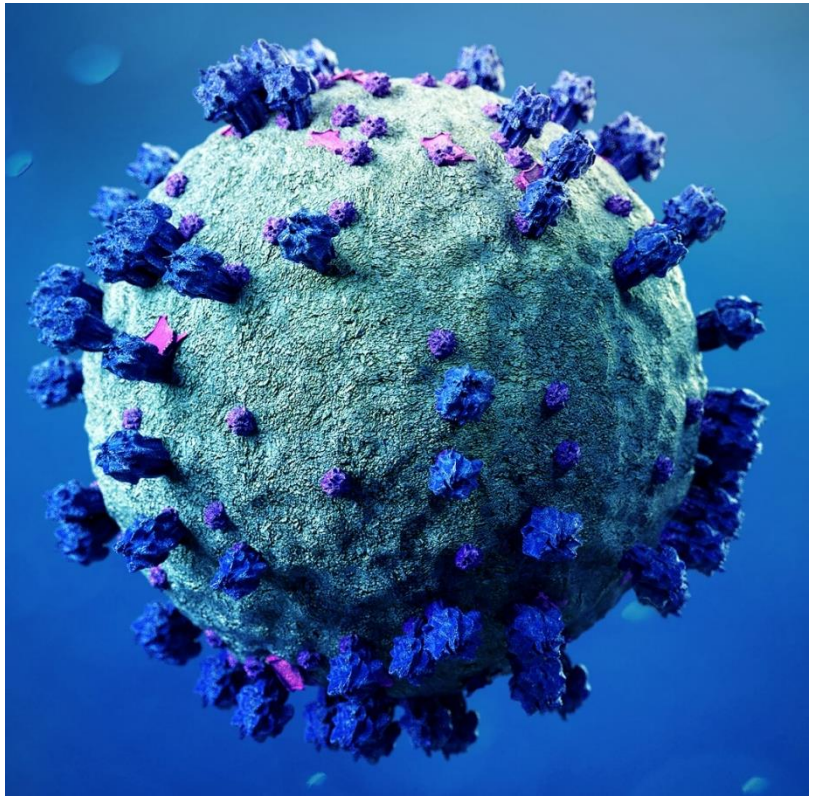
- Design
  - Randomized, single-blind, controlled trial
  - Interventions:
    - Ivermectin 200mcg/kg PO q day x 5 days + SoC vs
    - SoC alone



1. Okumus, et al. *BMC Infectious Diseases*, 2021; 21:411. DOI: https://doi.org/10.1186/s12879-021-06104-9

Ivermectin in Severe COVID-19[1]

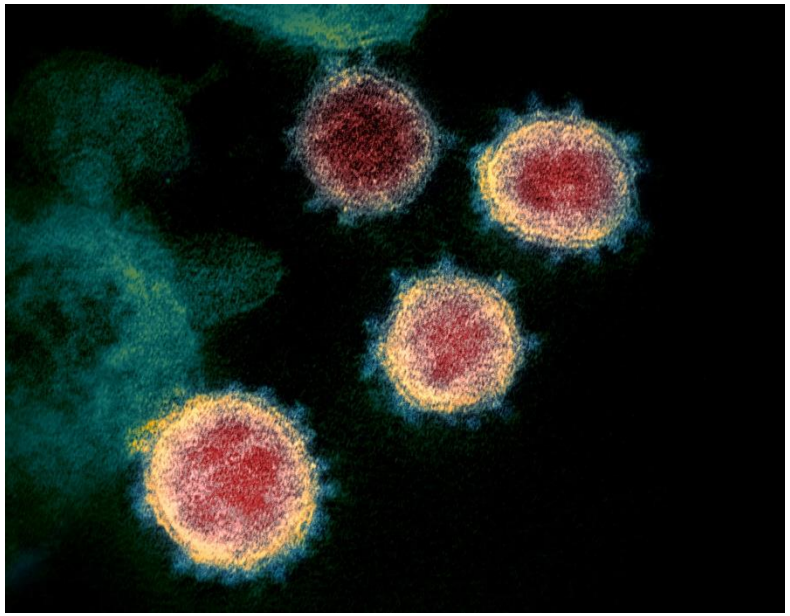
- Strengths:
  - Randomized, controlled trial
- Weaknesses:
  - Single blind trial
  - Small N (30 pts per arm)
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine impact of dosage on efficacy
  - Author's conclusions are not backed by statistical evidence



1. Okumus, et al. *BMC Infectious Diseases*, 2021; 21:411. DOI: https://doi.org/10.1186/s12879-021-06104-9

Ivermectin in Severe COVID-19[1]

- Results:
  - N=66
    - 30 ivermectin, 30 SoC, 6 pts excluded due to genetic mutations
  - Primary Outcome:
    - Rate of Clinical Improvement:
      - Ivermectin: 46.7%
      - SoC: 36.7%
      - P=0.43
  - Secondary Outcomes
    - No statistically significant differences in:
      - All cause mortality
      - SOFA Scores at end of follow up period
      - Oxygenation status at end of follow up period



1. Okumus, et al. *BMC Infectious Diseases*, 2021; 21:411. DOI: https://doi.org/10.1186/s12879-021-06104-9

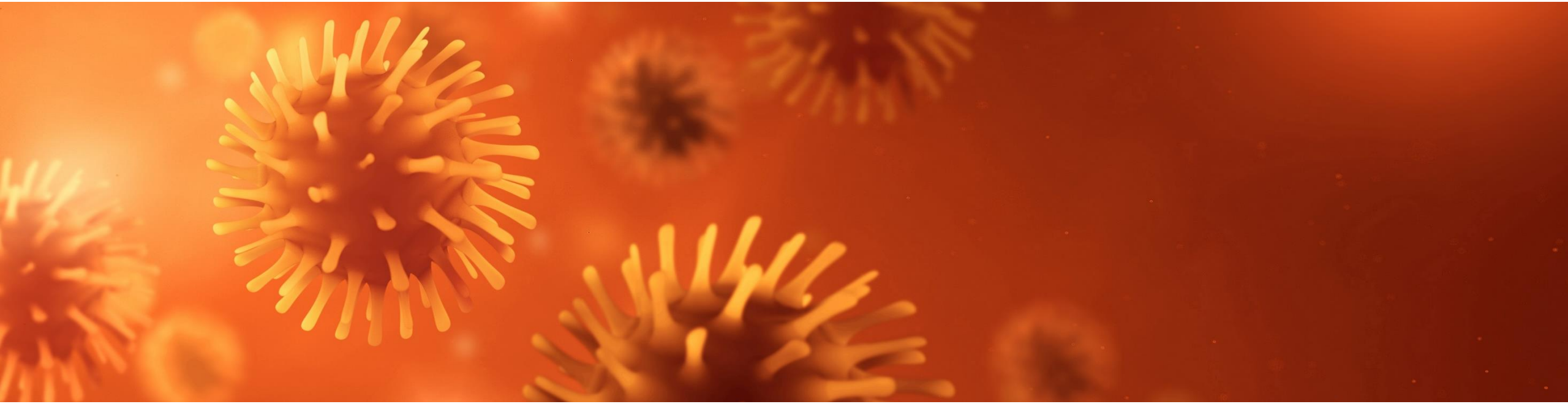
Ivermectin in Severe COVID-19[1]

- Pts:
  - Inclusion:
    - COVID-19 PCR+
    - Severe COVID-19 disease
  - Exclusion:
    - < 18 years old
    - Pregnant or breastfeeding pts
    - Concurrent autoimmune disease
    - Chronic liver or kidney disease
    - Immunosuppression
    - Mutations in MDR-1/ABC1 gene or CYP3A4 gene

1. Okumus, et al. *BMC Infectious Diseases*, 2021; 21:411. DOI: https://doi.org/10.1186/s12879-021-06104-9

3-Day Course of Ivermectin in Hospitalized Pts[1]

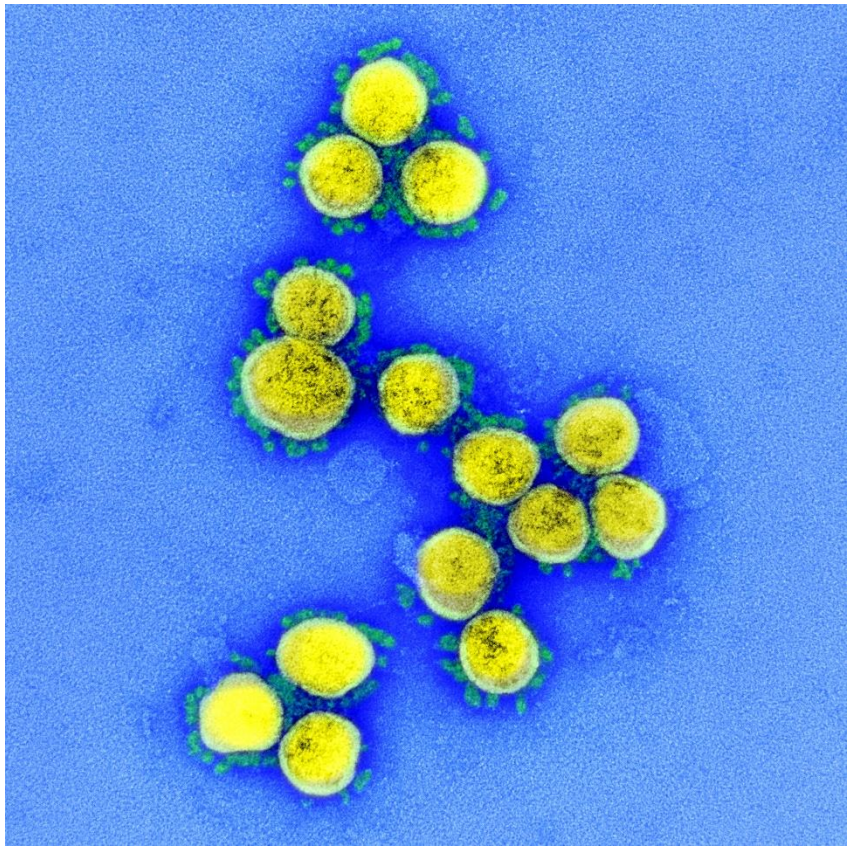
- Design
  - Randomized, open-label, controlled trial
  - Interventions:
    - Ivermectin 12mg PO q day x 3 days + SoC vs
    - SoC alone



1. Abd-Elsalam, et al. *J Med Virol*, 2021; 93:5833. DOI: https://doi.org/10.1002/jmv.27122

3-Day Course of Ivermectin in Hospitalized Pts[1]

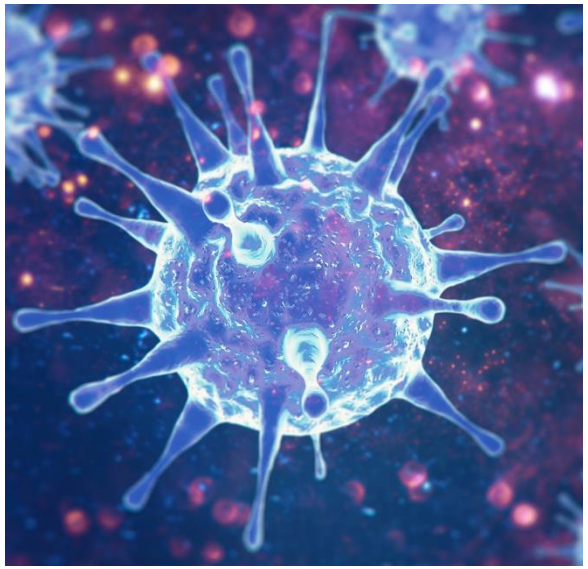
- Strengths:
  - Randomized, controlled trial
  - Appropriate statistical methodology
- Weaknesses:
  - Open label trial
  - Small N (82 pts per arm)
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine impact of dosage on efficacy



1. Abd-Elsalam, et al. *J Med Virol*, 2021; 93:5833. DOI: https://doi.org/10.1002/jmv.27122

3-Day Course of Ivermectin in Hospitalized Pts[1]

- Results:
  - N=164
    - 82 ivermectin, 82 SoC
  - Primary Outcome:
    - All cause mortality within 1 month of randomization
      - Ivermectin: 3 pts (3.7%)
      - SoC: 4 pts (4.9%)
      - P=1.00
  - Secondary Outcomes
    - No statistically significant differences in:
      - Length of hospital stay
      - Need for mechanical ventilation



1. Abd-Elsalam, et al. *J Med Virol*, 2021; 93:5833. DOI: https://doi.org/10.1002/jmv.27122

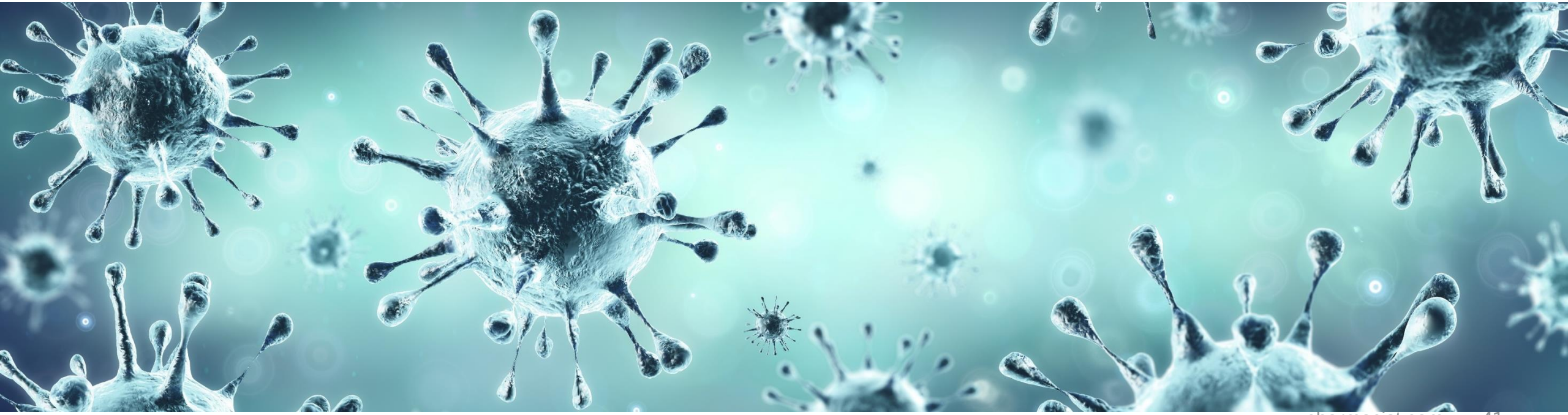
3-Day Course of Ivermectin in Hospitalized Pts[1]

- Pts:
  - Inclusion:
    - Hospitalized pts with COVID-19 PCR+
    - Age 20-65 years old
  - Exclusion:
    - Allergy to ivermectin
    - Contraindication to ivermectin
    - Pregnant or lactating pts
    - Pts with cardiac comorbidities

1. Abd-Elsalam, et al. *J Med Virol*, 2021; 93:5833. DOI: https://doi.org/10.1002/jmv.27122

2-Day Course of Ivermectin in Hospitalized Pts[1]

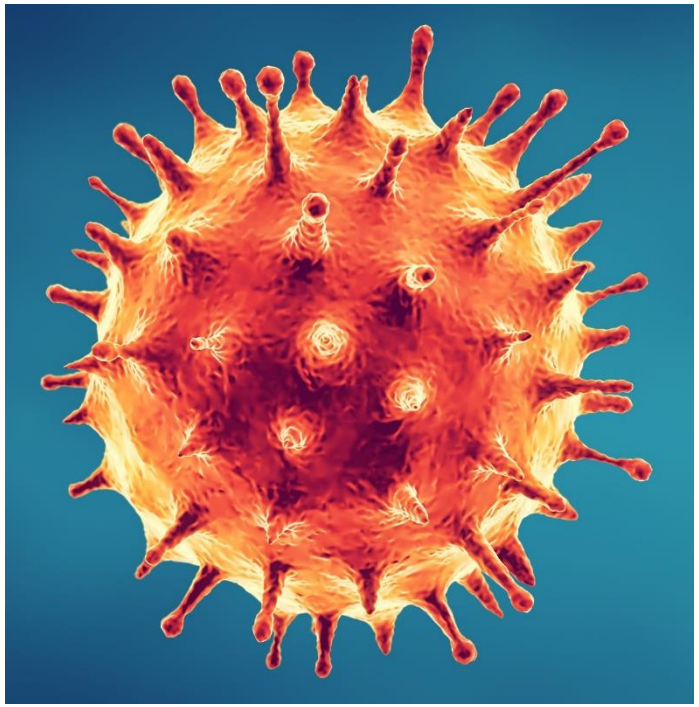
- Design
  - Randomized, double-blind, placebo-controlled trial
  - Interventions:
    - Ivermectin 12mg PO q day x 2 days vs
    - Placebo



1. Ravikirti, et al. *J Pharm Pharm Sci*, 2021; 24:343. DOI: https://doi.org/10.18433/jpps32105

2-Day Course of Ivermectin in Hospitalized Pts[1]

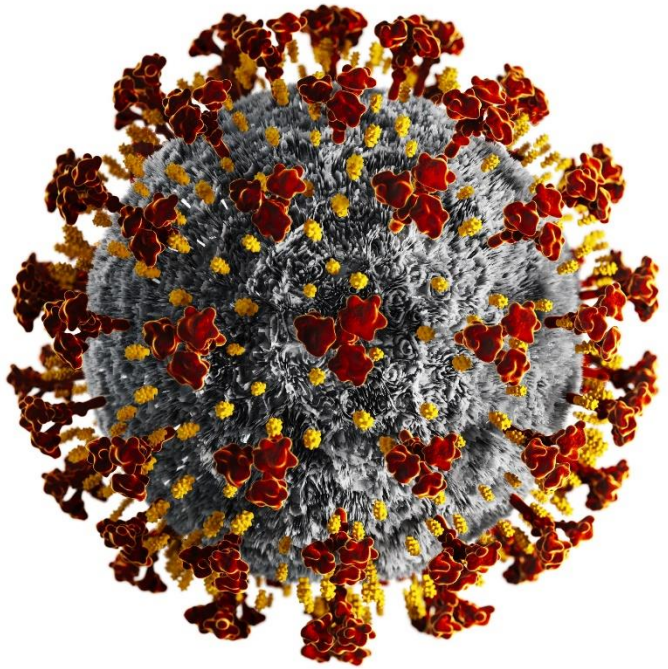
- Strengths:
  - Randomized, double-blind, placebo-controlled trial
  - Appropriate statistical methodology
- Weaknesses:
  - Small N (55-57 pts per arm)
  - Primary outcome = viral clearance at day 6 post-randomization
  - Ivermectin dosage may not be optimized
    - Need additional studies to determine impact of dosage on efficacy



1. Ravikirti, et al. *J Pharm Pharm Sci*, 2021; 24:343. DOI: https://doi.org/10.18433/jpps32105

2-Day Course of Ivermectin in Hospitalized Pts[1]

- Results:
  - N=112
    - 55 ivermectin, 57 placebo
  - Primary Outcome:
    - Viral clearance at day 6 post-randomization
      - Ivermectin: 23.6%
      - Placebo: 31.6%
      - RR: 0.8, 95% CI: 0.4-1.4, p = 0.348
  - Secondary Outcomes
    - No statistically significant differences in:
      - Resolution of Sx at day 6 post-randomization
      - ICU admission
      - Need for mechanical ventilation
    - Successful discharge was statistically significant:
      - 100% in ivermectin arm vs 93% in placebo arm (p=0.045)



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2-Day Course of Ivermectin in Hospitalized Pts[1]

- Pts:
  - Inclusion:
    - Hospitalized pts with COVID-19 PCR+ or rapid antigen test+
    - Mild to moderate COVID-19 at time of admission
    - Age ≥ 18 years old
  - Exclusion:
    - Allergy or adverse reaction to ivermectin
    - Unwillingness or inability to provide consent
    - Pregnant or lactating pts
    - Prior use of ivermectin during current illness

1. Ravikirti, et al. *J Pharm Pharm Sci*, 2021; 24:343. DOI: https://doi.org/10.18433/jpps32105

Presentation with Randy McDonough

Discuss pharmacists' authority to order and administer monoclonal antibody therapies and provide practical guidance on how pharmacists can become involved in administration of these therapies.

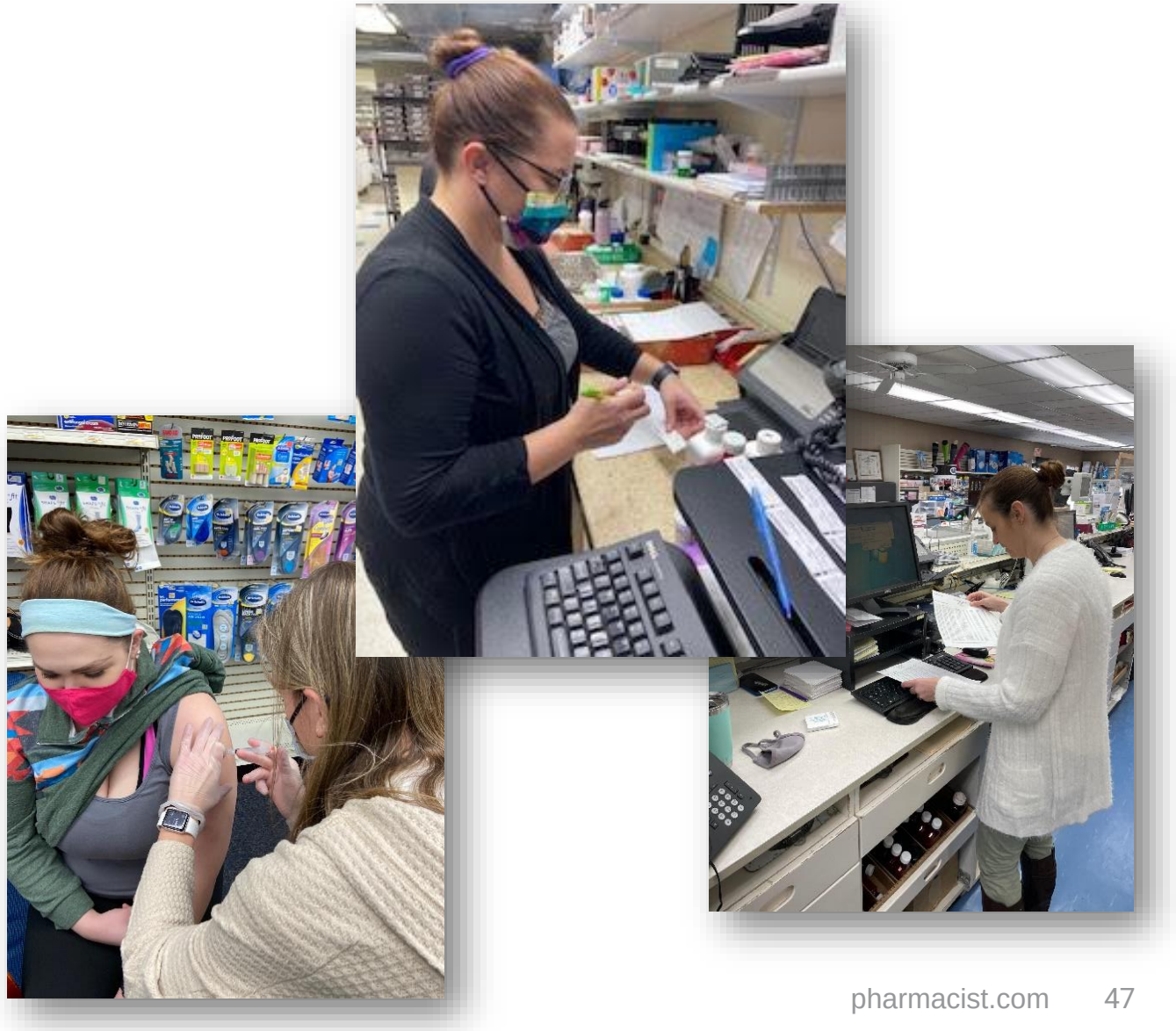
Enhanced Services

- Continuous Medication Monitoring (CoMM)
- Medication Reconciliation
- Medication Adherence Program (Adherence packaging)
- Clinical Medication Synchronization
- Medication Therapy Management (MTM)
- Enhanced MTM
- Med Check Program
- Influenza and Pneumococcal Vaccinations
- Shingrix Vaccination
- Tdap Vaccination
- COVID-19 Vaccination
- mAb Therapy Services
- Nursing Home Consulting

- CPAP service/Education
- Ostomy Consultations
- Drug Information Service
- Compounding
- Employer based health screenings
- Diabetic shoes
- Compression stockings

- **Wellness Center**
  - Cholesterol screening
  - Blood glucose screening
  - BP screening
  - Height and Weight
  - BMI

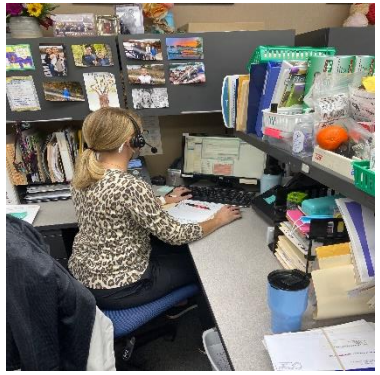
- **Specialized Focused**
  - Mental Health
  - Wellness
  - Geriatrics
  - End of life/palliative care



Preparing for New Services

Stoplight to limit flow of patients

Curbside delivery



Telephonic patient work-ups

Use of garages

Use of Warehouses

Curbside service delivery

Need to adjust and be creative

HHS: Pharmacists Are Nationally Authorized to Administer COVID-19 Tests Under PREP ACT

For Every Pharmacist. For All of Pharmacy.

Pharmacist authority to order and administer monoclonal antibody therapies

PREP ACT Declaration 9th Amendment—September 2021

The 9th amendment to the COVID 19 PREP Act Declaration provides liability immunity to and expands the scope of authority for **licensed pharmacists** to order and administer select COVID 19 therapeutics to populations authorized by the FDA and for **pharmacy technicians and pharmacy interns** to administer COVID 19 therapeutics to populations authorized by the FDA

Authority to Provide COVID-19 Therapeutics

Who can provide COVID-19 therapeutics?

- Pharmacists can order and administer COVID-19 therapeutics
- Pharmacy interns and pharmacy technicians are allowed to administer
  - For technicians, the supervising pharmacist must be immediately available
- Subject to certain requirements

What is a COVID-19 therapeutic?

- FDA approved, authorized, cleared, or licensed
- Administered SQ, IM, or orally
- Applies to: REGEN-COV (casirivimab/imdevimab) SQ
- Oral therapies anticipated

	Pharmacists	Pharmacy Technicians	Pharmacy Interns
Training Requirements	Must complete an ACPE-approved practical training **program that includes hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required by FDA.** These requirements can be met by completing the following training programs: • APhA's Certificate Training Program for Pharmacy-based Immunization Delivery meets the requirement for hands-on injection technique and general recognition and treatment of emergency reactions to COVID-19 therapeutics. • APhA's Monoclonal Antibodies: Assessment and Administration of COVID-19 Therapy training program reviews the clinical evaluation of indications and contraindications for COVID-19 therapeutics, adverse events, as well as and product-specific requirements or considerations related to FDA approval, authorization, clearance or licensing of COVID-19 therapeutics.		
Basic CPR Requirements	**Must have a current certificate in basic CPR**. An online basic CPR certification program accredited by ACPE, the American Nurses Credentialing Center, or the Accreditation Council for Continuing Medical Education satisfies.		
Recordkeeping Requirements	**Must comply with recordkeeping and reporting requirements of the jurisdiction** where pharmacists administer COVID-19 therapeutics, including informing the patient's primary care provider when available & complying with adverse-event reporting requirements.	The supervising qualified pharmacist must comply with recordkeeping and reporting requirements as described to the left.	Same as pharmacists.
Additional Requirements	Must comply with any relevant requirements or conditions of use that apply to the administration of COVID-19 therapeutics.		

Which Product Fits the Criteria?

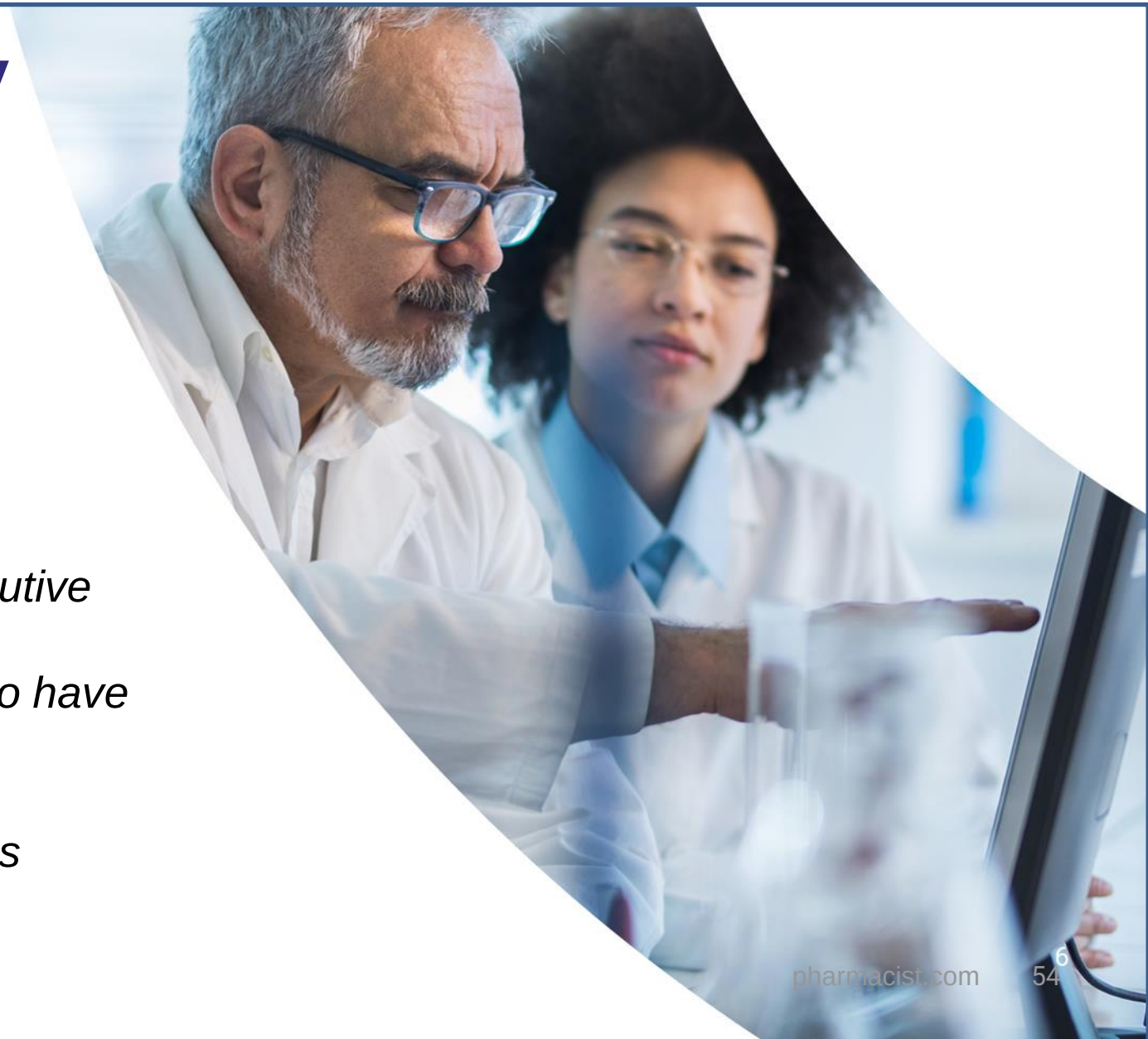
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™ (casirivimab and imdevimab)

- Can be given SQ for treatment in NON-HOSPITALIZED COVID-19 patients with mild to moderate illness with risk factors
  - ***FOR TREATMENT, INTRAVENOUS INFUSION IS STRONGLY RECOMMENDED***
  - *Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment*.
- Can be given IV or SQ for Post-exposure prophylaxis

Towncrest Pharmacy Clinical Team

Developing our mAb service

- A Focus on Learning about mAb
  - *CE Programs*
  - *CPESN-IA*
    - *Information provided by our Executive Director (Lindsey Ludwig)*
    - *Discussions with pharmacists who have already implemented service*
  - *CPESN-USA*
    - *Attending Best Practices webinars*
  - *Reading literature*
  - *Discussions with other providers*



Familiarizing Ourselves with the Product

Developing our confidence in providing mAb therapy

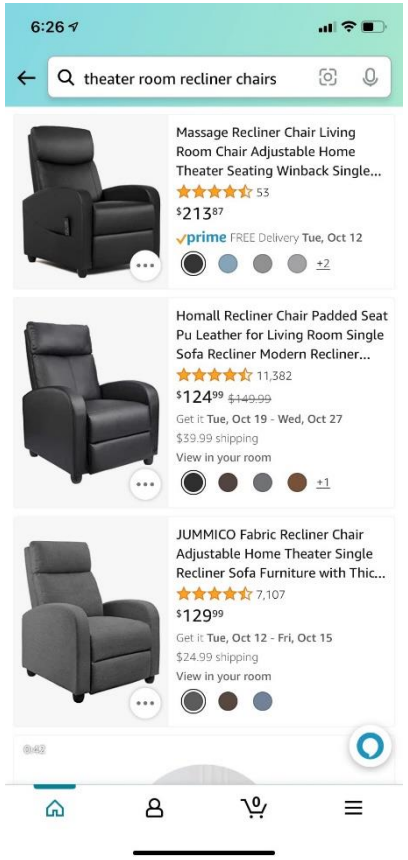
- Product considerations
  - *How do we get access?*
    - *This has evolved quickly from wholesaler to local state jurisdiction (for us Iowa Department of Public Health)*
  - *What are the storage requirements?*
  - *How do we prepare the final product for administration?*
  - *How long is it stable in a syringe?*
  - *How do we administer 4 SQ injections that are 2.5 ml in volume?*

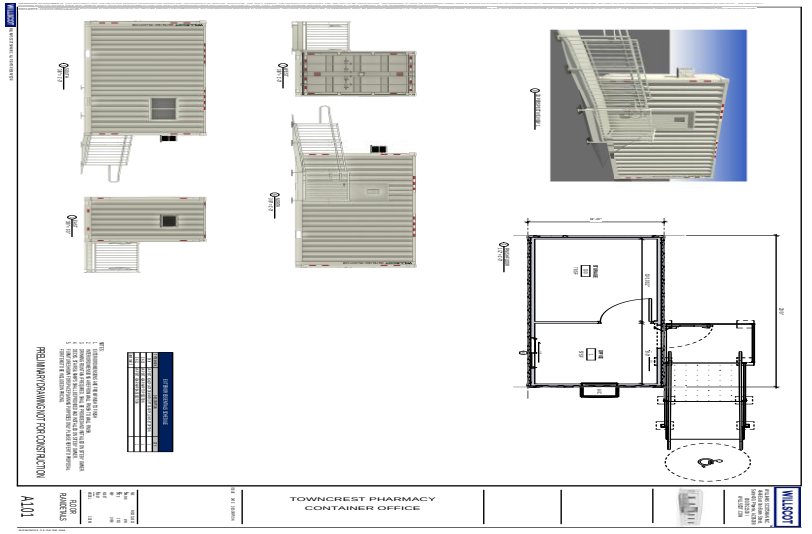
Making sure we fully understand the product, storage and handling, preparation, and administration

Where will we perform the mAb therapy?

Needed to prevent COVID-19 exposure

- Investing in a trailer (6 months)
- Working with city to get permits for both trailer and electricity hook-up
- Appropriate seating that is both functional and comfortable





Developing Service Processes

To: [redacted]

From: Kelly Kent, PharmD, RPh, BCPS
Director of Clinical Operations
Towncrest Pharmacy
2306 Muscatine Ave., Iowa City, IA 52240

Date: September 2021

Re: Monoclonal Antibody for Treatment and Post Exposure Prophylaxis of COVID-19 Collaborative Practice Agreement, Protocol, and Policy & Procedures

On behalf of Towncrest Pharmacy, thank you for your interest in serving the patients of our community by establishing a collaborative practice agreement for the monoclonal antibody treatment and post-exposure prophylaxis for COVID-19 in accordance with the Secretary of the Department of Health and Human Services (HHS) emergency use authorization (EUA).

The following collaborative practice agreement provides an opportunity for a pharmacy to collaborate with a supervising physician to administer monoclonal antibodies for treatment and post-exposure prophylaxis of COVID-19.

This document includes policies and procedures for screening and treating eligible patients and procedures for emergency responses in the event of adverse events from the monoclonal antibody treatment and post-exposure prophylaxis for COVID-19.

If you should have any questions or comments, please contact Kelly Kent at 319-337-3526 or at kkent@towncrest.com

Towncrest Pharmacy mAb CPA

Monoclonal Antibody Treatment Informed Consent Form

Patient Name: _____ Date of Birth: _____

Facts about the COVID-19 Emergency Use Authorization (EUA)

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for monoclonal antibody treatment. With an EUA, drugs are not reviewed in the same way as an FDA-approved or cleared product. The FDA may grant an EUA when certain standards are met, for instance, when there are no other choices for treating a health problem, like COVID-19. The FDA issues EUAs based on scientific proof that shows the product is likely to be safe and effective.

These monoclonal antibodies are being studied to treat COVID-19 in non-hospitalized patients with mild to moderate symptoms of COVID-19 who are at high risk for severe COVID-19 problems and/or a hospital stay. The drugs are being studied in patients who are not in the hospital. They must be 12 or older and weight at least 88 pounds, have a positive COVID-19 test, treated within 10 days of symptom onset, not needing oxygen therapy due to COVID-19. Because the drug is still being student, there is limited information on how safe or effective it is. After this drug treatment has been used on more people, additional side effects may be noted.

Risks and Common Problems

- ☐ There are risks associated with monoclonal antibody treatment including, but not limited to:
- ☐ Allergic reactions
- ☐ Changes in your heartbeat, chest discomfort, or chest pain
- ☐ Chills, fever, shivering, muscle aches, or headache
- ☐ Confusion
- ☐ Itching or rash
- ☐ Low blood pressure or dizziness
- ☐ Nausea, vomiting, or sweating
- ☐ Shortness of breath or wheezing
- ☐ Weakness or feeling tired

All drugs can cause side effects. Problems that are not expected may happen. These problems may be life threatening. If you have any severe symptoms after the treatment, seek medical attention immediately. (Call 911)

There is limited experience treating pregnancy women or breastfeeding mothers with monoclonal antibodies. It is recommended pregnant women should only receive this medication is the potential benefit outweighs the risk for the patient and her baby.

Towncrest Pharmacy mAb Treatment Informed Consent

2306 Muscatine Avenue, Iowa City IA 52240

REGEN-COV (casirivimab and imdevimab) Order Form

Patient Name:_____ **DOB:** _____
Address: _____
Phone #: (___) _____-_____ **Sex:** M / F / Prefer not to answer

Response	Inclusion Criteria (All must apply)
❑ Yes ❑ No	Authorized for use under an EUA for treatment of mild to moderate COVID-19 in adults and pediatric patients with **positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg**
❑ Yes ❑ No	**Symptomatic from SARS-CoV-2 ≤ 10 days** of direct SARS-CoV-2 viral testing
❑ Yes ❑ No	Are at **high risk** for progressing to severe COVID-19 and/or hospitalization. (**must meet 1 or more; select from below**)
	OR all of the following must apply
❑ Yes ❑ No	Adult or pediatric **(> 12 years of age and weighing at least 40kg)** patient at **high risk** for progressing to severe disease or death **(must meet 1 or more criteria from below)**
❑ Yes ❑ No	**Not fully vaccinated** or who are **not expected to mount an adequate immune response** to complete SARS-CoV-2 vaccination
❑ Yes ❑ No	**Have been exposed** to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC3 3 CDC's Quarantine and Isolation **OR – who are at high risk of exposure** to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons)
High Risk Criteria	
❑ Yes ❑ No	Older age (for example age ≥65 years of age)
❑ Yes ❑ No	Obesity or being overweight (for example, adults with BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
❑ Yes ❑ No	Pregnancy
❑ Yes ❑ No	Chronic kidney disease
❑ Yes ❑ No	Diabetes
❑ Yes ❑ No	Immunosuppressive disease or immunosuppressive treatment
❑ Yes ❑ No	Cardiovascular disease (including congenital heart disease) or hypertension
❑ Yes ❑ No	Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
❑ Yes ❑ No	Sickle cell disease
❑ Yes ❑ No	Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
❑ Yes ❑ No	Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of monoclonal antibodies under EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/peoplewith-medical-conditions.html . Healthcare providers should consider the benefit-risk for an individual patient.

Towncrest Pharmacy mAb Order Form

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™ (casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

Fact Sheet for Patients

Developing Policies and Procedures

Ensures consistency, accuracy, and quality

- Screening/Processing of patients
  - Online (using Acuity)
  - Telephonically
  - Complete forms
- Patient preparation
  - Initial set of vitals
    - (BP, Pulse rate, PulseOx, Temperature)
  - Patient Counseling
- Administration of mAb
- Monitoring/observing
- Follow-up

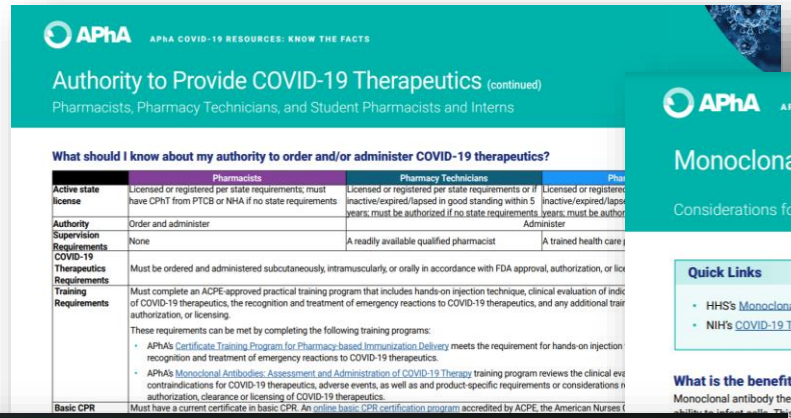
Other Considerations

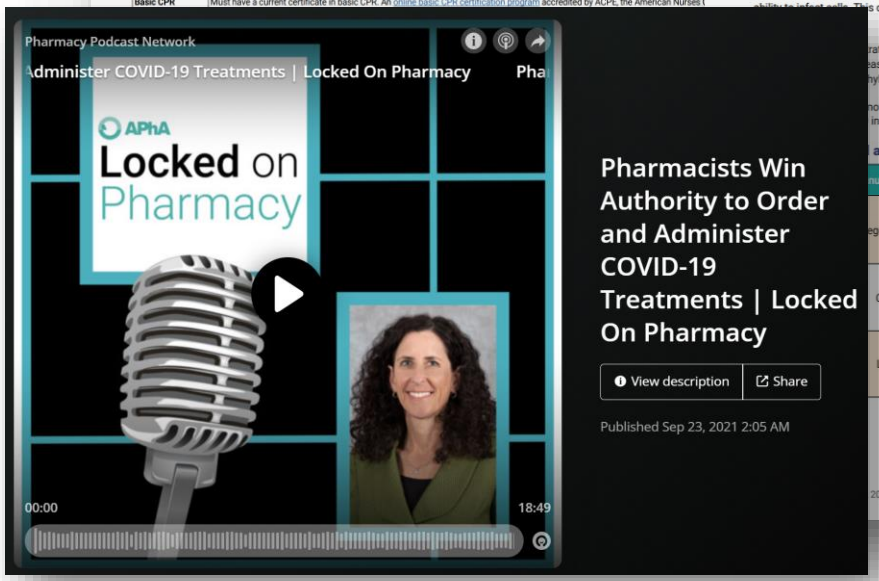
Ensuring we are in compliance

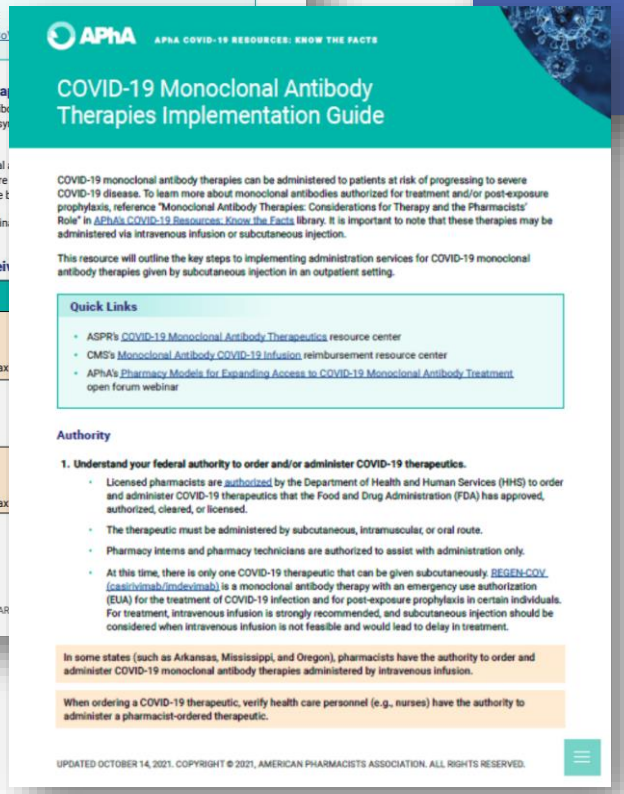
- Scheduling
  - *Onsite vs Home visits*
- Ordering
  - *Burn rate or throughput considerations*
- Equipment needed to monitor patient
  - *e.g. BP monitor, PulseOx, thermometer*
- Sanitizing work area, chairs, equipment, etc
- Appropriate PPE
- Required Documentation
- BILLING
  - *Work with billers to determine best practices (what do they need for documentation)*
    - *Copy of driver's license, insurance card, proof of positive COVID test*

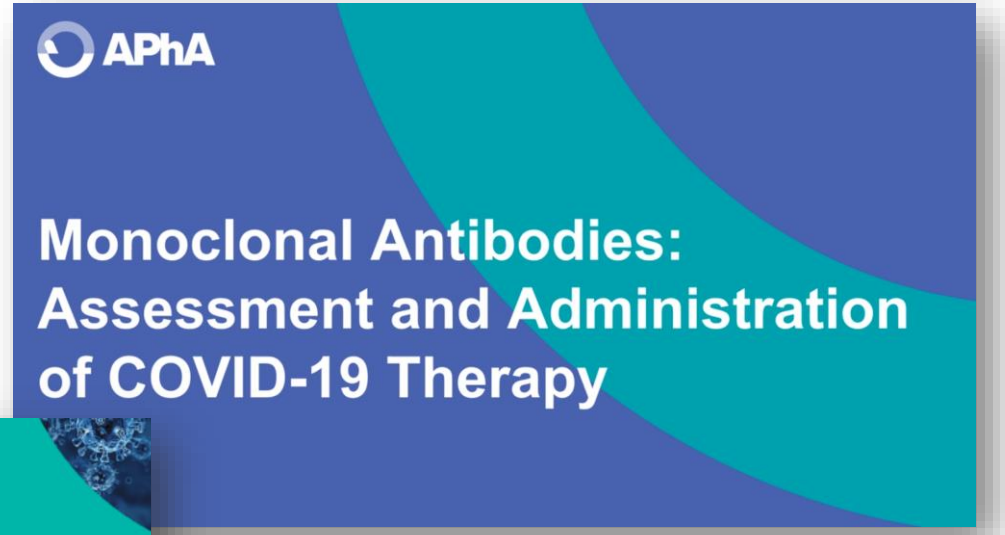
COVID-19 Therapeutics Resources

Access a library of resources at
https://www.pharmacist.com/Practice/COVID-19/Therapeutics









^Free training program designed to fully satisfy the requirements of the PREP Act by supplementing the Pharmacy-based Immunization Delivery certificate training program.
Learn more.

Don't miss our recent Locked on Pharmacy podcast!

Open Forum Discussion: Share Your Questions & Thoughts

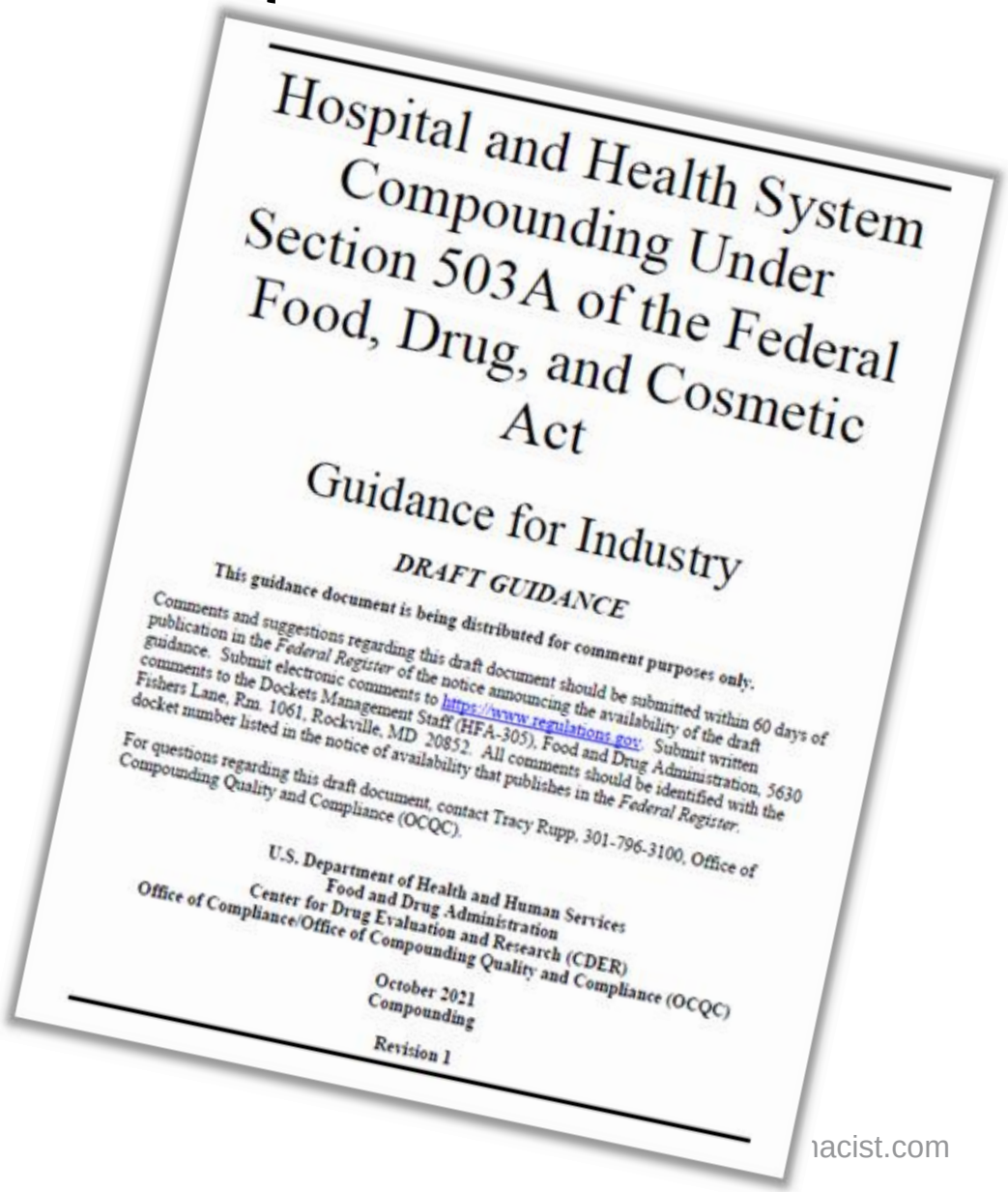
Review of APhA's Ongoing Activities & What's Coming

APhA Advocacy

Compounding – Hospital and Healthsystem

FDA released revised draft guidance for 503A hospital compounding to compound and distribute a compounded drug product **without first receiving a valid prescription order** (including a chart order) for an identified individual patient when:

- Administered only to patients within the hospital or health system (i.e., does not include products for home use)
- Used or discarded within 24 hours of transfer out of the pharmacy (i.e., for emergency use)
- Compounded in accordance with all other applicable legal requirements and FDA regulations (e.g., the drug products are not made under insanitary conditions or misbranded)



Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Tracy Rupp, 301-796-3100, Office of Compounding Quality and Compliance (OCQC).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/Office of Compounding Quality and Compliance (OCQC)

October 2021
Compounding

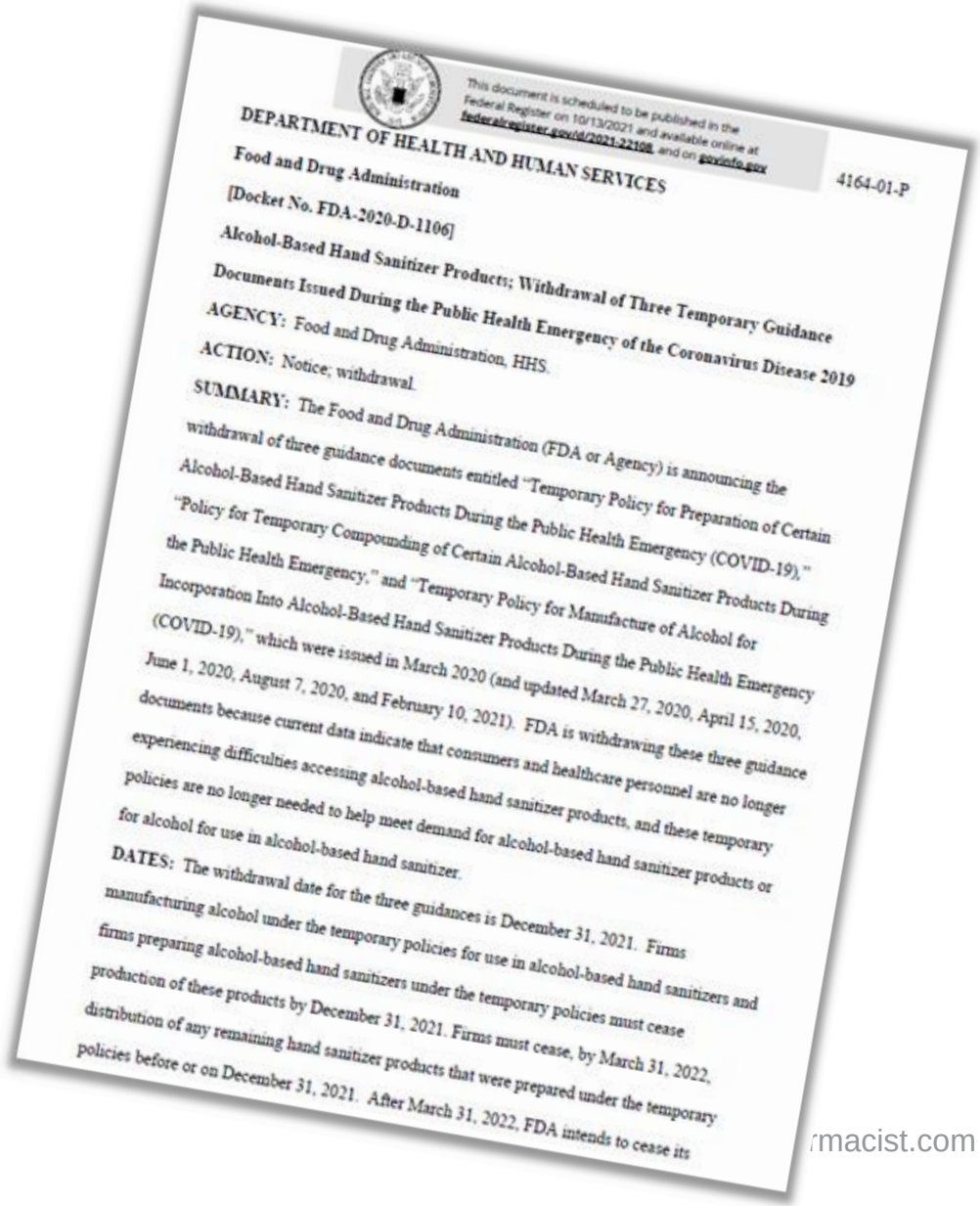
Revision 1

APhA Advocacy

Compounding – Hand Sanitizer

►Due to adequate supply, FDA is withdrawing 3 guidances:

- Firms manufacturing alcohol under the temporary policies for use in alcohol-based hand sanitizers and preparing alcohol-based hand sanitizers under the temporary policies must cease production of these products by **December 31, 2021**
- Firms must cease, by **March 31, 2022**, distribution of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021



This document is scheduled to be published in the Federal Register on 10/13/2021 and available online at federalregister.gov/d/2021-22108, and on govinfo.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

4164-01-P

Food and Drug Administration

[Docket No. FDA-2020-D-1106]

Alcohol-Based Hand Sanitizer Products; Withdrawal of Three Temporary Guidance Documents Issued During the Public Health Emergency of the Coronavirus Disease 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of three guidance documents entitled "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)," "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency," and "Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)," which were issued in March 2020 (and updated March 27, 2020, April 15, 2020, June 1, 2020, August 7, 2020, and February 10, 2021). FDA is withdrawing these three guidance documents because current data indicate that consumers and healthcare personnel are no longer experiencing difficulties accessing alcohol-based hand sanitizer products, and these temporary policies are no longer needed to help meet demand for alcohol-based hand sanitizer products or for alcohol for use in alcohol-based hand sanitizer.

DATES: The withdrawal date for the three guidances is December 31, 2021. Firms manufacturing alcohol under the temporary policies for use in alcohol-based hand sanitizers and firms preparing alcohol-based hand sanitizers under the temporary policies must cease production of these products by December 31, 2021. Firms must cease, by March 31, 2022, distribution of any remaining hand sanitizer products that were prepared under the temporary policies before or on December 31, 2021. After March 31, 2022, FDA intends to cease its

Mix-ups Between Flu and COVID-19 Vaccines

Possible Causative Factors

- Increased demand and coadministration of the vaccines
- Syringes near each other
- Unlabeled syringes
- Distractions
- Staffing shortages

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

Safe Practice Recommendations

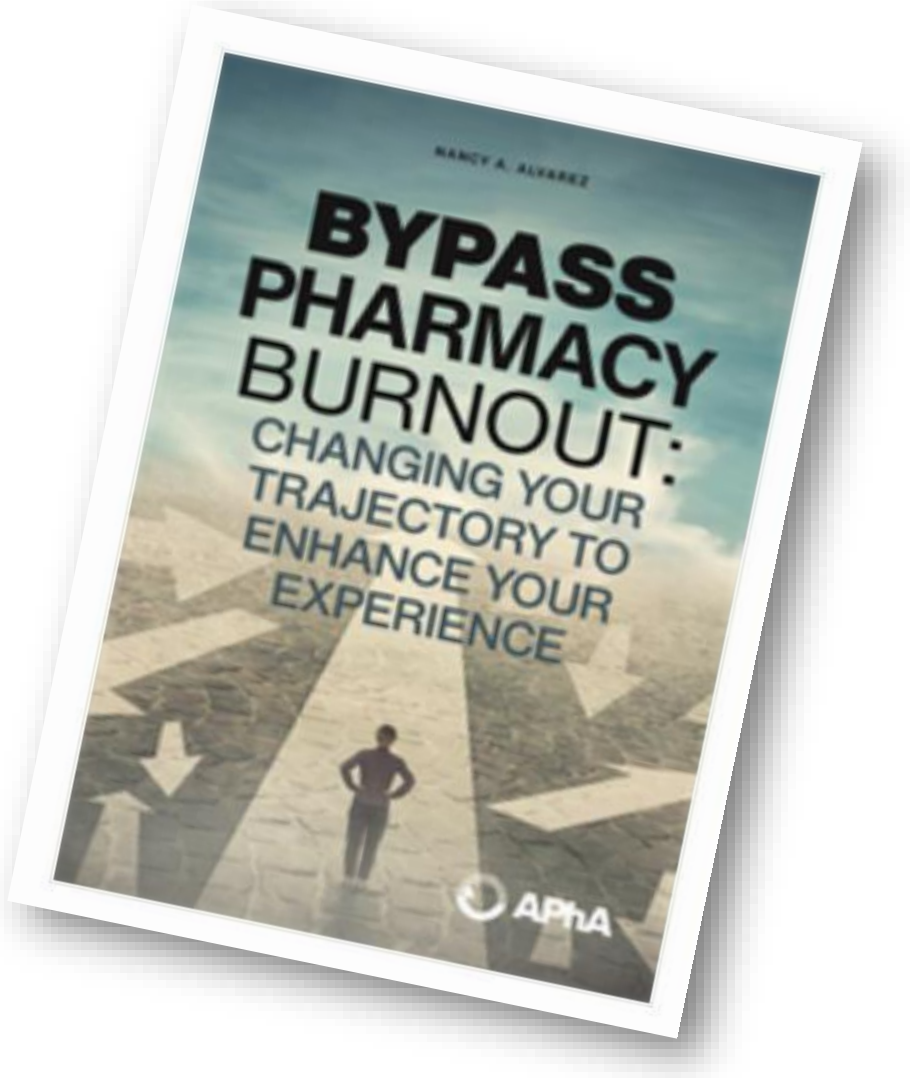
- Provide staffing support
- Separate vaccination areas
- Label the syringes.
- Separate the vaccines.
- Identify the patient & requested vaccine
- Involve the patient/parent in the checking process
- Document lot number/expiration date
- Scan the barcode
- Report vaccine errors internally as well as to the VAERS, which is mandatory for errors with the COVID-19 vaccines available under an EUA; ISMP also asks providers to report vaccine errors to the ISMP National Vaccine Errors Reporting Program (ISMP VERP)

APhA/NASPA Launch Pharmacy Workplace and Well-being Reporting (PWWR) Portal

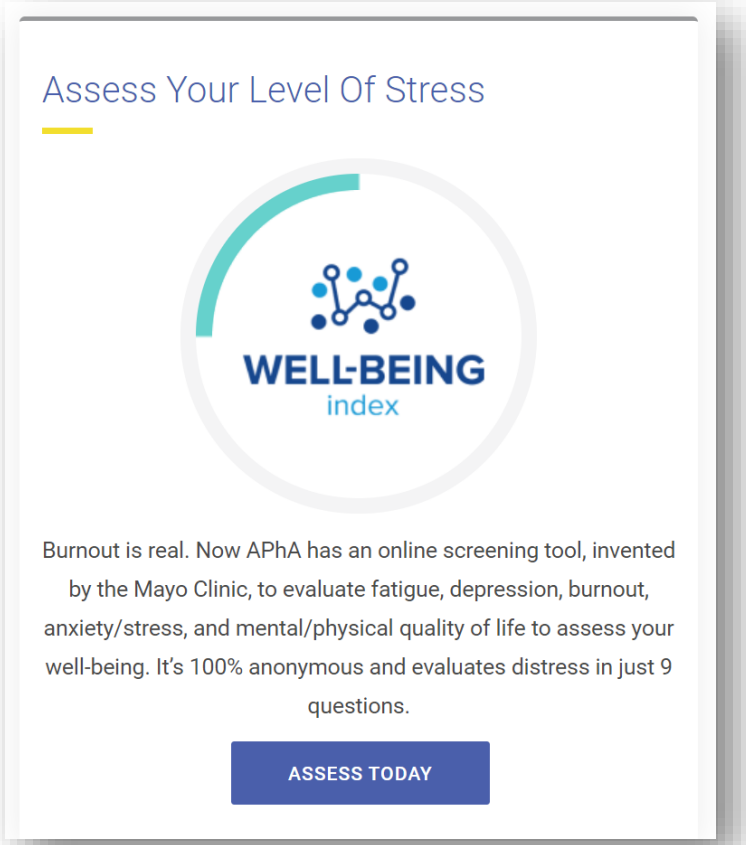
- Your voice is critical to enhancing and safeguarding the pharmacy workplace
- Pharmacists and pharmacy personnel are invited and encouraged to share their experiences—both positive and negative
- Your confidential and anonymous report will be collected and analyzed by a recognized and listed Patient Safety Organization (PSO), the Alliance for Patient Medication Safety (APMS)
- Respondents are afforded federal confidentiality and privilege protections, so you can voice and amplify your concerns and suggest suggestions without fear of identification or retaliation
- Access the portal and share your story today!

Book Launch!

- Aims to address how pharmacists can take care of their own well-being and individual personal development
- Provides readers with the skills to empower you to make the choices needed to cultivate happiness in both your life and career
- Read Bypass Pharmacy Burnout



Wellbeing Index for Pharmacists



- Anonymously assess your well-being
- Monitor by taking the assessment periodically
- Evaluate multiple dimensions of distress
- Access the Index & other resources at https://www.pharmacist.com/wellbeing

Join Us!

Thursday, October 28, 1:00-2:00 pm ET

Register here!

Today's webinar will be available soon

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

69

Which of the following is an appropriate interpretation of outcomes from a study that are not pre-specified?

a) They should be considered hypothesis generating only
b) They should only be considered clinically relevant if the p-value is highly significant (i.e., <0.001)
c) They should always be ignored, since they weren't pre-specified
d) They can be used for clinical decision making without further study as long as they demonstrate statistical significance

Which declaration provided pharmacists with the authority to order and administer COVID 19 therapeutics?

a) Federal Support Act, 1st amendment
b) PREP Act, 9th amendment
c) PREP Act, 5th amendment
d) DSHEA Act, 4th amendment

To implement a successful monoclonal antibody (mAb) therapy program (using sub-Q injections), the following steps should be taken, EXCEPT:

a) Determine which mAb product you will provide
b) Identify a safe and secure area to provide the mAb for treatment
c) Review how the product will be prepared for administration
d) Determine what documentation and/or reporting is needed

To claim CE

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 Therapeutics: Evidence-based Care and Practice Opportunities” session listed in your enrollments
4. Click on “COVID-19 Therapeutics: Evidence-based Care and Practice Opportunities ” under the “Activities” heading
5. Enter the attendance code
6. Complete the evaluation
7. Claim credit