



OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES

Pearls and Pitfalls of Pharmaceuticals in the COVID-19 Era

May 2021

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COI

In compliance with AOA and ACCME guidelines, I hereby declare:

- *I have financial/other relationships with the manufacturer(s) of commercial product(s) or provider(s) of commercial service(s). I will not promote the products or interests of these organizations/individuals in the content of this lecture.*
 - *Eli Lilly / National Institute of Allergy and Infectious Diseases*
- *Kelly Murray, PharmD*







Objectives

After participating in this presentation, the physician will be able to:

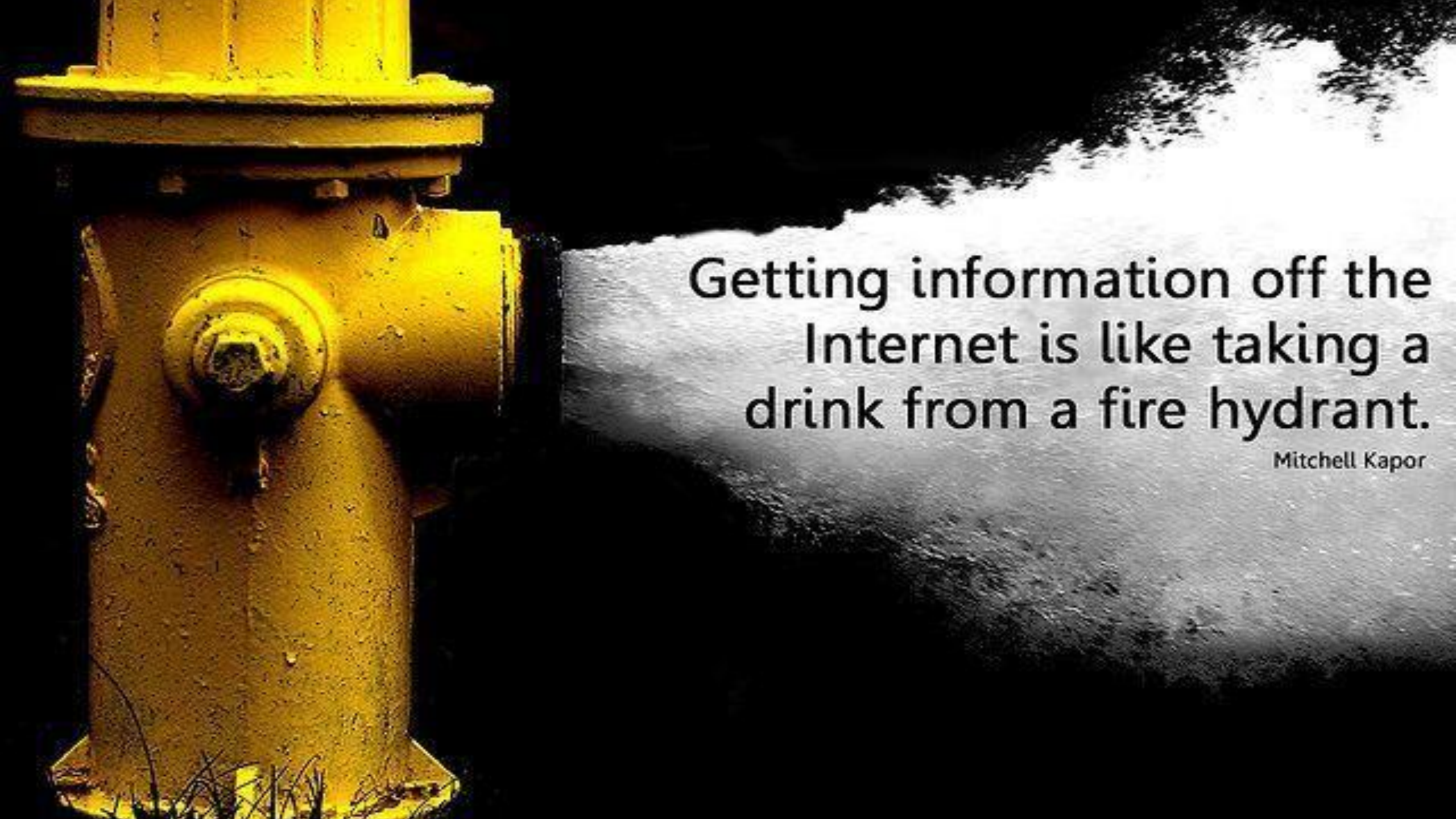
- Identify optimal clinical outcomes in COVID-19 pharmacotherapy studies
- Recall key outcomes from notable U.S. and international COVID-19 research studies
- Discuss medications without sufficient evidence to support use

Pitfalls of COVID-19 Pharmacotherapy



Pitfalls of Pharmacotherapy

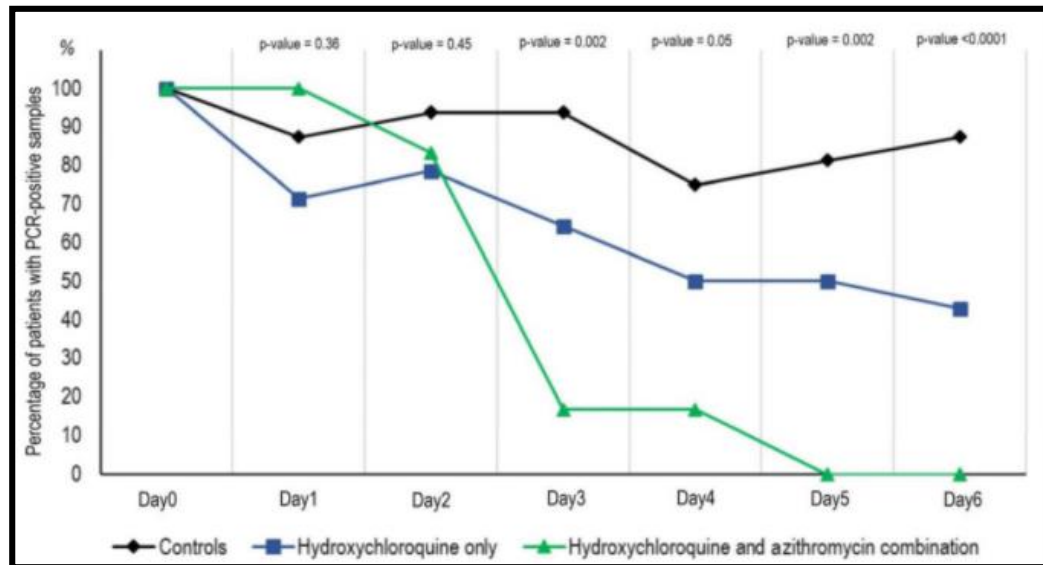
- Pace of information
- Preprints and press releases
- Emergency Use Authorization
- Repurposing
- Social media
- Meaningful study outcomes
- Fear of harm



Getting information off the
Internet is like taking a
drink from a fire hydrant.

Mitchell Kapor

Pitfalls of Pharmacotherapy: Preprints



Gautret et al. (2020). International Journal of Antimicrobial Agents – In Press 17 March 2020 – DOI : 10.1016/j.ijantimicag.2020.105949

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COVID-19 Preprints and Their Publishing Rate: An Improved Method

Francois Lachapelle
doi: <https://doi.org/10.1101/2020.09.04.20188771>

This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

Lachapelle F. medRxiv 2020.09.04.20188771; doi: <https://doi.org/10.1101/2020.09.04.20188771>

Emergency Use Authorization

- Section 564 of Federal Food, Drug, and Cosmetic Act
 - Effective 27 March 2020
- EUAs issued
 - Bamlanivimab + etesevimab
 - Casirivimab + imdevimab
 - Baricitinib + remdesivir
 - Convalescent plasma
 - Remdesivir (certain patients)
- EUAs revoked
 - Hydroxychloroquine
 - Remdesivir (FDA approval)
 - Bamlanivimab monotherapy

<https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>

Emergency Use Authorization Declaration

A Notice by the [Health and Human Services Department](#) on 04/01/2020



PUBLISHED DOCUMENT



AGENCY:

Department of Health and Human Services.

ACTION:

Notice of Emergency Use Authorization Declaration.

SUMMARY:

The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES:

The determination was effective February 4, 2020, and this declaration is effective March 27, 2020.

DOCUMENT DETAILS

Printed version:

[PDF](#)

Publication Date:

04/01/2020

Agencies:

[Department of Health and Human Services](#)
Office of the Secretary

Dates:

The determination was effective February 4, 2020, and this declaration is effective March 27, 2020.

Effective Date:

02/04/2020

Document Type:

Notice

Document Citation:

85 FR 18250

Page:

18250-18251 (2 pages)

Document Number:

2020-06905

DOCUMENT DETAILS

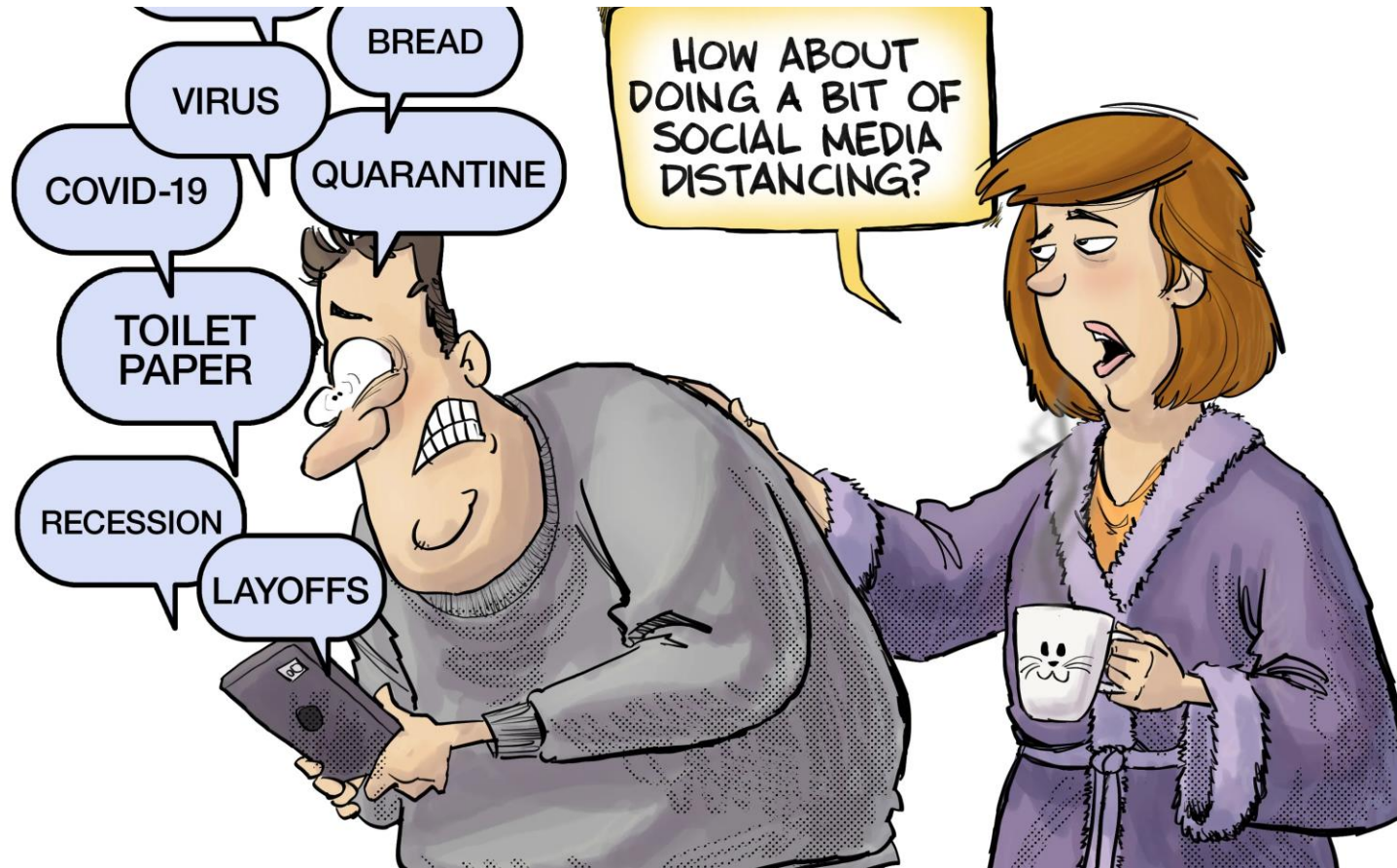
DOCUMENT STATISTICS

Pitfalls of Pharmacotherapy: **Repurposing Medications**

- Remdesivir initially studied for Ebola
- Baricitinib for Rheumatoid Arthritis (RA)
- Tocilizumab for RA
- Hydroxychloroquine for malaria, lupus, RA
- Ivermectin for onchocerciasis, strongyloidiasis



Pitfalls of Pharmacotherapy: Social Media



Pitfalls of Pharmacotherapy:

Meaningful Study Outcomes?

- Viral Load
- Viral Clearance
- Hospital discharge
- Time to recovery
- Mortality
- Mechanical ventilation
- ICU admission
- Hospital admission

Pitfalls of Pharmacotherapy:

Fear of causing harm

- First, Do No Harm
- Medication risks unknown
- Disease state risks unknown



Pitfalls of Pharmacotherapy:

Cost of Medications

- Dexamethasone 6 mg daily
 - PO x 10 days **~\$10**
 - IV x 10 days **~\$20**
- Remdesivir 200 mg x 1 then 100 mg
 - x 4 days **~\$3,120**
 - x 9 days **~\$5,720**

Overview of Notable Research Studies

Notable Research Studies



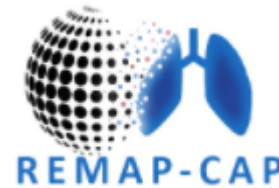
- N=12,000; 500 hospitals; 30 countries
- Repurposed drugs **remdesivir, hydroxychloroquine, lopinavir/ritonavir, interferon** had little to no effect on 28-day mortality or in-hospital course of COVID-19

Notable Research Studies



- N=39,371; 181 sites
- Azithromycin (14 Dec 2020)
- Hydroxychloroquine (5 June 2020)
- Lopinavir/ritonavir (29 June 2020)
- Convalescent Plasma (15 Jan 2021)
- Dexamethasone (16 June 2020)
- Tocilizumab (11 Feb 2021)
- Colchicine (5 Mar 2021)

<https://www.recoverytrial.net/>



A Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for Community Acquired Pneumonia

- 200 sites in 19 countries
- Macrolide therapy
- Corticosteroid
- Antivirals
- Immunomodulators
- Renin-angiotensin-aldosterone inhibitors
- Anticoagulation
- High dose vitamin C
- Simvastatin
- Aspirin or P2Y12 inhibitor
- Convalescent plasma

<https://www.remapcap.org/>

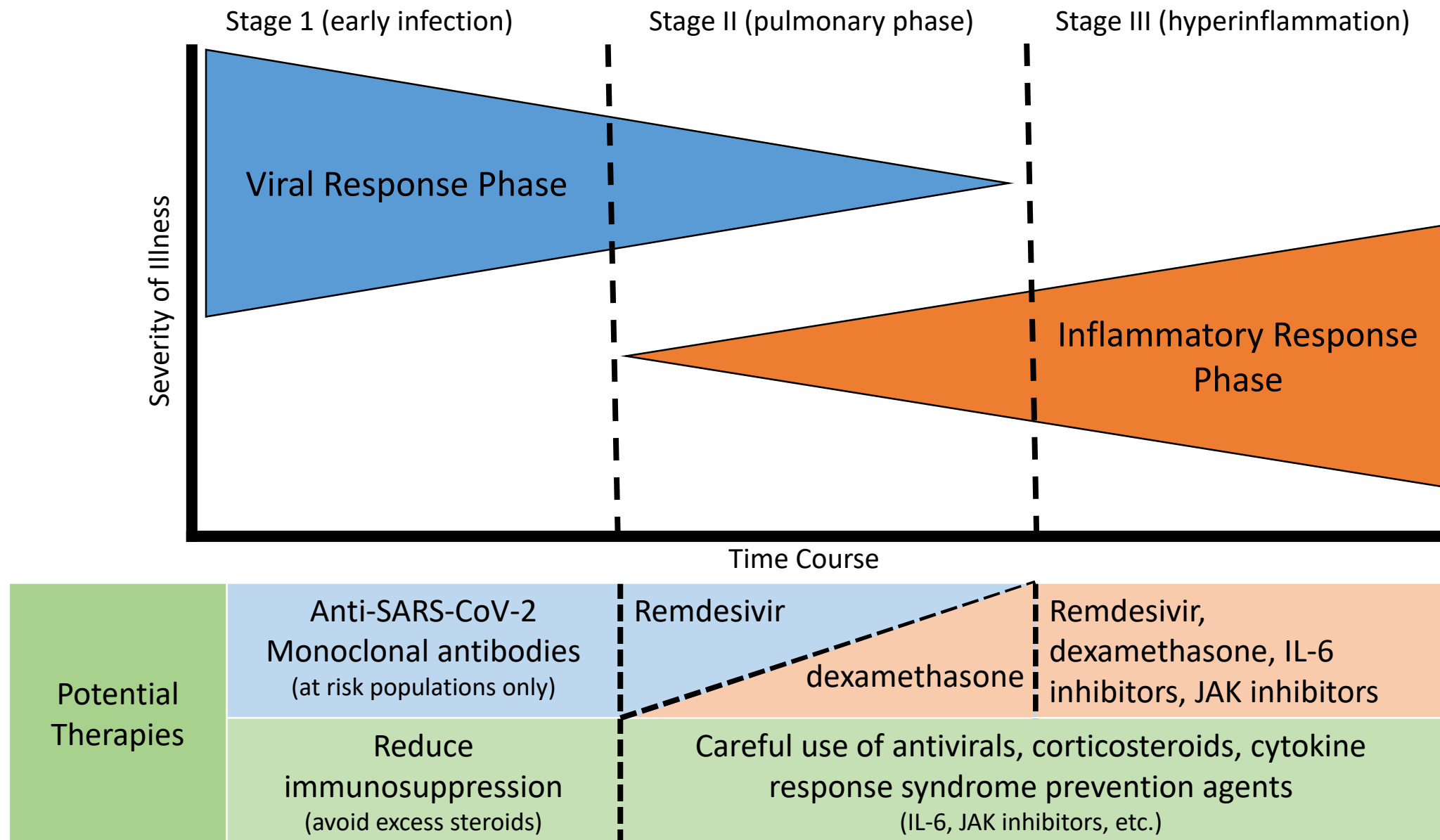
Notable Research Studies

ACCELERATING COVID-19 THERAPEUTIC INTERVENTIONS AND VACCINES (ACTIV)

- ACTIV-
 - 1 - Immune modulator compounds
 - 2 - Outpatient monoclonal antibodies and other therapies
 - 3 - Inpatient monoclonal antibodies
 - 4 - Antithrombotics
 - 5 - Big Effect Trial - remdesivir plus monoclonal antibody vs remdesivir plus placebo
- ACTT trials (The Adaptive COVID-19 Treatment Trials)
 - ACTT-1 - placebo, remdesivir
 - ACTT-2 - placebo, remdesivir, baricitinib
 - ACTT-3 - placebo, remdesivir, interferon beta-1a
 - ACTT-4 - placebo, remdesivir, baricitinib, dexamethasone

General Treatment Approaches

Treatment Approach



NIH Recommendations

Not hospitalized
(Mild/Moderate COVID-19)

- High risk: Bamlanivimab 700 mg + etesevimab 1400 mg (AIIa) or casirivimab 1200 mg + imdevimab 1200 mg (AIIa)
- Recommend against dexamethasone or other corticosteroids (AIII)

Hospitalized, no oxygen requirement

- Recommend against dexamethasone or other corticosteroids (AIII)
- Insufficient data to recommend for/against remdesivir

Hospitalized, oxygen required

- Remdesivir (BIIa) OR
- Dexamethasone plus remdesivir (BIII) OR
- Dexamethasone (when remdesivir n/a) (BI)

Hospitalized, requires HFNC/NIMV

- Dexamethasone (AI)
- Dexamethasone plus remdesivir (BIII)
- If recently hospitalized with increasing O2 need: add tocilizumab to one of the above options (BIIa)

Hospitalized, requires IMV or ECMO

- Dexamethasone (AI)
- If within 24 hours of admission to ICU: dexamethasone plus tocilizumab (BIIa)

Medications for COVID-19

Medications for COVID-19

Guideline Based Recommendations

- Remdesivir
- Monoclonal Antibodies
- Dexamethasone
- Tocilizumab
- Baricitinib

Additional Notable Primary Literature

- Budesonide
- Colchicine
- Ivermectin

Remdesivir

- Pearls:
 - Best benefit in hospitalized patients requiring oxygen
 - Reduced viral response + hydroxychloroquine
 - ACTT-1 = shorter time to recovery (10 vs. 15 days)
 - SOLIDARITY = drug did not reduce mortality, IMV, hospital duration
 - Inhaled version in Phase I
- Pitfalls:
 - Guidelines do not agree on place in therapy
 - Mortality benefit not yet proven

Monoclonal Antibodies

REGN-COV2, a Neutralizing Antibody Cocktail, in Outpatients with Covid-19

David M. Weinreich, M.D., Sumathi Sivapalasingam, M.D., Thomas Norton, M.D., Shazia Ali, Pharm.D., Haitao Gao, Ph.D., Rafia Bhore, Ph.D., Bret J. Musser, Ph.D., Yuhwen Soo, Ph.D., Diana Rofail, Ph.D., Joseph Im, B.S., Christina Perry, M.B.A., Cynthia Pan, B.Pharm., et al., for the Trial Investigators*

Effect of Bamlanivimab as Monotherapy or in Combination With Etesevimab on Viral Load in Patients With Mild to Moderate COVID-19 A Randomized Clinical Trial

Robert L. Gottlieb, MD, PhD; Ajay Nirula, MD, PhD; Peter Chen, MD; Joseph Boscia, MD; Barry Heller, MD; Jason Morris, MD, MS; Gregory Huhn, MD, MPHTM; Jose Cardona, MD; Bharat Mocherla, MD; Valentina Stosor, MD; Imad Shawa, MD; Princy Kumar, MD; Andrew C. Adams, PhD; Jacob Van Naarden, BS; Kenneth L. Custer, PhD; Michael Durante, MS; Gerard Oakley, MD; Andrew E. Schade, MD, PhD; Timothy R. Holzer, PhD; Philip J. Ebert, PhD; Richard E. Higgs, PhD; Nicole L. Kallewaard, PhD; Janelle Sabo, PharmD; Dipak R. Patel, MD, PhD; Paul Klekotka, MD, PhD; Lei Shen, PhD; Daniel M. Skovronsky, MD, PhD

A Neutralizing Monoclonal Antibody for Hospitalized Patients with Covid-19

ACTIV-3/TICO LY-CoV555 Study Group*

Monoclonal Antibodies

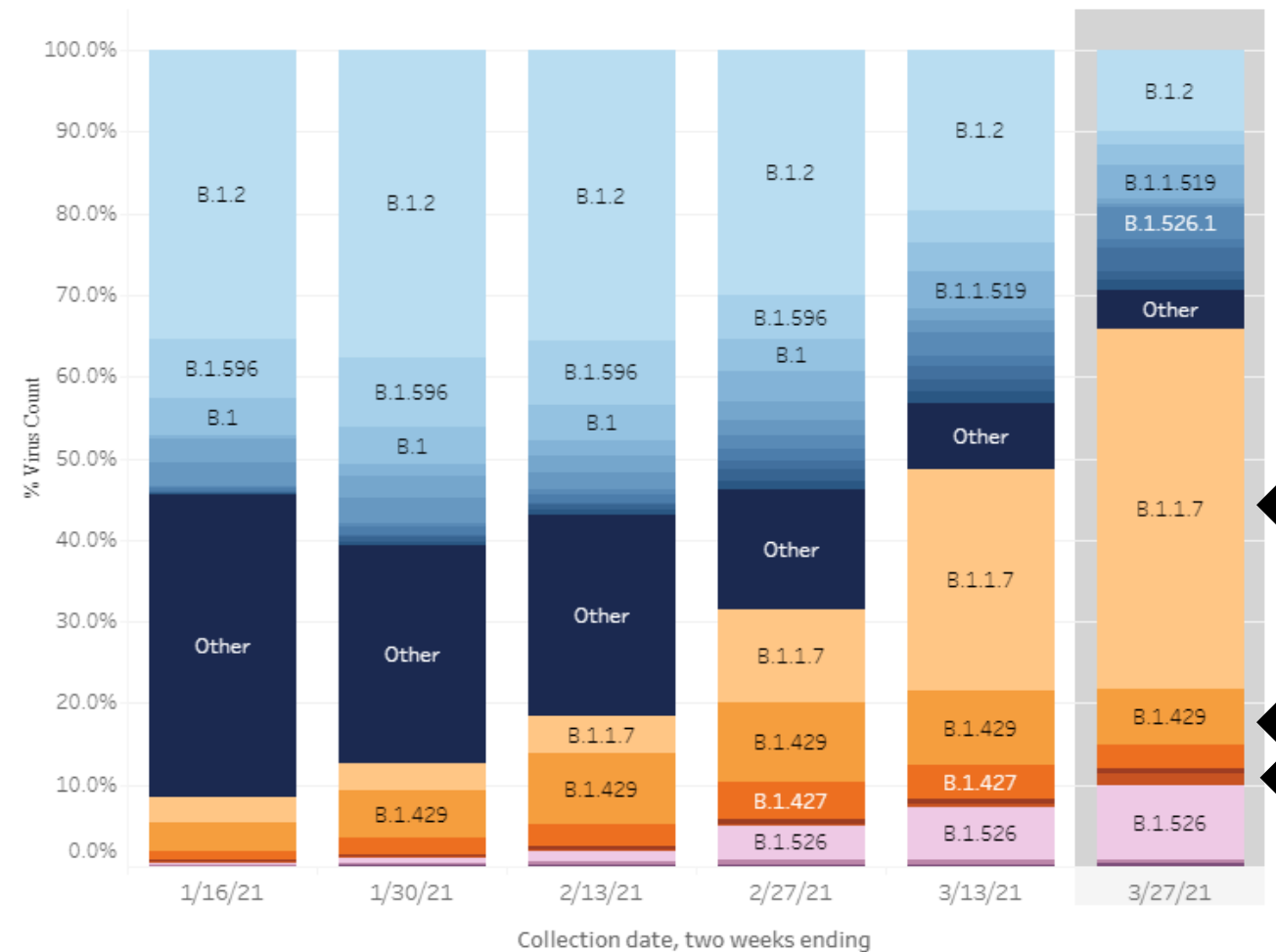
- Pearls:
 - EUAs define “at-risk populations” the same
 - Outpatients only, unless admitted to hospital for a non-COVID-19 reason
 - FDA MedWatch for adverse reactions
- Pitfalls:
 - Clinical endpoints needed to determine if benefit outweighs risk/cost
 - Wait 90 days for COVID-19 vaccine
 - Efficacy against variants (pseudovirus) varies
 - Bamlanivimab EUA revoked

COVID-19 Treatment Guidelines Panel. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed [24 Mar 2021].

CDC.gov. Interim clinical considerations for use of COVID-19 vaccines currently authorized in the United States. Last updated 5 March 2021. Accessed at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html> on 24 March 2021.

Variants in the United States by week

- B.1.1.7
 - “U.K. variant”
 - Increased frequency in U.S.
- B.1.351 (E484K)
 - “South African variant”
 - Infrequently detected in U.S.
- B.1.429/B.1.427 (L452R)
 - “California variant”
 - California, Arizona, Nevada



Monoclonal Antibodies:

Bamlanivimab + etesevimab

- Pearls:
 - NIH and IDSA guidelines agree on use in at-risk populations who are SARS-CoV-2 positive
 - BLAZE-1
 - Change in log viral load at day 11 = -0.057 (95% CI -1.00 to -0.14)
 - Hospitalization or ED visits 0.9% (1/112) vs. 5.8% (9/156)
 - Adverse Events:
 - Serious: 0/309 monotherapy, 1/112 combo, 1/156 placebo
 - Immediate hypersensitivity: 6/309 monotherapy, 2/112 combo, 1/156 placebo
 - Most common side effects: Nausea, diarrhea
- Pitfalls:
 - No clinical endpoint data
 - Different doses used in EUA vs. BLAZE-1 Phase 3 study
 - Availability not widespread
 - Retained efficacy against U.K. pseudovirus variant
 - Reduced efficacy against South African and California pseudovirus variants

CDC.gov. <https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-plus-etesevimab-eua/> accessed on 18 April 2021. Last updated 18 March 2021.

Gottlieb RL et al. Effect of Bamlanivimab as Monotherapy or in Combination with Etesevimab on Viral Load in Patients with Mild to Moderate COVID-19: A Randomized Clinical Trial. JAMA 2021;325(7):632-644.

Fact sheet. <https://www.fda.gov/media/145802/download> Accessed 26 Apr 2021.

Monoclonal Antibodies:

Casirivimab + imdevimab

- Pearls
 - NIH and IDSA guidelines agree on use in at-risk populations who are SARS-CoV-2 positive
 - Phase 1/Phase 2 results:
 - Reduced viral load
 - Reduced medical visits (6% of placebo vs. 3% of antibody cocktail)
 - Adverse events:
 - Serious: 4/258 regular dose, 2/260 high dose, 6/262 placebo
 - Hypersensitivity/infusion related: 0/258 regular dose, 4/260 high dose, 1/262 placebo
- Pitfalls
 - No clinical endpoint data
 - Remainder of phase 2 and 3 studies not peer reviewed
 - “Reduced risk of hospitalization and death by 70%”
 - Combination therapy retains efficacy against pseudovirus variants

Corticosteroids

- Pearls:
 - RECOVERY trial showed dexamethasone had lower 28-day mortality than standard of care alone (22.9% vs. 25.7%, NNT=29)
 - Greatest benefit in invasive mechanical ventilation (29.3% vs. 41.4%, NNT=8.5)
 - No benefit, potential harm with dexamethasone in group not requiring oxygen at baseline
 - Dexamethasone pharmacokinetics
 - Comparable dosing?
 - Prednisone 40 mg, methylprednisolone 3 mg, hydrocortisone 160 mg
- Pitfalls:
 - No other steroids have shown the same mortality benefit
 - Trials stopped early when RECOVERY trial results released
 - Delayed viral clearance if started in “viral response phase”

The RECOVERY Collaborative Group. Dexamethasone in hospitalized patients with COVID-19. N Engl J Med 2021;384:693-704.

COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed [24 Mar 2021].

IL-6 Antibodies: Tocilizumab

- Pearls:
 - Tocilizumab (8 mg/kg, max 800 mg single dose) + dexamethasone (10 days)
 - Hospitalized (<3 days), admitted to ICU (<24 hours), and require IMV, NIMV, HFNC, or rapid decline
 - Mortality benefit seen in REMAP-CAP and RECOVERY trials
 - REMAP-CAP: mortality benefit, shorter time to hospital discharge, fewer days on organ-support
 - RECOVERY: mortality benefit, shorter median time to be discharged alive
- Pitfalls:
 - RECOVERY- preprint, not yet peer-reviewed
 - Insufficient evidence to determine which patients benefit
 - Avoid in immunocompromised patients, high ALT, GI perf. risk, infection other than SARS-CoV-2, ANC <500, PLT <50,000
 - Strongyloidiasis infection
 - Availability and cost
 - No EUA for this medication

Janus Kinase Inhibitors: Baricitinib

- Pearls:
 - EUA approved for use with remdesivir in hospitalized patients requiring supplemental oxygen, IMV, or ECMO
 - ACTT-2 study showed
 - Shorter time to recovery (7 days vs. 8 days, $p=0.47$)
 - Mortality difference not significant
 - Always to be used with remdesivir (AIII)
- Pitfalls:
 - Data is insufficient to recommend for or against use
 - If corticosteroids cannot be used, NIH recommends remdesivir + baricitinib (BIIa)
 - Corticosteroid recommendations changed during ACTT-2
 - eGFR dosing
 - Potentially higher thromboembolic risk; prophylaxis required
 - Studies with ruxolitinib, tofacitinib not significant

Fact sheet for healthcare providers. Emergency Use Authorization of Baricitinib. Accessed at <https://www.fda.gov/media/143823/download> on 24 March 2021.

Kalil AC, et al. Baricitinib plus remdesivir for hospitalized adults with COVID-19. N Engl J Med 2021; 384:795-807.; COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Accessed [24 Mar 2021].

Budesonide

- Pearls
 - STOIC trial: 800 mcg inh BID vs. usual care started in non-hospitalized adults with symptoms suggestive of early COVID-19
 - Budesonide started within 3 days, continued for 7
 - Urgent care/ED/hospitalizations decreased in treatment group (2 vs 11, $p=0.009$), **NNT=8**
 - Fewer persistent symptoms at days 14 and 28
 - 5 patients with treatment-limiting adverse events
- Pitfalls
 - Not included in NIH guidelines (yet?)
 - More studies needed

Colchicine

- Pearls
 - Anti-inflammatory drug that may reduce neutrophil chemotaxis, inhibit inflammasome signaling, and decrease production of cytokines (IL-1 beta)
- Pitfalls
 - Patient outcomes centered data has not supported use
 - COLCORONA (outpatient)
 - No difference in death or hospitalization by day 30
 - More GI symptoms in treatment arm (13.7% vs 7.3%, $p < 0.001$)
 - More pulmonary emboli in treatment arm (11 vs. 2, $p = 0.01$)
 - RECOVERY (hospitalized) - halted early for futility

Ivermectin

- Pearls
 - Anti-parasitic, anthelmintic
 - Well tolerated at regular doses
 - Shown to inhibit replication of SARS-COV-2 in cell cultures
- Pitfalls
 - Dose required to inhibit replication is ~100 fold higher than usual dose
 - High doses can cause allergic reactions, seizures, liver injury, death
 - Not FDA approved for any viral infection
 - Insufficient evidence to recommend for or against ivermectin in COVID-19
 - Ivermectin for animal use is not safe for human use

Resources

FDA MedWatch: Adverse Event Reporting



Required by
Emergency Use
Authorizations



FDA MedWatch
Form



Sign up for FDA
MedWatch
Emails

[Reset Form](#)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500 (2/19)

The FDA Safety Information and
Adverse Event Reporting Program

For VOLUNTARY reporting of
adverse events, product problem
and product use/medication error

Page 1 of 2

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

A. PATIENT INFORMATION

1. Patient Identifier

In Confidence

2. Age

Year(s) Month(s)
 Week(s) Day(s)

or Date of Birth (e.g., 08 Feb 1925)

3. Gender
(check one)

☐ Female
☐ Male
☐ Intersex
☐ Transgender
☐ Prefer not to disclose

4. Weight

lb
 kg

5. Ethnicity (check one)

☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. Race (check all that apply)

☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Type of Report (check all that apply)

2. Dose or Amount

#1

#2

3. Treatment Duration
of length of treatment

#1 Start

#1 Stop

Is therapy still ongoing?

#2 Start

#2 Stop

Is therapy still ongoing?

5. Product Type

#1 ☐ OTC
☐ Combination
☐ Generic
☐ Biosimilar

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/about-medwatch-e-list>

Pharmacotherapy Quick Reviews

- American Society of Health Systems Pharmacists
 - <https://www.ashp.org/COVID-19>
- Society of Infectious Diseases Pharmacists
 - <https://sidp.org/covid19therapeuticreviews>

Updated 03-11-2021. The current version of this document can be found on the [ASHP COVID-19 Resource Center](#).

AHFS
Clinical Drug Information

Assessment of Evidence for COVID-19-Related Treatments: Updated 03/11/2021

The information contained in this evidence table is emerging and rapidly evolving because of ongoing research and is subject to the professional judgment and interpretation of the practitioner due to the uniqueness of each medical facility's approach to the care of patients with COVID-19 and the needs of individual patients. ASHP provides this evidence table to help practitioners better understand current approaches related to treatment and care. ASHP has made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information in the evidence table in any and all practice settings. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this evidence table and will bear no responsibility or liability for the results or consequences of its use.

ASHP's patient medication information is available at <http://www.safemedication.com/>. Visit our [website](#) for the latest information on current drug shortages.

Selected entries were updated 03/11/2021; these can be identified by the date that appears in the Drug(s) column. Within updated entries, select revisions that include the most important new information (e.g., new clinical trial data, new or revised guidance) are marked by **.

TABLE OF CONTENTS		
ANTIVIRAL AGENTS	SUPPORTING AGENTS	OTHER
<ul style="list-style-type: none">BALOXAVIRCHLOROQUINE PHOSPHATEUPDATED FAVIPIRAVIR (Avigan®, Avifavir®, Favilavir)HIV PROTEASE INHIBITORS (e.g., LPV/RTV, Kaletra®)HYDROXYCHLOROQUINE (Plaquenil®)NEURAMINIDASE INHIBITORS (e.g., oseltamivir)REMEDSIVIR (Veklury®)UPDATED SARS-CoV-2-SPECIFIC MONOCLONAL ANTIBODIESUMIFENOVIR (Arbidol®)	<ul style="list-style-type: none">ANAKINRA (Kineret®)UPDATED ASCORBIC ACIDUPDATED AZITHROMYCINBARICITINIB (Olumiant®)UPDATED COLCHICINEUPDATED CORTICOSTEROIDS (systemic)CORTICOSTEROIDS (inhaled)INHALED PROSTAGLANDINSUPDATED INTERFERONSNITRIC OXIDE (inhaled)RUXOLITINIB (Jakafi®)UPDATED SARILUMAB (Kevzara®)SILTUXIMAB (Sylvant®)SIRILIMUS (Rapamune®)UPDATED TOCILIZUMAB (Actemra®)VITAMIN DUPDATED ZINC	<ul style="list-style-type: none">ACE INHIBITORS, ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs)ANTICOAGULANTSUPDATED COVID-19 CONVALESCENT PLASMAFAMOTIDINEUPDATED HMG-CoA REDUCTASE INHIBITORS (statins)IMMUNE GLOBULINIVERMECTINNEBULIZED DRUGSNICLOSAMIDENITAZOXANIDE (Alinia®)NONSTEROIDAL ANTI-INFLAMMATORY AGENTS (NSAIDs)THROMBOLYTIC AGENTS (t-PA [alteplase], tenecteplase)

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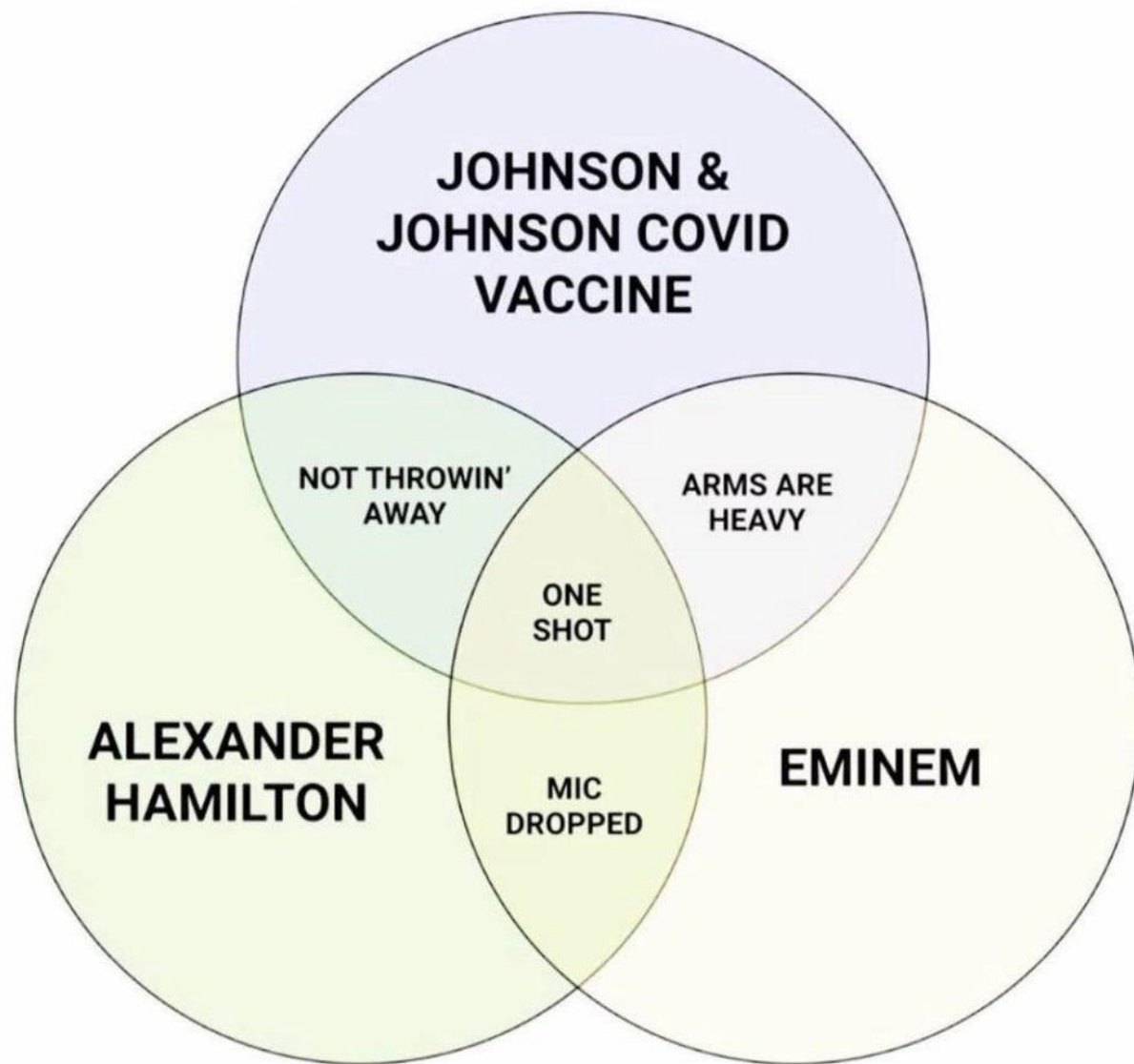
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Key Takeaways

Key Takeaways

- Each COVID-19 pharmacotherapy pitfall was well-intentioned
- Outcomes
 - Mortality benefit: dexamethasone
 - Mortality benefit?: tocilizumab + dexamethasone
 - Shorter time to recovery: remdesivir alone and with baricitinib
 - Decreased ED/hospitalizations: monoclonal antibody cocktail, budesonide(?)
- Continue to evaluate studies and reliable information sources for clinically relevant outcomes
- Report adverse events to FDA MedWatch





Thank you!

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