NURSE PRACTITIONER
2021 Virtual CE Summit

Evolving Recommendations Regarding COVID-19: What You Need to Know

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Faculty Disclosures

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Learning Objectives

- Explain the impact of COVID-19 on healthcare providers and health system infrastructures
- Discuss the epidemiology, clinical features, differential diagnosis, and treatment of COVID-19
- Review emerging vaccines and treatment options for patients with COVID-19

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Introduction

Audience Polling Question

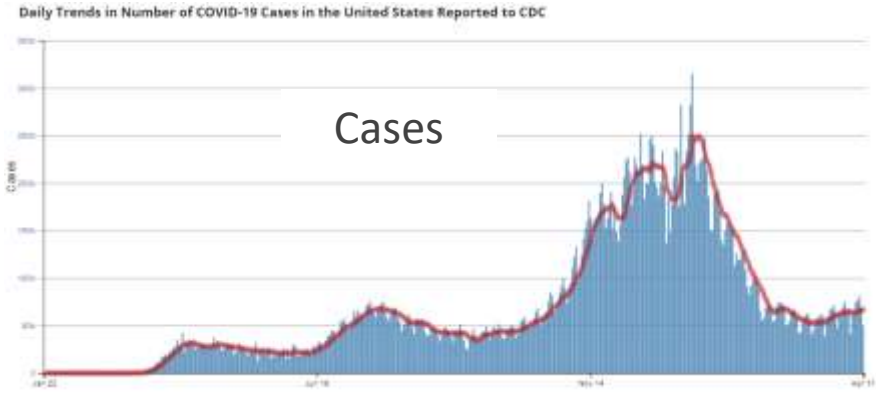
What is your agreement with the following statement?

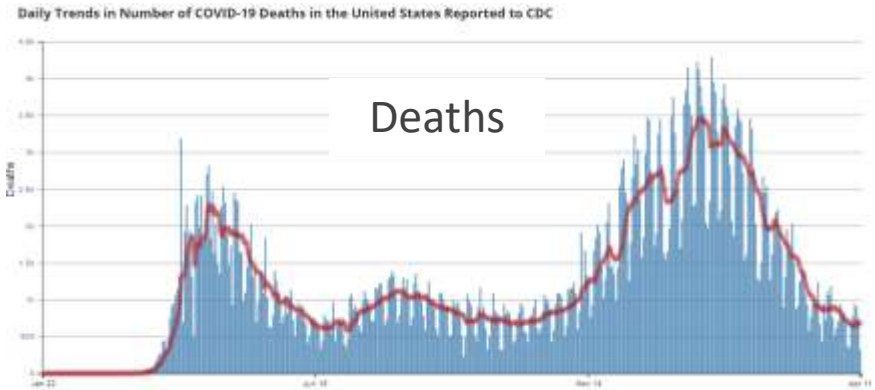
My healthcare system was sufficiently prepared to respond to the COVID-19 pandemic.

A. Strongly agree
B. Agree
C. Neutral
D. Disagree
E. Strongly disagree

Current COVID-19 Cases & Deaths in the US *as of May 12, 2021*

Total Cases	7-Day Case Rate Per 100,000	Total Deaths
32,571,814	80.5	579,366





Centers for Disease Control and Prevention. Accessed May 12, 2021. https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

Audience Polling Question

According to past surveys of health care workers, a good number of them believe that ***medical and nursing staff have a duty to deliver care to sick people even if it exposes them to personal danger***

What is your agreement with the above statement?

A. Strongly agree
B. Agree
C. Neutral
D. Disagree
E. Strongly disagree

Fear on the Front Lines

General practitioners account for 1/3rd of COVID-19 mortality among healthcare workers

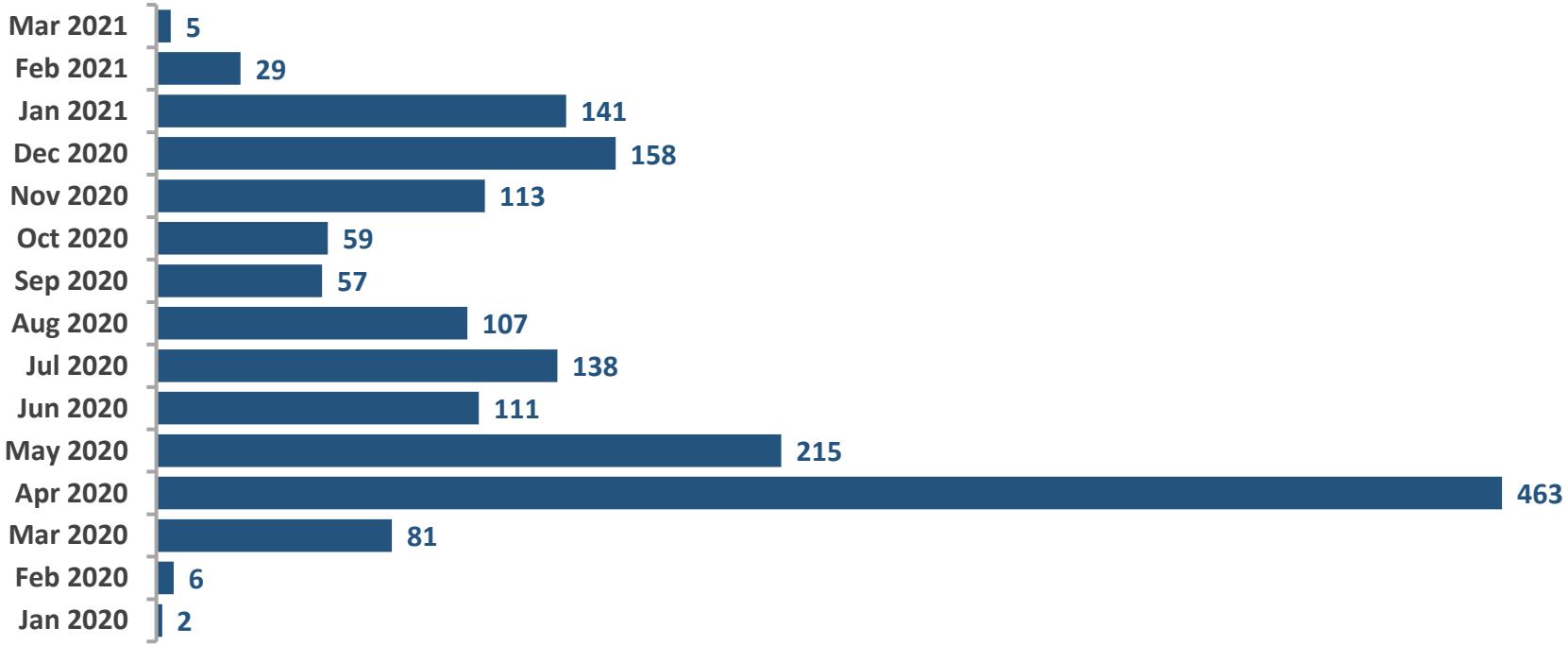
Mental health outcomes reported by HCPs on the frontlines of COVID-19

Risk of COVID-19 among front-line health-care workers and the general community: a prospective cohort study *Lancet Public Health* 2020; 5: e475–83

US Healthcare Worker Mortality in the First Year of the Pandemic

The highest number of the deaths were early in the pandemic

Of the 1,694 people for whom we have information on the exact date they died.



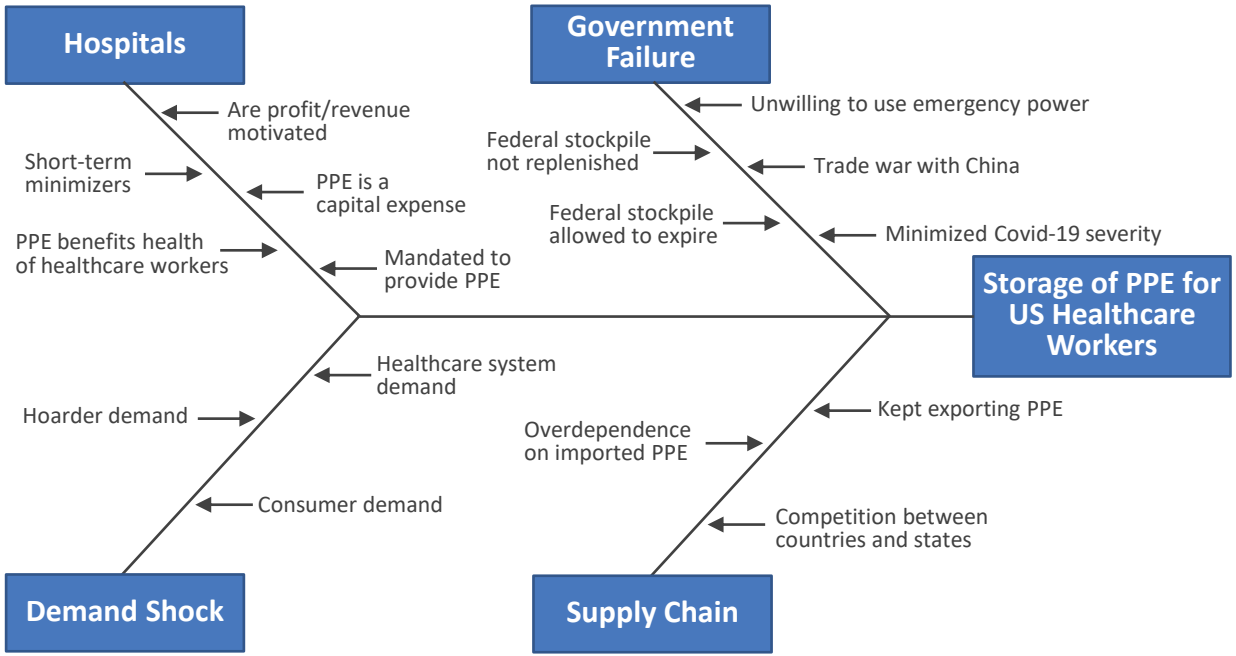
Joint KHN/Guardian Report. Available at: https://www.theguardian.com/us-news/ng-interactive/2020/dec/22/lost-on-the-frontline-our-findings-to-date

Shortage of PPE for US Healthcare Workers

How has the PPE shortage affected your practice since the pandemic began?

Is your institution still experiencing shortages?

Factors Contributing to PPE Shortage[1]



PPE, personal protective equipment.

Cohen J, van der Meulaen Rodgers Y. *Prev Med*. 2020;141:106263.

Discussion: Past, Present, and Future of Healthcare

- **COVID-19's long-term threat**
  - Have we passed the worst?
  - When will non-COVID patient volumes return?
- **Infection prevention**
  - How will regulatory bodies heighten infection prevention protocols, equipment inventory, and data collection?
- **Revenue loss**
  - How will the healthcare provider organization landscape evolve as so many struggle to stay afloat financially?
- **Virtual care**
  - Can virtual care improve chronic disease management, discharge management, readmissions, and reduce visits to emergency departments and urgent cares?

Audience Polling Question

What is your agreement with the following statement?

I am confident in my ability to diagnose and manage the treatment of a patient with COVID-19.

A. Strongly agree
B. Agree
C. Neutral
D. Disagree
E. Strongly disagree

COVID-19 Clinical Presentation & Screening

- Estimated incubation period up to 14 days from exposure
- Spectrum of illness ranges from asymptomatic to severe pneumonia with acute respiratory distress and death
- Screening patients before they enter a facility:
  - Reduces exposures for other patients and healthcare personnel
  - Helps prevent the spread of disease within the facility
  - Helps ensure personal protective equipment (PPE) is used effectively

The COVID-19 Treatment Guidelines Panel regularly updates the recommendations in these guidelines as new information on the management of COVID-19 becomes available. The most recent version of the guidelines can be found on the COVID-19 Treatment Guidelines website (https://www.covid19treatmentguidelines.nih.gov/).

Diagnosing COVID-19: NAATs vs Antigen Tests

	Nucleic Acid Amplification Tests (NAATs)	Antigen Tests
Intended use	Detect current infection	Detect current infection
Analyte Detected	Viral Ribonucleic Acid (RNA)	Viral antigens
Specimen Type(s)	Nasal, nasopharyngeal, sputum, saliva	Nasal, nasopharyngeal
Sensitivity	Varies by test, but generally high	Moderate
Specificity	High	High
Text Complexity	Varies by test	Relatively easy to use
Authorized for Use at the Point-of-Care	Most are not, some are	Most are, some are not
Turnaround Time	Ranges from 15 minutes to >2 days	Ranges from 15 minutes to >2 days
Cost/Test	Moderate (~$100/test)	Low ($5 - $50/test)

Centers for Disease Control. Interim guidance for antigen testing for SARS-CoV-2. Updated Dec 16, 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Ambulatory Care of Mild-to-Moderate Disease

IDSA

Bamlanivimab + etesevimab or casirivimab + imdevimab:

- *Suggested* for select patients:
  - ✔ Mild-to-moderate COVID-19
  - ✔ High risk of progression to severe disease
  - ✔ Hospital admission for non-COVID-19 reasons
- Consider local variant susceptibility in choice of neutralizing antibody
- Limited efficacy data for high-risk 12-18YOs

Ivermectin:

- *Suggested against* except in clinical trial

Baricitinib + remdesivir + corticosteroids:

- *Recommended only* in context of a clinical trial

NIH

Specific antiviral or antibody therapy:

- Data insufficient to recommend either for or against specific therapies

SARS-CoV-2 neutralizing antibodies

- Bamlanivimab + etesevimab & casirivimab + imdevimab
- Available through EUAs for outpatients at high risk of disease progression
- EUA does not authorize use in hospitalized patients

Dexamethasone

- Do not use

Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19. Available at: https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/. Accessed April 21, 2021.
https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/. Accessed April 21, 2021.

Care of Hospitalized Patients: IDSA Guidelines

Hospitalized: **mild-to-moderate disease without need for supplemental oxygen**	**Corticosteroids: suggest against use** **Tocilizumab: suggest against routine use** **Convalescent plasma: recommended only in the context of a clinical trial** **Remdesivir: suggest against routine use** **Famotidine: suggest against use except in a clinical trial**
Hospitalized: **severe but noncritical disease** **(spO_2 <94% on room air)**	**Corticosteroids: suggest use** If dexamethasone is unavailable, equivalent total daily doses of alternative glucocorticoids may be used **Tocilizumab: suggest against routine use** **Convalescent plasma: recommended only in the context of a clinical trial** **Remdesivir: suggest use** In patients on mechanical ventilation or ECMO, duration of treatment is 10 days. **Famotidine: suggest against use except in a clinical trial** **Bamlanivimab or casirivimab/imdevimab: recommended against use** **Baricitinib + remdesivir: suggest use** For hospitalized patients who cannot receive corticosteroids because of a contraindication. Baricitinib 4 mg daily dose for 14 days (or until hospital discharge). The benefits of baricitinib plus remdesivir for persons on mechanical ventilation are uncertain **Ivermectin: suggests against use except in clinical trial**
Hospitalized: **critical disease**	**Corticosteroids: recommend use** If dexamethasone is unavailable, equivalent total daily doses of alternative glucocorticoids may be used **Tocilizumab: suggest against routine use** **Convalescent plasma: recommended only in the context of a clinical trial** **Remdesivir: suggest use** Remdesivir appears to demonstrate the most benefit in those with severe COVID-19 on supplemental oxygen rather than in patients on mechanical ventilation or ECMO. **Famotidine: suggest against use except in a clinical trial**

Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19. Available at: https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/. Accessed February 13, 2021.

Care of Hospitalized Patients: NIH Guidance

Hospitalized[a] but does not require supplemental oxygen	**Dexamethasone** should not be used **(AIIa)**. There are insufficient data to recommend either for or against the routine use of **remdesivir**. For patients at high risk of disease progression, the use of remdesivir may be appropriate.
Hospitalized[a] and requires supplemental oxygen (But does not required oxygen delivery through a high-flow device, noninvasive ventilation, invasive mechanical ventilation, or extracorporeal membrane oxygenation [ECMO])	Use one of the following options: • **Remdesivir** (eg, for patients who require minimal supplemental oxygen) **(BIIa)** • **Dexamethasone plus remdesivir** (eg, for patients who require increasing amounts of supplemental oxygen) **(BIII)** • **Dexamethasone** (eg, when combination therapy with remdesivir cannot be used or is not available) **(BI)**
Hospitalized[a] and requires oxygen delivery through a high-flow device or noninvasive ventilation	Use one of the following options: • **Dexamethasone (AI)** • **Dexamethasone plus remdesivir (BIII)**
Hospitalized[a] and requires invasive mechanical ventilation or ECMO	**Dexamethasone (AI)**

Ratings of Recommendations: A = strong; B = moderate; C = optional; **Rating of Evidence:** I = one or more randomized trials without major limitations; IIa = other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = expert opinion.

https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/

Inpatient Treatment of COVID-19

- Monoclonal antibodies work for outpatients but are **not recommended** for inpatients
- Dexamethasone has been found to ***improve survival*** in hospitalized patients who require oxygen
  - Greatest effect seen in patients on mechanical ventilation

https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/

Discussion

- What clinical strategies are most useful in the treatment of COVID-19?
- What considerations and precautions must be taken in patients with comorbidities that predispose them to severe illness?

Remdesivir for Patients Hospitalized With COVID-19… But Not Without Controversy

ACCT-1 Trial[1]

- 1062 patients randomized to remdesivir or placebo
- Remdesivir **associated with clinical improvement at Day 15**
- Mortality estimates:

	Remdesivir	Placebo
Day 15	6.7%	11.9%
Day 29	11.4%	15.2%

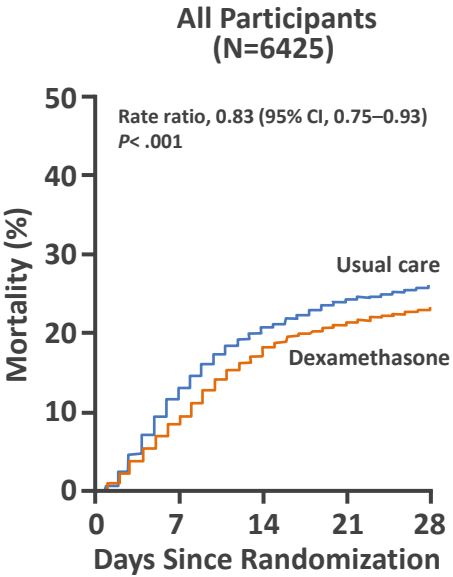
WHO Solidarity Trial[2]

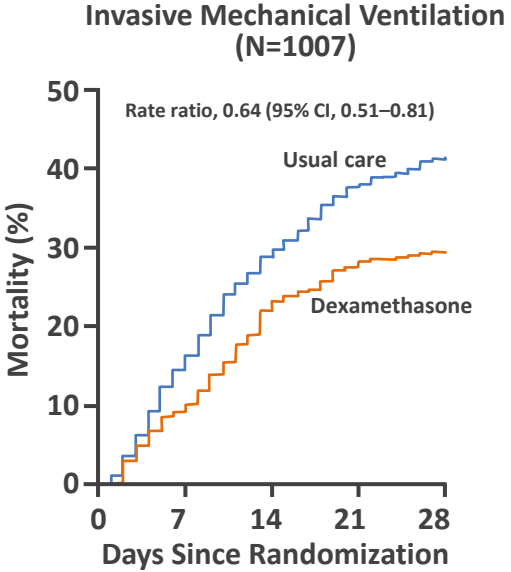
- 405 hospitals in 30 countries
- 11,330 patients randomized to remdesivir, hydroxychloroquine, lopinavir/ritonavir, interferon +/- lopinavir, or no drug[2]
- Interim results: All therapies had **little or no effect on mortality, initiation of ventilation, or duration of hospital stay**

1. Beigel JH, et al. *NEJM.* 2020;383:1813-1826. **2**. WHO Solidarity Trial Consortium. *NEJM*. 2020;384:497-511.

Dexamethasone Reduced 28-day Mortality in Patients Hospitalized with COVID-19

- **Intervention**:
  - Dexamethasone (N=2104) vs
  - Usual care (N=4321)
- **Findings**:
  - Dexamethasone ↓ 28d mortality in patients receiving invasive mechanical ventilation or oxygen alone at randomization
  - 28d mortality was *not affected* in patients receiving no respiratory support





RECOVERY Collaborative Group. *NEJM*. 2020. DOI: 10.1056/NEJMoa2021436.

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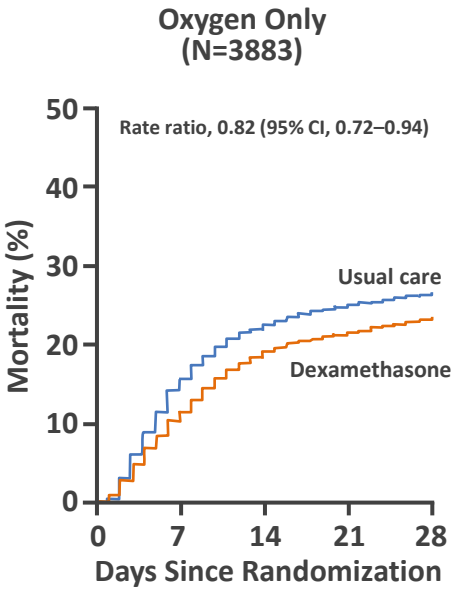
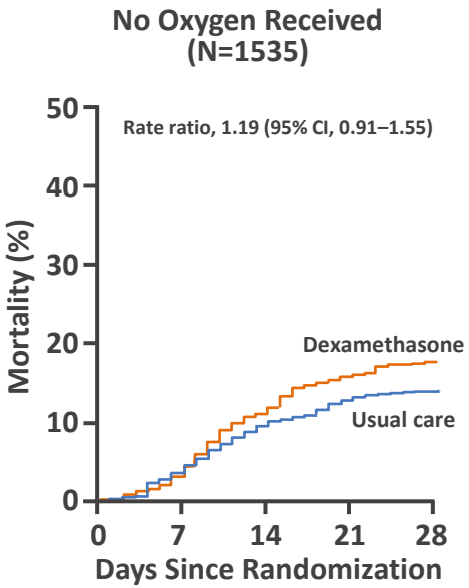




RECOVERY Collaborative Group. *NEJM*. 2020. DOI: 10.1056/NEJMoa2021436.

NIH Panel Recommendations on Emerging Therapies: January 2021

Therapy	Insufficient data to recommend for or against	Recommended against except in a clinical trial
Blood-derived products	• COVID-19 convalescent plasma • SARS-CoV-2 immunoglobulins	• Mesenchymal stem cells • Non-SARS-CoV-2-specific IVIG (does not preclude IVIG otherwise indicated for treatment of COVID-19-related complications)
Immunomodulators	• IL-1 inhibitors (eg, anakinra) • IFNβ for early (<7d from symptom onset) mild and moderate COVID-19	• Anti-IL-6 receptor monoclonal antibodies (sarilumab, tocilizumab) • Anti-IL-6 monoclonal antibodies (siltuximab) • IFNs α/β for severely/critically ill patients with COVID-19 • BTK inhibitors (acalabrutinib, ibrutinib, zanubrutinib) • JAK inhibitors (baricitinib, ruxolitinib, tofacitinib)

BTK, Bruton's tyrosine kinase; IFN, interferon; IL, interleukin; IVIG, intravenous immunoglobulin; JAK, Janus kinase SARS-CoV-2, severe acute respiratory syndrome coronavirus 2

National Institutes of Health. Coronavirus disease 2019 (COVID-19) treatment guidelines. https://www.covid19treatmentguidelines.nih.gov/

Long-term Complications of COVID-19: Consequences 6-Months After Discharge

- COVID-19, caused by SARS-CoV-2, can involve sequelae and other medical complications that last weeks to months after initial recovery, which has come to be called “Long-COVID” or “COVID long-haulers”
- Systematic review and meta-analysis of identified 55 long-term effects[1]
  - Most common were fatigue (58%), headache (44%), attention disorder (27%), hair loss (25%), dyspnea (24%)
- Ambidirectional cohort study of n = 1,733 patients in Wuhan, China[2]
  - At 6 months after acute infection, survivors were mainly troubled with fatigue or muscle weakness, sleep difficulties, and anxiety or depression
  - Patients who were more severely ill during their hospital stay had more severe impaired pulmonary diffusion capacities and abnormal chest imaging manifestations, and are the main target population for intervention of long-term recovery.

1. Lopez-Leon S, et al. *medRxiv*. 2021;2021.01.27.21250617. Preprint
2. Huang C, et al. *Lancet*. 2021;10270:220-232.

Long-term Complications of COVID-19: Consequences 6-Months After Discharge

Long-COVID: COVID-19 sequelae and other medical complications lasting weeks to months after initial recovery

- Systematic review and meta-analysis[1]
- 15 studies with original data for detecting long-term COVID-19 with ≥100 patients[1]
  - 55 long-term effects identified
  - Most common were fatigue (58%), headache (44%), attention disorder (27%), hair loss (25%), dyspnea (24%)

- Ambidirectional cohort study of 1,733 patients in Wuhan, China[2]
- 6mos after acute infection, primary complaints were fatigue or muscle weakness, sleep difficulties, and anxiety or depression
- Patients with **greater impairment of pulmonary diffusion capacities** and **abnormal chest imaging**:
  - Had more severe disease during hospital stay
  - Are main target population for intervention of long-term recovery

1. Lopez-Leon S, et al. *medRxiv*. 2021;2021.01.27.21250617; preprint; 2. Huang C, et al. *Lancet*. 2021;10270:220-232.

Audience Polling Question

Have you been vaccinated for SARS-CoV-2?

A. Yes

B. No

Audience Polling Question

Which of the following statements most closely reflects your view of the three vaccines available for SARS-CoV-2?

A. They're great! I encourage most of my patients to get vaccinated once available.

B. They're a necessary step in fighting the pandemic, but I have my concerns.

C. I don't trust the safety/efficacy of them, but I received my vaccination/intend to be vaccinated and tell my patients they should, too.

D. I don't trust the safety/efficacy of them, and I do not intend to be vaccinated or recommend vaccination to my patients.

Overview of Vaccines Currently Available or in Late-Stage Development

Vaccine	Pfizer	Moderna	Janssen	AstraZeneca-Oxford	Novavax
Type	mRNA	mRNA	Viral Vector DNA	Viral Vector DNA	Subunit Protein-Based
Doses	**2x doses** 21d apart	**2x doses** 28d apart	**1 dose**	**2x doses** ~4-12w apart	**2x doses** 21d apart
Storage	**Refrigeration** 2-8 °C ≤ 5d **Ultra-Frozen** -80 to -60 °C ≤ 6m	**Refrigeration** 2-8 °C ≤ 30d **Frozen** -25 to -15 °C ≤ 6m	**Refrigeration** 2-8 °C ≤ 3m **Frozen** ≤ -20 °C ≤ 2y	**Refrigeration** 2-8 °C ≤ 6m	**Refrigeration** 2-8 °C no time limit given
Availability	EUA for **≥16YO** EUA in 12-15YOs filed 4/9/21	EUA for **≥18YO**	EUA for **≥18YO***	EUA filing ~Q1 2021	EUA filing ~Q1 2021

***Distribution resumed 4/23 following CVST concerns; Women < 50 YO should be informed of rare risk of blood clots with low platelets after vaccination**

https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/Vaccine-candidate-tracking-table.ashx. Feb 8, 2021; https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/Pfizer-BioNTech-COVID-19-Vaccine/. Feb 4, 2021; https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/moderna-covid-19-vaccine/. Feb 4, 2021; https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines/#Phase3. Feb 9, 2021; https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/

Vaccines Currently Available or in Late-Stage Development: Efficacy Outcomes

Vaccine	Pfizer	Moderna	Janssen	AstraZeneca-Oxford	Novavax
Efficacy: Symptomatic COVID-19 (Primary Outcome), n	46,307	~30,000	43,783	32,449	~30,000
1st dose	52%	80%	66% (72% US trials)	76%	NR
2nd dose	91.3% (up to 6 months)	94%	Pending	76% (≥15d after 2 doses 4w apart) 85% (≥65YO)	96.4% 89.7% (Incl variants)
Secondary Efficacy Outcomes					
Severe Disease	100% (CDC definition) 95.3% (FDA definition)	100%	85%	100%	100%
Hospitalization/Death	100%	100%	100%	100%	100%

**Against mild to moderate infections only.*

https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/Vaccine-candidate-tracking-table.ashx. Feb 8, 2021. https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/Pfizer-BioNTech-COVID-19-Vaccine/. Feb 4, 2021. https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/moderna-covid-19-vaccine/. Feb 4, 2021. https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines/#Phase3. Feb 9, 2021. https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/. Voysey M, et al. Lancet. Feb 1 2021. https://www.wsj.com/articles/astrazeneca-vaccine-effective-against-u-k-covid-19-variant-in-study-11612530912. Feb 5, 2021.

Vaccines Currently Available or in Late-Stage Development: Efficacy Against Variants

Vaccine	Pfizer	Moderna	Janssen	AstraZeneca-Oxford	Novavax
Efficacy Against Variants	***In vitro neutralization potency (direct efficacy remains unknown)***				
UK (B.1.1.7)	Similar against B.1.1.7 & P.1, but lower against B.1.351	Not significantly changed for B.1.1.7, but reduced by 6-fold for B.1.351 & 2.8 fold for P.1	Data not available	70.4%	86.3%
South Africa (20H/501Y.V2 or B.1.351)			57%	10.4% (all severity)	48.6% (Overall) 55.4% (HIV-negative)
Brazil (P.1)			66% overall (Latin America; incl variant)	Data not available	No trial in Brazil

**Against mild to moderate infections only.*

https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/Vaccine-candidate-tracking-table.ashx. Feb 8, 2021. https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/Pfizer-BioNTech-COVID-19-Vaccine/. Feb 4, 2021. https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/moderna-covid-19-vaccine/. Feb 4, 2021. https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines/#Phase3. Feb 9, 2021. https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/. Voysey M, et al. Lancet. Feb 1 2021. https://www.wsj.com/articles/astrazeneca-vaccine-effective-against-u-k-covid-19-variant-in-study-11612530912. Feb 5, 2021.

COVID-19 Vaccine Hesitancy

Patient Vaccine Hesitancy

- **Harris poll** (Oct 2020)
  - 60% would get a COVID-19vaccine
- **Acceptance factors**
  - Are there side effects?
  - Does it work?
  - Is it safe?
  - How much does it cost?
- **US survey** (N=1,000; Aug & Dec 2020)
  - Expected benefit more influential vs side effects
  - Vaccine acceptance ↑ when efficacy >70%
  - Minor side effect risk was not impactful
  - SAE risk had a small but significant impact

Provider Vaccine Hesitancy

- **American Nursing Foundation Survey** (Oct 2020)
  - 63% were somewhat or very confident that the vaccine will be safe and effective
  - 34% would voluntarily receive a COVID-19 vaccine
  - 57% are comfortable discussing COVID-19 vaccines with patients
- **CDC HCP web survey** (Sept-Oct 2020)
  - 63% would get a COVID-19 vaccine

https://www.cdc.gov/vaccines/covid-19/; Kaplan et al. *PNAS*; 2021 Mar 9;118(10):e2021726118.

Audience Polling Question

Manage Vaccine Side Effects

- I feel comfortable recommending NSAIDs/APAP to manage side effects associated with COVID-19 vaccines.
  - True
  - False

APAP, automatic positive airway pressure; NSAIDs, nonsteroidal anti-inflammatory drugs.

Discussion

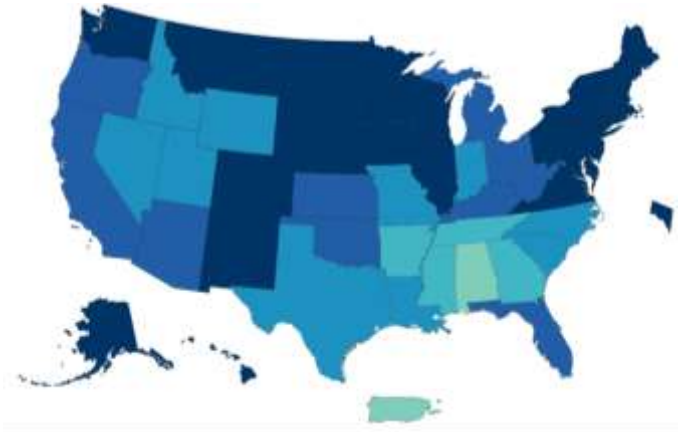
- What are some communication strategies for discussing the vaccine with patients?
  - Why doesn’t antigen testing work to confirm the vaccine’s efficacy?
- What does the evidence say re: NSAIDs/APAP?
  - Before, during, and after vaccine

Vaccine Distribution Challenges

KFF. Distributing a COVID-19 vaccine across the US—a look at key issues. Oct 20, 2020. https://www.kff.org/report-section/distributing-a-covid-19-vaccine-across-the-u-s-a-look-at-key-issues-issue-brief/

COVID-19 Vaccinations Given in the US *as of May 12, 2021*

Total Doses Administered Reported to the CDC by State/Territory and for Select Federal Entities per 100,000 of the Total Population



Total Doses Administered per 100,000

No Data | 0 | 1–15,000 | 15,001–20,000 | 20,001–25,000 | 25,001–30,000 | 30,001+

Total Vaccine Doses

Delivered **334,081,065**

Administered **263,132,561**

Learn more about the distribution of vaccines.

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	153,448,316	116,576,359
% of total population	46.2%	35.1%
Population ≥18 years of age	150,947,024	115,366,340
% of population ≥18 years of age	58.5%	44.7%
Population ≥65 years of age	45,861,467	39,186,618
% of population ≥65 years of age	83.8%	71.6%

Territories GU | AS | RP | FM | MP | PR | MH | VI

Federal Entities BoP | DoD | IHS | VHA

*Data for Federal Entities are presented here and are also incorporated into the respective jurisdictional totals.

Centers for Disease Control and Prevention. Accessed May 12, 2021. https://covid.cdc.gov/covid-data-tracker/#vaccinations

Discussion

- How do HCPs best prepare to distribute COVID vaccines?
- What are pitfalls to avoid in distribution efforts?
- What is a realistic timeline to providing vaccine to anyone that wants one?

Summary and Closing Thoughts

- COVID-19 caused an unprecedented shift in the US healthcare system and future developments in prevention and treatment are uncertain
- Disease presentation ranges from asymptomatic to severe illness
- Available testing can help reduce transmission, as well as diagnose and identify asymptomatic individuals
- Treatments for COVID-19 have specific strengths in outpatient and/or hospitalized patients
- Dexamethasone is the only treatment that has shown mortality benefit, particularly in patients requiring supplemental oxygen or mechanical ventilation
- Two vaccines are currently available, while others are currently in late development or under review
- Addressing vaccine hesitancy and supporting rollout efforts are critical for future prevention

NURSE PRACTITIONER
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Thank You!