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OCTOBER 12 – 13, 2020

# The COVID-19 Pandemic: What Worked, What Didn't

Douglas Fish, PharmD

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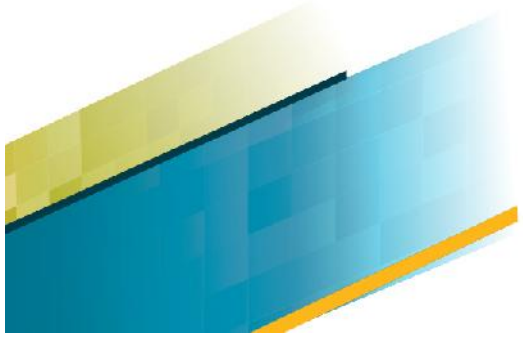

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# Disclosures

- Douglas Fish received research funding from Merck (as an independent contractor).
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# Objectives

At the conclusion of this presentation, the participant will be able to:

- Describe and outline general healthcare and public health responses to the COVID-19 pandemic.
- Discuss the application of principles of evidence-based medicine to treatment and prevention of infection during the COVID-19 pandemic.
- Describe the development and efficacy of drug therapies and vaccines for preventing and treating COVID-19 infection.
- Explain the roles of professional societies, governmental organizations, the internet, and social media in shaping and informing professional and public responses to the COVID-19 pandemic.

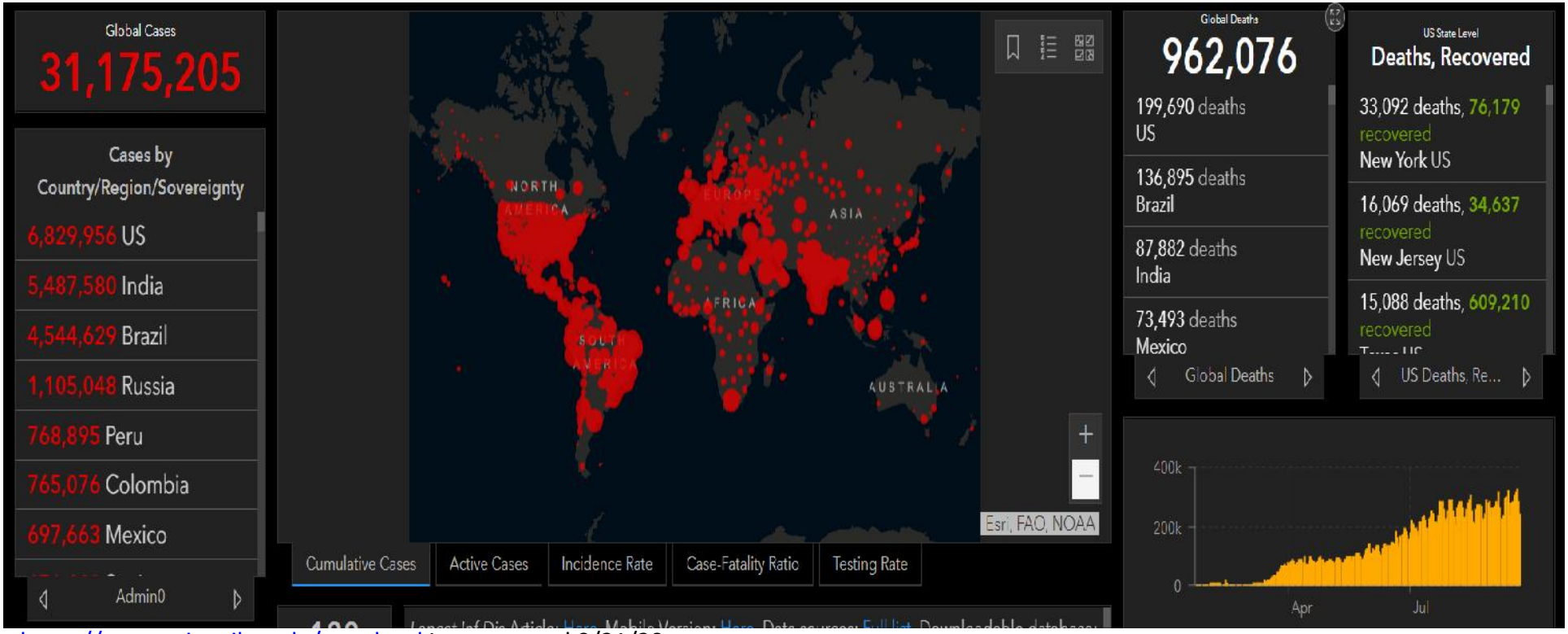
# Before we talk, the big disclaimers….

- The COVID-19 pandemic is still ongoing as this presentation was being put together
- Given the nature of rapid changes related to COVID-19, what's true today may not have been true yesterday, and may not be true again tomorrow
- Hindsight is often 20/20
- This presentation represents one man's opinions, your perspectives may be very different

## Looking back, my recollections of the early days of the COVID-19 pandemic are that it was mostly:

1. Very overwhelming, which lasted quite a while
2. Overwhelming initially, but this quickly passed
3. Challenging, but not overwhelming
4. Business as usual
5. What pandemic? I don't remember anything

# The SARS-CoV-2 Pandemic:




https://coronavirus.jhu.edu/map.html Last accessed 9/21/20.

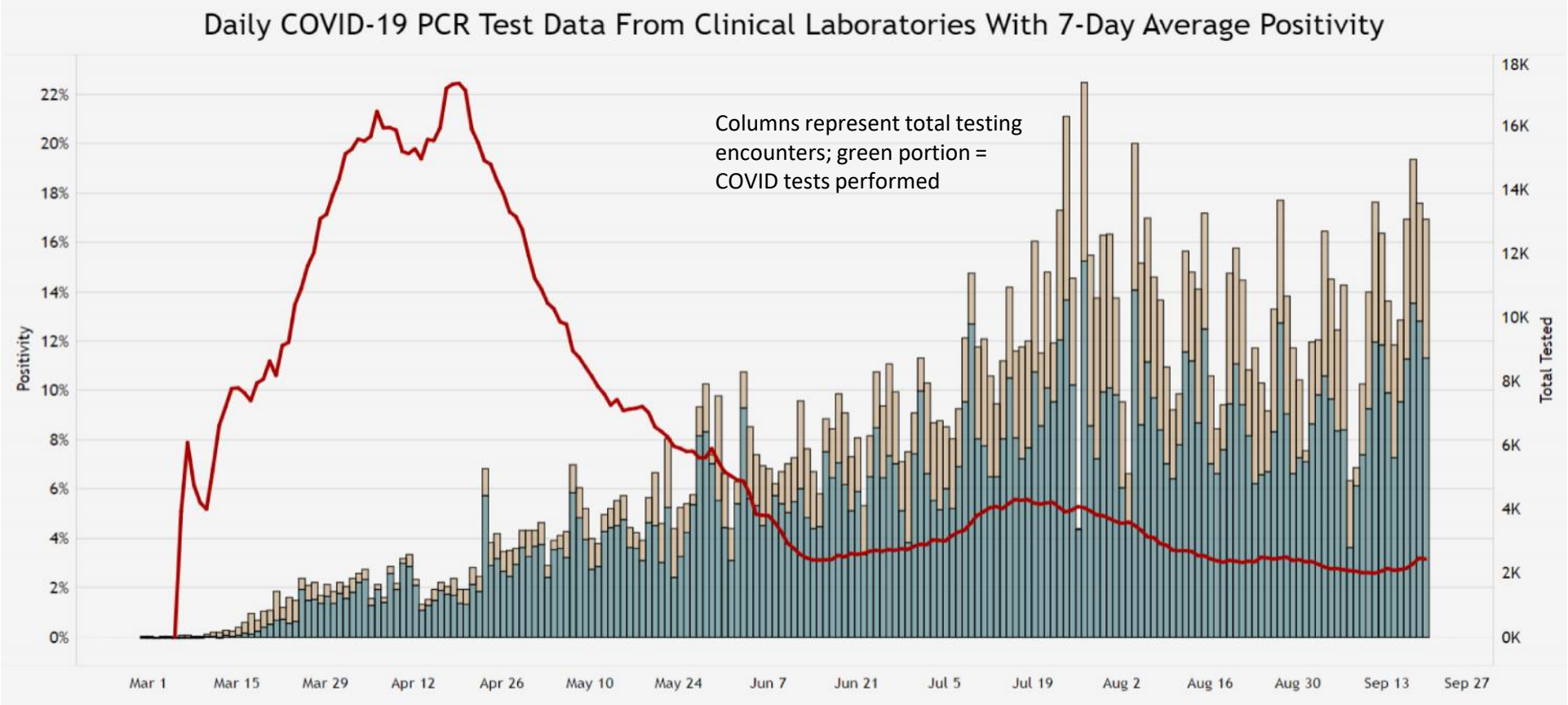
# Major Shortcomings in Preparation and Early Responses to the COVID-19 Pandemic

- Unavailability of reliable testing for SARS-CoV-2
- Critical early shortages of PPE, ventilators, drugs, personnel
- Poor support of community-based providers relative to shift to telehealth, billing & reimbursement processes, continued provision of routine healthcare services
- Inadequate reporting of data & slow application of public health protections, particularly among vulnerable populations (e.g. long term care, homeless, minorities, lower SE status)
- Often poor communications from health authorities at all levels

# One Thing That Went Terribly Right

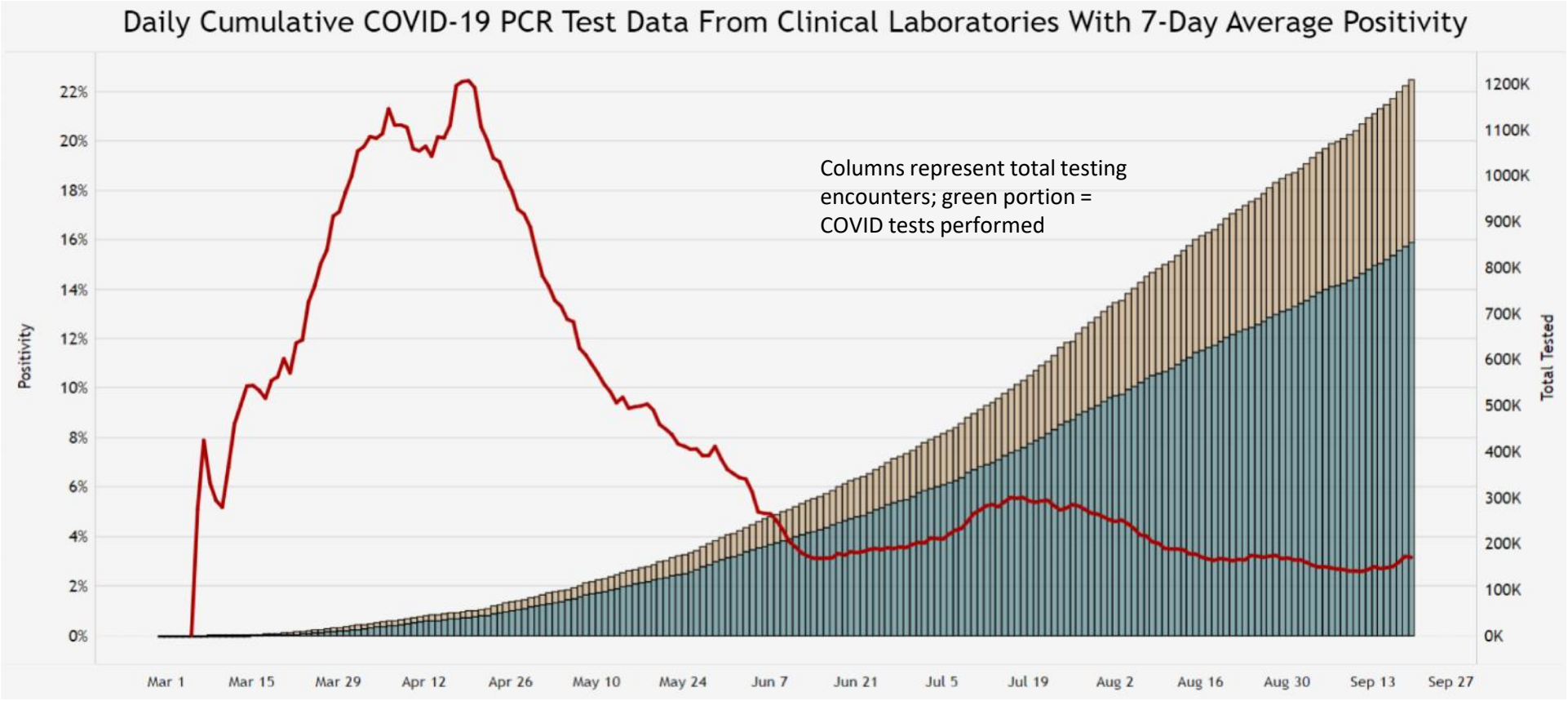
- With all the challenges, there was a severe need for teamwork and flexibility
- Teamwork and collaboration among healthcare workers was exceptional from Day 1
- We struggled and learned together as we went
- Patient care was always the highest priority

# COVID-19 Testing in Colorado (through 9/20/20)



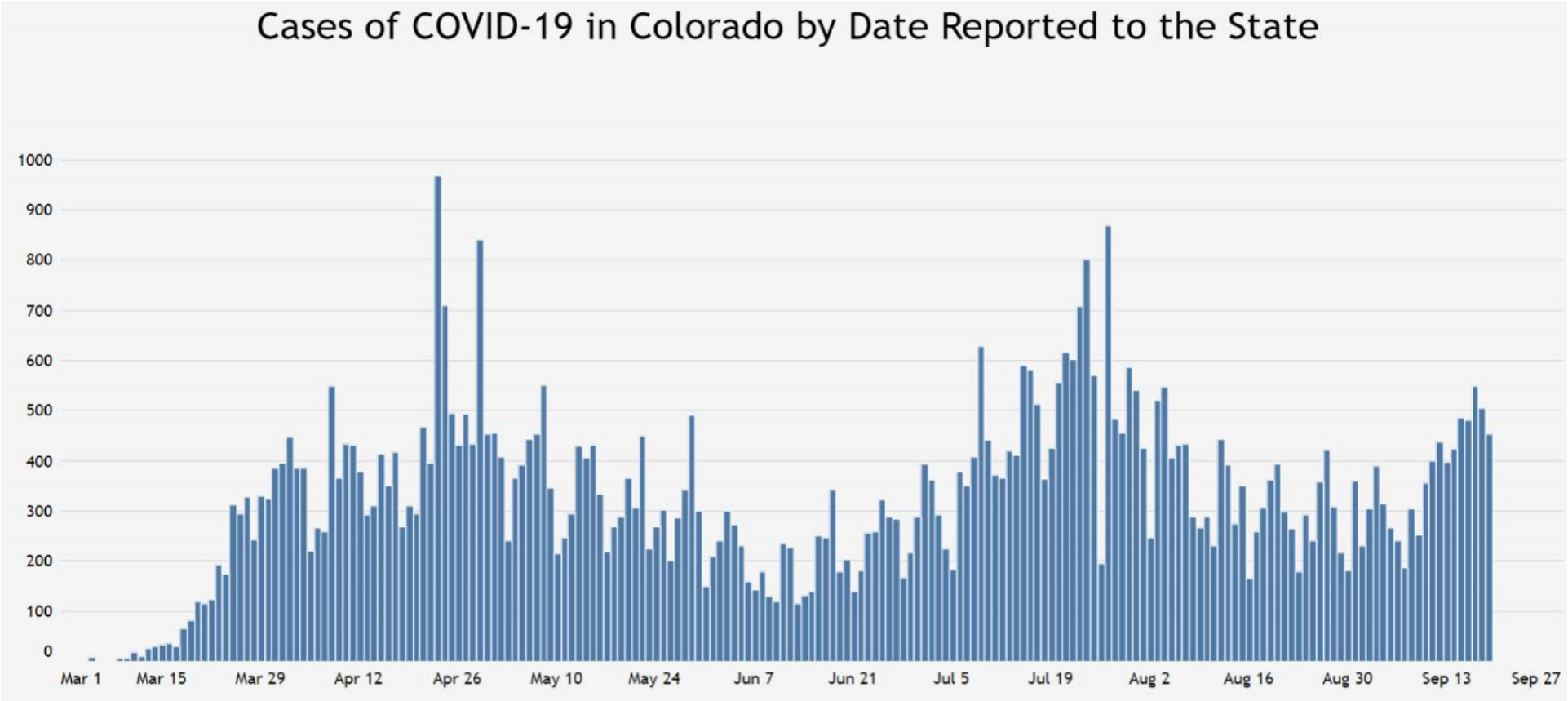

https://covid19.colorado.gov/data

# COVID-19 Testing in Colorado (through 9/20/20)



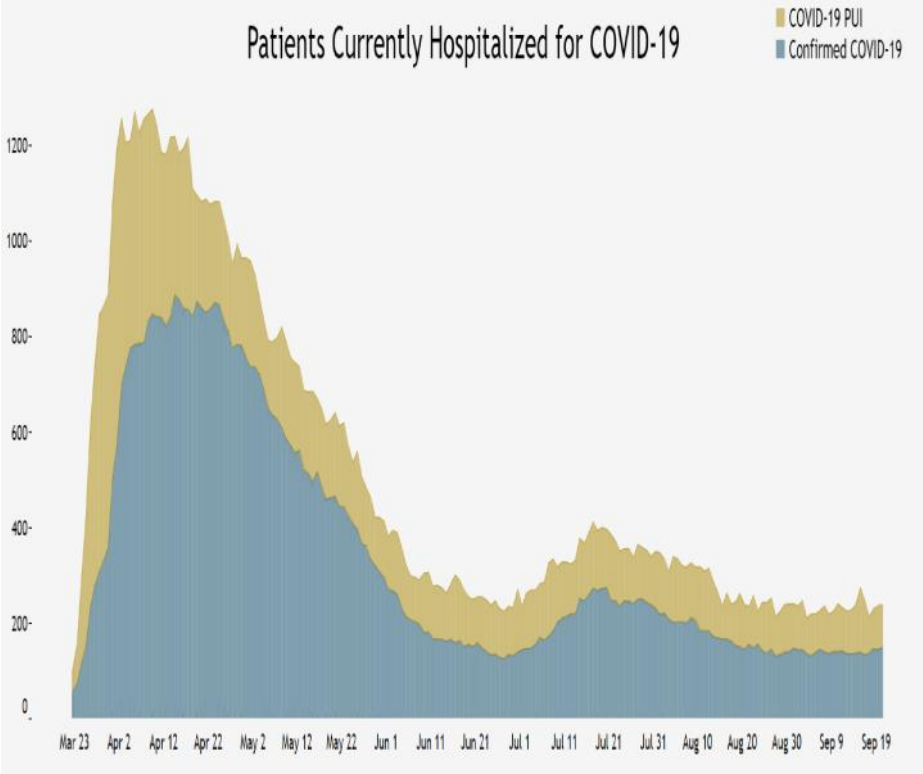

https://covid19.colorado.gov/data

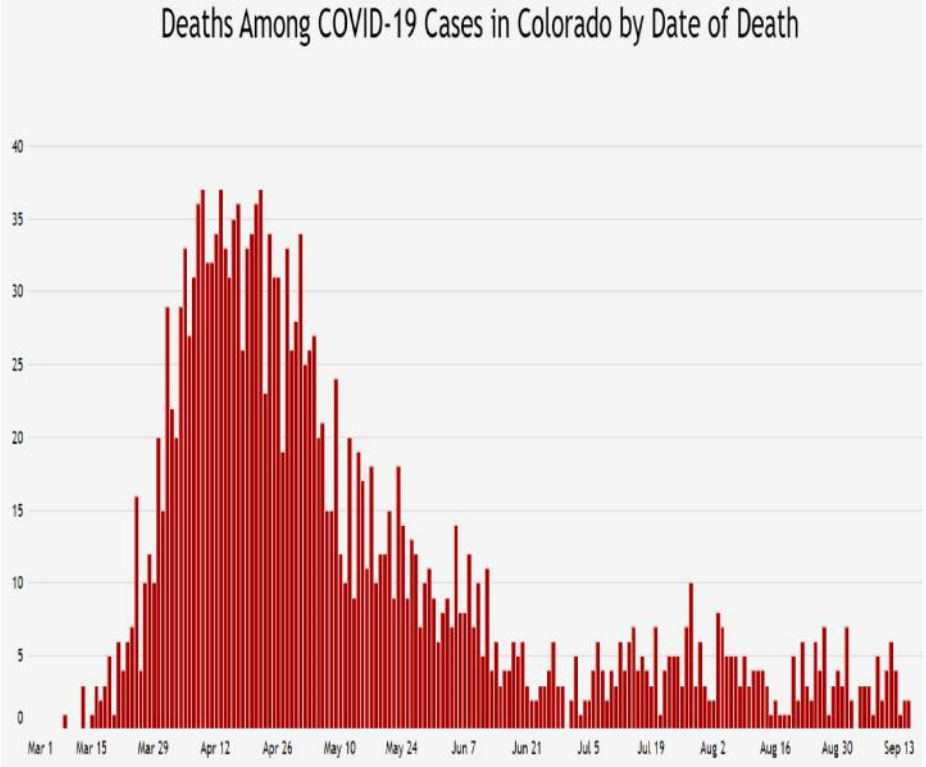
# COVID-19 Cases in Colorado (through 9/20/20)




https://covid19.colorado.gov/data

# COVID-19 Hospitalizations in Colorado (through 9/20/20)



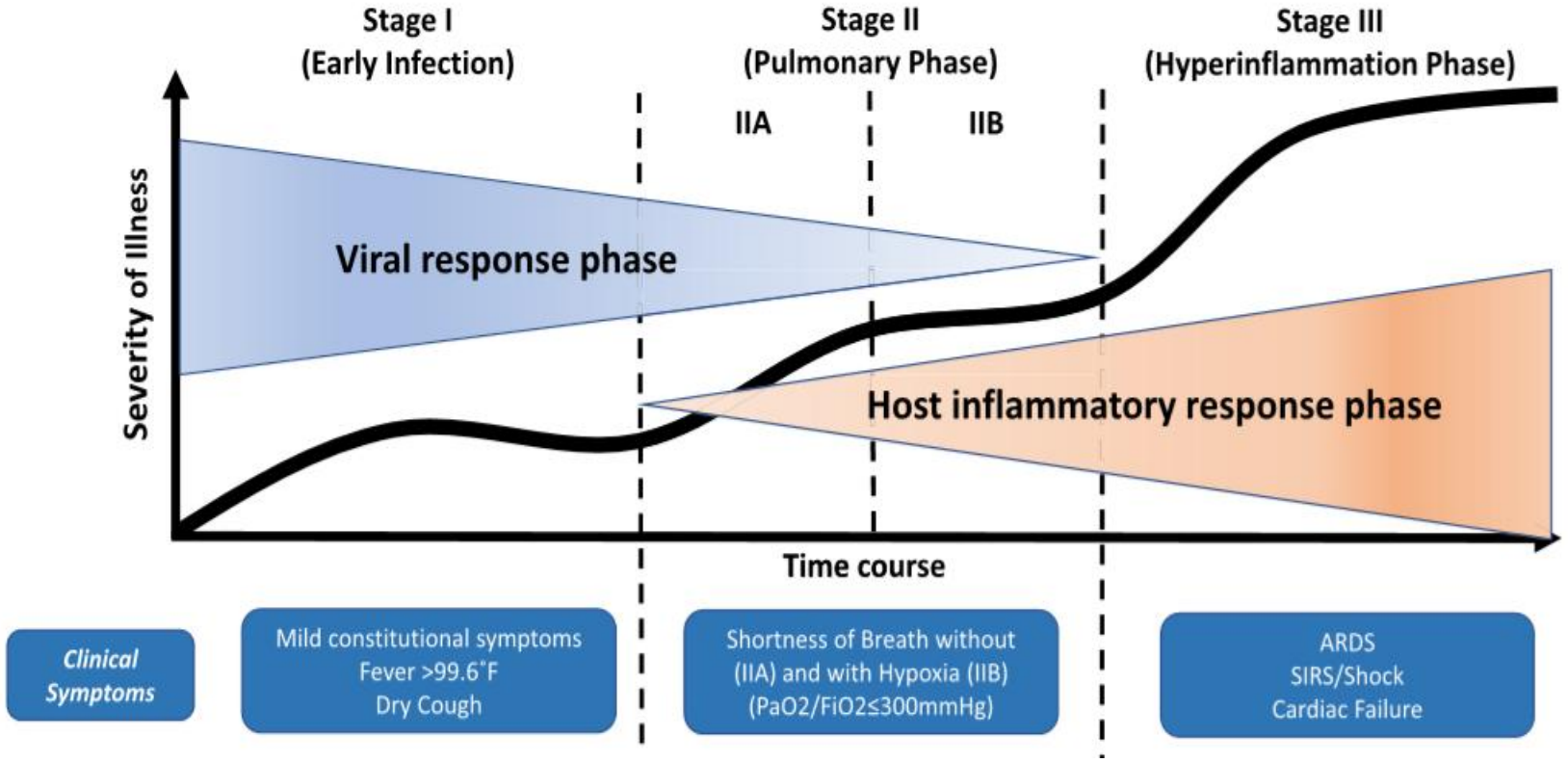




https://covid19.colorado.gov/data

# Improving Outcomes of Patients with Severe COVID-19 Disease: How Did We Do?

- Initial patient care efforts were hampered by:
  - Incomplete knowledge of modes of COVID transmission, proper infection prevention techniques
  - Unavailability of rapid & reliable testing
  - Shortages of PPE
  - No known effective treatments for COVID-19
  - Surging numbers that threatened to overwhelm capacities of hospitals, ICUs and properly trained personnel

# Time Course and Manifestations of COVID-19 Disease




Siddiqi HK, et al. J Heart Lung Transplant. 2020;39:405-7. https://linkinghub.elsevier.com/retrieve/pii/S1053-2498(20)31473-X

# What was (or is) your attitude regarding use of non-FDA approved treatments for COVID-19?

- OK to use without any data, someone has to be the first to try them
- OK to use based on case reports or anecdotal data
- OK to use based on retrospective studies
- OK to use based on well-designed clinical studies
- OK to use once recommended in guidelines (e.g. CDC, HHS)

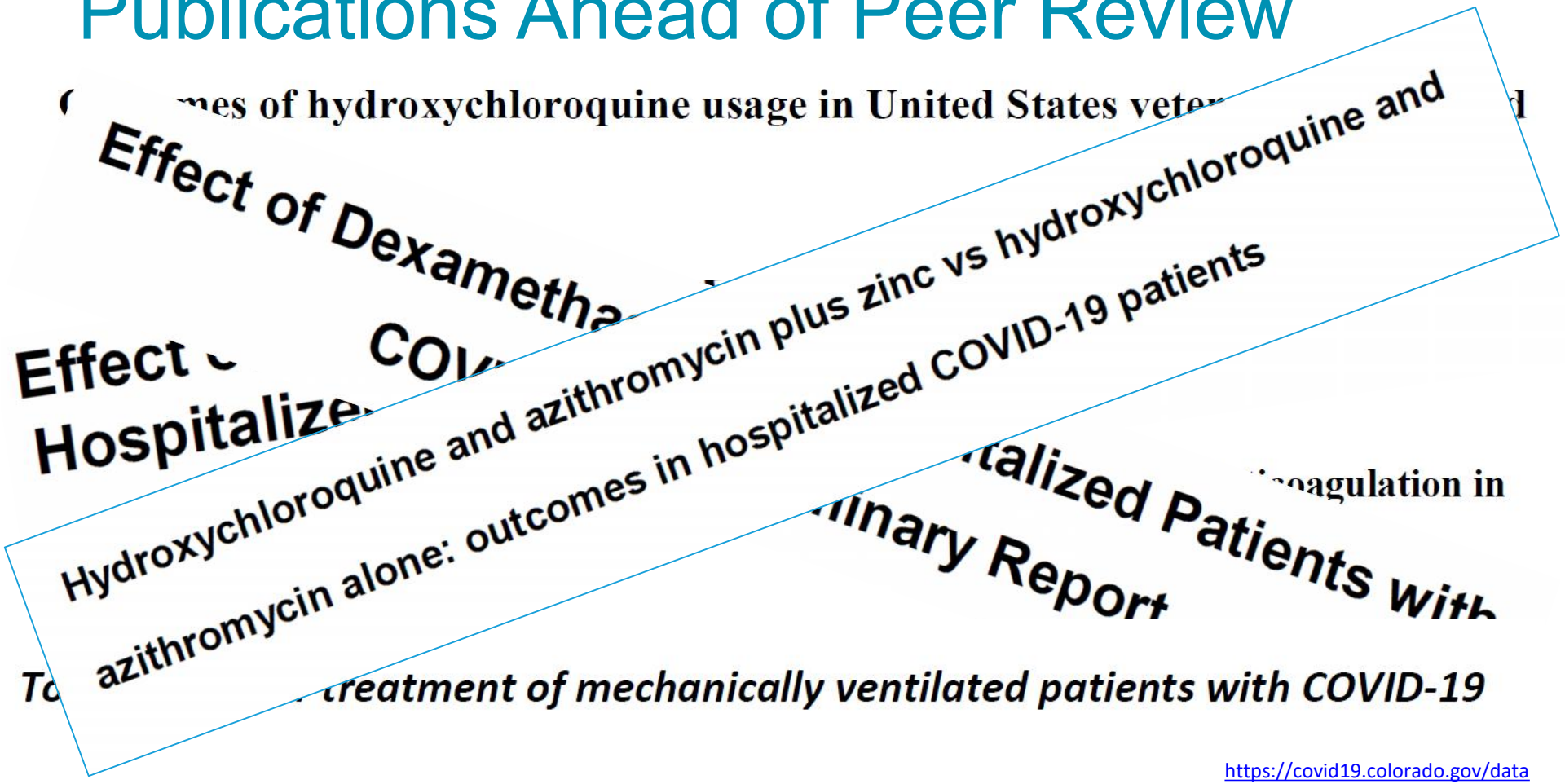
# Treatment of COVID-19 Disease

- With no treatments proven to be efficacious, potential therapies were based on:
  - Known features of viral life cycle (e.g. spike protein and ACE-2 receptors)
  - *In vitro* evidence (or suggestions) of drug activity against SARS-CoV and MERS viruses
  - Intervening in the inflammatory cascade
  - Experience with management of sepsis, ARDS in other populations
- Evidence-based medicine became an afterthought

# Throw it against the wall and let's see what sticks: How not to practice evidence-based medicine

- Acalabrutinib
- ACE inhibitors
- Adalimumab
- Anakinra
- Angiotensin receptor blockers
- Angiotensin II agonists
- Anticoagulants
- Antihistamines
- Atazanavir
- Azithromycin
- Baricitinib
- Certolizumab
- Choroquine
- Colchicine
- Convalescent plasma
- Dapagliflozin
- Darunavir/cobicistat
- Etanercept
- Famotidine
- Favipiravir
- Golimumab
- Hydroxychloroquine
- Ibrutinib
- Icatibant
- Infliximab
- Interferon alpha
- Interferon beta
- Ivermectin
- IVIG
- Linagliptin
- Lopinavir/ritonavir
- Melatonin
- Metformin
- N-acetylcysteine
- NSAIDs
- Proton pump inhibitors
- Quercetin
- Remdesivir
- Ribavirin
- Ruxolitinib
- Sarilumab
- Siltuximab
- Sitagliptin
- Statins
- Thiamine
- Tocilizumab
- Tofacitinib
- Umifenovir
- Vitamin C
- Vitamin D
- Zanubrutinib
- Zinc sulfate

# Publications Ahead of Peer Review




https://covid19.colorado.gov/data

# "Publication by Press Release": Dexamethasone

- "The survival benefit is clear and large in those patients who are sick enough to require oxygen treatment, so dexamethasone should now become standard of care in these patients."
- "These preliminary results from the RECOVERY trial are very clear – dexamethasone reduces the risk of death among patients with severe respiratory complications…it is fantastic that the first treatment demonstrated to reduce mortality is one that is instantly available and affordable worldwide."
- "Dexamethasone will likely now be part of the standard of care for COVID-19 patients requiring oxygen support and/or ventilation."
- "I think it needs to be validated, but it certainly suggests that this could be beneficial in this setting."

https://www.recoverytrial.net/files/recovery_dexamethasone_statement_160620_v2final.pdf

# Retractions of Published Articles in *Lancet* and *NEJM* (June 4, 2020)

## Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis

Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka, Amit N Patel

**Summary**

**Background** Hydroxychloroquine or chloroquine, often in combination with a second-generation m[acro]lide, are b[eing] widely used for treatment of COVID-19, despite no conclusive evidence of their benefit. Although [generally] safe when used for approved indications such as autoimmune disease or malaria, the safety and ben[efit] of the treatment regimens are poorly evaluated in COVID-19.

**Methods** We did a multinational registry analysis of the use of hydroxychloroquine [or] chloroquine with[out] or without a macrolide for treatment of COVID-19. The registry comprised data from 671 hospit[als] in six continents. We included patients hospitalised between Dec 20, 2019, and April 14, 2020, with a positive laboratory [test] for SARS-CoV-2. Patients who received one of the treatments of interest within 48 h of diagnos[is] were included in one of four treatment groups (chloroquine alone, chloroquine with a macrolide, hydroxychloroquine alone, or hydroxychloroquine with a macrolide), and patients who received none of these treatments formed the control group. Patients for whom one of the treatments of interest was initiated more than 48 h after diagnosis or while they were on mechanical ventilation, as well as patients who received remdesivir, were excluded. The main outcome of interest were in-hospital mortality and the occurrence of de-novo ventricular arrhythmias ([sus]tained or non-sustained ventricular tachycardia or ventricular fibrillation).

**Findings** 96 032 patients (mean age 53·8 years, 46·3% women) with COVID-19 were hospitalised during the study period and met the inclusion criteria. Of these, [mis]sing patients were in the treatment groups (1868 received chloroquine, 3783 received chloroquine with a macrolide, 3016 received hydroxychloroquine, and 6221 received hydroxychloroquine with a macrolide) and [mis]sing in the control group. 10 698 (11·1%) patients died in hospital. After controlling for multiple [con]founders (sex, race or ethnicity, body-mass index, underlying cardiovascular disease and its risk factors, diabetes, underlying lung disease, smoking, immunosuppressed condition, and baseline disease severity), when compared with mortality in the control group (9·3%), hydroxychloroquine (18·0%; hazard ratio 1·335, 95% CI 1·2[illegible]·457), hydroxychloroquine with a macrolide (23·8%; 1·447, 1·368–1·531), chloroquine (16·4%; 1·365, 1·318–1·531), chloroquine with a macrolide (22·2%; 1·368, 1·273–1·469) were each independently associated with an increased risk of in-hospital mortality. Compared with the control group (9·3%), hydroxychloroquine ([illegible]; 2·36, 2·935–2·900), hydroxychloroquine with a macrolide (8·1%; 5·106, 4·106–5·983), chloroquine (4·3%; [illegible], 3·4–4·596), and chloroquine with a macrolide (6·5%; 4·011, 3·344–4·812) were independently associated with an increased risk of de-novo ventricular arrhythmia during hospitalisation.

**Interpretation** We were unable to confirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital mortality and increased frequency of ventricular arrhythmias when used for treatment of COVID-19.

**Funding** William Harvey Distinguished Chair in Advanced Cardiovascular Medicine at Brigham and Women's Hospital.

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This online publication has been corrected. The corrected version first appeared at thelancet.com on May 29, 2020

See Online/Comment https://doi.org/10.1016/S0140-6736(20)31174-0

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ORIGINAL ARTICLE

## Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19

Mandeep R. Mehra, M.D., Sapan S. Desai, M.D., Ph.D., SreyRam Kuy, M.D., M.H.S., Timothy D. Henry, M.D., and Amit N. Patel, M.

ABSTRACT

**BACKGROUND**

Coronavirus disease 2019 (Covid-19) may disproportionately affect people with cardiovascular disease. Concern has been aroused regarding the potential harmful effect of angiotensin-converting–enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs) in this clinical context.

**METHODS**

Using an observational database from 169 hospitals [in] Europe, and North America, we evaluated the relationship of cardiovascular disease and drug therapy with in-hospital death among hospitalized patients with Covid-19 who were admitted between December 20, 2019, and March 20, 2020, [data] were recorded in the Surgical Outcomes Collaborative registry [who] have either died in the hospital or survived to discharge as of March 28, 2020.

**RESULTS**

Of the 8910 patients with Covid-19 for whom discharge status was available at the time of the analysis, a total [of] died in the hospital (5.8%) and 8395 survived to discharge. The factors [that] were found to be independently associated with an increased risk of in-hospital death were [an] age greater than 65 years (mortality of 10.0%, vs. 4.9% among those ≤65 years of age; odds ratio, 1.93; 95% confidence interval [CI], 1.60 to 2.41), coronary artery disease (10.2%, vs. 5.2% among those without disease; odds ratio, 2.70; 95% CI, 2.08 to 3.51), heart failure (15.3%, vs. 5.6% among those without heart failure; odds ratio, 2.48; 95% CI, 1.62 to 3.79), cardiac arrhythmia (11.[illegible]% among those without arrhythmia; odds ratio, 1.95; 95% CI, 1.[illegible] to 2.[illegible]), chronic obstructive pulmonary disease (14.2%, vs. 5.6% among those without disease; odds ratio, 2.96; 95% CI, 2.00 to 4.40), and current smoking (5.6% among former smokers or nonsmokers; odds ratio, 1.79; 95% CI, 1.29 to 2.47). No increased risk of in-hospital death was found to be associated with the use of ACE inhibitors (2.1% vs. 6.1%; odds ratio, 0.33; 95% CI, 0.20 to [illegible]) or the use of ARBs (6.8% vs. 5.7%; odds ratio, 1.23; 95% CI, 0.87 to 1.74).

**CONCLUSIONS**

Our study confirmed previous observations suggesting that underlying cardiovascular disease is associated with an increased risk of in-hospital death among patients hospitalized with Covid-19. Our results did not confirm previous concerns regarding a potential harmful association of ACE inhibitors or ARBs with in-hospital death in this clinical context. (Funded by the William Harvey Distinguished Chair in Advanced Cardiovascular Medicine at Brigham and Women's Hospital.)

From Brigham and Women's Hospital Heart and Vascular Center and Harvard Medical School, Boston (M.R.M.); Surgisphere, Chicago (S.S.D.); Baylor College of Medicine and Department of Veterans Affairs, Houston (S.K.); Christ Hospital, Cincinnati (T.D.H.); the Department of Biomedical Engineering, University of Utah, Salt Lake City (A.N.P.); and HCA Research Institute, Nashville (A.N.P.). Address reprint requests to Dr. Mehra at Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, or at mmehra@bwh.harvard.edu.

This article was published on May 1, 2020, and updated on May 8, 2020, at NEJM.org.

DOI: 10.1056/NEJMoa2007621



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# Intersections (Collisions?) of Science, Public Health, and Politics

- Hydroxychloroquine: "…the most bizarre episode in 21st-century medicine; the most baseless, cock-eyed madness to reach all the way to the President of the United States and the CEO of Space-X.…"

- Masks: "The U.K. and the U.S. have been lessons in how *not* to give clear messaging to the public."

Rohin Francis: "COVID-19: where science goes to die". medpagetoday.com


Remdesivir
Dexamethasone

# Remdesivir for the Treatment of Covid-19 (ACTT-1)

- Results:
  - **Time to recovery = remdesivir 11 days vs. placebo 15 days (rate ratio for recovery, 1.32; 95% CI, 1.12 - 1.55; P<0.001)**
  - Mortality = remdesivir 7.1% vs. placebo 11.9% (HR, 0.70; 95% CI, 0.47 - 1.0

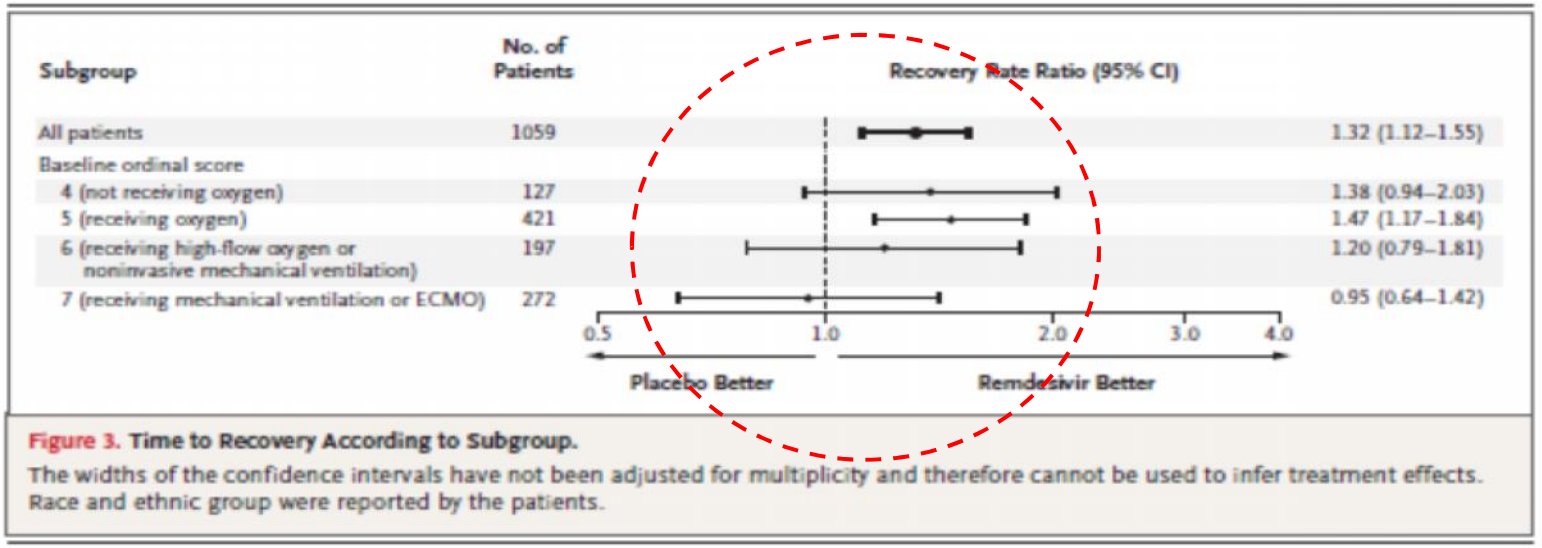


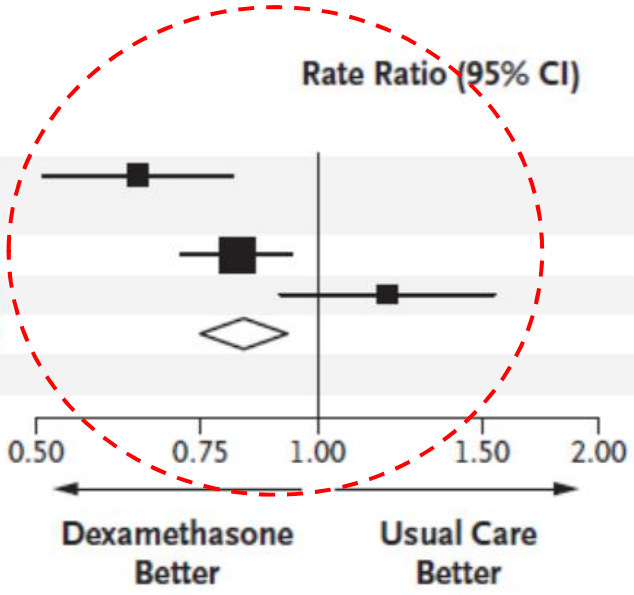

**Figure 3. Time to Recovery According to Subgroup.**
The widths of the confidence intervals have not been adjusted for multiplicity and therefore cannot be used to infer treatment effects. Race and ethnic group were reported by the patients.

Beigel JH, et al. NEJM. Published 5/22/20; DOI: 10.1056/NEJMoa2007764

# Dexamethasone for COVID-19 (RECOVERY): 28-Day Mortality

| Respiratory Support at Randomization | Dexamethasone | Usual Care | Rate Ratio (95% CI) |
|---|---|---|---|
| | *no. of events/total no. (%)* | | |
| Invasive mechanical ventilation | 95/324 (29.3) | 283/683 (41.4) | 0.64 (0.51–0.81) |
| Oxygen only | 298/1279 (23.3) | 682/2604 (26.2) | 0.82 (0.72–0.94) |
| No oxygen received | 89/501 (17.8) | 145/1034 (14.0) | 1.19 (0.91–1.55) |
| **All Patients** | **482/2104 (22.9)** | **1110/4321 (25.7)** | **0.83 (0.75–0.93)** |
| | | | **P<0.001** |

Chi-square trend across three categories: 11.5




› Also significant differences in progression to mechanical ventilation, discharge from hospital alive at 28 days

NEJM 2020;10.1056/NEJMoa2021436

# Remdesivir and Dexamethasone for COVID-19: Continuing Questions

- Safety and efficacy of remdesivir + dexamethasone
  - Dexamethasone appears most beneficial in ventilated patients
  - Remdesivir appears most beneficial in nonventilated patients
  - What happens if you use them together???
- Efficacy in key subgroups:
  - Age groups
  - Patients with comorbidities
  - Pregnancy
  - Children
- Still incomplete knowledge regarding safety of these regimens for COVID-19, particularly remdesivir

# An Unbelievable Pace of Drug Discovery

- Milken Institute COVID-19 tracker (https://covid-19tracker.milkeninstitute.org/)
  - 316 treatments under development
  - 206 new vaccines under development

- Clinical Trials.gov reports 3,176 COVID-19 related studies
  - 2,361 trials reported from the WHO's International Clinical Trials Registry Platform (WHO ICTRP), either ongoing or completed
  - 815 from U.S., including 78 federally funded

# Examples of Governmental and Professional COVID-19 Guidelines and Resources

- American Society of Health-System Pharmacists
- Canadian Medical Association
- European Medicines Agency
- Infectious Disease Society of America
- Society of Infectious Diseases Pharmacists
- U.S. Health and Human Services
- World Health Organization

# Dexamethasone for COVID-19: HHS Guidelines (revised 6/25/20)

**Press release → guideline inclusion = 9 days**

- Th… …nds usi… …up to me… …ID-19 me…
- Th… …one in … supplemental oxygen **(AI)**.

**Press release → peer-reviewed publication = 31 days**

The NEW ENGLAND JOURNAL of M…

Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report

The RECOVERY Collaborative Group*

https://www.covid19treatmentguidelines.nih.gov/dexamethasone/

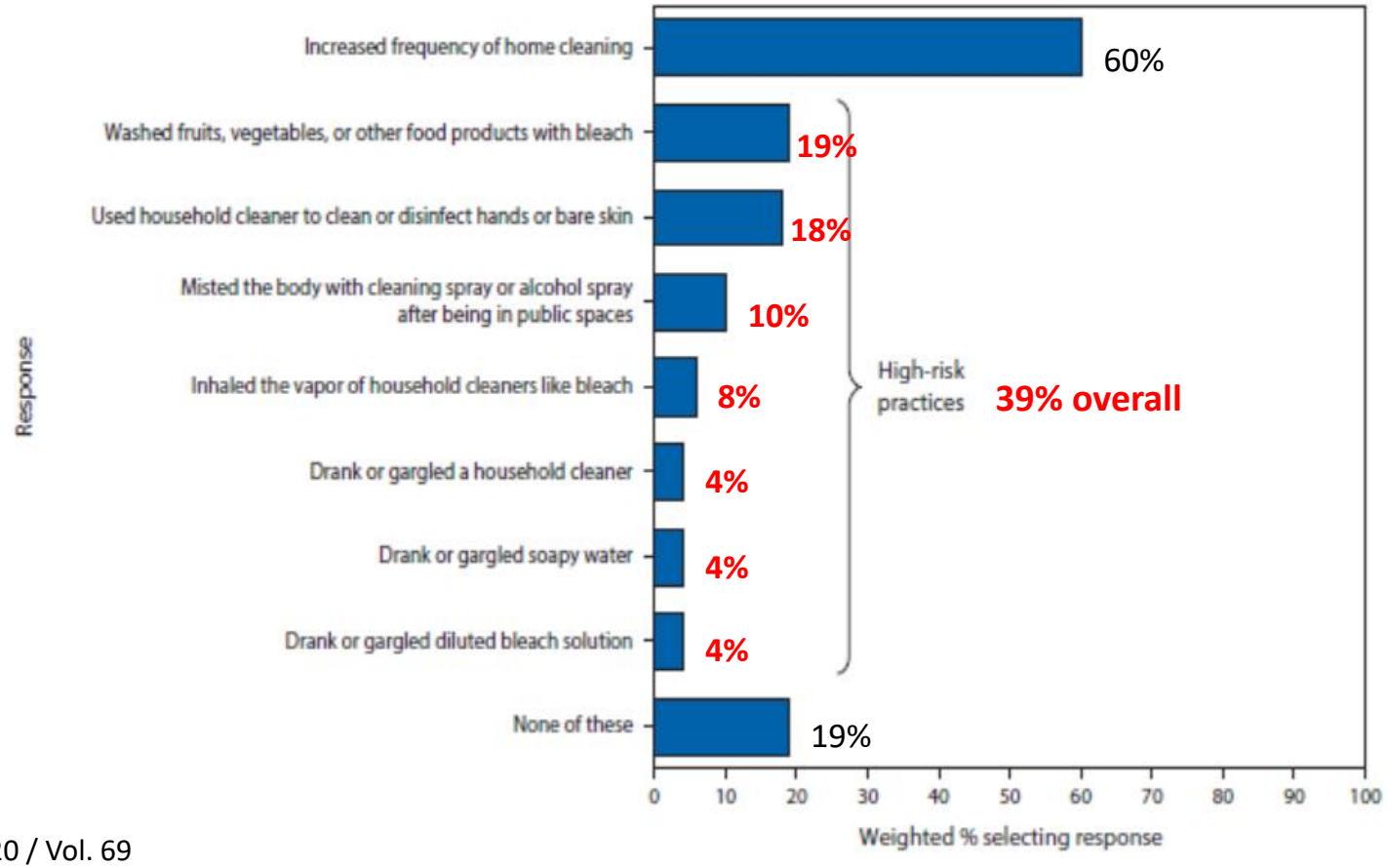
# Dexamethasone for COVID-19: IDSA Guidelines (revised 6/25/20)

- Among hospitalized patients with severe* COVID-19, the IDSA guideline panel suggests glucocorticoids rather than no glucocorticoids. (Conditional recommendation, Moderate certainty of evidence)
  - **Remark:** Dexamethasone 6 mg IV or PO for 10 days (or until discharge if earlier) or equivalent glucocorticoid dose may be substituted if dexamethasone unavailable. Equivalent total daily doses of alternative glucocorticoids to dexamethasone 6 mg daily are methylprednisolone 32 mg and prednisone 40 mg.
- Among hospitalized patients with COVID-19 without hypoxemia requiring supplemental oxygen, the IDSA guideline panel suggests against the use of glucocorticoids. (Conditional recommendation, Low certainty of evidence)

*Severe illness is defined as patients with $SpO_2$ ≤94% on room air, and those who require supplemental oxygen, mechanical ventilation, or ECMO.

https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-5

**FIGURE 2. Cleaning and disinfection practices in the previous month with the intent of preventing SARS-CoV-2 infection,*,† based on responses to an opt-in Internet panel survey§ (N = 502 respondents) — United States, May 2020**




MMWR. 6/5/2020 / Vol. 69

# What has been your most important source of information about COVID-19?

1. Professional colleagues
2. State or local health departments
3. CDC, NIH, and/or society resources
4. Online, print and/or broadcast media (e.g. newspapers, television news)
5. Social media, blogs, “unofficial” internet sites

# COVID-19–Related Infodemic and Its Impact on Public Health: A Global Social Media Analysis

- Evaluated COVID-19–related rumors, stigma, and conspiracy theories circulating on online platforms
  - E.g., fact-checking agency websites, Facebook, Twitter, online newspapers
- 2,311 reports of rumors, stigma, and conspiracy theories in 25 languages from 87 countries.
- Claims related to:
  - Illness, transmission and mortality (24%)
  - Control measures (21%)
  - Treatment and cure (19%)
  - Cause of disease including the origin (15%)
  - Miscellaneous (21%)
- **82% of claims were false**

Islam MS, et al. *Am J Trop Med Hyg*, 00(0), 2020, pp. 1–9. doi:10.4269/ajtmh.20-0812.

# Examples of Rumors, Stigma, and Conspiracy Theories Surrounding COVID-19

- "Mobile phones and 5G wireless can transmit coronavirus"
- "Novel coronavirus is a type of rabies"
- "Drinking bleach may kill the virus"
- "Spraying chlorine all over your body can prevent coronavirus infection"
- "Drinking cow urine and cow dung can cure coronavirus"
- "Rinse mouths with salt-water solution to prevent infection from COVID-19"
- "Keeping throat moist, avoiding spicy food and taking vitamin C may prevent the disease"
- "The COVID-19 outbreak was planned"
- "COVID-19 is a bio-weapon funded by the Bill & Melinda Gates Foundation to sell vaccines"
- "This outbreak is a population control scheme"
- "New coronavirus vaccines already exist but are being withheld"
- "United States and Israel were behind the creation and spread of COVID-19 as part of an economic and psychological war against China"
- "Every disease has always come from China"
- "Chinese dietary habits caused COVID-19"
- "Chinese are bioterrorists"

Islam MS, et al. *Am J Trop Med Hyg*, 00(0), 2020, pp. 1–9. doi:10.4269/ajtmh.20-0812.

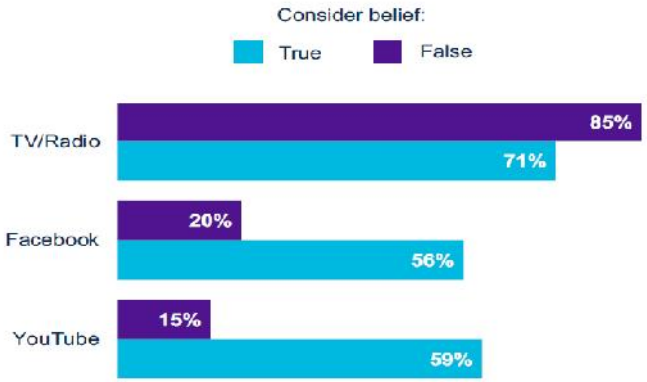
# Health-protective Behaviors, Social Media Usage and Conspiracy Belief during the COVID-19 Public Health Emergency

- Three studies conducted via online surveys in 5,453 individuals in the U.K.
- All three studies found negative relationship between COVID-19 conspiracy beliefs and COVID-19 health-protective behaviors
  - Hand-washing
  - Social distancing
  - Staying home if having symptoms that could be consistent with COVID-19
  - Not meeting up with friends or family inside or outside the home
- All three studies found positive relationship between COVID-19 conspiracy beliefs and use of social media as a source of information about COVID-19
- Two studies also found a negative relationship between health-protective behaviors and use of social media as a source of information

Arlington D, et al. *Psychological Medicine* 1–7. https://doi.org/10.1017/S003329172000224X.

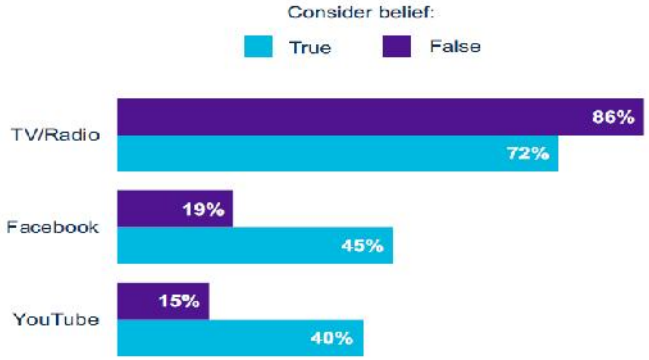
**% of conspiracy believers and non-believers who get a fair amount or great deal of information about coronavirus from following sources**

**There is no hard evidence that coronavirus really exists**

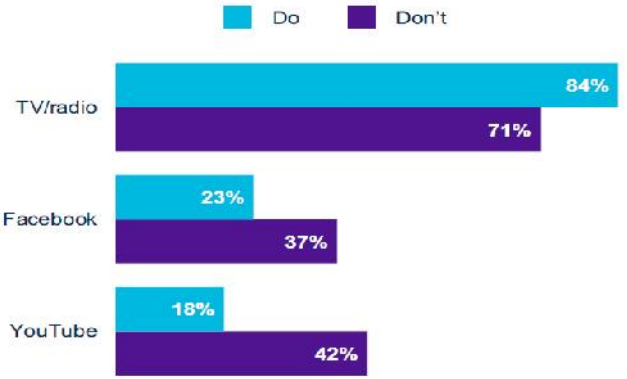



**% of conspiracy believers and non-believers who get a fair amount or great deal of information about coronavirus from following sources**

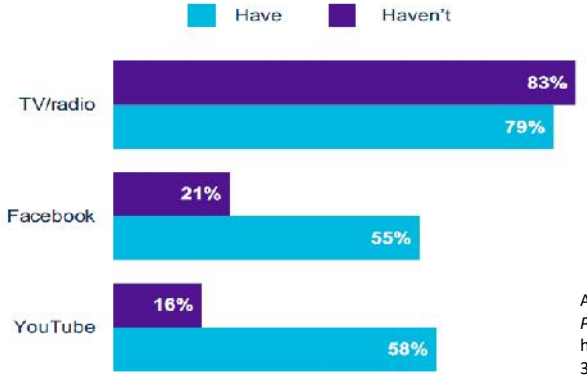
**The number of people reported as dying from coronavirus is being deliberately exaggerated by the authorities**




**% of those who do / don't stay 2 metres away from other people when outside their home who get a fair amount or great deal of information about coronavirus from...**




**% of those who have / haven't gone to work or outside despite having symptoms that could be coronavirus who get a fair amount or great deal of information about coronavirus from...**

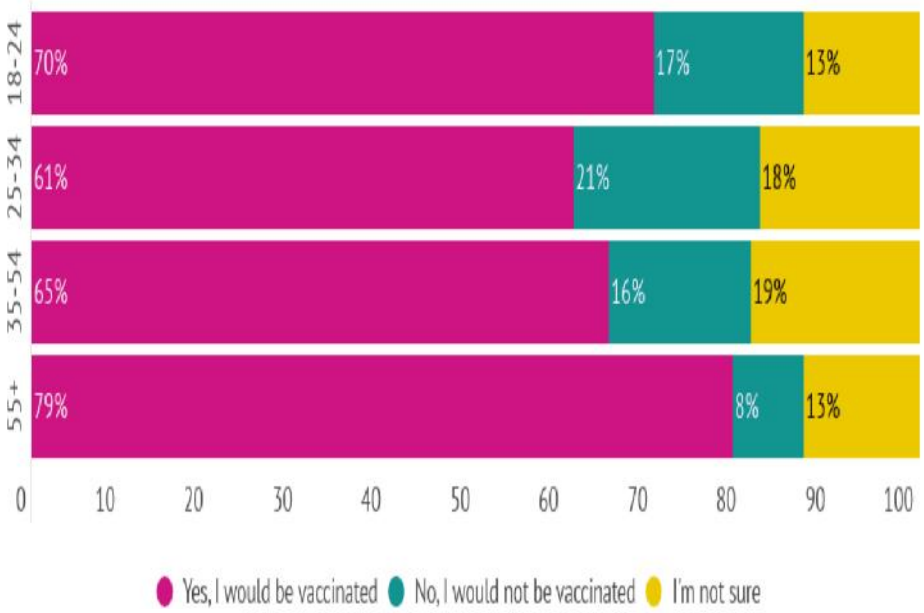



Arlington D, et al.
*Psychological Medicine* 1–7.
https://doi.org/10.1017/S00
3329172000224X.

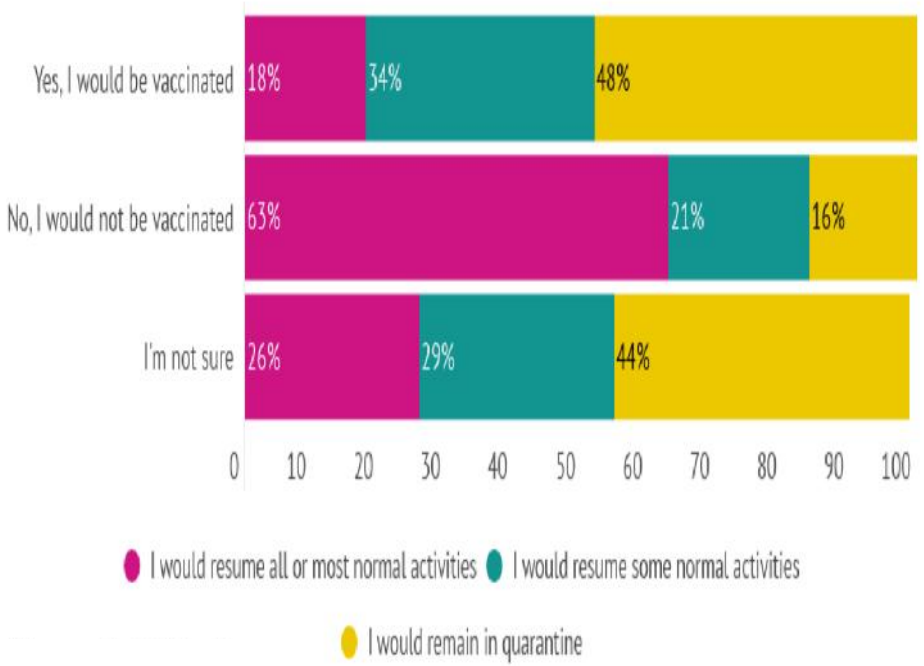
# COVID-19 Vaccines: Rapid Development, Slower Acceptance?

- The Pew Research Center reported that seven-in-ten Americans would get a vaccine if it was available (https://pewrsr.ch/2TqvaTM/)
- The research platform Civic Science found that among 2,900 adults, the percentage of people "very comfortable" with vaccinations declined by six points since January (https://civicscience.com/)
  - 69% of those surveyed would choose a coronavirus vaccine, 14% said they wouldn't, and 17% weren't sure.
- According to a survey of 3,500 Americans from Azurite Consulting, 22% say they will wait at least six months after the vaccine's release to get it and 29% plans on never taking it (https://www.azuriteconsulting.com/businessimpact.html#next)

## If / when a vaccine to protect people from the coronavirus becomes available, would you opt to receive it? by *Age*




## If / when a vaccine to protect people from the coronavirus becomes available, would you opt to receive it? compared with *Response to local / state lockdowns being lifted*



# Stemming the Misinformation Tide

- Effective patient and public education has been, and will remain, an essential cornerstone of progress forward in the COVID-19 pandemic
- Health care professionals remain a critical source of medical information
  - Top three sources of trusted SARS-CoV-2 information are:
    - CDC (65%)
    - State or local health departments (49%)
    - Doctors, nurses, or medical providers (48%)

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# COVID-19 Summary

- What went wrong?
  - Initial preparations and early public health responses, availability of resources
  - Abandonment of evidence-based medicine in favor of “we have to do something now”
  - Misinformation, mixed messages from numerous sources created chaos
- What went right?
  - Eventual extent of public health response r.e. infection prevention, testing
  - Rapid clinical investigations & availability of medications proven effective for treatment (and hopefully vaccines to follow)
  - Rapid availability of significant epidemiologic data, publication of studies and guidelines in record-setting times
  - Healthcare and public health professionals have been magnificent!