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Did Dismissals of Safe Outpatient Drugs Cause Needless COVID Deaths? Dissenting Doctors Say Yes

By RealClearInvestigations RealClearInvestigations View profile Follow | Jan. 2nd, 2022

For the first nine months of the COVID-19 pandemic, there were no officially approved outpatient treatments for combating the disease. From March 2020, when the virus first emerged in the United States, until that November, when the Food and Drug Administration authorized emergency use of monoclonal antibodies, health authorities advised that the infected do little but quarantine themselves, drink plenty of fluids and rest unless hospitalization was necessary.

During those chaotic final months of Donald Trump's presidency, the medical establishment expressed extreme caution regarding outpatient treatments for the virus, and these warnings were amplified by major media hostile to the president, for example when he touted the anti-malaria medicine hydroxychloroquine.

Although an estimated 12 percent to 38 percent of prescriptions (pdf) are written for FDA-approved drugs used "off-label" (including Botox and Viagra), Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, declared early on that providers should dispense only medicines proven to be safe and effective for COVID patients through "randomized, placebo-controlled trials." These can take months or years to conduct, and often at great cost.

Given the time involved, some governments and independent practitioners considered that standard a recipe for inaction that meant likely death for untold numbers of victims. These medical dissenters instead treated COVID-19 as physicians have long responded to newly emerging infectious diseases: by administering designer cocktails of cheap, safe and readily available agents–in this case including hydroxychloroquine, antibiotics, aspirin, and vitamins–that had proven effective in treating similar illnesses or otherwise demonstrated theoretical promise due to mechanisms of action.

Dr. Brian Tyson, a primary care physician and former hospital intensivist in Imperial County, Calif., who has championed outpatient treatment, explained the calculation: "If I'm wrong with the treatment I'm giving, people are still going to die. If I'm right, how many lives have we saved? How many can be saved? Why are we erring on the side of death instead of treatment?"

RealClearInvestigations spoke or corresponded with 12 such advocates for early outpatient treatment globally—from California, Texas and Honduras to France, Israel and India. Their track record appears to challenge the prevailing official clinical guidance under which more than 500,000 Americans, among nearly 3 million globally, died from the pandemic in its first year ending March 2021. These

physicians used their years of clinical experience to make educated guesses about what combinations of drugs might work. Few used the same cocktail; there is no consensus about which drugs worked best, though some were adamant about the benefits of specific agents; but all insisted the treatments proved most effective when administered as early as possible in the course of illness. Although the efficacy of the cocktails has not been verified in clinical trials–which could rigorously account for myriad factors including the age, weight, gender, medical history and level of illness of patients–all report that their improvised efforts improved care without doing harm.

A chemist displays hydroxychloroquine tablets in New Delhi, India, on, April 9, 2020. (Manish Swarup/AP Photo)

The dissenters became proactive early on, among them:

Dr. George Fareed, an Imperial, Calif.-based former National Institutes of Health virology researcher and Harvard Medical School grad who with his primary care colleague, Dr. Tyson, reports an early outpatient treatment track record of 7,000 COVID patients with only seven deaths.

Dr. Fernando Valerio, a former Dartmouth trainee who came to national prominence in Honduras for pioneering inpatient and outpatient protocols eventually implemented nationwide. As one of only four intensive-care doctors in San Pedro Sula, a city of 1.2 million, he quickly ruled out a hospitalization-heavy approach as impractical. Instead, he prodded the government to send medical providers door-to-door in virus hotspots to distribute at-home drug kits. And Honduras' mortality rate declined markedly–to roughly half that of the United States at current count.

Dr. Darrell DeMello in Mumbai, India, who has treated patients, including employees of some of the world's largest multinational firms, with a drug regimen similar to Dr. Fareed's, and with similar results. Out of an estimated 7,500 patients, he reports, he has lost 16.

Their work raises hard questions about what the responsible practice of medicine should look like when there are no approved medical treatments in the face of likely widespread death. Could there have been more and earlier life-saving innovation before the pharmaceutical industry's remarkable development much later of vaccines and novel therapeutics? Is trying something better than doing nothing until lengthy clinical trials are completed? Or, especially when the risks of "fake news" and its viral spread are high, do the demands of providing authoritatively endorsed treatments override all?

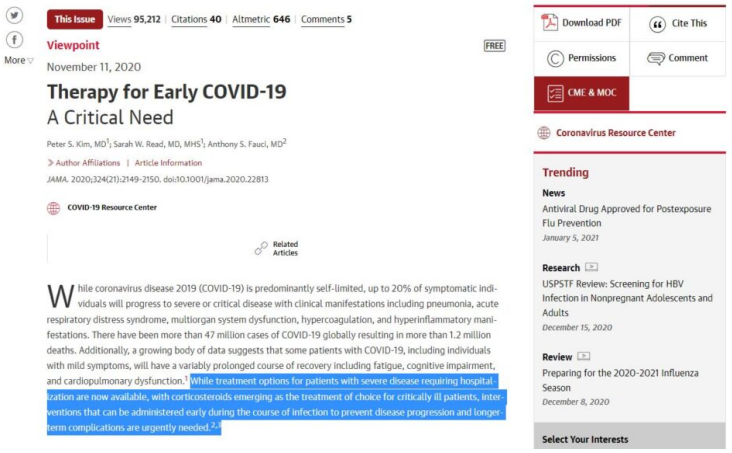
Researchers knew fairly early in the pandemic that COVID infections progressed through several stages marked by specific symptoms treatable with a slew of safe, FDA-approved medications.

For example, it was known in March 2020 that the illness progressed from a viral phase to massive inflammation across the body. Anti-inflammatory drugs–such as colchicine, the choice of Dr. DeMello in Mumbai–could have been administered at clinicians' discretion.

By June 2020 it was known that COVID could cause major blood clotting. The blood thinner Plavix, another choice of Dr. DeMello, is commonly used to prevent and treat clotting. As Dr. Tyson explained, if patients are "showing inflammatory changes, let's use an anti-inflammatory. We see people getting clots, dying of coronary artery clogs, let's use a blood thinner."

Authorities have been slow to accept this "if, then" approach. Many medical leaders have seemingly interpreted the Hippocratic dictum of "first, do no harm" as a call to wait for explicit guidance from regulatory agencies. But they were not wholly blind to or dismissive of the idea of developing early treatment regimens, including repurposed drugs, to prevent the disease's progression in infected patients–at least in theory.

In November 2020, nine months into the pandemic, Dr. Fauci co-authored an article in the authoritative Journal of the American Medical Association titled "Therapy for Early COVID-19: A Critical Need." In the article, Fauci and colleagues asserted that "interventions that can be administered early during the course of infection to prevent disease progression and longer-term complications are urgently needed." They stipulated that such treatments "must be safe with few adverse effects, easy to administer, and scalable." Yet the doctors dismissed the efficacy of a number of drugs that might fit such a regimen, including hydroxychloroquine (HCQ). Instead, they favored more expensive repurposed antivirals and endorsed "investments into targeted de novo drug design approaches for early treatment." They acknowledged that "[a]lthough this effort will be lengthy and more costly than repurposing, discovery of novel targeted antivirals may prove useful not only for COVID-19, but also in future pandemics."



Screenshot of the beginning part of article "Therapy for Early COVID-19 A Critical Need". (JAMANetwork.com/Screenshot via The Epoch Times)

It wasn't until April 2021 that the National Institutes of Health announced it would fund a large clinical trial to study repurposed drugs, including some of those favored by several of the doctors RCI interviewed–a trial that did not commence until June, and is not estimated to be fully completed until March 2023, three years after the initial, widely repeated public health goal of "two weeks to flatten the curve" of infection.

Why wasn't there greater urgency to conduct studies like this one?

President Trump's early advocacy of HCQ put him at odds with the Washington media and medical establishment. This may in part have colored public perceptions of the use of off-label drugs in the United States–just as his early suggestion that COVID might have originated in a Chinese lab sparked a powerful backlash against that possibility.

White House coronavirus adviser Dr. Scott Atlas speaks during a press conference in the Brady Press Briefing Room at the White House in Washington, DC, on Sept. 18, 2020. (Saul Loeb/AFP via Getty Images)

In both cases, articles in the highly influential medical journal The Lancet played a significant role–with one that pooh-poohed HCQ being retracted after proving

fraudulent. Although HCQ is used around the world every day to treat a variety of illnesses in adults and children, including lupus and malaria, health officials cast it as potentially dangerous; they largely dismiss the findings of those like Yale School of Public Health Professor Dr. Harvey Risch in favor of HCQ in treating COVID. "As a result," Dr. Scott Atlas, the often-dissenting adviser to the Trump White House Coronavirus Task Force, writes in his new tell-all, "A Plague Upon Our House," "urgently needed clinical trials by the NIH and FDA were never performed. In another unprecedented move, doctors were blocked from prescribing the drug, even though prescribing any other approved drug for an off-label use was routine."

U.S. tech giants censored much discussion of outpatient treatment, branding it "misinformation." YouTube in particular has silenced heterodox thinking, suspending the YouTube channel of Sen. Ron Johnson (R-Wis.), a proponent of early treatment who convened two hearings on the matter in late 2020, and removing several of Senate colleague Rand Paul's (R-Ky.) YouTube postings.

Such debates had far less resonance in resource-constrained, poorer countries. Dr. Valerio in Honduras explained to RCI that America's approach of keeping the infected home until they needed hospitalization was impracticable given his country's lack of large, state-of-the-art hospitals, and insufficient ICU beds for worsening patients. Instead, Honduras, India, Peru, and Mexico were among the countries that achieved promising results by combining cheap and widely available medicines long proven safe in treating other medical conditions. These included HCQ; azithromycin (AZM, an antibiotic sold under the brand name Zithromax with antiviral and anti-inflammatory properties); doxycycline (used to treat a variety of bacterial infections, and also with antiviral and anti-inflammatory properties); steroids; Tylenol; aspirin and the supplements Vitamins C, D, and zinc.

Most of these regimens also included ivermectin (IVM), a common drug that became increasingly controversial in the U.S. after the podcaster Joe Rogan said his doctor prescribed it off-label to him once he contracted COVID as part of a larger drug cocktail. Media voices opposed to unapproved treatments described the drug–which is widely given to people and livestock–as a "horse dewormer." The FDA has a picture of a horse on its web page addressing IVM and COVID, advising that "currently available data do not show ivermectin is effective against COVID-19." Yet IVM is one of the repurposed drugs being tested in the NIH-sponsored trial that began in June. The NIH calls IVM "generally well tolerated." In an October 2021 letter to Biden administration health officials, Sen. Johnson and colleagues expressed concern that the anti-IVM biases demonstrated by the FDA, Dr. Fauci's NIAID, and the CDC "cast doubt over the integrity of this study's eventual results."

Honduras's government deployed "medical brigades" to the homes of the infected to distribute kits filled with basic medicines, including a mouthwash of sodium hypochlorite and hydrogen peroxide, azithromycin, ivermectin, and zinc. If symptoms persisted more than seven days, the patients were given colchicine (an anti-inflammatory), prednisone (a steroid), and rivaroxaban (an anti-coagulant). The country also pursued more aggressive inpatient treatment. A study found the

protocols led to a significant decline in fatalities. Dr. Valerio's self-reported record of employing this protocol for outpatients–with the addition of fluvoxamine–has shown one death out of 440 patients.

After Mexico City implemented an outpatient treatment protocol last winter involving the distribution of some 83,000 at-home treatment kits containing IVM for COVID-positive outpatients, medical researchers observed a 55 percent–70 percent reduction in the risk of hospitalization among those who used them. Critics observed that "a causal link … cannot be ascertained" between the positive result and the drug. The kits also included aspirin, which has now been shown to reduce the severity of illness in inpatients receiving it prior to hospitalization.

A detailed analysis of Peru's drug deployment plan–which also featured IVM–appeared to demonstrate that, at least for a time, its door-to-door strategy showed a 14-fold decrease in deaths in provinces where it was employed.

In India's most populous state, Uttar Pradesh, COVID cases and deaths declined rapidly with the implementation of door-to-door visits, during which infected patients were given kits including IVM and doxycycline. Based on this success, India's national government quickly followed suit, issuing outpatient treatment protocols as cases nationwide reached their apex. For mildly afflicted outpatients, treatment included HCQ or IVM and, for patients who were not improving by day five, inhaled budesonide–a steroid used to fight lung inflammation in asthmatics that has been authorized for use in Britain, but not in the United States. India hasn't seen a spike since.

Reached in India, Dr. DeMello shared his theories about the causes and best treatments for Covid. "This is not [primarily] a viral disease," he told RCI. "This is a vascular, CNS, inflammation disease."

He said he gives his patients colchicine, which is commonly used to treat gout, because it's "like a fire retardant" against inflammation from COVID that can lead to severe, systemic illness in susceptible patients. If authorities really wanted to treat people effectively in the U.S., he says, medical providers should put "the obese, diabetics, and older people on colchicine so their bodies won't erupt into flames."

While Dr. DeMello is most emphatic about the importance of colchicine, he also typically prescribes IVM, and the blood thinner Plavix, since COVID also "is a clotting disease." The idea is to address what in his view are the three pillars of the illness: inflammation, viral replication, and coagulation.

To critics of India's approach, Dr. DeMello points to the decline in total mortality since India adopted outpatient treatment. "The government had no choice," he says. "People were dying left, right, and center. There was not enough space at the crematoriums, at the morgues."

People wait to receive their second dose of COVISHIELD, a COVID-19 vaccine manufactured by Serum Institute of India, outside a vaccination centre in Kolkata, India, on May 12, 2021. (Rupak De Chowdhuri/Reuters)

While these countries reported success with outpatient treatments, some researchers in the West who investigated the efficacy of various early treatments said they faced pushback from the medical establishment.

Dr. Stéphane Arminjon, a doctor in southeastern France with an advanced degree in systemic diseases from France's Université Grenoble, ran afoul of the country's National Council of Doctors for reporting that antihistamines like Benadryl, Zyrtec, Allegra and Claritin could be effective against COVID's extreme inflammation. He based his claim on his own hypothesis (subsequently echoed at Oxford and elsewhere) and on his team's small study of 26 patients who showed 100 percent improvement within 72 hours.

Dr. Arminjon told RCI that the long-established safety of antihistamines makes them "a perfectly applicable mass treatment." A larger study in Spain also supports his hypothesis, though the researchers conclude: "Clinical trials are necessary to determine its efficacy. As there are no commercial interests, they should be promoted by national health systems as a social responsibility."

Nevertheless, Dr. Arminjon was attacked after advocating that officials test his hypothesis in larger studies. A national medical columnist called him "a little doctor, since antihistamines are only for treating allergies." The Conseil National de l'Ordre des Médecins (National Council of the Order of Physicians) lodged a challenge that, Arminjon said, accused him of "quackery" in a case that is still pending. The council did not respond to a request for comment.

When COVID first emerged, Dr. Eli Schwartz, Israel's preeminent specialist in tropical diseases, suspected that IVM might help. So he conducted a double-blind randomized controlled study to test his hypothesis. It showed conclusively that a three-day course of IVM both reduced viral load within COVID patients and the viability of the remaining virus, suggesting an ability to severely limit

transmissibility. This finding appears significant because it suggests the medicine might fill a gap left by vaccines, which provide protection but do not prevent transmission.

Despite the possible significance of the study, Dr. Schwartz said major journals have not only declined to publish it, but some have even declined to review it. After publishing some 300 peer-reviewed papers in his career, he said he finds this strange: "Look, I thought that to have a double-blind randomized study, especially with our findings on culture viability ... I submitted it to the New England Journal of Medicine ... and they turned it down. Then the Lancet. They turned it down in a matter of hours. Sent to the journal of Clinical Infectious Diseases ... and again in a few hours they said it's not for us. ... It's strange, let's say. To be sent back within a few hours, it means they don't want to look at it."

The medical journals were not the only ones shunning IVM. In February 2021, as the drug began garnering greater coverage, its original developer, Merck, put out a curious press release. It "reaffirmed its position" that IVM not be used to treat COVID, emphasizing that there was "no scientific basis for potential therapeutic effect," "no meaningful evidence for clinical activity," and "a concerning lack of safety data in the majority of studies." Given that IVM is off-patent, it is not clear why Merck felt it needed to make this authoritative statement. Its claim that IVM raised safety concerns was also odd considering that the company had commissioned a study in 2013 confirming it was safe at 10 times the normal dose. More notable than the strangeness of the statement was that it made a glaring material omission.

A medical staff cleans her hands as she attends to a COVID-19 patient in the coronavirus disease ward of Sheba Medical Center, in Ramat Gan, Israel, on Oct. 12, 2021. (Nir Elias/Reuters)

For months Merck had been developing a new outpatient, antiviral pill for COVID called molnupiravir. In early October 2021 it announced that the pill reduced hospitalization and death by 50 percent, though subsequent data indicates only a 30 percent reduction. There are some questions about its long-term safety. Nevertheless, in late November, the FDA's advisory committee narrowly endorsed

the drug for high-risk adults, putting it on the path to potential FDA authorization. The Biden administration reserved $1.2 billion worth of the drug, pending FDA emergency-use authorization. The cost works out to $141 per day of treatment for an individual. By comparison, a 12 mg. daily dose of IVM costs roughly $19. A 24 mg. dose could be had for $38. Unlike molnupiravir, the drug has been around since 1981.

Asked about its February press release and its failure to mention that it was developing an antiviral that was a potential competitor to IVM, Merck responded that it had "nothing further to add."

To learn why only a handful of doctors publicly endorsed outpatient treatment during the first months of the pandemic, RCI reached out to more than 20 primary care physicians around the U.S.–many chosen from the Castle Connolly Top Doctors list–and asked if they would be willing to discuss early treatment of COVID. No one returned requests to discuss this issue. Reaching beyond primary care, RCI did hear back from one doctor who urged caution.

Dr. Russell Buhr, a pulmonary critical care specialist at UCLA who used to work in primary care, told RCI, "The single best thing primary care physicians can do now for preventing serious disease is to encourage their patients to get vaccinated." When asked why primary care physicians may have felt uncomfortable prescribing even relatively benign, long employed treatments to their COVID patients in the pre-vaccine era, he replied: "It's really tough to make those decisions and that's why clinical research studies are so important as they help us better understand what is safe and what actually works. I would encourage my colleagues to enroll patients in studies so we can expand our knowledge about what therapies truly help."

The dissenters see this as an insufficient approach in the context of a raging pandemic. Dr. Miguel Sierra-Hoffman, an associate professor of infectious disease at Baylor Scott & White Hospital and of pulmonary medicine at Texas A&M University, who has overseen the care of thousands of COVID patients at multiple hospitals, remains convinced that the embrace of outpatient treatments early on would have been a difference maker–and an economical one at that.

"We could have prevented this tragedy for $1. Dexamethasone, 5 cents. Ivermectin, 1 cent. Colchicine, 50 cents. Aspirin, 100 pills for four bucks," he said. "If we had given people aspirin, ivermectin, colchicine, and if they get complicated, a little dexamethasone, we could have saved the world with one dollar."

When RCI queried the NIH about why the outpatient guidelines remain devoid of strong recommendations for any of these repurposed agents, despite studies showing their promise, it replied:

"The NIH COVID Treatment Guidelines Panel reviews available information with an emphasis given to adequately-powered, well-conducted, peer-reviewed clinical trials; regardless of where they are published. Each section of the guidelines provides a description of the data reviewed and rationale behind the

recommendation. This information is there to help guide providers. The final decisions rest with the provider and the patient. The panel works diligently to review new information as it becomes available. The latest information on NIH COVID Treatment Guidelines Panel can be found here."

For his part, Sen. Johnson blames public health authorities for orchestrating a broader campaign against early treatment with repurposed drugs. "Rather than seriously consider evidence showing the potential of early treatments including ivermectin, your agencies prefer to mischaracterize, conflate and misconstrue anything that goes against the mainstream narrative and the financial interests of the pharmaceutical industry," he wrote in his October 2021 letter.

This article was written by Clayton Fox for RealClearInvestigations.

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