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Mitigating risks in prescribing and dispensing chloroquine and hydroxychloroquine for COVID-19

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During his March 19, 2020, press briefing,[1] President Donald Trump called chloroquine and hydroxychloroquine a "game changer" in the battle against COVID-19, the disease caused by the novel coronavirus that has caused a global pandemic. He went on to say, "It's shown...very, very encouraging early results. And we're going to be able to make that drug available almost immediately." The next day on Twitter, he exclaimed that "it" [chloroquine and hydroxychloroquine] must "be put in use IMMEDIATELY."[2]

Chloroquine and hydroxychloroquine are antiviral drugs that have been prescribed for decades. Approved by the U.S. Food and Drug Administration (FDA) to treat malaria, lupus, and rheumatoid arthritis, they have been brought to the forefront of public consciousness through the president's statements and anecdotal evidence repeated on the internet that the drugs are effective in the battle against COVID-19. The public attention on these drugs during the COVID-19 crisis has created serious compliance risks for healthcare organizations and medical professionals that must be addressed.

High demand despite unproven and untested claims

In February and March 2020, reports of French and Chinese studies involving chloroquine and hydroxychloroquine made their way around the internet. In the French study, Professor Didier Raoult, director of France's Research Unit on Emerging Infectious and Tropical Diseases, conducted testing under which 26 COVID-19 patients were treated with a combination of hydroxychloroquine and azithromycin, which is commonly known by one of its trade names, Z-Pak.[3]

After two weeks, 14 patients had been virologically cured. The U.S. Centers for Disease Control and Prevention (CDC) issued a statement on its website that a similar Chinese study "reported that chloroquine treatment of COVID-19 patients had clinical and virologic benefit versus a comparison group, and chloroquine was added as a recommended antiviral for treatment of COVID-19 in China."[4]

However, these and other limited studies with promising results have been sharply criticized as failing to comport with traditional clinical drug development procedures, such as employing test subject randomization and double-blind testing with control groups and placebos. Moreover, a more thorough review of these studies and others shows that their results are inconclusive at best.

For instance, in the French study, "six of the patients treated with hydroxychloroquine had adverse reactions within three days: one died, three were removed from the study when they were transferred to intensive care, one tested negative for the virus and one stopped the treatment because of nausea," *The Intercept* reported.[5] "Those failures were simply dropped from the study's statistics."

And a later Chinese study published in the *Journal of Zhejiang University* found that patients treated with hydroxychloroquine fared no better than patients who received conventional coronavirus treatment.[6] In that study, 30 COVID-19 patients were randomly split into two groups of 15. The first group received conventional coronavirus treatment, while the other received conventional treatment plus 400 milligrams of hydroxychloroquine for seven days. "Fourteen of the non-hydroxychloroquine group tested negative for COVID-19 at the end of the experiment, versus 13 of the people treated with hydroxychloroquine," reported *Newsweek.*

Nevertheless, the American public, understandably desperate for a glimmer of hope in the battle against COVID-19, has focused on these drugs as a possible cure. In one tragic example, an elderly Arizona couple reportedly ingested chloroquine phosphate to prevent contracting the coronavirus. The wife explained that after hearing the president talk about chloroquine and hydroxychloroquine during one of his press briefings, she noticed that chloroquine phosphate was an ingredient in a fish aquarium additive used as treatment against aquatic parasites. She said she thought to herself, "Hey, isn't that the stuff they're talking about on TV?"[7] She and her husband then mixed a small amount of the additive with soda and drank it. They both became severely ill immediately and were soon in critical condition. The wife recovered, but the husband eventually died.

That Arizona couple weren't the only Americans, desperate for a cure, who turned to chloroquine and hydroxychloroquine. In a press conference on March 22, 2020, New York Governor Andrew Cuomo announced that his state, which has been one of the hardest hit as of late March 2020, had acquired 70,000 doses of hydroxychloroquine, 10,000 doses of Zithromax, and 750,000 doses of chloroquine and would begin its own trials.[8] And as of late March 2020, human clinical trials testing chloroquine and hydroxychloroquine were underway in Spain and Norway.[9]