# FDA approves the emergency use of chloroquine for COVID-19

Enlarge / Medical staff at the IHU Mediterranee Infection Institute in Marseille shows packets of a Nivaquine (tablets containing chloroquine) and Plaqueril (tablets containing hydroxychloroquine) on February 26, 2020,.

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On Saturday, the Food and Drug Administration issued an Emergency Use Authorization that will allow patients suffering from COVID-19 to be treated using drugs without clear evidence of the drugs' efficacy. The move comes after President Donald Trump has touted the drugs' potential several times on the basis of tiny, anecdotal trials. There have also been reports of hoarding of the drugs, which are needed by people with some autoimmune disorders.

## Potential or hype?

The drugs in question are relatives of chloroquine, specifically chloroquine phosphate and hydroxychloroquine sulfate. Originally developed as an antimalarial, chloroquine has a variety of effects, including the ability to reduce immune activity. That has made it useful for the treatment of autoimmune disorders such as lupus and rheumatoid arthritis. Given its multiple effects, it's not surprising that the drug

also has a variety of side effects, the most significant probably being a slowing of the heart's rhythm that can potentially lead to fatal complications. (Technically, the drug extends the QT interval.)

What does any of this have to do with a coronavirus? As we discussed when exploring potential treatments for SARS-CoV-2, chloroquine can also alter the pH of the compartment in which some viruses are brought into the cell. This can interfere with the process of depositing the virus' genome inside the cell and thus block the virus' ability to reproduce. Experiments in cultured cells infected by SARS-CoV-2 indicated that chloroquine treatments can keep the virus from spreading within the culture.

But cultured cells are very different from the environments the drugs would encounter in the human body, and SARS-CoV-2 obviously behaves differently from earlier coronaviruses. So ideally, we would want evidence that it works in humans against the source of the current pandemic.

Unfortunately, all we have at present is anecdotal evidence. One small trial indicated that the drug was somewhat effective on its own, with its effectiveness enhanced by an antibiotic. But a recent perspective on the drugs' use noted that the trial had "serious methodological flaws," and follow-up work lacked any negative controls to compare with the treated group. There are also indications that the trial was rushed through peer review at a journal edited by one of its authors, who has been involved with research that contains fabricated data.

Meanwhile, a small study performed in China saw no indication that the drug was effective on its own. And it's not clear why an antibiotic, which normally targets bacteria, would enhance the effect of an antiviral treatment. Larger, properly controlled clinical trials are already in progress, but it may be months before they produce enough data for us to make

evidence-based decisions here.

## Wait for evidence?

But the absence of any other known treatments for this highly infectious disease has led to a number of people latching on to the anecdotal reports about chloroquine drugs, most prominently including President Trump. This has led to a nationwide shortage as doctors and even dentists have handed out unjustified prescriptions or attempted to hoard the drugs for themselves.

This has made the drugs difficult to obtain for those who use them to treat immune disorders, raising the prospect that some of the people with those autoimmune disorders will need extensive care from our overstretched medical system. And at least two people attempting to self-medicate have ended up dead. As a result, some scientists have been harshly critical of Trump's promotion of the drug.

But now the FDA has stepped in. In a letter released on Saturday, the FDA's Chief Scientist, Denise Hinton, responded positively to a request from the Department of Health and Human Services to provide an Emergency Use Authorization for chloroquine-based drugs. According to the law that governs Emergency Use, authorizations can be made after the Secretary of Health and Human Services declares a public health emergency, which has already happened. At that point, the judgement about whether an authorization should be granted is "based on the totality of scientific evidence available to the secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing" the cause of the emergency.

Obviously, "reasonable to believe" can mean different things to different people. Hinton specifically refers to what she terms the "limited" studies mentioned above and notes that a

handful of other countries have recommended the use of chloroquine. For her, this constitutes “reasonable.” For others, it almost certainly will not, ensuring that the decision will be controversial.

## Who gets it?

The perspective we linked to above recommends that any use of chloroquine attempt to prioritize availability for those in clinical trials, as well as those who need it to treat other conditions. The FDA’s Authorization will be specifically for those who cannot enroll in a clinical trial and will attempt to fulfill their needs using the Strategic National Stockpile, with distribution from there to regional health authorities. According to The Washington Post, two pharmaceutical giants have already agreed to supply the stockpile with additional doses. Use will be limited to hospitals, which should avoid issues with public hoarding, although the distribution of any materials to health care providers has been very chaotic in the United States.

The guidance to patients and doctors on the use of the drug emphasizes our uncertainty. “Chloroquine phosphate is experimental because we do not know if it works for COVID-19,” the guidance for patients notes, before going on to say that “There is limited information known about the safety and effectiveness (whether this will make you better) of using chloroquine phosphate for hospitalized patients with COVID-19.” Doctors are warned that [t]he optimal dosing and duration of treatment for COVID-19 is unknown” and instructed to carefully monitor heart activity for indications of problems caused by the drugs’ side effects.

Given that we probably have weeks to months to go before properly controlled clinical-trial data allows us to make conclusions about any drug’s effectiveness, it’s likely that chloroquine will remain the standard treatment for the peak of

several regional epidemics in the US. The one thing that this decision does ensure is that we’ll have lots of anecdotal reports on its use to complicate the public’s understanding of treatment options.

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