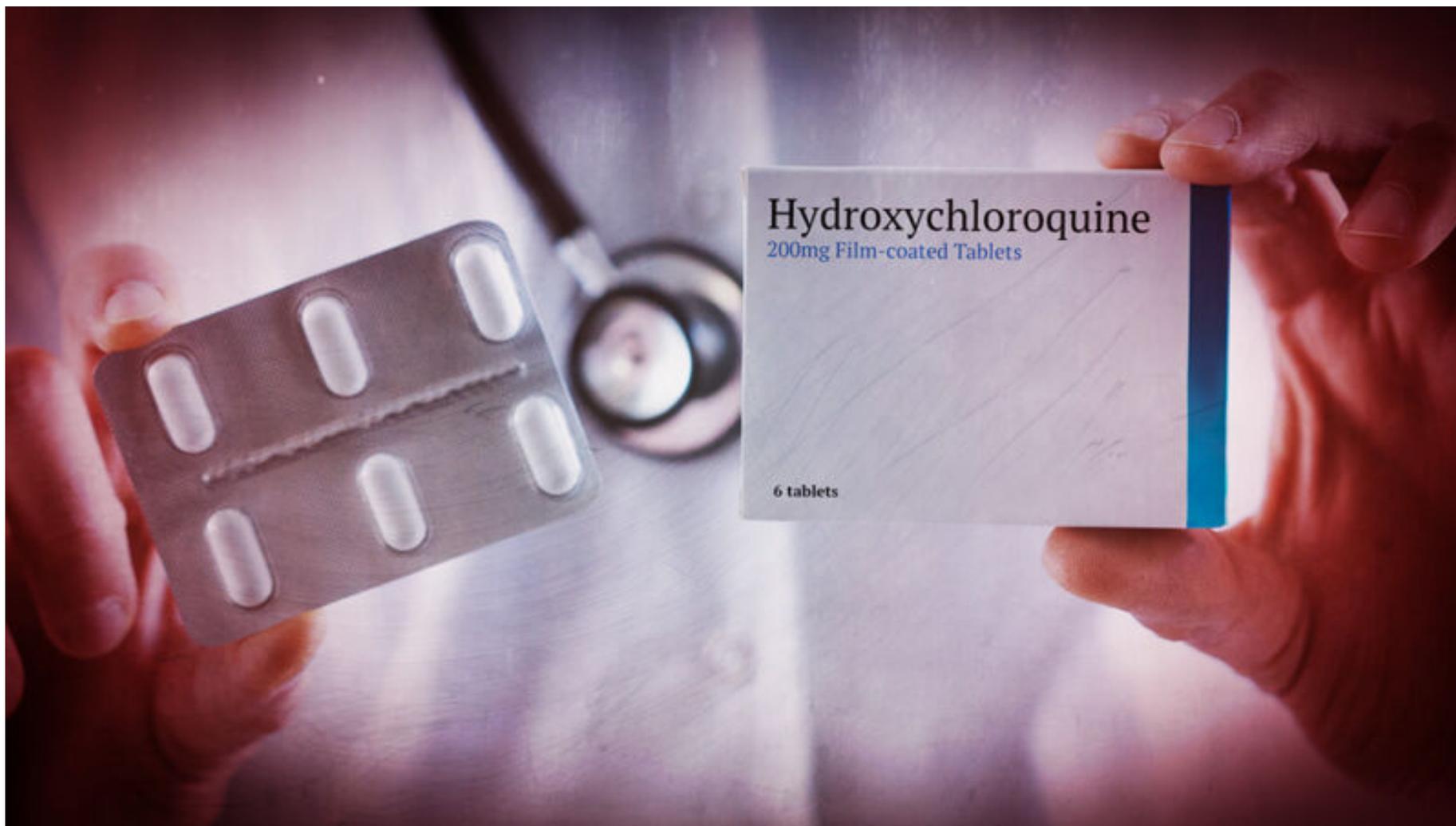


Doubt looms over hydroxychloroquine study that halted global trials

Researchers are skeptical of a data analytics company that has not shared data.

BETH MOLE - 6/3/2020, 4:50 AM



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The Lancet medical journal on Tuesday issued an “[expression of concern](#)” over the validity of a recent study suggesting that the anti-malarial drugs chloroquine and hydroxychloroquine raise the risk of death and heart complications in hospitalized COVID-19 patients.

More than a hundred outside experts have raised questions and skepticism about the data and analysis, even as researchers halted clinical trials in light of the study's findings.

The two drugs at the center of the controversy have had a high profile during the pandemic, with many prominent figures—most notably President Donald Trump—promoting them as effective against COVID-19. On May 18, Trump even told reporters that he was [taking the drugs](#) himself to prevent infection from the new coronavirus, SARS-CoV-2.

Despite the publicity, there's little evidence to support the efficacy of chloroquine or its analogue, hydroxychloroquine, to prevent or treat COVID-19. Small studies done so far have only provided mixed and inconclusive results in COVID-19 patients. The two drugs are only approved for use against malaria and autoimmune diseases, such as lupus and rheumatoid arthritis. They have also long been [linked to risks of heart complications](#).

The limited evidence for use against COVID-19 and the known risks [led the Food and Drug Administration to issue a safety warning](#) that the drugs “[should be limited to clinical trial settings or for treating certain hospitalized patients](#).”

In the Lancet study—which was published May 22 and [reported by Ars](#)—researchers aimed to provide some clarity of the drugs' effects in COVID-19 patients. The researchers claimed to do so using the largest set of data to date, involving more than 96,000 hospitalized COVID-19 patients from six continents. According to the authors, a thorough hashing of the data indicated that those taking either hydroxychloroquine or chloroquine had significantly higher risks of death and heart complications compared with COVID-19 patients who did not take either of the drugs.

The safety issues were concerning enough that on May 26, the World Health Organization announced that it was [suspending the use of hydroxychloroquine in its global Solidarity Trial](#), which is evaluating several potential COVID-19 therapies. Regulators in the UK and France also changed their recommendations surrounding the drugs.

A closer look

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Amid the global influence, outside researchers began closely examining the data behind the study—or at least tried to do so—and have been left concerned.

In an [open letter](#) sent to the study's authors and The Lancet, outside experts outlined ten significant problems, ranging from inadequate statistics, data irregularities, and a lack of ethics review. The letter was signed by more than a hundred researchers.

At the heart of the problem is that the data used for the study was from a data analytics company called Surgisphere, based in Illinois. The company claims to have an enormous trove of data harvested from electronic medical records held by hundreds of hospitals around the globe. However, Surgisphere says it cannot share said data due to data use agreements it has with the hospitals.

This is problematic for critics, [who are skeptical](#) of the data the company claims to have and would very much like to see it themselves and confirm that the analysis is accurate. In the open letter, for instance, outside experts noted that:

Data from Africa indicate that nearly 25% of all COVID-19 cases and 40% of all deaths in the continent occurred in Surgisphere-associated hospitals which had sophisticated electronic patient data recording, and patient monitoring able to detect and record 'nonsustained [at least 6 secs] or sustained ventricular tachycardia or ventricular fibrillation.' Both the numbers of cases and deaths, and the detailed data collection, seem unlikely.

In addition to a lack of transparency over the data, [a report by The Scientist magazine](#) also noted that Surgisphere's founder, Dr. Sapan Desai, has a less than pristine past. The magazine noted that Desai, who trained in vascular surgery and founded the company in 2008, resigned from a hospital position shortly after three medical malpractice suits were filed against him in 2019.

Further, before Desai and Surgisphere focused on data analytics, their most public-facing activity was selling medical textbooks. According to The Scientist, the textbooks had on Amazon from accounts impersonating actual physicians. One of the impersonated physicians, a breast surgical oncologist, told the magazine that she and colleagues eventually got Amazon to remove the reviews.

For several years, Desai also published a medical journal called [the Journal of Surgical Radiology](#), which abruptly shuttered in 2013 despite its website claiming to have accrued 50,000 subscribers in short order.

Ongoing concerns

In response to criticism and skepticism over the COVID-19 data, [Surgisphere issued a statement](#) saying, in part, that it will submit to an independent audit of its data. On May 30, some of the minor data irregularities—including a mislabeled hospital—[were corrected in The Lancet](#).

Surgisphere wrote in its statement that it is:

[V]itally important that our scientific colleagues around the world understand the validity of our database, particularly regarding data acquisition, warehousing, analytics, and related reporting processes. We are committed to demonstrating the high standards we hold at Surgisphere, and the robustness of the work that has been completed.

Nevertheless, on Tuesday, The Lancet issued an expression of concern over the study, saying that “although an independent audit of the provenance and validity of the data has been commissioned by the authors not affiliated with Surgisphere and is ongoing, with results expected very shortly, we are issuing an Expression of Concern to alert readers to the fact that serious scientific questions have been brought to our attention. We will update this notice as soon as we have further information.”

Two other COVID-19-related studies involving Surgisphere data have also been called into question. The New England Journal of Medicine issued its own [expression of concern on a Surgisphere-associated study](#). The research looked at the effect of preexisting use of angiotensin-converting enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs) in COVID-19 patients. Researchers have [also questioned a pre-print study](#) (one that has not yet been published or peer reviewed) looking at the anti-parasitic drug Ivermectin for COVID-19.

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