Written by **Dennis Behreandt** on June 5, 2020

Study Claiming Hydroxychloroquine Dangerous and Ineffective Is Retracted

A study that was published to great fanfare in the prestigious journal *The Lancet* has now been retracted.

The retracted study, titled "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis," was led by Dr. Mandeep R. Mehra, a cardiologist and medical director of the Brighman and Women's Hospital Heart and Vascular Center in Boston.

Using data sourced from a small company called Surgisphere, the study's authors, which also included Sapan Desai, the founder of Surgisphere, reached an alarming conclusion.

"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," the author's summarized. "Each of these drug regimens was associated with decreased in-hospital survival and an increased frequency of ventricular arrhythmias when used for treatment of COVID-19."

Shocked by this conclusion, researchers conducting or contemplating clinical trials involving hydroxychloroquine began to reevaluate their efforts based on worries that patients included in such studies might be harmed. "The World Health Organization and a number of national governments have changed their Covid-19 policies and treatments on the basis" of the study, *The Guardian* newspaper reported.

But almost immediately after the study was published, other researchers began to notice disquieting elements in the work.

"Critics were quick to point out anomalies … including implausible findings that should have been detected during the peer review process — like the … apparent inclusion of a large number of Covid-19 cases very early on in the pandemic, even in Africa, where few hospitals have electronic health records," the *New York Times* reported.

The *Times* continued: Many researchers were astonished to find out that such a database could exist, or that the gathering and analysis of tens of thousands of medical records on multiple continents could have been carried out so quickly."

A key element of science in general and scientific studies in particular is the idea of reproducibility. In scientific writing, it is expected and required that researchers provide sufficient details in a "materials and methods" section or sections of a paper so that other researchers can reproduce the described experiment. Such reproduction allows other researchers to evaluate the methods and data described while allowing other researchers to derive the conclusions — or not — for themselves. This is the central feedback loop in scientific publishing that prevents fraud and ensures accuracy of results.

This was the central failing of the studies (there were two in total) that were based on the Surgisphere

data.

After such concerns were raised, the authors of the paper who were not affiliated with Surgisphere arranged for an independent review of the data.

In their statement retracting their work, they described the outcome of this review:

> After publication of our Lancet Article, several concerns were raised with respect to the veracity of the data and analyses conducted by Surgisphere Corporation and its founder and our co-author, Sapan Desai, in our publication. We launched an independent third-party peer review of Surgisphere with the consent of Sapan Desai to evaluate the origination of the database elements, to confirm the completeness of the database, and to replicate the analyses presented in the paper.
>
> Our independent peer reviewers informed us that Surgisphere would not transfer the full dataset, client contracts, and the full ISO audit report to their servers for analysis as such transfer would violate client agreements and confidentiality requirements. As such, our reviewers were not able to conduct an independent and private peer review and therefore notified us of their withdrawal from the peer-review process.

Lancet published the retraction on June 4, noting that the study's authors "were unable to complete an independent audit of the data underpinning their analysis. As a result, they have concluded that they "can no longer vouch for the veracity of the primary data sources." *The Lancet* takes issues of scientific integrity extremely seriously, and there are many outstanding questions about Surgisphere and the data that were allegedly included in this study. Following guidelines from the Committee on Publication Ethics (COPE) and International Committee of Medical Journal Editors (ICMJE), institutional reviews of Surgisphere's research collaborations are urgently needed."

According to *The Guardian*, Surgisphere seems to have a colorful background, one that might not be expected of a professional scientific organization.

In its investigation, *The Guardian* found:

• "Several" of Surgisphere's employees "have little or no data or scientific background."

• One "science editor" for the company "appears to be a science fiction author and fantasy artist."

• One employee, "listed as a marketing executive is an adult model and events hostess."

• Until recently, the company's "get in touch" link on its website "redirected to a WordPress template for a cryptocurrency website."

• Company founder Desai in 2008 attempted to crowdfund some type of wearable device on Indiegogo described as a "next generation human augmentation device that can help you achieve what you never thought was possible."

The *Lancet* study on hydroxychloroquine was not the only study based on "data" from Surgisphere to be retracted. Also retracted was a study led, again, by Mandeep R. Mehra that was published in *The New England Journal of Medicine*. That study, titled "Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19" concluded that angiotensin-converting-enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs) were safe for use in COVID-19 patients with underlying cardiovascular disease.

In a letter to the editor of *The New England Journal of Medicine*, Mehra and his co-authors not affiliated with Surgisphere requested retraction on similar grounds to the retraction of the *Lancet* article.

"Because all the authors were not granted access to the raw data and the raw data could not be made available to a third-party auditor, we are unable to validate the primary data sources underlying our article, 'Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19,'" they wrote. "We therefore request that the article be retracted. We apologize to the editors and to readers of the *Journal* for the difficulties that this has caused."

The retractions have led to concerns that the integrity of the peer-review process in particular and of scientific publishing in general has been undermined.

The retractions "raise troubling questions about the state of scientific research as the pandemic spreads," said the *New York Times*. "Thousands of papers are being rushed to online sites and journals with little or no peer review, and critics fear long-held standards of even the most discerning journals are eroding as they face pressure to rapidly vet and disseminate new scientific reports."

It goes without saying that this situation is ripe for abuse by those seeking to use science to push political agendas.

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