

## Disputed Hydroxychloroquine Study Brings Scrutiny to Surgisphere

Scientists have raised questions about the dataset published in *The Lancet* last week that triggered the suspension of clinical trials around the world—and about Surgisphere Corporation, the company behind the study.



Catherine Offord

May 30, 2020

Surgisphere Corporation, the [company](#) that supplied data for a controversial study on the health risks of hydroxychloroquine for COVID-19 patients published in *The Lancet* last week (May 22), has found itself in the spotlight after researchers raised questions about the dataset.

The *Lancet* study, which lists Surgisphere founder and CEO Sapan Desai as one of four coauthors, reported harmful effects tied to the anti-malaria drug hydroxychloroquine among patients with COVID-19. In response to the findings, the World Health Organization (WHO) and several other health organizations [stopped or suspended clinical trials](#) of the drug while they look more closely into the compound's safety.

See [“WHO Halts Hydroxychloroquine Testing After Safety Concerns”](#)

The database used for the *Lancet* study, which the paper states includes 96,032 patients from 671 hospitals across six continents, is accessible only by Surgisphere. But in the week since the paper's publication, concerns about that dataset have swirled on social media, on the post-publication discussion website PubPeer, and in newspapers.

Initial concerns centered on the paper's statistical analyses, as well as the fact that COVID-19 patient data were surprisingly homogeneous across continents, despite known differences in demographics and underlying health conditions in those populations. More-recent concerns have broadened to other aspects of the dataset. Desai has since acknowledged one error in an Australian cohort and yesterday published a brief [correction](#). While he has said

---

ABOVE: 875 N Michigan Avenue, Chicago—the address on Surgisphere Corporation's website © ISTOCK.COM, [REDUNNLEV](#)

---

in an interview with *The Scientist* that he is looking into clearing up confusion around the study findings, Desai has continued to defend his work and the integrity of the Surgisphere data.

But that response has not assuaged the concerns of the scientific community. On May 28, an [open letter](#), which has now accrued more than 180 signatories at research institutions around the world, laid out multiple other problems with the study data and analyses. In addition, readers of the study are beginning to ask about the nature and history of Surgisphere, and how it managed to obtain such a complex dataset in a relatively short period of time.

## Sources of Surgisphere's global COVID-19 data

In explaining the decision to suspend hydroxychloroquine testing, WHO chief scientist Soumya Swaminathan said that although the *Lancet* data weren't from a randomized controlled trial, the gold standard in clinical research, they "came from multiple registries and quite a large number of patients, 96,000 patients," [NPR](#) reported earlier this week.

Concerns about the *Lancet* paper began appearing on [blog posts](#) and [PubPeer](#) soon after the study's publication, however. Statisticians and medical scientists pointed to several peculiarities, including a lack of information about how observational data were adjusted during statistical analyses, and surprisingly high mortality rates in patients who received hydroxychloroquine—a drug that, while unproven as a treatment for COVID-19, has been in use in hospital settings for decades and had not shown such major negative effects in studies up until this point.

The proportion of COVID-19 patients in Africa who were included in the dataset was also "rather high," one [PubPeer](#) commenter noted: while 15,738 COVID-19 cases had been [reported](#) across the continent by the African Centers for Disease Control and Prevention as of April 14, the study claimed to have data—including detailed electronic health records—for 4,402 hospitalized patients up to this same date.

[James Watson](#), a senior scientist at the Mahidol Oxford Tropical Medicine Research Unit in Thailand, says he has doubts that any research organization would have been able to obtain such detailed records for so many people in Africa so quickly. He outlined this and concerns about multiple other aspects of the study in the [open letter](#), which includes 17 signatories based at institutions in Africa.

**The profile of Surgisphere has risen dramatically during the COVID-19 pandemic.**

Based on healthcare workers' descriptions of medical record-keeping at many hospitals in Africa, "I just find it very hard to believe," Watson tells *The Scientist*. His unit [suspended a just-launched trial](#) of hydroxychloroquine following guidance from UK regulators shortly after the *Lancet* study was published.

Desai tells *The Scientist* that the high-quality hospital data in the publication result from Surgisphere working only with "top-tier institutions. . . . Naturally, this leads to the inclusion of institutions that have a tertiary care level of practice and provide quality health care that is relatively homogeneous around the world."

A signatory on the open letter to *The Lancet*, [Anthony Etyang](#), a consultant physician and clinical epidemiologist with the KEMRI-Wellcome Trust Research Programme in Kenya, writes to *The Scientist* that he too has doubts about the numbers of African patients in the dataset, adding that even private hospitals on the continent with top care often have poor medical records.

Study coauthors [Mandeep Mehra](#), the medical director of the Brigham and Women's Hospital Heart and Vascular Center, and [Frank Ruschitzka](#) of University Hospital Zurich did not respond to requests for comment.

In another development on May 28, *The Guardian* reported that researchers and journalists had been unable to verify the source of the Australian data included in the study. Surgisphere's dataset included 73 deaths in Australia as of April 21, even though Johns Hopkins University, which has been tracking COVID-19 cases and deaths since the start of the outbreak, had counted just 67 by that point, the *Guardian* reported.

Desai explained the discrepancy to the *Guardian* by noting that a hospital in Asia had inadvertently been included in the Australian dataset. He has told media outlets that he cannot share the names of any of the hospitals involved in Surgisphere studies due to pre-arranged privacy deals with those hospitals, but adds in an interview with *The Scientist* that he'll inquire if any hospitals are willing to voluntarily come forward to confirm their participation.

On May 29, [Jessica Kleyn](#), a press officer at *The Lancet* journals, informed *The Scientist* in an emailed statement that the authors had corrected the Australian data in their paper and redone one of the tables in the supplementary information with raw data rather than the adjusted data Desai said had been shown before.

"The results and conclusions reported in the study remain unchanged," Kleyn adds in the email. "The original full-text article will be updated on our website. The Lancet encourages scientific debate and will publish responses to the study, along with a response from the authors, in the journal in due course."

[Andrew Gelman](#), a statistician at Columbia University who has [blogged](#) about the article and started the [PubPeer](#) discussion on it, writes in an email to *The Scientist* that the authors' update "does not address many of the questions that have been raised about this study, but of course it is good for them to correct mistakes and omissions when they find them."

Watson writes in an email to *The Scientist* that the authors "have not addressed the other nine points referred to in the letter, and we do not understand why they cannot at least provide data aggregated by country rather than by continent." He adds that the signatories on the letter would also like to know which countries in Africa the team is working worth.

"By allowing the authors to post this correction and not address any of the other concerns," Watson continues, "The Lancet appear to [be] stating that so far they are not worried about the reliability of the study."

## Surgisphere and its founder

Surgisphere is currently [headquartered](#) in Palatine, Illinois, and run by Desai, who trained in vascular surgery, a subject on which he has published many scientific articles and books. Until February 10 of this year, Desai was employed by Northwest Community Hospital (NCH) in suburban Arlington Heights. He tells *The Scientist* that he resigned for family reasons.

Court records in Cook County, Illinois, show that Desai is named in three medical malpractice lawsuits filed in the second half of 2019. He tells *The Scientist* in a statement sent through his public relations representative [Michael Roth](#) of Bliss Integrated that while he can't comment on ongoing litigation, he "deems any lawsuit naming him to be unfounded."

He also sent a comment purporting to be from [Alan Loren](#), the executive vice president and chief medical officer of NCH: "Dr. Desai was employed at NCH and resigned in February 2020. We did not have any problems with him while he was here."

Asked by *The Scientist* if he made this statement, Loren says, "What I can tell you is that he was employed here and he did resign. I can't speak to whether or not there were any problems." He adds that he spoke to Desai on May 28 and told him that "what I recall is that he resigned. I don't remember the exact date. And that was it."

Desai is now focused on Surgisphere, which currently has 11 employees, he tells *The Scientist*. Surgisphere's [website](#) states that, "When Dr. Sapan Desai founded Surgisphere Corporation, the mission was simple: to harness the power

of data analytics and improve the lives of as many people as possible.” Desai tells *The Scientist* that his company has always been involved in data analytics.

When Desai established the company in 2008 while a surgical resident at Duke University in Durham, North Carolina, Surgisphere Corporation’s most visible activity was [marketing textbooks](#), produced by Surgisphere, to medical students.

Reviews of the company’s products on [Amazon](#) are polarized, and a handful of positive reviews that appeared to impersonate actual physicians were removed when those doctors complained to Amazon. [Kimberli S. Cox](#), a breast surgical oncologist based in Arizona, tells *The Scientist* that she was one of several practicing physicians who in 2008 discovered five-star reviews next to names that were identical or very similar to their own, that they had not written. She and her colleagues successfully persuaded [Amazon](#) to take the reviews down.

Desai denies that he knew about or was in any way involved in the posting of fake reviews for Surgisphere’s products. “If I wanted to review my own products, I could do it in my own name,” he says. Amazon did not return requests for comment before this story was published.

When Desai moved to the University of Texas Health Science Center at Houston in 2012 as a fellow in vascular surgery, he registered Surgisphere Corporation in Texas. By that point, Surgisphere had started publishing the *Journal of Surgical Radiology*, a medical journal that, according to its [website](#), “accrued over 50,000 subscribers spanning almost every country around the world” from 2010 to 2013.

The website further notes that, “With almost one million page views per month, *J Surg Rad* earned a reputation as one of the first high quality peer-reviewed *online* medical journals. The Journal was indexed by most of the major medical indexes, and specific articles still appear in PubMed, EBSCO, and other sources.”

“It was amazing how fast we were able to grow it,” Desai tells *The Scientist*. “We had quite the editorial board.” The last issue was published in January 2013. “Running a medical journal is a full-time job,” he says. “I ran out of time.”

## Surgisphere’s research during the coronavirus pandemic

**Sapan Desai says he can understand people’s concerns and that the burden of proof rests with Surgisphere.**

The profile of Surgisphere has risen dramatically during the COVID-19 pandemic. In addition to the recent *Lancet* study, Surgisphere provided data for a study published in the *New England Journal of Medicine* earlier this month. That study, which stated it was based on data from 169 hospitals in Asia, Europe, and North America, reported that cardiovascular disease was associated with increased risk of death among hospitalized COVID-19 patients.

However, heart drugs known as [ACE inhibitors and ARBs](#), which some other studies had hinted were associated with an increased risk of death in people hospitalized with COVID-19, were not associated with higher mortality in these patients, the study concluded.

Currently, Surgisphere is providing data for [another](#) COVID-19 study with [Lee Wallis](#), the head of emergency medicine for the Western Cape Government, the University of Cape Town, and Stellenbosch University. Like the study coauthors on the *Lancet* paper, Wallis and his collaborators helped design the study, but all of the raw data are kept by Surgisphere as proprietary information.

Wallis tells *The Scientist* that he has seen aggregated rather than hospital-level data, but that he is satisfied by Desai's detailed descriptions of the dataset, and that all the necessary ethical and data-ownership requirements have been met.

The company has publicized other projects, too. In early March, a [story](#) appeared on a medical device information site touting a COVID-19 diagnostic tool developed by Surgisphere that could identify patients "likely to have coronavirus infection" with "93.7% sensitivity and 99.9% specificity." The story, which Desai says Surgisphere did not write, quotes Desai as saying: "This tool is the first effective weapon in the fight against this global pandemic."

Desai says that the story he's quoted in "appears to misconstrue the resources we created," directing *The Scientist* to descriptions of a "COVID Severity Scoring Tool" and a "COVID-19 Triage Decision Support Tool" on the [company's website](#). *The Scientist* could not obtain more information about exactly how the tools worked or how estimates of their specificity and sensitivity were calculated.

As for *The Lancet* hydroxychloroquine study, Desai says he can understand people's concerns and that the burden of proof rests with Surgisphere. "We want to prove this to the world," he tells *The Scientist*. "One thing that we might be able to do is get what we've done audited. That will be external, third party, independent of who we are, and can help validate all of this."

**Keywords:**

chloroquine, clinical data, clinical research, coronavirus, corrections, COVID-19, data collection, disease & medicine, epidemiology, hydroxychloroquine, pandemic, privacy, publishing, pubpeer, research integrity, SARS-CoV-2, Surgisphere, The Lancet