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# Authors Retract Studies That Found Risks of Antimalaria Drugs for Covid-19

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Two major studies casting doubt on the ability of antimalaria drugs to treat Covid-19 patients based on data from a little-known Chicago company, Surgisphere Corp., were retracted Thursday.

The Lancet first pulled a study published late last month that found antimalarials provided no benefit as a treatment for Covid-19 infections while increasing the risk of heart problems and death. The New England Journal of Medicine then retracted a separate article, published in early May, that examined the impact of cardiovascular and blood-pressure drugs in Covid-19 patients.

Both articles featured three of the same authors, Mandeep Mehra, Amit Patel and Sapan Desai, and were based on data supplied by Dr. Desai's company, Surgisphere.

Surgisphere had said it collected the de-identified patient information from hospitals that was used in the studies. The Wall Street Journal contacted more than a dozen large U.S. hospitals, including some that treated high numbers of Covid-19 patients. None said they had an arrangement to share patient data with Surgisphere, and several said they had never heard of it.

Dr. Desai has said previously, through a spokesperson, that his firm was unable to identify the 671 hospitals in the Lancet study due to privacy agreements. He was an author on both papers. Though his name was on the New England Journal of Medicine retraction, it wasn't on the Lancet retraction.

He declined to comment through a representative on Thursday.

Three of the Lancet paper's authors said they decided to retract the paper after Surgisphere refused to share the full data set as part of a review triggered by concerns raised by outside researchers. The Lancet published a correction to the study on May 29.

"We always aspire to perform our research in accordance with the highest ethical and professional guidelines," the authors, Drs. Mehra, Patel and Frank Ruschitzka said in a statement. "We can never forget the responsibility we have as researchers to scrupulously ensure that we rely on data sources that adhere to our high standards. Based on this development, we can no longer vouch for the veracity of the primary data sources."

The authors also apologized for "any embarrassment or inconvenience that this may have caused."

The Lancet said in a statement it "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."

For the peer-reviewed study, the authors analyzed medical records they said Surgisphere aggregated from some 96,000 patients across six continents who were hospitalized with confirmed cases of Covid-19 between Dec. 20 to April 14. Of the total, about 15,000 patients were treated with the antimalaria drugs hydroxychloroquine and chloroquine, alone or in combination with an antibiotic.

The paper's findings indicated the antimalarials—which many doctors have used to treat Covid-19 patients—didn't help while increasing the risk of cardiovascular problems and death.

Following the study, the World Health Organization paused enrolling patients in clinical trials of hydroxychloroquine, although this week the organization said it resumed the trials.

In the days following publication of the study, however, other researchers began to raise questions about the Surgisphere data, first on social media and in emails, then in an open letter to The Lancet and the study's authors. More than 100 researchers signed on to the letter.

Following the Lancet's retraction today, Adrian Hernandez, director of Duke Clinical Research Institute at Duke University School of Medicine, and who wasn't involved in the study, said a retraction was appropriate but the authors still owed the research community an explanation.

"What happened here was a failure of the authors, and peer review, and the journal, and to prevent something like this from happening again we really need to understand what went wrong

here,” said Dr. Hernandez, who had signed the open letter. He said studies that harness large data sets or are observational should be as transparent as randomized clinical trials, including data origins, and allow for independent views.

Surgisphere said it has petabytes of data from more than 100 million patients, culled from some 1,200 hospitals and institutions on six continents.

One issue raised by outside researchers was with the numbers of patients purported to be in the data set: In certain cases, they exceeded the total number of Covid-19 patients in certain countries and regions. They criticized the authors’ decision not to share information about which hospitals or countries provided the patient data. Researchers also wondered about Surgisphere’s claim to have built such a massive database and analyzed the data so quickly.

“This is a bit weird to have a very large study with just four authors and no acknowledgments” thanking people involved with data processing and analysis, said James Watson, a senior scientist at the MORU Tropical Health Network, a research group, who had outlined criticisms of the study in an open letter to The Lancet that eventually drew more than 100 signatories. “That was one of the first things we thought was a bit odd.”

On May 29, the Lancet issued the correction to the study, saying that the study had incorrectly reported figures from Asia and Australia but that the overall findings remain unchanged. Earlier this week, both the Lancet and N.E.J.M. each issued a so-called expression-of-concern about each study.

Cedars-Sinai Medical Center in Los Angeles, IU Health Methodist Hospital in Indianapolis and Northwell Health in New York are among the hospital systems which said they hadn’t provided Covid-19 patient data and were unfamiliar with Surgisphere.

Dr. Mehra, the lead author who is a well-known cardiologist at Brigham and Women’s Hospital in Boston and a faculty member at Harvard University, said he was introduced to Dr. Desai and Surgisphere by one of his co-authors.

“When discrepancies in the data started to arise, I and the remaining co-authors immediately asked for a re-analysis from Surgisphere,” he said in a statement. They contracted with a private firm to conduct an independent review. He said Surgisphere declined Wednesday to turn over its data for an examination, citing client agreements.

“Since we do not have the ability to verify the primary data or primary data source, I no longer have confidence in the origination and veracity of the data, nor the findings they have led to,” Dr. Mehra said.

The authors of the New England Journal of Medicine paper said in a statement published on the journal’s website: “We are unable to validate the primary data sources underlying our article.”

A third paper with the authors looking at the antimicrobial drug ivermectin was posted online in early April on a so-called preprint server.

Dr. Desai founded the company in April 2008 while he was a surgery resident at Duke University School of Medicine. In filings with the state, he said the focus of Surgisphere's business was "medical education."

Last month, in an online presentation about using artificial intelligence and machine learning to tackle Covid-19, Dr. Desai said Surgisphere had built a massive health-care database. "Since at least 2010, we've collected very detailed information on about 240 billion unique patient encounters," he said. "It comes out to well over 100 million unique patients. And remember each of these encounters has literally a thousand plus data points attached to it. So, this is a petascale, a petabyte-sized database that exists today."

In 2015, Dr. Desai was the corresponding author on a paper about the potential for fraud in medical publications. "While peer-review may be an effective way to judge the scientific relevance of the article, whether it is an effective method for detecting fraud is doubtful, particularly since most peer-reviewers do not see the raw data or review high resolution images to evaluate for image manipulation," it said.

The article appeared in the Journal of Surgical Radiology, which was owned and published by Surgisphere.

Corrections & Amplifications Sapan Desai didn't initially respond to requests for comment Thursday. An earlier version of this article incorrectly said he didn't respond to requests for comment Friday. (Corrected on June 4)

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