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The Lancet Published a Fraudulent Covid-19 Study: Editor Calls It "Department of Error"

By Alliance for Human Research Protection
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Theme: Media Disinformation, Science and Medicine

On May 22, 2020, The Lancet published "Hydroxychloroquine or Chloroquine With or Without A Macrolide For Treatment of COVID-19: a Multinational Registry Analysis". It was described as an observational study purportedly involving more than 96,000 hospitalized Covid-19 patients in 671 hospitals across six continents. What was not disclosed is the fact that the two lead co-authors have significant, relevant financial conflicts of interest that just may have biased the reported findings.

- The database belongs to Surgisphere Corporation whose founder and CEO, is Dr. Sapan Desai, who is a lead co-author of the study. Dr. Desai has refused to disclose the data – for independent confirmatory review. In fact, he refuses to identify the participating hospitals, or even the countries.
- Dr. Mandeep Mehra, the lead co-author is a director at Brigham & Women's Hospital, which is credited with funding the study. Dr. Mehra and The Lancet failed to disclose that Brigham Hospital has a partnership with Gilead and is currently conducting TWO trials testing Remdesivir, the prime competitor of hydroxychloroquine for the treatment of COVID-19, the focus of the study.

The Lancet report claimed that COVID-19 "patients treated with hydroxychloroquine (with or without a macrolide) were at increased risk of de-novo ventricular arrhythmia and "a greater hazard for in-hospital death." Such an alarming finding from an inaccessible dataset should have raised concerns for the editor of the Lancet, about the integrity of the study and the accuracy of the claimed findings. In fact, within days of the Lancet publication, concerns about that dataset were raised on social media, on PubPeer, the post-publication discussion website, and in newspapers.

Within days of publication, Dr. Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases (NIAID) declared on CNN "*The scientific data is really quite evident now about the lack of efficacy*." A media blitz against hydroxychloroquine (HCQ) created panic: clinical trials aimed at testing hydroxychloroquine for COVID-19 were suspended by International public health institutions including the World Health Organization the UK government regulatory agency and the French government.

The chief scientist at the WHO, Soumya Swaminathan, stated that although the *Lancet* data weren't from a randomized controlled trial, the data were compelling because they "*came from multiple registries and quite a large number of patients, 96,000 patients*."

Knowledgeable scientists and experienced clinicians around the world were skeptical

The alarming findings and serious negative impact of the Lancet report led numerous scientists around the globe to scrutinize the report in detail. That scrutiny by legitimate, independent scientists has led to many serious questions about the integrity of the study, the authenticity of the data, and the validity of the methods the authors used.

An Open Letter posted online, is addressed to the authors of the report: Mandeep R Mehra, MD, Sapan S Desai, MD, Frank Ruschitzka, MD, Amit N Patel, MD, and to the editor, Dr. Richard Horton. The letter was signed by more than 200 prominent scientists across the world, including 17 from institutions in Africa.

The scientists question the evidence for claimed serious risks posed from the use of hydroxychloroquine in COVID-19 patients. Among the concerns raised by the scientists are the following:

- A range of gross deviations from standard research and clinical practices, such as: patients were prescribed inexplicably high daily doses of hydroxychloroquine –far higher than the FDA-recommended doses.
- There was no ethics review.
- The number of patients reportedly from Australia far exceeded the number of patients in the Australian government database;.
- Gross misrepresentation of the numbers of deaths in Australia.
- "Both the number of cases and deaths [the claimed 40% deaths in Africa], and the details provide seem unlikely."
- Refusal to identify the hospitals that contributed patient data.
- The ratios of patients who received chloroquine (49 %) to those who received hydroxychloroquine (50%) are implausible; in Australia chloroquine is not available without special government authorization.

The Guardian reported on May 28th that it could not confirm that UK's health agencies had even provided data for the study.

On May 29th *The New York Times* reported that 100 scientists and clinicians raised serious questions about the validity of the The Lancet report findings. It reported that on May 29th Dr. Mehra issued the following statement: "We *leveraged the data available through Surgisphere to provide observational guidance to inform the care of hospitalized Covid-19 patients*" [Perhaps someone can translate what "leveraged the data" means ….? The Times understated the number of scientists who signed the open letter; it is closer to 220]

Dr. James Watson, senior scientist at the MORU-Oxford Tropical Medicine Research Unit in Thailand doubts that any research organization could have obtained such detailed massive records for so many people in Africa that quickly. Based on healthcare workers' descriptions of medical record-keeping, at many hospitals in Africa, he indicated: "I just find it very hard to believe." Dr. Watson contributed concerns regarding the African data to the Open Letter. He had to suspend a just-launched trial of HCQ to comply with UK regulators following the Lancet report.

Dr. Anthony Etyang, a consultant physician and clinical epidemiologist with the KEMRI-Wellcome Trust Research Programme in Kenya, who is also a signatory to the Open Letter, wrote to The Scientist expressing his doubts about the numbers of African patients in the Surgisphere dataset, noting that even private hospitals on the continent have poor medical records.

Rather than investigating the serious issues raised about the integrity of the report, The Lancet editor posted the authors' claimed to "correction" of the numbers of patients in Asia and Australia on a page designated "Department of Error" – whatever that means!

- The nature and number of the serious "discrepancies" that have emerged following the Lancet publication of the Surgisphere "study," lead one to suspect out-and-out FRAUD.

Disputed Hydroxychloroquine Study Brings Scrutiny to Surgisphere, an investigative report by Catherine Offord in *The SCIENTIST*, May 30, 2020, looked deeper than others and uncovered background information about Dr. Desai and the changes in Surgisphere's product line and his marketing methods. In 2008, Surgisphere was the publisher of medical textbooks that ran afoul when physicians complained about falsified rave reviews. In 2010, Surgisphere became a high impact, online medical journal, whose website boasts that it "*accrued over 50,000 subscribers spanning almost every country around the world... with almost one million page views per month.*" The Journal of Surgical Radiology had a three-year run; its last issue was published in January 2013.

The Scientist reports that Dr. Desai is named in three medical malpractice lawsuits that were filed during the second half of 2019.

Additional disturbing facts about Surgisphere have been uncovered by a team of investigative reporters — Melissa Davey, Stephanie Kirchgaessner, and Sarah Boseley – for

The Guardian.

> "Surgisphere, the company that provided the database for studies published by two of the world's leading medical journals – The Lancet and The New England Journal of Medicine – based on Surgisphere data. The studies were co-authored the hydroxychloroquine studies.
>
> "Surgisphere's employees have little or no data or scientific background. An employee listed as a science editor appears to be a science fiction author and fantasy artist. Another employee listed as a marketing executive is an adult model and events hostess… until Monday, the "get in touch" link on Surgisphere's homepage redirected to a WordPress template for a cryptocurrency website, raising questions about how hospitals could easily contact the company to join its database."

The fiasco of the publication of essentially fraudulent reports in the journals with the greatest impact on both clinical treatment and public health policies, reveals how thoroughly corrupted so-called peer review has become because it lacks external, independent review by scientists who have NO STAKE in the study outcome. It was only after the reports by *The Scientist* and*The Guardian,* that the editors of The NEJM and The Lancet were compelled to issue an: "Expression of concern." This fiasco demonstrates why intelligent people seek alternative sources for reliable information.

The website, *Science Defies Politics* exposes numerous scientifically invalid studies that were essentially "hit jobs" against the use of hydroxychloroquine.

WHY are very powerful corporate-government stakeholders so intent on killing a drug with a 70 year track record? Because the drug works against the pandemic; it is readily available, and costs very little. Therefore, it poses a financial threat to both pharma companies and their partners in government and academia, those who are intent on profiting from the COVID-19 pandemic.

As uncovered by Science Defies Politics: 16 of the panel members selected by NIH to formulate the official COVID-19 Treatment Guidelines – including two of the three co-chairs – were paid by Gilead. They issued guidelines that raised fear, uncertainty, and doubt about the use of HCQ combined with AZ, while raising no fear, doubt, or uncertainty about using Gilead's unproven, unapproved, drug remdesivir; a drug that has shown mediocre performance in clinical trials. Seven of the NIH panelists failed to disclose their financial ties to Gilead. They are listed here.

The medical scientific literature is infested with financially motivated, shoddy, studies aimed at promoting products and, when a life-saving, non-patentable product, proves effective, scientists are hired to author study reports that are designed to tarnish scientists' reputations, and to proclaim findings that refute legitimate findings. In this case, studies designed to "debunk" the effectiveness of hydroxychloroquine against COVID-19.

Examples of countries and physicians who have witnessed the effectiveness of the HCQ – Az combination as a treatment for covid-19, are viewed by corporate-government collaborating partners as posing a major threat to their marketing agendas.

For example, Senegal and India are putting their hopes in hydroxychloroquine, marketed by Sanofi, under the trade name Plaquenil. A Sanofi spokesperson stated: "We are providing

the drug to hospitals and doctors to enable them to carry out clinical trials to determine whether hydroxychloroquine is effective or not, but not to treat Covid-19."

On May 23rd the Indian Council of Medical Research (ICMR) issued expanded revised guidelines for use of hydroxychloroquine (HCQ) for COVID-19:

> "The Joint Monitoring Group and the NTF have recommended prophylactic use of HCQ in asymptomatic frontline workers, such as surveillance workers deployed in containment zones and paramilitary/police personnel involved in Covid-19 related activities, asymptomatic household contacts of laboratory confirmed cases and all asymptomatic healthcare workers involved in containment and treatment of Covid-19 and working in non-Covid hospitals/non-Covid areas of Covid hospitals/blocks.".

Didier Raoult, MD, PhD — "a Science Star" — as the NYT described him in a recent profile, who has identified 500 novel species of human-borne bacteria; a scientist known all over the world as the discoverer of the first giant virus, a discovery that earned him the Grand Prix, one of France's most prestigious awards.

Dr. Raoult is the founder and director of the research hospital, the Institut Hospitalo-Universitaire Méditerranée Infection (IHU). He is a professor on the faculty of Medicine of Ais-Marseille University, and since 2008, he has been the director of the Infectious and Tropical Emergent Diseases Research Unit), which employs more than 200 people and runs a hospital with 3,700 patients. He has more than 2,300 indexed publications and was classified among the ten leading French researchers by the journal *Nature*. Dr. Raoult has a reputation for bluster but also for creativity that others lack. As the Times noted, "He looks where no one else cares to, with methods no one else is using, and [he] finds things."

Since publishing favorable reports about a treatment combination of two cheap, widely prescribed medicines: hydroxychloroquine and the antibiotic azithromycin, as a treatment of choice against Covid-19, Dr. Raoult has become the subject of intense demonization by the corporate-influenced medical establishment, the media, and the who resort to this tactic whenever they lack evidence or legitimate grounds to support public health policies that cause people harm. Their fallback tactic is to demonize every doctor who challenges them and refuses to adhere to their financially – driven prescribing decrees.

Dr. Raoult's latest scientific report about HCQ, Early Diagnosis and Management of COVID-19 Patients: A Real-Life Cohort study of 3,737 Patients, Marseille, France was posted on May 27, 2020,

> It is a retrospective study report of the clinical management of 3,737 patients, including 3,054 (81.7%) treated with hydroxychloroquine and azithromycin (HCQ-AZ) for at least three days and 683 (18.3%) patients treated with other methods. Outcomes were death, transfer to the intensive care unit (ICU), ≥ 10 days of hospitalization and viral shedding.
>
> "Treatment with HCQ-AZ was associated with a decreased risk of transfer to the ICU or death (HR 0.19 0.12-0.29), decreased risk of hospitalization ≥10 days (odds ratios 95% CI 0.37 0.26-0.51) and shorter duration of viral shedding (time to negative PCR: HR 1.27 1.16-1.39). QTc prolongation (>60 ms) was observed in 25 patients (0.67%) leading to the cessation of treatment in 3 cases. No cases of torsade de pointe or sudden death were observed.

Conclusion
Early diagnosis, early isolation and early treatment with at least 3 days of HCQ-AZ result in a significantly better clinical outcome and contagiosity in patients with COVID-19 than other treatments."

In France, doctors who have followed the research of Dr. Raoult, and have themselves witnessed the effectiveness of the HCQ-AZ combination, are suing the government. They demand the right to treat their patients with these drugs before easing of the lockdown. They seek to prevent complications and deaths from a second wave of Covid-19.

Dr. Violaine Guérin, an endocrinologist who conducted a trial on 100 doctors infected with COVID-19, and their families, reported her study findings that demonstrated the effectiveness of prescribing HCQ combined with azithromycin at the first sign of symptoms. The drugs substantially reduced the viral load of Covid-19:

"*Taking hydroxychloroquine and azithromycin on the outset of flu symptoms can prevent Covid-19 from getting worse. We can treat people now before they end up on a ventilator.*" Her findings replicated those Dr. Didier Raoult.

Dr. Guérin recommends prescribing hydroxychloroquine for health workers infected by the coronavirus, which is outside of its approved uses. Health unions in France warned that almost 12,000 health care professionals out of 550,000 – roughly a quarter of the country's health force – were sick with Covid-19. Dr. Guérin recommends its use on compassionate grounds, stating:

"*From the very beginning, doctors have been calling for the right to self-prescribe because they are the ones on the frontline of the coronavirus battle. We cannot waste time when we can treat Covid-19 now, as long as this is done in the early stages of the virus and patients are screened for pre-existing medical conditions*."

Soon after this favorable study was published, the Minister of Health Olivier Veran in bald political arm twisting fashion, asked the highest health authority to review its authorization for the use of HCQ to treat Covid, suggesting further restriction.

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