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Investigating the Retraction of the Hydroxychloroquine COVID-19 Study Published in The Lancet

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Abstract. On or around May 22, 2020, a paper entitled "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis", authored by Mehra et al. was published by Lancet [Lancet (2020) DOI: 10.1016/S0140-6736(2013)31180-6]. Following, several protestations with respect to the authenticity of the data presented in the said paper, Lancet had no choice but to retract the said paper. In view of the fact that the paper by Mehra et al. contain blatant instances of Data Fabrication, Data Falsification and Dishonest Scientific Reporting, it is legitimate to ask why the paper by Mehra et al. was accepted and published by Lancet in the first place. Was there any so-called peer review before the paper by Mehra et al. was accepted by Lancet. Who are the so-called experts who reviewed the paper by Mehra et al. Should Lancet and other outfits like Lancet initiate an investigation of their so-called independent peer review system. Who is ultimately responsible for this fiasco. Should the Editor in Chief of Lancet take responsibility for the fiasco by voluntarily resigning and letting someone who is still working at the bench with his/her brains and hands take over. (The former minister of the United Kingdom, Michael Bates, Minister of State in the Department for International Development offered his resignation after being late for a question session by 1 minute). If the Editor in Chief does not wish to resign voluntarily, should the Managing Editors (if we know who they are) of Lancet fire the Editor in Chief of Lancet for being incompetent and ignorant at doing his job. Are there other papers at Lancet that contain Data Fabrication, Data Falsification and Dishonest Scientific Reporting.

The paper entitled "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis", authored by Mehra et al. was published by Lancet [Lancet (2020) DOI: 10.1016/S0140-6736(2013)31180-6] was published on or around May 22, 2020. Thereafter, a group of fairly courageous scientific researchers [2] launched an initiative to denounce the "rubbish fake article" of Mehra et al. [1]. On or around June 13, 2020, for reasons which still baffle most people, instead of initiating an investigation for the purpose of retracting the "rubbish fake article" by Mehra et al. [1], Lancet issued an "Expression of Concern" [3] implying that there was redeemable merits to the said paper. Issuing an "Expression of Concern" instead of "Quarantining" or "Retracting the paper" showed that the Editor in Chief of Lancet and Lancet in general was living in an alternative world. They could not determine whether a paper contained "rubbish made up data" when it is clear that any bona fide scientific researcher who still uses his/her brain power could see that the paper was filled with red flags (See below). If there was any semblance of so-called independent peer review by so-called independent scientific experts, the "rubbish fake article" of Mehra et al. [1] would never have been accepted for publication in the first place. It is a complete mystery as to how the "rubbish fake article" of Mehra et al. [1] even got through the first editorial screen of Lancet (In most so-called top-tier scientific journals, the first editorial screen is performed a committee of ex-postdocs who could not make it in the world of real scientific research. At some so-called top-tier scientific journals, the Editor in Chiefs are ex-postdocs who could not make it in the world of real science or arm-chair scientists who had stopped doing science at the bench with their brains and hands many moons ago [4].). It was only on or around June 5, 2020, that Lancet published a Retraction of the "rubbish fake article" by Mehra et al. [5] as if it is the most normal thing to do in the world (Publish a paper and retract the paper without any consequences. Lancet has become a rag journal that publishes "rubbish fake paper"). No-one is to be blamed. Things just happen! What Mehra et al. [1] has done is called Data Fabrication, Data Falsification and Dishonest Scientific Reporting which constitute Scientific Misconduct [6,7]. In the United States, it is a crime to use the fruits of Scientific Misconduct to solicit money

contribution from whoever, including any United States agencies such as the National Institutes of Health [7].

In the retracted paper [1], Mandeep R. Mehra blames his co-author, Sapan Desai for the made-up data presented in Mehra et al. [5]. Mandeep R. Mehra must be living in an alternative world and must have been smoking something that he should not have when he supposedly analyzed the data presented to him by Sapan Desai and when he wrote the paper. As the first and corresponding author, Mandeep R. Mehra is supposed to have custody of all original data presented in the paper by Mehra et al. [1], not Surgisphere Corporation or the Surgical Outcomes Collaborative. The excuses that Mandeep R. Mehra provide in his retraction note are pathetic excuses [5]. He intended to profit from the "rubbish fake paper" and wrote the paper intending to fool the world with his paper. How can one write a paper without knowing the source of the data and not having custody of the paper. It would appear that he did not write the paper and merely lent his name to the paper, a practice which is unfortunately a lot more common than reported. Harvard Medical School and Bingham and Women's Hospital must initiate a full and open investigation into how Mandeep R. Mehra became the first author and corresponding author of the retracted paper [1]. It is highly unusual for a Principal Scientific Researcher (or Principal Investigator) to be the first author of a paper unless he/she has personally done the collection of the data. In this case, it is clear that Mandeep R. Mehra did not do any data collection nor did he analyzed any data. Data collection was supposedly done by Surgical Outcomes Collaborative (whoever and whatever it is) and Surgisphere Corporation (most probably employees of Surgisphere Corporation). Sanpan Desai is apparently the Founder and CEO of Surgisphere, implying that he must have been the one who did the data collection and data analysis. As far as the other co-authors, Frank Ruschitzka and Amit N. Patel, their contributions in the paper are probably close to zero. They mostly likely thought that they could get away with a complimentary authorship without lifting their fingers or engaging their brains (if they have one).

In their introduction, Mehra et al. [1] stated that "the purpose of this study was to evaluate the use of chloroquine or hydroxychloroquine alone or in combination with a macrolide

for treatment of COVID-19 using a large multinational registry to assess their real-world application. Principally, we sought to analyse the association between these treatment regimens and in-hospital death. Secondarily, we aimed to evaluate the occurrence of de-novo clinically significant ventricular arrhythmias". In their method section. Mehra et al. [1] stated that "We did a multinational registry analysis of the use of hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19. The registry comprised 671 hospitals located in six continents (appendix p 3). The Surgical Outcomes Collaborative (Surgisphere Corporation, Chicago, IL, USA) consists of de-identified data obtained by automated data extraction from inpatient and outpatient electronic health records, supply chain databases, and financial records. The registry uses a cloud-based health-care data analytics platform that includes specific modules for data acquisition, data warehousing, data analytics, and data reporting. A manual data entry process is used for quality assurance and validation to ensure that key missing values are kept to a minimum". The statements of Mehra et al. [1] in their introduction and method section should have alarmed the Editor in Chief of Lancet, the committee of ex-postdocs who could not make it in the world of real scientific research and the so-called experts-reviewers of Lancet but for some mysterious reasons they did not (it is possible that they never read the paper or they do not have the requisite brain power to read the paper!). Why should they have been alarmed. They should have been alarmed because the authors in Mehra et a. [1] did not provide any reference to the so-called "multinational registry" that comprised of 671 hospitals located in six continents and to the "Surgical Outcomes Collaborative" nor was there a description of what they were. The readers are supposed to just accept the big black box which magically provided all the data presented in the paper. There was no description of how data collection was achieved. In their method section, Mehra et al [1] stated that "The Surgical Outcomes Collaborative (Surgisphere Corporation, Chicago, IL, USA) consists of de-identified data obtained by automated data extraction from inpatient and outpatient electronic health records, supply chain databases, and financial records. The registry uses a cloud-based health-care data analytics platform that includes specific modules for data acquisition, data warehousing, data analytics, and data reporting. A manual data entry process is used for quality assurance and validation to ensure that key missing values are kept to a minimum. The Surgical Outcomes

Collaborative (hereafter referred to as the Collaborative) ensures compliance with the US Food and Drug Administration (FDA) guidance on real-world evidence. Real-world data are collected through automated data transfers that capture 100% of the data from each health-care entity at regular, predetermined intervals, thus reducing the impact of selection bias and missing values, and ensuring that the data are current, reliable, and relevant. Verifiable source documentation for the elements include electronic inpatient and outpatient medical records and, in accordance with the FDA guidance on relevance of real-world data, data acquisition is performed through use of a standardised Health Level Seven-compliant data dictionary, with data collected on a prospective ongoing basis. The validation procedure for the registry refers to the standard operating procedures in place for each of the four ISO 9001:2015 and ISO 27001:2013 certified features of the registry: data acquisition, data warehousing, data analytics, and data reporting". It is unlikely that Mandeep R. Mehra, a Professor at Harvard Medical School and a Practicing Surgeon at Bingham and Women's Hospital could have written the above nonsensical mumbo-jumbo (unless the standard at Harvard Medical School and Bingham and Women's Hospital is not what it used to be). It is worse than a sorcerer's recipe. What is "a cloud-based health-care data analytics platform that includes specific modules for data acquisition, data warehousing, data analytics, and data reporting" exactly?

In their results section, Mehra et al. [1] stated that they "included all patients hospitalised between Dec 20, 2019, and April 14, 2020, at hospitals participating in the registry and with PCR-confirmed COVID-19 infection, for whom a clinical outcome of either hospital discharge or death during hospitalisation was recorded" and among others, apparently showed that mortality was higher in the treatment groups (Hydroxychloroquine plus macrolide) compared with the control group ($p < 0.0001$). In table S4a and Figure 2, the Adjusted Hazard Ratio in North America for Hydroxychloroquine plus macrolide was reported to be: 1.4198%; 95% CL, 1.328 to 1.516 which contradicted the reported results of Magnanoli et al [7] which showed that the Adjusted Hazard Ratio for Hydroxychloroquine plus Azithromycin in a group of patients the United States was: 1.14; 95% CL 0.56 to 2.32, $p = 0.72$. Mehra et al [1] did not highlight the discrepancy in their paper and the Editor in Chief, of Lancet, the committee of ex-postdocs who could

not make it in the world of real scientific research and the so-called experts-reviewers of Lancet did not notice the discrepancy neither. Not referencing results that contradict one's paper is called Dishonest Scientific Reporting. As discussed above, the paper by Mehra et al. should never have been accepted by the Editor in Chief of Lancet because there was no description backed by any references of how the data presented in the paper was collected and analyzed. As the first author and corresponding author of the paper [1], Mandeep R. Mehra's claim that he had/has no access to the data that is apparently held by Surgisphere Corporation is pathetic and disingenuous To further claim that he is a victim is like asking someone to swallow a live chameleon.

There is a complacency with respect to this scandal and fiasco. Most probably, it will be swept under the carpet. It is important for those who study the History and Philosophy of Science and for the new graduate students in the biomedical sciences that both Lancet and Harvard Medical School and Bingham and Women's Hospital initiate an open investigation and deliver an open report of the investigation. The following questions must be asked and answered by Lancet: (i) Why the paper by Mehra et al. was accepted and published by Lancet. (ii) Was there any so-called peer review before the paper by Mehra et al. was accepted by Lancet. (iii) Who are the so-called experts who reviewed the paper by Mehra et al. [1]. (iv) Who is ultimately responsible for this fiasco. (v) Should the Editor in Chief of Lancet take responsibility for the fiasco by voluntarily resigning and letting someone who is still working at the bench with his/her brains and hands to take over. (The former minister of the United Kingdom, Michael Bates, Minister of State in the Department for International Development offered his resignation after being late for a question session by 1 minute). (vi) If the Editor in Chief does not wish to resign voluntarily, should the Managing Editors (if we know who they are) of Lancet fire the Editor in Chief of Lancet for being incompetent and ignorant at doing his job. (vii) Are there other papers at Lancet that contain Data Fabrication, Data Falsification and Dishonest Scientific Reporting. The following questions must be asked and answered by Harvard Medical School and Bingham and Women's Hospital: (i) How Mandeep R. Mehra became the first and corresponding author of the paper by Mehra et al. [1]. (ii) Did

Mandeep R. Mehra see and analyze any data presented in the paper by Mehra et al. [1] (In order to determine the rate of mortality of patients in the paper by Mehra et al. [1], Mandeep R. Mehra must surely have analyzed some data if he claims that he deserved to be the first author and corresponding author of the said paper. There should be some computer file(s) that document(s) that Mandeep R. Mehra analyzed the data that gave rise to the results described in the paper by Mehra et al. [1]) (iii) In view of the fact that Mandeep R. Mehra is the first author and corresponding author of the paper by Mehra et al. [1], why Mandeep R. Mehra does not have custody of the original data that gave rise to the results described in the paper by Mehra et al. [1].

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Outcomes of hydroxychloroquine usage in United States veterans hospitalized with Covid-19.