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Commentary

Correcting COVID-19 vaccine misinformation Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force Members*

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Here we provide a brief "primer" to assist healthcare providers in correcting a growing body of misinformation surrounding COVID-19

To date, just over 100 million COVID-19 immunizations have been administered, led by the United States accounting for more than onethird (35 million), followed by China (24 million) and the European Union (14 million). In 2020, up to one-third or more of people surveyed both globally and in the United States indicated they might refuse the first COVID-19 vaccines when released through emergency use authorization (EUA). Their rationale included questions about vaccine efficacy, potential side effects, or speeding through

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regulatory approval processes. Even among healthcare workers, high rates of COVID-19 vaccine hesitancy were noted [1]. Another issue is the politicization of COVID-19 vaccines, or suspicions circulating in the African American community linked to structural racism and historical experiences with the biomedical community [2,3]. Thus, while overall vaccine confidence may be increasing in some countries globally [4], the opposite might be happening regarding COVID-19 vaccination confidence. Currently, organizations dedicated to antivaccine activities exploit COVID-19 vaccine hesitancy to fuel discord or discredit vaccine efficacy and safety [5]. Ultimately, halting transmission may require at least 70–80% vaccine coverage [6].

Rushing Vaccines: Reporting global efforts to develop COVID-19 vaccines as a "race" while tying it to national identities or imbuing the US COVID-19 vaccine program with Star Trek imagery were not helpful. For years, a central but false tenet of the antivaccine lobby has been that vaccines are not adequately tested for safety. In both the US and internationally, phase 3 trials were well-powered studies of 30,000 to 60,000 human volunteers, equivalent to other large vaccine clinical trials required to license vaccines [7].

An "average vaccine" requires a 10.7-year timeline beginning with the preclinical phase [7], whereas COVID-19 vaccine programs may complete clinical testing leading to EUA in less than a year. However, the research on COVID-19 vaccines did not first begin in 2020, but instead built on a decade of previous research on coronaviruses, leading to proof-of-concept for the spike protein as a lead vaccine target. Therefore, when Chinese scientists placed the SARS-2 coronavirus genomic sequence on preprint servers in January 2020, it was possible to quickly adapt previous vaccine concepts to this new virus pathogen. A second accelerant was the use of new mRNA and adenovirus technologies allowing a fast turnaround time from elucidating the genomic sequence to making early prototype vaccines. A third and bona fide speed component was building factories for vaccine manufacturing in parallel with clinical testing. Known as manufacturing "at risk", this is in contrast to traditional approaches in which vaccines might typically go through full approval before embarking on manufacture. Finally, the first COVID-19 vaccines are already being released through EUA mechanisms due to the lengthy time often required for formal approval of a biologics license application (BLA). American, European, and British national regulatory authorities undertook extensive measures to approximate full BLA approval both in terms of adequately assessing COVID-19 vaccines for efficacy and safety, and inspection of vaccine manufacturing facilities. Ultimately, the COVID-19 vaccines are expected to complete the full licensure process.

Health freedom: An emerging anxiety is a fear that mandates or forced vaccinations might be imminent globally. In the US, "health freedom" objections against vaccines required for school entry accelerated beginning in 2015, especially in California and Texas [5]. This led to significant increases in vaccine exemptions culminating in measles epidemics. In 2020, health freedom movements expanded to include protests against social distancing and face masks, eventually extending to Western European capitals hosting large anti-vaccine and anti-mask rallies [5]. Currently, no COVID-19 vaccination mandates are anticipated for the general or civilian public [8], although we cannot exclude potential downstream requirements for military personnel or for some college or university students living dormitories, similar to some mandates for meningococcal meningitis immunizations.

"Genetically Modified Humans": The early successes of mRNA COVID-19 vaccine approaches incited claims from antivaccine groups that this constitutes genetic manipulation. It alleges vaccination will insert foreign genes into our genome. Adopting the language from genetically modified organisms(GMO), vaccine critical groups have sensationalized the idea of the vaccine creating "genetically modified humans"(GMH). In fact, the mRNA from these vaccines enters human cells and translates into polypeptides in the cytoplasm and not the nucleus. Moreover, while overexpression of LINE-1 or HIV-1 reverse transcriptase in HEK cell lines in vitro can produce cellular DNA corresponding to COVID-19 virus sequences [9], there is no evidence that this finding has relevance to human clinical medicine.

5 G, Implanting Microchips and thalidomide: One conspiracy claims that COVID-19 is caused by the new availability of 5 G mobile. Another claim falsely asserts that COVID-19 vaccines serve as a device to insert microchips for purposes of tracking or surveillance, sometimes led by software and computer developers. Another circulating fear is that COVID-19 vaccine trials might result in unintended consequences similar to the tragedy during the 1950s-60s when the drug thalidomide was used to treat nausea in early pregnancy.

Fetal Abortions: Two human fetal cell lines are used to produce five COVID-19 vaccines. They include four vaccines that use HEK-293 cells, a cell line derived from the kidney from a fetus aborted in the early 1970s, and one using a PER.C6 cell line from an aborted fetus in 1985. These cell lines, used to produce the AstraZeneca Oxford, Johnson & Johnson, and CanSinoBio adenovirus-vectored vaccines have been propagated for decades and no longer contain remnants of actual fetal tissue. Vaccines for hepatitis A, rubella, and varicella also employ similar cell lines. Recently, the Vatican has indicated that the public health benefits of vaccination outweigh the moral opposition to vaccines from these cell lines [10].

Concluding Remark - It is imperative that government leaders prioritize evidence-driven communication strategies in their COVID-19 vaccine programs, while healthcare providers maintain situational awareness, respond to public concerns, and counter unfounded claims by those seeking to undermine public confidence in vaccines.

Author contributions

The authors contributed equally, and all verified the information presented here.

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Declaration of Competing Interest

MEB and PH are developers of a COVID-19 vaccine construct, which was licensed by Baylor College of Medicine to Biological E Ltd., a commercial vaccine manufacturer for scale up, production, testing and licensure. MG participates in one of eight SARS-CoV-2 vaccine development projects supported by The Scientific and Technological Research Council of Turkey (TÜBİTAK) since March 2020. JK reports personal fees from SK biosciences. JPF and GK are members of the WHO SAGE Working Group on COVID vaccines. GK is independent director of Hilleman Laboratories Private Limited and Vice Chair of the Board, Coalition of Epidemic Preparedness Innovations (CEPI). SG has a patent ChAdOx1 licensed to Vaccitech, and a patent ChAdOx1 nCoV-19 licensed to AstraZeneca. SG also reports other work from Vaccitech outside the submitted work. MH is Founder and Managing Director of SaudiVax. HL reports grants and other from GSK, and grants and other from Merck, grants from J&J, outside the submitted work. TS reports grants from National Institute of Allergy and Infectious Disease, research contracts from GlaxoSmithKline, research contracts from ViiV Healthcare, and grants from Fastgrants. SS reports grants from Ansun, personal fees from Amplyx, grants from Astellas, personal fees from Acidophil, grants from Cidara, grants from F2G, personal fees from Jannssen, grants from Merck, grants from T2, personal fees from Reviral, grants from Shire, grants from Shionogi, grants from Gilead, personal fees from Intermountain Health, personal fees from Karyopharm, personal fees from Immunome, personal fees from Celltrion, outside the submitted work. NSW reports being a member of the steering committee of the COVID-19 research coalition and sponsor of a COVID-19 therapeutics trial. All other authors declare no conflict of interests. The authors views and opinions in the Commentary do not necessarily represent the views, decisions, or policies of the institutions, universities, or health systems with which they are affiliated.

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