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Article

An Overview on the Integrity of COVID-19 Health Decisions

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Abstract: The COVID-19 pandemic opened an unprecedented debate that was often hampered by censorship, especially in the area of the 'COVID-19 vaccines' effectiveness and role of public health authorities and medical products regulatory agencies. Another controversy that is slowly being resolved by new available facts is the origin of SARS-CoV-2. Indeed, a critical review of recent developments points to a possible misuse of medical information and involvement of public health officials in misleading the public about the nature and management of the pandemic. Moreover, the introduction of recombinant technology-based vaccines against COVID-19, strongly pushed by authorities as the primary solution to the proclaimed pandemic, increasingly raises concerns over their safety and efficacy. This is substantiated by a number of patents and published scientific research pre-dating the pandemic that suggest the possibility of a prior manipulation of viral proteins, including spike protein with a goal of development of new products such as vaccines, for global marketing. Despite some early studies and medical groups during 2020 and 2021 reported on existing drugs showing potential efficacy in treating COVID-19, the focus shifted towards emergency vaccine use, leading to the approval of untested vaccine technology on the whole population. Importantly, scientific evaluations of vaccine impacts are still hampered by unreliable data, unclear cases numbers, and unreliable mortality calculations. At last, the term "long-COVID" has been confused with the post-vaccination syndrome, and adverse effects from vaccines are more evident as evidenced by the scientific literature. Regulatory agencies, such as the FDA and EMA, have faced criticism for approving the 'COVID-19 vaccines' without adequate safety evaluation and for not adequately addressing post-vaccination complications. As the evidence on these complications rises, the necessity for further investigation into the safety and efficacy of COVID-19 vaccines remains urgent.

Keywords: COVID-19 vaccination; EMA; Our World Data

The foundation for addressing the COVID-19 issue using a standard scientific approach that is based on logic, evidence, and repeatability, lies in recently released public data and activities that indicate an organized misuse of medical information and the medical profession in managing the COVID-19 situation. For instance, the Vires Law Group, in collaboration with the Former Feds Group Freedom Foundation, submitted formal criminal referral requests against Dr. Fauci and other high-ranking public health officials to the Attorneys General of Arizona and Pennsylvania, following similar filings made on behalf of constituents in Florida, Louisiana, Texas, Missouri, and Oklahoma (1). The listed charges include for example, involuntary manslaughter, negligent homicide, neglect, and abuse of a care-dependent person. In addition, the US White House released publicly the documentation on the lab leak true origins of COVID-19 (2) while the narrative of zoonotic origin and natural evolution of SARS-CoV-2 has been strongly prevailing in the scientific literature over the last years (3, 4). What would a scientific and critical thinking approach look like when evaluating the unpleasant public information released in recent months, including the two examples mentioned above? Firstly, a crude look into the facts available on these two questions gathered by independent scientists and experts in the field should be undertaken. This might immediately shed light on the possible origin of the SARS-CoV-2 construct or viroid as well as on the involvement of public health agencies and medical institutions in the political agenda underlying the management of the proclaimed COVID-19 pandemics. Let's enlist some verifiable key facts that are available to the reader for an own critical thinking evaluation in the next paragraph.

Key Facts Surrounding the Proclaimed COVID-19 Pandemics

Several scientific studies and patents related to construction of viroid SARS virus particles and manipulation with the viroid protein structure, particularly with the Spike protein, has been published since 2003. The list of patents on viroid construction and coronavirus vaccines development preceding the proclaimed COVID-19 pandemics and the 'outbreak' of the SARS-CoV-2 may be publicly found in the document created by the American doctor David E. Martin, expert in innovative finance and patents archived on the Internet (5). The document reports on involvement of the U.S. Department of Health and Human Services in funding of amplifying the infectious nature of coronavirus between 1999 and 2002. In addition, provided information point to experiments for artificial enhancement of animal coronaviruses and early vaccine research involving Spike protein and mRNA, involving Moderna, Pfizer, and U.S. government funding, including DARPA. The document raises concerns over the involvement of key figures like Anthony Fauci, Ralph Baric and Zhengli Shi in controversial virus manipulation and patenting (a complete list of scientific papers pointing to his work on virus engineering of Dr. Baric is available online (6)). The report raises alarms about the potential consequences of engineered 'superviruses' and the financial and military interests behind such experiments. The next portion of facts that should be critically evaluated is related to scientific and clinical research or papers on possible cures for the COVID-19 condition by use of existing drugs in the period from 2020-2021 (7-9). This is relevant in light of granting the emergency use of experimental recombinant gene technology-based products for COVID-19 vaccination at the end of 2020. Emergency use indeed, is granted if no other existing solutions are available.

Moreover, the harmful effects of the Spike protein (recombinant Spike protein is the main product of the recombinant gene technology-based products for COVID-19 vaccination) have also been documented in the scientific literature so far (10-13). The above-mentioned facts, only a minor -part of total data emerging about the COVID-19 after 2020, have been provided to the public in spite of enormous resistance of the public creators of the COVID-19 narrative, despite strict censorship in both the media and often in the scientific literature. At this point it may be concluded that publicly communicated elements of the positive effects of COVID-19 vaccines are seriously compromised and need a wide, free and open debate.

Another phenomenon occurring parallelly in the scientific literature is publishing of so called 'modelling' or 'estimation' publications on the COVID-19 vaccine usefulness in "saving millions of lives". The logical question while evaluating such publications arises on how the mortality rate for COVID-19 was calculated and assessed. Just one example how misleading may the calculation be performed is presented in a paper by Preskon where he points that a change in definition of the "COVID-19 case" immediately led to a 5-fold drop in mortality rate calculation (14), or in the paper of Kelly et al. showing that calculation of COVID-19 mortality rates varies substantially among countries due to COVID-19 death reporting or even public health measures implemented to control the pandemic (15). Moreover, a recent Greek study suggests a significant misclassification of COVID-19 deaths during the Omicron wave. The study reports on nearly half of registered deaths lacking clinical evidence of a COVID-19 cause (16). This infers a similar situation in other western countries that all shared similar death-coding practices. Discrepancies in how COVID-19 cases and deaths are reported, add to significant potential misinterpretations. Many scientists have pointed out flaws in studies estimating COVID-19 deaths or the impact of COVID-19 vaccines on overall mortality, due to insufficient or inadequate data as a key problem. We accordingly, want to point specifically to a study published recently in The Lancet Respiratory Medicine that claims COVID vaccines saved millions of lives and reduced global mortality in 2020 by 63% in 2021 (17). Let's discuss the topic of saved lives with 'COVID-19 vaccination' for the year 2021. The living circumstances on the planet were similar in 2020 and 2021; we had the proclaimed COVID-19 pandemic in both years. The main difference in the living circumstances of the global population was however, the COVID-19 vaccination campaign in 2021. In 2021, 6.08 million more people died than in 2020. Our World Data confirms that COVID-19 vaccination increased the "global mortality" in 2020, which was 6.30 million, by an additional 6.08 million in 2021, which means 96.5%. The claim in article (17) that vaccination reduced global mortality in 2020 by 63% in 2021 is accordingly, a huge error of 159.5% (18).

Another article in The Lancet claims that in 2021, the COVID-19 vaccination saved 14 million lives globally (19). The article does not compare the mortality rate of vaccinated and unvaccinated parts of the population, which is the only plausible scientific method to evaluate the effectiveness of COVID-19 vaccination. The article is not supported by a mathematical model based on statistical data. The most used term in this article is "we estimate"; its results thus, have no scientific validity (18). The paper has nevertheless, been used as a reference 1162 times and serves as a framework for the contemporary world's public health policy, which point to a complete collapse of the public health system and the scientific-based decision process. This is probably due to the guidance of the WHO, an agency mainly financed by

private investors with a direct interest in selling of the medical products, *i.e.* vaccines. How such scientific frauds may have passed the peer review process, remains a separate question that merits further investigation to preserve The Lancet's scientific integrity. Both articles (17, 19) constitute scientific malpractice, have caused significant harm to global public health, and should be retracted without delay. Another element that has to be considered by scientists while evaluation the COVID-19 effects and 'COVID-19 vaccines' effect is a clear distinction among long-Covid and the post-vax syndrome that is habitually confused with long-Covid. This issue is elaborated in more details in the next section.

Long Covid vs. Post-vaccination syndrome

The term post-vaccination syndrome or long-vax/post-vax is still largely being ignored in the scientific literature. Independent scientists with a molecular-biological background offer the explanation for this state based on the mechanisms of action of the 'COVID-19 vaccines', al designed to produce unknown quantities of the recombinant spike protein *in vivo* in the target host cells. Moreover, 'COVID-19 vaccines' have been shown to have non-declared DNA contamination, unverified effects of the pseudo-RNA used in mRNA products, to contain nanocarriers that pass through all body barriers, and induce a deposition of the harmful recombinant spike protein in places where it would otherwise not be able to penetrate, e.g. the brain or placental barrier (20,21). This is precisely why the consequences of the post-vax syndrome after COVID-19 vaccination are significantly more pronounced. According to a recent publication by Walach and Klement, the infection fatality rate of COVID-19 was comparable to that of influenza, and people of advanced age and with comorbidities have succumbed. About 80% of coronavirus cases are mild to moderate, which ranges from having a fever and a cough to low-grade pneumonia. The recovery may be tedious but happens at home (22). Vaccination, in such cases, should have been, at best, only one of several voluntary measures in managing the medical situation, provided that its safety was proven, at least in basic elements, which was not the case. Additionally, vaccination statistics are often either incorrectly documented or entirely absent from official medical records. The fact that no adequate databases are existing covering exact data on COVID-19 vaccinated and non-COVID-19 vaccinated people makes it extremely difficult to perform any proper scientific comparison or estimation. Nevertheless, a growing number of scientific papers are finally published upon peer-review that point to negative consequences of COVID-19 vaccination and to the fact that long-Covid often stays often as a cover for post-vaccination complications. Here, it should be noted again that usage of available side-effects databases for COVID-19 vaccines, *i.e.*, VAERS (USA), EudraVigilance (EU), or Yellow Card (UK), provide only a portion of side-effects. These are passive surveillance systems, meaning they rely on individuals or healthcare providers to report side effects voluntarily (23-26). While the quality of the recombinant gene technology-based products for COVID-19 vaccination, evaluation of their safety and final marketing decision is clearly a liability of drug regulatory agencies, *i.e.* FDA and EMA, the liability for medical consequences in each patient including the post-vaccination syndrome seem to be put on physicians that administered the COVID-19 vaccines. Indeed, The European Court of Justice has, in its judgement case C-586/23 P involving Italian physician Giovanni Frajese and the European Commission, clarified that physicians are not liable for the inherent characteristics of vaccines but are accountable for the clinical decisions they make for individual patients (27).

Differential diagnosis of COVID-19 and usage of PCR-based methods

As elaborated above, controversies surround the COVID-19 cases and COVID-19 deaths. Early during the proclaimed pandemics, the PCR method as a main diagnosing tool for COVID-19 has been questioned by a number of scientists and up to now it became clear that the currently used PCR-based protocol is inadequate for such purposes. PCR based tests used to diagnose COVID-19 suffer from a number of technical and primer design issues (28,29). and it makes it very difficult to understand its continued use for diagnosing COVID-19. The silence of the profession in the public sphere in understanding the true pathogenesis of this condition and adjusting the diagnostic procedure accordingly, also completely lack scientific curiosity and scientific drive for new knowledge. Only few scientific papers have shown scientific courage to challenge the public COVID-19 narrative and open alternative research possibilities in the field. One of them is for example the study of Rubik and Brown postulating the role of environmental factors within the COVID-19 epidemiological triad (agent-host-environment) and the potential role of ambient radiofrequency radiation (RFR) from wireless communication systems, such as 5G, in the COVID-19 pandemic (30). The authors of the study emphasize that the evidence, even though biologically plausible, does not establish a direct causal relationship between RFR exposure and COVID-19 severity and recommend further research to clarify these potential associations. The scientific consensus remains that SARS-CoV-2 is the primary causative agent of COVID-19 however, several cofactors or contributing elements have been proposed so far besides RFR in the literature that may influence the onset, severity, or

spread of COVID-19 such as for example air pollution (PM2.5, NO2) (31) or coinfections with other viruses, bacteria, or fungi that may worsen outcomes but are not causative of COVID-19 (32). The latter has a direct implication in treatment and management of COVID-19 patients as bacterial pneumonia in COVID-19 patients has been a known complicating factor that caused death in many patients. Therefore, the medical professionals should give very good reasons why they favoured and almost imposed protocols for usage of respirators, remdesivir and sedatives in such patients while treatment for respiratory infections, especially pneumonia, include well-studied and safe treatments used so far. Maybe a wrong approach to treatment may be correlated with a certain number of long-covid cases as well? The use of ivermectin, antimalarial and antibiotics, in some cases in combination with corticosteroids and antihistamines, along with supplementation of Zinc has been early suggested as a good option in treatment of COVID-19 patients with complications (33-35). Why were physicians not allowed to treat patients according to the instructions and experience from practice (so-called evidence-based medicine) including the experiences from world medical experts? Some of these questions were already raised in the scientific literature (36). COVID-19 may accordingly end as an example of the biggest medical failures in recent history, especially due to low number of autopsies of those people who died from COVID-19. How can both science and medicine move forward without an accurate diagnosis of the cause of death?

The role of regulatory agencies in establishing of the adequate COVID-19 management

A number of scientists now pose relevant questions addressed to regulatory agencies pertaining the marketing permissions given to COVID-19 vaccines producers. This decision was indeed pivotal in management of the disease and probably halted development of alternative treatments or repurposing of existing known drugs. Some important questions that deserve public attention include: How was the safety of COVID-19 vaccines evaluated with regard to the distribution of the Spike protein throughout the body following vaccination, particularly in relation to its ability to cross the blood-brain and placental barriers?; Why were these products meant for COVID-19 vaccination, based on gene therapy technology, approved and brought to market without thorough long-term testing, while the potential repurposing of existing drugs with possible efficacy against COVID-19 was largely put aside?; How should we address the potential risk of frameshift mutations following COVID-19 vaccination? (37,38)

Given the broad and indiscriminate recommendations regarding COVID-19 vaccination that do not consider a personalized, risk-based approach, a number of important questions arise. For example, how can the recommendation to vaccinate individuals who have already recovered from COVID-19 be justified? It is well-established now that specific antibodies can persist in the body for several months post-infection (39,40). If natural immunity offers lasting protection, what is the rationale behind vaccinating those who have already recovered? Notably, the Cleveland Clinic, in one of its studies, concluded that individuals with prior COVID-19 infection may not benefit from vaccination (41). Additionally, why did regulatory agencies fail to mandate independent, state-led monitoring and safety assessments of these vaccines, especially given their experimental nature?

Due to all these open questions, prof. Pavelic, co-author of this paper decided to officially ask EMA about specific elements pertaining the granting of recombinant gene technology-based products for COVID-19 vaccination for marketing and wide application in the public. The whole correspondence with EMA is available in the Supplementary material. The answers received have a very general character and do not provide clear, technical and scientific information or criteria used for approval and safety evaluation. Safety reports are also generally written with hidden names of experts that performed the evaluation as a confidential information. It seems that all information made available by independent scientist and physicians in recent years have not been taken into the safety post-marketing assessment. The pressure on independent science is extremely high, and a good example is the largest autopsy study of COVID-19 vaccine deaths to date republished in a peer-reviewed journal after being censored twice from Preprints with The Lancet and Forensic Science International (42,43). The study has been again peer-reviewed and published in another journal (44) showing data on a high possibility of a causal link between COVID-19 vaccines and death. The authors call for urgent additional investigation in order to clarify the presented findings. Moreover, researchers at Heidelberg University, published data from standardized autopsies on 25 patients who had no prior health issues and were "unexpectedly found dead at home" within 20 days following vaccination, revealing that five of them exhibited "cardiac autopsy findings consistent with (epi-)myocarditis." (45). At last, a newest systematic review of 28 autopsy cases in the literature established a strong association between COVID-19 vaccination and myocarditis-related deaths. Importantly, majority of individuals affected were relatively young, with a mean age of 44.4, and deaths typically occurred within a few days of vaccination. The authors call for urgent additional

studies following these findings (46). It would be accordingly, expected that the criteria for a product recall may already be met, warranting an immediate re-evaluation and/or withdrawal from the market. Both FDA and EMA up to our knowledge do not take any action Following a number of serious warnings coming from experts and scientists. All in all, we went through a 5-year period in which some basic medical achievements were violated, such as *primum non nocere*, informed consent, the Hippocratic Oath not to mention the legal aspects. The concept of evidence-based medicine was not respected and is still not respected.

Conclusion

The management of COVID-19 pandemic has raised numerous concerns about the transparency and accountability of public health bodies, the safety of 'COVID-19 vaccines', and the origins of the SARS-CoV-2 construct. Both the public and medical professionals openly started to question the recombinant gene-vaccine technology granted for a wide public usage by regulatory agencies especially in light of suppression of alternative treatments both for COVID-19 and long-Covid and Post-vax syndromes. Comprehensive, independent safety assessments of these products are accordingly, urgently needed to establish the exact correlation between 'COVID-19 vaccines' to adverse health effects such as myocarditis and the post-vax syndrome. As more data becomes available, it is essential for the scientific community to prioritize an evidence-based, transparent approach to the ongoing COVID-19 situation. Widespread concerns surrounding the pandemic response and COVID-19 vaccines should be addressed first scientifically and afterwards legally, only through rigorous investigation, open debate, and a commitment to medical ethics.

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Authors contributions: KP – concept and writing; SKP – literature search and writing; ASŠ – writing and elaboration of mathematical aspects and models for estimation of COVID-19 cases and COVID-19 deaths. All authors agreed upon final version of the text.

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