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Mandatory vaccinations, the imposing of fines, the segregation of citizens and promotion of inequality in the modern democracy of Greece. Is science allowed to "enforce" or silently back-up such policies?

Charalampos Mavridis¹, Georgios Aidonidis, Athanasios Kalogeridis

¹ University of Crete

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Abstract

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Undoubtedly COVID-19 is one of the most important health issues with more than 5,000,000 deaths worldwide to date. Each country's government was tasked with taking several measures to protect public health, without causing direct or indirect harm, either in the short or the long term, to its citizens. It is the responsibility of science to provide without any bias or partiality the direction to ensure the maintenance of public health at the least cost. The MEDLINE database contains over 240,000 articles on COVID-19 and about 2000 related meta-analyses. As we are still in a period of "learning", during which a massive amount of medical data is constantly added on a daily basis, not to mention the associated legal, social, and psychological implications, it is utterly inappropriate to create mandates out of any guidance that emerges. The proportionate degree of the measures against the pandemic, which can include the use of masks, COVID passes, lockdowns, fines, and mandatory vaccination, varies considerably from country to country. However, the global trends tend to merge on the fact that transparency in the conveying of information and the promotion of educated self-choice provide more rational, humane and effective management of the pandemic[1]. The opinion of experts as displayed on television and the media carries the least degree of scientific credibility and recommendation, as defined in evidence-based medicine. Contrary to that, we should take into serious consideration, the degree of evidence that form the basis of the large study by Subramanian et. Al, where it was shown that vaccination for COVID-19 cannot control its spread regardless of the level of vaccination coverage, with data from 68 countries and 2947 counties in the US[2]. Initial data from phase 3 clinical trial showed that the number needed to vaccinate (NNTV) *to prevent* one case of COVID-19 was about 119 and especially to prevent severe disease, about 2380 (figure 1)[3].

Vaccinated health care workers (HCWs) are now known to transmit COVID-19, with publications even showing over-transmission of the disease[4-8]. Even after the 4th dose, HCWs who were infected were infectious, with a relatively high viral load, as the vaccination showed very low efficacy against covid-19[9]. So, the definitive argument against vaccine mandates comes very recently in the form of a shocking Letter to the Editor of the New England Journal of Medicine by

Israeli Healthcare Officials, who underline the low effectiveness of the vaccines in HCWs.

A careful review of the weekly COVID-19 Vaccine Surveillance Reports of the UK Health Security Agency (UKHSA), beginning from Week 37 of 2021[10], which is based on data from 18/8/2021 – 3/9/2021 and moving on, unfortunately displays clearly a constant and repeating pattern, which is that in the age groups from 30-80 years old, after the prevalence of the delta strain, the new covid-19 cases per 100,000 of the respective population (case rate) are invariably more, sometimes even twice as many in the fully vaccinated individuals compared to the unvaccinated. The case rate among vaccinated individuals was also increased in the remaining age groups, with the exception of <30 and >80 years old. One can verify this pattern by running through the following weekly reports: Week 37 (p.13), Week 38 (p.13), Week 39 (p.14), Week 40 (p.13), Week 41 (p.13), Week 42 (p.13), Week 43 (p.19), Week 44 (p.20), Week 45 (p.22), Week 46 (p.23), Week 47 (p.33), Week 48 (p.44), Week 49 (p.35), Week 50 (p.39), Week 51 (p.40)[10,11]. As far as we know, there was never a lockdown affecting only the unvaccinated in the UK, as compared to Greece. Beginning at Week 3 2022 (p. 38), the UKHSA started to produce these tables by counting only on people who had undergone booster vaccination, 3 doses in total, in the vaccinated group, and still the same pattern is observed. Moreover, moving forward to the most recent reports in 2022, Week 9 (p.45), Week 10 (p. 45), Week 11 (p.45), the pattern seems to become even worse, since the case rate among booster-vaccinated individuals in the aforementioned age groups climbs to three or even four times more than among the unvaccinated[11]. Unfortunately, it seems that mass vaccinating of the population could have actually produced over-transmitters of the disease, instead of working towards the fallacy of creating an immunity wall. The aforementioned tables correctly point out that the proportionate rate of ER admissions and deaths are definitely lower in the vaccinated group compared to the unvaccinated, progressively increasing in proportion with age, although this difference has blunted considerably and has even gotten to even terms with the prevalence of the omicron strain. Consequently, taken all the facts in consideration, vaccination against COVID-19 is clearly an individual protective measure, and not a collective one. In accordance with this, reports from Robert Koch Institute (RKI) in Germany mentioned that breakthrough infections are possible also among vaccinated staff at a similar viral load[12].Data of the last month from RKI underline that vaccinated were 66% out of new cases and died more frequently than unvaccinated[13], although vaccine effectiveness against hospitalization and ICU-treatment was preserved. In Israel, a new in-hospital outbreak has recently occurred where the source was a fully vaccinated patient with COVID-19[14]. The US Centers for Disease Control and Prevention (CDC) announced four of the top five counties with the highest percentage of fully vaccinated population (84.3 - 99.9%) as "high" transmission counties[14].Consequently the Lancet has published a correspondence where it is noted that after the prevalence of Delta and ongoing Omicron variant and the waning of immunity over a few months, "stigmatizing unvaccinated people is unjustified" according to the cumulative data of the pandemic[15].

Last but not least regarding mandatory HCWs vaccination against COVID-19, a House of Lords committee in a dramatically written newsletter refused to acknowledge the need for a mandate, since it is not economically, scientifically and morally confirmed[16]. This has led to the total revoking of the measures of mandatory HCWs vaccination and the vaccination-as-condition-of-deployment (VCOD) in the UK, as officially stated in the Government resolution of 01/03/2022[17].Consequently, the UK has not suspended or sacked a single HCW in the NHS, during the massive winter outbreak. The same rationale was followed by other western countries, such as Sweden and other Scandinavia, who

never even considered mandatory vaccinations in HCWs or other population groups, and they have definitely managed to keep the pandemic's toll to a far better level than in Greece. The green pass of convalescent patients in Greece is valid for 3 months. This is totally incomprehensible, as the superiority of naturally-acquired immunity has been recently demonstrated by the CDC (19-01-2022)[18]. In this report, by studying the 18% of the population of the United States, it has been shown that naturally-acquired immunity was more potent, up to 5 times, and longer-lasting compared to vaccine-acquired immunity against delta variant. The systematic review and meta-analysis by Chivese T. et al. in a total of 18 countries and 12,011,447 patients showed strong immune memory in covid-19 patients for at least 8 months, with a 0.2% probability of reinfection[19], and there are studies showing protection against reinfection for 1.5-2 years, as well as protection for severe infection for many years, even in asymptomatic covid-19 infected individuals[20,21]. The hesitancy to acknowledge the superior duration and quality of naturally-acquired immunity seems totally unreasonable and out of alignment with global expert opinions and evidence-based studies[22]. The same applies to the undeniably more benign epidemiologic course of the omicron variant, which seems to increase the hazard ratio of breakthrough infection among vaccinated[18]. Moreover, relying solely on mass vaccination with an imperfect vaccine, as defined by its inability to control the horizontal and vertical transmission of the infection disease, carries significant public health issues, eventually negating any expected benefits[23,24].

The translation product of the new vaccine technologies, spike protein (S) alone, which as it is not inactivated, appears to modify the normal function of ACE2 receptors and trigger several molecular mechanisms via signal transduction pathways. Briefly could be mentioned, that S protein alone could cause either impairing of the DNA repair mechanism, inducing dysfunction of the tumor suppressor proteins, p53 and BRCA1,2[25-27] or downregulation of ACE2 receptor and inhibition of mitochondrial function resulting in serious damages of vascular endothelial cells.

While it was initially thought that the spike protein would remain in deltoid muscle cells, we now know that it migrates and circulates for at least 4 months after vaccination[28], with higher levels even than severely ill COVID-19 patients[29]. It was also initially thought that the mRNA contained in the respective vaccines cannot affect the cell's DNA in any way, but this again has been overthrown by a recent study[30] in which the presence of DNA as a product of reverse transcription, as well as up-regulation of endogenous reverse transcriptase LINE-1 (long interspersed nuclear element-1) gene, is demonstrated in a hepatic cellular line as early as 6 hours after vaccination. Although the probability of this phenomenon is low, it is generally known that through the nuclear pore complexes, molecules are transported to and from the nucleus. In particular, transport of various proteins and RNAs can take place through binding with importin- β [31]. Furthermore, since vaccine mRNA can be detected up to 60 days post vaccination in lymph nodes[29], there are multiple questions arising in regards to accuracy, quantity and quality of the ongoing mRNA translation.

During the pandemic, the antibody-dependent enhancement (ADE) of infection is a possible crucial factor since the present strains are different from the original with potential harmful consequences[32]. Although ADE and antibody-enhanced disease (AED) are theoretically rare phenomena for genetic vaccines, they should be studied more extensively[33]. Since Vaccine-Associated Enhanced Disease (VAED) was observed in the SARS-CoV-1 pandemic, the same trials to investigate VAED should be repeated for the current SARS-COV-2 pandemic as well[33]. Additionally, the fact of the increased hospital and ICU admission rates in the fully vaccinated patients, is a cause for concern, as according to Munoz FM et. Al., the criteria with a possible diagnostic certainty for VAED are met[34].

In the meantime, myocarditis, predominantly in young males, due to direct toxic effects[35], detection of unusual thrombotic events such as cerebral sinus thrombosis (implicating blood-brain barrier penetration)[36], cardiovascular deaths, including sudden cardiac deaths attributed to the particular pathophysiology of the well-described Kounis syndrome[37], as well as miscellaneous other adverse events with common feature the activated inflammatory and thrombogenic process[38], compose a dynamic profile of vaccines requiring a continuous alert of safety[39].

The questions that arise need to be clarified transparently by properly structured randomized clinical trials, with the investigation of molecular pathways in more samples. Along with this, the deadlines for the completion of studies by pharmaceutical companies are 2023 and 2024[40].

A major issue, arising from the reduction in number available of HCWs in countries where mandatory vaccinations are implemented, is the quantitative and qualitative understaffing of health care units. The availability and lack of training and specialization of health personnel are clear factors in increasing mortality[41,42]. Department understaffing results in an increase in mortality for each inpatient by 3% daily[43]. On the contrary, countries which invested in the steady improvement of medical services achieved a reduction in ICU mortality over time[44]. Politics is a completely different science from medicine. Transparency does not reduce the intention to vaccinate[1], so there is no need to use extreme pressures measures.

Stigmatization and segregation are not appropriate in civilized societies as they can lead by themselves to further major public health issues[45]. There has already been an increase in domestic violence and suicide attempts among young people[46,47].

Under the current laws in Greece, from six months now, there is an ongoing social occlusion of the unvaccinated citizens who cannot eat indoors in a restaurant, cannot attend a cinema, cannot enter a stadium, and cannot visit a shopping mall or bar even with a negative PCR or rapid test.

It is important to research additional pharmacological and non-pharmacological prevention options to establish health and social equilibrium, to avoid the nightmare that is setting in with general confidence in medicine constantly declining[48]. Authorities should be flexible in renewing guidelines and adapting new concepts about COVID-19[49]. They should also be aware of the outcomes of major legal actions against vaccine mandates, in order to review their nation's policies. Foremost amongst them is the decision of the U. S. District Courts for the Western District of Louisiana and the Eastern District of Missouri, which both found the HCWs mandatory vaccination rule in the USA defective and entered preliminary injunctions against its enforcement. [Louisiana v. Becerra, 2021 WL 5609846 (Nov. 30, 2021); Missouri v. Biden, 2021 WL 5564501 (Nov. 29, 2021)]. In each case, the Government moved for a stay of the injunction from the relevant Court of Appeals, which was DISMISSED by the Supreme Court of the USA on 13 January 2022 [Nos. 21A240 and 21A241, Cite as 595 U. S. ____ (2022)].

Ultimately, science exists only through transparent dialogue and the use of reliable methods, under the rationale of proposing rather than imposing solutions. Healthcare has many dimensions as there is a social dimension in addition to the physical, mental and spiritual. The fight against any health crisis, regardless of its source, is about multidimensional healthcare, looking forward to the future.

As can be concluded, the policy of putting unvaccinated HCWs on suspension, has not only failed to improve the pandemic's outcomes, but on the contrary has produced a significant shortage of experienced staff, increasing inpatient

mortality and leading the remaining staff to physical and emotional exhaustion. For more than seven months unpaid HCWs have been facing serious issues with survival, and there have been colleagues on an ongoing hunger strike. The proper course of action to promote safe healthcare, in addition to upholding the relevant preventive measures, would be to ensure that the HCW come to work healthy, which means not being infected by or even asymptomatic carriers of the virus, which can be established only through regular diagnostic testing on both vaccinated and unvaccinated individuals of the institution's staff. Consequently, as the pandemic tends to wane, even these measures will eventually become obsolete.

Efficacy End Point	BNT162b2		Placebo		Vaccine Efficacy, % (95% Credible Interval)‡	Posterior Probability (Vaccine Efficacy >30%)§
	No. of Cases	Surveillance Time (n)†	No. of Cases	Surveillance Time (n)†		
	(N=18,198)		(N=18,325)			
Covid-19 occurrence at least 7 days after the second dose in participants without evidence of infection	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.3–97.6)	>0.9999
	(N=19,965)		(N=20,172)			
Covid-19 occurrence at least 7 days after the second dose in participants with and those without evidence of infection	9	2.332 (18,559)	169	2.345 (18,708)	94.6 (89.9–97.3)	>0.9999

A) $162/18325 = 0,0088$, B) $8/18198 = 0,0004$ Γ) $0,0088-0,0004 = 0.0084$ Δ) $1/0,0084 = 119$

Efficacy Endpoint Subgroup	BNT162b2 (30 µg) (N ^a =21669)		Placebo (N ^a =21686)		VE (%)	(95% CI*)
	n1 ^b	Surveillance Time ^c (n2 ^d)	n1 ^b	Surveillance Time ^c (n2 ^d)		
Severe COVID-19 occurrence after Dose 1	1	4.021 (21314)	9	4.006 (21259)	88.9	(20.1, 99.7)
After Dose 1 to before Dose 2	0		4		100.0	(-51.5, 100.0)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	1		4		75.0	(-152.6, 99.5)

A) $9/21686=0,00046$, B) $1/21669=0,00004$ Γ) $0,00046-0,00004=0.00042$ Δ) $1/0,00042=2.380$

Figure 1. Calculation of the Number Needed to Vaccinate (NNTV) for covid-19 occurrence (first table) and for severe illness (second table). Data from phase 3 clinical trial of BNT16b2[3].

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