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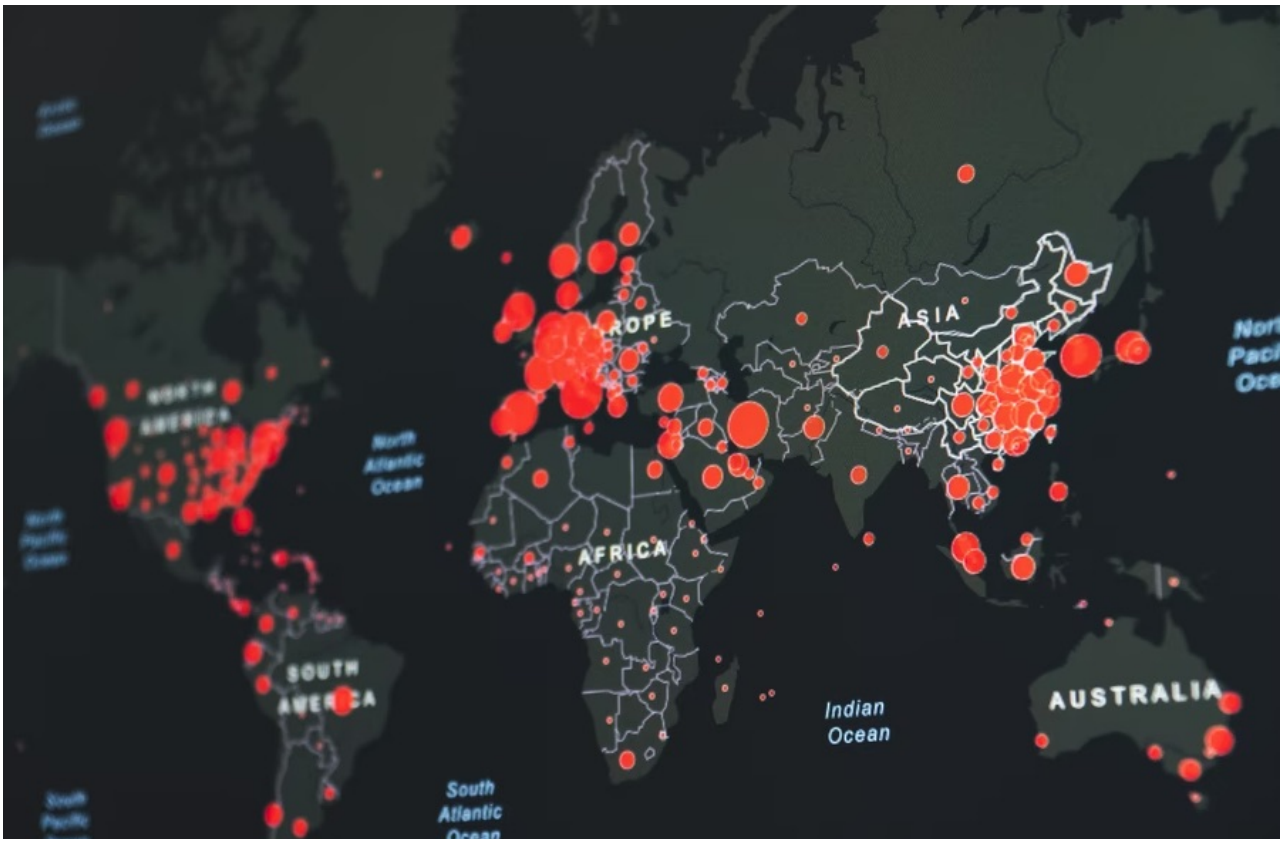
# Why can't C-19 vaccine mandates be taken seriously?



First, there is no evidence that any of the C-19 vaccines proven to be efficacious in a clinical research setting will prevent the virus from successfully exploiting its evolutionary capacity when challenged by widespread immune pressure exerted by the population on the very protein that these vaccines are directed at (i.e., at spike [S] protein). However, population-level immune pressure on S protein is the inevitable consequence of mass vaccination. There isn't even any precedent to the use of non-replicating viral vaccines in mass vaccination campaigns conducted during a pandemic, or even epidemic, of a highly mutable virus. The challenge to such an undertaking becomes even much higher when more infectious antigenic variants are already predominantly circulating as this has been the case by the time the first mass vaccination campaigns started. At least three more infectious variants were already expanding in prevalence before the campaigns were initiated (i.e., Alpha, Beta, Gamma variant). Their spread was featured by distinct temporal and geographic patterns, the underlying mechanism of which was not understood. Prior to the start of this universal vaccination program (and until today!), no single publication existed that came even close to suggesting that mass vaccination campaigns using non-transmission-blocking vaccines could be successful in extinguishing a pandemic of a highly mutable virus, let alone if several more infectious variants had already expanded in prevalence. There is ample evidence from similarly highly mutable RNA viruses like *Influenza virus* and *Enterovirus* that expansion in prevalence of antigenic variants is driven by selective immune pressure on viral infectiousness exerted by antibodies and that antigenic variation diminishes or even abolishes the protective neutralization capacity of *Influenza virus* or *Enterovirus* vaccines that are directed at a specific antigenic lineage (1, 2). Consequently, nonreplicating monovalent enteroviral vaccines, for example, are only used in scale vaccination campaigns of *vulnerable t*arget groups (e.g., children) that are deployed to fight recurrent epidemics of life-threatening enterovirus infection (e.g., EV-A71) in the Asia Pacific region (3). Interestingly, the US FDA did not approve these vaccines due to '*concerns about the effectiveness against different pandemic strains*, *safety*, and quality control of vaccine production' (3).

Mass vaccination programs previously conducted to combat viral epidemics/pandemics (e.g., smallpox, polio, measles, yellow fever) have nothing in common with the ongoing mass vaccination campaigns today as those viruses are very different in terms of their pathogenesis, transmissibility, route of infection, potential reservoirs, predominant effector mechanisms

with regard to the vaccines used (all prior vaccination campaigns involved live-attenuated virus).

In addition, vaccine *efficacy* as assessed during clinical trials is different from viral *effectiveness*, which reflects how well a vaccine performs *in the field.* Viral effectiveness, therefore, depends on the level of *infectious pressure* exerted by the viral *population* and the level of *immune selection pressure* exerted by the host *population* (among other factors). Those can be very different from the ones prevailing during clinical trials. This particularly applies when the vaccine is used in *mass* vaccination campaigns rolled out in the middle of a *pandemic of more infectious variants*. Because of large-scale pharmaceutical (e.g., mass vaccination) and nonpharmaceutical (e.g., infection-prevention measures) human interventions, significant changes in viral infectious pressure and population-level immune pressure can suddenly take place and dramatically accelerate or slow down the evolutionary dynamics of a pandemic, especially if *more infectious* variants are circulating.

Whereas the final target population should have the same profile as the one enrolled in the vaccine trials, current Covid-19 (C-19) vaccines are now administered to several segments of the population that have not been part of the pivotal clinical trials that enabled their authorization for emergency use (e.g., children, elderly, pregnant women, women of childbearing age, individuals who previously recovered from Covid-19 disease). Furthermore, the follow-up of study participants in the clinical trials did not extend beyond 3 months as the WHO had declared the pandemic a health *emergency* of international concern. Short-term results from clinical vaccine trials that were conducted on a *small subset* of a *specific target population* during a *short period of a pandemic* caused by a *specific SARS-CoV-2 lineage* (most notably the original Wuhan strain) cannot even be considered informative for vaccine effectiveness of *mass vaccination* campaigns deployed globally across *almost all population segments* over a *prolonged period of a pandemic* trajectory involving several waves of infection caused by *several different more infectious viral variants*. For example, enhanced propagation and dominance of more infectious variants occurs as a result of widespread (i.e., population-level) immune selection pressure on viral infectiousness, and the corresponding impact on the effectiveness of the vaccines rapidly evolves as a function of rising vaccination coverage rates. Stated more bluntly, *short-term* results from *small-scale* vaccine efficacy studies are anything but representative of the public health

campaigns during a pandemic of more infectious variants. This alone clearly illustrates that the use of current vaccines in the ongoing mass vaccination campaigns is purely experimental and empirical from a perspective of effectiveness on public health.

Mass vaccination with imperfect vaccines is prone to promoting propagation of naturally selected, spike(S)-directed immune escape variants in the population, and ongoing campaigns are causing the population to place even more pressure on viral infectiousness. This is, therefore, likely to expedite the already worrisome evolution of mutants into immune escape variants that further resist neutralizing vaccinal Abs while also presenting other problematic characteristics such as enhanced infectiousness or virulence (4, 5). It goes without saying that such 'super variants', as molecular epidemiologists tend to call them, bear life-threatening potential to both unvaccinated and vaccinated individuals.

Furthermore, re-exposure to circulating viral variants in the presence of low affinity antibodies (**) could potentially provoke life-threatening antibody-dependent enhancement of C-19 disease (ADE). Clearly, results from clinical studies do not permit the drawing of any conclusions regarding the impact of viral exposure in the presence of low affinity antibodies. Consequently, big question marks remain as to the likelihood that ADE, or whether other immunogenicity-related adverse events could occur as an indirect result of vaccination (6). It is important to note that previous efforts to develop a SARS-CoV-1 (***) vaccine had been abrogated due to the occurrence of ADE in preclinical models (7).

Emerging data have shown that the S protein itself is a crucial element responsible for the vascular pathology of SARS-CoV-2 virus infection (8). Therefore, C-19 vaccines that induce human cells to produce the very same protein that is involved in viral pathogenicity should be carefully tested to make sure that such protein is not expressed systemically in the body after vaccination, or the effects of vaccination could result in a pathology similar to C-19 disease itself. However, data on the biodistribution in the human body of *de novo* synthesized S protein after vaccination are, for example, lacking and there were no pre-clinical animal studies done to evaluate this either. To this day, what tissues produce the S protein after vaccination with nucleic acid

emerging. The disproportionally high number of severe and common adverse events observed after administration of nucleic acid-based C-19 vaccines, such as deep-venous thrombosis, stroke, myocarditis, death, and others (9), suggests that the S protein can be expressed in a variety of tissues in the body, where it exerts pathogenic effects in subjects that experience adverse events. Many questions remain unanswered regarding the pathogenic mechanism underlying the observed vaccine-associated adverse events, while mass vaccination continues, and 16,310 deaths from C-19 vaccination have been reported as of October 1st, 2021, in the US alone (9).

Based on all the above, widespread deployment of current Covid-19 vaccines in large-scale vaccination campaigns should first and foremost be considered *highly experimental and empirical* in terms of the efficacy and safety (****) outcome as well as in terms of the impact on individual and public health. Because the experimental use of current Covid-19 vaccines raises serious concerns regarding their effectiveness and their potential to cause serious harm to both individuals and the public at large, one can only conclude that vaccination mandates are completely unethical.

(*) 'imperfect' vaccine relates to a vaccine that has no viral transmission-blocking capacity

(**) Low affinity binding of anti-S antibodies may occur when titers of vaccinal antibodies against viral variants wane or as a result from asymptomatic infection of unvaccinated persons.

(***) SARS-CoV-1 is another beta-coronavirus; it emerged in 2003 (in Guangdong Province, China) and caused severe acute respiratory syndrome coronavirus (SARS-CoV).

(****) An extensive description of reported safety issues associated with one or more Covid-19 vaccines can be found at: https://docs.google.com/document/d/1AD0lL3Rm4lDExo4q7McBxeeHOqO8bCWWerlGu7YJubQ/edit

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Geert Vanden Bossche received his DVM from the University of Ghent, Belgium, and his PhD degree in Virology from the University of Hohenheim, Germany. He held adjunct faculty appointments at universities in Belgium and Germany. After his career in Academia, Geert joined several vaccine companies (GSK Biologicals, Novartis Vaccines, Solvay Biologicals) to serve various roles in vaccine R&D as well as in late vaccine development.

Geert then moved on to join the Bill & Melinda Gates Foundation's Global Health Discovery team in Seattle (USA) as Senior Program Officer; he then worked with the Global Alliance for Vaccines and Immunization (GAVI) in Geneva as Senior Ebola Program Manager. At GAVI he tracked efforts to develop an Ebola vaccine. He also represented GAVI in fora with other partners, including WHO, to review progress on the fight against Ebola and to build plans for global pandemic preparedness.

Back in 2015, Geert scrutinized and questioned the safety of the Ebola vaccine that was used in ring vaccination trials conducted by

published by WHO in the Lancet in 2015 was sent to all international health and regulatory authorities involved in the Ebola vaccination program. After working for GAVI, Geert joined the German Center for Infection Research in Cologne as Head of the Vaccine Development Office. He is at present primarily serving as a Biotech / Vaccine consultant while also conducting his own research on Natural Killer cell-based vaccines.

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