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# [Viewpoint] Vaccination campaigns against Covid-19 may promote vaccine hesitancy toward mostly well-established, safe, and effective vaccines

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## Abstract

The use of thorough clinical trials, open scientific debate and the building of trust in public institutions have been key factors in the acceptance of vaccines in the past. The Covid-19 vaccination programmes were implemented under emergency legislation, limiting safety assessments and traditional vaccine protocols. Transparency and potential conflicts of interest were an issue, with serious side effects neglected. This has fed public distrust nurturing vaccine hesitancy. Studies on the possible relations between Covid-19 vaccines and an increase in all-cause mortality rates have not merited official concern. This Opinion argues that in order to negate a growing public perception of a causal relationship between Covid-19 vaccinations and serious adverse effects, raw data should be released further research promoted, and open debate permitted without exclusion.

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Vaccinations have been remarkably successful in averting many childhood infections and saving millions of lives. However, about 1.5 million children under the age of 5 still die each year from vaccine-preventable diseases, mainly due to a lack of access to essential childhood vaccines.<sup>1</sup>

Pathogens that have killed millions of people over the centuries are largely under control thanks to improved living conditions, better nutrition and access to health care, including the availability of safe and effective vaccines. In 1980, the World Health Assembly declared smallpox the first disease to be globally eradicated. Thanks to global vaccination efforts since the 1960s, significant progress has been made towards polio eradication.

The WHO estimates that immunization currently prevents 3.5-5 million deaths every year from diseases like diphtheria,

tetanus, pertussis, influenza and measles.<sup>2</sup>

Most of these vaccines use established development platforms ensuring safe and effective vaccines, whether based on live attenuated viruses, inactivated whole pathogens, toxoids, or parts of pathogens, such as natural or recombinant proteins, polysaccharides, and others. But most of all public consensus on vaccinations was reached through information, discussion and even some debate about their positives and negatives. As a result, public acceptance and confidence about most of childhood and some adult vaccines in the UK has been a positive one due also to thorough clinical trials and open scientific debate.

Trust in public institutions has been a key factor in the acceptance of vaccines in the past. However, with the Covid-19 vaccination programme it took a different turn. Implemented under emergency legislation, immunotherapeutic drugs (mRNA and viral vector technology) were authorised as conventional vaccines, limiting preclinical, clinical and post-marketing safety assessments.<sup>3</sup> Raw data is yet to be released despite substantial public funding for vaccine development, and repeated requests from scientists, including a rallying call by the BMJ on behalf of the public.<sup>4</sup> Contracts with pharmaceutical companies were put under seal and allowed non-liability for the manufacturers. Potential conflict of interest was not disclosed, with their critics in the media censored.

Reportedly, MHRA gave Conditional Marketing Authorisation for the Covid-19 vaccines under intense political pressure, and numerous reports and warnings about the risks of approval of the Covid-19 vaccines on such limited evidence were not considered.<sup>5</sup> Serious side-effects emerged immediately as with other medications in the past, highlighting the need to listen to patients.<sup>6</sup>

In Italy, independent scientists have repeatedly but in vain requested the WHO for an open discussion on its questionable support for booster doses of COVID-19 vaccinations.<sup>7</sup>

In the US, scientists from renowned institutions have been calling on the FDA to publish its own studies on the raw data of Covid-19 clinical trials.<sup>8</sup> Nothing has been published by the FDA to allay expert concerns or public confidence.

More and more questions are being asked about the quality of oversight by the FDA, EMA and national regulators on the clinical trials undertaken by pharma companies. Authorities have responded with an ominous silence.

“The lack of full transparency and data sharing does not allow physicians and other medical scientists to confirm the data independently and make comprehensive risk-benefit assessments,” argues Gortler fellow at the Ethics and Public Policy Centre think-tank in Washington DC.<sup>9</sup>

However persistent challenges from scientists and researchers from the Public Health and Medical Professionals for Transparency (PHMPT) group, against the FDA eventually led to legal action for a lack of transparency and access to data on the monitoring of the Covid-19 vaccine trials and processes. The legal action has recently obliged the FDA to produce the Pfizer clinical trial and Moderna’s documents. The latter is yet to be released. Analysis and discussion of this data is still in process.<sup>10</sup>

Whilst scientists and experts have been at loggerheads with the FDA in the US, it seems to be a different story in the UK. The need to allay concerns about side effects has focused mostly on immediate minor events such as swelling at site, rash, minor fever, etc.<sup>11</sup>. Questions regarding the more serious and longer-term potential side effects have met with no response from public health authorities such as the Medicines Regulatory Authority (MHRA). There have also been numerous mishaps with reporting through the yellow card system. This includes an apparent reluctance of GPs to accept patient concerns over adverse effects or to work out whether they were indeed related to the Covid-19 vaccinations. The forms themselves were according to the Patient groups too complex to file by patients although many were forced to do so. Whilst a large number of yellow cards were either lost or misplaced.<sup>12</sup>

Mounting evidence links Covid-19 vaccines with clots, myocarditis, heart attacks and strokes as well as myelitis and neuropathy.<sup>13</sup> Some websites have reviewed already published evidence about side-effects.<sup>14</sup>

Studies arguing about a possible relation between Covid-19 vaccines and an increase in all-cause mortality rates overall in Europe and specifically in the UK are a major challenge to publish.<sup>15</sup> The issue was also raised in selected social media.<sup>16</sup> The lack of answers about these potential effects has not only led to questions about the failure in the duty of care towards patients by the Regulator and public health authorities, but it has also dangerously fed into conspiracies about what was intended by the vaccination programme all along.

In the longer term this will not only worsen but also nurture vaccine hesitancy. Instead of building trust between public policy and the population, the vaccination campaign was largely premised on a 'war' narrative, building fear and alarm without taking into consideration some of the real concerns of the public. The tactics utilized to support a 'national emergency' were not only unwarranted, but unethical and divisive.<sup>17</sup>

So we are now left with two avenues. First to continue on the narrative of fear and coercion which can only lead to further vaccine hesitancy increasing mistrust in public institutions due to a lack of transparency and accountability; or to answer questions about the mounting evidence of potentially serious adverse effects as part of relevant and routine scientific inquiry. Opening up raw data would clearly allow further research to negate a growing public perception of a causal relationship between Covid-19 vaccinations and serious adverse effects. Open debate should be facilitated and censorship in research and in the media suspended.

What is not acceptable however is to label legitimate questions about the Covid-19 vaccination programme, as arising from nothing other than ill-informed conspiracy.

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## Footnotes

<sup>1</sup> <https://www.who.int/news-room/facts-in-pictures/detail/immunization> (last accessed 24 August 2023).

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