



UK Medical Freedom
ALLIANCE

Open Letter From: UK Medical Freedom Alliance

To: The Medicines and Healthcare products Regulatory Agency (**MHRA**)

To: The Joint Committee on Vaccination and Immunisation (**JCVI**)

Cc: Matt Hancock (Secretary of State for Health and Social Care)

Re: **Advertisement, Offer and Administration of Vaccines for COVID-19 in the UK**

Sent by Email on 23 November 2020

To All Concerned:

CONCERNS AND SUGGESTIONS REGARDING THE UK'S COVID-19 VACCINE AGENDA

We are an alliance of medical practitioners, scientists, academics and lawyers who are concerned about the current climate surrounding the impending use of a possible vaccine (“**a Covid Vaccine**”) that may be advertised, offered and administered among the general public in response to the recent pandemic that has been attributed to a virus called SARS-CoV-2, which we are told causes the symptoms of a disease called COVID-19.

In this letter we outline our concerns and highlight some of the potential negative outcomes that could arise if these concerns are not taken seriously. We also offer some suggestions for your consideration. These practical suggestions may help avert, or alleviate, some of the negative impacts that are likely to result if no action is taken and the current vaccine agenda continues unchecked.

Our Concerns about a Covid Vaccine, at the present time (and subject to additions or amendments as the situation progresses) fall into the following four areas:

- I) [Over-Estimation of the Public Health Risk from SARS-CoV-2](#)
- II) [Inadequate Assessment of the Public Health Risk from a Covid Vaccine](#)
- III) [Medical Freedom and Informed Consent](#)
- IV) [Media Claims and Misinformation](#)

These are explained in detail below.

I) Over-Estimation of the Public Health Risk from SARS-CoV-2

Concerning epidemiological indicators for assessment of risk:

(1) When the “novel” coronavirus named SARS-CoV-2 was initially discovered in China in late 2019, we were told that not a lot was known about this virus and it was necessary to take urgent steps to protect the public at large. The steps included, inter alia,

lockdowns and social distancing. Whether those steps were reasonable or necessary back in March is outside the scope of this letter and our position is reserved as to these steps.

- (2) Nevertheless, when determining that a virus is so deadly as to justify a rushed rollout of a vaccine intended for use by an entire population, one must consider what is meant by 'deadly.' We must consider the proportion of the general public who are likely to die, or to suffer serious illness from the effects of that virus. At the outset of the current crisis, real data were not available, and the Government relied, amongst others, on the mathematical modelling of Imperial College London, led by Professor Neil Ferguson (**the Fergusson Model**), to drive its coronavirus response. This response includes the current drive for a quick rollout of a Covid Vaccine, which is intended for the entire population of the UK.
- (3) We now have ample real data, including the Case Fatality Rates (**CFR**) and Infection Fatality Rates (**IFR**) that are attributed to various age groups. Most importantly, we have the data to show excess deaths from all causes. Excess deaths is an ideal measure of the effect of a pandemic virus in a population because, as is the case with SARS-CoV-2, where the vast majority of deaths attributed to this virus or the disease COVID-19 could also have been attributed to comorbidities such as heart disease, COPD, cancer, etc., we can clearly see whether the overall death rate in the population is significantly above what one would expect in the year 2020 based on prior estimates, had those people died from their underlying illnesses.
- (4) The Office of National Statistics (**ONS**) is considered the 'Gold Standard' for data and statistics in the UK. Using mortality statistics as the benchmark, the data from the ONS website suggest that there are no longer any significant excess deaths above a 5-year average.¹ From this, and for the purposes of the UK Government's Covid Vaccine agenda, we may conclude that ***any serious public health risk from SARS-CoV-2 is over.***
- (5) The latest estimate of average population IFR for SARS-CoV-2 is 0.23%,² (0.05% for <70 years) which is around ***the same level as seasonal influenza*** (0.1-0.3%).
- (6) The IFR in younger age groups (<45 years) is ***significantly below 0.23%***, up to a factor of 10 or more, shown in Table 2 of a recently published report from Imperial College.³

¹<https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregisteredweeklyinenglandandwalesprovisional/weekending6november2020>

²<https://www.medrxiv.org/content/10.1101/2020.05.13.20101253v3>

³<https://spiral.imperial.ac.uk:8443/handle/10044/1/83545?fbclid=IwAR1552TA-za-UmzVYxzBPsBUMjV1rYl2FEhqbzLRoWTywjs78Ifdvdwxtg>

- (7) Data analysis by the Centre for Evidence Based Medicine at Oxford University has shown that the median age of death **with** SARS-CoV-2 in the UK is 82.4 years⁴. This is **higher than the age of normal life expectancy** in the UK (81.1 years)⁵.
- (8) Studies indicate 20-50% of the population have **pre-existing immunity to SARS-CoV-2**, due to, among other factors, T-cell cross-reactivity from previous coronavirus infections.⁶ Studies suggest that **naturally acquired** T-cell and B-cell immunity from SARS-CoV-2 will be **long-lasting (for many years)**, including after mild disease.⁷
- (9) The above points appear to be reinforced by the words of **Professor Chris Whitty**, the UK government's Chief Medical Adviser and the Chief Scientific Adviser for the Department of Health and Social Care (**DHSC**). He stated at a press conference on 11 May 2020 (at the height of the apparent first wave) that:

*"...the fact that actually the great majority of people will not die from this, and I will just repeat something I said right at the beginning, because I think it is worth reinforcing. **Most people, er, well, a significant proportion of people, will not get this virus at all, at any point in the epidemic** which is going to go on for a long period of time. Of those who do, some of them will get the virus without even knowing it. They will have the virus with no symptoms at all, asymptomatic carriage, and we know that happens. Of those that get symptoms, the great majority, probably 80%, will have a mild or moderate disease, [it] might be bad enough for them to have to go to bed for a few days, **not bad enough for them to have to go to the doctor.**"⁸*

Concerning accuracy and representation of the epidemiological data:

- (10) There has been much debate about the accuracy and representation of the epidemiological data relating to SARS-CoV-2 infections and associated deaths. Many reputable scientists believe the severity of the **threat to public health has been exaggerated**.⁹
- (11) The Ferguson Model has also been widely criticised by the scientific community.¹⁰

⁴ <https://www.thesun.co.uk/news/12886370/average-age-covid-death-82-4-years-shield-vulnerable/>

⁵ <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies>

⁶ <https://pubmed.ncbi.nlm.nih.gov/32753554/> and <https://pubmed.ncbi.nlm.nih.gov/32753554/>

⁷ <https://www.biorxiv.org/content/10.1101/2020.11.15.383323v1> and

<https://www.nature.com/articles/s41591-020-01143-2> and

<https://www.medrxiv.org/content/10.1101/2020.08.11.20171843v2>

⁸ <https://youtu.be/adj8MCsZKlg>

⁹ <https://www.bmj.com/content/370/bmj.m3374>

¹⁰ See, for example, <https://www.telegraph.co.uk/technology/2020/05/16/neil-fergusons-imperial-model-could-devastating-software-mistake/> and <https://www.spectator.co.uk/article/six-questions-that-neil-ferguson-should-be-asked>

- (12) **The RT-PCR test** has been inappropriately employed as a screening and diagnostic tool for SARS-CoV-2¹¹ and has been used at Cycle Thresholds (40-45) which are above those that correspond to the likely detection of any live virus in a cell culture (<36).¹² Used thus, it **cannot indicate an active case or infectivity**; however, the mass screening of asymptomatic individuals is producing huge numbers of what are being referred to as “cases” by the Government and media alike. Thus, Government decisions around isolation, lockdown, cause of death and the ‘urgent’ need for a Covid Vaccine are based on what can only be the **misuse and misinterpretation of the RT-PCR test**.
- (13) Most of the registered PCR-positive SARS-CoV-2 associated deaths have **significant co-morbidities** (an average of 2.6 co-morbidities per associated death, as reported by the CDC¹³); and all recorded UK deaths with SARS-CoV-2 are deaths **within 28 days of a positive PCR test** so we cannot say with any certainty that these deaths were caused by SARS-CoV-2 or COVID-19.

Conclusion and suggestion:

- (14) In conclusion, we assert that wrongly augmented numbers of both COVID-19 “cases” and deaths with SARS-CoV-2 (or ‘coronavirus’ in general, as they are commonly referred to) have driven government policies and pronouncements, which have led to hysteria and unnecessary fear-mongering in the mainstream media. The data have not been viewed in the context of other real and ongoing challenges to public health, including mortality and morbidity from heart disease, Alzheimer's, diabetes, cancer and mental health. The data do not indicate large numbers of excess deaths in the country, such as would be expected if there were a pandemic of a deadly and dangerous virus that requires a vaccine to suppress its spread. This over-estimation of the risk to public health from SARS-CoV-2, and/or COVID-19, must be considered when making decisions about an urgent rollout of a Covid Vaccine.

II) Inadequate Assessment of the Public Health Risk from a Covid Vaccine

- (15) We understand that MHRA’s primary responsibilities include: “ensuring that medicines [...] meet applicable standards of **safety, quality, and efficacy**” and

¹¹ [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30453-7/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30453-7/fulltext). See also <https://off-guardian.org/2020/11/20/portuguese-court-rules-pcr-tests-unreliable-quarantines-unlawful/>.

¹² <https://link.springer.com/article/10.1007/s10096-020-03913-9>

¹³ https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR3-wrg3tTKK5-9tOHPGAHWVFO3DfslkJ0KsDEPQpWmPbKtp6EsoVV2Qs1Q

“helping to educate the public and healthcare professionals about the risks and benefits of medicines [...] leading to safer and more effective use”¹⁴

(16) The JCVI’s terms of reference as agreed by the UK health departments are: “To advise UK health departments on immunisations for the prevention of infections and/or disease following **due consideration of the evidence on the burden of disease, on vaccine safety and efficacy** and on the impact and cost effectiveness of immunisation strategies...”¹⁵

(17) It is well established that **vaccines can cause serious injury and death**. This acknowledgement is embodied in the UK government’s compensation payments to victims of vaccine injury and death which, even with its restricted access, have paid out tens of millions.¹⁶ Safe and effective vaccine development takes time, to assess short-term and long-term risks and benefits. Despite this, dramatic media coverage and political pronouncements over the last eight months have created a false sense of urgency, justifying the fast tracking of a Covid Vaccine.

(18) In a recent letter to the British Medical Journal (BMJ), physician Arvind Joshi warned against the disaster that could result from this misguided policy and outlined the serious risks involved to the public and other serious issues that are being taken if a Covid Vaccine is rushed out without thorough and adequate safety and efficacy testing:

“There seems to be a great rush for bringing SARS-CoV-2 Vaccines in market. People are also eager for the Vaccine. In ordinary course a drug takes about 10 years from concept to market. If a drug is fast-tracked, it still takes about 3 years to be approved for use.

“One has to be wary of haste in marketing Vaccines. Following points must be kept in mind:

- 1) How long the Immunity conferred by the Vaccine will last?*
- 2) If the virus mutates, will the Vaccine protect against the new mutant?*
- 3) Will the Vaccine protect people of all geographic and ethnic origins equally well?*
- 4) Will the Vaccine be suitable for people of all ages?*
- 5) Will there be very late onset adverse effects of the Vaccine?*

“Very late onset adverse effects such as Subacute Sclerosing Pan Encephalitis (SSPE), cannot be ruled out with short duration trials.

¹⁴ <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about>

¹⁵ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/224864/JCVI_Code_of_Practice_revision_2013_-_final.pdf

¹⁶ <https://www.gov.uk/vaccine-damage-payment>

“Adverse effects like Subacute Sclerosing Pan Encephalitis, Ascending Polyneuritis, Myopathies, Autoimmune Diseases, and rarer chance of triggering development of malignancies are most dreaded possibilities.

“Also, worrisome prospects are that should any of these adverse effects develop, people will lose faith in vaccination and anti-vaccine campaigns will get a stick to beat with.

“The rush for the Vaccines should not lead to disaster.”¹⁷

(19) Echoing the above sentiments, the World Health Organisation (WHO), defines the discipline of patient safety as the **“coordinated efforts to prevent harm, caused by the process of health care itself, from occurring to patients.”**¹⁸ It is vital to ensure that any roll-out of a Covid Vaccine does not lead to harm in the form of side-effects, serious illness and death, in the population.

(20) We note that a recent tender document indicates that the MHRA is anticipating a **high volume of Adverse Drug Reactions (ADRs)** from a Covid Vaccine roll-out, requiring an enhanced AI system to cope with ADR reports from the public.¹⁹ This is concerning because the general public are not aware of the anticipated likelihood of ADRs. This lack of awareness will affect their ability to make an informed risk-benefit assessment and give informed consent to a Covid Vaccine.

(21) Vaccine manufacturers recognise the real risk that an accelerated vaccine trial process will bring, of unanticipated injury and death, and have therefore demanded, and been granted, **full immunity from liability for injury or death** from a Covid Vaccine. In defending the demand for immunity from liability for harms caused by the vaccines, a spokesperson from Astra Zeneca has said, “This is a unique situation where we as a company simply cannot take the risk if in ... four years the vaccine is showing side effects”.²⁰

(22) Other factors which we believe require a cautious and measured approach to be taken with any Covid Vaccine roll-out are:

(a) Several Covid Vaccines involve the use of a completely new technology - mRNA vaccination - whose large-scale use in healthy human subjects is unprecedented and long-term effects unknown.²¹ Exogenous mRNA is inherently immunostimulatory, and **this feature of mRNA could be beneficial or detrimental.**²² In addition, a study found evidence of molecular mimicry

¹⁷ <https://www.bmj.com/content/370/bmj.m3096/rapid-responses>

¹⁸ <https://www.who.int/patientsafety/about/en/>

¹⁹ <https://ted.europa.eu/udl?uri=TED:NOTICE:506291-2020:TEXT:EN:HTML&src=0>

²⁰ <https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability-idUSKCN24V2EN>

²¹ <https://www.bulatlat.com/2020/08/21/hazards-of-the-covid-19-vaccine>

²² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5906799/> and

<https://www.bulatlat.com/2020/08/21/hazards-of-the-covid-19-vaccine/>

between SARS-CoV-2 spike glycoprotein and mammalian proteomes which could cause harmful autoimmune pathologies.²³

- (b) This technology also incorporates vehicles or platforms such as non-biodegradable PEGylated lipid nanoparticles. Increasing exposure to these foreign particles is likely to increase already identified issues with toxicity.²⁴
- (c) Virus-vectored and genetically engineered vaccines could undergo recombination or hybridisation with **unpredictable outcomes**, while vaccines produced with cell cultures are often contaminated with naked nucleic acids, genomic fragments, retroviruses and other foreign materials that carry uncertain but **potentially serious hazards**.
- (d) Covid Vaccine trials have already demonstrated significant side effects, including cases of transverse myelitis (a known vaccine side effect) in the Astra Zeneca vaccine trial²⁵; and fever, headache, myalgia, fatigue and pain, including cases of hospitalisation in other trials²⁶. In the Moderna trial, **100% of subjects in the high dose group experienced systemic side effects** after their second dose – some severe.²⁷
- (e) Previous attempts to develop coronavirus and other vaccines e.g., RSV and dengue, have been hampered by the problem of ‘antibody dependent enhanced immunity’ (ADEI), which has led to **severe illness and deaths** in the animals and human subjects involved in the trials²⁸. This phenomenon only becomes apparent after vaccination, when the subject is exposed to wild virus at some point in the future. Worryingly, the Covid Vaccine trials have not been conducted in a way to exclude the possibility of this serious sequelae occurring months or years after vaccination.

²³ [Molecular mimicry between SARS-CoV-2 spike glycoprotein and mammalian proteomes: implications for the vaccine \(bc3-production-blobs-us-east-2.s3.us-east-2.amazonaws.com\)](https://bc3-production-blobs-us-east-2.s3.us-east-2.amazonaws.com)

²⁴ https://link.springer.com/chapter/10.1007%2F978-3-7643-8679-5_8

<https://onlinelibrary.wiley.com/doi/pdf/10.1002/ygh2.336>

<https://pubmed.ncbi.nlm.nih.gov/26540613/>

<https://pubmed.ncbi.nlm.nih.gov/27271335/>

<https://academic.oup.com/mutage/article/17/3/261/1080981>

<http://www.inchem.org/documents/jecfa/jecmono/v14je19.htm>

²⁵ <https://edition.cnn.com/2020/09/17/health/astrazeneca-vaccine-trial-document/index.html> and

https://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf and

²⁶ <https://www.statnews.com/2020/05/26/moderna-vaccine-candidate-trial-participant-severe-reaction/>

²⁷ https://www.nejm.org/na101/home/literatum/publisher/mms/journals/content/nejm/2020/nejm_2020_383.issue-20/nejmoa2022483/20201106/images/img_xlarge/nejmoa2022483_f1.jpeg

²⁸ <https://pubmed.ncbi.nlm.nih.gov/32908214/>

- (f) **Late onset adverse vaccine effects** such as Subacute Sclerosing Pan Encephalitis (SSPE), Ascending Polyneuritis, Myopathies, Autoimmune Diseases, Infertility and Cancers cannot be ruled out with short duration trials.²⁹
- (g) Covid Vaccine trial subjects are usually **pre-screened to exclude** people with many underlying **health problems**, but it is these people with underlying health problems, such as the elderly, who are likely to be the first receivers of the vaccine.³⁰
- (h) Most of the Covid Vaccine trials have reduced or skipped vital animal studies, needed to properly assess safety and side effect profiles.³¹
- (i) Many of the trials have not used a saline placebo but have used another vaccine as the 'control', e.g., the Astra Zeneca trial used the MenACWY vaccine.³² A fully inert placebo (saline), in the control group, is needed to elucidate the full range and level of side-effects from the trial vaccine. Additionally, the control group must stay free of a second vaccination for a period of years to enable collection of and maintain integrity of long-term safety data.
- (j) Co-administration of the influenza vaccine with a Covid Vaccine is being proposed. This could generate further safety issues, as this combination of vaccines has not been tested and proven to be safe and effective when administered together. **The influenza vaccine is known to challenge the immune systems of vaccinees** and can leave them temporarily vulnerable to other (non-influenza) upper respiratory infections, including coronaviruses.³³ There is also evidence suggesting that influenza vaccines may increase mortality from Covid-19 in the elderly³⁴
- (23) Multiple studies and data suggest that up to 80% of those who test positive for SARS-CoV-2 on RT-PCR are completely asymptomatic, and 15% only mildly symptomatic.³⁵ To balance risk and benefit, this means the acceptable levels of mild to moderate side-effects from a Covid Vaccine would need to be very low (below 5%).

Conclusion and suggestion:

²⁹ <https://www.bmj.com/content/370/bmj.m3096/rapid-responses>

³⁰ <https://clinicaltrials.gov/ct2/show/record/NCT04516746>

³¹ <https://www.statnews.com/2020/03/11/researchers-rush-to-start-moderna-coronavirus-vaccine-trial-without-usual-animal-testing/>

³² <https://www.ovg.ox.ac.uk/news/oxford-covid-19-vaccine-begins-human-trial-stage>

³³ <https://pubmed.ncbi.nlm.nih.gov/22423139/> and <https://pubmed.ncbi.nlm.nih.gov/31607599/>

³⁴ <https://peerj.com/articles/10112/>

³⁵ <https://thorax.bmj.com/content/75/8/693.full> and <https://www.dovepress.com/three-quarters-of-people-with-sars-cov-2-infection-are-asymptomatic-an-peer-reviewed-article-CLEP>

- (24) It is important not to repeat the mistakes of the past. In 2009, the swine flu (**H1N1**) vaccine was rushed into circulation, even though the morbidity and mortality risks of the H1N1 virus were extremely low. The population was assured the vaccine was safe but, in fact, resulted in over 1000 children and teenagers across Europe, as well as some NHS staff, developing the debilitating and permanent neurological illness, ***narcolepsy***.³⁶ Those NHS staff are no longer able to work in their former careers.³⁷
- (25) We would therefore like to make it clear that we reject the idea that every person in the country should be inoculated with a Covid Vaccine as soon as possible. In our professional opinion and having regard to all the information and data available, this would be a reckless and unnecessary course of action. At the time of writing (November 2020), only a few months' worth of safety data is available and only several tens of thousands of (mainly healthy) people have received a Covid Vaccine in clinical trials. We suggest that the safety and long-term effects of a Covid Vaccine ought to be studied meticulously over a ***minimum of five years***, but ideally for an entire generation. This can only be done properly alongside a control group of individuals who have not taken the vaccine.

III) Medical Freedom and Informed Consent

- (26) In the UK, “Respect for patients’ autonomy is expressed in consent law; to impose care or treatment on people without respecting their wishes and right to self-determination is not only unethical, but illegal.”³⁸ For consent to be valid: the patient must be competent; the patient must have ***sufficient information*** to make a choice – including risks of harm, likelihood of benefit and time to ask questions; and the patient must be able to make that consent freely, with no coercion and enough time to consider the options.
- (27) The United Nations Educational, Scientific and Cultural Organisation (**UNESCO**) Universal Declaration on Bioethics and Human Rights (2005) states, at Article 6.1 (Consent) that: “*Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on **adequate information**.*”³⁹ What constitutes ‘adequate information’ is the subject of this section and will be discussed in the following paragraphs.

³⁶ <https://www.narcolepsy.org.uk/resources/pandemrix-narcolepsy>

³⁷ <https://www.buzzfeed.com/shaunintern/these-nhs-staff-were-told-the-swine-flu-vaccine-was-safe>

³⁸ <https://www.medicalprotection.org/uk/articles/eng-consent-the-basics>

³⁹ http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

(28) The NHS Constitution for England (“**the Constitution**”) (last updated 2015) states, under the heading “Respect, consent and confidentiality” that every person has the right to:

- (a) be treated with dignity and respect, in accordance with their human rights.
- (b) accept or refuse treatment that is offered, and not to be given any physical examination or treatment unless they have given valid consent.
- (c) be given information about the test and treatment options available, what they involve and **their risks and benefits**.
- (d) be involved in planning and making decisions about their health and care with their care provider or providers.⁴⁰

(29) Points (b), (c) and (d) above were particularly relevant in the **Supreme Court judgment** of *Montgomery v Lanarkshire*.⁴¹ The clear ratio of that case was that:

*“An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any **material risks** involved in any recommended treatment, and of any **reasonable alternative or variant treatments**”*

Furthermore, Lady Hale stated in this judgment that:

“...it could now be stated “with a reasonable degree of confidence” that the need for informed consent was firmly part of English law.

“It is now well recognised that the interest which the law of negligence protects is a person’s interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall and shall not be done with their body.

*“An important consequence of this is that it is not possible to consider a particular medical procedure in isolation from its alternatives. Most decisions about medical care are not simple yes/no answers. **There are choices to be made, arguments for and against each of the options to be considered, and sufficient information must be given so that this can be done:** see the approach of the General Medical Council in *Consent: patients and doctors making decisions together (2008)*, para 5, quoted by Lord Kerr and Lord Reed at para 77 and approved by them at paras 83 to 85”*

(30) Some may argue that a ‘pandemic’ or ‘public emergency’ warrants a derogation of certain human rights, such as informed consent for a vaccine, because it is “for the

⁴⁰https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf

⁴¹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

greater good.” However, even in such circumstances, the maxim, “First, do no harm” must still apply, i.e., vaccinating everybody in the country must not do more harm than the virus itself could create. So, where the information, evidence and data allow, one must first compare the potential risk to the individual from the vaccine with the risk to the public from the virus. And, on the wealth of the evidence discussed above, for SARS-CoV-2 and COVID-19, it would appear that the risk from the virus to the entire population (including the high-risk groups) is not sufficient for a derogation of the right to be fully informed and to choose whether to accept or decline a Covid Vaccine.

Our suggestions about informed consent:

(31) Considering the above, we would suggest that obtaining informed consent for a Covid Vaccine involves the following steps, to comply with the Montgomery case and the Constitution. We think these points would be best delivered by way of a clear, concise, plain English information leaflet, and that the patient should be encouraged to read this leaflet before signing a consent form:

- (a) **“Effectiveness” should be defined** clearly to the patient, as it could be misunderstood. It should be explained that none of the current Covid Vaccine trials are designed to detect a reduction in any serious outcomes such as hospital admissions, use of intensive care, or deaths, or detect if the vaccine can interrupt transmission of the virus.⁴²
- (b) We understand that any Covid Vaccine will likely be offered first to those who are most likely to suffer serious effects from SARS-CoV-2. Since these vulnerable groups, elderly or with comorbidities, were not represented by participants in clinical trials, this **lack of safety or efficacy data** for these groups must be highlighted and presented to potential vaccinees so that they can give fully informed consent.
- (c) Information should be given as to whether a Covid Vaccine has been tested on subjects who previously had SARS-CoV-2 (so were already immune), and if pre-existing immunity may increase the risk of a negative vaccine reaction.
- (d) A **full list of all adverse reactions** reported in the vaccine trials (mild, moderate, and serious) should be presented to the patient for consideration.
- (e) Safety **data must be presented in a way that allows the patient to weigh up** their individual (age and comorbidity) risk from COVID-19⁴³ against their risk of

⁴² <https://www.bmj.com/content/371/bmj.m4037>

⁴³ <https://spiral.imperial.ac.uk:8443/handle/10044/1/83545?fbclid=IwAR1552TA-za-UmzVYxzBPsbUMjV1rYl2FEhqbzL.RoWTywjS78Ifdvdwxtg>

side effects (mild, moderate and serious) from a Covid Vaccine, to enable them to give informed consent.

(f) Patients must be informed that there are only a few months of safety data available for the vaccine, and that it has been developed in less than a year, while the average length of time for development of a vaccine is 10 years⁴⁴. It should be made clear that there is ***no information available about potential long-term side effects resulting from a Covid Vaccine***. This is especially important with an mRNA vaccine, which is a novel vaccine technology.

(g) Any individual who consents to a Covid Vaccine should be made aware of an active surveillance programme (run by MHRA or another body) to monitor short- and long-term side effects. This programme should be made directly accessible to the individual (rather than their GP). They should be given a website address and ***encouraged to report any side effects or new illnesses that occur in the next five years***.

(32) To summarise, we want to ensure that, in the haste to roll-out a Covid Vaccine under what are being described as emergency measures, all proper procedures are being followed. The Government must ensure that due process is carried out to uphold the right of the individual to make a fully informed choice regarding vaccination. Doctors, nurses and others who may be authorised to vaccinate the public have a duty to facilitate this right under international agreements, conventions, and European and British law. It is worrying that recent Parliamentary discussions seem to not attach proper weight to any concern about vaccine risks and the right to informed consent, while focussing solely on strategies to increase the uptake of vaccines in the general population.

IV) Media Claims and Misinformation

(33) There has recently been extensive coverage in the mainstream news that certain Covid Vaccines have been ‘shown’ to be 90% or 95% “effective.” The manufacturers’ claims of ‘effectiveness’ were put out in the media before their data had been peer-reviewed, and without detailed data available for public scrutiny. So, these media headlines ***may create a false expectation*** in the public of the benefits from a Covid Vaccine, especially if the figure is revised downwards once the peer review has taken place.

(34) The public understanding of the term “effective” could be very different from the reality. It is likely to be understood that out of 100 people, 90 of them will become

⁴⁴ https://wellcome.org/sites/default/files/styles/standalone_image_full_width/public/infographic-vaccine-development-1200x1850.png?itok=y0Cq0Vr2

completely immune to SARS-CoV-2 and will not to transmit the virus to their loved ones. As mentioned in section (III), none of the current Covid Vaccine trials are designed to detect a reduction in any serious outcome such as hospital admissions, use of intensive care, or deaths or can determine whether they can interrupt transmission of the virus.⁴⁵

(35) As pointed out in a recent BMJ Rapid response letter, “90% effective” sounds impressive, but closer analysis of the data available shows that the absolute risk reduction for an individual is only about 0.4%. The Number Needed to Vaccinate (NNTV) is calculated as 256 which means that, to prevent just 1 COVID-19 case, 256 individuals must get the vaccine; the other 255 individuals derive no benefit but are still subject to potential vaccine adverse effects.⁴⁶

(36) With the planned direct-to-consumer advertising proposed for a Covid Vaccine, it is crucial to ensure that such advertising provides consumers with accurate information of risks as well as benefits. Article 10 of the European Convention on Human Rights (“ECHR”) states that:

*“The exercise of [freedom of expression], since it carries with it duties and responsibilities, may be **subject to such formalities, conditions, restrictions or penalties** as are prescribed by law and are necessary in a democratic society, in the interests of [...] public safety, [...] **for the protection of health** or morals, for the protection of the reputation or rights of others...”⁴⁷*

It would appear, then, that it is the duty of Government, as advised by its appropriate advisers, to closely monitor and identify when consumers are at risk of being harmed by potentially misleading claims and content.

(37) For the same reason, particularly “**for the protection of the reputation or rights of others**,”⁴⁸ we also challenge and object to the increasing use and definition of the term “vaccine hesitancy” by the Government and groups such as the Vaccine Confidence Project⁴⁹ as a “threat to public health.”⁵⁰ Wikipedia defines ‘vaccine hesitancy’ to include anyone who has legitimate questions or concerns about one specific vaccine e.g., a Covid Vaccine, and draws no distinction between this and outright activism against ALL vaccines, otherwise known as “anti-vax.”⁵¹ Such broad use of this term, and the assumption that it is a threat that must be eliminated, rather than a genuine concern

⁴⁵ <https://www.bmj.com/content/371/bmj.m4037>

⁴⁶ <https://www.bmj.com/content/371/bmj.m4347/rr-4>

⁴⁷ https://www.echr.coe.int/Documents/Convention_ENG.pdf

⁴⁸ https://www.echr.coe.int/Documents/Convention_ENG.pdf

⁴⁹ <https://www.vaccineconfidence.org/research-feed/vaccine-hesitancy>

⁵⁰ <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>

⁵¹ https://en.wikipedia.org/wiki/Vaccine_hesitancy

that should be addressed, ignores the fact that different vaccines carry different risks and benefits for different individuals, just as is the case for other pharmaceuticals. The negative labelling of people as “vaccine hesitant” or “anti-vax” may be harmful and certainly threatens the “*reputation or rights of others*” if people are then made to feel as though they must not ask questions about medical interventions such as vaccines.

Overall Conclusion

The morbidity and mortality impact on public health from SARS-CoV-2 must be balanced with the risks and costs of a vaccine roll-out. We have shown that the mortality and morbidity from SARS-CoV-2 is no longer an existential threat to society.

It is a huge responsibility to roll out a vaccine manufactured with *novel technology*. To do so with the intention that all 60+ million people in the UK should receive the vaccine as soon as possible, without full transparency as to potential risks, may be viewed as irresponsible, potentially even negligent, from a legal standpoint. We urge you to heed the wisdom in the Hippocratic Oath: “***First, do no harm***”.

We are confident that the MHRA, JCVI and the DHSC are each aware of their respective duty of care to the UK public and would not wish to take unnecessary risks with our health. We therefore expect that you will take our concerns seriously. Even in circumstances where the Government has declared a national emergency, we trust that you will make the time to thoroughly digest our letter and the numerous references we have provided.

In closing, we thank you in advance for allowing us the opportunity to assist and advise you, on behalf of the general public, on these issues of public concern at such an unprecedented time.

Your sincerely

UK Medical Freedom Alliance

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