17 May 2021

Open Letter from the UK Medical Freedom Alliance to the General Medical Council (GMC)

- **Dame Clare Marx – Chair General Medical Council**

Re: The role of UK Doctors in the Covid-19 vaccine rollout

The UK Medical Freedom Alliance (UKMFA) is an alliance of UK medical professionals, scientists and lawyers campaigning for Medical Freedom, Informed Consent and Bodily Autonomy to be preserved and protected.

We wish to register our alarm at certain practices that are expected of UK doctors with regards to the rollout of Covid-19 vaccines. We hereby wish to notify you that there are compelling reasons to investigate such practices and those who insist upon enforcing them. We further point out that any doctors resisting such practices should receive protection from their regulatory body, the General Medical Council (GMC), as we understand that, currently, they have cause to fear investigation, and possible suspension.

Below, we specify the practices of concern and the principles of Good Medical Practice they violate.

1. **Evidence-based practice**
2. **Conflicts of interest**
3. **Informed Consent**

1. Evidence-based practice

Expected Practice relating to Covid-19 Vaccines

UK doctors are currently expected to **support the rollout of Covid-19 vaccines unreservedly and unquestioningly**. This support involves administering vaccines, counselling patients about the vaccines, and being vaccinated themselves. We have witnessed doctors, raising concerns about any part of this process, being accused of promoting vaccine hesitancy, or vilified and labelled as someone opposing all vaccines. There has also been aggressive censorship of doctors raising questions, in the media and within the NHS.

Good Medical Practice

It is the duty of any doctor registered with the GMC to ***"be competent and keep your professional knowledge and skills up to date"*** [i]. Doctors are trained to appraise scientific literature and clinical trial data and are required to scrutinise evidence on a regular basis to ensure they apply principles of best practice with regards to safety and efficacy. Furthermore, doctors are required to ***"take prompt action if you think patient safety is being compromised"***. This includes a duty to raise concerns when practices are observed that are based on poor or insufficient evidence and have the potential to cause harm to patients.

Violation of Good Medical Practice

1. Covid-19 vaccines are being rolled out to the general population before completion of the Phase 3 clinical trials, contrary to established practice. They are widely perceived to be fully approved; however, they have only received temporary authorization for emergency use and remain, at this stage, experimental. Since the authorisation by the MHRA following review of early clinical trial

data, further analyses have been put into the public domain by manufacturer's press releases, rather than in peer-reviewed, published studies. Raw clinical trial data are not being made available for independent scrutiny until the trials end in early 2023. This is **inconsistent with the high-quality research** that UK doctors have been accustomed to, as a basis for evidence-based medicine.

2. **The long- and even medium-term effects of the Covid-19 vaccines are unknown**, as all of them are based on novel technologies that have never previously received full regulatory approval for use in humans on such a massive scale. **Safety data are extremely limited** due to the short timescales of the trials up to the interim analyses (under 6 months) and will be heavily reliant on post-marketing surveillance. This is complicated by the uncertainty regarding the potential nature of adverse events, due to the novel technologies used. Although trial protocols are commonly described as "robust", it appears they may be significantly compromised and never formally completed, as participants in the control arm are now being offered the vaccine, thus removing the control group[ii]. There is a notable discrepancy in the demographics of the largely healthy trial participants and the elderly, frail and disabled people who are prioritised for vaccination, and therefore safety data may not simply be extrapolated.

3. Despite the paucity of available data, there are **grave safety concerns**, which ought to be raised by any UK doctor adhering to their duty.

    a. Attempts at developing a Coronavirus vaccine have been in progress for almost 20 years, since the emergence of SARS-CoV-1 in 2002, but were unsuccessful, mainly due to serious safety issues in the animal trials[iii] [iv] [v] [vi]. These specifically related to an observed phenomenon called **Antibody Dependent Immune Enhancement (ADE**) where vaccinated animals developed a more severe and occasionally fatal disease on subsequent exposure to the pathogen[vii]. ADE has not been ruled out for the Covid-19 vaccines, as animal trials were only limited, and its potential remains of significant concern[viii] [ix].

    b. The mRNA vaccines (Pfizer-BioNTech and Moderna) contain polyethylene glycol (PEG), a known allergen which carries a **risk of serious, potentially fatal allergic reactions**[x]. A significant proportion of the population may have antibodies against PEG, increasing the risk of an allergic reaction[xi] [xii]. The US Centre for Disease Control (CDC) issued advice that anyone allergic to PEG or its close relative, Polysorbate, should not receive either of the currently available mRNA vaccines[xiii], but this is not being considered in the UK. As of the 6 May 2021, there have been 875 reports of anaphylaxis to the Yellow Card system of the UK Medicines and Healthcare products Regulatory Agency (MHRA) with two fatalities[xiv]. The reports related to the Pfizer-BioNTech Covid-19 vaccine in 283 cases, but 590 incidents also occurred following the AstraZeneca vaccine.

    c. Covid-19 vaccines induce an immune response against the SARS-CoV-2 spike protein that the body has been prompted to produce itself, by transcription and translation (DNA vaccine) or translation only (synthetic mRNA vaccine) in recipient cells. It is hypothesised that this immune response will be limited to the target protein and not directed to any innate human proteins. However, in vitro studies have shown potential cross-reactivity between SARS-Cov-2 spike protein

antibodies and 28 out of 55 human tissue antigens, highlighting the potential **risk of autoimmunity**[xv]. Autoimmune complications may not manifest for many months or even years.

d. It is of further potential concern that spike proteins appear to play a key role in the pathogenicity of SARS coronaviruses[xvi], and the effects of spike proteins being expressed innately are entirely unknown. There is evidence of direct activation of the alternative complement pathway by SARS-CoV-2 spike proteins[xvii] as well as papers demonstrating their potential to cause cell to cell fusion, forming syncytia, which may lead to endothelial damage and clot formation[xviii]. This serves as a plausible explanation for the occurrence of **thrombotic disorders**, specifically cases of cerebral venous thrombosis in connection with the AstraZeneca vaccine, which have led to temporary and permanent suspensions and restrictions of this vaccine in various countries, and recent related concerns regarding the Johnson & Johnson vaccine. As the production of spike proteins is induced by all the vaccines, this has the potential to be a class effect[xix]. As of the 6 May 2021, 3515 events of thrombosis and embolism have been reported to the MHRA, the majority (2973) after the AstraZeneca vaccine but also over 500 relating to the Pfizer-BioNTech vaccine[xiv].

e. A **considerable number of deaths** have been reported to several databases, which are capturing adverse events that have occurred in relation to the administration of Covid-19 vaccines. Many deaths have occurred in young and previously healthy people. These databases rely on passive reporting and are known to capture merely a fraction of true events - about 1% in the case of the US Vaccine Adverse Events reporting System (VAERS) according to a Harvard study[xx].

   i. In the UK, a total of 757,564 adverse events, have been reported to the **MHRA**, as of the 6 May 2021, with **1102** fatalities[xiv].
   ii. The **WHO** database records 780,073 adverse events and **5027** deaths as of the 16 May 2021[xxi].
   iii. The European database **Eudravigilance** reports 405,259 adverse events and **10,570** deaths as of 8 May 2021[xxii].
   iv. **VAERS** in the US has recorded **4057** deaths relating to Covid-19 vaccines as of 7 May 2021[xxiii]. This is over twenty times the average annual number of all vaccine-related deaths usually reported to VAERS (under 200 per year) in a period of 4 months. 46% of these deaths occurred in people who fell ill within 48 hours of being vaccinated[xxiv].

These deaths cannot all be dismissed as coincidental and must be investigated.

4. Pregnant women were not included in any Covid-19 vaccine trials, and therefore there is **no published, peer reviewed, scientific evidence regarding safety in pregnancy** and effects on the gravida or the foetus. Recent guidance by the Joint Committee for Vaccination and Immunisation (JCVI) advising that pregnant women should be offered the Covid-19 vaccines at the same time as the rest of the population, states that "available data on the Pfizer-BioNTech and Moderna vaccines provide confidence that they can be offered safely to pregnant women"[xxv], failing to elaborate that this "data" is merely observational, relying on a passive smart-phone based reporting system that is neither robust nor thorough. A current trial by Pfizer and BioNTech

evaluating the safety and tolerability of their Covid-19 vaccine in pregnant women does not even include any outcome measures evaluating potential effects on the foetus[xxvi].

Previous advice from Public Health England stated that *"the vaccines have not yet been tested in pregnancy, so until more information is available, those who are pregnant should not routinely have this vaccine. Non-clinical evidence is required before any clinical studies in pregnancy can start, and before that, it is usual to not recommend routine vaccination during pregnancy"*[xxvii]. More recent advice conceded that *"there are some circumstances in which the potential benefits of vaccination are particularly important for pregnant women"* who may then "*choose to have COVID-19 vaccine in pregnancy following a discussion with her doctor or nurse"*[xxviii].

Notably, no additional trials or published evidence on the safety of Covid-19 vaccines in pregnancy have occurred in the interim, to support this concession or in fact the most recent JCVI guidance. Covid-19 vaccines are entirely experimental at this stage when used during pregnancy. **Administering a Covid-19 vaccine to a pregnant woman should therefore only occur as part of a clinical trial** with rigorous monitoring systems in place. We have recently detailed our concerns in an Open Letter to the JCVI[xxix] and fail to comprehend how these vaccines may be responsibly offered to pregnant women without any supporting scientific evidence base and in light of the safety concerns mentioned above.

5. **No children were included in the original Covid-19 vaccine trials**. The recently commenced Oxford trial recruiting children is underpowered to detect uncommon adverse effects, with a target of only 300 participants, and does not have a placebo arm with the control group receiving a meningitis vaccine[xxx]. The Pfizer and Moderna trials on children are similarly underpowered, with no more than 3000 children included in each trial, half of whom will receive the placebo[xxxi] [xxxii].

   Healthy children are at almost no risk from Covid-19, with the recovery rate in this age group calculated at 99.997%[xxxiii] [xxxiv]. It has been reported that up to 50% of children with a positive PCR test remain "asymptomatic", and admissions to hospital or intensive care are exceedingly rare[xxxv] [xxxvi]. Children have also been shown to be less likely to transmit the infection[xxxvii] [xxxviii] [xxxix]. Therefore, current, available evidence clearly indicates that **children will receive almost no benefit whilst facing unknown, potentially serious risks from experimental Covid-19 vaccines**.

   Children have a lifetime ahead of them, with their immunological and neurological systems still in development, making them potentially more vulnerable to adverse effects, specifically any potential long-term sequelae such as allergies, autoimmune diseases, infertility, and carcinogenesis. Despite the absence of any such data and any appreciable benefit for children, proposals for vaccine rollout in this age group are already being mooted[xl]. We have recently detailed our concerns in an Open Letter[xli], in which we conclude that it may be considered **irresponsible and unethical**, as well as unnecessary, to include any children in either the national Covid-19 vaccine rollout, or even in any clinical trials, in light of the data set out above.

2. Conflicts of interest

Expected Practice

Current practice, concerning Covid-19 vaccination, requires doctors to place **complete trust** in the advice from government experts in the Scientific Advisory Group for Emergencies (SAGE) and the vaccine regulators (MHRA and JCVI). Whilst Covid-19 was initially declared a pandemic by the WHO, it was also downgraded and no longer considered to be a high consequence infectious disease (HCID) in the UK as of 19th March 2020, just before lockdowns were introduced[xlii]. Therefore, there does not appear to a plausible justification for suspending established pathways for developing advice on managing health and illness. **With regards to no other health matter are doctors expected to submit to government directives rather than their studies of scientific evidence.** The opinions and viewpoints of the body of practising doctors are neither sought nor acknowledged but indeed restricted.

In addition, doctors are expected to trust that the post-marketing surveillance (effectively Phase 4 trials) of the Covid-19 vaccines will be carried out by the MHRA with due diligence, yet appear not to have been actively encouraged themselves to report any adverse events that their patients may experience, via the Yellow Card reporting scheme.

Good Medical Practice

It is the duty of any GMC registered doctor to ***"maintain trust in you and the profession by being open, honest and acting with integrity"*** [i]. This expectation of integrity extends to the medical community, as well as their sources of information and support.

Violation of Good Medical Practice

1. Several members of SAGE are not bound by the GMC Code of Conduct or by the Hippocratic Oath but have affiliations to industry and other organisations with **financial interests**[xliii] [xliv].

2. Clinical trials to establish efficacy and safety of the Covid-19 vaccines are not conducted by independent research teams but by the pharmaceutical companies, who stand to gain financially from the sale of their products. Raw trial data are not yet accessible to be scrutinized. Interim analyses and claims are communicated by press release, without peer review, and instantly assimilated into advice to the public.

3. Covid-19 vaccine manufacturers demanded, and have been granted, **exemption from any liability** for adverse effects caused by their products as they could not afford the financial risk of liability[xlv] [xlvi]. The entire process of bringing a completely new product to market, for immediate mass administration, has been highly irregular and inconsistent with established scientific practice.

4. In November 2020, the MHRA invested £1.5 million in an artificial intelligence tool to be able to capture adequately the ***"expected high number of adverse events"***, that their legacy system would otherwise have been unable to cope with[xlvii]. In the absence of completed Phase 3 trial data, post-marketing surveillance and diligent pharmacovigilance is vital for ensuring the safety of the Covid-19 vaccines. As previously referenced, weekly summaries of adverse event reports are issued by the MHRA, but no investigations or amendments to public advice follow, despite substantial numbers of reports including fatalities.

5. Many MHRA board members have affiliations to the pharmaceutical industry[xlviii] and the MHRA as an organization receives sponsorship from organizations with a direct interest in a continued and unhindered vaccine rollout[xlix] [l]. There is a clear **potential for compromised integrity** within the groups and organizations which UK doctors are relying on for guidance and support, so that patients are protected from harm[li].

3. Informed Consent

Expected Practice

UK doctors are expected to **encourage patients' participation in the vaccine rollout**. They are not encouraged to highlight to patients that the vaccines remain experimental at this stage, or to alert them to the safety concerns outlined above, for fear of encouraging vaccine hesitancy[lii] [liii] [liv]. Doctors are also expected to support the practice of these experimental products being administered to patients by non-medical personnel, who are not bound by the GMC Code of conduct and not trained in the process of obtaining informed consent[lv].

Good Medical Practice

Informed consent is the cornerstone of good medical practice and is specifically referenced in the NHS Constitution[lvi]. Informed consent is also firmly embodied in UK law following the Supreme Court decision in Montgomery v Lanarkshire Health Board (2015)[lvii]. It is the duty of any GMC registered doctor to ***"give patients the information they want or need in a way they can understand"*** and also *"treat patients as individuals and respect their dignity"* and **respect their right to reach decisions** about their treatment and care[i].

Administering an experimental, unlicensed Covid-19 vaccine, under temporary, emergency authorisation, confers a legal and ethical obligation that all the relevant information must be provided to patients, specifically with regards to safety and efficacy and the experimental nature of the vaccines, and to ensure that this information is understood and accepted before proceeding. Providing information about treatments and preventative options as an alternative to vaccination is also required for the consent to be fully informed.

We have previously outlined salient points, in published Open Letters, to be observed during this consent process[lviii] [lix], with reference to the GMC Guidance[lx] and the decision in the case of Montgomery v Lanarkshire Health Board [2015] UKSC 11[lxi].

Violation of Good Medical Practice

1. Without full regulatory approval, or the completion of clinical trials, Covid-19 vaccines remain experimental. Nevertheless, the public is given the impression that safety and efficacy have been conclusively established, and that they are **obliged to comply** with the government's recommendations. This is communicated by Government rhetoric and advertising, propagated by the media, as well as multiple texts, letters, phone calls and even house visits by "persuaders" to those who choose not to take up the offer of a vaccine, which constitutes coercion and harassment.

2. Detailed discussions between doctor and patient, of known and unknown risks versus benefit to that individual, are not encouraged. Written information prior to vaccine administration is not

always provided. The term "vaccine hesitancy" is perceived and portrayed as an obstacle to the rollout, rather than respected as a person's right to informed consent, to decline a medical intervention. The program has not focussed on patients as individuals, with the sole aim appearing to be to vaccinate the entire population as swiftly as possible **without reflection or due consideration of individual circumstances.** Resources have even been made available to try and modify behaviour with the specific aim to avoid delayed vaccine uptake[lxii] [lxiii] . This is a violation of Informed Consent, as required by the GMC, the NHS Constitution, and the Montgomery ruling.

Conclusions and Requests

We have outlined practices that violate good medical practice. These are extremely concerning and should be investigated immediately. We ask that doctors should be supported, not vilified, when adhering to the GMC code of conduct and respecting a patient's right to informed consent.

We wish to notify the GMC that the above-mentioned practices have a **high propensity to result in significant harm to patients**, and that it is within the remit of the GMC to address and rectify this situation.

We thank you for taking the time to read this letter and consider its contents. We request that you kindly acknowledge this letter and all the references within, and either confirm that appropriate actions are being instigated or lay out the reasoning for not doing so.

UK Medical Freedom Alliance

www.ukmedfreedom.org

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