

18 July 2022

Open Letter from UK Medical Freedom Alliance to:

- Dame Carrie MacEwen, Chair General Medical Council (GMC)

Dear Dame Carrie

Re: COVID-19 vaccines - Doctors are failing to comply with GMC Guidelines for Decision Making and Consent

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

We have grave concerns that the GMC is failing to maintain standards of decision-making and informed consent as determined by its own guidanceⁱ.

This guidance is supported by case law, for example:

- *Montgomery v Lanarkshire Health Board* [2015] UKSC 11ⁱⁱ
The duty to make sure that patients are aware of any material risks involved in treatment and any reasonable alternative treatment options
- *Thefaut v Johnston* [2017] EWHC 497 (QB)ⁱⁱⁱ
The duty to give patients accurate information and adequate time and space to make decisions

The GMC has allowed Public Health England (PHE) to develop its own recommendations for informed consent^{iv} which are not in accordance with GMC Guidelines, either by variance or by omission. In consequence and contrary to its stated role, the GMC is failing to protect patients and failing to adequately regulate doctors. This is bringing the medical profession into disrepute.

Specific concerns relate to:

1) Provision of care in COVID-19 vaccination centres

Prior to carrying out any medical procedure or administering any pharmaceutical product, it is imperative that an individual assessment of benefits and risks is carried out, which should be discussed with the individual in detail. COVID-19 vaccination centres are not set up in a way which would facilitate this process e.g.

- Vaccinees are largely unknown to the vaccinators, and inquiries into medical history do not take place due to lack of time and expertise
- Information shared and discussion with vaccinees prior to administering the product is minimal and inadequate
- Vaccinators are not expected to assume any medical or legal responsibility for any adverse effects from the procedures they are carrying out

2) Omission of information regarding risks of COVID-19 vaccines when obtaining consent

Written information provided to vaccinees is limited to the guidance issued by PHE:

“The COVID-19 vaccination will reduce the chance of you suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective and it takes a few weeks for your body to build up protection from the vaccine. Some people may still get COVID-19 despite having a vaccination,

but this should lessen the severity of any infection. If you are currently pregnant, planning pregnancy or breastfeeding please read the detailed information at www.nhs.uk/covidvaccination.

The vaccine cannot give you COVID-19 infection, and two doses will reduce your chance of becoming seriously ill. You will still need to follow the guidance in your workplace, including wearing the correct personal protection equipment and taking part in any screening programmes. Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them. Please read the product information for more details on the vaccine and possible side effects by searching Coronavirus Yellow Card. You can also report suspected side effects on the same website or by downloading the Yellow Card app. Visit www.coronavirus-yellowcard.mhra.gov.uk

No reference is made at all to the numerous, serious adverse events reported to the many official reporting systems across the world:

- As of 25 May 2022, the [MHRA Yellow Card reporting system](#)^v has recorded a total of 1,496,682 adverse events based on 457,287 reports. The total number of fatalities reported is 2,161.
Pfizer (26.9 million first doses) now has one Yellow Card in 157 people vaccinated. Deaths: one in 34,576 people vaccinated (778).
AstraZeneca (24.9 million first doses) has one Yellow Card in 102 people vaccinated. Deaths: one in 19,499 people vaccinated (1,277).
Moderna (1.7 million first doses) has one Yellow Card in 44 people vaccinated. Deaths: one in 28,814 people vaccinated (59).
- [Eudravigilance](#)^{vi} – European version of the Yellow Card reporting system – 4,419,726 reactions from 1,829,048 reports as of 4 June 2022, of which 1,994,775 were deemed as serious. 45,346 fatal reactions were reported with an approximate actual number of deaths being 14,567 (due to a 3.11 reporting rate in fatalities across multiple reactions).
- [VAERS](#)^{vii} – American version of the Yellow Card reporting system – 1,287,595 reports of adverse events following COVID-19 vaccines as of 4 June 2022, including 28,532 deaths and 236,700 serious injuries. For children up to the age of 17, there have been 49,372 reports, of which 4,561 were deemed serious and 118 fatalities.
- [DAEN Australia](#)^{viii} – Australian equivalent of the Yellow Card reporting system – 129,923 adverse events reported as of 27 May 2022, including 877 deaths.

In the table below (p. 3-6), we juxtapose the practical aspects of GMC Guidelines with PHE Guidance and the experience of doctors and patients in daily practice with regards to COVID-19 vaccination.

Your own “*Ethical Guidance for Doctors*”^{ix} is clear that the phrase “*You must*” in a GMC Guideline is used for an “*overriding duty or principle*” as opposed to “*You should*” which is used “*where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance*”.

Therefore, the statement “*You must*” makes the guideline an imperative for doctors. From this alone it follows that much of the PHE guidance is not in compliance with GMC Guidelines.

Conclusion and Requests

The GMC must act urgently to address this situation. We have copied in the Professional Standards Regulator^x and wish to make the following two requests:

- Please advise us within the next 14 days how you intend to proceed
- Under the FOI Act requirements^{xi}, please supply us with details of any discussions which may have occurred within the GMC with respect to the above concerns. If there have been none then please inform us of this.

Yours sincerely

UK Medical Freedom Alliance
www.ukmedfreedom.org

Cc: Professional Standards Regulator

ⁱ <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent>

ⁱⁱ <https://www.supremecourt.uk/cases/uksc-2013-0136.html>

ⁱⁱⁱ <https://www.2harecourt.com/training-and-knowledge/thefaut-v-johnston>

^{iv} <https://www.gov.uk/government/publications/covid-19-vaccination-consent-form-and-letter-for-adults>

^v <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions>

^{vi} <http://www.adrreports.eu/en/index.html>

^{vii} <https://www.openvaers.com/covid-data>

^{viii} <https://apps.tga.gov.au/Prod/daen/daen-entry.aspx>

^{ix} <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/professionalism-in-action>

^x <https://www.professionalstandards.org.uk/home>

^{xi} <https://www.legislation.gov.uk/ukpga/2000/36/contents>

GMC Guidance states: (MUST is an imperative)	PHE Guidance and Commonly accepted practice with regards to COVID-19 vaccination
<i>10. You must give patients the information they want or need to make a decision.</i>	The 175-word statement quoted above is the entire PHE written information given to most adults prior to a COVID-19 vaccine. This is incomplete and insufficient (and in places inaccurate) information to cover risks, benefits and alternatives to obtain fully informed consent.
<i>This will usually include: [...] options for treating or managing the condition, including the option to take no action</i>	No options are offered to patients. They are given the clear impression this is the only possible option for prevention. (MUST is disregarded)
<i>the nature of each option, what would be involved, and the desired outcome</i>	For example, Vitamin D is known to be highly protective against serious sequelae of COVID-19 infection (as is weight loss and giving up smoking). Such options are rarely offered or discussed. (MUST is disregarded)
<i>the potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action</i>	Patients are rarely told that all COVID-19 vaccines remain in the experimental stages based on novel technology which has never previously been applied to humans and long-term outcomes are unknown. (MUST is disregarded)



<p><i>By ‘harm’ we mean any potential negative outcome, including a side-effect or complication.</i></p>	<p>Serious side effects, including death, as reported to the Yellow Card system, VAERS, Eudrovigilance or DAEN (quoted above) are rarely mentioned.</p>
<p><i>11. You must try to make sure the information you share with patients about the options is objective. You should be aware of how your own preferences might influence the advice you give and the language you use. When recommending an option for treatment or care to a patient you must explain your reasons for doing so, and share information about reasonable alternatives, including the option to take no action. You must not put pressure on a patient to accept your advice.</i></p>	<p>It has become accepted practice to over-emphasise the risks from COVID-19, to the point of inducing fear in the patient, whilst sharing very little information regarding the risks of COVID-19 vaccines, which is anything but objective. Patients are often pressurised into accepting vaccination to the point of being coerced. (MUST is disregarded)</p>
<p><i>12. You should not rely on assumptions about: the information a patient might want or need the factors a patient might consider significant the importance a patient might attach to different outcomes.</i></p>	<p>Rarely considered, if ever – as above</p>
<p><i>13. Other examples of information that might be relevant and, if so, should be shared with patients include: whether an option is an innovative treatment designed specifically for their benefit, whether there is a time limit on making their decision and what the implications of delaying might be, the names and roles of key people who will be involved in their care, and who they can contact (and how) if they have questions or concerns, their right to refuse to take part in teaching or research their right to seek a second opinion, any bills they will have to pay, any conflicts of interest that you or your organisation may have, any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.</i></p>	<p>Rarely discussed, if ever</p>
<p><i>15. You should not withhold information a patient needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and, if so, it may be appropriate to withhold it. In this context ‘serious harm’ means more than that the patient might become upset, decide to refuse treatment, or choose an alternative. This is a limited exception and you should seek legal advice if you are considering withholding information from a patient.</i></p>	<p>Essential information regarding serious risks from COVID-19 vaccination is commonly withheld – as outlined above</p>
<p><i>16. You must listen to patients and encourage them to ask questions.</i></p>	<p>Patients are actively discouraged from inquiring about evidence for short- and long-term safety of COVID-19 vaccines to the point of being demonised/ridiculed (and labelled as “anti-vaxxers”) if they do ask any questions</p>

<p>17. You should try to find out what matters to patients about their health – their wishes and fears, what activities are important to their quality of life, both personally and professionally – so you can support them to assess the likely impact of the potential outcomes for each option.</p>	<p>COVID-19 vaccination centres are not set up to allow for personalised care (as outlined above)</p>
<p>20. You should explore with patients what risks they would and wouldn't be prepared to take to achieve a desired outcome, and how the likelihood of a particular outcome might influence their choice.</p>	<p>COVID-19 vaccination centres are not set up to allow for personalised care (as outlined above) – an individual vaccine risk assessment is rarely undertaken and any concerns raised are readily dismissed rather than discussed and respected</p>
<p>Discussing benefits and harms 21. You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.</p>	<p>The data regarding reported adverse events after COVID-19 vaccination (as above) is rarely shared by doctors and other health professionals before administering COVID-19 vaccines. (MUST is disregarded)</p>
<p>22. It wouldn't be reasonable to share every possible risk of harm, potential complication or side-effect. Instead, you should tailor the discussion to each individual patient, guided by what matters to them, and share information in a way they can understand.</p>	<p>The discussion regarding potential complications is not tailored but largely omitted.</p>
<p>25. You must answer patients' questions honestly and accurately, and as fully as is practical in the circumstances. You must be clear about the limits of your knowledge and, if you can't answer a question, explain whether it is something you are uncertain of or something that is inherently uncertain.</p>	<p>The uncertainties and unknowns about potential adverse effects (especially in the long-term) of COVID-19 vaccines, whilst they remain in the experimental phases of a completely novel gene-based technology, are not being disclosed or discussed. (MUST is disregarded)</p>
<p>26. If you are uncertain about the diagnosis, or the clinical effect a particular treatment might have, or if the available evidence of benefits and harms of an option is unclear, you should explain this to the patient. Some things will become clearer after treatment starts, so you should discuss in advance what the arrangements will be for monitoring the effect of the treatment and reviewing the decision to provide it. You should also explore in advance what options the patient might prefer in the future, depending on how treatment progresses, and the factors that might influence their choice.</p>	<p>Most doctors have failed to keep up to date with, and are not encouraged to share, information regarding reported adverse effects of COVID-19 vaccination (as above). Most are either unaware themselves or fail to share information about the MHRA Yellow Card system with their patients to capture and monitor post-marketing safety signals.</p>
<p>27. Patients need relevant information (see paragraph 10 above) to be shared in a way they can understand and retain, so they can use it to make a decision. To help patients understand and retain relevant information you should:</p> <ul style="list-style-type: none"> - share it in a place and at a time when they are most likely to understand and retain it - anticipate whether they are likely to find any of it distressing and, if so, be considerate when sharing it 	<p>Rarely considered, if ever</p>



<p><i>accommodate a patient's wishes if they would like to record the discussion</i></p> <ul style="list-style-type: none"> - <i>accommodate a patient's wishes if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions and/or help them make decisions</i> - <i>use an interpreter or translation service if they have difficulty understanding spoken English</i> - <i>share it in a format they prefer - written, audio, translated, pictures or other media or methods</i> <p><i>give them time and opportunity to consider it before and after making a decision.</i></p>	
<p><i>30. You must check whether patients have understood the information they have been given, and if they would like more information before making a decision.</i></p>	<p>Rarely happens, if ever (MUST is disregarded)</p>
<p><i>32. For some patients, there are foreseeable circumstances when they will have a choice of options at a time when they might find it more difficult to make decisions – for example because: they may be in pain, confused or afraid their capacity or insight may be impaired by their condition or the effects of an intervention a decision may need to be made quickly so there will be less time for dialogue.</i></p>	<p>A fear message has been propagated by the government, media and medical profession throughout the pandemic, with risks from COVID-19 being highlighted incessantly and COVID-19 vaccines being promoted as the only way to combat this object of fear. This type of persistent messaging, which does not acknowledge the huge difference in risk of COVID-19 for different cohorts, does not facilitate rational and balanced decision-making.</p>
<p><i>34. Discussing options in advance doesn't remove the need to have a further dialogue immediately before providing treatment, and at regular intervals as treatment or care progresses. Even if there's a care plan in place, or the patient's made an advance decision, you should still talk to them about the options available in case the options have changed or the patient has changed their mind.</i></p>	<p>Some doctors have stated publicly that attending an appointment for COVID-19 vaccination may be taken as implied consent without the need for any further discussion</p>
<p><i>36. A patient may want to nominate someone to make decisions on their behalf if they lose capacity or they may want to make an advance statement about refusing or requesting a particular treatment. In these circumstances, you should let patients know that there are ways to formalise their wishes and suggest that they seek support and independent advice about this.</i></p>	<p>There has been at least one known case of a patient who was administered a COVID-19 vaccine against his (past stated) will and against his daughter's Power of Attorney.</p>
<p><i>37. You must record a summary of your discussion with the patient about their future care and any decisions they make, including as much detail as practical about the patient's wishes and fears, their preferences about future options for care, and the values and priorities that influence their decision making. If possible, you should make this record while the patient has capacity to review and understand it.</i></p>	<p>The decision-making process surrounding COVID-19 vaccination is rarely documented. Vaccination centres are not set up to record and keep such documentation.</p>