

**Open Letter from the UK Medical Freedom Alliance (UKMFA) to
Mr Ian Trenholm – Chief Executive of the Care Quality Commission (CQC)**

Dear Mr Trenholm

01 July 2021

Re: Concerns about the COVID-19 Vaccine Consent Form currently used by Public Health England (PHE)

The UK Medical Freedom Alliance (UKMFA) are 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 are reporting our concerns with respect to the administration of COVID-19 vaccines. We represent doctors, nurses, and patients who have administered, or have been in receipt of, COVID-19 vaccinations.

- **We believe the CQC is responsible for ensuring that service providers meet the legal standards required when they are administering COVID-19 vaccines to patients.**
- **PHE provides a standard consent form to be used by practitioners who administer vaccines that is in breach of GMC guidance, NHS guidance and international law, as it does not allow for proper informed consent to be made.**
- **This is putting healthcare providers and patients at serious risk.**
- **We have been advised by the Medical Defence Union that if valid consent is not obtained, then a doctor or healthcare provider may find themselves facing possible criminal proceedings for battery or even assault.**
- **We ask that you investigate PHE's 'consent form' that is in use**

The administration of any vaccination MUST be done in accordance with GMC Guidelines. Must is a legal imperative. The GMC Guidelines were updated in November 2020 to encompass the Montgomery v Lanarkshire Supreme Court Judgement of 2015.

Proper informed consent is defined by the General Medical Council's Guidance Decision making and consent (updated Nov 2020)¹.

The UKMFA has prepared a referenced summary of correct informed consent based on the updated GMC guidelines².

The PHE consent forms currently in use are published on their website³.

We contend that the PHE consent forms do not conform with GMC Guidelines. We believe that many healthcare providers are being misled by these inadequate PHE consent forms, which could put them at risk of prosecution because patients are not being informed of '**all material risks**' nor '**reasonable alternatives**' nor given '**sufficient time**' to consider their choice.

¹ <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent>

² <https://www.ukmedfreedom.org/resources/covid-19-vaccine-info#Vaccine-consent>

³ <https://www.gov.uk/government/collections/covid-19-vaccination-programme#consent-forms-and-letters>



GMC Guidance states that doctors MUST address the following information below. Although the MHRA Yellow Card system documents vaccine-associated injuries and deaths reported by patients and doctors, with reports released weekly to the public, patients are not being informed of such.

GMC Guidance	Documented harms (reference published MHRA Yellow Card data ⁴)
<p>a) <i>Recognise risks of harm that you believe anyone in the patient’s position would want to know. You’ll know these already from your professional knowledge and experience.</i></p>	<p>A. Bleeding, Clotting and Ischaemic ADRs e.g. Vaccine Induced Thrombotic Thrombocytopenia (VITT)</p> <p>B. Immune System ADRs e.g. myocarditis</p> <p>C. ‘Pain’ ADRs</p> <p>D. Neurological ADRs e.g. Bell’s Palsy, Guillain-Barré Syndrome</p> <p>E. ADRs involving loss of Sight, Hearing, Speech or Smell</p> <p>F. Pregnancy ADRs</p>
<p>b) <i>The effect of the patient’s individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient’s medical history, you’ll know some of what you need to share already, but the dialogue could reveal more.</i></p>	<p>PHE forms do not address any of these issues – they simply request a desire for vaccination. This is not consent.</p> <p><i>“I want to receive the full course of COVID-19 vaccination.”</i></p>
<p>c) <i>Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them.</i></p>	<p>PHE forms are misleading: <i>“Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them.”</i></p> <p>Latest MHRA Yellow card data – between 09 December 2020 and 16 June 2021. In total 1,356 deaths and 970,696 ADRs (285,219 individual reports) were reported during this period.</p>
<p>d) <i>Any risk of serious harm, however unlikely it is to occur.</i></p>	<p>See above. Patients must be informed of the risks</p>
<p>e) <i>Expected harms, including common side effects and what to do if they occur.</i></p>	<p>Side effects are trivialised.</p> <p>The possibility of death following vaccination is not disclosed.</p>

⁴ <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>

We have been informed by many healthcare providers and patients that these GMC Guidelines are not being followed when COVID-19 vaccines are administered. For example, consent is being given in a rushed and haphazard manner and coercion is often employed. We are aware that some of those administering vaccines have expressed the opinion that to report their concerns to the CQC will result in them being labelled whistle-blowers and may result in losing their job.

We took our concerns to the Medical Defence Union who appear to validate our concerns and informed us that:

“For consent to be valid the patient must have capacity, provide consent freely (without coercion) and be fully informed i.e. an explanation must be given to the patient, in non-technical language about the nature, purpose and risks of the proposed treatment. Healthcare professionals who do not respect this principle may be liable both to action by their professional body and legal action by the patient.”

and:

“From the legal perspective, if valid consent is not obtained, then a doctor may find themselves facing possible criminal proceedings for battery or even assault. Perhaps more commonly, a patient may make a complaint about a doctor who they felt had not obtained valid consent before providing them with treatment. It would be open to the patient to direct their complaint to the GMC, if they considered the doctor’s practice did not accord with GMC guidance.”

“Furthermore, if proper consent has not been obtained, healthcare practitioners will not be covered by the new indemnity scheme for pandemic related clinical negligence claims and...may still be found liable both to action by their professional body and legal action by way of criminal proceedings.”

The UKMFA and Dr Sarah Myhill (GP) have taken the following steps:

- Sent an Open Letter to Dame Marx, Chair of the General Medical Council⁵ on 27 November 2020 and engaged in subsequent correspondence.
- Contacted all Public Health authorities in UK and all Clinical Commissioning Groups, detailing informed consent concerns.
- Emailed our concerns to Professor Duncan Selbie, Chief Executive of Public Health England on 25 February 2021. This and subsequent correspondence did not result in any changes to the PHE’s consent forms.
- Consulted with the Medical Defence Union

These actions have changed nothing. COVID-19 vaccines continue to be administered to patients without proper informed consent. There are standards that the PHE has a legal responsibility to meet, and patients have a right to expect whenever or wherever they receive care. However, the current PHE consent form does not meet legal standards.

⁵ https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5fc76472f7141980b2083573_UKMFA_Sarah_Myhill_Open_Letter.pdf



The CQC is the regulator of health and adult social care in England, responsible for checking, inspecting, and monitoring that service providers (here more specifically Public Health England) adhere to required legal standards, in order to provide high quality and safety of care. The GMC is the independent regulator for doctors in the UK. The CQC is required to investigate particular issues and concerns of service providers. The PHE is a service provider organisation. The PHE (an organisation) is required to promote the GMC consent guidelines and are bound to follow. The role of the CQC includes regulation of Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11 – Need for Consent⁶

“The intention of this regulation is to make sure that all people using the service, and those lawfully acting on their behalf, have given consent before any care or treatment is provided. Providers must make sure that they obtain the consent lawfully and that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment that they are asking consent for. Consent is an important aspect of providing care and treatment, but in some cases, acting strictly in accordance with consent will mean that some of the other regulations cannot be met. For example, this might apply with regard to nutrition and person-centred care. However, providers must not provide unsafe or inappropriate care just because someone has consented to care or treatment that would be unsafe.”

We understand that the CQC can prosecute for a breach of this regulation or a breach of part of the regulation and can move directly to prosecution without first serving a Warning Notice. Additionally, CQC may also take other regulatory action. Therefore, we demand that you investigate this matter urgently and take appropriate action.

Please inform us as a matter of urgency how you intend to proceed, and how we can track CQC actions to ensure such is taking place.

Yours sincerely

UK Medical Freedom Alliance

www.ukmedfreedom.org

⁶ <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent>