[Name]

[Address1]

[Address2]

[City/Town]

[Postcode]

[Date]

**NOTICE-OF-LIABILITY**

**High Priority – COVID-19 experimental vaccination for Care (and other) Workers(including Care Home Staff) entering premises.**

Dear [Name of Care homeOwner/Manager, Care home Company CEO, Sheltered Housing Manager, Social Services Managers and Social Workers]

**Re: This is a Notice of Liability setting out your personal responsibilities/liabilities for requiring staff including care (and other) workers to be Covid-19 vaccinated and or encouraging staff to be Covid-19 vaccinated.**

**Personal Liability**

This legal and lawful notice of liability may be used as evidence in court if needed and intends to enlighten you and protect you from attracting civil and criminal liability whether domestic or international and whether in an existing court or one to be convened under Natural Law principlesin relation to your action**(**s) and all your omissions in relation to the alleged SARS-CoV-2 pandemic and the measures that have been/are being taken within the United Kingdom and world-wide to control its alleged spread and effect(s) including, but not limited to, the requiring of, encouragement of and /or administration of experimental COVID-19/SARS-CoV-2 mRNA gene therapies/injections/vaccines (and or viral vector injections/vaccines) and the harm and death caused.

You may be held personally liable for and/or privately liable for and/or civilly and/or criminally liable for participating in unlawful, illegal and/or criminal activity and/or for supporting crimes against humanity, genocide, bio-warfare and/or failing to prevent acts so defined, including but not limited to acts that are purposely committed as part of a widespread and/or systematic policy, directed against living men and women, and in particular in your case, care (and other) workers, committed in furtherance of state/government policy.

The government has recently passed a statutory provision for care (and other) workers to be vaccinated. This is unenforceable.

Care (and other) workers,

1. that have been caused harm by ‘complying’ in anticipation of the provision, or

2. that are caused harm for not complying with the unenforceable provision,

may have cause to be compensated for any harms caused.

**The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021**

Paragraph 5 amends the: **The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014**

With regulation 12 which states,

“(3) For the purposes of paragraph (2)(h), a registered person (“A”) in respect of a regulated activity specified in paragraph 2 of Schedule 1 (accommodation for persons who require nursing or personal care) in a care home must secure that a person (“B”) **does not enter the premises** used by A unless— (b) B has provided A with evidence that satisfies A that either— (i) B **has been vaccinated with the complete course of doses of an authorised vaccine**… (ii) …”

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 has a parent Act, the Health and Social Care Act 2008.

**Health and Social Care Act 2008**

Section 129 amended the Public Health (Control of Disease) Act 1984 with sections 45C and 45E.

**Public Health (Control of Disease) Act 1984**

Section 45C states, “Health protection regulations: domestic (1) The appropriate Minister may by regulations make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England and Wales (whether from risks originating there or elsewhere). (3) Regulations under subsection (1) may in particular include provision— (c) imposing or enabling the imposition of restrictions or requirements on or in relation to persons, things or premises in the event of, or in response to, a threat to public health.”

*Thus, regulation 12(3)(b)(i) imposes the requirement on care workers to vaccinate in accordance with the Public Health (Control of Disease) Act 1094 section 45C as provided by the Health and Social Care Act 2008*.

***However, section 45E states, “Medical treatment (1) Regulations under section 45B or 45C may not include provision requiring a person to undergo medical treatment. (2) “Medical treatment” includes vaccination and other prophylactic treatment***.”

Therefore, **section 45E of the Public Health (Control of Disease) Act 1984 expressly overrides the regulation 12(3)(b)(i) requirement to vaccinate.**

**This means that regulation 12(3)(b)(i) is unenforceable because the provisions of an Act take precedence over the provisions of a regulation.**

**Clinical reasons for not vaccinating :-**

**The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, regulation 12** also states,

“(3) For the purposes of paragraph (2)(h), a registered person (“A”) in respect of a regulated activity specified in paragraph 2 of Schedule 1 (accommodation for persons who require nursing or personal care) in a care home must secure that a person (“B”) does not enter the premises used by A unless— (b) B has provided A with evidence that satisfies A that either— (i) B has been vaccinated with the complete course of doses of an authorised vaccine; or (ii) **that for clinical reasons B should not be vaccinated with any authorised vaccine.”**

**At no time when the government explained its plans to vaccinate care (or other) workers did they explain that there would be valid clinical reasons for not being vaccinated as provided by regulation 12(3)(b)(ii).**

**Not explaining the right to clinical exemption is at best disingenuous because care (and other) workers are:**

**1. feeling coerced to vaccinate to save their jobs,**

**2. being harassed to vaccinate,**

**3. leaving their jobs because they exercise their legal right to informed consent and decline to be vaccinated and**

**4. being subjected to discrimination.**

Doubtless a proportion of these workers will be clinically exempt.

**This means that a proportion of workers will have been caused harm by,**

**1. coercion,**

**2. harassment, and**

**3. discrimination**

**4. loss of income,**

**due to the failure of the government (and their employer/place of work) to advise workers that there would be a clinical exemption to being vaccinated (despite the fact the requirement was never going to be enforceable).**

The regulations may conflict with the [Human Rights Act 1998](https://www.legislation.gov.uk/ukpga/1998/42/contents)and [the Equality Act 2010](https://www.legislation.gov.uk/ukpga/2010/15/contents) as well as [internationally observed conventions on free and informed consent](http://portal.unesco.org/en/ev.php-URL_ID%3D31058%26URL_DO%3DDO_TOPIC%26URL_SECTION%3D201.html) and bodily integrity. The regulations have had an equality impact assessment as required under the Equality Act 2010 but the assessment does not deal with the issues as fully as it could and completely ignores anyone who has cogent philosophical or ethical beliefs connected to bodily autonomy or other vaccine related beliefs.

It is not clear which legal rights are supreme and until it becomes clear the legal status quo of every individual must be respected in full, in particular the common law right to [free and informed consent and bodily autonomy.](https://www.rcseng.ac.uk/news-and-events/blog/the-right-to-autonomy-of-treatment-is-a-common-law-right/)

Your care (and other) workers have the following rights at common law, under domestic law and as human rights recognised internationally.

1. [The right to decline any medical intervention without any penalty](https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf).

2. [The right to autonomy over their own body](https://www.rcseng.ac.uk/news-and-events/blog/the-right-to-autonomy-of-treatment-is-a-common-law-right/).

3. [The right to keep their medical records confidential.](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/special-category-data/) This includes:

a.  vaccination status.

b. any clinical reason why they should not be vaccinated.

4. The right to full indemnity in the workplace for losses sustained from any requirement imposed on them by their employer.

5. [The right to respect for their private life](https://www.legislation.gov.uk/ukpga/1998/42/schedule/1).

6. The right [not to suffer dismissal or detriment](https://www.legislation.gov.uk/ukpga/1998/23/section/1) for upholding and asserting their legal rights and bringing matters relating to alleged breach of legal obligations to the attention of their employer.

7. The right not to be discriminated against where such discrimination relates to a [protected characteristic.](https://www.legislation.gov.uk/ukpga/2010/15/section/4)

**You may be breaching or proposing to breach your obligations owed to care workers by:**

1. Requiring that care workers produce personal data on their vaccination status when [the Regulations at 5 (5) specifically provide that the Data Protection Act 2018 applies](https://www.legislation.gov.uk/ukdsi/2021/9780348224993/regulation/5). The common law and international law do not authorise disclosure.

2. [Requiring that care workers produce personal data on any exemption from vaccination](https://www.legislation.gov.uk/ukpga/2018/12/section/35/enacted)

when [the Regulations at 5 (5) specifically provide that the Data Protection Act 2018 applies](https://www.legislation.gov.uk/ukdsi/2021/9780348224993/regulation/5). The common law and international law do not authorise disclosure.

3. Implicitly requiring care workers to vaccinate or lose their livelihood.

4. Failing to provide full indemnity for any losses arising out of any serious adverse event arising from vaccination.

5. Implicitly requiring care workers to give up their [common law right to free and informed consent.](https://www.supremecourt.uk/cases/docs/uksc-2013-0136-press-summary.pdf)

6. Implicitly requiring care workers to give up autonomy over their bodies.

7. Requiring care home workers to disclose their disability and any exemption discriminates directly and indirectly against disabled care workers and puts such care workers at a [substantial disadvantage.](https://www.legislation.gov.uk/ukpga/2010/15/section/19) [The Assessment that acknowledged 22% of care workers](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001051/vaccination-as-a-condition-of-deployment_public-sector-equality-duty2.pdf) are disabled. Care workers have the right not to disclose their disability to their employer.

8. [Indirectly discriminating against care workers](https://www.legislation.gov.uk/ukpga/2010/15/section/19) who as an occupational group are [mainly women.](https://www.carersuk.org/news-and-campaigns/press-releases/facts-and-figures)    [Women have greater vaccine hesitancy than men](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001051/vaccination-as-a-condition-of-deployment_public-sector-equality-duty2.pdf).

9. [Directly or indirectly discriminating against pregnant women](https://www.legislation.gov.uk/ukpga/2010/15/section/18) in that [the requirement to vaccinate also puts pregnant care workers at a substantial disadvantage as none of the clinical trials for  the vaccines included any pregnant women see 10.4.2 of Pfizer trial.](https://media.tghn.org/medialibrary/2020/11/C4591001_Clinical_Protocol_Nov2020_Pfizer_BioNTech.pdf) Women who were breastfeeding were also excluded.

10. [Indirectly discriminating against care workers](https://www.legislation.gov.uk/ukpga/2010/15/section/19) who do not have [English as a first language.](https://www.skillsforcare.org.uk/adult-social-care-workforce-data/Workforce-intelligence/publications/Topics/Workforce-nationality.aspx)

11. Discriminating against those care workers who hold[philosophical belief](https://www.bailii.org/uk/cases/UKEAT/2009/0219_09_0311.html)s that government should not determine what medical treatment a care worker has.

12. Discriminating against those care workers who have [philosophical beliefs](https://www.bailii.org/uk/cases/UKEAT/2009/0219_09_0311.html) based on natural remedies and/orthe non-use of animals in clinical trials. It is to be noted that the Equality Impact Assessment did not include the risk of discrimination against care workers holding particular philosophical beliefs.

13. Discriminating against those care workers who have a [religious belief](https://www.legislation.gov.uk/ukpga/2010/15/section/10) relating to the [constituent materials from which some vaccines are made.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6027112/)

14. Indirectly discriminating against members of [BAME](https://www.legislation.gov.uk/ukpga/2010/15/section/9)communities who have vaccine hesitancy based on [past injustice relating to medical treatment.](https://www.cdc.gov/tuskegee/timeline.htm) [The Equality Impact Assessment acknowledges the BAME community’s loss of trust in authority.](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001051/vaccination-as-a-condition-of-deployment_public-sector-equality-duty2.pdf)  It is alleged that the covid response has not rebuilt that loss of trust.

15. Directly or indirectly discriminating against younger care workers who face less risk from covid infection but risk a serious adverse event from the vaccination which is disproportionate to the risk being mitigated. It is to be noted that care home residents have their right to decline vaccines respected. [It is also to be noted that only 10% of residents have not been vaccinated.](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001051/vaccination-as-a-condition-of-deployment_public-sector-equality-duty2.pdf) The Equality Impact Assessment acknowledges that younger female care workers have concerns over whether the vaccine may impact fertility. Those concerns are cogent since there is no long-term evidence of fertility impact yet reports of adverse events from vaccination include heavier menstruation. [It is also to be noted that the bio-distribution study Pfizer supplied to Japan may have found a build-up of the spike protein in the ovaries together with concerns over breast feeding mothers.](https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf) [The relevant extract is here](https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf). [Canadians have raised concerns on this issue](https://files.catbox.moe/k2miut.pdf). In particular where uncertainties exist on toxicity that the precautionary principle should be applied. In 2021 every person should have their right to bodily autonomy respected and those who wish to adopt a wait-and-see policy with regards to vaccination should not be penalised for that choice. That’s their right and a right that should be respected

The Covid-19 vaccinations are all currently in phase 3 of clinical trials which are due to end at various points throughout 2023 dependent on the vaccine concerned, understandable given that some of the vaccines are using for the first time in humans mRNA (messenger RNA) technology.Notwithstanding the emergency use authorisation for the administration of these experimental medications, it is our understanding that the Government is only underwriting the manufacturers of these experimental medications against any liability arising from their administration; we do not believe that the same applies to Care Home Managers/Owners, Care Home Company Directors, Social Services managers, Social Workers, or anyone else acting in advising and or encouraging men or women to take these experimental medications.

The efficacy of the vaccines have been exaggerated by the pharmaceutical companies, as reported in the medical journal, The Lancet[2](#Covid19VaccineEfficacyAndEffectivenessTh);

***“Vaccine efficacy is generally reported as a relative risk reduction (RRR). It uses the relative risk (RR)—ie, the ratio of attack rates with and without a vaccine—which is expressed as 1–RR. Ranking by reported efficacy gives relative risk reductions of 95% for the Pfizer–BioNTech, 94% for the Moderna–NIH, 90% for the Gamaleya, 67% for the J&J, and 67% for the AstraZeneca–Oxford vaccines. However, RRR should be seen against the background risk of being infected and becoming ill with COVID-19, which varies between populations and over time. Although the RRR considers only participants who could benefit from the vaccine, the absolute risk reduction (ARR), which is the difference between attack rates with and without a vaccine, considers the whole population. ARRs tend to be ignored because they give a much less impressive effect size than RRRs: 1·28% for the AstraZeneca–Oxford, 1·24% for the Moderna–NIH, 1·19% for the J&J, 0·93% for the Gamaleya, and 0·84% for the Pfizer–BioNTech vaccines.”***

The Nuremberg Code[3](#TheTenPointsOfTheNurembergCode)first principle provides that medical experiments or trials require voluntary and informed consent of all participants.

Of relevance to the issue of informed consent is the Yellow Card System[4](#YellowCardSystemReports) which the UK Government has established. This System shows that death has been listed as an outcome related to COVID-19 vaccines as of May 6, 2021 at least 1,143 times, a figure which at July14, 2021 had risen to 1,490. For the same period, Deafness as an outcome related to COVID-19 vaccines has increased from a minimum of 280 occasions to 393, and Blindness as an outcome at least 180 times for COVID-19 vaccines to 279 occasions. It follows that the rates of increase of death and significant harm (excluding blood clotting/strokes/heart attacks are increasing as the vaccination programme is rolled out. As at July 14, 2021 the System shows a total of over a million adverse reactions to the experimental vaccines. It is a failing as regards informed consent not to make available this information to any person whether vulnerable adult or child in relation to providing informed consent.The government estimates that the number of adverse reactions/deaths reported in the Yellow Card System are under stated such that the true figure could be 90 – 99% higher than this.

In addition, on the VAERS[5](#VaersReportUsa) USA (Vaccine Adverse Events Reporting System) Death has been listed as an outcome related to COVID-19 vaccines at least 3,924 times as of May 8, 2021 a figure which at July 23, 2021 had risen to 11,955.On the European database EndraViligance Death has been listed as an outcome related to COVID-19 vaccines at least 18,928 times as of July 17, 2021 and includes 1,687,527 adverse reactions.

Absent emergency authorisation which is being used by the UK Government and others around the world to roll out the experimental vaccines, these medications would have to be withdrawn from the “market”. In the USA, for example, deaths in relation to other vaccines numbering as few as 50 (in a country with a population in excess of 360 million) would cause withdrawal of the relevant medication. Comparable provisions apply in the UK and in Europe.This too is something directly relevant to informed consent, as is the data which shows that children who participated in the Pfizer covid vaccine clinical trials have had an adverse reaction rate at 86%

FDA Trial pdf <https://www.fda.gov/media/144413/download>

NHS Guidance limits the advice to be provided in relation to “informed consent” to communication of “the anticipated benefits of vaccination in the simplest of terms”, “the likely side effects from vaccination and any individual risks they may run should be addressed”, and “the disbenefits of not consenting to the vaccination”. It will be noted then that the stance of the NHS as regards the issue of consent is inadequate when compared with provision of fully informed consent, as shown in the**attacheddocument**which sets out the law relating to informed consent which should be gone through with every person in order to enable them to provide informed consent.

Principle 5 of the Nuremberg Code[3](#TheTenPointsOfTheNurembergCode)states that no medical experiments or trials should be conducted where there is an a priori (theoretical) reason to believe that death or disabling injury will occur. You will appreciate that these medical experiments (the trials for which conclude in 2023) are not theoretical as regards death or disabling injury: there is clear evidence of both arising.

**Receipt of this email shows that you have been made aware that death or other serious injuries are possible outcomes for men and women taking the COVID-19 experimental vaccinationsand that you are accepting responsibility for any injuries/deaths that result from said experimental vaccinations taken as a result of your encouragement or requirement.**

**Furthermore, that not explaining the right to clinical exemption may cause coercion, harassment, discrimination and/or loss of income.**

**Furthermore, that you may be breaching or proposing to breach your obligations owed to care workers as set out above.**

In conclusion, given the clear evidence that serious harm (or worse) can and does arise as a consequence of these experimental vaccines given to men and women, the care home (whether the manager, director of the care home company, or any other social services manager or employer) involved in the process of encouraging, requiring or the administration of Covid-19 vaccinations renders themselves liable to criminal prosecution for assault/wounding or worse if death results before the domestic courts, in addition to liability for prosecution before the International Criminal Court for breaches of the Nuremberg Code. This is quite separate to any civil liability that arises, or any prosecution for offences contrary to common law.

In those circumstances I seek your reassurance that you will ensure that no Care (or other) workers are required and or encouraged by you to obtain a covid-19 experimental vaccine and that you will ensure that your staff are not put under pressure, coerced, or caused harassment or discrimination.

I would also encourage you to send a letter to all care (and other) workers who may wish to enter the premises informing them of the points raised above so as to suitably inform any decisions they may take.

Kind regards

[Your Name]

### Cited References;

1. COVID-19 vaccine efficacy and effectiveness—the elephant (not) in the room - [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247%2821%2900069-0/fulltext)
2. The ten points of the Nuremberg Code

The ten points of the code were given in the section of the judges' [verdict](https://en.wikipedia.org/wiki/Verdict) entitled "Permissible Medical Experiments"

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

<https://en.wikipedia.org/wiki/Nuremberg_Code>

1. YELLOW CARD SYSTEM REPORTS (UK)
	1. Website of vaccine reported adverse events - <https://coronavirus-yellowcard.mhra.gov.uk>
	2. Sample of Pfizer reported adverse events - <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/986035/DAP_Pfizer_050521.pdf>
	3. Sample of Astra Zeneca reported adverse events - <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/986033/DAP_AstraZeneca_050521.pdf>
	4. Sample of Moderna reported adverse events - <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/986034/DAP_Moderna_050521.pdf>
	5. Sample of unspecified reported adverse events - <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/986036/DAP_Unspecified_050521.pdf>
2. VAERS REPORT (USA)

Run your own report to check results here by clicking link below and follow instructions:

<https://wonder.cdc.gov/vaers.html>

**Instructions for use**

Click ‘I agree’

Click ‘Data Report’

Choose from section 1. ‘Group results by - Vaccine manufacturer’

Choose from section 3. ‘Vaccine products - Covid 19 vaccines’

Choose from section 5. ‘Event category - Death’

Scroll to bottom of page and press ‘Send’

View latest data for deaths reported from Covid Vaccines grouped by Vaccine manufacturer

1. OTHER SUPPORTING REFERENCES

“The ongoing phase III trials for covid-19 vaccines are some of the most consequential randomised trials ever done.”.....“The covid-19 vaccine protocols should be scrutinised by the widest possible readership, to open a critical discussion of many questions about their design and conduct. These include why children, immunocompromised people, and pregnant women have been excluded from most trials; whether the right primary endpoint has been chosen; whether safety is being adequately evaluated; and whether gaps in our understanding of the clinical implications of pre-existing T cell responses to SARS-CoV-2 are being addressed.11”

<https://www.bmj.com/content/371/bmj.m4058>

“Following extensive pre-clinical testing, this next phase of the trial will allow us to refine our innovative, self-amplifying RNA vaccine for the first time in humans.”

<https://www.imperial.ac.uk/covid-19-vaccine-trial/>

**COVID-19 VACCINATION CONSENT FORM**

Purpose:

This form has been designed to support the Informed Consent process for Covid-19 vaccinations.

FOR THE LEGAL ADMINISTRATION OF ANY CV19 VACCINE, BOTH PARTIES MUST READ AND SIGN THIS

DOCUMENT

Audience:

• Doctors (or their delegated Health Care Professionals)

• Patients receiving Covid-19 Vaccine

Background:

This document is based on the Montgomery Judgement and GMC Guidelines.

The Montgomery Judgement and Informed Consent

https://www.themdu.com/guidance-and-advice/guides/montgomery-and-informed-consent

This Supreme Court judgement of Montgomery v Lanarkshire (2015) changed the standards of consent. The key

passages from Montgomery Judgement state:

“...The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware ofany material risks involved in any recommended treatment, and of any reasonable alternative or varianttreatments....”

“The test of materiality is whether, in the circumstances of the particular case, a reasonable person in thepatient's position would be likely to attach significance to the risk, or the doctor is or should reasonably beaware that the particular patient would be likely to attach significance to it.”

Before Montgomery, a doctor's duty to warn patients of risks was based on whether they had acted in line with aresponsible body of medical opinion - known as the “Bolam test”. Now, doctors must provide information aboutall material risksto which a reasonable person in the patient's position would attach significance. This puts the patientat the centre of consent process, as their understanding of material risk must be considered. Both patient and doctorneed to sign this document.If doctors fail to properly discuss the risks and alternative treatments with the patient, this renders them personallyresponsible for damages. This document therefore protects the patient and the doctor.

General Medical Council Guidance - Decision Making and Consent (2020)

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

This states that doctors MUST attempt to find out what matters to patients, so they can share information about thebenefits and harms of proposed options and reasonable alternatives.Note the word MUST makes this a legally binding directive.GMC Guidance states doctors MUST address the following information:

a) Recognise risks of harm that you believe anyone in the patient’s position would want to know. You’ll knowthese already from your professional knowledge and experience.

b) The effect of the patient’s individual clinical circumstances on the probability of a benefit or harmoccurring. 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.

c) Risks of harm and potential benefits that the patient would consider significant for any reason. These willbe revealed during your discussion with the patient about what matters to them.

d) Any risk of serious harm, however unlikely it is to occur.

e) Expected harms, including common side effects and what to do if they occur.

**References**

|  |  |  |
| --- | --- | --- |
| **Vitamin D** | **Vitamin C** | **Iodine** |
| 1. https://www.researchsquare.com/article/rs-21211/v12. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC75138353. https://www.grassrootshealth.net/wp-content/uploads/2020/04/Grant-GRH-Covid-paper-2020.pdf4. https://www.bmj.com/content/356/bmj.i6583 | 1. http://orthomolecular.org/resources/omns/v16n25.sHtml2. <https://orthomolecular.activehosted.com/index.php>3. https://ccforum.biomedcentral.com/articles/10.1186/s13054-020-03249-y4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592143/ | 1. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=35630922. https://www.medrxiv.org/content/10.1101/2020.05.25.20110239v13. https://www.researchgate.net/publication/340769844\_Iodine\_Intake\_to\_Reduce\_Covid-19\_Transmission\_and\_Mortalityhttps://www.medrxiv.org/content/10.1101/2020.09.07.20180448v1 |

**Iodine**

**Vaccine development & testing timeframes**:

“The discovery and research phase is normally two-to-five years, according to the Wellcome Trust. In total, a vaccine can take more than 10 years to fully develop”

<https://www.weforum.org/agenda/2020/06/vaccine-development-barriers-coronavirus/>

**Vaccines trigger post viral syndromes:**

“We present epidemiological, clinical and experimental evidence that ME/CFS constitutes a major type of adverse effect of vaccines” (2019 paper)

<https://www.sciencedirect.com/science/article/abs/pii/S1568997219301090>

**Allergy and autoimmunity effects of vaccines:**

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**References**

With Respect to the new COVID-19 vaccinations the Doctor MUST inform the patient of the following and tick the box to indicate such:

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| **Montgomery Judgement & GMC Guidance**  | **Facts** | **Notes** | **Discussed** |
| 2015 Montgomery Judgement on Informed Consent | The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of .......... any reasonable alternative or variant treatments. | Vitamin D, 5,000iu daily has proven benefit to prevent and treat Covid-19 Vitamin C, 5 grams daily has proven benefit to prevent and treat Covid-19 Topical antiseptics (such as iodine) are of proven benefit to reduce the loading dose, and hence disease severity, of Covid-19 | Yes/no |
| **GMC Guidelines to Doctors** | **Facts** | **Notes** | **Discussed** |
| Recognised 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. | Limited short-term safety data: NO long-termsafety data available on current CV-19 vaccines, including potential impacts on fertility. mRNA vaccines are a completely novel technology - essentially experimental, with the possibility of unanticipated/unpredictable longterm/late onset health effectsRisk of Antibody Dependent Enhancement causing more severe Covid-19 illness on exposure to virus post-vaccination | CV-19 vaccine development accelerated. Vaccine safety testing normally c.10 years. Current CV-19 vaccines trialled for a few months with little/no animal testing. PHASE 3 trials won’t complete for 2 years https://www.bmj.com/content/370/bmj.m3096/rrhttps://www.bulatlat.com/2020/08/21/hazards-of-the-covid-19-vaccine/CV-19 vaccines may sensitise recipients to more severe diseasehttps://doi.org/10.1111/ijcp.13795Potential cross-reactivity of vaccine-induced antibodies to virus spike protein, with the placental protein syncytin-1, could cause infertility https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-allcorona-vaccination-studies-and-call-for-co-signing-the-p | Yes/no |
| continued | There have been reports of some serious sideeffects including 2 cases of transverse myelitisand neurological conditions in the Astra Zeneca vaccine trial. | Astra Zeneca Transverse Myelitis report https://www.nature.com/articles/d41586-020-02594-whttps://www.nytimes.com/2020/09/19/health/astrazeneca-vaccinesafety-blueprints.html?auth=login-email&login=email | Yes/no |
| continued | The CDC identified 6 case reports of anaphylaxis following Pfizer-BioNtech vaccine meeting Brighton Collaboration criteria for anaphylaxisCDC updated advice on equipment necessary at all vaccination sites to deal with anaphylaxis | Anaphylaxisreports: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020- 12/slides-12-19/05-COVID-CLARK.pdf Preparationsto manage anaphylaxis vaccine recipients: https://www.cdc.gov/vaccines/covid-19/info-byproduct/pfizer/anaphylaxis-management.html | Yes/no |

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| **GMC Guidelines to Doctors** | **Facts** | **Notes** | **Discussed** |
| **b. 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.** | It is known that vaccines can switch on allergy and autoimmunity.May be contraindicated with pre-existingautoimmune conditions or CFS/ME, or previousvaccine injury/reactions.MHRA 09 December 2020: Any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose should not be given to anyone who has experienced anaphylaxisfollowing administration of the first dose | Any patient with a history or strong family history of allergies or autoimmune conditions may choose to refuse a CV-19 vaccine. Doctors working with CFS/ME patients already advise them to avoid vaccination as this may trigger a relapse.https://www.gov.uk/government/news/confirmation-of-guidance-tovaccination-centres-on-managing-allergic-reactions-following-covid-19-vaccination-with-the-pfizer-biontech-vaccine | Yes/no |
| **c. 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.** | **Patient’s individual risk from Covid-19 MUST be discussed – IFR <0.05% for <70 years to weigh up against risk from vaccine. Patient expectation of vaccine benefit i.e. reducing risk of severe illness, hospitalisation and preventing infection with and transmission of SARS-Cov-2 Patients MUST be made aware of the full list of vaccine ingredients** | **Covid-19 IFR estimate by age (Table 2):**https://spiral.imperial.ac.uk:8443/bitstream/10044/1/83545/8/2020-10-29-COVID19-Report-34.pdfMake patient aware that current trials are not designed to show if CV-19 vaccine will reduce their risk of hospitalisation or death or will prevent infection and transmission of virus as may affect risk v benefit profile https://www.bmj.com/content/371/bmj.m4037Ethical/religious considerations e.g. animal products - vegetarianism/veganism, WI-38 human diploid cells (aborted fetus source) - pro-life/religious belief | **Yes/no** |
| **d. Any risk of serious harm, however unlikely it is to occur.** | The Doctor MUST consider the significance that the Patient may place on risk of material harm.Patient MUST be made aware that the vaccinemanufacturers have demanded and been granted immunity from liability for injury or death caused by the vaccines | One example may be if a patient has first-hand knowledge of a relativewho has suffered serious harm following vaccination.https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments-for-covid-19-and-flu/outcome/government-response-consultation-on-changes-to-the-human-medicines-regulations-to-support-the-rollout-of-covid-19-vaccines#extending-immunity-from-civil-liability | **Yes/no** |
| **e. Expected harms, including common sideeffects and what to do if they occur.** | Full list of adverse reactions in insert to be shared. Common side-effects include chills, fever,myalgia, fatigue, arthralgia, headache, and pain at the injection site.A reaction to the first dose increases risk of a major reaction to a second dose | Moderna vaccine -100% of high-dose participants report systemic side effects after second dose, some severehttps://www.nejm.org/doi/full/10.1056/NEJMoa2022483Before a second dose, the patient must be asked about their reaction to the first dose. | **Yes/no** |

**To be signed by both parties and a copy held by both parties for at least 7 years.**

**Doctor confirmation:**

**I confirm that I have discussed the above issues at length with the patient below, in accordance with the 2015 Montgomery Judgement and GMC Guidelines.**

**I understand that failure to correctly and fully inform my patient renders me personally and legally responsible for any damages.**

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| **Date and Time** |  |
| **Name of doctor or Nurse****administrating** |  |
| **Professional number of doctor** **(GMC) or nurse (GNC** |  |
| **Name of vaccine, batch number** **and date of administration** |  |
| **Signature** |  |

**Patient consent:**

**I confirm that I have discussed the above issues at length with the doctor or health professional above. I accept that I have been correctly informed of possible side effects of the Covid-19 vaccine and the alternatives to vaccination. I choose and consent to receive the Covid-19 vaccination.**

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| **Date and Time** |  |
| **Name of Patient** |  |
| **Name of parent or guardian if consenting on behalf of a child** |  |
| **Contact phone number or email** |  |
| **Signature** |  |