

THE RULE OF LAW

MEDICAL LAW

INFORMED CONSENT - THE CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

Article 7 of the International Covenant on Civil and Political Rights (1966) is enshrined in Article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164) (1997), Oviedo, Spain (the "Oviedo Convention"). **The Oviedo Convention is a legally binding international legal instrument on the protection of human rights in the medical field.** It sets out fundamental principles applicable to daily medical practice and is regarded as such in the European Treaty on patient's rights. Chapter II - Consent, Article 5 - General Rule states:

"Chapter II – Consent
Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time."
(emphasis added)

<https://rm.coe.int/168007cf98>

MEDICAL LAW (1)

CONSENT IN MEDICAL TREATMENT

THE RIGHT to accept or refuse medical treatment and or medical procedures.

THE RIGHT TO BODILY INTEGRITY includes the **long-established common law right** of the individual to choose to accept or refuse medical treatment or interventions, as confirmed in the case of *Re T (Adult - Refusal of Treatment)* (1993) Fam 95 at 107, Lord Donaldson stated:

*"An adult patient who...suffers from no mental incapacity has an **absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered.** This right of choice is not limited to decisions which others might regard as sensible. It exists notwithstanding that the reasons for making the choice are rational, irrational, known, unknown or even non-existent.*

*This position reflects the value that society places on **personal autonomy** in matters of medical treatment and the very long established right of the patient to choose to accept or refuse medical treatment from his or her own doctor (**voluntas aegroti suprema lex- Over his or her own body and mind, the individual is sovereign**) (John Stuart Mill, *On Liberty*, 1859.).";*

<https://www.globalhealthrights.org/wp-content/uploads/2013/03/EWCA-1992-In-re-T-adult-refusal-of-medical-treatment.pdf>

The law of Negligence applies with respect to a breach of the Right to bodily integrity - Informed consent - freely given - must be obtained prior to medical procedures and or medical treatments and or participation in a live human experiment

The **law of negligence** is engaged when a person's physical and psychiatric integrity is breached. In UK case law, in the judgement in the Supreme Court decision in the case of *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 Lady Hale stated inter alia:

*"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 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."*

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

<https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>
<https://www.supremecourt.uk/cases/uksc-2013-0136.html>

MEDICAL LAW (2)

THE LEGAL DUTY TO OBTAIN INFORMED CONSENT BY BEFORE TREATMENT WITH BODILY INTEGRITY IS UNDERTAKEN

In the Supreme Court judgment in the UK case of *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (the "Montgomery case")_was cited in the UK High Court (Queen's Bench) case of *Thefaut v Johnston* 2017] EWHC 497 (QB)_in the Judgment of the court at paras [52] and [53] entitled "Informed consent", which states, inter alia:

"52. *In Montgomery v Lanarkshire Health Board [2015] UKSC 11 ("Montgomery") in the joint judgment of Lord Reed and Lord Kerr (with whom Lord Neuberger, Lord Clarke, Lord Wilson and Lord Hodge agreed) it was stated at paragraphs [87]...*"

"87. *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.***" ; (emphasis added)

MEDICAL LAW (3)

INFORMATION ON ADVERSE EFFECTS

The legal Duty of Care to ensure the patient is aware of any Material Risks involved in any medical treatment and of any reasonable alternative or variant treatments - the test of Materiality of Risks

In the UK case of *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 in the Judgment of Lord Reed and Lord Kerr (with whom Lord Neuberger, Lord Clarke, Lord Wilson and Lord Hodge agreed) it was stated at paragraphs [87], inter alia:

*"87. (cont.) 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.**"*

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

In the UK case of *Thefault v Johnson*, at paragraph [53] and [56] of the judgment, the court clarifies how "Materiality" of risks is measured.

*53. "... **"Materiality" is measured according to that which the patient would attach significance to, i.e. in the context of the decision to be taken.**"; and*

56. Paragraph [89] suggests that the subjective element could extend quite far.....:

*"89. Three further points should be made. **First**, it follows from this approach that **the assessment of whether a risk is material cannot be reduced to percentages.** The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, **the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives.***

*The **assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.**" (emphasis added)*

MEDICAL LAW (4)

THE REQUIREMENT TO ENSURE THAT "ADEQUATE TIME AND SPACE" IS PROVIDED TO THE INDIVIDUAL TO HAVE A "DIALOGUE" REGARDING THE MATERIAL RISKS INVOLVED AND THE NEED TO "DE-JARGONISE COMMUNICATIONS"

In the UK case of *Thefaut v Johnston* 2017] EWHC 497 (QB), in the Judgment of the court at paras [58] and [59] under the sub heading "Informed consent", the Judgment states, inter alia:

"58. Paragraph [90] of Montgomery is significant in shedding light on the modus operandi of communication. Two points emerge. First the centrality of "dialogue" is stressed.The issue is not so much the means of communication but its adequacy. Mr Peacock used the apt expression "adequate time and space" to describe the characteristics of a "dialogue" that satisfied the test in law.;

59. The second point arising from paragraph [90] is the need to de-jargonise communications to ensure that the message is conveyed in a comprehensible manner....this can include caution in the use of percentages. There is the risk that they can convey false degrees of certainty where, in truth, none really exists. ... Paragraph [90] states:

"90. Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible.

The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form." (emphasis added)

<https://www.bailii.org/ew/cases/EWHC/QB/2017/497.html#para58>
<https://www.bailii.org/ew/cases/EWHC/QB/2017/497.html#para59>

MEDICAL LAW (5)

NHS CONSTITUTION

The NHS Constitution for England (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 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." (emphasis added)**

<https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

MEDICAL LAW (6)

THE GENERAL MEDICAL COUNCIL

Doctors are expected to keep up to date with and practise in line with GMC guidance and the law

The General Medical Council's (the "GMC") factsheet entitled "Key legislation and case law relating to decision making and consent", states that

"This factsheet sets out some of the key legislation and case law relating to **medical decision making and consent in the UK. It is not intended to be a comprehensive list, nor is it a substitute for independent, up-to-date legal advice.**

We expect doctors to keep up to date with and practise in line with our guidance and the law."(emphasis added)

<https://www.gmc-uk.org/-/media/documents/factsheet---key-legislation-and-case-law-relating-to-decision-making-and-consent-84176182.pdf>

The right to refuse medical treatment includes the **right to refuse life-saving treatment** as per the UK Court of Protection's decision in the case of King's College NHS Foundation Trust v C [2015] EWCOP 80 in which the Judgment states, inter alia:

"A capacious individual is entitled to decide whether or not to accept medical treatment. The right to refuse treatment extends to declining treatment that would, if administered, save the life of the patient."

<https://www.familylawweek.co.uk/site.aspx?i=ed151871>

The GMC factsheet cites the following in relation to the case of King's College NHS Foundation Trust v C [2015] EWCOP 80:

"Assessing a patient's capacity when they make a decision that is considered unwise:

The Court of Protection held the following.

A person with capacity is entitled to decide whether or not to accept medical treatment. The right to refuse treatment extends to declining treatment that would save the life of the patient.

A person must not be judged to lack capacity to make a decision solely because they make a decision that is considered to be unwise."

<https://www.gmc-uk.org/-/media/documents/factsheet---key-legislation-and-case-law-relating-to-decision-making-and-consent-84176182.pdf>

MEDICAL LAW (7)

CAPACITY TO INFORMED CONSENT

The Mental Capacity Act 2005 - the legal framework for assessing an individual's mental capacity to provide informed consent to medical treatment

The GMC factsheet cites the following in relation to the law applicable to individual's aged 16 and over and their individual capacity to consent to medical treatment in England and Wales as follows:

"Mental Capacity Act 2005

This Act provides a legal framework for making decisions on behalf of people **aged 16 or over who lack capacity to make decisions themselves**. It clarifies:

- who can make decisions, including decisions about medical care and treatment, for people who are unable to decide for themselves
- how those decisions should be made.

Doctors and other healthcare professionals must refer to the Mental Capacity Act Code of Practice, which explains how the Act should work on a daily basis and sets out the steps that those using and interpreting it should follow when:

- assessing a person's capacity
- reaching a decision in the best interests of a person who does not have capacity."

<https://www.gmc-uk.org/-/media/documents/factsheet---key-legislation-and-case-law-relating-to-decision-making-and-consent-84176182.pdf>

<https://www.legislation.gov.uk/ukpga/2005/9/contents>

<https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice>

<https://www.bma.org.uk/advice-and-support/ethics/adults-who-lack-capacity/mental-capacity-act-toolkit>

Patients lacking capacity but who previously objected to vaccination could not be forcibly treated with a COVID-19 vaccine

In a recent ruling by the Court of Protection, *SS v Richmond* [2021] EWCOP 31, it was found that a dementia patient who lacked capacity but who previously objected to vaccination could not be forcibly treated with a COVID-19 vaccine.

-<https://www.courtprotectionhub.uk/cases/ss-v-london-borough-of-richmond-upon-thames-anor-2021-ewcop-31>
<https://www.bailii.org/ew/cases/EWCOP/2021/31.html>

MEDICAL LAW (8)

THE IMPOSITION OF MEDICAL TREATMENT WITHOUT CONSENT CONSTITUTES AN INTERFERENCE WITH ARTICLE 8 OF THE EUROPEAN CONVENTION ON HUMAN RIGHTS

The case law of the European Court of Human Rights establishes that the provision of medical treatment without consent constitutes an interference with article 8 of the European Convention on Human Rights ("the ECHR"). The imposition of medical treatment without the consent of a mentally competent patient, would interfere with a person's physical and or mental integrity in a manner capable of engaging the rights protected under article 8 (1) of the Convention as held in the case of Pretty v United Kingdom (2002) 35 EHRR 1 (EctHR), in which the court held, inter alia:

*"the imposition of medical treatment, **without the consent of a mentally competent adult patient, would interfere with a person's physical integrity** in a manner capable of engaging the rights protected under article 8 (1) of the Convention [the ECHR]."*
(emphasis added)

<https://www.globalhealthrights.org/wp-content/uploads/2013/10/ECtHR-2002-Pretty-v-United-Kingdom.pdf>

https://www.echr.coe.int/Documents/Guide_Art_8_ENG.pdf