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## Informed consent

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'Informed' consent

by

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## Abstract

Consent is a fundamental aspect of healthcare; yet what is consent and what aspects of consent do you need to consider before treating a patient? There are three aspects to legally valid consent. The aim of this article is to consider each so that the consent you obtain from your patients is legally valid.

## Introduction

'Informed' consent is a misnomer and a tautology. The term implies that there is a form of consent that is not 'informed'; however, this is not so. To be legally valid, all consent must have the necessary degree of information, the issue, as we shall see later, is in how much information needs to be given to patients. 'Informed consent' is an American principle and one that is frequently used within ethical discussions. There is no English equivalent of the principle and in English law the term valid or real consent is used to denote consent that has a legal basis. In this article we will consider the principles of legally valid consent.

## What is consent?

A legal definition of consent is 'compliance with or deliberate approval of a course of action' (Curzon 1994). At its simplest level, consent is permission from someone for someone else to do something. Within the health care context, consent is permission from a patient for the health care practitioner to perform an investigation or treatment on them.

Consent provides the patient with the right to determine what happens to their body, the ethical principle of self-determination. Without this principle, individuals would have no control over what happens to their bodies. The principle of self-determination was first recognised in an American legal case in 1914. In that case the Judge, Justice Cardozo, stated that:

'every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault' (Schloendorff v. Society of New York Hospital 1914 p. 126).

Although the case is American and one hundred years old, it is still relevant to the modern British health care setting and is something that underlies the modern law on consent. It is the law on consent that provides patients with legal enforcement of their right of self-determination. However, consent is not something that merely protects the patient. Where consent has been obtained in accordance with established legal principles, the fact that there is a legally valid consent can also protect the health care practitioner from both legal action and action by their regulatory body or employer.

It is also important to remember that consent is not something that you do. You can't go and consent Mr Jones. Rather consent is an aspect of the therapeutic relationship that exists between patient and health care practitioner. It sets the boundary between what is and is not permissible and can be an interchange of information between both. Only when valid consent has been obtained can treatment proceed.

### Legal principles for valid consent

There are four principles which have to exist for consent to be considered legally valid. These are that:

- The person who provides the consent must be competent to do so;
- The person consenting must be adequately informed about the nature of the procedure or treatment;
- The person must be acting voluntarily; and
- The person must not be providing their consent under duress or undue influence.

(Kennedy & Grubb 1998 at page 111)

The third and fourth principle are, for all practical purposes, the same in that someone who is acting voluntarily would not be acting under duress or undue influence and so will be discussed as one in this article.

So, if a competent person, who has been adequately informed about the procedure to be performed, acts voluntarily in giving their consent, that consent will be legally valid.

## *Competence*

It was noted above that one of the principles of legally valid consent is that it is given by someone who is competent to do so; therefore, we need to consider what competence is.

In a legal sense, competence refers to the ability of someone to do a particular thing. In terms of consent, it means that they are able to make a decision, based on information given to them, about a particular form of treatment. That is, they can decide whether or not to have the treatment being proposed.

Many legal cases have centred on the patient's competence to be able to make a decision. Prior to the coming into force of the Mental Capacity Act 2005 in October 2007, competence was determined by principles of common law. This means that judges looked at other cases to see what had been decided on when a person was competent or not. The most influential of these occurred in 1993 and concerned the possible amputation of the foot of a man suffering with schizophrenia. The man, known as Mr C, was deemed by his doctors to need to have his foot amputated because it was dangerous. However, Mr C protested against this form of treatment and wanted something less radical than amputation. The case went to court where it was stated by those acting for the hospital and doctors that, because of his schizophrenia, Mr C was not able to make a decision of this sort and was therefore not competent.

However, the judge in the case, Mr Justice Thorpe, provided a three-stage test to determine competence:

- the person must be able to comprehend and retain the relevant information
- they must believe the information they are given
- they must be able to weigh the information they have been given in the balance so as to arrive at a choice regarding the proposed treatment, balancing both risks and needs (Re C [1994] at page 824).

Mr Justice Thorpe went on to apply this three-stage test to Mr C and concluded that he was able to comprehend and retain the information he had been given regarding the gangrene and the proposed treatment; that Mr C did believe the information he had been given; and that Mr C had weighed all the information he had been given,

taking into account both risks and needs to reach his own decision against having the operation. Therefore Mr Justice Thorpe concluded that Mr C was in fact competent and the operation could only go ahead if Mr C consented, which he did not.

Since the Mental Capacity Act 2005 came into force, the determination of competence has been more straightforward. This is because, under the Mental Capacity Act 2005 Section 1(2), everyone is deemed to be competent unless it can be proved otherwise. What this means is that as a health care practitioner, unless there is a declaration of incompetence, you can assume that the patient before you is competent to make their own decisions regarding their health care and treatment options.

Some patients may need support to be able to reach or communicate their decision, for example they need a writing board as they cannot speak or they need someone to explain things to them in terms they can understand. The need for support does not mean that they lose their competence, rather all patients should be helped in their decision making, unless or until they are declared to be incompetent.

Making a decision that others would not make (for instance Mr C's decision not to have his foot amputated may fall into this category) does not mean that someone is incompetent to make a decision. Section 3(1) of the Mental Capacity Act 2005 provides that a person is unable to make a decision if s/he is unable:

- (a) 'to understand the information relevant to the decision,
- (b) to retain that information,
- (c) to use or weigh that information as part of the process of making the decision, or
- (d) to communicate his/her decision (whether by talking, using sign language or any other means)'.

The competence of the patient has to be determined by the person who is proving the treatment to the patient, noting that under the Mental Capacity Act 2005 all patients are deemed to be competent unless declared otherwise. Therefore, if you are treating a patient, you would have to prove that they were incompetent. So unless you can prove one or more of the criteria in Section 3(1) is present, your patient is competent

to make their own decisions. If you are unsure of your patient's ability to consent to their own treatment you should consult someone more senior.

### *Information giving*

The second principle mentioned above regarding valid consent is that the patient has to be adequately informed about the nature of the treatment being proposed. The question arises as to when the patient is 'adequately informed' to be able to make a decision. How do you know when you have provided your patient with 'adequate' information?

The amount of information to give a specific patient about a specific procedure is a matter for the health care practitioner who is going to treat that patient. It is only they who will have the information about the patient's condition, their needs and their desires as well as that of the benefits and risks associated with the procedure for that particular patient. Therefore, in some ways, it can be said that the process of information giving is subjective. However, in order to protect patients from paternalism, where they are just told they are having a procedure and little else, and to give patients the ability to exercise their self-determination, there are some general legal principles that can be applied.

The first of these arises from a 1981 case (*Chatterton v. Gerson* [1981]). In that case, it was decided that in order for consent to be legally valid, the patient needs to receive information related to the reasons for the proposed treatment; that is, why they need it the actual procedure or treatment that is going to be performed, and the benefit of the procedure along with any side effects or risks.

Whilst this seems straightforward, it can lead to differences in the actual information that patients are given. For instance, suppose that there are 6 key aspects (risks or benefits) to a particular procedure. Some health care practitioners only tell their patients of 2 of these. Others tell their patients those 2 and an additional factor. Other health care practitioners tell their patients a different 2. Looking at the information all the patients received, you would see that patients had different information depending upon which health care practitioner they saw. Indeed, it

could be argued that the consent given by some or all of the patients was not based on adequate levels of information and the consent obtained was not legally valid.

In order to avoid this situation, the legal principle enshrined in the 'Bolam Test' is used for information giving when obtaining consent from a patient. In essence, the 'Bolam Test' holds you to the actions of your peers and requires you to demonstrate the same standard as they would in a given situation, such as obtaining consent (for a fuller discussion of the Bolam Test see Cornock 2014). So to look at the procedure with the 6 key aspects discussed earlier, the 'Bolam Test' would require you to discuss the same key aspects as other health care practitioners working within your area of expertise. Therefore, if other health care practitioners would inform the patient of 3 key aspects, numbers 1, 2 and 3 and you only mention 1 and 2 to your patients you would be deemed to have failed the 'Bolam Test' and the consent you obtain would not be legally valid. However, if you would have discussed aspects 1, 2, 3 and 5 you would have exceeded the standard required by the 'Bolam Test' because you would have provide the same information as the other health care practitioners and then provided additional information. In the latter situation, your standard would mean that the consent you obtained from your patients would be legally valid.

As noted earlier, there is no principle of informed consent in English law. However, whilst this means that you cannot be expected to provide your patients with ALL the information regarding a particular treatment, you should ensure that you provide them with the information they need to be able to make a decision as to where they should have the procedure or not. You need to take the particular patient's needs and understanding into consideration when providing the information. At a minimum, you need to consider the information requirements from the Chatterton v. Gerson case and possibly any alternative procedures they could have, how their condition would be managed if they did not have the procedure, and any future health needs they might have by not having the procedure.

Additionally, if the patient asks you a specific question relating to the procedure, its effects or aftercare, you are expected to provide them with an answer that would be in keeping with the requirements of the 'Bolam test'. If you do not know the answer to a particular question, tell the patient this and inform them how you will get an



answer for them. It is important not to give the patient incorrect or inaccurate information. Remember that the patient is basing their decision on the information you provide; if that information is not accurate then the patient's consent will not be valid. If you do not have valid consent, then you have no lawful authority to touch that patient and, if you do, you will be assuming the risk of committing an assault or battery upon them.

### *How do you provide information to patients?*

Of paramount importance is to ensure that you give the information to the patient in a way that they can understand it. There is no legal issue with providing the information to patients in a written leaflet, so long as it is in a language that the patient understands and that you provide an opportunity for the patient to ask any questions they have and for these to be answered. Providing an information leaflet could be said to be fulfilling the requirements of the 'Bolam Test' as it means that all patients receive the same information.

### *Acting voluntarily*

The final aspect of legally valid consent is that the consent is given voluntarily and without any undue duress or undue influence.

In the normal course of practice it is reasonable to assume that a patient's consent is voluntary. It is only where you have knowledge that the patient's consent is not voluntary or where there is reasonable doubt that you need to take action. One point to make here is that the patient can be under duress to consent but can be equally under duress not to consent, so you need to be vigilant about patients who refuse to consent because they are under duress as well as those who are not consenting voluntarily.

If you have any doubts, you need to base your actions on your knowledge of the patient. Where appropriate you could speak to the patient away from anyone else and ask them if they want the procedure, informing them that you only want to act in their best interest. If this is not possible, you may want to refer the matter to a more senior colleague or manager.

It is possible that the duress on the patient may come from you, so you need to ensure that you do not put the patient under any form of duress or influence in seeking consent from them. Ensure that the patient knows that, although you believe the procedure you are offering is in their best interests, they are free to choose whether to have the procedure or not and that not having the procedure will not mean that you will just abandon them. Likewise when you are giving the information about the procedure to the patient ensure that you are neutral in your delivery and do not over-emphasise the importance of having the procedure unless there is evidence for this or be aggressive in your presentation of the information.

### A final thought

Who should obtain consent from a patient for a specific procedure? Ideally the person who performs the procedure should be the one who has spoken to the patient about it, provided them with the necessary information, answered their questions, and obtained their consent, ideally in writing.

However, it is not a perfect world and in many situations one health care practitioner goes through the procedure with a patient whilst another health care practitioner actually undertakes the procedure. There is nothing legally wrong with this, so long as the health care practitioner performing the procedure checks that there is valid consent. This can be as simple as asking the patient if the procedure has been explained to them and whether they have any further questions and that they are still happy for the procedure to go ahead. One point to note is that the person who actually obtains the consent needs to have the ability to perform the actual procedure so that they can adequately answer the patient's questions. It would not be appropriate for a person with no experience of the procedure to obtain consent.

As to the need for written consent, this is not a legal requirement. Whenever it is possible to obtain written consent, this is the best from a legal perspective; however legally valid consent will be obtained if the patient verbally states that they agree to have the procedure. Written consent is preferred because it is less open to dispute as to whether consent was obtained as the patient has signed to say that they are consenting to the procedure. It is a judgement call for the health care practitioner as to whether they need to obtain a written consent. Most National Health Service

establishments have a policy regarding written consent and when it is needed and this will need to be followed. In general, the legal principle is that the greater the degree of bodily interference the greater the need for written consent. If you are applying a cast to a patient's lower leg then written consent may seem excessive although your NHS Trust may require it. However, for a procedure that requires you to give the patient an anaesthetic and then perform an operation via an incision, legal advice would be to obtain written consent.

## Conclusion

Most patients you meet within your professional life will be there to seek your expert guidance and to receive the treatment that you consider to be in their best interests. Consent is relatively straightforward if you remember the three guiding legal principles of the patient being competent, having adequate information upon which to base their decision and making their decision voluntarily without any undue duress or undue influence.

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