Revisiting informed consent

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RE revisit ‘INFORMED’ CONSENT:
A revisit and a revision

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This article is based on a previous article entitled ‘informed consent’ (Cornock 2015) which was published in this journal in 2015. The abstract of that article is as follows: 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.

This article shares the same aim; to consider the three aspects of legally valid consent so that consent that is obtained from a patient is in fact legally valid consent in each and every instance that it is needed.

The reason for revisiting the original article is that shortly after it was published the judgment in a medical law case was handed down by the Supreme Court. This case, Montgomery v Lanarkshire Health Board [2015], has subsequently become a landmark case not only in terms of the law around consent but in medical law in general. The article as published was not able to consider the implications of that landmark case due to the timing of publication. In the five years since publication of the original article it has become apparent that the section on ‘information giving’ has needed a revision and update to address the judgment from the Montgomery case.

Rather than write and publish a totally new article on the same topic of consent, the decision has been made to revisit, revise, and update the original in terms of the section on information that needs to address the judgment in the Montgomery case but to keep as much of the original article as is possible, whilst also addressing a few minor niggles in the original, and undertaking a general update as well.

Keywords: Consent, informed consent, legal principles of consent, information giving in consent, Montgomery v Lanarkshire Health Board [2015]

Introduction

On almost any discussion on consent, at some point you will hear the term ‘informed consent’ being used. Indeed, on many consent forms, particularly those used by
researchers, put also in this author’s experience on some hospital consent forms, the forms will be called and headed ‘informed consent’. Yet ‘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 not where information has to be provided at all but 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. However, as we shall see in the section on information giving, informed consent may have moved a step closer as a result of the judgment in Montgomery v Lanarkshire Health Board [2015].

This article considers the legal principles that underpin any consent process and is structured along the lines of those principles. Following this introduction is a consideration of what consent is, followed by a discussion of the legal principles of consent. This is followed by three sections that each deal with one of the legal principles that are considered to underpin consent in the health care setting. Finally, the article concludes by discussing who should obtain consent and whether all consent has to be recorded on a consent form.

What is consent?

Consent itself is not a complex issue. It is the processes around consent that can seem to make the procedure of engaging with a patient about their treatment and gaining their permission complex and burdensome.

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 principal, 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 over 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. Indeed, 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, as well as protecting the patient and allowing them to exercise their self-determination.

It is also important to remember that consent is not something that you do. Consent is not a verb. 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, and should, be seen as an interchange of information between both patient and health care practitioner. 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.
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 in relation to competence for consent 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 gangrenous. However, Mr C protested against this form of treatment and wanted something less radial 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 care unable to speak or they need someone to explain things to them in terms or a language 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. The presumption is that a person is competent until it can be proved otherwise, and Section 3(1) of the Mental Capacity Act 2005 provides that a person is unable to make a decision only 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).

If the patient can do all these four things then they would be considered to be competent to make a decision at that particular time, if they are unable to do at least one of them then they would not be considered to be competent in relation to that particular treatment. Although, even if deemed to be incompetent for that particular treatment at that particular time, they may be competent in relation to other treatment either now or in the future as assessing a patient’s competence is both time and situation specific.

The competence of the patient has to be determined by the person who is providing 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 and do not believe that they are able to make a decision in relation to the proposed treatment being offered, that they are not in fact competent at that particular time, 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 should be deemed to be competent to make their own decisions.

Most health care practitioners are not experienced in assessing a patient’s ability to make decisions, which is usually the preserve of psychiatrists and psychologists etc., therefore, If you are unsure of your patient’s ability to be able 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 particular 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 the subjective nature of information giving and also paternalism, where the patient is 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 need to 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.

So far so good, and the above was in the original article. However, this is where things start to change.

The original of this article went on to consider how a health care practitioner could ensure that they met the legal requirement for information giving based on what others would do in the same circumstances. This is what was said in 2015 before the judgment in the
Montgomery case, it is included here so that we can see how the law has evolved into what is required today.

The 2015 version of this article stated that 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 provided 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.

In stating that the ‘Bolam Test’ was the standard used to determine how much information a patient should be given on a specific procedure or treatment in order for them to make a decision whether to have that treatment or not, the original article was linking the principle derived from the Sidaway v Bethlem Royal Hospital Governors [1985] case with the legal test used to determine whether a health care practitioner has been negligent (the Bolam Test). The Sidaway case was heard in the House of Lords and its judgment was the legal basis for information giving until the judgment was delivered in the Montgomery v Lanarkshire Health Board [2015] case.

For Herring (2016) the judgment in Sidaway v Bethlem Royal Hospital Governors [1985] held [that] a doctor was required to disclose the amount of information that a responsible body of medical opinion thought appropriate (at page 174).

Essentially both the Sidaway judgment and the ‘Bolam Test’ were saying the same thing: how much information to give to a particular patient in relation to a particular procedure or treatment was based on what other practitioners thought would be needed. Whilst this was indeed the legal principle what was used whenever any determination of practice was needed, it was subject to criticism that it was paternalistic and focussed not on what a patient needed but on ensuring that practitioners reached a particular standard. In doing this it did not allow the patient to make an informed choice.
Some commenters have advocated that a prudent patient test be accepted as best practice. This is a test which asks what a reasonable person in the same circumstances as the patient (the so-called prudent person) would want to know. This level of information then becomes the minimum standard for information giving in that set of circumstances.

**The current situation regarding information giving**

The Montgomery v Lanarkshire Health Board [2015] case was a negligence claim which concerned a woman with diabetes who was not told of the risk of shoulder dystocia (which is when one or more of the shoulders of the baby become stuck behind the mother’s pelvis during labour, after the head has been born) during her ante natal care. Shoulder dystocia is more common with higher weight babies and woman with diabetes tend to have higher weight babies. Mrs Montgomery was noted to be having a larger than normal baby but was not warned of the risk of proceeding with vaginal delivery and the possibility of instead having an elective caesarean delivery. Unfortunately, shoulder dystocia did occur during the birth of Mrs Montgomery’s son and this resulted in her son having severe disabilities.

Mrs Montgomery claimed that if she had been warned of the risks associated with a vaginal delivery she would have elected to have her son delivered by caesarean section. The doctor concerned was aware of the risk but stated that she did not discuss the risk with patients because the risk involved was small and if she did then all patients in this situation would request a caesarean section which would not be in their interests.

The Supreme Court found in favour of Mrs Montgomery. They also gave opinion as to how much information a patient should be entitled to receive. With the result that the approach developed from the Sidaway case and enshrined by the ‘Bolam Test’ is no longer valid. Herring (2016) is of the opinion that

that approach has been rejected and following Montgomery it is the patient, not the doctors, who determine how much information should be given. The shift here is away from ensuring the doctor follows a standard professional practice to requiring the doctor to enable the patient to exercise a choice’ (at page 174).

Jackson (2019) states

Significantly, the Supreme Court in Montgomery went beyond the ‘prudent patient test’ … [which] while an improvement on Bolam, might still fail to protect individual patients’ interests in information. People have different priorities, beliefs, and family histories, all of which affect the relative importance they attach to the risks and benefits of medical treatment. Giving every patient the information which the abstract reasonable [or prudent] patient would consider material might be preferable to the Bolam
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standard, but it would still result in some patients being deprived of information which might be especially important to them. Instead the Supreme Court in Montgomery acknowledged that people have variable information needs, and it imposed a duty upon doctors to tailor their disclosures according to the individual patient’s priorities and concerns (at page 209).

There are two exceptions given in the judgment in the Montgomery case to the provision of information based on a patient’s need. These are that the doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient’s health. The doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision (Montgomery v Lanarkshire Health Board [2015] at paragraph 88).

What this means is that whilst 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. You need to ensure that you make the patient aware of any material information that is relevant to them.

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 (Montgomery v Lanarkshire Health Board [2015] at paragraph 87).

At a minimum, you need to consider the information requirements from the Chatterton v. Gerson case (see above) and 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. 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 a battery or assault upon them. You can only withhold information based on the two principles outlined above: because the patient is unconscious or otherwise unable to make a decision, or because to provide that information would be detrimental to the patient’s health. Take note that withholding information because of a detrimental effect on the patient, also known as the therapeutic privilege exception, is one that should be caused with caution As Herring (2016) notes this is likely to apply to cases where if a patient is informed of a risk their health will be seriously harmed. It is clearly not sufficient simply to show that informing the patient about the risk will cause them to worry or be upset. Nor can it be used on the basis that if the patient is informed of the risk they will refuse to consent and that will be harmful to them. Rather, it would need to be shown that if the patient were told of a risk they would suffer a clear harm, such as a panic attack or depression (at pages 175 – 6).

Informed consent
It was noted earlier that there is no principle of informed consent in English law, however the judgment in the Montgomery v Lanarkshire Health Board [2015] case has certainly moved it a few steps closer to being a reality.

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. This means in a language they can understand, using interpreters if necessary, and at a level suited to their ability to comprehend information. 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.

Acting voluntarily

The final principles of legally valid consent that we need to consider 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, the health care practitioner, so you need to ensure that you do not put the patient under any form of duress or influence in discussing the treatment and/or procedure and 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.

Who should obtain consent?

As to 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 though the procedure with a patient whilst another heath 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 for the procedure to be performed. 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 they would not be in a position to fully address any questions that the patient may have.

Does all consent have to be in writing?
As to the need for written consent, it is not a legal requirement that consent has to be recorded in writing. 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’s policy 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.

If your Trust or employer has a policy in place regarding consent, and it would be surprising if they didn’t, follow it with regard to whether consent has to be in writing and, if so, if it needs to be recorded on a specific type of form. If there is no policy or no blanket requirement for written consent, consider the explanation above as to when written consent may be preferable to that of verbal consent. If in doubt, as always, consult with another colleague, preferably someone who is senior to you for their advice on the specific situation you are facing.

Express vs implied consent

Express consent is the form of consent we have discussed above. It occurs when discussion is had with the patient regarding a procedure or treatment and the patient expresses their wish to go ahead with the treatment or procedure being offered. The key here is that the patient expresses their consent either verbally or in writing.

Implied consent is very different. In some ways the term implied consent is another misnomer in that it can be said that no actual consent is given by the patient. Rather it is an inference made by another as to what the patient’s actions are implying. An example would be that you want to give a take a patient’s blood pressure. You explain this to the patient and rather than speaking to you the patient rolls up their sleeve, smiles to you and offers you their arm.

On this set of facts what would a reasonable person infer from the patient’s actions other than the patient was happy for you to take their blood pressure. The actions of the patient,
rolling up their sleeve, offering you their arm and smiling, imply what they want to happen. These actions lead you to infer that they are consenting to you taking their blood pressure.

Implied consent is a perfectly legally valid form of consent. In everyday health care practice implied consent is acceptable and used in many interactions between health care practitioners and patients. Indeed, it would be nigh on impossible for health care practitioners to function if they had to obtain express consent for every single thing they do, at best it would increase their workload.

One thing to note about implied consent, whilst it is a legally acceptable way of treating a patient, the more invasive the procedure the more advisable it is for the health care practitioner to obtain express consent from the patient that they can document.

A final thought

There is nothing mystical or magical about consent. It is not a legal device designed to trap you into poor practice or make you run through a series of ever decreasing hoops in order to achieve the impossible. Indeed, as has hopefully been demonstrated above, 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.

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. They will be guided by you and your advice and present you with no difficulties with regard to that treatment and you will be able to discuss their consent to that treatment through the therapeutic relationship.

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