Consent – the legal evidence base

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Consent - the legal evidence base

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Although not a new phenomenon, evidence based practice can be confusing because of the need to have evidence for practice decision-making. In this article an evidence base for practice is explored through the examination of what constitutes the legal evidence for consent in a health care setting.

Keywords: Evidence base; EBP; consent

Introduction

This article examines the evidence base in relation to consent in health care, specifically in the clinical practice of health care practitioners. Its aim is to provide the information upon which a health care practitioner can base their decision making and ensure that their practice, in relation to consent, fulfils regulatory and legal requirements.

It will begin by considering what evidence based practice is and then proceed to note why consent is important in health care practice, before looking at the actual evidence base that is currently available around consent.

Evidence based practice

Evidence based practice (EBP) is not a new concept, having been around for approximately 30 years in its present form. Linsley and Barker (2019) state that *its introduction in the 1990s has had a direct impact on health and social care policy the world over and has led to, among other things, the expansion of the nurses' role* (at page 3).

Evidence based practice is now so accepted that it is taught as part of pre-registration education and to not use it in clinical practice would be seen as practising below the required standard (Cornock 2017). In fact, using EBP in your clinical decision making is seen as part of the duty of care owed to your patients and clients (Cornock 2014).

As to what EBP is, returning to Linsley and Barker (2019) it is noted as being *more than using findings from research … it is the integration of … evidence and knowledge into current clinical*

practice, for use at a local level, ensuring that patients receive the best quality care available. Implicit in such discussions is the message that healthcare, wherever it is delivered, must be based on good, sound evidence (at pages 4 – 5).

Evidence based practice means using the knowledge and experience of the health care practitioner combined with the best available evidence and the patient's known wishes, to offer the most appropriate care and treatment to that patient. It is the health care practitioner's clinical judgement which is important in deciding which evidence to apply and how to apply it in a practice situation for a particular patient.

The question to which will be addressed throughout the rest of this article, after considering why consent is important, is what is the evidence in relation to consent that a health care practitioner can use to guide their practice?

Why is consent important?

Many commentators writing about consent do so without considering its importance. This is probably because they do not consider that it is necessary to discuss whether consent is important or not because its importance is not in doubt. In many ways they are right, consent is so important that it should be taken as being read that it is utilised in health care practice. However, there are cases that come before the professional health care regulator fitness to practise committees which centre on whether consent has been provided by patients. So, we should not be complacent in believing that consent is always obtained by all health care practitioners. This section will therefore look at the importance of consent in the health care context.

Consent is a key concept in the delivery of patient care and treatment and in health care practice. In this author's experience consent is a key part of pre-registration curriculum and features in every programme of study designed to prepare students for registration with the professional health care regulators, for instance the Nursing and Midwifery Council (NMC) and the Health and Care Professions Council (HCPC).

As to why consent has attained this status, it is because of the ethical principles of autonomy and self-determination. For Sköstrand et al (2013) autonomy relates to the right of a patient to be a part of the decision making process relating to their care and treatment.

Without autonomy paternalism prevails and rather than being involved in their care and the decision making around that, the patient would be told what care and treatment they were to receive based upon the professional opinion of the health care practitioner. A sort of health care practitioner knows best situation where the opinion of the patient is not needed or

sought. Thankfully, as Fullbrook (2007) notes, *the days when the prevailing doctrine of paternalistic medicine and passive nursing were the overarching models of care provision, are long gone* (p. 236).

From the perspective of the law, consent may be seen as the legal recognition of the ethical principles of autonomy and self-determination. Laurie et al (2019) support this viewpoint when they state that *freedom of the individual – autonomy and the right of self-determination – is … a deeply ingrained feature in many societies* [and] *based on the strong moral conviction that everyone has the right of self-determination with regard to his or her body, the common law has long recognised the principle that every person has the right to have his or her bodily integrity protected against invasion by others* (at pages 64 - 65). They go on to note that it is the legal concept of consent that provides this legal recognition.

Within the United Kingdom, and other legal jurisdictions, the legal recognition of consent is enshrined in the law of that country either through statutory or common law provisions, both of which are examined below in relation to the United Kingdom.

From this we can see that consent has attained its level of importance because it is through the consent process, that is the giving or withholding of consent by a patient, that a patient's right to autonomy and self-determination is legally recognised and upheld.

As Hoppe and Miola (2014) note, before you can treat a competent patient you need to ensure that you have a legally valid consent. To treat a patient without legally valid consent could mean that the health care practitioner is subject to criminal and civil legal action for battery and negligence as well as a NMC/HCPC fitness to practise investigation.

In 2017 McHale provided a useful summary of the importance of consent when stating that it remains *important to notice the extent of the relevance of consent… a valid consent licenses [legally authorises] what would otherwise be unlawful* (at page 422). By this she means that the law on consent allows someone to touch (treat) another person without fear of prosecution or being sued as consent provides a defence to any legal action which would otherwise be possible were consent not given.

Forms of evidence available

This section considers what evidence could you use in your practice to base your actions around consent: where you obtain information, or could obtain information, in relation to the consent process.

There are various sources of evidence available to you for your clinical practice. These include books and journal articles which may report primary or secondary research, employer protocols and policies, clinical guidelines and standards from recognised bodies such as the Royal Colleges, information available from internet searches, Department of Health papers and circulars, professional regulatory body guidance (e.g. NMC/HCPC), and documents from bodies such as the Care Quality Commission etc..

However, as many authors such as Linsley, Kane and Barker (2019) acknowledge, not all evidence is the same. Some sources will be more reliable and have more weight in supporting clinical practice than others. *Being able to identify different types of evidence, make judgements about their reliability and credibility, and decide when evidence is needed to support our arguments is essential* (Birrell Ivory 2021 at page 97).

Over a number of years, many authors have highlighted the importance of the code of conduct to health care practitioners, and that health care practitioners need to acknowledge and adhere to the provisions within the codes published by the professional regulatory bodies (for instance Pyne 1981, Heywood Jones 1999, Gomez et al 2019).

Because of the importance of the regulatory body codes to health care practice, you may think that the codes of conduct issued by the professional regulatory bodies would provide you with the information you need regarding consent in clinical practice. Alas this is not always the case. For instance, whilst The Code, issued by the NMC, does discuss consent it only mentions it once at paragraph 4.2 where, when discussing how to act in the best interests of your patients, it states *make sure that you get properly informed consent and document it before carrying out any action* (Nursing & Midwifery Council 2018). Which is useful but limited in providing an evidence base upon which to practise. However, the general consensus amongst the literature is that the underpinning features of the NMC code are for prioritising the needs of individuals and involving them in their own care and that it is this which provides regulatory evidence for the use of consent within nursing practice. Which also relates back to the earlier point about consent being a key feature of pre-registration curriculum content.

It is likely that employers will have guiding and policies regarding consent, and you would be best advised to read these. However, to judge their reliability and credibility you have to know if they are current and correct.

From a legal perspective, the best available, or primary, evidence is the legislation and cases in any one area of law. So, for consent the evidence on which to base clinical practice would be the legislation on consent and the legal cases where consent was an issue before the courts. In terms of a hierarchy of law, legislation is considered before case law. So, where there is legislation this is the first evidence to consult and where there is no legislation in an area of law, legal cases should be considered (Kelly 2020).

Secondary sources of legal evidence include books and articles which discuss legislation and legal cases and provide a commentary. As with all other forms of evidence the more reliable these books and articles are the more authority they have. It is therefore these primary and secondary legal sources that should be consulted for the evidence to support the consent process in clinical practice.

The legal evidence base in relation to consent

The legal evidence base for consent has been developing to its present from for over a hundred years. It can be said that the legal recognition of self-determination occurred in 1914 in an American case (Schloendorff v Society of New York Hospital, 1914). The judgment in the case meant that where a patient who is competent refuses a particular treatment that treatment cannot be given to them, even if the risk of not doing so will result in harm to the patient or even the death of the patient.

Since the judgment in that case many legal commentators have sought to establish the legal principles or elements needed for consent to be valid (see for instance Jackson 2019 or Stauch & Wheat 2019 who outline many of the discussions in this area).

In 1998 Kennedy & Grubb outlined, in one of the most authoritative medical law texts of its time, four legal principles which had to be satisfied for consent to be valid. These were:

- 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 and Grubb 1998 at page 111).

These principles have persisted to the present day and the current version, taking into account the legal changes that have occurred since, is stated as *to be a valid consent, the law requires:*

1) *That it is given by a competent person (or by someone who can validly give consent on behalf of a person who cannot consent such as a child or by a done under a Lasting Power of Attorney);*
2) *That the person or the substituted decision maker must be adequately informed about the 'nature' of what he is agreeing to; and*
3) *That the person or the substituted decision maker should be acting voluntarily and not under the influence of another (McHale 2019 at page 422).*

*A Lasting Power of Attorney allows someone to appoint a trusted person to act on their behalf in decision-making if they become incapacitated. This must be set out and agreed in a formal and legal document. The 'attorney' becomes a proxy decision maker on behalf of the patient.

Each of these principles will be discussed in turn through legislation and cases that have moved the legal principles and requirements in relation to consent forward to that which is in force today.

Competent or not?

This section asks how do you know if your patient is competent to consent and, do you assess each patient to determine their competence, if so how, or do you assume that they are competent?

The legal literature in the UK points to the Mental Capacity Act 2005 (for England and Wales and similar legislation such as the Adults with Incapacity (Scotland) Act 2000 in Scotland and the Mental Capacity Act (Northern Ireland) 2016 for Northern Ireland) as providing current best practice. Indeed, it necessary to follow the appropriate Act to ensure that your practice is lawful, in relation to competence for consent.

However, *the Mental Capacity Act 2005 does not provide a positive definition of competence, instead it defines it in the negative* [that is it] *defines when a person lacks competence (*according to Cornock 2021 at page 71). This is because a guiding principle of the Mental Capacity Act 2005 is the assumption that a person has competence until it can be proved that they do not (section 1) and provides detailed guidance as to how a lack of competence can be proved (section 2) before outlining the principles in treating someone who is unable to consent and the use of proxy consent.

This means that, although the Mental capacity Act 2005 provides the key principle of everyone over 16 being competent until proven otherwise, we would need to turn to alternative evidence to define exactly how competence is viewed from a legal perspective.

Cornock (2021) observes that *until the commencement of the Mental Capacity Act 2005, which became fully in force on 1st October 2007, the law around competence to consent was based on common law principles. This means that it was based on judgments, or decisions, made in cases that came before the Courts (at page 69).*

One of the key cases that defined legal competence in relation to consent is that of Re C. With Stauch & Wheat noting that *until the 1990s, there remained surprisingly little authority*

[evidence] *on the definition of capacity* [competence] *to consent to medical treatment… further guidance was given by the High Court in Re C* (2019 at page 106).

This case, which was reported in 1994, concerned Mr C a patient diagnosed with paranoid schizophrenia who was detained at Broadmoor hospital. Mr C had gangrene of his right foot and was informed that he needed an amputation of his foot as he an 85% chance of dying due to the gangrene if he didn't have the amputation. He accepted that the doctors believed what they were telling him but refused the amputation on delusional belief that he was a gifted doctor who could treat his limb without amputating it, and that he did not believe God wanted him to have the amputation.

The judge hearing the case noted that there were three stages of competence: *first, comprehending and retaining treatment information, second believing it and, third, weighing it in the balance to arrive at a choice* (Re C 1994 at page 824). This has become known as the Re C test of competence. When applying the test to the facts of the case the judge stated *I am satisfied that he* [Mr C] *has understood and retained the relevant treatment information, that in his own way he believes it, and that in the same fashion he has arrived at a clear choice* (Re C 1994 at page 824). It was therefore determined that Mr C had the competence to make his own decision regarding the treatment of his gangrenous foot.

As an aside, Mr C did not have the amputation, and lived with a largely recovered foot, having responded *to more conservative treatment* (Stauch & Wheat 2019 at page 107).

It is acknowledged in the legal sources that until 1st October 2007, when the Mental Capacity Act 2005 came into force, the approach to determining competence was that of the Re C test and its three stages. After 1st October 2007 the principle was that of the presumption of competence in all adults under the Mental Capacity Act 2005 and the need to prove someone was incompetent rather than the individual having to prove they were competent if their decision making was being challenged.

Pattinson (2017) makes the point that although the emphasis on the test for competence has changed, from proving competence to proving incompetence, what has to be proved as part of that test, understanding of information, believing and retaining it and making a decision, is essentially the same between the statutory and common law tests.

Patients who are deemed to be incompetent

Where a patient is incompetent to consent, how can they be legally treated?

Prior to the coming into force of the Mental Capacity Act 2005 there was no legal provision for someone to provide consent on behalf of an adult who was incompetent to do so on their

own behalf. As Jackson (2019) notes, proxy decision making was one of the features of the Mental Capacity Act 2005.

The use of proxy decision makers is a major feature of the Mental Capacity Act 2005 and many sections are devoted to its function. The main way that one can adult can take over decision making for another who is incompetent is through the use of Lasting Powers of Attorney, described in section 9 of the Act (Pattinson 2017).

Some commentators see a drawback of Lasting Powers of Attorney being that they need to be made in advance of someone becoming incompetent and so where there is not one in existence, either the courts can make a decision or appoint a deputy to make decision on the patient's behalf or the court can rule that a treatment decision by a health care practitioner is a lawful treatment. All of these decisions must be made in the best interests of the patient, taking into account their known wishes and views (Herring (2020).

The child and consent

How can a child who is not deemed to be competent to consent for themselves be legally treated?

Section 105 of the Children Act 1989 defines a child as someone under the age of 18. Because the legal evidence base on consent presented above relates to those classified as adults, i.e. over the age of 18 (see Herring J 2020, Jackson E 2019 and Pattinson S 2017) additional evidence is needed to determine the legal position of the child in relation to consent.

Brazier & Cave (2016) advise that ether are two ways in which a child may consent to their own treatment. The first applies to those aged 16 – 17 and this is by virtue of a provision in the Family Law Reform Act 1969, specifically section 8. This states that a child who has attained their 16th birthday is to be treated as if they were an adult for the purposes of providing consent to a treatment on their own behalf. The Mental Capacity Act 2005 also provides that someone aged 16 or above does not have to prove their competence in relation to providing consent but that it is autontiacllyy assumed that they are competent.

The second situation for Brazier & Cave (2016) occurs where the child is under 16, who may consent where they are deemed to be 'Gillick competent'. This arises from the Gillick v West Norfolk and Wisbech Area Health Authority and another [1985] case. In that case Lord Scarman put forward that a child under 16 could consent on their own behalf when they have attained *sufficient discretion to enable him or her to exercise a wise choice in his or her own interests* and where the *child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed* (Gillick v West Norfolk and Wisbech Area Health Authority and another [1985] at page 423).

Alternatively, where the child is not deemed to be competent, someone with parental responsibility for the child may provide consent on the child's behalf (Cornock 2007).

Best interests

Where it is not possible to obtain consent from a proxy decision maker on behalf of an incompetent patient the evidence from legal case is that the law allows treatment to be provided to patients where it is their best interests to receive that treatment. However, there is an acknowledgment in the evidence that it cannot be in a patient's best interests to receive treatment that they have previously refused when they were competent to do so (Cornock 2021).

Adequate information

It is widely acknowledged that the amount of information that needs to be given to patients for it to be considered legally adequate has been the subject of many court cases over the years. Each time a case is decided a small advancement is made in the understanding of how much information is needed for it to be seen as being adequate. Jackson (2019) cites Chatterson v Gerson [1981], Sidaway v Board of governors of the Bethlem Royal Hospital and the Maudsley Hospital [1985] through to Chester v Afshar [2004] as cases which have been instrumental in deciding what information needs to be provided to patients.

The current legal position is from the case of Montgomery v Lanarkshire Health Board [2015] (Herring 2020). This case has resulted in a change from what a reasonable health care practitioner would do to one which considers the actual patient in front of the practitioner.

As Herring (2020) notes, as a result of this case, it *is the patient, not the doctors, who determine how much information should be given* (at page 198). Whilst for Pattinson (2017) the case means that *instead of asking what a reasonable doctor would disclose, a doctor must inform the patient of the "material risks", understood as those that either (a) a reasonable person in the patient's position would regard as significant or (b) the doctor should be reasonably aware that the particular patient would regard as significant* (at page 116).

The judgment in the Montgomery case means for Cornock (2021) that *although not every piece of information regarding a procedure has to be given to the patient, the patient can expect to receive information that they consider they need to be able to decide whether to accept the treatment or not* (at page 75).

Thus, the current best available evidence on information giving to patients in relation to consent is to consider what the patient before you needs in order to exercise their autonomy to make a decision regarding the treatment being proposed to them.

Whilst individual patients would have differing information needs, the literature presented in this article agrees that this would include information about:

- *the nature of the patient's condition that causes them to require the proposed treatment or procedure*
- *the nature of the procedure*
- *the reason for the procedure*
- *the benefits and risks of having the procedure against the benefits and risks of not having it*
- *the time element regarding the need for a decision. Is the procedure needed immediately, soon, or can the patient take their time in reaching a decision?*
- *the fact that the patient has a choice and if they decide not to proceed with the proposed treatment, what other treatment they could be provided with*
- *any common complications or side effects of the treatment, along with how these can be managed*
- *any future treatment they may need* (Cornock 2021 at page 75-76)

Voluntarily and without duress

Various legal case have come before the courts where the issue of consent being voluntary has been central, for instance Re T (adult: refusal of medical treatment) [1992]. In the cases that have arisen, the courts have been quite clear that unless consent is freely given it is not a legally valid consent

To be freely given consent needs to be something that the patient choose to give and has made a choice to do so. Rather than merely accepting a treatment because they believe that they have no choice but to do so. They may believe they have no choice because they are not informed of any possible alternatives, or because the health care practitioner tells them that this is the only course of action for their health care need.

Best practice evidence in relation to consent

So, how do you know that you are following an evidence based approach and obtaining legally valid consent from your patients?

The legal evidence for best practice requires that for consent to be legally valid it needs to be given:

- by a competent person, either someone over 16 or deemed to be Gillick competent or someone legally acting on behalf of someone who is incompetent;

- in response to adequate information provided in response to the particular patient's needs; and
- voluntarily

If the permission you receive from your patients meets these three criteria it is likely that you will have a legally valid consent from the patient that meets the best available evidence and therefore meets EBP requirements.

Conclusion

The evidence presented above requires that to practice according to the principles of best practice, a health care practitioner needs to ensure that they have a legal basis to treat their patient. For competent patients this will be legally valid consent. For incompetent patients this may be through the provision of consent by a legally recognised proxy decision maker, for example a parent providing consent for a child, or where this is not possible treatment may be provided in the patient's best interests.

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