Valid consent to Medical Treatment

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Abstract

When consent to medical treatment is described as 'valid' it might simply mean that it has a sound basis, or it could mean that it is legally valid. Where the two meanings are regularly interchanged, however, it can lead to aspects of the sound basis or the legal requirements being neglected. This article looks at how the term is used in a range of guidance on consent to treatment and argues for consistency.

Introduction

At common law, the informational component of consent to treatment is different in relation to 'valid consent' (or 'real consent') and 'informed consent'.[1] A failure to obtain *valid* consent can result in criminal assault and a civil claim of trespass to the person (battery) whereas a failure to obtain *informed* consent can constitute negligence. The latter concept was gradually adopted by the courts, recognised 'with a reasonable degree of confidence' in 2004[2] and firmly embraced in the case of *Montgomery v Lanarkshire Health Board* ('*Montgomery*') in 2015, where Lords Kerr and Reed said:

> 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.[3]

Today, patients consenting to treatment must be given the information on risks, benefits and alternatives that they need to make a decision. This development has occurred in the

[1] See Niselle P. Rapid response: 'Valid' -v- 'informed' consent'. *BMJ*. 21 June 2008. Available: https://www.bmj.com/rapid-response/2011/11/02/valid-v-informed-consent [Accessed 6 April 2020].
[2] *Chester v Afshar* [2004] UKHL 41.
[3] *Montgomery v Lanarkshire HB* [2015] UKSC11, [87].

law of negligence and does not change the law of battery which merely requires that the patient is furnished with basic information.

The requirement of valid consent to treatment is referred to in various clinical guidelines. However, the meaning ascribed to the term 'valid' is inconsistent. In some cases, it means that the consent is on a sound basis. In other cases, it means that the consent provides a valid defence to battery. This can be confusing and could potentially lead to elements of consent being neglected. This paper argues that it would be better to avoid the term in basic guidance and concentrate instead on the ethical and legal requirements of both valid and informed consent. In more detailed guidance, it would be helpful to allude to the law.

Valid consent

Consent is on a sound basis if it complies with ethical principles and with the law. Common law and ethics require that consent is voluntary, that it is made by a person with capacity and that it is adequately informed. Since *Montgomery* in 2015, the requirement of informed consent is 'firmly part of English law'.[4] Patients should be given the information they want and need to make the relevant decision. A failure to do so could lead to a claim in negligence. The General Medical Council (GMC) promulgates advice on consent which requires that patients are duly informed and endorses a partnership model.[5] A failure to follow advice from the General Medical Council on consent can result in charges of professional misconduct which ultimately may affect a doctor's registration.

However, consent can be technically legally valid even if the healthcare professional (HCP) is found to have breached the standard of care set out in *Montgomery*. A lack of valid consent can result in battery. The predominant view is that consent is a defence to battery[6] and without it, any physical touching that occurs as part of treatment would amount to battery. The legal position was set out in 1981 in *Chatterton v Gerson*.[7] Mrs Chatterton

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[4] *Montgomery,* ibid, [107] (Lady Hale).

[5] GMC, *Consent: Patients and Doctors Making Decisions Together*, 2008. Available: https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---consent---english_pdf-48903482.pdf?la=en&hash=588792FBA39749E57D881FD2E33A851918F4CE7E [Accessed 6 April 2020]. New guidance is under development and will apply in 2020.

[6] An alternative view is that lack of consent is part of the cause of action in which case the burden of proving it lies with the patient. *Freeman v Home Office (No. 2)* [1984] QB 524 (CA), 539 (McCowan J).

[7] *Chatterton v Gerson* [1981] QB 432, p 443.

underwent an operation with the aim of relieving intractable pain. The operation was competently performed but resulted in permanent immobility of her leg. She sued in battery and negligence because she had not been warned of this risk. Bristow J found that she had been informed in broad terms of the nature of the procedure (that it was an operation on her right leg) and she had not been deceived. Her consent was voluntary, she had capacity and she had been provided with basic information sufficient to understand what was proposed. Therefore, she had given a valid consent and had no action in battery. At p 444 he said that a failure to warn of any 'real risk of a misfortune inherent in the procedure' could potentially give rise to liability, but under the law of negligence, not battery.

Thus, the law has rejected the idea that a failure to provide adequate warnings of risk invalidates consent. Recognition in *Montgomery* of the doctrine of informed consent does not alter this fact. Post-*Montgomery* in *Shaw v Kovac,* the Court of Appeal held that a failure to obtain informed consent does not give rise to a separate head of damages. One of the reasons for this was that a failure to obtain *informed* consent does not vitiate consent:

> It has long been the law that where a doctor has failed to provide proper information as to risk prior to a medical procedure and that failure leads to consent being given which otherwise would have been withheld, and loss results, then that is actionable in negligence. The consent so given is not regarded as a nullity; and accordingly in the usual case the claim is not to be pleaded as one of trespass to the person. … That being so … one then has to identify … just what it is that the appellant's proposed award is required to compensate.[8]

Turning briefly to the normative justifications for the legal position, arguably the threshold set for information disclosure in the law of battery is too low. Reluctance to extend the threshold may flow from battery's incendiary name and the fact that a battery might also constitute a criminal assault. At least where there has been no deception, there is an understandable reluctance to label HCPs with these legal wrongs. On the other hand, in the 1980s Feng argued that the law of battery would be a preferable legal mechanism to the

[8] *Shaw v Kovac* [2017] EWCA Civ 1028, [68].

law of negligence to protect patient autonomy,[9] and the courts have made some attempt to distance the crime from the tort, reserving the former for wrongdoing and the latter for technical breaches of the law of battery.[10] The growing judicial recognition of the importance of patient autonomy and move away from medical paternalism raise the potential for development of the tort of battery.[11] The justification of the legal position does not need to be settled for the purpose of this article but does provide context to the different legal positions regarding aspects of consent.

In conclusion then, at common law a valid consent requires capacity, voluntariness and basic information. Ethically, and to comply with legal principles established in the law of negligence and advice from the GMC, consent also requires that the person is given sufficient information to make an autonomous decision.

At this point it is worth noting that legislation can relax the requirements, such as allowing deemed consent to organ donation,[12] or make additional requirements for valid consent. For example, the EU Clinical Trials Regulation 536/2014 (not yet applicable) explicitly requires *informed* consent for the purposes of clinical trials.[13]

Guidelines

Setting aside these specialist situations governed by statute, there are numerous guidelines that set out the requirements of consent at common law. Some follow the legal distinction set out above, some avoid reference to 'valid consent' and refer more broadly to the relevant legal and ethical principles and some state that to obtain 'valid consent' patients must be adequately informed of risks and alternatives. I set out of examples of each and then consider why the latter could be problematic.

a) Guidance distinguishing between valid and informed consent

[9] Feng TK. Failure of medical advice: trespass of negligence? *Legal Studies* 1987;**7**:149-168.
[10] *R v Richardson* [1999] QB 444 (Otton LJ). Discussed in Brazier M, Ost S. *Bioethics, Medicine and the Criminal Law* Volume 3. Cambridge: CUP 2013, p 45.
[11] See, for example, Cave E, Purshouse C. Think of the children: liability for non-disclosure of information post-Montgomery. *Medical Law Review* 2019. Available: https://doi.org/10.1093/medlaw/fwz023 [Accessed 6 April 2020].
[12] Organ Donation (Deemed Consent) Act 2019 (from 20 May 2020).
[13] Art 2(2)(21).

Department of Health 2009 guidance[14] recognises that 'touching a patient without valid consent may constitute the civil or criminal offence of battery' (page 5) and that the question of whether a person has received sufficient information involves consideration of validity and adequate information:

> **Has the person received sufficient information?**
>
> 13. To give valid consent, the person needs to understand the nature and purpose of the procedure. Any misrepresentation of these elements will invalidate consent. …
>
> 15. Although informing people of the nature and purpose of procedures enables valid consent to be given as far as any claim of battery is concerned, this is **not** sufficient to fulfil the legal duty of care to the person. Failure to provide other relevant information may render the practitioner liable to an action for negligence if a person subsequently suffers harm as a result of the treatment received. (pp 11-12)

The separation of issues of validity and wider information disclosure in this guidance is clear and accurate, if rather technical and legalistic.

b) Guidance focusing on ethical and legal requirements rather than 'validity'

The Care Quality Commission issues brief guidance based on Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which requires that 'care and treatment of service users must only be provided with the consent of the relevant person'. Compliance guidance requires that consent is based on *adequate* information,[15] and this in turn requires that information is provided about risks and alternatives.

Much more detailed GMC guidance (currently under revision) on consent[16] successfully encompasses issues of capacity, voluntariness and adequate information, without distinguishing between the laws relating to battery and negligence. However, it does make passing reference to the concept of validity, recognising that involuntary consent

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[14] DH. *Reference Guide to Consent for Examination or Treatment*. 2nd ed. July 2009. Available https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition [Accessed 6 April 2020].

[15] CQC. *Regulation 11: Need for Consent*. Available: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-11-need-consent [Accessed 6 April 2020]

[16] GMC. *Consent: Patients and Doctors Making Decisions Together*, 2008. Available: https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---consent---english_pdf-48903482.pdf?la=en&hash=588792FBA39749E57D881FD2E33A851918F4CE7E [Accessed 6 April 2020].

may not be valid (p 39) and that refusal of basic information 'might mean that their consent is not valid' (para 15). This is entirely accurate, but one might question how far the references to validity are helpful absent an explanation of what constitutes valid consent.

c) Guidance that merges requirements of 'valid' and 'informed' consent

Guidance from the NHS states that:

> For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision.

This is legally accurate, as is the advice that to be informed:

> the person must be given all of the information about what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead.[17]

However, as discussed above, the requirement for informed consent is not relevant to validity, which requires only basic information (rather than information about risks, benefits and alternatives). These two statements are only technically legally accurate if viewed separately rather than conjointly as part of the requirements of a valid consent. The NHS definition of 'informed' for the stated purpose of defining *valid* consent is not accurate.

Similarly, Medical Protection in their 'Consent: the basics' webpage states that:

> For consent to be valid:
> **The patient must be competent** …
> **The patient must have sufficient information to make a choice** – without adequate information, patients are unable to make decisions about their treatment. The information provided should, for example, include: an explanation of the investigation, diagnosis or treatment; an explanation of the probabilities of success, or the risk of failure; or harm associated with options for treatment. …

[17] NHS. *Consent to Treatment*. https://www.nhs.uk/conditions/consent-to-treatment/ [Accessed 6 April 2020].

The patient must be able to give their consent freely …[18]

The components of competence, sufficient information and free consent are relevant to valid consent but the description of what constitutes sufficient information is not an accurate description of what is required in order for consent to be valid.

Other examples include the General Dental Council, which recognises that valid consent is different to informed consent. It sees this as an important distinction because informed consent might not incorporate all the elements of valid consent (voluntariness and capacity), but it goes on to incorporate the requirement of informed consent within valid consent.[19] The Royal College of Obstetricians and Gynaecologists in their 2015 guidance 'Obtaining valid consent' describe the legal requirements of informed consent.[20] The General Optical Council in their consent guidance on 'Obtaining valid consent' accurately set out the requirement for valid consent (para 14) and then when considering the information component of valid consent, refer to a requirement to 'satisfy yourself that the patient has in some way consented to all aspects of the care you are providing' (para 16) which seems to envisage more than mere basic information as required to prevent a battery.[21]

Does the label matter?

If the law requires that consent is valid and also that it is informed, then professional guidance is right to require both of these elements. It has been pointed out that some do so under the term 'valid consent' and that this is not technically legally accurate. However, the law does not have a monopoly on the use of the term 'valid'. If consent is legally valid but not ethically valid then treatment should not be countenanced, in which case there is an argument that there is merit in professional guidance making clear that consent that is not duly informed is not valid consent.

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[18] Medical Protection, *Consent – The Basics*. Available: https://www.medicalprotection.org/uk/articles/eng-consent-the-basics [Accessed 6 April 2020].
[19] GDC. Standards Q&A – Principle 3 – Obtain valid consent (updated 2019). Available: https://www.dentalprotection.org/uk/articles/principle-3-obtain-valid-consent [Accessed 6 April 2020].
[20] RCOG. *Obtaining Valid Consent* (2015), https://www.rcog.org.uk/globalassets/documents/guidelines/clinical-governance-advice/cga6.pdf [Accessed 6 April 2020].
[21] GOC. *Obtaining Valid Consent* (2019). Available: https://standards.optical.org/supporting-guidance/consent/informed-consent/ [Accessed 6 April 2020].

On the other hand, given that the guidelines above do not make clear that this is the ethical rather than the legal position on validity, the statements are potentially obfuscatory, especially given the variation between guidelines. Furthermore, the legal distinction is not purely technical or theoretical: it has practical importance.

a) Different causes of action

Where treatment occurs without a valid consent the patient may claim in battery and this is so even if the patient cannot establish any tangible injury. The injury in cases of battery is often simply the invasion of bodily integrity and patient autonomy that flows from the lack of valid consent. If damages are paid, they will reflect any direct damage that occurred. Where insufficient information is provided and the law of negligence invoked, on the other hand, damage must be proved, and the defendant is only liable for reasonably foreseeable damages.

The relevance of the cause of action should not be overstated. It is a positive development that the focus on consent in professional guidance is decreasingly about shielding the doctor from liability and increasingly about what is owed to patients to protect their rights and interests. However, this aim could be achieved without sacrificing legal accuracy and potentially misleading patients as to what access to justice they might have if the rules are breached.

b) The right not to know

According to Lords Kerr and Reed in *Montgomery*, patients who do not want to know information about risks, benefits and alternatives can refuse it.[22] The same is unlikely to be true in relation to battery: if patients do not have basic information about a medical procedure, then there is no valid consent.

If there is to be a consensual operation on their left leg, then as a minimum, the patient needs to know that this is proposed and agree to it. A failure on the part of HCPs to understand this position could lead to two contrasting problems. An HCP might insist that a patient hears information about material risks that the patient does not want to know,

[22] *Montgomery*, [85] (Lords Kerr and Reed).

because the HCP fears that otherwise the consent will not be valid. This denies the patient autonomy and risks harm. Alternatively, where a patient says they do not want to know unnecessary information, an HCP might fail to inform them of even basic information about what is proposed. This would not be sufficient to secure a valid consent and would deny the patient autonomy. From the HCP's perspective the former might result in negligence if the information causes harm and the latter could result in battery.

Arguably, some of the guidance referred to above is not sufficiently clear to avoid these potential pitfalls. On the advice of Medical Protection, for example, information about risk might be disclosed notwithstanding a patient's wish that it is withheld, to comply with perceived requirements of valid consent. As we saw above, the GMC's 2008 guidance recognises that refusal of basic information 'might mean that their consent is not valid' (para 15) but it does not explain the requirements of valid consent or the consequences of not obtaining it.

c) The therapeutic exception

A related issue flows from the potential application of the 'therapeutic exception' in negligence, which applies when disclosure of material risks would cause the patient serious harm.[23] It is unlikely that this exception also applies to the tort of battery[24] and confusion as to this fact could lead to HCPs withholding even basic information from patients where HCPs believe that disclosure would cause serious harm.

d) <u>The threshold for mental capacity</u>

The introduction of the Mental Capacity Act 2005 raises the issue of whether there is now an informational component to capacity that goes beyond 'basic information'. If someone has an impairment of the mind or brain (section 2) and cannot make a particular decision because they cannot understand, retain, use and weigh the information or communicate a decision (section 3) notwithstanding all practicable steps to facilitate understanding (section 1(3)) then they will lack capacity. What information must they understand? It is likely that a person with an impairment of the mind who is unable to understand information about

[23] *Montgomery*, [88] (Lords Kerr and Reed).

[24] It is not listed as a defence to trespass to the person by Jones M (ed). *Clerk & Lindsell on Torts* 22nd ed. London: Sweet & Maxwell, 2019, 15.49.

material risks could be said to lack capacity provided it leaves them unable to make a decision. It does not follow that understanding information about material risks is now a requirement of capacity. According to section 1(2), capacity is assumed. If a person ostensibly consents and argues that they did not understand information on material risks, then any legal action is likely to lie in negligence. If it is clear that they could not understand basic information because they lacked capacity, then they might sue in battery on the basis that there was no valid consent.

A patient's inability to grasp all the material risks and alternatives will not always result in a lack of capacity. Some patients with an impairment of the mind will be able to understand enough to make a decision provided they can understand the 'salient details',[25] even if they cannot grasp some of the peripheral information.[26] If HCPs were led to believe that a patient needs to understand all the information about material risks in order to give a valid consent, then this would have potential to raise the threshold for capacity for anyone satisfying the diagnostic condition for incapacity.

Conclusion

Informed consent is not necessarily valid (if it is not voluntary or capacitous) and consent that is valid is not necessarily adequately informed. This flows from the different informational thresholds that apply in battery and negligence. This is not always made apparent in the plethora of guidance on consent.

Not all guidance needs to set out the legal distinction between battery and negligence. In many cases, basic guidance serves as a reminder of the key principles of what a patient should expect, and an HCP should provide when seeking patient consent. This can be achieved by setting out the requirements of consent without engaging with the concept of validity at all.

For more detailed guidance, such as is provided by the GMC, it is relevant to supply more detail as to the distinction between valid and informed consent. A failure to do so could lead to contradictory or unclear guidance. It could also lead to practical

[25] See *LBL v RYJ* [2010] EWHC 2664 (Fam) [58].
[26] *KK v STCC* [2012] EWCOP 2136, [69] (Baker J); *Re SB* [2013] EWHC 1417 (COP); *WBC v Z* [2016] EWCOP 4.

misinterpretations that heighten the threshold for capacity, require that patients receive information they do not want, or leave some patients without even basic information if patients are capable of providing consent but do not want to know the details or where HCPs think that information might cause the patient serious harm.

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