The Royal College of Pathologists
Pathology: the science behind the cure

A brief guide on consent for pathologists

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1. Nature

1.1. Dictionary definitions of "consent" include:

- to be of the same mind
- an agreement or yielding to what is proposed
- compliance,

illustrating that there may be a spectrum of emphasis in the relationship between proposer and consenter.

2. Autonomy

2.1 The overriding principle of consent is to ensure that competent patients retain maximum autonomy and that incompetent patients have their best interests protected.

3. Validity

3.1. The validity of consent is based on the following.

(i) The provision of accurate information, which is sufficient to enable a decision to be made.

(ii) The patient's understanding of the information and the issues involved. This includes the use of a language understood by the patient, if necessary with the help of an experienced advocate.

(iii) An appreciation of the consequences of a course of action. Clinicians often find it difficult to know how much information to offer in this context, since it is difficult for patients to judge the likelihood or severity of a wide range of possible outcomes.

(iv) Competence to give consent.

It must be noted that an individual may be, at the same time, competent to give consent in one situation but not in another. Competent adults are entitled to refuse investigation or treatment.

The legal framework for the treatment of adults who lack capacity differs across the UK: The Mental Capacity Act 2005 applies in England and Wales; the Adults with Incapacity (Scotland) Act 2000 applies in Scotland; Northern Ireland is still governed by the common law. While there are differences between the three approaches, all of them place clinicians under a duty to support the patient's ability to make a decision for him or herself, wherever possible, perhaps by using simple language or visual aids. If a patient lacks capacity, they should be treated in their best interests (England, Wales and Northern Ireland), or treated in order to safeguard or promote their physical or mental health (Scotland). In all cases, in working out whether treatment is appropriate the clinician must, so far as is reasonably practicable, facilitate and encourage the patient to participate in decision-making, and must take their past and present wishes, feelings, values and beliefs into account.

Further information is available in the GMC's guidance *Consent: patients and doctors making decisions together*. The Mental Capacity Act Code of Practice offers detailed guidance on its application.

Children are in a special situation and consent is usually given by a parent or legal guardian but children's views must be taken into account, especially if, despite their age, they are capable of giving a measured view. At 16 a young person can be presumed to have the capacity to consent but a young person under 16 may also have the capacity to consent, depending on their maturity and ability to understand what is involved. The legal framework for the treatment of 16- and 17-year-olds who lack the capacity to consent differs across the UK and in some circumstances a parent or legal guardian or a court may consent to treatment for a person under the age of 18, even when the young person refuses. It may therefore be advisable to seek the consent of the parent and the patient between the ages of 16–18.

(v) Lack of duress or manipulation.

3.2. Consent is valid when the above criteria have been fulfilled. The fact that consent is written down does not ensure its validity. 'Informed consent' is a term that is often used as shorthand for validity, but either concept is difficult to measure and whether consent is or was valid remains, in the final analysis, a matter for the courts to decide.

4. Variety

4.1. Consent may be obtained in many ways. The following terms are not always mutually exclusive.

(i) **Presumed**: Here the consenter appears to play no part, but some information is assumed to be available, together with an understanding of the opportunity to object.

(ii) **Implied**: In this case, some action is required to indicate that consent has been given. The 'outstretched arm' is an example of implied consent in the context of clinical medicine. Tacit consent indicates non-verbal acceptance and is equivalent to implied consent.

(iii) **Explicit or express**: Consent is clearly and openly given (but the means are not defined).

(iv) **Specific**: Consent is confined to a particular event or events, such as an investigation or operation.

(v) **General**: There is a wide-ranging consent to a relatively unlimited course of action. The wider the range, the greater is the necessary level of trust.

(vi) **Oral**: Consent is given by word of mouth. The use of 'verbal' consent is often seen in this context though, strictly speaking, verbal consent is any consent in which words are used.

(vii) **Written**: The consent is recorded, usually by the patient's signature on a consent form. The General Medical Council guidance recommends that written consent should be obtained if:

(a) the investigation or treatment is complex or involves significant risks
(b) there may be significant consequences for the patient's employment, or social or personal life
(c) providing clinical care is not the primary purpose of the investigation or treatment
(d) the treatment is part of a research programme or is innovative treatment designed specifically for their benefit.

4.2. If a procedure is straightforward and carries little or no risk of adverse consequences, then it is common for consent to be more general, implied or oral, while more complex or hazardous undertakings more often involve explicit, specific and/or written consent.

Specific consent must be obtained from prospective donors of blood or other tissue to be used for clinical purposes. Clear arrangements are made to manage the results of necessary microbiological or other testing, for the use of surplus material for research and for the management of unexpected results with clinical importance

It is usually a requirement of Research Ethics Committees that consent to take part in research is written.

4.3. None of these forms has anything to do with validity or is more intrinsically valid than another.

5. Recording of Consent

5.1. Although valid consent does not need to be written it is good practice to make an appropriate note in the patient's medical records if a consent form has not been used. It is particularly important to record the consent of donors as discussed in 3.2 above and for those who accept screening tests. It is not possible to know when a subsequent challenge or important clinical consequences may ensue.

6. References

Department of Health website on 'Consent'. www.dh.gov.uk > Policy and guidance > Health and social care topics > Consent

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