

Introduction

Consent to treatment lies at the heart of the relationship between the patient and the health care professional. The patient relies on the professional's expertise, knowledge and advice, but it is up to the patient to decide whether he/she will accept or reject treatment, or in some circumstances request that the professional make the decision. The focus on patient centred care and shared decision making highlights the importance of informed consent, and this is reinforced by professional guidelines and the law. However, the issue of consent to treatment is not quite as straightforward as it may seem on initial inspection. For consent to treatment to be meaningful a person must be able to understand the information he/she is given, which must be sufficient for him/her to evaluate the available choices, and he/she must feel free to make that choice. Determining the appropriate amount of information or a person's ability to understand and evaluate it can be difficult in a health care context, and the very nature of the health care relationship and health care setting can lead to implicit if not explicit coercion. Thus issues around consent can lead to ethical dilemmas that may be brought to a clinical ethics committee. In this section we provide a brief overview of the ethical and legal approaches that apply to consent and then look at some specific issues that may present to clinical ethics committees illustrated by hypothetical cases. The section concludes with some suggested further reading on the issues.

This section does not provide a comprehensive overview of the issues around consent and refusal, and does not make recommendations about what an ethics committee should do. It highlights issues that a committee may wish to consider and provides some ethical and legal frameworks for approaching the subject.

Ethical considerations

Respect for Autonomy

The principle of respect for autonomy underpins the requirement for valid consent to treatment. This principle acknowledges the right of a person to determine how his or her life should be lived and to make choices that are consistent with his/her life's plan. While respect for autonomy is often associated with deontological theories, utilitarian philosophers such as John Stuart Mill also stress the importance of an individual's right to determine how he/she lives his/her life, free from coercion:

".....the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinion of others to do so would be wise, or even right" (Mill JS, *On Liberty*, 1982, Harmondsworth: Penguin, p 68).

Autonomy is not all or nothing. Very few of us are able to make fully autonomous choices all the time. Some of us, in certain situations, will not have the ability to understand and evaluate the options in order to make a choice. The more complex the choice and the more impaired our ability to understand, the less we are likely to be able to make an autonomous decision. This has implications for respecting autonomy in the context of health care, specifically in relation to consent to treatment. First, health professionals have an obligation to endeavour to enhance autonomy and facilitate the likelihood of a patient being able to make an autonomous decision. Second, where a patient is unable to make an autonomous decision, it is the duty of the health professional to act in the patient's best interests. However, even in these situations, an effort should be made to discover any previous preferences of the patient, or current wishes, in order to respect his/her autonomy as far as possible.

Rationality, competence and autonomy

Does an autonomous decision have to be rational?

"In the ideal of autonomy day - to -day decisions should be rational, i.e. consistent with the person's life plans" (Hope, Savulescu and Hendrick, Medical Ethics and Law, the core curriculum, Churchill Livingstone 2003 p 34).

However this internal rationality may not be viewed as rational by an external view. A health professional may judge the rationality of a patient's decision by its consistency with the professional's view of what would be in the best interests of the patient. A decision that is seen as contrary to the patient's best interests may be interpreted as irrational by the health professional and therefore the patient may be seen, erroneously, as not competent to make an autonomous choice. It is the internal rather than the external rationality that is important here. A patient is not necessarily incompetent simply because he/she doesn't agree with the health professional about the suggested treatment. A good example of this is the case of a Jehovah's Witness who refuses a life saving blood transfusion. The decision appears irrational to the health care professional but is internally consistent with the beliefs of the patient.

Beneficence and Best Interests

The principle of beneficence highlights the moral importance of doing good to others. When a patient is unable to make an autonomous choice the health professional has a duty of beneficence. Beneficence is usually considered to rely on an objective view of what would be best for the patient whereas respect for autonomy identifies what the patient subjectively considers to be in his/her best interests.

The concept of 'best interests' is linked to well-being / beneficence but includes considerations wider than purely medical risks and benefits such as the religious and cultural interests of the patient. This implies a duty to discover if possible what the patient

would have wanted or what is likely to be appropriate in the context of this patient's particular life. Thus respecting the patient as an individual person (or respecting his/her autonomy) is an intrinsic part of the process of determining best interests.

There is generally no conflict between beneficence and the principle of respect for autonomy - most patients would choose the course of treatment that is objectively considered to be in his/her best interests. However difficulties arise where the view of a competent adult patient as to what is in his/her best interests conflicts with medical opinion - for example where a Jehovah's Witness patient refuses treatment using blood products. The principle of respect for patient autonomy overrides the principle of beneficence in a competent patient. If the patient is unconscious, then knowledge of what he/she would have wanted in the circumstances is part of the assessment of what is in his/her best interests. If the patient is able to communicate but is not competent to make the particular decision, the health professional should still seek to ascertain any wishes, preferences and values of the patient that may be relevant to the decision.

It may be helpful to consider how judges in legal cases have used the concept of best interests.

Re F [1990] 2 AC 1

The House of Lords considered whether it was in the best interests of an incompetent adult female patient to be sterilized to prevent her becoming pregnant. The court took the view that treatment would be in the best interests of a patient if it is carried out to:

- A) save the life of the patient, or to
- B) ensure improvement / prevent deterioration in the patient's physical or mental health.

This would cover basic care such as dental care and washing and dressing the patient.

The concept of best interests is wider than a consideration of purely medical issues:

Re Y [1996] 35 BMLR 111

The patient (Y) was 25 years old, severely mentally and physically handicapped. She lived in a nursing home but had a close relationship with her family. One of her three sisters suffered from leukaemia and needed a bone marrow transplant. The patient was the only suitable donor. The court considered that it was in Y's best interests to donate bone marrow to her sister even though there was no therapeutic medical benefit to Y (and a minimal risk to Y from the procedure). The court considered that it was in Y's emotional, social and psychological interests, since, if Y's sister died, Y's mother would have to look after the sister's daughter and therefore be unable to spend as much time visiting Y in the nursing home.

There is much discussion in ethics literature about the interpretation of best interests. If a wide interpretation is given to "best interests" then the interests of those other than the patient may be taken into account in determining the interests of the patient and there is a danger of moving away from the patient as a focus for legal / ethical decision-making.

Legal considerations

In England and Wales the Mental Capacity Act (2005) sets out the legal position relating to determination of capacity and the principles for treating adults who lack capacity. The Act is applicable to people aged 16 years and older and states that capacity should be assumed unless it is established that he or she lacks capacity. A similar Act (Adults with Incapacity (Scotland) Act 2000) sets out the legal framework in Scotland. There is no statutory legislation governing consent in children under the age of 16 years but there is clear case law to guide practitioners (see below). A further key piece of statutory legislation in relation to consent to treatment is the Mental Health Act (2007) which provides the legal framework for treating adults without their consent in carefully specified circumstances of mental illness.

A comprehensive review of the Mental Capacity Act for clinical ethics committees can be found on this site.

Form of Consent (Express / Implied)

Consent provides lawful justification for treatment. If valid consent is not given, any treatment which involves touching e.g. physical examination, surgery, dressing a wound, would amount to a **battery**.

There is no legal requirement that consent should be written, or be in a particular form - oral consent is valid (or it may be implied from circumstances, where for example a patient undresses prior to examination). However a written consent form provides evidence of consent and is recommended for major interventions such as surgical procedures. The Department of Health has produced standardized [consent forms](#).

Consent may be withdrawn at any time, even after signing of a consent form, and to proceed with treatment where consent has effectively been withdrawn would constitute a battery.

In order for consent to be valid it must be:

- given by someone who is competent (has legal capacity)
- sufficiently informed
- freely given

Battery

Battery is any non-consensual touching - it does not have to harm the patient. A doctor can commit a battery even though the doctor considers he is acting in the best interests of his patient by treating him/her. To avoid liability in battery the patient should be informed in broad terms of the nature of the procedure that is intended to be carried out and give consent to it.

There are very few cases where a doctor has been successfully sued for battery.

Devi v West Midlands RHA [1980] C.L.Y. 687

A woman underwent a hysterectomy to which she did not consent (she had given consent to repair her uterus). The Court found the surgeon liable in battery as there was total lack of consent to the nature of the operation.

Negligence

If the patient claims that he has not been sufficiently informed about the risks inherent in the treatment and alternatives to the treatment then liability does not lie in battery but rather in negligence. In deciding whether non-disclosure is negligent it is necessary to determine whether there is a responsible body of clinicians in the relevant field who would warn of the relevant risks (the Bolam test). In the area of disclosure of risk, however, the judges are more ready than in other areas of clinical negligence to go against expert medical evidence in deciding what amounts to "responsible" practice.

Past judgments in legal cases have suggested that a patient should be informed of risks if:

- the incidence of the risk is sufficiently high - for example a 1% risk of stroke
- if the risk materialised it would have serious consequences for the patient (It is worth noting that identifying serious consequences for the patient requires knowledge of what might be important consequences for the patient)
- the patient specifically asks about a risk

Chatterton v Gerson [1981] 1 ALL ER 257

Mrs Chatterton suffered intractable pain as a result of a trapped nerve following a hernia operation. Dr Gerson, a pain specialist, performed an operation to relieve the pain, but this resulted in permanent immobility of her right leg. Mrs. Chatterton said that she should have been informed of this risk and claimed in battery.

It was held that she had been informed in broad terms of the nature of the procedure ie. she had been informed and consented to an operation to her right leg. The fact that she may not have been informed of the risks of paralysis to her leg could not amount to battery

but any claim would have to be made in negligence.

Capacity to consent to treatment

Capacity is treatment specific - it depends on the treatment to be performed. If the treatment is risky / has potential serious side effects / is complicated, it may require a greater degree of understanding to make a decision than is necessary for treatment that is straightforward or less invasive. Thus a patient can have capacity to consent to one procedure, but not to another. Capacity can also fluctuate.

Tests of capacity

People aged 16 years and over

The Mental Capacity Act sets out the criteria for capacity.

A patient has capacity to consent / refuse medical treatment if he/she can:

- Understand the information relevant to the decision
- Retain the information long enough to make a decision
- Weigh the information and make a choice
- Communicate the decision

Young people aged under 16 years

For young people under 16 there is precedent in case law governing consent to treatment. The law was set out in the case of Gillick (Gillick v West Norfolk and Wisbech AHA [1986] AC 112).

This states that if a minor has sufficient intelligence and understanding to enable him / her to understand the treatment and implications of treatment then he / she is 'Gillick competent' and can consent to treatment. (However a refusal of treatment may be treated differently - see below). The Gillick case referred specifically to consent regarding contraceptive treatment and the guidance set out by Lord Fraser in the House of Lord's Judgment in the case has been used as the template for determining whether to treat a young person without obtaining the consent of his or her parents. These are as follows:

The young person understands all aspects of the advice and its implications

The health care professional cannot persuade the young person to tell their parents or to allow the health professional to tell them

In relation to contraception and STIs, the young person is very likely to have sex with or without such treatment

Their physical or mental health is likely to suffer unless they receive such advice or treatment, and

It is in the best interests of the young person to receive the advice and treatment without parental knowledge or consent.

For babies, young children and teenagers who are not competent in law someone else must consent on their behalf. This can be a proxy or the Court. A proxy is usually a parent or another person with parental responsibility. In making a decision about medical treatment the proxy must act in the child's best interests and if this is not the case then the decision can be overridden by the court. Usually consent need be obtained from only one parent (although if treatment involves an operation that is irreversible and not medically necessary e.g. male circumcision and if the two parents disagree it is advisable to seek advice from the court). If there is a difference of opinion between the parent (s) and the clinician regarding best interests the matter can be referred to the Official Solicitor who is likely to make an application to the court. In an emergency situation, where a parent cannot be contacted, the child can be treated without consent, but only where treatment is immediately necessary.

Where consent cannot be obtained from an adult patient

The Mental Capacity Act 2005 and in Scotland the Adults with Incapacity (Scotland) Act 2000 provide that competent individuals over 18 (over 16 in Scotland) can appoint someone to make decisions about medical treatment on their behalf if they become unable to do so. (Lasting Power of Attorney) If no such power of attorney has been executed then no-one can consent to or refuse treatment on behalf of an adult (over 18 in England, over 16 in Scotland).

There are two categories of situation where decisions about medical treatment need to be taken for incompetent patients:

- When a patient is temporarily incompetent, e.g. if he/she is unconscious following an accident or acute medical event.
- When a patient is unlikely ever to be able to make a competent decision about treatment, e.g. severe dementia or learning disability or permanent vegetative state.

In the first situation the healthcare professional should do no more than is necessary in the circumstances. This does NOT justify treatment that is against the known wishes of the patient. In both situations the health professional act in the best interests of the patient. The principle of best interests also governs decisions made by Donees of Lasting Power of Attorney.

When Consent may not be needed - s63 Mental Health Act 1983

A patient who has been sectioned under the Mental Health Act may be treated without the requirement for consent. This is only applicable for treatment for the mental illness.

<http://www.doh.gov.uk/mentalhealth/>

A more in depth discussion of treating adults who cannot consent can be found in the section on the Mental Capacity Act

Refusal of Treatment

Adults

A competent adult may refuse treatment even if his/her life depends on it. The right to refuse treatment also applies to a pregnant woman even though the exercise of the right to refuse treatment may result in the death of her unborn child.

The English courts protect strenuously the right to be self-endangeringly eccentric, as these extracts from judgments illustrate:

"The patient is entitled to reject [the] advice for reasons which are rational, or irrational, or for no reason." Per Lord Templeman in *Sidaway v Board of Governors of Bethlem Royal Hospital* [1985] 1 AC 171

"It is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that, if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even....though they do not consider it to be in his best interests to do so...." Per Lord Goff in *Airedale NHS Trust v Bland* [1993] AC 789.

Children

A child who is competent can consent to treatment. However, a refusal of treatment may be overridden by a parent or the Court where such a refusal would be likely to result in the death or permanent disability of the child. Then the wishes of the child may be overridden to preserve his or her long-term interests.

Re M [1999] 2 FLR 1097

M was a competent 15 ½ year old who sustained acute heart failure and required a heart transplant. She stated that she did not want someone else's heart and refused to give consent. It was considered to be in her best interests to have the transplant and (although she ultimately consented to the operation) it is clear that treatment would have been declared lawful despite a refusal.

Advance Statements

Advance statements about future medical treatment can be made by those who understand the implications of their choices in order to anticipate situations where they may lose mental capacity.

See End of life section and Mental Capacity Act section.

Professional guidance

General Medical Council

[Consent: Patients and doctors making decisions together. 2008](#)

The guidance provides a comprehensive overview of a doctor's duties with regard to sharing information with patients, obtaining appropriate consent, respecting patients' wishes regarding information disclosure, and treating people who lack capacity to consent.

Paragraph 2 sets out the principles on which the guidance is based.

2. Whatever the context in which medical decisions are made, you must work in partnership with your patients to ensure good care. In so doing, you must:

- a. listen to patients and respect their views about their health
- b. discuss with patients what their diagnosis, prognosis, treatment and care involve
- c. share with patients the information they want or need in order to make decisions
- d. maximise patients' opportunities, and their ability, to make decisions for themselves
- e. respect patients' decisions.

[0-18 years: guidance for all doctors \(2007\)](#)

This guidance covers all aspects of treating children and young people under the age of 18. Paragraphs 22-33 specifically look at issues of consent

The GMC website's interactive section GMP in action has a set of case studies relating to issues of consent [Waiting room 2](#)

British Medical Association

The BMA has a range of publications and guidance in relation to consent and capacity. These can be found on the ethics pages of the [BMA website](#)

The fifth edition of the BMA [Consent toolkit](#) (2009) consists of a series of cards relating to specific areas of consent such as providing treatment to children, consent and research, obtaining consent for teaching purposes, assessing competence and determining best interests.

The Department of Health has published a range of guidance on consent for both clinicians and patients [Key documents](#)

The Nursing and Midwifery Council

The Council's Professional Code has a [section on consent](#)

Issues that may present to a CEC

- A competent patient refuses treatment
- An incompetent patient refuses treatment

The following worked examples of hypothetical case studies show how ethical principles would apply to practical problems.

A competent patient refuses treatment

Mrs X is 35 and is in need of dialysis. She is refusing treatment because she is scared of the treatment which she believes is invasive. She has been counseled about the nature of the treatment - there are no alternatives that would be of practical benefit. She is competent to make treatment decisions. She understands that if she refuses dialysis she will die. She has a daughter of 15 years who lives at home. The clinician feels very strongly that she should receive dialysis but despite numerous attempts to persuade her she refuses.

Can the clinician treat her?

Issues that a clinical ethics committee / group may consider:

Mrs X is competent and so has autonomy to make treatment decisions. If the principle of respect for autonomy is given the highest value then her refusal should be respected despite the resulting harm. It is clear that she considers invasive long term treatment not to be in her best interests.

It is important however that Mrs X is making an informed and voluntary decision - a decision made in ignorance could not be said to be an autonomous one (although arguably a patient makes an autonomous choice if he delegates his decision to the clinician/ healthcare professional). Mrs X has received dialysis counseling but she still believes it to be invasive. Could more be done to inform her - perhaps she could be taken around a dialysis ward? Are some types of dialysis less invasive or more acceptable to Mrs X? Can a compromise be reached? If she has been sufficiently informed then does she need to make an objectively 'rational' decision? This seems unduly paternalistic and not respectful of autonomy which is the expression of individual wishes. However it is important to consider whether an irrational fear, for example of needles, might be interfering with her free choice in this matter. Any causes of coercion should be identified and where possible steps taken to alleviate these.

The clinician may feel that he is not protecting his patient from harm or acting in her best interests if he allows her to die for lack of dialysis. But forced dialysis will also be harmful to Mrs X. In addition, to what extent are the interests of Mrs X's daughter to be considered?

Her exercise of autonomy has enormous repercussions for her daughter - has she been involved in discussions / expressed a view?

If Mrs X has capacity her refusal must be respected - otherwise a battery may be committed. If through lack of treatment her condition deteriorates and she becomes incompetent through illness, then her previously expressed wishes, made when competent, should be respected. If she really does not want treatment even if this results in her death she should be encouraged to complete an advance refusal of treatment.

An incompetent patient refuses treatment

Mrs Y is 56 years old. She has a learning disability and lives in a care home. She is admitted to hospital with an ovarian cyst. The cyst is blocking her ureter and if left untreated will result in renal failure. Mrs Y would need an operation to remove the cyst. Mrs Y has indicated quite clearly that she does not want a needle inserted for the anaesthetic for the operation to remove the cyst - she is uncomfortable in a hospital setting and is frightened of needles.

The clinician is concerned that if the cyst is not removed Mrs Y will develop renal failure and require dialysis which would involve the regular use of needles and be very difficult to carry out given her fear of needles and discomfort with hospitals. The anaesthetist is concerned that if Mrs Y does not comply with the procedure then she would need to be physically restrained. Mrs Y's niece visits her in the care home every other month. The niece is adamant that her aunt should receive treatment.

Should the surgeon perform the operation despite Mrs Y's objections?

Issues that the clinical ethics committee may consider:

An initial step may be to clarify all the facts in the case, for example does Mrs Y have any understanding of the risks of not having this treatment? Her learning disability means that she is unlikely to be competent to consent or refuse the operation, but an attempt should be made to explain to her, in terms that she could understand, what the treatment would involve and what the outcome would be without treatment. Have alternative forms of anaesthetic and ameliorating strategies such as local anaesthetic cream or a sedative drink prior to injection been discussed? Has her autonomy been enhanced as much as is possible? If the conclusion is that she is unable to understand the consequences of non treatment, or that her fear of needles is stopping her evaluating the risks, then she will not be competent to make a decision. However, this does not mean that her fears and concerns should not be acknowledged.

The consequences of the various courses of action need to be considered. If she is not treated then she is likely to develop renal failure. Dialysis would cause her repeated distress as it is an ongoing treatment. If dialysis cannot be maintained she will die. Treatment will

involve some degree of force or deception, which could cause increased distress, possible physical harm, and have long term effects on her future cooperation with health care professionals. A balancing of the harms and benefits of the various options is required to determine what would be in Mrs Y's best interests. In this case, in view of the serious and prolonged harm of not treating her, and the circumscribed nature of the harm of treatment, it would seem to be in her best interests to be treated. If dialysis is the proposed treatment the balance of harms and benefits may be such that treatment would not be in her best interests if it causes severe distress on a regular basis such that her life is intolerable. If the decision is to perform the operation on Mrs Y, then once again respect for her wishes and concerns should influence the approach to treatment so that her fears are mitigated as much as possible.

This approach reflects that it would not be ethical simply to assess Mrs Y as incompetent and then proceed to treatment in the most convenient manner for the health professionals without regard for Mrs Y as a person.

The views of Mrs Y's niece should be acknowledged but they can only be given weight in the decision if they contribute to the assessment of what would be in her best interests. Legally, no person can give consent or refuse treatment on behalf of another adult unless they have been given Lasting Power of Attorney.

Suggested reading

Hope, Savulescu and Hendrick, Medical Ethics and Law, the core curriculum, Churchill Livingstone 2008, Chapter 6

O'Neill O. Some limits of informed consent. J Med Ethics. 2003 Feb;29(1):4-7.

Mason JK, Laurie GT. Law and Medical Ethics. 7th edition. Oxford. Oxford University Press. 2006. Ch 10.

O'Neill O. Autonomy and Trust in Bioethics. Cambridge. Cambridge University Press. 2002. Chapter 7

Delany C. Making a difference: incorporating theories of autonomy into models of informed consent [J Med Ethics 2008;34:e3](#)

Hope T, Slowther A, Eccles J. Best interests, dementia and the Mental Capacity Act. [J Med Ethics 2009;35:733-738](#)

Slowther A Determining best interests in patients who lack capacity [Clinical Ethics 2007;2\(1\)](#)

Slowther A. Refusal of treatment by patients Clinical Ethics 2(3): 121-123

Slowther A. The concept of autonomy and its interpretation in health care. Clinical Ethics 2007;2(4): 173-175;