

Obtaining consent for the immunization of adults

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Effective immunization in adults is a desired health outcome, however it is not mandatory. Immunization of adults must be undertaken in accordance with a patient's real and informed consent. This paper discusses requirements for the lawful administration of an immunization to both capable and incapable adults.

Introduction

The right to self-determination is given legal expression in the law relating to consent. Justice Cardozo in *Schloendorff v Society of New York Hospitals* (1914) held that 'every human being of adult years and sound mind has a right to determine what shall be done with their body'.¹ Forcing or deceiving an unwilling capable adult into having the 'flu vaccine would be considered both a crime and tort or civil wrong.²

It is essential both to protect health professionals from liability in trespass to the person and to the propriety of the treatment that consent is obtained from the patient prior to administering the injection.³

An adult's consent may be expressed in writing or declared verbally. Consent may also be implied by the actions of the adult in response to a request from the health professional. In *O'Brien v Cunard SS Co* (1891) a woman failed in her claim for trespass against a doctor who injected her with smallpox vaccine on a ship bound for Boston.⁴ The court held that the woman had stood in line for the vaccination, offered her arm to the doctor and made no complaint when he injected her. Her behaviour indicated consent and the doctor was right to proceed.

Therefore if an adult responds when asked to consent to vaccination by rolling up their sleeve and presenting their arm for the injection this would indicate consent. Each type of consent is equally effective in law.

Elements of a Valid Consent

To be valid consent must be full, free from duress and reasonably informed.

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Full

Adults must consent to all the immunizations they are to receive (i.e., either all components within a vaccine or all different vaccines) for consent to be valid.⁵ It is essential that they are aware of every procedure that is to be carried out. If more than one immunization procedure is to be performed then each needs a separate consent. Some adults are offered both the 'flu vaccination and a pneumococcal vaccine. Both would need a valid consent for lawful administration.

Free from duress

The second element of a valid consent is that it must be the free choice of the individual. Undue influence from family or health professionals will negate the consent.⁶ When discussing the administration of vaccinations with adult patients it is open to health professionals to try and encourage them to have the injection by highlighting the benefits but they cannot go so far as to threaten a patient. They cannot force their will on the person to the extent that leads them to exclude other considerations when making their decisions.

Reasonably Informed

The third element of a valid consent requires that adults are given sufficient information about treatment to be able to reach a decision. The law requires two types of information to be given. Firstly the patient needs to know in broad terms what the procedure entails. In the case of an immunization they need to know that the intention is to give a vaccine by injection. In trespass, a real or effective consent requires that the health professional explains in broad terms the nature of the procedure. As long as the broad nature of the touching has been explained then no cause of action in trespass will arise.⁷ If a health professional gives misinformation or false information to a patient, then consent will be negated and liability in trespass will arise. The second source of information required by law is a duty to explain the risks inherent in a procedure. The imposition of a duty to go into risks is founded in the law of negligence and is part of the health professional's duty of care.

Duty to Give Information

Health professionals have a duty to give advice and information to a patient so that the patient understands the nature of the proposed immunization and can make a rational.⁸ The courts do not distinguish between advice given in a therapeutic and non-therapeutic context.⁹ However, the courts have been quick to point out that a failure to disclose risks does not reverse a real

consent and no action is possible in trespass.⁸ The proper cause of action in disclosure of risks cases falls in negligence.

For the last thirty years the amount of information about the risks inherent in treatment to be disclosed to a patient when obtaining consent was generally left to the health professional to decide based on the *Bolam Test*.¹⁰ That is, health professionals were required to disclose information that a respected body of their professional peers would disclose to the same person in the same circumstances. This paternalistic approach to disclosure of risks was confirmed by the House of Lords in *Sidaway v Bethlem Royal Hospital* [1985].¹¹

The United Kingdom Supreme Court has now ruled that this approach to the duty to warn of risks is no longer acceptable in 21st Century Britain, principally because the relationship between health professionals and their patients is now very different from 1985. Adult patients are now active partners in decisions about their healthcare and should have the right to sufficient information about treatment, including immunization and any alternatives to enable them to make an informed choice.¹²

Prudent Patient Test

In *Montgomery v Lanarkshire Health Board* [2015] the Supreme Court held that health professionals could no longer rely on the paternalistic *Bolam Test* as the standard for disclosing information about risks inherent in treatment.¹² The Court found that greater importance was now attached to personal autonomy and, when asked to make a decision about treatment that might have an effect on their health and wellbeing, patients were entitled to information about risks and about alternative treatments that might be available.

Since the introduction of the Human Rights Act 1998 the courts have increasingly reflected the fundamental values of the European Convention on Human Rights (Council of Europe 1950) including the value of self-determination set out in the right to respect for a private and family life (Human Rights Act 1998, schedule 1, part 1, article 8).¹³

The duty to advise patients of the risks of proposed treatment no longer falls within the scope of the *Bolam* test. An adult person of sound mind is entitled to decide which, if any, of the available forms of immunization to undergo, and their consent has to be obtained before immunization is undertaken.¹⁴

There is now a duty to take reasonable care to ensure that a patient is aware of any material risks involved in any recommended immunization, and of any reasonable alternative or variant to immunization. Health professionals can no longer selectively choose what information to disclose.¹²

Material Risks

What constitutes a material risk has also been changed by the Supreme Court judgment in *Montgomery*. In *Sidaway* the materiality of a risk was largely based upon the percentage chance of it

occurring. A risk with less than a ten percent chance of occurring was not generally disclosed.

In *Pearce v United Bristol Healthcare NHS Trust* [1999] the court confirmed that significant risks, again regarded as those with around a ten percent chance of occurring, should be disclosed. Lord Woolf held that¹⁵

In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a [health professional] to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt. (at paragraph 21)

In *Montgomery v Lanarkshire Health Board* [2015] the Supreme Court now requires health professionals to judge the materiality of a risk by considering¹²

whether, in the circumstances, a reasonable person in the patient's position would be likely to attach significance to the risk, or the [health professional] was or should reasonably be aware that the particular patient would be likely to attach significance to it (at paragraph 87)

This prudent patient approach to the duty to disclose risks brings the law in the United Kingdom into line with the law in other common law jurisdictions including the United States,¹⁶ Canada,¹⁷ and Australia.¹⁸

Giving an Immunization to a Patient Incapable of Consenting

The law regulating decision making on behalf of incapable adults in England and Wales is the Mental Capacity Act 2005. The Act sets out the rights of both incapacitated adults and their carers and allows people to make pre-emptive decisions about their health care through the use of advanced decisions refusing healthcare (Mental Capacity Act 2005, section 24). It will also allow a person to make decisions about another's personal welfare including consent to treatment. This can be achieved either by a person nominating someone to act in this role through a lasting power of attorney or by the Court of Protection appointing a deputy with powers to make decisions relating to a person's medical treatment (Mental Capacity Act 2005, sections 9 and 16).

The 2005 Act establishes a statutory framework for determining a person's capacity and introduces a checklist of factors that will need to be considered when determining a person's best interests.(see **Table 1, boxes 1 and 2**)

Health professionals are required to abide by the provisions of the Mental Capacity Act 2005 and have a duty to refer to its code of practice (Mental Capacity Act 2005, section 42).

Table 1. MENTAL Capacity Act 2005 statutory framework for determining a person's capacity (Mental Capacity Act 2005, sections 9 and 16)

Box 1: Capacity – Mental Capacity Act 2005, sections 2 & 3

People who lack capacity

For the purposes of this Act, a person lacks capacity

If he is unable to make a decision because of an impairment of, or a disturbance in the functioning of, the mind or brain.

It does not matter whether the impairment or disturbance is permanent or temporary.

A lack of capacity cannot be established merely by reference to:

- A person's age or appearance, or;
- A condition or aspect of behaviour, which might lead others to make unjustified assumptions about his capacity.

Any question whether a person lacks capacity within the meaning of this Act must be decided on the balance of probabilities.

No power is exercisable in relation to a person under 16.

Inability to make decisions

A person is unable to make a decision for himself if he is unable-

To understand the information relevant to the decision,

To retain that information,

To use or weigh that information as part of the process of making the decision, or

To communicate his decision (whether by talking, using sign language or any other means).

A person is not to be regarded as unable to understand the information relevant to a decision if he is able to understand an explanation of it given to him in a way that is appropriate to his circumstances (using simple language, visual aids or any other means).

The fact that a person is able to retain the information relevant to a decision for a short period only does not prevent him from being regarded as able to make the decision.

The information relevant to a decision includes information about the reasonably foreseeable consequences of:

- Deciding one way or another, or;
- Failing to make the decision.

Box 2: Determining Best Interests – Mental Capacity Act 2005, section 4

Cannot make a determination of best interests merely on the basis of-

(a) the person's age or appearance, or

(b) a condition or aspect of behaviour, which might lead others to make unjustified assumptions about his capacity.

The person making the determination must consider all the relevant circumstances and

whether it is likely that the person will at some time have capacity in relation to the matter in question, and

if it appears likely that he will, when that is likely to be.

You must, so far as reasonably practicable, permit and encourage the person to participate, or to improve his ability to participate, as fully as possible.

Where the determination relates to life-sustaining treatment you must not, in considering whether the treatment is in the best interests of the person concerned, be motivated by a desire to bring about his death.

You must consider, so far as is reasonably ascertainable:

- The person's past and present wishes and feelings (and, in particular, any relevant written statement made by him when he had capacity);
- The beliefs and values that would be likely to influence his decision if he had capacity, and;
- The other factors that he would be likely to consider if he were able to do so.

You must take into account, if it is practicable and appropriate to consult them, the views of:

- Anyone named by the person as someone to be consulted on the matter in question or on matters of that kind;
- Anyone engaged in caring for the person or interested in his welfare;
- Any donee of a lasting power of attorney granted by the person, and;
- Any deputy appointed for the person by the court, as to what would be in the person's best interests

A health professional who fails to discharge their duty under the Mental Capacity Act 2005 can face prosecution for ill treatment or wilful neglect of a person who lacks capacity (Mental Capacity Act 2005, section 44).

Conclusion

Health professionals who administer the immunizations to adults need to be sure that they have a valid consent. Consent may be written, oral or implied. However, to be valid the consent must be to the full procedure, free from the duress of family or

health professionals and be reasonably informed. To assist them in making their decision, patients have a right to be told in broad terms the nature of the procedure. Health professionals also have a duty to give information about the material risks inherent in the procedure. Where patients are unable to consent through incapacity then an immunization may still be given in accordance with the requirements of the Mental Capacity Act 2005.

Disclosure of Potential Conflicts of Interest

There are no potential conflicts of interest.

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