Legal aspects of administering the flu vaccine

Although effective, the influenza vaccine is not compulsory and it is essential that doctors only administer the injection in accordance with a patient's real and informed consent. This article discusses the requirements for the lawful administration of flu vaccine to both capable and incapable patients.

Influenza, or flu, is a highly infectious viral infection that occurs mainly during the winter months. An unpleasant but self-limiting illness for most people, flu is a significant cause of more serious illness in at-risk groups such as those over 65 years of age and those with chronic medical conditions. Even where the general incidence of flu is low, some 3000–4000 deaths annually are attributed to the disease (Joint Committee on Vaccination and Immunization (JCVI), 2004).

Influenza immunization has been offered as a means of directly protecting people in at-risk groups since the 1960s. In 2000 the Government extended its policy to include all people over 65 years of age. However, influenza immunization is not compulsory and those in at-risk groups can choose to exercise their autonomy and decline the offer of a vaccination, even though contracting the illness may lead to severe infection or death.

Consent

The right to self-determination is given its legal expression in the law relating to consent. Justice Cardozo in *Schloendroff* 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'.**

Forcing or deceiving an unwilling capable adult into having the flu vaccine would be considered both a crime and a civil wrong (*Airedale NHS Trust* v *Bland* [1993]).

It is essential, both to protect doctors from liability in trespass to the person and to the propriety of the treatment, that consent is obtained from the patient before administering the injection (*F* v *West Berkshire HA* [1990]).

The patient's consent may be expressed in writing or declared orally. Consent may also be implied by the actions of the patient in response to a request from the doctor. For example, 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. 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. Each type of consent is equally effective in law.

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Elements of a valid consent

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

Full

Patients must consent to all the treatment they are to receive for consent to be valid (*Williamson* v *East London & City HA* [1998]). It is essential that a patient is aware of every procedure that is to be carried out. If more than one procedure is to be performed then each needs a separate consent. For example, some patients are now offered both the flu vaccine 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 (*Re T (Adult: Refusal of Treatment)* [1992]).

In *Mrs U* v *Centre for Reproductive Medicine* [2002] Mr U had signed a consent form in which he had agreed that his sperm could be used after his death. He later withdrew this aspect of his consent at the request of a specialist nursing sister. Mr U died and the centre sought to destroy the specimen of sperm. Mrs U opposed this, arguing that her husband had withdrawn his consent reluctantly and only because he believed that, if he did not, fertility treatment would cease.

The court held that the withdrawal of consent to the posthumous storage and use of sperm had not been the result of undue influence. The nurse had explained the ethical concerns to Mr U and he had used this information when weighing in the balance whether or not to withdraw his consent, i.e. the nurse influenced Mr U's decision but not unduly so.

Therefore, when discussing the uptake of flu vaccinations with patients, it is open to doctors to try to

encourage patients 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 patient to the extent that the patient excludes other considerations when making his/her decisions.

Reasonably informed

The third element of a valid consent requires that patients are given sufficient information about treatment to be able to reach a decision.

The law requires two types of information to be given to the patient. First, the patient needs to know in broad terms what the procedure entails. In the case of an influenza immunization the patient needs to know that you intend to give a flu vaccine by injection.

In trespass a real or effective consent requires that the doctor explains in broad terms the nature of the treatment to the patient. As long as the broad nature of the procedure has been explained then no cause of action in trespass will arise. In *Potts* v *NWRHA* [1983], a patient successfully sued for battery when she was led to believe that she was having a routine postnatal vaccination. In fact she was given the long-acting contraceptive Depo-Provera. If a doctor gives misinformation or false information to a patient, then consent will be negatived 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 doctor's duty of care towards the patient.

A duty to give information

A doctor has a duty to give advice and information to a patient so that the patient understands the nature of the treatment proposed and can make a rational choice (*Hills* v *Potter* [1983]). The courts do not distinguish between advice given in a therapeutic context and that given in a non-therapeutic context (*Gold* v *Haringey HA* [1998]).

The courts have been quick to point out that failure to disclose risks does not reverse a real consent, and no action is possible in trespass (*Hills* v *Potter* [1983]). In cases where patients believe they were not adequately warned of risks inherent in their treatment the law of negligence applies.

Breach in the standard of care

Doctors owe a duty to their patients to take reasonable care not to cause harm. They are required to give advice to the standard of the ordinary doctor professing to have that particular skill (*Bolam* v *Friern HMC* [1957]). This is tested by reference to what information a reasonable body of doctors would have given in the same circumstances. However, one has to be mindful that the court can reject a practice if it does not stand up to logical analysis (*Bolitho* v *City & Hackney HA* [1997]).

Different circumstances require different levels of information. Guidance on information giving in particular circumstances has been given by the courts and doctors would do well to inform their practice by reference to this guidance.

The unquestioning patient

The degree of information to be given to a patient about risks is based on the standard of care espoused in the Bolam test (*Sidaway* v *Governors of the Bethlem Royal Hospital* [1985]). Sufficient information must be given to enable the patient to make a choice. There is a duty to disclose material risks and a duty to withhold information where a patient would be frightened if told all the risks where the likelihood of occurrence was very small.

Where treatment involves a substantial risk of grave consequences then a patient should be told of the risk, as no prudent health professional should refrain from telling the patient of that type of risk. For example, in *Goorkani* v *Tayside Health Board* [1991] a doctor was found negligent for failing to tell a patient about the risk of irreversible infertility at the time of prescribing chlorambucil for Behçet's disease. The risk of infertility when chlorambucil is used over the longer term rose to 95% and this transpired in Mr Goorkani's case.

Patients making general enquiries about risks

When questioned by a patient about risks involved in a particular treatment, the doctor's duty must be to answer both truthfully and as fully as the question requires. While withholding information is appropriate in these circumstances, the court considers lying about risks to calm a patient a breach of duty (*Sidaway* v *Governors of the Bethlem Royal Hospital* [1985]).

The issue of how much information should be given in response to a general enquiry about risks was considered in *Blyth* v *Bloomsbury HA* [1993]. Mrs Blyth sued when she suffered side-effects from the contraceptive Depo-Provera. She argued that, despite asking questions, she was not told about all the side-effects of that drug. The court held that what a patient should be told in answer to a general enquiry cannot be separated from the Bolam test any more than when no such enquiry is made. In both cases the answer must depend upon the circumstances, the nature of the enquiry, the nature of the information that is available, its reliability, relevance, the condition of the patient and so forth. No patient is entitled to a truly full and honest answer in response to a general inquiry. The answer only has to be as full and honest as a respected body of professionals would have given in those circumstances.

Patients asking specific questions about risks

A different test applies to patients who ask specific questions about risks inherent in treatment (*Chester* v

Afshar [2002]). When responding to specific questioning from a patient about risks then the health professional is required to answer fully and truthfully, regardless of the likelihood of the risk materializing. When a specific question is asked about risks, patients are entitled to full and honest answers.

Risk information and the flu vaccine

In common with the majority of medicines, flu vaccine does have some adverse effects. The JCVI (2004) states that following administration of the vaccine patients commonly report pain, swelling and redness at the site of the injection, and a general malaise, headache, shivering and fatigue in the days following the injection. More seriously, patients occasionally report immediate reactions to the injection such as urticaria and angio-oedema, and anaphylaxis that is probably caused by hypersensitivity to egg protein.

The JCVI also reports that very rarely neuralgia, convulsions, encephalomyelitis and neuritis have been reported. One US study found that one in one million people vaccinated developed Guillain–Barré syndrome (Lasky et al, 1998).

Table 1. Capacity – Mental Capacity Act 2005, sections 2 and 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 years of age

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

As previously stated, the doctor's duty of care includes a duty to inform patients about the adverse effects of the flu vaccine (*Sidaway* v *Governors of the Bethlem Royal Hospital* [1985]). The amount of information given depends on whether the patient is unquestioning, making general enquiries or asking specific questions (*Chester* v *Afshar* [2002]). The standard required by the courts will be based on what a responsible body of professionals would have told a patient in those circumstances. Clearly this depends on the patient's character, degree of nervousness, importance of the treatment and the likelihood of adverse effects occurring (*Blyth* v *Bloomsbury HA* [1993]). Generally, therefore, patients will be told about the common adverse reactions and questioned about their sensitivity to egg protein, but the profession does not require patients to be told about every adverse reaction associated with the flu vaccine.

However, where a patient seeks a response to a specific question about a specific risk then he/she is entitled to a full and honest answer (*Chester* v *Afshar* [2002]).

Giving the flu vaccine to patients who are incapable of consenting

After April 2007 the law relating to the making of decisions for incapable adults will change with the introduction of 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 advance decisions refusing health care (Mental Capacity Act 2005, section 24). It also allows a person to make decisions about another's personal welfare that will include consent to treatment. This is achieved either by a person nominating someone to act in this role through a lasting power of attorney or by a newly reformed Court of Protection appointing a deputy with powers to make decisions relating to a person's personal welfare (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 (*Tables 1* and *2*).

Doctors will be required to abide by the provisions of the Mental Capacity Act 2005 and its code of practice in order to avoid liability in trespass when providing treatment, including giving the flu vaccine, to an incapable adult (Mental Capacity Act 2005, section 5).

Conclusions

The Government's flu vaccination policy seeks to protect individuals at risk from the complications of flu by annual immunizations. However, despite this health protection policy, those people at risk have the legal right to choose whether or not to participate in the scheme. Doctors who administer the vaccine 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. Doctors also have a duty to give information about the common risks inherent in the procedure. Where the patient asks for information about specific risks then the doctor has a further duty to answer those questions truthfully and fully, regardless of how small the likelihood of the risk occurring.

Where patients are unable to consent through incapacity the flu vaccine may still be given in accordance with the requirements of the Mental Capacity Act 2005.

To aid evidential certainty by demonstrating that the law has been complied with, doctors must make a contemporaneous record of the administration and any discussion of the risks inherent in the treatment.

By informing their practice with the guidance of the courts and Mental Capacity Act 2005, doctors will ensure that the flu vaccine is administered in accordance with the law. **BJHM**

Conflict of interest: none.

Airedale NHS Trust v *Bland* [1993] AC 789
Blyth v *Bloomsbury HA* [1993] 4 Med LR 151
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Bolitho v *City & Hackney HA* [1997] 3 WLR 1151
Chester v *Afshar* [2002] EWCA 724
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O'Brien v *Cunard SS Co* (1891) 28 NE 266
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Re T (Adult: Refusal of Treatment) [1992] 3 WLR 782
Schloendroff v *Society of New York Hospitals* (1914) 211 NY 125
Sidaway v *Governors of the Bethlem Royal Hospital* [1985] AC 871
Williamson v *East London & City HA* [1998] Lloyd's Rep Med 6

Table 2. Determining best interests – Mental Capacity Act 2005, section 4

- You cannot make a determination of best interests merely on the basis of:
  - the person's age or appearance, or
  - a condition or aspect of behaviour which might lead others to make unjustified assumptions about his capacity
- You 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

KEY POINTS

- The flu vaccine can only be administered with the consent of the patient or in an incapable patient's best interests.
- Consent is equally effective whether it is written, oral or implied.
- A doctor's duty of care includes informing patients of the risks inherent in having the flu vaccine.
- Contemporaneous record keeping is vital to demonstrate that the doctor has fulfilled the legal requirements relating to flu vaccinations.