The legal concept of informed consent has the potential for interfering in the clinician's judgment of what is in the best interest of the patient: a discussion paper

Jay Nair
Team Manager
Bedfordshire and Luton Mental Health and Social Care Partnership NHS Trust

DISCUSSION PAPER

Introduction
It has been the accepted practice that health care professionals must obtain the patient's consent prior to commencing treatment or performing an intervention. There is a presumption that an adult patient is competent to give consent to treatment. Lord Donaldson, in Re T (Adult: Refusal of Medical Treatment) (1992) 4 All ER 649, stated: 'The right to decide one's own fate presupposes a capacity to do so. Every adult is presumed to have capacity but it is a presumption that can be rebutted. This is not a question of the degree of intelligence or education of the adult concerned.' It is a patient's prerogative to accept or refuse treatment even in life threatening/saving circumstances. Therefore, consent to treatment is at the very heart of the clinician - patient relationship that is underpinned by ethical and legal concepts. Lord Donaldson, in Re W (A Minor) (Medical Treatment) (1992) 4 All ER 627, 633, stated that in this relationship, consent firstly provides legal justification to care and secondly a clinical function in that it is to secure the patient's trust and cooperation. Legal justification protects the clinician from committing a Crime (battery) and a Tort (trespass to person) when physical contact is made with the patient in treatment. The clinical aspect has wider implications and is recognised in English law through the law of negligence. In Sidaway v Board of Governors of the Bethlem Royal and the Maudsley (1985) 1 All ER 643, Lord Diplock, in endorsing the Bolam's test, propounded that a clinician may be negligent if he failed to counsel and provide information (including the disclosure of
material risks) in a way recognised by his peers.

In exploring whether informed consent has the potential to interfere with clinical judgment, this paper will firstly examine the ethical concepts of Autonomy and Paternalism, showing how these concepts have not only shaped clinical practice but also, and more importantly, have legal implications. The notion of informed consent is in itself ambiguous and contentious. This widely used phrase may not even be part of English law. Discussion as to what are informed consent and the law surrounding consent to treatment will attempt to clarify the position.

Ethical Considerations

Autonomy

The right to autonomous decision-making and medical paternalism is seen as two opposing notions and nowhere more apparent than in the area of consent to treatment. The principle of autonomy imposes on the clinician the obligation of respect for the patient’s self-determination. There is an absolute right to self-determination as long as the patient has the capacity to make decisions. The reason for requiring consent is due to the strongly held view that physical integrity is inviolable in a competent patient. To violate this even in a situation where it benefits the patient is an affront to the deference placed on the notion of bodily integrity. The most famous and frequently quoted statement by Justice Cardozo, in Schleondorff v New York Hospital (1914) 105 NE 92, supports this notion of bodily inviolability: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent, commits an assault…'.

Mill’s Libertarian philosophy affirms the view that the right to autonomous medical decision making is paramount and the only justification of imposing treatment is to prevent harm to others. ‘...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 forebear 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 1982: 68).

Mill, on utilitarian grounds, asserted that respect for autonomy furthers human welfare. Although there has been criticism of Mill’s approach, there has been support from Oxford Professor R.M. Hare and philosopher John Gray, where autonomy is seen as a corollary of the principle of utility. This is because human happiness is constituted, in part, by the exercise of individual autonomy. Kant, on the grounds that man acts as a rational agent, recognises the requirement to treat people as ends in themselves, as self ruling or autonomous. It is questionable whether all rational agents necessarily recognise the moral obligation to respect others as autonomous. Undoubtedly, whenever one imposes decisions upon people without consulting them, let alone against their will, whether or not these decisions are designed to be beneficial, one is treating them as things or as animals or as children, and not as rational agents, nor as ends in themselves.

It has been asserted that autonomy is the ability to know and understand the situation and seek personal goals free of compulsion. Self-determination implies ‘sovereignty over one’s life….the right to control what happens to one’s person’ (Beauchamp & McCullough 1984). Two reasons are given
to protect this individual sovereignty: the
danger of imbalance of power between the
individual and the state (others) tilting on the
side of the latter; and, the conflict between
the individual and others regarding what is it
that is in the best interest for the individual.
Individual rights reset this imbalance,
limiting the power of clinicians and
protecting the individual from improper
intrusions.

The deference given to autonomy is not
absolute. It is one thing to respect the
informed and free choice made by a patient
capable of making it, but this may be
problematic when some mental disability is
involved or in the case of children. It is a
dilemma in law of where the boundaries of
mental capacity are set.

It has been traditionally asserted that the
training of doctors clearly places them in the
best position to be able to diagnose and
treat illness, but many issues relating to
health care are not purely clinical matters.
There is a need to take account of the
values held by patients. This has grown into
a dominant ethical principle of autonomy or
self-determination - respecting patients'
right to make their own choices.

**Paternalism**

It is asserted that since the development of
medical practice, from the Hippocratic times
to modern day, the model of paternalism
has a significant role to play in the doctor -
patient relationship. Paternalism (unlike
beneficence), in simple terms, means the
doctor knows best and regards himself as
the best judge as to what is for the patient's
own good.

Following Harris' argument (Stauch et al
2002: 32), as clinicians, the duty to act in the
best interest of their patients meant
concerns for the welfare of patients. With
welfare being paramount, then anyone
wishing to act contrary to their well-being
can be ignored because paternalism
involves only genuine concerns for the
welfare of others, denying the individual
control over his life and treating him as
incompetent to run his own life as he
chooses - respecting others wishes may not
be part of the equation.

Hart states that paternalism is the protection
of people against themselves and although
autonomy is very much part of 20th century
life, he believes there is a decline in the
belief that we are the best judges of our own
interest. He states that there are factors
which significantly affect free choice or
consent, namely under inner psychological
compulsion, in pursuit of transitory desires
etc... Hart endowed the autonomous person
described by Mill with the features of a
middle aged man (a normal person), but in
medicine, when in the judgment of the
doctor the patient does not display these
features (e.g. the person is a child or with
mental disabilities), then paternalism is
justified i.e. acting in the best interest of the
person (welfare). The doctor who is the
knowledgeable doer has only the best
interest of the patient at heart. The grading
of patients in terms of their qualities which
results in the way clinicians are entitled to
regard them is reflected in case law.

It may be the patient's competence or
incompetence that sets the necessary
conditions for paternalism. Incompetence,
together with the probable harm/risk to the
patient, may be a strong reason for
paternalistic actions to be undertaken
against the wishes or choice of patients.
This may not be only in the treatment and
diagnosis of patients but also in the
disclosure of information, including risks.
Although these decisions and judgments
are in the clinical realm, they have to fall
within the Bolam standard to have any legal
impact.
The Hippocratic tradition has perpetuated a potent image of the doctor as a moral force and a reservoir of knowledge, with challenges to this in recent times coming through government policies and through the governing professional body - General Medical Council (GMC 1999). Judicial empathy towards the medical profession is being clearly shown by the House of Lords and the Court of Appeal in the Sidaway case, endorsing medical paternalism. In the Sidaway case in the House of Lords, except for Lord Scarman, all of the other Law Lords with a slight divergence from each other endorsed the Bolam's test (the professional standard test).

Legal Considerations

Consent to Treatment
The principle of autonomy as stated by Justice Cardozo in Schleondorff v Society of New York Hospital (1914) has been endorsed by the English courts. This has been vigorously restated in Airdale NHS Trust v Bland (1993) AC 789 p 882: 'Any treatment given by a doctor to a competent patient, which is invasive..... is unlawful unless done with the consent of the patient: it constitutes the crime of battery and the tort of trespass to the person.'

Consent could be expressed or implied. Expressed consent would be in written or oral form. It is contended that a written form is some evidence to consent but more importantly whether the patient was in substance told about the procedure/treatment. Consent must only be for the agreed treatment, and any other treatment done in the course of the agreed treatment, even if the outcome is beneficial to the patient, is considered as battery (Devi v West Midlands RHA 1981). Such a situation may be defensible in emergencies and life threatening circumstances.

Any consent form is no more than a piece of evidence that the patient agreed to what was done to him. If the patient can show that, despite a consent form, he did not give any real consent, than battery may have occurred. In Chatterton v Gerson (1981) 1 all ER 257 p265, Justice Bristow stated: '...once the patient is informed in the broad terms of the nature of the procedure which is intended, and gives consent, that is real consent...' - a position that was endorsed by Lord Donaldson in RE T (Adult: Refusal of Treatment) (1992) 4 All ER 649 and by the NHS Executive (1990), which stated: 'it should be noted that the purpose of obtaining a signature on the consent form is not an end in itself. The most important element of a consent procedure is the duty to ensure that patients understand the nature and purpose of the proposed treatment. Where a patient has not been given appropriate information then consent may not always have been obtained despite the signature on the form.'

Consent must be given freely and without being deliberately misled, which may constitute misrepresentation or fraud. Implied consent is when patients, by their actions, indicate acceptance of the treatment e.g. by putting out their hand and pulling the sleeve up for the doctor to either take bloods or give an injection.

Valid Consent
For consent to be valid there are three essential elements that have to be fulfilled or established: the patient must be competent to make decisions i.e. have sufficient understanding and the mental capacity to make the decision (Re T 1992); the patient must understand the nature and purpose of the treatment, being given sufficient information about the proposed treatment (Chester v Afshar (2004) 4 All ER 587); and, the patient must consent to
treatment of his own free will, free from coercion or undue influence (Re T 1992). The presumption that a patient is competent to give consent unless rebutted is accepted law.

Guidance on the issue of capacity was given by Justice Thorpe in Re C (Adult: Refusal of Treatment (1994) 1 WLR 290). He set out three stages of decision-making: comprehension and retention of the information about the treatment (in this case even where the patient is suffering from mental illness, there is the presumption of competence); believing the information; and, weighing up that information in the balance so as to arrive at a choice. This was approved by the Court of Appeal in Re MB (Medical Treatment (1997) 2 FLR 426 Butler-Sloss LJ).

The Mental Capacity Act 2005 sets out the principles and criteria and the protection in the area of capacity. The impact of this Act will depend on how the courts interpret it with existing case law. The issue of capacity and competence has risen in difficult areas of health care such as sterilisation, abortion, treatment withdrawal, euthanasia, mental disabilities and in children. The principles so far stated have relevance to these as well. Some of these areas are also governed by legislation e.g. Mental Health Act 1983 Part IV deals with consent to treatment for a specific category of patients. This is a minefield and the correctness of some of the decisions by the courts are questionable e.g. enforcing physical treatment using the Mental Health Act, which is specifically for the treatment of mental illness only (B v Croydon Health Authority (1995) 1 All ER 683; Tameside and Glossop Acute services Trust v CH (a patient) (1996) 1 FLR 762).

Informed Consent
The expression, 'informed consent', is widely used in relation to medical treatment. The meaning of the phrase has been vague and ambiguous, leading to a number of interpretations and often being misused. The emphasis on the word 'informed' does not tell us anything about the amount of information required. Maclean thought that it simply referred 'to a particular requirement regarding quantity and perhaps - quality of the information disclosed.' He also suggests that there is no single doctrine but it is a legal term of art in the context of medical treatment.

The distinction between real consent, as defined by Justice Bristow in Chatterton v Gerson (1981) and informed consent, is in the nature of the information disclosed. Real consent meant that the patient is informed in broad terms of the nature of the procedure and gives consent (this does not include the disclosure of risks or the alternative treatment possibilities), so as to avoid liability in battery. Informed consent seems to imply that the disclosure of risks and alternatives are necessary in order to avoid liability in negligence. Both in America and England, the courts have been reluctant to find doctors liable in battery, which has connotations, equating 'the doctor who fails to disclose a risk with a mugger who assaults his victim.' Lord Scarman, in the Sidaway case, condemned the idea to base the law in medical cases of this kind to assault and battery.

The doctrine of informed consent was developed by the landmark case on America Canterbury v Spencer 464 2d 772 (1972). Justice Robinson set out the 'prudent patient' test. 'A risk is material when a reasonable person, in what the physician knows or should know to be the position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy.' He stated that the respect for a patient's right of self determination requires an objective standard set in law for the doctors. He was
not prepared to follow the professional standard test in this circumstance, where a duty arises to disclose risks and the alternatives. He also stated exceptions to the test: in a genuine emergency, where the patient is not capable of consenting; and, where harm would result imminently if there was a failure to treat and it outweighs any harm threatened by the proposed treatment i.e. disclosure poses such a threat or detriment to the patient (therapeutic privileges).

In Sidaway, Lord Scarman endorsed the 'prudent patient' test of Canterbury v Spencer and accepted the exception of therapeutic privilege in relation to harm i.e. disclosure would pose a serious threat or harm (psychological) to the patient. All the other Law Lords in the Sidaway case endorsed the professional standard based on the Bolam's test, with some variations. Lord Diplock stated that information may only deter a patient from having the treatment, where the doctor is the best person to decide in the patient's best interest. He indicated that the duty to disclose is part of the duty of care in Bolam's test.

Lord Bridge (Reibl v Hughes (1980)) held that based on the patient's right to decide, a judge could find a doctor liable for negligence where: 'disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonable prudent medical man would fail to make it...'. Lord Templeman stated: 'At the end of the day, the doctor, bearing in mind the best interest of the patient and bearing in mind the patient's right of information which will enable the patient to make a balanced judgment must decide what information should be given to the patient and in what terms that information must be couched.' He also indicated that a patient has a right to know if the danger is of a special kind or magnitude or special to the patient.

Following the Sidaway case, there have been some indications that the courts have been moving away from the Bolam approach (Smith v Tunbridge Wells Health Authority (1994) 5 Med LR 334; Bolitho v City & Hackney HA (1998) AC 232; Pearce v United Bristol Health Care NHS Trust (1999) 48 BMLR 118). There appears to be a shift from the traditional position of Bolam, but are these actual departures an attempt to move towards the doctrine of informed consent? There is mixed opinion from academics: Kennedy criticised the decision in Sidaway for failing to endorse fundamental human rights of making informed choice and also questions why doctors should be placed in a special position compared with other professionals. There is great reluctance by the courts to depart from Bolam. In reading the various judgments in the various cases mentioned above, it appears that Bolam's approach could be interpreted and expanded to meet the patients' rights without having to resort to a new doctrine of informed consent. On the other hand, there is an opportunity to modify and modernise the law in line with present day society, where patients' rights are in the ascendancy, with the doctrine of informed consent protecting such rights in health care. Professor Jones suggests that as professional attitudes change to the question of disclosure of information, patients will be entitled to more information under the Bolam standard (Jones 1999). The change has already begun not by the courts but by the General Medical Council (GMC), which issued guidelines about the disclosure of information (GMC 1999). This may be viewed as a proactive step by the GMC to ensure patients' rights are safeguarded and professionals are protected.

The flawed strict adherence to the models of autonomy or paternalism can hinder the
therapeutic care and, from the NHS experience, increased the cost of litigation. A move towards more collaboration would lead to decision-making based on good communication, openness and trust. The doctor patient relationship is one based on trust and partnership. For this to foster, there has to be a genuine effort on the part of professionals and this is noted by the GMC guidelines on seeking consent. There are obstacles to this 'therapeutic alliance', some of which are created by the parties themselves and others by the system in which health care is provided. It has been noted that the technical nature of the present day training of doctors detaches them from developing the skills of communication with patients. A training that may not overtly propagate paternalistic attitudes is needed. It is difficult to remove from the psyche that doctors want to act in the best interest of their patients and therefore, by virtue of their knowledge, skills and training, maintain professional dominance.

Conclusion

The deference shown by the judiciary to the medical profession is reflected in case law. The speech of Lord Diplock in the Sidaway case projects the strong base paternalism has when deciding on medical issues. The doctrine of informed consent has not made many in-roads in America and has some judicial support in England. The Sidaway case was probably the first English case to analyse the doctrine of informed consent in the dissenting judgment of Lord Scarman. The ethical concepts of autonomy and paternalism have shaped practice in health care. Any tide to erode the traditional professional standard test with the prudent patient test has been abated. At the present time, the doctrine of informed consent has no place in English law but there are encouraging signs that some recognition is given in the speeches of some judges.

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