Consent with understanding: a movement towards informed decisions

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ABSTRACT – The development of consent processes over the last decade is reviewed. The need for an understanding of information is recognised, although the legal definition of competence does not require actual understanding, but rather capacity to understand. The need to move responsibility for procedures towards patients is discussed in terms of an informed decision about choices rather than an informed consent to a single option.

KEY WORDS: consent, informed decisions

The growth of informed consent as part of the clinical care of patients undergoing investigations and treatment or of those taking part in ethically approved clinical trials has been a major element in the movement away from paternalistic 'doctor knows best' attitudes to a shared decision-making process. Following Bristol, we should all welcome these developments, but not delude ourselves into the belief that simply because we subscribe to such an approach then it will be put into effective clinical practice.

The Bristol Inquiry challenged the current legal stance of the doctor making a clinical decision as to the extent of information a patient should receive. The Inquiry felt:

> *the issue is no longer whether to inform a patient, but how to do so effectively … We believe that healthcare professionals have a duty to empower patients, providing information is one means of empowerment. We accept that each patient is different and may wish for varying amounts of information at various times, with the constant ability to say 'enough'. But this fact does not serve as a reason for not setting out on the information journey.*[1]

In order to achieve these objectives, the Inquiry recognised that in practice:

> *Patients … should always be given the opportunity and time to ask questions about what they are told, to seek clarification, and to ask for more information.*[2]

Although judges in England and Wales may have in general rejected the American concept that consent can only be obtained if it is supported by detailed and comprehensive information, it seems unlikely such a view will stand once accepted practice requires clinicians to conform to such an approach. Through *Bolam*[3] and *Bolitho*[4], informed consent will be seen as the way in which an average competent doctor practises on a daily basis.

The intelligibility of information

In *Smith* v. *Tunbridge Wells Health Authority* [1994][5], Morland J made the important point that:

> *The doctor, when warning of the risks, must take reasonable care to ensure that his explanation of the risks is intelligible to his particular patient. The doctor should use language, simple but not misleading.*[6]

In *Pearce* v. *United Bristol Healthcare NHS Trust* [1999][7] Lord Woolf expressed similar views about providing information on risk:

> *The doctor … has to take into account … the ability of the patient to comprehend what he has to say to him or her.*[8]

In *Gillian Karen Carver* v. *Hammersmith & Queen Charlotte's Special Health Authority* [2000][9], a senior house officer who discussed antenatal testing for Down's syndrome failed to explain it was only a screening test and, unlike amniocentesis, not diagnostic. Ms Carver had a child with Down's syndrome and the Health Authority was found liable in negligence. Nelson J held that the SHO's

> *explanation of the test generally was not given in such terms as could reasonably have brought home to her the fact that the test was not diagnostic. As a result, the*

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Key Points

- **Patients should receive comprehensive and easy-to-understand information about procedures**
- **Account should be taken of patients who cannot read**
- **Account should be taken of patients for whom English is not their first language**
- **Trusts should provide information to patients about risks**
- **Patients' understanding of procedures and risks should be formally tested and recorded**
- **There should be a movement away from passive informed consent towards active informed decisions by patients**

claimant came away from the consultation with the doctor with the clear, albeit mistaken, view that the Bart's test would determine whether or not she had a handicapped child.[9]

Clearly the quality of information and the way it is understood is critical. The fact the client was told about the test was inadequate. She needed sufficient information to make a balanced decision and the clinical judgement of the SHO should have taken into account Gillian Carver's determination to avoid having a child with learning difficulties.

Central to the concept of consent is the need to understand the information about the procedure or the clinical trial and an ability to retain that information for a period. Only then can a patient be deemed competent and have the capacity to give consent. Clearly understanding the information that is being presented is critical. It is this understanding that both clinicians and researchers frequently fail to address and, if they do address it, they do not do so in a formal and checkable manner. However, Kennedy and Grubb have raised an interesting question about the nature of understanding and its relationship to consent:

If the test of understanding is actual understanding… then whether or not the girl understands and therefore is competent to consent may turn on what she is told. Indeed, this seems to have been Lord Donaldson's approach in Re R (A Minor) (Wardship: Consent to Treatment) [1991] *… If the girl is not given certain information she may not understand enough, but this would not be the product of any lack of competence but merely that she decided in ignorance. It would be an unsatisfactory state of law if doctors could be controlling the information given to a patient and thereby grant or deny her competence … It must, therefore, be the law that competence is determined by reference to the unvarying conceptual standard of capacity or ability to understand.*[10]

The consequence of such thinking is that when a patient fails to understand the information given to him or her, further explanation will be mandatory before seeking consent to the procedure. This also applies to patients who clearly have capacity, but cannot understand because of problems with literacy or linguistic difficulties.

The need for adequate translation

This concerns the ability of a patient to understand English, which was seen in the Canadian case of *Reibl* v. *Hughes* [1980][11]:

It must have been obvious to the defendant that the plaintiff had some difficulty with the English language and that he should, therefore, have made certain that he was understood.[12]

Although this has not yet been an issue in medical cases in the UK, it has been of importance in other situations. In *Kunnath* v. *The State* [1993][13], Kunath was convicted in Mauritius, where proceedings were in English. He stated from the dock that he did not understand what was being said and as a result it was held that he 'could not be said to have had a fair trial'[13]. His conviction was quashed. In another case, the Court of Appeal upheld the decision of the original judge that the transfer of a lease, which had been obtained by fraud, was void. The respondent was Iranian and illiterate, and the transfer of the lease had been 'procured without his knowledge or consent at a time when he could not read, speak or understand English'[14].

The signing of clinical consent forms by patients not fluent in English and use of non-professional translators, such as hospital porters, family or friends, could equally be regarded as void. Clearly there needs to be provision of accurate translation when seeking consent from a patient for whom English is not their natural language. This was emphasised in a recent study of patients' understanding of endoscopy procedures[15]. Similar difficulties can arise when someone is illiterate[16]. The relevance of *Lloyds Bank plc* v. *Waterhouse* [1990][16] to patients with poor reading skills or lack of English is clear. The clinician has a duty to answer any questions clearly and to ensure that they are understood.

Presenting information

Information sheets about procedures and research projects need to be written in simple language that is easy to understand[17]. That language needs to be well understood by the patient and if it is not their first language there is even more reason for formal testing of their comprehension of the information. Of course, a significant number of patients are unable to read. This does not mean that they cannot sign their name and in order to avoid embarrassment they may be more than ready to sign any document rather than question its contents.

Simple requests to sign a statement that the patient has understood the procedure and its purpose are as valueless as the signature on a consent form. Understanding requires formal testing and where alternatives are available this too should be checked, perhaps on a decision or 'voting' form, eg where the choice of investigation may be either endoscopy, radiology or no active investigation. The need to document the patient's decision is critically important in case at some later stage there is a suggestion that information was inadequate or incomplete.

Assessing comprehension

How can comprehension be assessed? The concept of testing people through simple True/False questions or even the use of Cloze techniques[18], in which the correct words are placed in incomplete sentences, is one which is foreign to medicine. However, we need to be open to such approaches. Then we will clearly identify the patients we have failed – the failure in any True/False test will reflect on the process of consent rather than on the patient. When a patient fails to understand the form of sedation or the existence of risks associated with a clinical procedure, the information and consent process are clearly not robust. Because of the lack of understanding they obviously do not have the capacity to give consent.

In a study of information leaflets used in an endoscopy unit[15], 75% of solicitors who held a clinical negligence franchise felt consent should be obtained two weeks before the procedure,

compared with 44% of patients. It was linked with the solicitors' view that patients should be told about the test on at least two occasions. Most patients (72%) wanted to receive information from the doctor who did the test, whereas solicitors favoured a booklet (79%). Videos were also significantly more popular with solicitors than patients as a means of providing information. Interestingly, the proposed model consent form for use by trusts acknowledges the need for information in the form of leaflets or videos.

Clinical negligence solicitors and patients had different views on the type of information patients should have as part of the informed consent procedure. Solicitors believed:

- Patients should know why the test is needed.
- Patients should know common dangers of the test.
- Patients should know how the test is done.

These values were all significantly higher than for patients. Eighty-three per cent of patients only wished to know of risks greater than 1 in 1000; whereas 58% of specialist solicitors believed that patients should be made aware of risk less than 1 in 10,000. Indeed 16% of specialist solicitors believed patients should be made aware of risks of 1 in 1 million, compared with 6% of patients.

In this study[15], 69% of patients wanted to know whether the practitioner was fully trained and 39% the annual number of complaints registered against him or her. However, the majority of patients wanted the procedure done immediately rather than delay in order to have it done by a trained practitioner or by a doctor in preference to a nurse.

Other approaches to the problem of informed consent

In 1989 the Louisiana Supreme Court in *Hondroulis* v. *Schumacher* ruled that 'loss of function of an organ'[19] was too generic and that doctors needed to be more specific. A surgeon had failed to mention specifically that loss of bladder function could be a complication of a lumbar laminectomy. This led to doctors listing many potential risks when seeking consent. In 1990 the Louisiana legislature passed the Uniform Consent Law and created a Medical Disclosure Panel (R.S. 40: 1299.40E)[19]. The purpose of the Panel is to define which risks must be disclosed for any given procedure. The Panel consists of six doctors, a dentist and four attorneys and meets bimonthly. It is developing a list of risks for all procedures.

Such a development addresses the thorny question of how much to disclose and removes it from both the individual clinician and the court. The format of the disclosure is:

> *in writing, signed by the patient or a person authorised to give the consent and by a competent witness, and if the written consent specifically states, in such terms and language that a layman would be expected to understand, the risks and hazards that are involved in the medical care or surgical procedure in the form and to the degree required by the panel.*[20]

Provided Louisiana clinicians comply, this will be strong evidence against accusations of negligence linked to a failure to obtain informed consent.

The precedent for a Medical Disclosure Panel was set in 1979 by the Medical Liability and Insurance Improvement Act of Texas[21]. In this Act, hysterectomy was seen as a specific problem area (sec 6.08) and the need was recognised that information about the procedure and its risks:

> *shall be available in English, Spanish, and any other language the panel considers appropriate. The information shall be presented in a manner understandable to a lay person.*[22]

Patients' right to know

There is considerable interest in England and Wales in providing patients with the performance statistics of hospitals and clinicians. In the future such information may be used as part of the process by which patients make an informed choice about their treatment. In 1996 the Florida legislature enacted the Patient's Right to Know Act. This Act gives patients the additional right to know:

- *number of patients in each Diagnosis-Related Groups … for which the provider discharged at least 25 patients during the preceding calendar year.*
- *mortality rate for each DRG*
- *infection rate for each DRG.*[23]

With the development of new consent forms throughout the UK, now is an opportunity for trusts to introduce local Disclosure Panels. Such bodies could mirror the developments in some American states and help identify which risks should be routinely disclosed to patients. Their work could be supported by the internal production of information sheets, which would cover benefits, risks and alternatives to investigative and therapeutic procedures. Such developments would encourage the movement away from the passive patient who gives informed consent to the responsible client who makes an informed decision.

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