Education and training of healthcare professionals has led to a significant reduction in suicide rates among depressed patients.[8] There is a need for protocols and training on how to address the issue of suicide in psychoeducational settings for mental health professionals.


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## Roles of authors

- Mohamed Ahmed: Designer of questionnaire second draft and feedback form; data collector of main study; deliverer of psychoeducation sessions; writer of manuscript first draft; literature searcher.
- Michael Reilly: Originator of study design; study co-supervisor; collaborator on psychoeducation session content; data input; manuscript second draft corrector.
- Carol Cassidy: Designer of questionnaire first draft; data collector of pilot study; literature searcher.
- Laura Mannion: Study supervisor; manuscript third draft corrector.

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Review

# Informed consent in psychiatric practice: where does the law now stand?

Peter Leonard

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## Abstract

**There is an established ethical and legal duty upon psychiatrists to obtain informed consent before treating a patient, although some exceptions do apply under Mental Health Legislation. The required standard for informed consent has been the subject of important case law in Ireland and other common law jurisdictions and this has caused some uncertainty for clinicians. The standard of informed consent can be viewed from the point of view of what the medical profession thinks is appropriate, or alternatively from the position of what a patient would reasonably expect to be told. These contrasting approaches are discussed in detail. A recent decision of the Irish Supreme Court establishes the 'patient-centred' standard for informed consent as the relevant standard in Irish law. The current legal position on informed consent is discussed in relation to common clinical scenarios in psychiatric practice.**


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## Introduction

It has long been established in law that healthcare interventions must be carried out with the consent of the patient.[1] Intervention without consent may amount to a breach of the patients unenumerated constitutional right[2] to bodily integrity[3] (an unenumerated right is not written in the Constitution but is established through case law), a criminal assault,[4] trespass[5] or professional negligence in the law of tort.[6]

This consent may be implied through our actions[7] or in situations of extreme urgency,[8] and it may be given expressly in verbal or written form. For consent to be valid it must be given voluntarily, by a person with legal capacity to consent (ie. an adult of sound mind), and finally it must be informed (the doctor has provided all information relevant to the decision).

The issue of decision-making capacity is crucial to receiving valid consent. It is commonly found in clinical practice that patients with, for example, dementia or intellectual disability may lack capacity to consent to treatment but fall outside of the remit of Mental Health Legislation because they do not meet the legal test for 'mental disorder'. In such cases there are limited options for substitute decision-making other than making the patient a Ward of Court. Contrary to common belief and practice, relatives do not have a legal entitlement to consent on behalf of an adult.



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A specific clinical dilemma relates to adults who lack capacity but who are acquiescent with treatment. This issue was highlighted in the well known Bournewood case.[9,10] This case involved the admission and treatment of a patient who lacked capacity to give consent to treatment but was acquiescent and co-operative.

The British House of Lords initially ruled that the person in question did not require to be admitted involuntarily under Mental Health Law but a later 2004 ruling by the European Court of Human Rights found that the patient was deprived of his liberty contrary to article 5(1) of the European Convention on Human Rights because his admission was not "in accordance with a procedure prescribed by law" and was contrary to article 5(4) because he was unable to "take proceedings by which the lawfulness of his detention shall be decided speedily by a court".

No similar case has occurred in Ireland but the so called 'Bournewood gap' clearly exists in this jurisdiction. Hopefully the Irish Capacity Bill of 2008 will eventually be enacted and prevent an Irish Bournewood case. Irish capacity law could provide a solution for situations where a person does not meet the legal criteria for mental disorder but does lack capacity to make decisions about healthcare, social care or financial issues.

When faced with the dilemma of treating a patient who cannot give consent in situations of great urgency many doctors will turn to the 'doctrine of necessity'. This principle provides legal justification for treating someone without valid consent where there is 'necessity to act'.[11]

This principle has also been applied to other situations where a person acts for the greater good, such as an ambulance driver driving through a red traffic light to get an emergency quickly.

Rather than providing an equivalent to valid consent the doctrine of necessity instead provides a defence if a doctor's actions were challenged at a later date.[12]

For example, this situation would apply to the treatment of an unconscious patient who presents to an emergency department, and has suffered significant physical trauma. In such a situation it is clearly not possible to obtain consent and the 'doctrine of necessity' is applied so that the patient can be treated immediately.

Another example where the 'doctrine of necessity' may apply is where a patient has presented to the emergency department with an intentional overdose and is refusing treatment. In such a situation the Mental Health Act permits treatment of a mental disorder, if present, but does not permit treatment of a physical condition.

If the patient is incapable of consenting to treatment due to mental disorder or due to the physical effects of the overdose on their brain and cognitive abilities, then physical treatment could be given without valid consent, using the 'doctrine of necessity' as a justification. But if the patient refuses treatment and has decision-making capacity, the doctrine of necessity does not apply.

## Irish statute law

The requirement for receipt of consent for psychiatric treatment is now enshrined in Irish statute law and Part 4 section 56 of the Mental Health Act 2001[13] sets out a definition of consent as follows:

*"'Consent' in relation to a patient means consent obtained freely without threats or inducements, where –*

*(a) The consultant psychiatrist responsible for the care and treatment of the patient is satisfied that the patient is capable of understanding the* ***nature, purpose and likely effects of the proposed treatment***

*(b) The consultant psychiatrist has given the patient* ***adequate information in a form and language that the patient can understand, on the nature, purpose and likely effects of the proposed treatment."***

An exception to this requirement is made for those who meet the test for 'mental disorder',[14] are involuntarily detained and are effectively incapable of giving consent. In this case the patient can be treated without consent for an initial period of three months. To counterbalance this, special requirements are outlined in relation to authorisation of electroconvulsive therapy which requires a second opinion, or psychosurgery which requires authorisation of a Mental Health Review Tribunal .

However it should be noted that section 59 which deals with ECT is flawed in that it states that inability or unwillingness to give consent to ECT may be overruled by a consultant with a second opinion. This effectively departs from the functional capacity test set out in section 57(1).[15] The same criticism applies to section 60 which addresses consent to administration of medicine beyond an initial three month period.

Regardless of the legal standard of disclosure there is also an ethical duty which requires doctors to disclose information in a truthful manner. The Medical Council of Ireland has given instruction to doctors in its Guide to Ethical Conduct and Behaviour:[16]

*"A request for information from a patient always requires a positive response. In general doctors should always ensure that a patient…(is) as fully informed as possible about matters relating to an illness….They should be encouraged to ask questions. These should be answered carefully and in non-technical terms".*

## Case law – the historical background

Cardozo J made the following comments in New York in 1914[17] and in doing so established the necessity to obtain full consent before medical treatment and heralded the more stringent standards that would face doctors in a less paternalistic age:

*"Every human being of adult years and sound mind has a right to determine what should be done with his body; and a surgeon who performs an operation without his patients consent commits an assault for which he is liable in damages".*

However, the dominance of paternalism has been quite evident in Irish case law until recently. This is illustrated by the renowned 1954 case of Daniels v Heskin[18] in which a doctor omitted to inform a female patient that he had left a fragment of a needle in her perineum after he had stitched her following childbirth. In this case Kingsmill-Moore J found as follows:

*"I cannot admit any abstract duty to tell patients what is the matter with them…all depends on the circumstances – the character of the patient, her health, her social position, her intelligence, the nature of the tissue in which the needle is embedded".*



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It is now clear that a doctor is required to communicate the basic nature and purpose of a procedure[19] but the exact legal standard of informed consent is not defined in Irish statute law and has been the subject of evolving case law both in Ireland and internationally.

## What is the legal standard of informed consent?

There are two main approaches to informed consent which have developed from Irish and International case law. These are as follows:

- The 'doctor centred' or 'reasonable doctor' approach which defines the acceptable standard of information disclosure as that set by the medical profession itself.
- The 'patient-centred' or 'reasonable patient' approach refers to a standard which reflects what a 'reasonable patient' would wish to know.

## International case law

*The doctor centred approach*

This approach considers whether or not a doctor provided the same information a reasonable, comparable doctor would have provided. This has been the focus of early informed consent cases such as the Salgo case.[20]

The doctor centred approach has also been applied in England in the Sidaway case.[21]

In this case it was contended that the failure of a doctor to disclose all material risks in the course of treatment constituted a breach of the acceptable standard of information disclosure and consequently a breach of duty of care. The House of Lords found by a majority in favour of a standard of disclosure set by the medical profession:

*"An issue whether non disclosure of a particular risk or cluster of risks in a particular case should be condemned as a breach of the doctor's duty of care is an issue to be decided on the basis of expert medical evidence. In the event of a conflict of evidence the judge will have to decide whether a responsible body of medical opinion would have approved of non-disclosure in the case before him".*

This clearly establishes the 'doctor centred' approach as the preferred standard in England.

*The patient-centred approach*

In the US the case of Canterbury v Spence[22] fully upheld informed consent as a legal doctrine and also found in favour of a patient-centred approach. In this case a 19-year-old man presented to a doctor with shoulder pain. The doctor suspected that the man had a ruptured vertebral disc and performed a laminectomy. After the procedure, the man suffered paralysis from the waist down. This was a potential adverse effect which had not been disclosed from the outset. Dr Spence argued unsuccessfully that disclosure of complications which have a low absolute risk was not good practice as it might deter patients from undergoing necessary treatment. The trial judge found that all risks which might significantly affect the patients decision must be disclosed. In this case the Court observed as follows:

*"Respect for the patients right to self determination…… demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves".*

A similar finding arose in the Canadian case of Riebl v Hughes[23] which further supports the patient-centred approach. In this case it was found that:

*"To allow expert medical evidence to determine what risks are material and, hence, (what risks) should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of duty."*

Another case which emphatically supports the patient-centred approach is the Australian case of Rogers v Whittaker.[24] The Australian Court reasoned that a patient could not reasonably decide to undergo a procedure based only on the information that the doctor was willing to share. In its decision the court outlined the doctor's duty disclose all material facts:

*"..(a) risk is material if , in the circumstances of the particular case, a reasonable person in the patients position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it."*

## Case law in Ireland

*The doctor-centred approach*

The Irish cases of Bolton v Blackrock Clinic[25] and Walsh v Family planning services Ltd[26] have both confirmed the doctors duty to inform patients as well as supporting a doctor-centred approach. The conclusions of these cases have been summarised by Mills and are paraphrased as follows:[27]

- A failure on the part of a doctor to obtain valid consent constitutes clinical negligence
- The issue of whether consent is informed or not should be judged by the **standard test of negligence**
- In practice this means comparing the conduct of the clinician to a **reasonable body of medical opinion held by practitioners of like skill and specialisation** to the doctor whose practice is being scrutinised
- If the clinician's practice of informing the patient is **consistent with that of a reasonable body of opinion** held by **comparable medical professionals**, then he or she will not be found negligent
- If the **Court** considers that the standard of disclosure adopted by the profession is not good enough it can set a higher standard.

The Walsh case also established the principle that a higher level of disclosure is required for elective procedure. It is clear from the judgement of O'Flaherty J in the Walsh case that there is a duty to disclose "in the clearest possible language" a risk "however exceptional or remote of grave consequences involving severe pain stretching for an appreciable time into the future".

*The patient-centred approach*

The case of Geoghegan v Harris[28] marked a change in Irish case law towards a patient-centred approach. In this case a patient presented to a dentist for dental implant surgery. Following the procedure the patient suffered from chronic severe pain which he later argued he had not been warned of. The doctor argued that he had warned of pain but even if he had not, he was not obliged to, as the risk was so remote. The judge held that this was in fact a "material risk" as it was a risk that the "reasonable patient" would wish to know: "each



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case it seems to me should be considered in the light of its own particular facts, evidence and circumstances to see if the reasonable patient in the plaintiff's position would have required a warning of the particular risk".

The decision of the Irish Supreme Court in the Fitzpatrick v White[29] case further consolidates the position of the patient-centred approach. This case involved an alleged failure to give full disclosure of risk prior to eye surgery. In his judgement Kearns J stated:

*"The argument that the giving of an adequate warning, far from being a source of nuisance for doctors, should be seen as an opportunity to ensure they are protected from subsequent litigation at the suit of disappointed patients. I am thus fortified to express in rather more vigorous terms than I did in Geoghegan v Harris my view that the patient-centred test is preferable, and ultimately more satisfactory from the point of view of both doctor and patient alike.."*

## Implications for clinical practice

As discussed above, Part 4 (section 56) of the Mental Health Act 2001 gives guidance as to how one should adequately disclose information to a patient. The disclosed information should pertain to the nature, purpose and likely outcome of treatment. The disclosure should also be of adequate breadth or scope. Information should also be communicated in a manner which can be understood by the patient. Case law has determined that the scope of information provided extends to anything the patient might attach significance to. This ultimately requires a very inclusive approach.

The law puts an onus on clinicians to assist their patients in overcoming educational problems, sensory impairments and intellectual impairments. In order to do this successfully the assistance of colleagues from disciplines such as occupational therapy and speech and language therapy may be required.

People with intellectual disability may of course have decision-making capacity but often present with communication problems due to difficulties with expressive and receptive language and sensory deficits. The UK Department of Health has published guidance for obtaining consent from people with Intellectual Disability.[30] In summary this document recommends the use of pictures and simple terms expressed in short sentences which may need to be repeated and reworded. Sign language such as Makaton (in UK) or Lamh (in Ireland) may also be crucial to communicating effectively. It is also important that this process is given adequate time and the patient is given several opportunities to receive and understand relevant information.

The Royal College of Psychiatrists has published a series of extremely useful 'Books beyond words' which use pictorial representations of everyday situations such as 'Going to Hospital'[31] and can assist in making an easily understood disclosure of information.

The issue of organic brain syndromes raise a particular dilemma as this represents a psychiatric manifestation of a medical condition and as such necessitates consent to medical rather than psychiatric treatment. Such states may impair decision-making capacity, but as their cause relates to a medical complaint rather than a psychiatric disorder their treatment is not covered by the Mental Health Act 2001. In such cases treatment may have to proceed under the doctrine of necessity.

The requirement to provide patient-centred information is very pertinent to psychiatric treatments which are either controversial or have potentially grave side effects.

The process of obtaining consent for electroconvulsive therapy (ECT) has been clearly prescribed by the Mental Health Commission in the Rules Governing the use of Electroconvulsive Therapy.[32] These state that each patient should undergo a capacity test and receive detailed information relating to the nature and purpose of ECT, intended benefits, likely adverse effects (including short term cognitive impairment), treatment alternatives and possible consequences of not having ECT. Information must be provided in oral and written form.

Another treatment worth specific mention is clozapine. This medication is most notably associated with the potentially life threatening side effect of agranulocytosis. Less grave but significant side effects must also be disclosed, particularly weight gain, dyslipidaemia, diabetes mellitus and sedation. In addition the requirement for regular phlebotomy should be discussed in detail.

In a similar manner disclosure of information in relation to lithium must cover its toxic potential, the features of toxicity and situations which may induce toxicity such as dehydration. Nephrotoxicity and thyroid toxicity should be discussed, in addition to less grave side effects which a patient may consider significant such as fine tremor, polyuria or a subjective experience of diminished creativity.

Great clinical skill is required to balance a thorough disclosure of information with one's duty and desire to recommend a particular course of treatment. This is a challenge that requires time and consideration.

The process of obtaining consent should also be a fluid one which is repeated at intervals (for example every three months as is required in the Mental Health Act 2001). Repetition of this process is particularly pertinent if a patient's mental state fluctuates with a consequent emergence of impairment of decision-making capacity.

In general the highest procedural standards should apply to those patients who are involuntarily detained. One must always seek consent for treatment regardless of a patients legal status but it is more likely that those who are involuntarily detained may lack capacity to consent due to the mental disorder from which they suffer.

Where a doubt arises regarding issues of diagnosis, treatment, appropriateness of involuntary detention or decision-making capacity it is advisable to obtain a second opinion. The role of a second opinion doctor is primarily to provide an independent clinical assessment, opinion and recommendations. The importance of this clinical independence has been confirmed by the Health Service Executive Forum on Provision of Second Opinions[33] which instigated the drawing up of a national panel of psychiatrists from whom a candidate can be drawn randomly.

Finally it is worth considering exactly which interventions constitute treatment and require consent. The Mental Health act 2001 defines treatment as "the administration of physical, psychological and other remedies relating to the care and rehabilitation of a patient under medical supervision intended for the purposes of ameliorating a mental disorder". The use of the phrase 'and other remedies' does broaden



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this definition of treatment.

It is worth considering whether we should regard restrictive practices and deprivation of liberty as 'treatment' in themselves. Section 69 of the Mental Health Act 2001 stipulates that seclusion and restraint should only be used in accordance with Mental Health Commission Rules and "for the purpose of treatment and or to prevent the patient from injuring himself or herself or others". This section clearly includes restrictive practices within the legal definition of 'treatment'.

The obvious implication of this point is that most interventions may be considered 'treatment' of a sort, and require that consent at least be sought. Clearly a detailed process of receipt of informed consent cannot be performed for every day to day clinical interaction and the degree to which this process should be subject to prescriptive procedures will depend on how intrusive or potentially harmful the intervention is. At a very basic level patients should always have their care plan explained to them and they should be given the opportunity to exercise choice.

## Conclusion

There is a well established ethical and legal obligation on psychiatrists to obtain informed consent for treatment. An exception applies to those who are involuntarily detained under the Mental Health Act 2001 for an initial period of three months and are effectively incapable of consenting to treatment.

Under normal circumstances, a doctor who treats a patient without full consent could be liable for prosecution for a criminal offence or legal proceedings for a civil wrong such as negligence.

For consent to be valid it must be 'informed', the patient must have decision-making capacity and must be free from duress. The legal standard of informed consent is addressed in the Mental Health Act 2001 but has been established in greater detail in case law which has developed both in Ireland and internationally. The test of informed consent can be approached from the point of view of a standard set be the medical profession ('doctor-centred') or set by the patient ('patient-centred') .

The Irish Supreme Court has recently favoured the 'patient-centred approach'. This means that when disclosing risks of a treatment, psychiatrists must put themselves in their patient's shoes and inclusively disclose information they consider their patient would reasonably wish to know. This process takes time and consideration.

Ultimately the precise standard required when obtaining informed consent for psychiatric treatment from a patient will be tested in the courts and form the basis of future Irish case law.

Declaration of Interest: None.

Disclaimer: This paper and any information given therein is not and should not be taken to be medical, legal or medico-legal advice.

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