

Patient Consent in Living Donor Transplantation after Montgomery

- Manchester International Living Donor Meeting 2018
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Live organ donation

- Where a living donor wishes to donate blood or regenerative tissue there are few legal or ethical objections
- The main issue is whether there is consent
- A distinction is made between blood and regenerative tissue and non-regenerative tissue
- In the early days doubts were cast about whether it was lawful for a person to agree to donate a solid organ, such as kidney to another during his lifetime.

Live organ donation

- Where there is non-regenerative donation such as a kidney the issue is more problematic
- The infliction of actual bodily harm can constitute a crime regardless of consent *R v Brown* [1993]
- By 1995 the Law Commission said with confidence that once a valid consent has been forthcoming, English law now treats as lawful donation of regenerative tissue and also non-regenerative tissue not essential to life

Living Organ Donation

- Statutory basis for the live donation of organs from a living adult for transplant
- Human Organs Transplant Act 1989 repealed by the Human Tissue Act 2004, Human Tissue (Scotland) Act 2006, Human Transplantation (Wales) Act 2013
- It provides it is lawful to remove organs for a living adult for transplant with, but only with, his appropriate consent

Consent

- Donation of a single kidney, segment of liver or a lobe of a lung is permissible if the donor is in good health
- The donor must understand fully the process involved
- The potential donor may be closely related to the potential recipient and the psychological pressure enormous
- Crucial to establish the donor did give consent –real or valid consent
- The Act does not provide great assistance with this question

Genetic Relationship

- All cases of altruistic non-directed donation must be referred to the HTA for approval
- Where the donor is a relative the assumption is that the motivation is understood and is subject to less scrutiny
- It has been argued by ethicists that this distinction is not so clear cut.
- In the case of a relative there may be significant emotional pressure to donate and there may be no 'real' consent

Montgomery

- This is a case about choice, options, alternatives
- Nadine Montgomery was not given information about the option's for delivery of her baby
 - Elective caesarean section
 - Vaginal delivery with the option to proceed to caesarean section should problems be encountered
- Both were reasonable options
- To enable her to exercise choice she required to be advised of the risks and benefits of each option
- The choice was hers to make when fully informed

Informed Consent

- This was a doctrine developed in US jurisprudence and was designed to expand the liability of doctors
- *Salgo v Leland Stanford Junior University Board of Trustees* (1957)
 - Initially said a doctor should disclose the facts necessary for the basis of “intelligent” consent
 - Then referred to “informed” consent
- In *Sidaway* Lord Scarman recognised that it is a misnomer to use the term informed consent
 - To obtain real or valid consent the patient must be informed.

Informed Consent

- The use of this term has led to a flawed interpretation of information disclosure
- The main focus of patient self-determination is **choice** rather than consent
- It incorrectly focuses on obtaining patient consent when in fact a refusal ought to be respected equally
- Patients should make informed decisions about the **options available** and in that situation real or valid consent is obtained

Pre-Montgomery test- Information Disclosure

- For many years in law a patient's right to information has been circumscribed by what doctors as a professional body thought they should be told
 - *Sidaway v Bethlem Royal Hospital Governors*
- The test was based on *Hunter v Hanley* and *Bolam* with an exception to the use of the test
 - Where a patient asked specific questions
 - Where a risk was material or significant
 - Lord Bridge talked about a substantial risk of grave consequences
 - There was a lack of consistency in this decision

GMC Guidance

- Since 1995 the GMC has recognised the right of the patient to be fully involved in decisions about their care
- Specific consent guidance was provided as early as 1998 and there was a recognition that information disclosure was linked to the particular patient
 - provide patients with appropriate information, which should include an explanation of any risks to **which they may attach particular significance to**

GMC Guidance

- The 1998 Guidance on consent explained that the information patients might want or ought to know, before deciding whether to consent to a treatment or investigation may include:
 - Details of the diagnosis, and prognosis, and the likely prognosis if the condition was left untreated
 - Uncertainties about the diagnosis including options for further investigation prior to treatment
 - Options for treatment or management of the condition, including the option not to treat

GMC Guidance

- In 2008 the specific guidance on consent was updated and a basic model was provided for patients who had capacity to make decisions for themselves
- The doctor uses specialised knowledge and experience and clinical judgement, **and the patient's views** and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient

GMC Guidance

- The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment
- The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them
- The patient decides whether to accept any of the options, and if so which one
- They have the right to accept or refuse an option for a reason that may seem irrational to the doctor, or for no reason at all

Other common law Jurisdictions

- Canada introduced a patient-focused test in the 1980's in *Reibl v Hughes*
- 1992 the Australian High Court in *Rogers v Whitaker* introduced what was at that time the most patient- orientated doctrine of consent amongst the common law jurisdictions
- In 1992 Southern Ireland first made reference to the principles in *Reibl v Hughes* and in 2000 there was a move towards a reasonable patient standard further clarified in 2007

Other common law jurisdictions-Australia

- In 1992 Australia adopted a “reasonable patient” test and rejected an approach on information disclosure based upon professional practice
- In *Rogers v Whitaker* the court adopted a “particular patient” test rejected by the UK in *Sidaway*.
- *Rogers v Whitaker* was decided two years after the UK decision in *Sidaway*

Australia-Rogers v Whitaker

- Choice is meaningless unless it is made on the basis of relevant information and advice
- The choice to be made calls for a decision by the patient on information known to the medical practitioner but not to the patient
- It would be illogical to hold that the amount of information provided can be determined from the perspective of the practitioner alone
 - Or the medical profession

Canada

- Since *Reibl v Hughes* in 1980 the Canadian courts have rejected the professional standard test in information disclosure cases
- Under the Canadian test a doctor must disclose all material risks in a treatment or option for treatment
- A risk is material when a reasonable person, in that patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forgo the proposed therapy

The Montgomery test

- The Supreme Court set out the correct legal test to be applied to cases of information disclosure
- The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in *Sidaway* by Lord Scarman, and by Lord Woolf MR in *Pearce*, **subject to the refinement made by the High Court of Australia in *Rogers v Whitaker***

Montgomery-Duty of the Doctor

- A doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment
- And of any **reasonable** alternative or variant treatments
- The test of materiality is replicated directly from the Australian decision of *Rogers v Whitaker*

When is a risk material?



- Whether a risk is material is a question of fact and all relevant facts should be taken into account
- The duty is to warn of a material risk in the proposed treatment
- A risk is material if,
 - in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to the risk (objective limb),
 - 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 (subjective limb)

The Montgomery test

- It is important to recognise that the test is a two-limbed test
- The first limb of the test applies objective criteria and focuses on the requirements of a reasonable or ordinary person in the patient's position
- The second limb of the test allows the courts to consider the particular patient and their requirements or fears (reasonable or unreasonable)
- The latter is subject to the caveat that the doctor is or ought to be aware of them

What is a Material Risk?



- This has been considered extensively in other jurisdictions
- A risk has been held to be significant if it is material to a reasonable patient's decision
- It is not simply a question of the incidence of the risk but also depends on the severity of the consequences should the risk materialise
- GMC position in *Montgomery* was that where there is a risk of catastrophic injury, even at a low level this required to be discussed with the patient

Material Risk -the GMC 2008 Guidance

- You must tell your patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small.
- You should also tell patients about less serious side effects or complications if they occur frequently, and explain what the patient should do if they experience any of them.
- Adverse outcome is defined as resulting in death, permanent or long-term pain, admission to hospital, or other outcomes with long-term or permanent effect of a patient's employment, social or personal life

Alternative treatment options

- A patient should be advised of the alternative methods of treatment, including the risks of those alternatives
- Failure to advise of the options denies a patient the right to make a fully informed **choice**
- A reasonable alternative may be to delay a treatment or procedure either to obtain more information or to try alternative or conservative measures
- This is also found in the 2008 GMC Guidance on Consent

Use of Professional practice test

- There is no suggestion in the GMC Guidance that information disclosure to patients should be filtered in any way based on what doctors normally advise
- In *Montgomery* it was argued that the *Bolam* and *Hunter v Hanley* tests had no place in the area of information disclosure
- Neither Australia nor Canada use the professional practice test to permit justifiable **filtering** of information

The Right to Refuse Treatment

- A competent adult person has an absolute right to “choose” whether to consent to treatment, refuse it or choose another treatment being offered
- Doctors do not have a duty to persuade patient’s to change their minds if they consider the choice made on the basis of proper information disclosure is wrong
- A patient may also insist they want no information 2008 GMC Guidance on consent
 - This should be recorded

Re M (child: refusal of medical treatment)

- 15 ½ year old girl in acute heart failure was denied the right to refuse a heart transplant operation
- She had said she didn't want to die but also that she did not want someone else's heart and she did not want to take medication for the rest of her life
- It was held by the court it was in her best interests to receive the heart and the surgeon was authorised to perform the procedure
- She finally acquiesced but the decision was heavily criticised as countenancing forced transplantation

Can a patient force treatment a doctor does not consider is in the best interests of the patient?

- GMC Guidance provides that:
 - If the patient asks for treatment that the doctor considers would not be of overall benefit to them, the doctor should discuss the issues with the patient and explore the reasons for the request
 - If after discussion the doctor considers that the treatment would not be of overall benefit to the patient, they do not have to provide the treatment
 - They should explain the reasons to the patient, and explain any other options that are available, including the option of seeking a second opinion.

Is there a duty to ensure that the patient makes the 'right' decision

- A doctor is under no duty to ensure that the patient chooses what the doctor considers is the 'right' option
- Information should be given in a balanced way
- The GMC provides that a doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice

Therapeutic Exception

- There will be cases where a patient is unable or unwilling to accept information
- The Supreme Court in *Montgomery* has held that a doctor is entitled to withhold information reasonably considered to be detrimental to the patients health or in circumstances of necessity
- The Supreme Court warned that this exception must not be abused or used to prevent patients from making decisions that the doctor may see as contrary to the patient's best interests
- The scope remains undefined but reasons for withholding information must be specific to the patient

Emergencies

- In an emergency situation where a patient is unable to give consent and there is no available evidence of a patient's own wishes, a doctor does have authority to act in the best interests of the patient and do whatever is necessary to preserve life or prevent a serious deterioration
- The treatment provided must be the least restrictive of the patient's future choices (GMC)

Fraud or Misrepresentation

- Where there is coercion, fraud or misrepresentation there is no consent
- Where there is a deliberate lie or a dishonest answer to a direct question from a patient this can be seen as evidence of bad faith vitiating consent

Where a patient asks questions

- Where a patient asks questions and the nature of the questioning reveals their concerns or personal fears this can now be said to satisfy the second limb of the test if *Rogers v Whitaker* is applied.
- It has always been UK law that where a patient asks questions it is the duty of the doctor to answer those questions truthfully-GMC since 1998
- It is interesting that prior to *Montgomery* the patient who asked questions was in fact entitled to more information than the patient who did not

Patient understanding

- Imparting information does not of itself ensure that a patient makes an informed decision
- The patient's right to receive information should be tested independently from the ability of the patient to understand the information
- The doctor fulfills the duty by making appropriate disclosure in a reasonable way to facilitate patient understanding
- There is case law to support that the doctor does not have an obligation to ensure the patient understands
- GMC Guidance does cover this

Patient Understanding

- *Montgomery* -the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and the risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision
- This role will only be performed effectively if the information provided is comprehensible
- The doctor's duty is not fulfilled by bombarding the patient with technical information which she cannot be expected to grasp

Supreme Court-Montgomery

- Patients are now widely recognised as persons holding rights, rather than as the the passive recipients of care of the medical profession
- Social developments point away from a model of the relationship between the doctor and the patient based on medical paternalism
- An important feature is patient autonomy, their freedom to decide what shall be done with their own body

Montgomery-Underlying concepts

- Recognition of the importance of patient autonomy or self-determination in the area of information disclosure
- Recognition that the issue of information disclosure to patients can and should be separated from the question of diagnosis and treatment
- Recognition that the *Bolam/ Hunter v Hanley* tests are inappropriate in the area of information disclosure

Montgomery- Underlying concepts

- Introduction of a particular patient-focused test in the area of information disclosure
- Focus on the test as set down in the Australian case of *Rogers v Whitaker*
- Focus on the Guidance issued by the GMC
- Recognition that the patient also has a responsibility in relation to their own health care needs and decisions
- Where a patient does ask questions this questioning imposes a specific duty on the doctor within the second limb of the test

Basic Principles

- A competent patient has the right to accept or refuse treatment, even treatment a doctor considers is in the patient's best interest
- The doctor cannot impose treatment on a competent patient no matter how beneficial or necessary the doctor considers it to be
- Valid consent cannot be substituted by a medical judgement that a treatment is in the patient's best interests

Basic Principles



- A patient's right to receive information is not dependent on making a request for information
- The patient must receive information on alternative methods of treatment and the risks and benefits of those alternatives
- A doctor does not require to provide a patient with every hypothetical option for treatment
- The disclosure of information to patients on alternative treatments is not based on professional practice of what doctors usually do

Australian and Canadian experience



- In Australia the medical profession received the decision of the High Court in *Rogers v Whitaker* with some consternation
- It was said that the floodgates of informed consent litigation appeared to be opening
- In Canada it was suggested their Supreme Court in *Reibl v Hughes* had prescribed some strong medicine to improve the doctor patient relationship
- In reality cases failed because information had been disclosed

The Supreme Court



- There was recognition that the guidance issued by the GMC in 2008 had addressed the issue of what was required
- “It is nevertheless necessary to impose legal obligations, so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires. “

The Supreme Court



- There was recognition that the decision may not be welcomed by some healthcare providers
- “The approach which we have described has long been operated in other jurisdictions, where healthcare practice presumably adjusted to its requirements. “
- ”In so far as the law contributes to the incidence of litigation, an approach which results in patients being aware that the outcome of treatment is uncertain and potentially dangerous, and in their taking responsibility for the ultimate choice to undergo that treatment, may be less likely to encourage recriminations and litigation in the event of adverse outcome”

The Supreme Court -The Final World



- “We would accept that a departure from the *Bolam* test will reduce the predictability of the outcome of litigation, given the difficulty of overcoming that test in contested proceedings. It appears to us however that a degree of unpredictability can be tolerated as the consequence of protecting patients from exposure to risks of injury which they would otherwise have chosen to avoid.”
- “The more fundamental response to such points, however, is that respect for the dignity of patients requires no less.”