THE LAW ON INFORMED CONSENT

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DEVELOPMENT OF LAW ON CONSENT

• RETREAT FROM *BOLAM*
• ADVANCE OF RIGHTS BASED CARE
• MONTGOMERY
• DIALOGUE WITH PATIENTS
• EXCEPTIONS TO MONTGOMERY
BOLAM TEST FOR NEGLIGENCE

Facts: Mr Bolam was a voluntary patient at Freirn Hospital. He consented to undergo electro-convulsive therapy. He was not given any muscle relaxant, and his body was not restrained during the procedure. During the ECT he flailed about violently and he suffered serious injury. He alleged negligent failings: (1) not issuing relaxants (2) not restraining him (3) not warning him about the risks involved.
BOLAM TEST

1957 case, jury trial. McNair J:
A doctor “is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.”
• *Bolam* test approved by Supreme Court
• = departure from normal negligence test of reasonableness
• Clinical negligence judged by standards of medical profession
• *Bolam* test applies to diagnosis and treatment cases
QUALIFICATION OF BOLAM TEST

The Bolam responsible body of opinion defence is subject to logical analysis.

Bolitho House of Lords 1997, Lord Browne-Wilkinson:

“In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.”
DOES BOLAM TEST APPLY TO MEDICAL ADVICE OR CONSENT CASES?

*Sidaway v Board of Governors of the Bethlem Royal Hospital & The Maudsley Hospital*  HL 1985

Facts: Claimant suffered from recurrent pain in her neck, right shoulder and arms. In 1974 a senior neuro-surgeon advised her to undergo surgery. He did not mention an inherent, material risk of damage to the spinal column and nerve roots. Risk was 1-2%. The operation was performed non-negligently. The inherent risk of harm materialised. Claimant sued on basis of surgeon’s omission to warn her of risks.
SIDAWAY

Trial judge found that the surgeon’s omission to warn was a practice which in 1974 would have been accepted as proper by a responsible body of skilled and experienced neuro-surgeons. The Bolam defence was made out.

The Claimant appealed to Court of Appeal (lost) and then to House of Lords.
HOUSE OF LORDS IN SIDAWAY

Majority decision: medical advice was part of clinical judgment

A qualified *Bolam* test should apply to advice/consenting process

Claimant lost her appeal
SIDAWAY QUALIFICATION OF BOLAM TEST

“But even in a case where, as here, no expert witness in the relevant medical field condemns the non-disclosure as being in conflict with accepted and responsible medical practice, I am of opinion that the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it. The kind of case I have in mind would be an operation involving a substantial risk of grave adverse consequences, as, for example, the ten per cent. risk of a stroke from the operation..” (Lord Bridge)
• Duty to disclose substantial risk of grave adverse consequences, even if responsible body of opinion did not do so (per Lords Bridge and Keith)

• If the patient wanted to be fully informed, doctors were under a duty to provide requested information (per Lord Diplock)
LORD SCARMAN IN SIDAWAY

“Where there is a "real" or a "material" risk inherent in the proposed operation (however competently and skilfully performed) the question whether and to what extent a patient should be warned before he gives his consent is to be answered not by reference to medical practice but by accepting as a matter of law that, subject to all proper exceptions (of which the court, not the profession, is the judge), a patient has a right to be informed of the risks inherent in the treatment which is proposed.” = doctrine of informed consent
Lord Scarman:

“It is, I suggest, a sound and reasonable proposition that the doctor should be required to exercise care in respecting the patient's right of decision. He must acknowledge that in very many cases factors other than the purely medical will play a significant part in his patient's decision-making process. The doctor's concern is with health and the relief of pain. These are the medical objectives. But a patient may well have in mind circumstances, objectives, and values which he may reasonably not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion. The doctor's duty can be seen, therefore, to be one which requires him not only to advise as to medical treatment but also to provide his patient with the information needed to enable the patient to consider and balance the medical advantages and risks alongside other relevant matters, such as, for example, his family, business or social responsibilities of which the doctor may be only partially, if at all, informed.”
Lord Scarman’s conclusion:

“English law must recognise a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing: and especially so, if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk.”
PEARCE v UNITED BRISTOL HEALTHCARE NHS TRUST, CA 1999

Facts: Claimant had been pregnant and pregnancy had proceeded beyond term. Her consultant obstetrician advised her to allow nature to take its course and to proceed to a normal delivery rather than caesarean section. He did not advise of the small 0.1 to 0.2% increased risk of a stillbirth. The baby died in utero.
Pearce

Issue: should the claimant have been warned of that risk?

- CA applied a qualified *Bolam* test.
- The claimant lost because the risk had not been significant.
CA on duty to inform:

“if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt”
Facts: The pursuer was pregnant. Her pregnancy was high risk because she was diabetic and small in stature. Her obstetrician told her that she was having a larger than usual baby, but advised she should be able to deliver vaginally. She was not offered the option of elective caesarean section. Her obstetrician did not tell her that diabetic women had a 9–10% risk during a vaginal delivery of shoulder dystocia.
The obstetrician’s reasons for withholding this information were:

• if shoulder dystocia did occur, the risk of a grave problem for the baby was very small

• if shoulder dystocia were mentioned, most women would ask for a caesarean section, which was not in their interest (i.e. medical paternalism)
The complication of shoulder dystocia arose. The baby’s head became stuck. The obstetrician had to perform a symphysiotomy. The baby’s head was pulled with ‘significant traction’. The baby sustained severe brain damage. A claim was brought on behalf of the child for a failure to inform of the risks from vaginal delivery and the option of caesarean section delivery.
The claim was lost in the Scottish courts, based on application of qualified *Bolam* test.

Appealed to Supreme Court

GMC intervened

7 SC judges decided in favour of claim
MONTGOMERY SC RATIONALE

Doctor/patient relationship has moved on since Sidaway 1985

Patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices.
Patients are better informed:

It has become far easier, and far more common, for members of the public to obtain information about symptoms, investigations, treatment options, risks and side-effects via such media as the internet (where, although the information available is of variable quality, reliable sources of information can readily be found), patient support groups, and leaflets issued by healthcare institutions.

It would therefore be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent on a flow of information from doctors.
GMC GUIDANCE

The SC attached weight to GMC guidance on doctor/patient relationship

Good Medical Practice 2013:
“Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care.”
“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 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. 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.”
MONTGOMERY ON PATIENTS’ RIGHTS

At common law: the value of self-determination

Human Right to respect for private life (Article 8 ECHR)

Social and legal developments have moved away from medical paternalism
Treat patients so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.

The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations).
MONTGOMERY DECISION

An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken.

The doctor is therefore 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 whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.
The test of materiality is not a question of percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have on the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.
CONSENT INVOLVES DIALOGUE

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 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 therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.
DOCTOR’S DUTY WHEN ADVISING

• enter in to dialogue
• advise on investigation and treatment options
• provide advice effectively
• provide information in comprehensible way
• check information is understood
• = shared decision-making
DOCTOR’S DUTY WILL NOT BE DISCHARGED BY

• OTT information
• confusing detail
• advice = lengthy unexplained information sheets
  – no dialogue
  – no check patient understands
• a signature on a consent form
RECOGNITION IMPACT ON HEALTHCARE PROVIDERS

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. This 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.
LESS LITIGATION?

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 an adverse outcome, than an approach which requires patients to rely on their doctors to determine whether a risk inherent in a particular form of treatment should be incurred.
EXCEPTIONS TO MONTGOMERY

Patients lacking capacity to give informed consent
• children (parents/ guardians decide, or Gillick competent children decide)
• mentally incapacitated adults

Emergency situations
• e.g. patient requires emergency treatment but is unconscious or unable to make a decision

Patient can decide he/she does not want to be informed of risks:
• no obligation on doctor to force discussion of risks
THERAPEUTIC EXCEPTION

• No obligation on doctor to explain risks if doctor decides that would be seriously detrimental to the patient’s health

• This decision would be made in the reasonable exercise of medical judgment (i.e. subject to Bolam test)

• SC warning to doctors: it is important that the therapeutic exception should not be abused. It is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests.
SPENCER v HILLINGDON HOSPITAL NHS TRUST

1st instance decision of Judge Collender QC (Deputy HC Judge)

Facts: claimant underwent surgery on an hernia. He was given no post-operative advice about the risk of DVT & PE due to the operation and immobility. He was not given advice as to likely signs and symptoms they might cause. He was discharged home. The claimant felt unwell on day 2 and by day 3 had developed calf pain which he attributed to lack of activity. He did not seek medical help. In fact he had developed DVT and went on to suffer PE.
Judge’s approach: applied *Bolam* test but with a *Montgomery* gloss:

*Would the ordinary sensible patient be justifiably aggrieved not to have been given the information about post-operative risks?*

- = duty to warn of healthcare risks
- = extension of *Montgomery* beyond treatment decisions
Thank you

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