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Legal aspects of informed consent and non-medical prescribing

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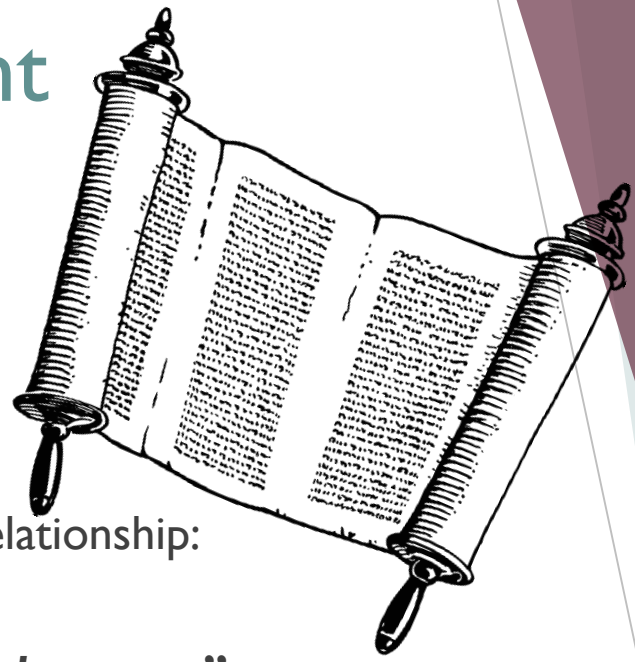
History of Informed Consent



- A question of patient autonomy and rights
- In the past, there was a paternalistic attitude to the doctor-patient relationship:

"for many patients through this cause have taken a turn for the worse"

(Hippocratic Oath, *Decorum,* XVI, 500BCE)

"the provision of too much information may prejudice the attainment of the objective of restoring the patient's health"

(Lord Templeman, *Sidaway*, 1985)

History of Informed Consent

- Starting point:
  - Does D's act/omission fall below the standard of a reasonable person?

- A higher standard applies to professionals: D is not 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 v Friern Hospital Management Committee)*
- Exception: Where evidence is given that other practitioners would have adopted the method employed by the defendant doctor, it must be demonstrated that the method was **logically defensible**. (*Bolitho v City and Hackney HA*)

History of Informed Consent

- Applying that to informed consent (*Sidaway v Board of Governors of the Bethlem Royal Hospital)*:
  1. Was the omission accepted as proper by a responsible body of medical opinion?
  2. Did that medical opinion stand up to logical scrutiny?

  If so, not negligent.

  - Exception:

    When it comes to warning about risks, the kind of training and experience that a judge will have undergone at the bar makes it natural for him to say (correctly) it is my right to decide whether any particular thing is done to my body, and I want to be fully informed of any risks there may be involved of which I am not already aware from my general knowledge as a highly educated man of experience, so that I may form my own judgment as to whether to refuse the advised treatment or not. No doubt if the patient in fact manifested this attitude by means of questioning, the doctor would tell him whatever it was the patient wanted to know; but we are concerned here with volunteering unsought information…

Development of the law and changes in society

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- Society has changed:
  - The doctor-patient model is no longer one of paternalism, patients are now seen more as consumers exercising choices.
  - There is a wider range of choice and access to alternative healthcare professionals.
  - Patients have other sources of information on symptoms, investigations, treatment options, risks and side effects
  - Patients are used to information sheets and lists of side effects.

- The law had already moved to a significant degree (*Chester v Afshar*)
  - Failure to inform of 1-2% risk of these operations going (badly) wrong.
  - C developed cauda equina syndrome.
  - If C had known, she would have sought advice and looked at alternatives, but probably would have had operation at later date.
  - Held: Doctor liable.

Montgomery v Lanarkshire Health Board 2015

- Mrs Montgomery was pregnant with her first child.
- She was short and suffered from insulin dependent diabetes mellitus
- Women with this condition have larger babies with bigger shoulders. 9-10% chance of shoulder dystocia.
- Mrs Montgomery was aware she was having a large baby and expressed concern about her ability to deliver it vaginally. She was reassured.
- Her doctor decided not to tell her about the risks of shoulder dystocia because the risk of a grave problem for the baby was very small (around 0.1-0.2%) and if you told every mother of this risk "then everyone would ask for a caesarean section".
- Baby (born weighing 4.25kg) suffered shoulder dystocia leading to 12 minute delay between delivery of head and birth. Sadly suffered cerebral palsy as a result.

Montgomery v Lanarkshire Health Board 2015

- The lower courts applied *Sidaway* and rejected the Claimant's claim for damages.

- The Supreme Court held that this was wrong:

> **"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.**

What is a material risk?

"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."

- Cannot be reduced to percentages.
- The assessment is fact-sensitive, and sensitive also to the characteristics of the patient.
- Depends upon:
  - the nature of the risk,
  - the effect which its occurrence would have upon 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.

Does not just apply to doctors

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- There will be situations where a non-prescribing professional will have to seek a patient's consent.
- *Darnley v Croydon Health Services NHS Trust* 2018
  - Man suffering from a head injury
  - He booked in at the A&E reception.
  - The receptionist told him that the waiting time was 4-5 hours when in fact a triage nurse would see a head injury patient within 30 minutes.
  - He left after waiting 19 minutes.
  - Later collapsed out of hospital and suffered serious brain damage which would have been avoided if he was in hospital at the time.
  - The lower courts held that the receptionist could not be held responsible.
  - The Supreme Court held that the Hospital Trust owed a duty of care and you could not distinguish between medical and non-medical staff in respect of the duty of care. The distinction only mattered in deciding whether there was a negligent breach of duty; there the degree of skill which can reasonably be expected of a person will be likely to depend on the responsibility with which he/she is charged.

What is a medical professional required to do?

- The advisory role involves dialogue, the aim of which is to ensure the patient understands:
    1. the seriousness of his/her condition;
    2. the anticipated benefits and risks of the proposed treatment; and
    3. any reasonable alternatives and their risks and benefits.

  Information should be provided in comprehensible language so that the patient can make an informed decision.

- The previous exceptions (information would be seriously detrimental to health; patient needs treatment urgently and is unconscious or unable to make a decision) are preserved but should be treated with caution.

Still a role for the *Bolam* test in consent cases

- *Duce v Worcestershire Acute Hospitals NHS Trust* 2018
  - Court of Appeal held that the first question was what risks were or should have been known to the medical professional. This **is** a question for the experts and a reasonable body of medical opinion (*Bolam*).
    - If it was an unknown risk, no breach in failing to communicate it.
  - Montgomery was relevant to the decision of whether the patient should have been told about such risks by reference to whether they were material.
  - Legatt LJ made a useful observation to bear in mind:
    - In consent cases the duty is not to protect the claimant from a risk of injury;
    - The duty is to enable the claimant to decide whether or not that risk is acceptable to her.

So what should a medical professional do?

1. Assess **what risks** there are with the procedure/treatment (keep up-to-date)

2. Does the patient know about the **material risks** of the treatment proposed?
   i. What sort of risks would a reasonable person in the patient's shoes want to know about?
   ii. What sorts of risks would this particular patient want to know about?

3. Does the patient know about **reasonable alternatives** for treatment? What risks do the alternatives have including the options of conservative management/doing nothing?

4. Has reasonable care been taken to ensure the patient actually **understands** all of this information?

5. Do any of the **exceptions** to the duty to disclose apply in this instance?

So what should a medical professional do?

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- Most importantly, do not get too anxious about consent.
  - The effect of *Montgomery* has been over-exaggerated. It's an important decision, but:
    - Causation remains the single greatest hurdle for a claimant to overcome.
    - There is no free standing right to compensation (*Diamond v Royal Devon & Exeter NHS FT*).
    - The Courts recognise that most patients will accept a medical professional's advice about treatment (*Pearce v United Bristol Healthcare NHS Trust*) and that all claimants in consent cases claim in hindsight they would not have had treatment.

Any Questions?