Consent – legal developments

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Module 7

UK IMPLANTOLOGY YEAR COURSE

Recent changes in consent law

1. Disclosure of risk
2. Treatment alternatives

Recent changes in consent law

PATERNALISM

Historical contact

The Hippocratic oath (500BC)

Advises physicians to 'reveal nothing to the patient of her present or future condition'

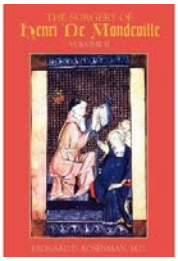
Historical contact

Citrobulus and Alexander the Great

Historical contact

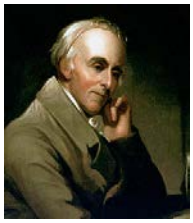
Henri de Mondeville

- French surgeon in 1300s
- Doctors must 'promise a cure'
- Helps healing process
- Essentially to lie about the prognosis
- Patient's requests must not interfere with the treatment
- Confidence more important than consent



Historical contact

Benjamin Rush



- American physician in late 1700s
- Encouraged by 'Age of Enlightment'
- Share as much information as possible with the patient
- Patient must be obedient to their doctor
- Still no concept of consent!

Historical contact

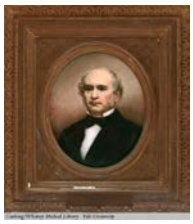
Thomas Percival

- Famous British Physician
- 1803 published 'Code of Medical Ethics'
- First coined the phrase 'medical ethics'
- Became key source for new AMA code 1847
- Still no mention of consent!

'Patients have a right to truth, but when the physician could provide better treatment by lying or withholding information, the physician must do as he thinks best'

Historical contact

Worthington Hooker



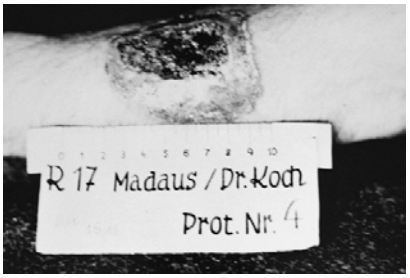
- Professor of Theory and Practice of Medicine at Yale University, USA.
- Vice President of American Medical Association in 1864
- Published 'Physician & Patient' in 1849
- Taught that deception was not fair to the patient
- His ideas were not widely accepted

Medical experimentation

Nuremberg Trials (1947):

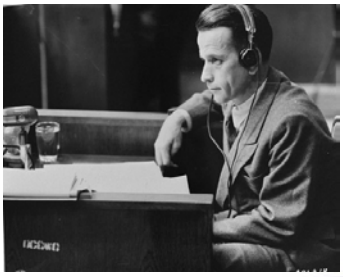
Medical experimentation

The Doctors Trial – medical experiments (1947):



Medical experimentation

The Doctors Trial – defense of consent (1947):



Medical experimentation

Nuremberg Trials (1947):

The Nuremberg Code

The Nuremberg Code :

'The voluntary consent of the human subject is absolutely essential'

Medical Ethics - consent

The declaration of Helsinki (1975) :

'The provision of consent in writing is required'

Bolam Precedent (1957)

BOLAM

Bolam v Friern Hospital Management Committee [1957] 1 WLR 582

Bolam Precedent (1957)

Mr Bolam had ECT without muscle relaxants or restraints

Bolam v Friern Hospital Management Committee [1957] 1 WLR 582

Bolam Precedent (1957)

'not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men'

Bolam v Friern Hospital Management Committee [1957] 1 WLR 582

Canturbury v Spence (1972) – Informed Consent

- Back operation with 1% risk of paralysis
- Not warned as doctor thought pt could reject the surgery
- Patient became paralysed
- Court rejected the 'responsible doctor' standard

Canterbury v Spence (464 F2d 772) 1972

Canturbury v Spence (1972) – Informed Consent

'to enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential'

Canterbury v Spence (464 F2d 772) 1972

Reibl v Hughes (1980) – 'prudent patient test'

- Surgical removal of blocked artery
- 'Small' stroke risk 10%
- Patient suffered stroke

Reibl v Hughes (1980) 114 DLR (3d) 1

Reibl v Hughes (1980) – 'prudent patient test'

'a patient must be informed about <u>all</u> potential material risks, even if the statistical chances of it occurring are small' (10%)

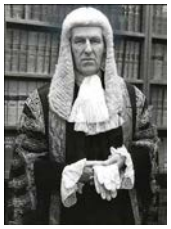
Reibl v Hughes (1980) 114 DLR (3d) 1

Sidaway (1985)

- Cervical cord decompression – suffered paralysis
- <1% chance of this occurring
- Patient was not told of this risk

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 2 WLR 480

Sidaway (1985)



Lord Bridge

Referred to 10% risk quoted in Canadian Supreme Court

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 2 WLR 480

Sidaway (1985)

Lord Scarman's dissenting position…

expressed the opinion that a risk should be discussed with the patient if the risk was **material**

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 2 WLR 480

Sidaway (1985)

Lord Scarman's dissenting position…

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

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 2 WLR 480

Rogers v Whitaker (1992)

the statistical risk in this case was only **1 in 14,000**

Rogers v Whitaker (1992) 175 CLR 479

Rogers v Whitaker (1992)

High Court of Australia

'the gravity of a risk was more important than the chance of the risk occurring'

Rogers v Whitaker (1992) 175 CLR 479

Chester v Ashfar (2004)

the doctor had a duty to warn the patient of the risk in that particular case, which was in the region of 1%-2%

Chester v Afshar [2004] UKHL 41; [2005] 1 AC 134

Chester v Ashfar (2004)

General Medical Council

Department of Health

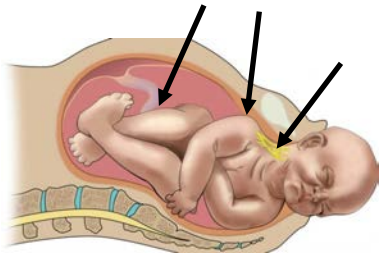
Adopted the Chester disclosure threshold of 1%-2%

Chester v Afshar [2004] UKHL 41; [2005] 1 AC 134

Montgomery (2015)

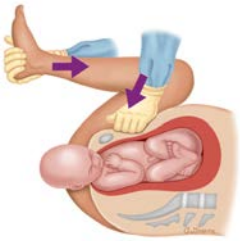
Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Shoulder Dystocia



Montgomery (2015) – Shoulder Dystocia

9-10% chance of shoulder dystocia occurring

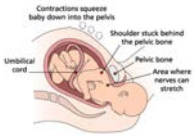


Montgomery (2015) – Shoulder Dystocia

If shoulder dystocia occurred…..

1 in 500 risk of brachial plexus injury

1 in 1,000 risk of cerebral palsy



Montgomery (2015) – Shoulder Dystocia

For the claimant…..

- 1 in 5,000 risk of brachial plexus injury (0.02%)
- 1 in 10,000 risk of cerebral palsy (0.01%)

Montgomery (2015) – Case at CSOH

COURT OF SESSION
HIGH COURT OF JUSTICIARY

Montgomery (2015) – case at CSOH

Court determined…..

- Risk of grave complication very low
- Majority medical opinion against C section

Montgomery (2015) – Appeal to CSIH

Montgomery (2015) – Appeal verdict

LOSER

Montgomery (2015) – Appeal to CSIH

'Too much in the way of information … may only serve to confuse or alarm the patient, and it is therefore very much a question for the experienced practitioner to decide…'

Montgomery (2015) – Appeal to Supreme Court

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Appeal to Supreme Court

1.DISCLOSURE OF RISK

2.TMT OPTIONS

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Materiality of risk

Montgomery (2015) – Materiality of risk

Materiality is no longer based on the STATISTICAL chance of it happening

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Materiality of risk

Materiality is now based on the significance that THE PATIENT or a REASONABLE PATIENT would attach to the risk rather than it's statistical probability.

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Treatment options

[Practitioners are] 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.

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Controversy

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Treatment options

- No new witnesses
- Had incomplete transcripts from previous hearings

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – Reaction

'This calls into question the competence of the courts to adjudicate on matters of clinical judgement

Prof Jonathan Montgomery – Faculty of Law, UCL

Montgomery (2015) – overriding majority medical opinion

….such an operation would have been outside the clinical guidelines issued by the Royal College of Obstetricians and Gynaecologists (RCOG).

Royal College of Obstetricians & Gynaecologists

Montgomery (2015) – RCOG: EBP

Montgomery (2015) – NICE guidelines

NICE National Institute for Health and Care Excellence

Montgomery (2015) – SC verdict

"the risk involved in an elective caesarean section, for the mother (is) extremely small and for the baby virtually non-existent"

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery (2015) – SC verdict

…almost five times as likely that a diabetic woman who has a CS, rather than a vaginal birth, will suffer a cardiac arrest.

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence. Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period. London: NICE, 2015.

Montgomery (2015) – SC verdict

…over twice as likely that she will need a hysterectomy due to postpartum haemorrhage.

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence. Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period. London: NICE, 2015.

Montgomery (2015) – SC verdict

… a 46% increase in the probability that a woman who has had a CS, will have no more children within 5 years of the operation

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence. Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period. London: NICE, 2015.

Montgomery (2015) – SC verdict

… and an increased relative risk of maternal mortality and stillbirth in subsequent pregnancies.

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence. Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period. London: NICE, 2015.

Montgomery (2015) – overriding majority medical opinion

Modern consent – end result???

The patient is agreeing to take full responsibility for their decision

Modern consent – Key Aspects

Patients cannot demand that YOU provide any particular treatment alternative

Modern consent – Key Aspects

1. **Any** 'reasonable' treatment alternative MUST be discussed, even if against our own advice, against National Guidelines or against majority opinion. MUST INCLUDE OPTION OF NO TREATMENT.

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Modern consent – Key Aspects

2. All material risks for **any offered** option must be discussed

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Modern consent – Key Aspects

3. **Risks** that this particular patient or a 'prudent patient' would consider materially significant must be disclosed, irrespective of the statistical chance of occurrence

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Modern consent – Key Aspects

"A person can of course decide that she does not wish to be informed of risks of injury……."

"…..a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter."

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Montgomery – recent cases citing

Spencer v Hillingdon Hospital NHS Trust

[2015] EWHC 1058 (QB)

- Spencer suffered DVT and PE after hernia surgery under day-case GA
- Risk was 0.04%
- Was not warned of the risk
- Spencer won the case

Montgomery – recent cases citing

Inglis v Brand

[2016] SC EDIN 63

- Fully erupted LL8 extracted
- Resulted in paraesthesia
- IDN damage warnings were given but not the percentage risk
- Judge ruled against the patient as percentage no longer relevant


THE END