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Consent in clinical negligence claims

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Montgomery v Lanarkshire Health Board [2015] UKSC 11

Consultant obstetrician did not inform the pursuer of the risk of shoulder dystocia (9 – 10%)

A caesarean section was not deemed in the patient's interests

The pursuer's baby suffered both a brachial plexus injury and brain damage

The pursuer's claim failed in both the Outer and Inner Courts of Session: *Bolam* test

Montgomery v Lanarkshire [2015] UKSC 11

New understanding of patient rights and self-determination.

The proper approach to the duty of care:

"*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 [2015] UKSC 11

Material Risk: *"A reasonable person in the patient's position would be likely to attach significance to the risk, or a doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it".*

Assessment cannot be reduced to percentages

Montgomery v Lanarkshire [2015] UKSC 11

Assessment of materiality

1. Nature of the risk

2. Effect of its occurrence on the life of the patient.

3. Importance to the patient of the benefits sought to be achieved by the treatment.

4. Alternatives and the risks involved in those alternatives

Exceptions to *Montgomery*

Necessity. Example - patient who is '*unconscious or unable to make a decision*'

Therapeutic Privilege. Disclosure would be '*seriously detrimental to the patient's health'.* This exception should **not** be abused.

Montgomery v Lanarkshire [2015] UKSC 11

Shoulder dystocia was a major obstetric emergency.

There was a virtually non-existent risk for a baby from a Caesarean section.

Clinician should have explained the treatment options to the pursuer. **Claim succeeded.**

Consent post-*Montgomery*

Role of *Bolam* in identifying risks

Patients who lack capacity

The interpretation of '*reasonable alternatives'* in *Montgomery*

The identification of material risks

Duce v Worcestershire Acute Hospitals NHS Trust [2018] EWCA Civ 1307

2008. Claimant agreed to a total abdominal hysterectomy and bilateral salpingo-oophorectomy

Registrar mentioned a risk of post-operative pain; but no mention of Chronic Post-Surgical Pain (CPSP)

Claimant suffered from CPSP and alleged a failure to warn of the same

Duce v Worcestershire [2018] EWCA Civ 1387

First-Instance: Insufficient understanding among gynecologists in 2008 of CPSP.

Permission to Appeal granted: Had HHJ Worcester relied on *Bolam* rather than *Montgomery?*

Appeal dismissed.

Duce v Worcestershire [2018] EWCA Civ 1387

The identification of a material risk is a bipartite test:

1. Identification of risks associated with an operation is a matter falling within the expertise of medical professionals

2. Disclosure of those risks is governed by whether they are ‘material’. This is not governed by expert evidence alone.

NHS Trust v JP [2019] EWCOP 23

JP suffered from microcephaly and associated behavioural issues.

Dispute between mother and clinicians: a natural birth or a birth in hospital?

Court of Protection application to transfer, sedate and deliver JP's baby

NHS Trust v JP [2019] EWCOP 23

JP lacked capacity.

Best interests for her to undergo a planned caesarean operation

Deception was justified because it was in JP's best interests. Compliant with Article 8 ECHR.

An NHS Foundation Trust v An Expectant Mother [2021] EWCOP 33

Mother had been diagnosed with agoraphobia

Unable to make decisions about where to give birth

Mr. Justice Holman: Agoraphobia was "*so overwhelming that it exerted a significant effect on her ability to weigh matters in the balance*".

Reasonable Alternative Treatments

Bailey v George Elliot Hospital [2017] EWHC 3398

Treatment of deep vein thrombosis.

Failure to advise treatment by an iliofemoral venous stent.

Bailey v George Elliot Hospital [2017] EWHC 3398

1. Reasonable treatment must depend upon the patient, their treatment and prognosis.

2. The treatment must be within the knowledge of a reasonably competent clinician (*Bolam*).

3. It must be an accepted practice at the relevant time.

4. It must be an ‘appropriate treatment’, not a possible one.

McCulloch v Forth Valley Health Board [2021] CSIH 21

Pursuer suffered from nausea and chest pain. Underwent three echocardiograms.

Clinician was satisfied that it was not life-threatening.

Pursuer suffered a cardiac arrest, and died.

McCulloch v Forth Valley Health Board [2021] CSIH 21

One Issue: Failure to prescribe non-steroid anti-inflammatory drugs (NSAIDs)

Claim dismissed. The question ought to be determined by *Bolam*.

Permission granted to appeal to the Supreme Court

Issues of Causation

- Discussion of the nexus between Montgomery and Chester v Afshar – given the previously “paternalistic” dynamic within the doctor/patient relationship has now shifted towards the enabling of patient autonomy: a patient is entitled to decide which, if any, of the available forms of treatment to undergo, and consent must be obtained before treatment is undertaken.

- What effect does Montgomery have on the issue of causation?

- Updates on case law since Montgomery and the treatment of causation issues in consent cases

First Principles

If a patient suffers physical harm during medical treatment when a risk materialises about which the doctor failed to warn the patient, there are two key issues to the patient's negligence claim:

(1) it must be shown that the doctor was negligent in failing to warn the patient about the particular risk.

(2) it must normally be shown that this failure to warn was a cause of the damage suffered.

Montgomery changes the test for (1), but what about the effect on (2)?

Chester v Afshar [2004] UKHL 41

Mrs Chester underwent an operation performed without negligence by the defendant surgeon.

Nonetheless, she suffered nerve damage during the operation resulting in cauda equina syndrome, leaving her with substantial disability.

She had been anxious to avoid surgery if possible but was not presented with non-surgical options, and the risks involved in surgery were not adequately explained.

Chester v Afshar [2004] UKHL 41

The risk in Chester was 1% to 2%.

The claimant in Chester may still have undergone the procedure but she would probably have taken more time to make her decision, seeking a second opinion, so delaying the operation.

Under Chester, if the patient can prove that if properly informed she would have refused the treatment there and then – claim is made out.

How to view Chester in light of Montgomery?

Chester v Afshar [2004] UKHL 41

In Chester, the House of Lords (3:2 majority) found that causation was not established on normal principles (either through factual and/or legal causation).

Nonetheless, per Lord Steyn's terms, a 'narrow and modest' departure from established legal principles was required in order to ‘vindicate the patient's right of autonomy and dignity’ and hence to allow the claim to succeed.

So the judicial desire is for the claim not to fail because of causation issues i.e. to dismiss the claim on this basis would empty the important “duty to warn” of its content / relevance.

Does this sit happily with Montgomery’s moving away from the inquiry into what a reasonable doctor would warn about and instead towards the emphasis on patient autonomy?

Chester v Afshar [2004] UKHL 41

Issues with causation:

The falling tree syndrome of Hart and Honore on factual versus legal causation.

But for the negligent failure to warn Mrs Chester would not have proceeded with the surgery… Or...

Query whether Mrs Chester's injury suffered was merely coincidental to the negligence because the defendant's failure to warn did not increase the risk of injury, since Ms Chester was ultimately willing to undergo the operation with the same risks on a different occasion.

Contrast with a patient delaying surgery in order to reduce the risk (e.g. by employing a more specialist surgeon).

Chester v Afshar [2004] UKHL 41

So what's the point of the duty in Montgomery vis-à-vis these issues of causation?

- to enable the patient to choose whether or not to run those inherent risks of which they have been warned and thereby to avoid the occurrence of the particular physical injury the risk of which the patient is not prepared to accept? Or…
- In Montgomery, Lord Kerr and Lord Reed stated that '[t]he rationale of the duty … [i]s "to enable adult patients of sound mind to make for themselves decisions intimately affecting their own lives and bodies"'.
- Lady Hale speaks to a person's autonomy: "autonomy, their freedom to decide what shall and shall not be done with their body".

Post Montgomery…
Webster v. Burton Hospitals NHS Foundation Trust [2017] EWCA Civ 62

Breach of Duty admitted: Consultant Obstetrician in charge of pregnancy should have arranged further ultrasound scanning every two weeks in view of the foetus being small for the gestational age.

Causation: baby injured during birth: hypoxic ischaemic brain injury as a result of a relatively short period of umbilical cord compression

Webster v. Burton Hospitals NHS Foundation Trust [2017] EWCA Civ 62

Lost at first instance on causation: the results of any further scans would not have altered The Trust's management plan, although accepted that the results would have been discussed with Ms Butler. Therefore, dreadful injury would always have occurred in any event. Bolam test applied and claim dismissed.

Court of Appeal apply Montgomery and hold that if material risks had been explained to mother, she would have opted for an earlier delivery which would have avoided baby's delivery = but for causation.

But NB the duty to warn of risks, however, related to the baby's development but did not specifically include a risk of cord damage in utero i.e. was coincidental.

Correia v University Hospital of North Staffordshire NHS Trust [2017] EWCA Civ 356

The court emphasised at [28] that if

“the exceptional principle of causation” established by Chester is to be relied upon it is necessary to plead and prove that, if warned of the risk, the claimant would have deferred the operation.

Duce v Worcestershire Acute Hospitals NHS Trust [2018] EWCA Civ 1307

Some attempt to clarify the position on causation:

Hamblen LJ:

“I agree with the respondent that the majority decision in Chester does not negate the requirement for a claimant to demonstrate a “but for” causative effect of the breach of duty, as that requirement was interpreted by the majority, and specifically that the operation would have not have taken place when it did.”

Shaw v Kovac [2017] EWCA Civ 1028

Permission to appeal was granted to the claimant on the basis that the case raised questions as to whether a doctor's failure to obtain the informed consent of a patient (this being a key issue in the case) could give rise to a separate award for compensation.

Court of Appeal held no freestanding right to damages as a result of breach of "personal autonomy".

Claim arises from negligence and must show loss.

Diamond v Royal Devon and Exeter NHS Foundation Trust [2019] EWCA Civ 58

Claimant had had an abdominal hernia repaired using surgical mesh, which was then liable to affect future pregnancies. She was not advised of the possible alternative of a suture repair.

Breach of duty established in failing to warn of risks.

Case lost on causation.

Claimant would have had the surgery even if given appropriate warning.

CA hold that Chester and Montgomery do not give rise to a free-standing claim for damages arising from a failure to obtain fully informed consent without more (i.e. an invasion of the right to personal autonomy).

CA essentially approving factual causation.

***Diamond v Royal Devon and Exeter NHS Foundation Trust* [2019] EWCA Civ 58**

Argued Judge wrongly taken an objective test “what a rational patient” would do, not the subjective test.

Court of Appeal held reasonable to consider “rationality” when assessing what a Claimant would do.

To have opted for the suture repair would have been irrational given the expert view that a suture repair would be liable to fail, with a very high recurrence risk of the hernia.

***Keh v Homerton University Hospital NHS Foundation Trust* [2019]**

Patient was advised to elect induction of labour at 37 weeks due to concerns about the growth of baby in utero.

Labour did not progress and she gave birth by emergency caesarean section (CS). She developed post-natal sepsis and died three weeks after the birth.

Breach of duty in failing to advise her that she was at significantly higher risk than the average pregnant woman of needing an emergency CS.

Yet claim was dismissed: a finding of fact that, even if properly advised, the Deceased would still followed the recommendation to proceed to induction of labour.

This finding of Stewart J was contrary to evidence of widower.

Mills v Oxford University Hospitals NHS Trust [2019] EWHC 936 (QB)

C suffered permanent and severe neurological injury as a result of haemorrhage and stroke during brain surgery to resect a glioma.

Surgeon had used a new surgical technique, not used by many neurosurgeons.

Surgery performed non-negligently.

However, surgeon had failed to advise that the proposed surgical technique was new, and that an alternative, was available.

Had appropriate information been given, the Claimant would have elected to undergo surgery using the standard technique.

The difference in techniques was relevant to the complications that arose. The innovative technique made it harder to control haemorrhaging. Causation was therefore established.

Malik v St George's University Hospitals NHS Foundation Trust [2021] EWHC 1913

Patient required emergency spinal surgery in the form of a laminectomy and discectomy at T10/11. No criticism was made of the performance of the surgery.

Post-operatively Mr Malik experienced ongoing numbness and weakness in his left leg. His surgeon recommended further revision decompression surgery which unfortunately left Mr Malik with an incomplete paraparesis.

When this surgery failed, alleged failure to offer alternative treatment – injections.

Held, on causation, even if offer of alternative treatment made, Cl would have elected surgery.

Negus v Guy's and St Thomas' NHS Foundation Trust [2021] EWHC 643

C underwent implantation of a 19mm mechanical valve. That implant proved insufficient, and resulted in a 'patient-prosthesis mismatch', a type of cardiac dysfunction.

Therefore, in March 2015, C underwent re-do surgery to insert a larger valve which required an aortic root enlargement procedure ("ARE").

C developed complications during post-operative recovery, and her condition then deteriorated leading to her death from heart failure in January 2020.

Claim alleged patient should have been warned that might need ARE back in 2014. Had it been done then more likely to be successful.

***Negus v Guy's and St Thomas' NHS Foundation Trust* [2021] EWHC 643**

Mrs Justice Eady concluded that the surgeon was under a limited duty to warn patient of the possible risk that he might need to undertake an ARE during the valve replacement operation.

However, in that scenario, the patient would likely have proceeded to surgery and thus causation was not made out.

We are firmly in the loss "in any event" defence.

Summary

- The case of Duce appears to limit the application of Chester, with judicial comment that it is –
    - Problematic in relation to ordinary causation principles;
        - Only applies in exceptional circumstances;
            - Relies on unclear policy grounds.
- But for causation remains necessary.
- No freestanding right to damages for breach of autonomy i.e. one logical extension of Montgomery is dismissed
- The issue of whether a patient would have consented to the alternative treatment, had they been informed of the same, is a question of fact to be determined by the trial judge.
- Likely need to show C would have not had the treatment if properly informed, or as a minimum would have deferred it.

Practical Tips

Dealing with disputed accounts of consenting process

- Take early statements.
- Clinicians can rely on usual practice – but not best evidence.
- Beware hindsight – for both parties.
- Are notes fairly full – so that absence of warning stands out – or habitually brief?
- Compare clinic notes and correspondence

Experts

- Ensure your expert understands their role – much more limited when applying *Montgomery* than *Bolam*.
- Although evidence of common practice can still be helpful.
- It is not the expert's role to say what, on the balance of probabilities, C would have done.

Proving a counterfactual

- Lead evidence on the precise advice C should have been given.
- Look at the risks C did consent to. Is it likely that information about the risk which materialised would have changed their mind?
- Consider the benefits. What would doing nothing entail? Was there a realistic alternative?
- Materiality – consider what is known about C. E.g. a young adult with no children is more likely to be put off by risks to fertility than an older one with a complete family.

Dealing with reasonable alternatives

- Was a treatment available as a matter of fact? Was it available at the same hospital? Would there have been a wait?

- The alternative must be reasonable – greater role for expert opinion here.

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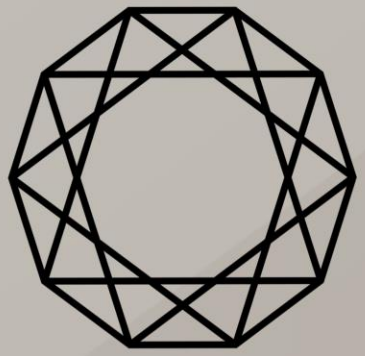
Thank you for your attention.

Questions?



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