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Informed Consent

Where are we now?

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1. In *Montgomery -v- Lanarkshire Health Board* [2015] 1 AC 1430; [2015] UKSC 15, the Supreme Court held:

> *[87] 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 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.*

2. Whereas the Supreme Court asserted patient autonomy, subsequent cases have demonstrated that, when considering the issue of informed consent, the *Bolam* test is still of relevance. In *Duce -v- Worcester Acute Hospitals NHS Trust* [2018] EWCA Civ. 1307, the Court of Appeal held that the application *Montgomery*, involved a two-stage approach:

    a. the risks that were (or should have been) known to the clinician is a matter falling within the expertise of medical professionals; and

    b. Whether any given risk is a material risk is a matter for the Court to determine

3. The claimant in *Duce* sustained nerve damage and chronic post-surgical pain following a total abdominal hysterectomy and bilateral salpingo-oophorectomy. Whilst the surgery was performed competently, it was alleged that there had been negligent pre-operative counselling.

4. The claimant lost at trial. She appealed, contending that the trial Judge had failed to apply the test or materiality per *Montgomery*. The Court of Appeal rejected that complaint, on the basis that the *'…reason that the judge did not address the issue of materiality is that he had found the claim failed at the first hurdle: proof that gynaecologist were or should have been aware of the relevant risks, which is a matter for expert evidence.'*

5. Whilst *Duce* concerned the quality of the advice given about the risks of the recommended treatment, the case of *Bayley -v- George Eliot Hospital* [2017] EWHC 3398 (HHJ Worster sitting as Deputy High Court Judge), concerned advice about alternatives to the recommended treatment. The claimant unsuccessfully alleged that the defendant had been negligent when failing to advise her of the possibility of an alternative treatment to that which she in fact underwent for DVT, namely the insertion of an ilio-femoral venous stent.

6. When considering what test should be applied to determine whether an alternative treatment was '*…reasonable…*', HHJ Worster held that the matter must be judged by what was known, or ought to have been known, about the alternative treatments. The question of reasonableness had to be approached by reference to all the circumstances of the case.

7. In so doing, HHJ Worster held that Claimant had not established that a reasonably competent vascular surgeon would, or ought to, have known about alternative treatment by way of the insertion of an ilio-femoral venous stent. He also held that the suggested alternative treatment option was not a viable alternative treatment, with the opportunity to insert stenting having passed.

8. Whilst the findings made by HHJ Worster made easier the task of concluding that stenting was not a '…reasonable…' alternative, query what the situation would be in circumstances whereby a clinician knew of an alternative viable treatment but did not consider it to be a reasonable alternative. Is there not the risk that by allowing (*Bolam*) professional judgment to dictate what is (or is not) a reasonable alternative treatment, the sovereignty of patient autonomy is undermined?

9. For example, suppose an innovative treatment is being used by 10% of clinicians, and that although a patient's clinician knows of such treatment, they consider it not to be a reasonable alternative because it has not been sufficiently tried and tested. Applying *Bolam*, a court may well conclude that it was not negligent to have failed to mention the alternative to the patient. But, would that not be the very kind of act of medical paternalism, which the Supreme Court in *Montgomery* was striving to end?

10. Furthermore, the difficulty of establishing causation in the context of consent cases was demonstrated in *Diamond -v- Royal Devon and Exeter NHS Foundation Trust* [2019] EWCA Civ 585. The claimant alleged that her surgeon failed to obtain her informed consent to a mesh repair of a post-surgical abdominal hernia.

11. Although the trial Judge found the defendant to be in breach of duty, by reason of its failure to inform the claimant of the risks that the mesh repair would present in the event she became pregnant, the claimant lost at trial on the issue of causation. The claimant's evidence, to the effect that she would not have elected to undergo the mesh repair, had she been fully informed of the risks, was not accepted.

12. On appeal, the claimant argued that the trial Judge had applied a test of 'rationality' to her decision making process. Nevertheless, the Court of Appeal held that the trial Judge had legitimately found, as a fact, that the claimant would have gone ahead with the operation in any event, and it was reasonable to consider the rationality of doing otherwise when assessing her credibility.

13. Issues of causation were also raised in *Keh -v- Homerton University Hospital NHS Foundation Trust* [2019] EWHC (QB), a Fatal Accident Act claim. The deceased 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.

14. There was found to be a 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. However, the claim was dismissed on the basis of a finding of fact that, even if properly advised, the deceased would still have followed the recommendation to proceed to induction of labour.

15. The issue of consent in the context of innovative treatment was also raised in *Mills -v- Oxford University Hospitals NHS Trust* [2019] EWHC 936 (QB). The claimant suffered permanent and severe neurological injury as a result of haemorrhage and stroke during brain surgery to resect a glioma. The surgeon had used a new surgical technique, not used by many neurosurgeons.

16. The Court held that although the surgery had been performed non-negligently, the 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.

17. By way of conclusion, and by way answer to the question first posed: where are we now?

    a. It would seem apparent that *Bolam* still applies to the first stage of the two-stage *Montgomery* approach to consent, per *Duce -v- Worcester Acute Hospitals NHS Trust* [2018] EWCA Civ. 1307;

    b. Arguably, such an approach inconsistent with the paternalistic approach, which the Supreme Court in *Montgomery* was striving to end, especially in the context of innovative treatments, namely in the very context in which patient autonomy ought perhaps to be at the fore; and

    c. 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 by reference to, amongst other issues, the touchstone of 'rationality.'

18. If any questions arise upon the reading of this note, or generally, please do not hesitate to contact me in Chambers.

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To view Christopher's profile, please click here.