

Consent in clinical negligence



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The Test: *Montgomery v Lanarkshire Health Board* [2015]

UKSC 11

- ▶ *"the doctor is ... 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"* [87].
- ▶ *"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"* [87].

The Test: *Montgomery*

- ▶ What makes a risk material?
 - ▶ Whether a reasonable patient would attach significance to the risk and whether this particular patient would attach significance to the risk.
 - ▶ The SC specifically referred to the following factors [89]:
 - ▶ The nature of the risk;
 - ▶ The effect it would have on the patient's life if it materialized;
 - ▶ The importance of the intended benefits of the treatment to the particular patient;
 - ▶ The alternatives available; and
 - ▶ The risks associated with the alternatives.
- ▶ Not simply a matter of percentages.
 - ▶ Although higher percentages are likely to make a risk more material.

The Test: *Montgomery*

- ▶ The risk needs to be communicated – was the patient made aware?
 - ▶ *"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" [90].*
 - ▶ The patient needs to understand, not just sign, the consent form.
 - ▶ There should be evidence to that effect.

GMC Guidance

- ▶ Took effect in November 2020
- ▶ [Decision making and consent \(gmc-uk.org\)](https://www.gmc-uk.org)
- ▶ Seven principles of consent
- ▶ Principle 4: “doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action”
- ▶ Principle 5: “Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements. “

GMC Guidance

The information you give patients

10 You must give patients the information they want or need to make a decision. This will usually include:

a diagnosis and prognosis

b uncertainties about the diagnosis or prognosis, including options for further investigation (See also paragraphs 25–26 on Dealing with uncertainties.)

c options for treating or managing the condition, including the option to take no action

d the nature of each option, what would be involved, and the desired outcome

e the potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action. (By 'harm' we mean any potential negative outcome, including a side effect or complication. See also paragraphs 21–24.)

GMC Guidance

11 You must try to make sure the information you share with patients about the options is objective. You should be aware of how your own preferences might influence the advice you give and the language you use. When recommending an option for treatment or care to a patient you must explain your reasons for doing so, and share information about reasonable alternatives, including the option to take no action. You must not put pressure on a patient to accept your advice.

12 You should not rely on assumptions about:

a the information a patient might want or need

b the factors a patient might consider significant

c the importance a patient might attach to different outcomes.

GMC Guidance

13 Other examples of information that might be relevant and, if so, should be shared with patients include:

a whether an option is an innovative treatment designed specifically for their benefit

b whether there is a time limit on making their decision and what the implications of delaying might be

c the names and roles of key people who will be involved in their care, and who they can contact (and how) if they have questions or concerns

d their right to refuse to take part in teaching or research

e their right to seek a second opinion

f any bills they will have to pay

g any conflicts of interest that you or your organisation may have

h any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.

GMC Guidance

Supporting patients' decision making

27 Patients need relevant information (see paragraph 10) to be shared in a way they can understand and retain, so they can use it to make a decision. To help patients understand and retain relevant information you should:

- a** share it in a place and at a time when they are most likely to understand and retain it
- b** anticipate whether they are likely to find any of it distressing and, if so, be considerate when sharing it
- c** accommodate a patient's wishes if they would like to record the discussion (See paragraph 53 on Visual and audio recordings.)
- d** accommodate a patient's wishes if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions and/or help them make decisions
- e** use an interpreter or translation service if they have difficulty understanding spoken English
- f** share it in a format they prefer - written, audio, translated, pictures or other media or methods
- g** give them time and opportunity to consider it before and after making a decision.

Key principles of consent cases: cause of action

- ▶ There is no freestanding cause of action for failure to consent alone: *Shaw v Kovac* [2017] EWCA Civ 1028.
 - ▶ Hearing for the assessment of damages, various traditional heads of loss awarded.
 - ▶ C argued on appeal that a separate head of loss should have been awarded for “unlawful invasion of personal rights”.
 - ▶ Appeal dismissed.
 - ▶ No entitlement to a separate head of loss arising from the nature of the tort, that is properly compensated by general damages in the usual way.

Key principles of consent cases

- ▶ Breach of duty
- ▶ *Hassell v Hillingdon Hospitals NHS Foundation Trust*
[2018] EWHC 164 (QB)
- ▶ Patient not informed of the risk of paralysis prior to spinal surgery
- ▶ Also not told of conservative treatment options
- ▶ Judge found that C would not have had surgery with a proper consent process

Key principles of consent cases

- ▶ Breach of duty
- ▶ *Ollosson v Lee* [2019] EWHC 784 (QB)
- ▶ About risks of vasectomy
- ▶ "small risk" is an acceptable way of describing risk – no need for precise percentages
- ▶ *"156. In the light of all that evidence, was it adequate to describe the risk as 'small'? In my judgment it was. Of course 'small' may mean different things to different people, but the word 'small' is clearly an everyday word which encompasses and satisfactorily conveys the level of risk involved. I agree with Mr Parkinson that a 'small' risk does not imply a small impact. I would in fact, in agreement with Mr Reynard, be less comfortable about describing the risk as 'rare' as the BAUS consent form in 2012 51 labelled it, albeit in the context of providing a percentage. While adequate information must be given to a patient without him having to ask a question, a patient told of a 'small' risk can ask for further clarification."*

Key principles of consent cases

- ▶ Breach of duty
- ▶ *Connolly v Croydon Health Services NHS Trust* [2015] EWHC 1339 (QB)
- ▶ Catheterisation for an angiogram – consent information misleading, but not breach of duty
- ▶ *“32. Implicit within the scope of the duty to provide sufficient information to permit a patient to make a proper informed choice is the obligation to provide accurate information. The giving of inaccurate or misleading information to a patient may vitiate their consent and amount to negligence that gives rise to a cause of action if causation of damage is established. However, English law has avoided adopting the American doctrine of informed consent. (See Lord Diplock in Sidaway [Supra] at 894.)”*

Key principles of consent cases

- ▶ Breach of duty
- ▶ *Thefaut v Johnston* [2017] EWHC 497
- ▶ Over-optimistic information about surgery
- ▶ Did not advise the patient properly of the option of not having surgery
- ▶ Important point: later advice thought by the patient to have superseded earlier advice

Key principles of consent cases

- ▶ Breach of duty
- ▶ *Gallardo v Imperial College Healthcare NHS Trust* [2017] EWHC 3147
- ▶ Surgeon did not originally make C aware that the stomach tumour removed was malignant
- ▶ When the malignancy was first identified C was in ICU
- ▶ Failure to properly inform C of the outcome of the treatment, prognosis, and follow-up options
- ▶ Discussion should occur as soon as C well enough to participate fully in the discussion and take in information

Key principles of consent cases

- ▶ *Jones v Royal Devon and Exeter NHS Foundation Trust* [2015] 9 WLUK 420
- ▶ C consented to operation on the basis that a particular surgeon with a national reputation would be doing it
- ▶ A different surgeon did the surgery and the non-negligent complication of cauda equina arose
- ▶ Risk was very small and probably would not have occurred had the original surgeon done the surgery

Key principles of consent cases

- ▶ *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307
- ▶ State of the knowledge at the time relevant to what risks should be warned about
- ▶ *“The judge is finding that in 2008 there was insufficient understanding among gynaecologists of the existence of a risk of “chronic pain, or of neuropathic (or nerve) pain, whether that was long term or short term” to justify the imposition of a duty to warn of such a risk. That reasoning is consistent with the Montgomery approach – a clinician is not required to warn of a risk of which he cannot reasonably be taken to be aware.”*[43]

Key principles of consent cases

- ▶ *Correia v University Hospital of North Staffordshire NHS Trust* [2017] EWCA Civ 356
- ▶ Allegedly negligent foot surgery because the 3rd step, relocation of the nerve was missed out
- ▶ However, surgical negligence does not vitiate consent:
- ▶ *“However, it does not follow that the negligent omission of the third stage negated her consent. In my judgment it did not. The negligent failure to deal appropriately with the nerve ending did not make this either a different operation for the purposes of consent, nor an operation for which specific consent was required. It was a breach of duty which had the potential to give rise to liability for damages if all the other elements of the tort of negligence were made out. The claimant made an informed choice to have the surgery”* [26]

Factual causation

- ▶ Factual causation: all about the counter-factual and proving/ disproving it.
- ▶ But for the failure to obtain informed consent, what would C have done differently on the BOP?
 - ▶ Would they have elected the surgery or some other alternative on the BOP?
- ▶ Evidence:
 - ▶ For C:
 - ▶ Witness statement explaining what they think they would have done and why.
 - ▶ If related to a family member's/ friend's experience, obtain evidence in relation to that.
 - ▶ Statistics as to what most people choose.
 - ▶ For D:
 - ▶ Absence of any positive evidence in support of the expressed counter-factual.
 - ▶ Evidence pointing the other way.
 - ▶ Statistics as to what most people choose.

Factual causation: reliability of the evidence

- ▶ Often, factual disputes over consent processes turn on the patient's recollection vs the doctor's account of what their usual practice was at the time.
- ▶ Factors influencing reliability:
 - ▶ The fallibility of memory, particularly in the context of litigation: *Gestmin* [2013] EWHC 3560 (Comm) [paras 15 to 22].
 - ▶ "*Our memories of past events are revised to make them more consistent with our present beliefs*" [15].
 - ▶ "*the process of civil litigation itself subjects the memories of witnesses to powerful biases*" [19].
 - ▶ Hindsight: *Diamond v Royal Devon and Exeter NHS Foundation Trust* [2019] EWCA Civ 585.
 - ▶ Evidence of "*usual practice*" versus the specific consultation.

Factual causation: hindsight

- ▶ *Diamond v Royal Devon and Exeter NHS Foundation Trust* [2019] EWCA Civ 585:
 - ▶ C gave evidence that but for the negligent failure to advise she would not have had the procedure.
 - ▶ C's evidence was rejected at first instance, as upheld on appeal.
 - ▶ At first instance:
 - ▶ *"I conclude that the Claimant genuinely believes and has convinced herself that she would have opted for a suture repair, if she had been provided with all the relevant information. Accordingly, what she said to me in evidence accords with her honestly held belief. But it does not of course, automatically follow that what she now believes to be the case would in fact have been the position at the material time"* [47].
 - ▶ *"I have weighed up, as I must, all the available evidence (both objective and subjective) on this issue and I have come to the conclusion, on the balance of probabilities that even if she had been in a position to give informed consent, exactly the same procedure would have been undertaken"* [48].

Factual causation: hindsight

- ▶ *“Having heard and seen the Claimant, my reasons for coming to this view are as follows:*
 - i. She would have been told that a primary suture repair was almost certain to fail ultimately and likely to fail within 2 years.*
 - ii. She would have been told that a mesh repair stood a very high chance of success.*
 - iii. She would have been told that virtually all surgeons would do a mesh repair in these circumstances.*
 - iv. Mr Wajed would have given her the strongest possible advice that she should have a mesh repair.*
 - v. Mr Wajed would have expressed enormous reluctance to do a suture repair.*
 - vi. She would not have been told that she could not have children in the future – only that there were certain risks. (That to my mind is a crucial distinction.)*
 - vii. She was single at the time. A pregnancy was not within her immediate contemplation albeit that she had thought about having a child two years earlier with her ex-partner.*
 - viii. Overall, in the face of this information, looking at the matter both objectively and subjectively in the face of the advice which would have been given to her, it would have been irrational for her to opt for a suture repair; and I find that she is not a person who would act irrationally”[49].*

- ▶ *“I stress that, in my judgment, even if the operation had been performed two months' earlier when the lesion may have been a little smaller, a mesh repair would still have been the outcome”[49].*

Factual causation: other examples

- ▶ *Plant v El Amir* [2020] EWHC 2902 (QB):

- ▶ Claim for alleged failure to obtain informed consent prior to elective eye surgery.
- ▶ C relied on her ws dated 2 years post-surgery; she couldn't be cross-examined due to dementia [12]. D relied on a contemporaneous document that indicated risks were discussed and consent was obtained. The records were generic and had missing information.
- ▶ J: on balance D **did not** advise.
 - ▶ C's ws "*had the ring of truth and [was] inherently plausible and ... consistent with ... her letter of complaint*" [33].
 - ▶ "*there is no evidence that the pro forma checklist of advice to patients at consultation document was discussed with C in detail by Dr Qureshi and I do not accept at face value the cursory notes that merely record that there was a long discussion and C was aware that AMD may progress and the medical risks of surgery*" [21].
 - ▶ "*I cannot conclude that the pro forma documents ... were explained and gone through with [C]*" [82].

Factual causation: other examples

- ▶ *Brint v Barking UH NHS Trust* [2021] EWHC 290 (QB):
 - ▶ Claim arising from a routine CT scan that caused an extravasation injury, C's case was that D failed to advise of that risk.
 - ▶ C's recollection versus D's account of his usual practice. In XIC D's doctor described advising of the risk as his "*usual practice*"; in XX he said he was "*certain*" he had advised [29].
 - ▶ J: on balance D **did** advise.
 - ▶ "*I found [C's] evidence on the whole to be unconvincing and unreliable*" [9].
 - ▶ "*although [D's doctor's] recollection is probably significantly influenced by his usual practice there is no reason for me to conclude that he did not follow his usual practice on this occasion*" [34].
 - ▶ A records entry two days post-scan "*confirms there was some significant discussion ... in accordance with his usual practice*" [34].

Medical causation

- ▶ Would the outcome have been any different?
- ▶ Need to ensure carefully pleaded – and the difference between “would” and “should”.

Key principles of consent cases

- ▶ *Correia v University Hospital of North Staffordshire NHS Trust* [2017] EWCA Civ 356.
 - ▶ Surgeon advised appropriately of the procedure that ought to have been carried out and associated risks; but the surgery was negligently performed.
 - ▶ CA: the fact that the surgery was negligently performed did not vitiate C's consent: she made an informed decision to have the surgery: the injury that materialised was not "intimately linked" to the duty to warn.
 - ▶ C had sought to rely on the exceptional causation principle from *Chester v Afshar* but failed. CA noted that a C seeking to rely on it ought to plead that case and support it with evidence.

Key principles of consent cases

- ▶ The CA gave guidance on *Chester v Afshar*.
- ▶ *“On any view the facts of Chester v. Afshar were unusual. The defendant neurosurgeon advised the claimant to undergo an operation on her spine but failed to explain that, if performed without negligence, the procedure carried a small (1-2%) unavoidable risk of a neurological damage leading to a disabling condition. The claimant agreed to the procedure on a Friday and the operation was performed on the following Monday. She subsequently developed the disabling condition which left her partially paralysed, and sued the surgeon for negligence.”*[13].
- ▶ *“In these circumstances, claimants had needed to show that, if a relevant warning had been given, they would not have undergone the procedure. That finding was not made in Chester v. Afshar. The trial judge held that the defendant had not performed the operation negligently, but that he had negligently failed to warn the claimant of the risks of developing the disabling condition and that, if she had been aware of the risks, the claimant would have sought advice on alternatives to surgery and the operation would not have taken place when it did. The judge held that there was a sufficient causal connection between the failure to warn of the inherent risks of the operation and the damage sustained by the claimant, and that the link was not broken by the possibility that the claimant might have consented to the surgery in the future. The Court of Appeal dismissed the defendant's appeal and he appealed to the House of Lords.”*[13].

Key principles of consent cases

- ▶ *Chester v Afshar* HOL:
- ▶ *“For some the choice may be easy - simply to agree to or to decline the operation. But for many the choice will be a difficult one, requiring time to think, to take advice and to weigh up the alternatives. The duty is owed as much to the patient who, if warned, would find the decision difficult as to the patient who would find it simple and could give a clear answer to the doctor one way or the other immediately.”*[86].
- ▶ *“To leave the patient who would find the decision difficult without a remedy, as the normal approach to causation would indicate, would render the duty useless in the cases where it may be needed most. This would discriminate against those who cannot honestly say that they would have declined the operation once and for all if they had been warned. I would find that result unacceptable. The function of the law is to enable rights to be vindicated and to provide remedies when duties have been breached. Unless this is done the duty is a hollow one, stripped of all practical force and devoid of all content. It will have lost its ability to protect the patient and thus to fulfil the only purpose which brought it into existence. On policy grounds therefore I would hold that the test of causation is satisfied in this case. The injury was intimately involved with the duty to warn. The duty was owed by the doctor who performed the surgery that Miss Chester consented to. It was the product of the very risk that she should have been warned about when she gave her consent. So I would hold that it can be regarded as having been caused, in the legal sense, by the breach of that duty.”*[87].

Summary/Practical points

▶ If for C:

- ▶ Plead the counter-factual i.e. but for the negligent failure to obtain informed consent, on the BOP C would have done x.
- ▶ Include C's detailed recollection in their statement, including reasons and evidence in support of those reasons.
- ▶ Be wary of matters influenced by hindsight. Test your client's evidence appropriately.

▶ If for D:

- ▶ Test whether your client's evidence is based on usual practice or specific recollection.
- ▶ Check whether your client's evidence is supported by the contemporaneous records; if not can they explain why not.
- ▶ Check whether the records indicate the likely counter-factual.



Next seminar: Wednesday 20 April on Causation

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