Law of Consent and Reasonable treatment options post McCulloch

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17 November 2023

Pre Montgomery

- *Sidaway v Board of Governors of the Bethlehem Royal Hospital* [1985] AC 871
- Held that the professional practice test as per *Bolam* (here, *Hunter v Hanley*) applied to discussions about treatment options between a doctor and their patient

Sidaway

- Lord Scarman dissented and said:
- “In my view, the question whether or not the omission to warn constitutes a breach of the doctor's duty of care towards his patient is to be determined not exclusively by reference to the current state of responsible and competent professional opinion and practice at the time, though both are, of course, relevant considerations, but by the court's view as to whether the doctor in advising his patient gave the consideration which the law requires him to give to the right of the patient to make up her own mind in the light of the relevant information whether or not she will accept the treatment which he proposes.”

Other cases

- *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR 53
- A doctor should normally inform a patient of a "significant risk which would affect the judgement of a reasonable patient."
- *Chester v Afshar* [2005] 1 AC 134
- A doctor's duty is to provide information "to enable patients of sound mind to make for themselves decisions intimately affecting their own lives and bodies"
- Commonwealth authority
- *Reibl v Hughes* [1980] 2 SCR 880
- *Rogers v Whitaker* (1992) 175 CLR 479

Montgomery v Lanarkshire Health Board 2015 SC (UKSC) 63

- Test for whether a doctor (in this case) has obtained the informed consent of the patient is no longer applied by reference to the *Hunter v Hanley* test
- Rather, the test is to consider what the reasonable patient might wish to know. This is a matter for the court
- The court stated that the model of the relationship between doctor and the patient is no longer based on medical paternalism
- Acknowledged that patients are persons with their own rights and views on matters and akin to customers exercising choices
- Recognition of developments in patients sourcing their own information from the internet in particular
- "it would be a mistake to view patients as uninformed, incapable of understanding medical matters or wholly dependent upon a flow of information from doctors."

Montgomery

- Paragraph 87
- “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. 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”

Subsequent cases

- *Britten v Tayside Health Board* [2016] SC DUN 75
- "It seems to me that the question of whether an alternative treatment is or is not reasonable must be a matter for the court to assess on the basis of the evidence presented to it. That will include the views of the medical experts, but also the evidence of the Pursuer, so as to determine whether a reasonable person, in the Pursuer's position, might reasonably consent to such treatment"

AH v Greater Glasgow Health Board 2018 SLT 535

- Pursuers argued that what would be regarded as a reasonable alternative treatment is one which should be defined by the patient
- The defenders argued that the test should be as per *Hunter v Hanley*
- A doctor is not under a duty to advise the patient of an alternative treatment if it was not considered by the doctor to be a reasonable alternative

AH

- “In my opinion the submissions for the doctors are to be preferred. If the pursuers are right the doctor may well be obliged to advise the patient of alternative treatments which he or she as a doctor would not consider as clinically suitable for the patient.”
- “What the treating doctor cannot do is to withhold information about a reasonable alternative treatment and the risks associated with it on the basis of their own preferences. If a treatment is reasonable and available it should be discussed with the patient.”

AH

- Emphasized the importance of dialogue between doctor and patient but that this only went so far
- “It may well be that during that process the availability of other treatments may be discussed including those which the doctor may consider not clinically advisable. A good doctor will no doubt explain the reasons for not pursuing a particular alternative. However as a matter of law I do not consider that a doctor can be held to be in breach of a duty to the patient for failing to advise on an alternative treatment which if performed by the doctor would be a breach of their duty of care to the patient.”

Taylor v Dailly Health Centre [2018] CSOH 91

- Case of GP negligence
- Lord Tyre held that
- Quoting from Montgomery, he said :
- “at paragraph 82 the court drew a clear distinction between "…on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved".
- The former role was described (paragraph 83) as "an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling with the expertise of members of the medical profession".

Taylor

- *Montgomery* :
- "The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a *non sequitur* to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions."

Duce v Worcestershire Acute Hospitals NHS Trust [2018] 6 WLUK 96

- Case about information given about the risks of proceeding with an operation
- Not about reasonable alternative treatments as such therefore
- However, in the context of warning about risks the court distinguished between, firstly, knowledge of the risks which was to be determined by the professional practice test of *Bolam*
- And, secondly, the duty to warn of such risks which is not (as per *Montgomery*)

Duce

- Court set out a two stage test for the duty of care to inform as follows :
- "(1) What risks associated with an operation were or should have been known to the medical professional in question. That is a matter falling within the expertise of medical professionals…
- (2) Whether the patient should have been told about such risks by reference to whether they were material. That is a matter for the Court to determine …. This issue is not therefore the subject of the *Bolam* test and not something that can be determined by reference to expert evidence alone…"

Duce

- Useful comments on the test of materiality of risk:
- "Factors of relevance to determining materiality may include: the odds of the risk materialising; the nature of the risk; the effect its occurrence would have on 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 associated with them."

Bayley v George Eliot Hospital NHS Trust [2017] EWHC 497 (QB)

- “The Supreme Court gave some guidance on what "material" meant in the context of risk, but "material" was not the qualification applied to the provision of information as to alternative treatments. The concept of materiality has an obvious application to risks, but the question of what is a reasonable treatment is a different one, and the concept of materiality is not such an easy fit. The better approach is to consider what "reasonable" means in this context, rather than importing another word. I am not really assisted by trying to draw an analogy between the two. However, what does assist is the approach of the courts in these two cases to the process of assessing (there) what is material. For whilst what is material is a different concept to what is reasonable, both involve the court making a value judgment.”
- Adopted a more holistic approach to how a court would consider was a reasonable alternative treatment
- Did not seem to be only one supported by expert evidence as per *Bolam*

What is “treatment” ??

- *Tasmin v Barts Health NHS Trust* [2015] EWHC 3135 (QB)
- Defenders tried to argue that taking fetal blood samples and allowing birth to continue was not medical “treatment”
- Rejected by the court as FBS was part of labour which is clearly medical treatment
- Where do you draw the line, if any though ?
- Do investigative procedures which do not treat in any way fall within *Montgomery* ?
- Does medical treatment = medical care ?

Material risks

- Test of materiality is a subjective/objective one - *Thefout v Johnston* [2017] EWCH 497 (QB)
- *A v East Kent Hospitals Trust* [2015] EWHC 1038 (QB)
- Birth case where claimant said she was not advised of a chromosomal disorder at 28 weeks gestation and whether she would have sought an amniocentesis if given this information
- Court held no. Risk was only 1 in 1,000 (court rejected expert evidence that risk was between 1-3% which would have mandated being mentioned to the claimant)
- Also useful comment on materiality of risk in *Tasmin*

Conclusions pre McCulloch

- Following on from Montgomery, the law was not consistently and clearly applied on how a court would define a "reasonably alternative treatment"
- The law appeared on balance to more support it being defined as per *Hunter v Hanley*
- But not wholly clear at all
- Issues arose regarding the definition of "material risk"
- What happens if advice is given on material risks but the wrong advice on the actual risks if given ?

And so to McCulloch….

- Jennifer McCulloch & others v. Forth Valley Health Board [2020] CSOH 40
- Part One – The Outer House
- **First admission**
- 23 March – Emergency admission
- 24 March - Admission to ITU
- 26 March – First review by Dr Labinjoh
- Review principally to consider the findings of two echocardiograms taken in ITU.

McCulloch – the Outer House

- “This man’s presentation does not fit with a diagnosis of pericarditis. He has been unwell with weight loss for months and presents with vomiting, abdo [ie abdominal] pain, fever and hypotension, pleuritic chest pain. Anaemic on admission at 97. CRP [ie C- reactive protein] 40. His JVP [ie jugular venous pulse] was not elevated making significant pericardial constriction very unlikely. I will discuss with Dr Woods [sic] who was exploring immunocompromise, malignancy. Care to continue under general medicine. I’ll review echo”
- Discharge on 30 March

McCulloch – the Outer House

- Second admission
- 1 April – Readmitted
- 2 April – Third Echocardiogram performed
- 3 April – review by Dr Labinjoh
- "I note echo, essentially unchanged. No convincing features of tamponade or pericardial constriction. On examination Tachycardia BP 80 systolic - no palpable paradox - no oedema - JVP low RR20 - All of which go against pericardial constriction. The effusion is rather small to justify the risk of aspiration v possible diagnostic utility. I am not certain where to go for a diagnosis from here. Happy to liaise. Please keep us informed."
- Discharged on 6 April

McCulloch – the Outer House

- Proof heard in January 2020 before Lord Tyre
- "The Lord Ordinary found that Dr Flapan's view had the support of clinical experience that patients who are prescribed NSAIDs usually get better and any pericardial effusion usually diminishes. He noted that gastric protection measures could be taken to minimise side effects and liver function could be monitored. He also found that there was logical support for Dr Bloomfield's view that there were good reasons not to prescribe NSAIDs to Mr McCulloch. This was not a straightforward case of acute pericarditis: the diagnosis remained uncertain. There was no study-based evidence in medical literature that NSAIDs prevent the development or progression of pericardial effusions, or that the effect of reduction of inflammation is reduction of the size of the effusion. There was no evidence from clinical trials that NSAIDs alter the natural history of pericardial effusions even if they successfully treat pain and inflammation. Patients often simply get better on their own. He found that "neither of these views" (Dr Flapan and Dr Bloomfield) could be described as unreasonable or lacking in logical support (para 91).

McCulloch – the Outer House

- *Hunter v. Hanley test*
- "If the opinion of Dr Bloomfield that Dr Labinjoh adhered to a usual and normal practice is to be rejected, I require to be satisfied that that opinion is not reasonable and cannot logically be supported" (para 66).
- *Montgomery*
- "*Montgomery* imposes an obligation on the doctor to discuss the risks associated with a recommended course of treatment and to disclose and discuss reasonable alternatives. It does not go so far as to impose upon the doctor an obligation to disclose and discuss alternatives that he or she does not, in the exercise of professional judgement, regard as reasonable. If the doctor is wrong either about the risks of the recommended course or about the reasonableness of any alternative, then he or she might be liable for any consequent loss or injury, but that would be decided by application of the *Hunter* v *Hanley* test. "
- The Lord Ordinary agreed with the decision of Lord Boyd in *AH* v *Greater Glasgow Health Board* [2018] CSOH 57, 2018 SLT 535 ("*AH*") in which a similar argument by the pursuer based on *Montgomery* was rejected. In that case it was held that a doctor was not under a duty to advise the patient of an alternative treatment if it was not considered by the doctor to be a reasonable alternative.

McCulloch – the Outer House

- "In the light of his findings in relation to the prescription of NSAIDs and the applicable legal test, the Lord Ordinary concluded that this was not a reasonable alternative treatment which was required to be discussed with Mr McCulloch. As he explained, Dr Labinjoh "did not prescribe NSAIDs because she did not, in her professional judgement, regard it as appropriate to do so when Mr McCulloch said that he was not in pain, and where there was no clear diagnosis of pericarditis" (para 112); and this was a judgment supported by the evidence of Dr Bloomfield whose opinion was neither unreasonable nor illogical. In these circumstances, "there was, accordingly, no risk in a recommended course, or a reasonable alternative, to discuss with him. Properly analysed, the pursuers' complaint is that Dr Labinjoh was negligent in her professional assessment, not that she identified a reasonable alternative (prescription of anti-inflammatories) but then failed to discuss it with Mr McCulloch" (para 112). He accordingly concluded that "no case based on failure to advise of the risks of a recommended course of treatment, or of alternative courses of treatment, along the lines of *Montgomery*, has been made out" (para 114)"

McCulloch – the Inner House (part deux)

- [2021] CSIH 21
- Reclaiming motion and cross appeal
- "The Inner House …….noted a number of facts which had been established in evidence in relation to the prescription of NSAIDs …. It stated that the evidence that NSAIDs were commonly used in the treatment of pericarditis requires to be seen in the context of the typical presentation and symptoms of pericarditis and that Mr McCulloch presented a complex picture. After looking at medical literature, it concluded….that "the literature does not seem to support the assertion that NSAIDs have a benefit beyond pain relief".
- The Inner House agreed with Lord Boyd's analysis in *AH* and the Lord Ordinary's decision that "*Montgomery* has no application in the circumstances of the present case" (para 40)"

McCulloch (Supreme Court)

- [2023] UKSC 26
- The two principal issues on appeal were:
- (1) What legal test should be applied to the assessment as to whether an alternative treatment is reasonable and requires to be discussed with the patient?
- (2) In particular, did the Inner House and Lord Ordinary err in law in holding that a doctor's decision on whether an alternative treatment was reasonable and required to be discussed with the patient is determined by the application of the professional practice test found in *Hunter v Hanley* and *Bolam*?
- Thereafter, If the Inner House and the Lord Ordinary did so err in law then various causation issues potentially arise, including whether they are a matter for this court.

McCulloch (the Supreme Court)

- "What is the correct legal test to be applied to the assessment as to whether an alternative treatment is reasonable and requires to be discussed with the patient? And did the lower courts err in law in deciding that the correct legal test is the professional practice test found in *Hunter v Hanley* and *Bolam*?"
- The correct legal test is the professional practice test as applied by the lower courts [PARA 56]
- i.e. the correct legal test to be applied to the question of what constitutes a reasonable alternative treatment is the professional practice test found in *Hunter v Hanley* and *Bolam*.

McCulloch (Supreme Court)

- SIX REASONS for deciding that the professional practice test is the correct legal test in respect of reasonable alternative treatments
- Consistency with Montgomery
- Consistency with Duce
- Consistency with medical professional expertise and guidance
- Avoiding an unfortunate conflict in the doctor's role
- Avoiding bombarding the patient with information
- Avoiding uncertainty

McCulloch (Supreme Court)

- TWO POSSIBLE QUALIFICATIONS OF THE APPLICATION OF THE PROFESSIONAL PRACTICE TEST IN THE CONTEXT OF REASONABLE ALTERNATIVES
- whether there should be an additional filter turning on whether it is reasonable for a doctor to inform the patient of all reasonable alternative treatments?
- whether the doctor is under a duty of care to inform the patient of a possible alternative treatment that, applying the professional practice test, he or she does not regard as a reasonable alternative treatment but where the doctor is aware (or perhaps ought to be aware) that there is a responsible body of medical opinion that does regard that alternative treatment as reasonable.

McCulloch (Supreme Court – the final word?)

- What do we take from decision?
- Greater certainty for the legal and medical profession.
- Consistency between judgements and jurisdictions.
- What's next?

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