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1

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LEGAL ISSUES IN MESH CASES
(And some practical solutions)

Laura Elfield
Barrister, Accredited Mediator

Lelfield@9goughchambers.co.uk

2

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Breach of Duty: Bolam / Bolitho

Don't forget this potential cause of action! – eg negligent surgery; wrongly diagnosing SUI.

- ***Bolam***: A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.
  - ***Bolitho:*** if the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.
  - So – doctor's opinion of what the practice was is still the starting point, supplemented by asking if the doctor's view is indeed reasonable.

3

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Montgomery v Lanarkshire [2015] UKSC 11

- Diabetic small mother, large baby
- Risk of shoulder dystocia 9 – 10%
- Risk of brachial plexus injury in cases of dystocia – 0.2%
- Risk of cerebral palsy less than 0.1%
- Shoulder dystocia occurred, baby was deprived of oxygen resulting in severe disabilities.
- D did not inform C of risks, or offer C-section on the basis that the doctors considered the risk of grave problems from dystocia was very small and it was D's view that if women were advised of the risk they would all opt for C section which was not in the maternal interest
- SC accepted that D's decision not to advise C of the risk accorded with a responsible body of opinion. BUT – in wholesale review of law on informed consent held – C should have been told of the risks of shoulder dystocia and had the alternative course of treatment – namely C section – explained and discussed with her.

4

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Montgomery v Lanarkshire [2015] UKSC 11

- Key paras at 81, 85, 87 – 90 of SC decision.
- An adult of sound mind is entitled to decide which, if any, of the available treatment options to undergo and her consent must be obtained before treatment interfering with her bodily integrity is undertaken.
- **Doctor under a duty to take reasonable care to ensure that a patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments.**
- The doctor's role involves dialogue – the aim of which is to ensure that the patient understands the seriousness of her condition and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives so that she is in a position to make an informed decision. This role will only be performed effectively if the information is comprehensible.
- The approach to the law attempts to treat patients as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks; accepting responsibility for the taking of risks affecting their own lives; and living with the consequences of their choices.

5

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Montgomery v Lanarkshire [2015] UKSC 11

- The test of materiality is whether, in the circumstances, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor was or should reasonably be aware that the particular patient would be likely to attach significance to it.
- The assessment of whether a risk is material cannot be reduced to percentages. The assessment is fact sensitive and sensitive also to the characteristics of the patient.
- Non-exhaustive factors include: the nature of the risk; the effect which 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 involved in those alternatives.
- There remains a limited therapeutic exception – unlikely to be relevant to mesh claims – doctor is entitled to withhold information as to a risk if doctor reasonably considers that its disclosure would be seriously detrimental to the patient's health; and in situations of necessity – eg where urgent treatment is required and patient is either unconscious or otherwise unable to make a decision.

6

When is a risk "material"?

- Mixed objective/subjective test:
  - whether, in the circumstances, a reasonable person in the patient's position would be likely to attach significance to the risk, or
  - the doctor was or should reasonably be aware that the particular patient would be likely to attach significance to it.
- In ***Thefaut v Johnston*** [2017] EWHC 497, QB Green J at 55 – 56 considered the extent to which the subjective element was relevant and the potential factors as follows:
  - *"Some characteristics of a patient are obvious: In particular that person's actual medical condition which would include its severity. Other personal factors may be less self-evident: such as the patient's tolerance for or stoicism towards pain, or the ability to manage pain. Other factors might be quite remote from the medical or physiological condition of the patient, such as the patients need to return to work, or the fact that the patient has suffered a recent event in his/her life (such as a bereavement or a divorce) which renders that person unusually fragile and (say) unwilling to take chances at that particular time".*

7

When is a risk "material" - Thefaut

- C succeeded in showing that the *"comforting and optimistic advice"* received *"failed to give her full and accurate advice about risks and benefits."*
- Note - D advised chance of surgery eliminating leg pain *"at least 90%"* and there was *"every chance"* that her back pain would settle as well. Expert evidence: in fact closer to 50% for back and 85% for leg. D described the risks of surgery as *"fortunately very small"* – a 0.1% risk of nerve damage. Again, Court concluded on basis of expert evidence it was 1% - a *"material difference"*. He did not advise up to 5% risk non-negligent surgery could exacerbate back pain. Advice not to undergo surgery discussed but not formally set out.
- Held - C was a cautious person by nature and would have rejected the surgery altogether if she had understood the chances in relation to the back pain.
- ***Thefaut*** also dealt with timing of discussion of risks – which was NOT immediately before the patient underwent surgery. There needed to be *"adequate time and space"* for a sensible dialogue and for free choice to be exercised.

8

When is a risk "material" - percentages?

- In ***A v East Kent Hospitals University NHS Foundation Trust*** [2015] EWHC 1038 (QB): C claimed that she should have been warned of the risk of chromosomal abnormalities while pregnant. D established the risk was theoretical or negligible - tests had excluded the kind of chromosomal abnormality in issue and the risk was 1 in 1,000. C's evidence – risk was 1 – 3%. Had her evidence been preferred (it wasn't), Court said she should have been warned.
- In ***Ollosson v Lee*** [2019] EWHC 784 – description of chronic risk of testicular pain post-vasectomy as *"small"* held sufficient to describe 5% risk.
- In ***Webster v Burton Hospitals NHS Foundation Trust*** [2017] EWCA Civ 62 there was *"emerging but recent and incomplete material showing increased risks of delaying labour"*. Had the mother been advised of these, as she should have been, she would have opted for induction and C would have avoided brain injury. Principal highly relevant in mesh cases (depending on date of claim).

9

When is a risk "material"

- In ***Negus v Guy's & St Thomas' NHS Foundation Trust*** [2021] EWHC 643 –C complained had not been warned of risks relating to implanting a smaller valve when undergoing aortic valve replacement surgery and that there was no discussion of implanting the largest possible valve, although this would involve a risk of ARE. Eady J - duty to warn that may need to undertake an ARE during a valve replacement operation, which may double the risks of the op but the duty did not extend to technical decisions such as eg size of valve, make and design of valve – ie the various possible choices that could arise intra-operatively and could only be determined by surgeon at that stage. Also - C would have had the op anyway.
- ***Malik v St George's University Hospital NHS Foundation Trust*** [2021] EWHC 1913 (QB): failure to discuss alternatives to surgery was in this case not unreasonable – a reasonably competent body of surgeons would have considered that there were no reasonable alternatives to surgery. Also – C would have had the op anyway.

10

Materiality

- In ***Duce v Worcester Acute Hospitals Trust*** [2018] EWCA Civ 1307: 2-fold approach:
  - What risks associated with the operation should have been known to the medical professional in question. That is a matter for experts.
  - Whether the patient should have been told about the risks by reference to whether or not they were material. That is a matter for the Court.
- ***Jones v Royal Wolverhampton Hospitals NHS Trust*** [2015] EWHC 2154 (QB): the importance of pleading materiality as fully and properly as possible was confirmed. Not only identification of risk but also C's case on its nature and materiality.

11

Causation & the risks of hindsight

- *C must still prove causation on "but for" basis (subject to any remaining* **Chester** *arguments – topic for another day): if properly advised would/wouldn't have opted for x course of treatment eg would have opted for PFMT rather than mesh.*
- *Consider what risk important –* ***Montgomery*** *- the risk of shoulder dystocia – itself a major obstetric emergency - rather than the more rare risks associated with it should it occur. D's own evidence – if warned C's of risk of shoulder dystocia would opt for C-section. Consider – likely response of* "women in general" .
- ***Webster v Burton*** *– subjective – her evidence: if any suggestion of risk to baby, would have wanted delivery; background in nursing; willingness to take responsibility for pregnancy.*
- *Objective element starting to be increasingly emphasised in case law.*

12

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Causation & the risks of hindsight

- In ***Pepper v Royal Free Hospital NHS Trust*** [2020] EWHC 310 (QB):
  - C underwent major surgery to remove pancreatic head, part of bile duct and gall bladder on basis of surgeon's assessment that likely to be suffering from pancreatic cancer.
  - She didn't have cancer & was left with long-term disability.
  - C said she hadn't been properly advised & wouldn't have had the operation if she had been.
- Objective evidence – C should have been advised that the risk of cancer was: *"greater than 50% and probably significantly more".*
- Held – C would have opted for surgery. Claim failed.

13

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Causation & the risks of hindsight

- In ***Pepper*** (citing ***Smith v Barking, Havering & Brentwood HA*** [1995] 5 Med LR 285):
  - "There is a peculiar d*ifficulty involved in this sort of case - not least for the plaintiff herself - in giving, after the adverse outcome of the operation is known reliable answers to what she would have decided before the operation had she been given proper advice as to the risks inherent in it. Accordingly, it would, in my judgment, be right in the ordinary case to give particular weight to the objective assessment. If everything points to the fact that a reasonable plaintiff, properly informed, would have assented to the operation, the assertion from the witness box, made after the adverse outcome is known, in a wholly artificial situation and in the knowledge that the outcome of the case depends upon that assertion being maintained, does not carry great weight unless there are extraneous or additional factors to substantiate it Of course, the less confidently the judge reaches the conclusion as to what objectively the reasonable patient might be expected to have decided, the more readily will he be persuaded by her subjective evidence".*

14

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Causation & the risks of hindsight

- In ***Diamond v Royal Devon and Exeter NHS Trust*** [2019] EWCA Civ 58:
  - *Breach of duty established in failing to warn of risks of hernia mesh repair in event of a pregnancy and that primary suture repair was an option, even if likely to fail.*
  - *C's evidence – would have opted for primary suture repair – which 1st instance judge found to be truthful.*
  - *Held that a "rational patient" would not have opted for primary suture repair & C was not an "irrational person" – C failed on causation.*
  - *Decision upheld by CA.* Again – risks of hindsight emphasised.
- See also ***Keh v Homerton*** [2019] EWHC 548 (QB): judge held Deceased would have taken same course of action anyway – against evidence of widower.

15

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Importance of documentary evidence

- D usually has notes. C usually only has recollections.
- Recent authorities place emphasis on difficulties of relying on memory.
- *See:* **Gestmin v Credit Suisse** [2013] EWHC 3560 where Leggatt J emphasised the fallibility of memory, especially where past beliefs are concerned. At para. 18 he said:
- *"Our memories of past beliefs are revised to make them more consistent with our present beliefs. Studies have also shown that memory is particularly vulnerable to interference and alteration when a person is presented with new information or suggestions about an event in circumstances where his or her memory of it is already weak due to the passage of time ……all remembering of distant events involves reconstructive processes…*
- Leggatt J also emphasised the *"considerable interference with memory"* introduced in civil litigation by the procedure of preparing for trial (paras 19-20).

16

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Importance of documentary evidence

- ***Gestmin*** was followed in the clinical negligence context in **Mills v Oxford University Hospitals NHS Trust** *[2019] EWHC 936 (QB)* where the Court found that the documentary evidence as to what was discussed in consultation was a *"far more reliable guide"* than either the memory of C or the consultant. The Court also accepted the consultant's account of the nature of the information that he would ordinarily give.

- However in **Pepper** Geoffrey Tattersall QC noted that while in Gestmin it was said that: *"the best approach for a judge to adopt was to place 'little if any reliance at all on witnesses recollections of what was said in meetings and conversations and to base factual findings on inferences drawn from the documentary evidence and known or probable facts' had much to commend them, I believe that such dicta, although appropriate to commercial litigation, are inappropriate here".*

- *Good review of the principles/case law in* **Ismail v Joyce** *[2020] EWHC 3453 (QB).*

17

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Importance of documentary evidence

- ***Gestmin*** *is not a rule of law.*

- *Documentary evidence is still likely to trump unsupported oral recollections.*

- *However where "notes fall short, and are ambiguous and there are gaps", while the burden remains on C, in* **Asante v Guys and St Thomas' NHS Foundation Trust** *[2018] EWHC 2570 (QB) held that: "the Defendant should not have the benefit of those deficiencies, nor of unexplained lack of explanatory witness evidence".*

18

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Practice Points on Consent

- Early conferences with client and expert essential.
- Get expert to deal with:
  - What risks should have been known to consultant;
  - What treatment options were available;
  - What risks and benefits involved in the various treatment options;
  - Whether NICE and GMC guidelines complied with;
  - Is the information leaflet (if provided) up-to-date and/or comprehensive?
  - Review consent form, clinical notes and letters to GP.
  - What course would reasonable person have opted for and what do people opt for in their experience?
- Get C to deal with:
  - Obviously review consent form, clinical notes and letters to GP. Were any letters to GP also sent to C?
  - Factors on materiality – eg active sex life if relevant risk is dyspareunia; time and ability to undergo PFMT if that is a relevant option.
  - Causation – what would she have opted for and why?
  - Be aware of the risks of hindsight – evaluate this – likely to be the primary risk in case.
  - Did husband or partner attend with them? Can they assist? Did they discuss risks?

19

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LIMITATION

- The usual rules apply. Today is not a complete overview of limitation – just of points to look out for!
- LA S11(4): claim shall not be brought after expiration of 3 years from:
  - Date of accrual of cause of action; or
  - Date of knowledge (if later) of person injured.
- Subject to discretion to extend pursuant to LA S33.
- Most of these cases will hinge on date of knowledge and S33.

20

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The Estate of Mossa v Barbara Wise [2017] EWHC 2608

- C underwent surgery for urinary stress incontinence in January 2007 – Mossa, consultant gynae, inserts a TVT.
- C has initial improvement in symptoms but then relapse after about 6 months. Increasing pain and in July 2011 a heavy vaginal bleed. Investigations revealed erosion of the mesh.
- She underwent corrective surgery in September 2011.
- In January 2013, she had colposuspension and a hysterectomy.
- Proceedings issued against Mossa in July 2015.
- At that stage, Mossa in final stages of terminal illness and in hospital. Died unaware of proceedings.

21

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The Estate of Mossa v Barbara Wise [2017] EWHC 2608

- C argued DoK ran from when she obtained expert evidence in December 2014. Master Cook – no – September 2011 – date of the corrective surgery.
- She succeeds under S33 – notwithstanding death of Mr Mossa and this is upheld on appeal (noting the ambit of the discretion at 1st instance).
- On crucial question of whether it was still possible to have a fair trial on the available evidence – death was not determinative of the issue. It was unlikely Mossa would have any detailed recollection of C or his dealings with her; there was a written record of the consent procedure; D had oral evidence from the consultant in charge of the continence care clinic before Mr Mossa, who could give evidence as to usual practice.
- It was also relevant that medical professionals were under a duty to keep accurate clinical records and it would be difficult for a doctor to allege he had provided significant information by way of dialogue which went well beyond what was recorded.
- There would be substantial prejudice to C if she were not permitted to proceed with her claim.

22

Limitation

Cf – ***Azam v University Hospital Birmingham NHS FoundationTrust*** [2020] EWHC 3384 (QB) – 18.5 year delay (21 years since surgery carried out) and death of surgeon did not prevent fair trial on issue of negligent surgery but did prejudice D on issue of consent.

23

Practice Points on Limitation

- Take early steps to agree an amnesty as to limitation, if possible!
- Consider both actual and constructive knowledge – will involve detailed review of medical records and steps taken by C to date to obtain advice (legal and medical).
- Don't be disheartened by limitation issues – S33 applies.
- It will be case dependent as to whether a preliminary hearing on limitation should be agreed to.
- Always plead S33 if limitation raised by D (or is likely to be).

24

Procedure – Mackintosh v Sheffield Teaching Hospitals NHS Foundation Trust [2020] EWHC 683 (QB)

- Master Cook stated that claim forms and statements of case contain words: "TVT/TOT/TVM mesh implant (consent) Litigation". Cases will then be assigned to him.
- He would not, at that stage, consider a preliminary system of co-ordinated case management in respect of numerous mesh claims being run by 3 firms of solicitors.
- He noted many cases were threatened which often did not materialise!
- It would be helpful if a bespoke pre-action protocol could be agreed with NHS resolution and this would accord with overriding objective.

25

Thank you for listening!

26