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Snow v Royal United Hospitals Bath NHS Trust

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Snow v Royal United Hospitals Bath NHS Trust [2023] EWHC (KB)

In a reserved judgment handed down on 13 January 2023, Judge Richard Roberts, sitting as a High Court Judge, ruled that negligent failures of clinical governance, informed consent and surgical technique at Royal United Hospitals Bath in 2015 resulted in a rectal cancer patient suffering from devastating pelvic nerve injuries.

The facts

On 28 September 2015 the Claimant was referred by his GP to the colorectal clinic at RUH Bath with a recent history of change in bowel habit associated with rectal bleeding.

Following an initial assessment on 15 October 2015, the Claimant underwent CT and MRI scans and a colonoscopy, which showed that he had a malignant mid-rectal tumour with significant spread to pelvic lymph nodes.

On 4 November 2015 the Claimant consulted a consultant colorectal surgeon, Mr Edward Courtney, at the private Bath Clinic. He was informed of the results of the investigations, and that his case would be discussed at the RUH Bath colorectal surgical multi-disciplinary team ('MDT') meeting the following day.

After the MDT meeting Mr Courtney telephoned the Claimant and advised him to see a consultant oncologist, Dr Emma de Winton, as he would probably require pre-operative short course radiotherapy ('SCRT'). He also told him that the necessary laparoscopic surgery would be at the RUH Bath under the NHS.

Judge Roberts rejected Mr Courtney's evidence that he also explained to the Claimant that because of his elevated body mass index, narrow male pelvis and low tumour, he would use a new laparoscopic technique to access the pelvis from below, called a transanal total mesorectal excision ('TaTME'), in which he and his colorectal surgical colleague, Mr Stephen Dalton had been trained.

Judge Roberts also rejected Mr Courtney's evidence that in a subsequent telephone call, he had not advised the Claimant to cancel a pre-operative appointment at RUH Bath under the NHS on 11 November 2015. In consequence, the Claimant did not undergo any process of formal informed consent by either surgeon prior to the surgery on 8 December 2015, after SCRT.

On 8 December 2015 a written consent was obtained by Mr Courtney for the TaTME procedure. It was common ground that a written consent on the day of surgery was not evidence of adequate informed consent under the principles established in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. Further, the Claimant was not informed that the surgeons had only performed the procedure once before, after completing a course in which they operated on two cadavers, or that there were any alternative surgical procedures.

The TaTME operation itself, performed by Mr Courtney and Mr Dalton, lasted for nearly 9 hours. In an extremely short operation record completed by Mr Dalton, it was recorded that there had been a difficult dissection, but otherwise no intraoperative complications were recorded.

Unfortunately, it later transpired that the Claimant had suffered from multiple serious intra-operative pelvic nerve injuries, resulting in total impotence, inability to ejaculate or to experience orgasm, inability to completely empty his bladder, and urgency and incontinence of urine. He also suffered from complete disruption of his internal anal sphincter, due to prolonged insertion of the anal access port, resulting in an increased frequency of anal incontinence.

The issues

The Claimant alleged that there had been a negligent failure to appraise him pre-operatively as to the relative benefits and material risks of TaTMe, compared with conventional laparoscopic or open TME. Conventional TME for rectal cancer, where access was obtained from above the tumour via the abdomen, rather than from below, had been the 'gold standard' for many decades.

He also alleged that there had been a negligent failure to inform him that both surgeons were on the very early stage of a 'learning curve', when it was known or ought to have been known that rates of complications were higher.

He also alleged that the Trust had failed to inform him of guidance on TaTME published by the National Institute for Health and Care Excellence ('NICE') in March 2015, informing patients that there was not enough evidence to know if the TaTME procedure was safe enough, and worked well enough, compared with alternative procedures.

He alleged that but for the negligence, he would have opted for conventional laparoscopic or open TME, which would have avoided the pelvic nerve injuries and their sequelae. He also alleged that the internal anal sphincter injury was negligently inflicted and would have been avoided.

The Trust made limited admissions of breach of duty in relation to the failure to discuss pre-operatively some material risks of TaTME. It denied that there were any reasonable alternative procedures, due to the Claimant's elevated BMI, narrow pelvis, and the position of the tumour low in the pelvis. In consequence a TME would have been doomed to fail, resulting in conversion to an abdominoperineal excision of rectum ('APER'), with formation of a permanent colostomy.

It asserted that the Claimant would therefore have opted for TaTME in any event. It denied that laparoscopic or open TME would have avoided the pelvic nerve injuries, as the outcomes for TaTME and TME were similar. It also denied that the internal anal sphincter injury was negligently inflicted.

The findings

Judge Roberts found that there had been negligent failures of clinical governance, of obtaining informed consent, and of intraoperative care. He found that the Claimant would have opted for a TME, thereby avoiding the pelvic nerve and internal anal sphincter injuries

Clinical governance

Judge Roberts noted, citing *Price v Cwm Taf University Health Board* [2019] PIQR P14, that failing to follow NICE guidance is not prima facie evidence of negligence, but there would need to be an explanation for not following its guidance. In this case the 2015 NICE guidance had required special arrangements for clinical governance, which Judge Roberts suspected had not been followed:

"69. *Initially, Mr Feeny said that it was not proportionate to disclose documents relating to governance procedures because the Defendant had admitted that the Claimant had not been properly consented. This position subsequently changed to being that there were documents relating to governance and procedures for implementing TaTME at the Hospital but they had all been lost. I find this unconvincing. In the absence of any witness statement or documentary evidence from the Defendant that it put in place special arrangements for the introduction of TaTME at the Hospital, I am unable to accept that all of the documents have been lost as this is implausible. There would be documents relating to approval from the local ethics committee or the local clinical governance committee. Furthermore, my findings below strongly suggest that there was a systemic failure by the Defendant to put in place special arrangements for the introduction of TaTME*."

Failures of training, mentoring and supervision

Judge Roberts found that RUH Bath had negligently failed to follow earlier guidance published by the Royal College of Surgeons of England for the introduction of new surgical techniques in their document "Good Surgical Practice", published on 29 August 2014:

"75. *I reject Mr Meleagros' [defence colorectal expert] evidence and find that the need for training, mentoring and supervision before introducing new surgical operations and procedures was known prior to 2015…I find that Mr Meleagros was "flying a kite" because training, supervision and mentoring were not referred to in the NICE documents. His argument was unsustainable and damaged his credibility… 86. I find that the Defendant was negligent in failing to provide a mentor for Mr Courtney and Mr Dalton. Further, it is concerning that far from acknowledging that a mentor was necessary, Mr Courtney suggested that in his case, one was unnecessary… 90. I find that the Defendant was negligent in failing to provide supervision during the Claimant's TaTME on 8 December 2015. Again, it is also concerning that Mr Courtney did not consider supervision to be necessary*."

Failures to record patient selection and adequate MDT minutes

Judge Roberts found that the Trust had negligently failed to follow the 2015 NICE guidance by failing to document the process of how the Claimant had been selected for TaTME [95]. He also found that the MDT minutes were incomplete [99]:

"*I find that the Defendant's record of the MDT is negligent and substandard in very material respects:*

i) *Most importantly, there is no record that a decision was made to carry out a TaTME, nor is there a record of a care plan. Indeed the MDT note does not state what operation was to be carried out on the Claimant.*

ii) *There is no record of alternative surgical procedures, namely TME carried out as a laparotomy or a laparoscopy, being considered.*

iii) *There is no record of the Claimant being carefully selected. Mr Courtney said that the selection of patients for TaTME was recorded in the note of the MDT, but there is no such record here.*

iv) *The names of the attendees are not recorded and they have not signed the note of the MDT. No separate record of attendees at the MDT has been disclosed and Mr Courtney did not say that such a record was kept in this case*."

Failures of consent on the day of surgery and of proceeding with surgery

Judge Roberts was also critical of the consent obtained on the day of surgery:

"*105. I find that Mr Courtney's consenting on the day of the operation was not merely negligent and sub-standard, but was entirely consistent with his total disregard for the need for clinical governance, training, mentoring, supervision, documentation of patient selection and an adequate MDT note…Mr Courtney accepted that the Claimant was not informed of six out of seven material risks identified by NICE. He accepted that his consenting process was sub-standard and not in accordance with the GMC guidance. I accept Dr Ellis's submission that it is difficult to see how advising the Claimant of the other six risks identified by NICE would have taken more than a few minutes…*

[103] I accept Mr Jenkins' evidence that the operation on 8 December 2015 should have been cancelled to enable the Claimant to be properly consented, bearing in mind that NICE had stated that special governance should be in place for TaTME and extra care taken in the consenting process as a consequence of the lack of evidence as to the efficacy and safety of the procedure."

Overall findings on consent

Judge Roberts concluded:

"111. I find that the negligent failure to consent goes far beyond the Defendant's admission at paragraph 3 of the amended Defence and the Defendant's email of 10 January 2020. I find that as part of the consenting process, the Claimant should have been:

i. Advised that NICE had considered the evidence on the safety and efficacy of TaTME and found that it was limited in both quantity and quality and that patients needed to understand that there was uncertainty.

ii. Given the 2015 NICE guidance "Transanal total mesorectal excision of the rectum, information for the public".

iii. Informed that Mr Courtney was only carrying out his second TaTME.

iv. Informed of the alternative operations he could have undergone, namely a TME laparotomy and a TME laparoscopy.

v. *Informed of all of the risks identified by NICE in their 2015 interventional procedures guidance at section 5.*"

Negligent operation record: completing documentation is not mere 'form-filling'

Judge Roberts found that the operation record was negligently brief. Further:

" 120. In his closing submissions, Mr Feeny submitted that the multiple failures to follow the NICE guidance in relation to consenting the Claimant and recording the selection process for a TaTME, and the inadequacy of the MDT meeting and the operation record, was a matter of form filling…121. I find that the Defendant's multiple failures to follow and properly document the correct procedure it is not mere form filling but has led to the very serious negligent or sub-standard care which the Claimant has received. It was inappropriate to trivialise it by suggesting it is form filling."

Factual causation

Judge Roberts found that the Claimant was a truthful witness and that he had proved on the balance of probabilities that if he had been properly consented, he would have elected to undergo a laparoscopic TME, either on 8 December 2015 or shortly thereafter [164].

Medical causation: you can't compare chalk with cheese

Judge Roberts found that the multiple pelvic nerve injuries and their sequelae would have been avoided with a conventional TME since:

The Claimant would have been a suitable candidate for a TME [184]

The tumour was mid-rectal, now low [194]

He did not have a narrow pelvis [210].

APER and colostomy was unlikely to be required with a TME [204].

The surgeons were on an early learning curve for TaTME [223]:

"*A significant and oft-repeated strand of the Defence to the Claimant's causation case is that the medical literature shows that there is no difference between the outcomes of a TaTME and a TME. I find that this is a bad point because an equivalence between a TaTME and a TME must be predicated on the medical practitioners carrying out the operations being equally experienced in both and not being in the early learning curve in one*."

The surgeons would or should have identified and preserved the pelvic nerves [248].

The internal anal sphincter injury would also have been avoided [361].

Experts in the dock again

Judge Roberts made numerous criticisms of the defence colorectal surgical expert, Mr Luke Meleagros:

"[170] I found Mr Jenkins to be a thoughtful and reliable witness who did not overstate the position and made all appropriate concessions. For example, Mr Jenkins contends that the Claimant's LARS is more severe as a result of having undergone the TaTME. However, when cross-examined about whether this increased severity led to a difference in the Claimant's quality of life, he said: "I think it would be difficult to prove a difference in terms of quality of life".

[171] I have found Mr Meleagros to lack the independence required of an expert and to be unreliable:

i. *I found Mr Meleagros' evidence that the need for training, supervision and mentoring in respect of TaTME was not known until 2018 unsustainable…The need for training, supervision and mentoring when introducing a new surgical procedure is stated in terms in the Royal College of Surgeons of England's 'Good Surgical Practice', published in 2014, and is common sense.*

ii. *I found Mr Meleagros' evidence as to what advice should have been given to the Claimant when he was consented in December 2015 failed to reflect the 2015 NICE guidance…He provided no adequate reason for departing from NICE's advice. I bear in mind that NICE's concerns in 2015 were validated by the fact that in 2021 TaTMEs were suspended, with the procedure now only used in this country in the context of research.*

iii. *I find below that Mr Meleagros' attempt to go behind the consultant radiologists' agreement that the Claimant's tumour was mid-rectal, not low, was not within his expertise and was unsustainable…*

iv. *…I reject [below] Mr Meleagros' evidence that only the Japanese carry out autonomic nerve preservation and prefer Mr Jenkins' evidence. The medical*

literature shows that autonomic nerve preservation has been carried out for thirty years all around the world, including in the UK.

[173] It is clear and well-established procedural law that experts provide a list of published literature and only provide copies of unpublished literature. Mr Jenkins annexed a list of medical literature to his report dated February 2022, which included 17 papers. In addition the agenda for Mr Meleagros and Mr Jenkins for their joint discussion said on the first page, "Please confirm that you have read the statements of case, the factual witness statements, each other's reports and the literature."

[174] It transpired at trial that despite this Mr Meleagros had not read three of the papers, one of which, the St Gallen paper, he himself described as a seminal paper once he had read it during the trial. When asked why he had not read three of the papers when he was questioned about them, he repeatedly said that none of them were provided to him: "Yes, so once again I admit that none of the article copies were sent to me. … I was always under the impression that each side discloses literature to the other side."

[175] Mr Meleagros' answer displayed a misunderstanding of his duties as an expert to obtain copies of published medical literature himself.

[176] Mr Meleagros frequently did not answer the question.

[177] When challenged as to errors in his report, he frequently sought to defend them before admitting that he was in error. For example, he was referred to his answer to the first question in the joint statement, where he says, "The cancer extended below this point due to its pedunculated nature to 7.1-7.6cm from the anal verge." He was asked if this was correct and said that it was. There was then the following exchange: "Dr Ellis: No. Now, pedunculated means on a stalk. Yes? Mr Meleagros: It could mean that but the stalk could be broad. Dr Ellis: I'm sorry, the dictionary definition of a peduncle, as we all know, is a stalk. This hasn't got a peduncle, a stalk? Mr Meleagros: You're right, it hasn't. Wrong use of the word."

Further, the defence urologist, Professor Sethia, did not escape criticism:

"[286] Professor Sethia had never suggested that the only paper on which he relied, namely the Lange paper [to support the view that sexual dysfunction was inevitable with a TME], was unreliable in his expert reports or in the joint statement with Mr Reynard.

[290] I find that Professor Sethia did not have an answer to the fact that the Lange paper showed that of the male patients who were sexually active before treatment, 68.5% were sexually active after three months and 71.5% were sexually active two years after treatment. His response, suggesting that many papers dealing with sexual dysfunction, including the Lange paper, do not use objective measures was not said in his report or in the joint statement. To the contrary, he relied upon the Lange paper. Further, I found his evidence that some of the men who claimed to be sexually active may only have been referring to stimulating their partners not credible and a desperate attempt to explain away inconvenient data in the only paper upon which he relied in his report.

[291] For completeness, I would add that Professor Sethia wrongly said in his liability and causation report that the Claimant had a BMI of 35, which moves it out of Class 1 obesity. In cross-examination he accepted that this was wrong and that in fact the Claimant had a BMI of 32, and so was in Class 1.

[292] For the aforementioned reasons, I prefer the evidence of Mr Reynard to that of Mr Sethia and find that the Claimant has proved on the balance of probabilities that if he had undergone a laparoscopic TME, he would not have suffered total impotence, loss of ejaculatory function and anorgasmia."

Dr Peter Ellis represented the successful Claimant, instructed by Associate Rosaline Wong in Slater and Gordon's London office.

Dr Peter Ellis
Hailsham Chambers
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