Neutral Citation Number: [2019] EWHC 784 (QB)

Case No: HQ18C00233

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 29/03/2019

Before:

MR JUSTICE STEWART

- -

Between:

MR MARC OLLOSSON	**Claimant**
- and -	
DOCTOR ALAN LEE	**Defendant**

- -
- -

Mr Julian Matthews (instructed by **Taylor & Emmet LLP**) for the **Claimant**
Ms Nadia Whittaker (instructed by **Medical Protection Society**) for the **Defendant**

Hearing dates: Wednesday 13th, 14th, 15th and 18th March 2019

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

....

MR JUSTICE STEWART

Mr Justice Stewart:

Introduction

1. On 15th November 2012 the Claimant underwent a vasectomy carried out by the Defendant. The Defendant is a general practitioner specialist in vasectomy. As a result of the vasectomy the Claimant suffers from chronic scrotal pain, a recognised complication of the vasectomy procedure.

2. The case has been listed for a liability only trial.

3. The particulars of negligence are contained in paragraph 3 of the Particulars of Claim as follows:

> "i) failing to provide the Claimant, an intelligent man attending for an elective procedure, with the appropriate information about the risks associated with the proposed procedure, such that he could provide properly informed consent to the same;
>
> ii) failing to advise the Claimant sufficiently, adequately or at all as to the specific known risks identified in paragraph 2.6 above[1];
>
> iii) failing to ensure that, before offering, as a purported specialist, vasectomy, that he ensured he was fully informed about the associated risks, such that he was able to ensure that patients could be adequately and properly advised about the attendant risks …"

4. An outline chronology in this case is:

- 7th June 1968: Claimant's date of birth

- 7th August 2012: Claimant visits his GP Doctor Macris. Discussion with GP about vasectomy. Doctor Macris says he will send out a referral letter. Subsequently Claimant receives a "choose and book" letter listing different places which could do the vasectomy. He chooses the Drayton and St Faith's Medical Practice ("the practice"). Claimant makes appointment for 15th November 2012. The practice sends out literature in advance.

- 15th November 2012 consultation with the Defendant and the Claimant. The Claimant's wife is in attendance. Discussion about the procedure and risks. Claimant alleges no discussion about risk of chronic long-term disabling pain. Consent form completed by Claimant and his wife. Vasectomy performed.

Key issues

5. In summary there are three matters in dispute namely:

[1] The risks relevant to this case will be referred to later in this judgment.

a) what information was given to the Claimant relating to the risk of chronic testicular pain before he underwent the vasectomy;

b) was the extent of the information provided regarding the risk adequate for the Claimant's informed consent to the vasectomy?

c) if there was a breach of duty, would the Claimant have decided not to undergo the vasectomy had adequate information been given to him.

Witnesses

6. There were the following witnesses of fact:

• the Claimant, witness statement 4th June 2018;

• the Claimant's wife, Karen Ollosson, witness statement 4th June 2018;

• the Defendant, witness statements 6th July 2018 and 15th November 2018;

• Julie Keene, nurse of the practice, witness statement 7th July 2018;

• Gillian Moore, vasectomy administrator at the practice, witness statement 8th March 2019;

Ms Keene's and Ms Moore's statements were agreed.

7. I heard from the following expert witnesses:

(*for the Claimant*)

• Doctor Feltbower, general practitioner: report 4th August 2018;

• Mr Reynard, consultant urological surgeon: reports 24th February 2017 and 11th September 2018;

(*for the Defendant*)

• Doctor Hampton, general practitioner: report November 2018;

• Mr Parkinson, consultant urologist: report November 2018;

(*joint statements*)

• Doctor Feltbower and Doctor Hampton: 22nd January 2019;

• Mr Reynard and Mr Parkinson: January 2019.

Case law

Consent

8. In *Montgomery v Lanarkshire Health Board*[2], where the facts of the case involved the question of caesarean section/vaginal delivery, Lord Kerr and Lord Reed said:

> "81. The social and legal developments which we have mentioned point away from a model of the relationship between the doctor and the patient based upon medical paternalism. They also point away from a model based upon a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors (and then being prone to sue their doctors in the event of a disappointing outcome), treats them so far as possible 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.
>
> 82. In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment. This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively on medical considerations, are important. They point to a fundamental 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.
>
> 83. 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.

[2] [2015] UKSC 11; the Claimant also drew my attention to statements in *Chester v Afraz* [2004] UKHL 41 at [56]-[58], [86]-[87] and [92]-[93] which provide further context for the subsequent decision in *Montgomery*.

84. Furthermore, because the extent to which a doctor may be inclined to discuss risks with a patient is not determined by medical learning or experience, the application of the Bolam test to this question is liable to result in the sanctioning of differences in practice which are attributable not to divergent schools of thought in medical science, but merely to divergent attitudes among doctors as to the degree of respect owed to their patients.

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….

89… the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, 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. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.

90 Secondly, the doctor's advisory 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 then in a position to make an informed decision. 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."

9. In *Thefaut v Johnson*[3] Green J (as he then was) said this:

"58. Paragraph [90] of *Montgomery* is significant in shedding light on the *modus operandi* of communication. Two points

[3] [2017] EWHC 497

emerge. First the centrality of " *dialogue* " is stressed. No doubt, in this day and age, dialogue can occur, for example, face to face, or by skype, or over the phone. A patient who suffers from a disability or who is abroad may engage in a perfectly adequate " *dialogue* " via electronic means. The issue is not so much the means of communication but its adequacy. Mr Peacock used the apt expression " *adequate time and space* " to describe the characteristics of a " *dialogue* " that satisfied the test in law……

78. It is also accepted that the brief discussion between Mr Johnston and Mrs Thefaut on 17th May 2012 immediately prior to surgery was not, by itself, sufficient to warn Mrs Thefaut of the risks and benefits. I would make one general observation about this. It is routine for a surgeon immediately prior to surgery to see the patient and to ensure that they remain wedded to the procedure. But this is neither the place nor the occasion for a surgeon for the first time to explain to a patient undergoing elective surgery the relevant risks and benefits. At this point, on the very cusp of the procedure itself, the surgeon is likely to be under considerable pressure of time (to see all patients on the list and get to surgery) and the patient is psychologically committed to going ahead. There is a mutual momentum towards surgery which is hard to halt. There is no " *adequate time and space* " for a sensible dialogue to occur and for free choice to be exercised. In making this comment I am not of course referring to emergency situations where the position might be quite different. In relation to the facts of the present case Mrs Thefaut's evidence was that this meeting between herself and Mr Johnston was brief, Mr Johnston was in scrubs and impatient to proceed. She felt drowsy and not in a position to question him on matters relating to risk/benefit."

10. In *Webster v Burton Hospitals NHS Foundation Trust*[4] Simon LJ said:

"38. So far as the presentation of information is concerned, the Judge found at §86[C] that Mr Hollingworth had failed to inform himself about the implications of the rare combination of SGA and polyhydramnios. The information should have included a list of anomalies and complications which could not be avoided by earlier delivery, but also the increased risk of perinatal (the period around birth) mortality, including ante partum (before delivery) mortality, based on a very small statistical base, see §86[D].

39. During the course of the argument on appeal we were taken to some of the papers which formed the basis of this finding. These included: Sickler et al: Polyhydramnios and fetal intrauterine growth restriction: ominous combination. J

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[4] [2017] EWCA Civ 62

Ultrasound Med 16, 1997 609-14, and Furman et al: Hydramnios and small for gestational age: prevalence and clinical significance. Acta Obstet Gynecal Scand 79 (2000). The latter was more directly in point and supported the Judge's conclusions at §86[D] in two material respects: first, an association of the rare combination of SGA and polyhydramnios with ante partum mortality; and secondly, the small (or extremely small) statistical base for this finding, as might be expected from what is said to be a rare combination.

40. What then should Mr Hollingworth have told Ms Butler on 27 December 2002? In my view, the answer is to be found in the last words of the judgment at §86[G]: namely, that there was 'an emerging but recent and incomplete material showing increased risks of delaying labour in cases with this combination of features."

11. As Simon LJ in *Webster* summarized the position at [26]-[31], certain clear themes emerge from *Montgomer*y namely:

i) a change of approach as to the nature of the doctor and patient relationship;[5]

ii) the extent of the patient's right to information;[6]

iii) whether a risk is material cannot be reduced to percentages;[7]

iv) the importance of dialogue between patient and doctor as part of the doctor's advisory role;[8]

v) the *Bolam* approach is no longer appropriate in cases of informed consent.[9]

Consent/Causation

12. In *Duce v Worcester Acute Hospitals NHS Trust*[10], Hamblen LJ said:

"33. In the light of the differing roles identified this involves a twofold test:

- (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

[5] *Montgomery* at [81]-[82]
[6] *Montgomery* at [83]
[7] *Montgomery* at [89]
[8] *Montgomery* at [90]
[9] Montgomery at [84], [85], [87] and [115]
[10] [2018] EWCA Civ 1307

> and not something that can be determined by reference to expert evidence alone….
>
> 69. ……. the majority decision in *Chester* does not negate the requirement for a claimant to demonstrate a "but for" causative effect of the breach of duty, as that requirement was interpreted by the majority, and specifically that the operation would have not have taken place when it did…."

The Booklet

13. It is common ground that the Defendant sent a Booklet to the Claimant containing information about the procedure.

14. The Booklet contained the following relevant extracts:

> "**About Your Vasectomy**
>
> "This booklet has been written to explain the operation. It will help you to make an informed decision in relation to consenting to the operation. **Please read this booklet, the questionnaire and consent form carefully …**
>
> **What is a Vasectomy?**
>
> Vasectomy is one of the safest, simplest and most effective methods of contraception but because it should also be considered permanent, it is important for you to be fully informed before deciding to proceed …
>
> A vasectomy will not affect your sex drive or ability to enjoy sex.
>
> ….
>
> The Vasectomy procedure must be seen as permanent
>
> There is no evidence of any long-term risk to men's physical or mental health after vasectomy ..[11]
>
> **After the operation**
>
> ….
>
> Most men are able to return to light/office work after 3-4 days of rest. If you have a manual job you should avoid heavy lifting for at least 10 – 14 days.
>
> Most problems after vasectomy are caused by not resting enough after the operation. There may be some discomfort after

[11] This is on page 5 of the Booklet.

the anaesthetic wears off and taking Paracetamol can relieve this.

Risks/Complications

Complications, although uncommon, can occur with any surgical procedure, however minor and if you are worried about anything please feel free to call us for advice.

• In rare cases (1 in 1,000) the tubes may not have been sealed completely or the sealed ends of the tubes may grow back together again and, since this usually happens in the first three months, we are able to detect this by testing the semen.

• There is a remote chance (1 in 2,000) that the vas deferens may rejoin spontaneously even after you have been sterile for some time (re-canalisation). If this happens, you may no longer be sterile.

• As with any surgical procedure there is a risk of infection or haematoma. Following our advice will reduce the likelihood of either of these occurring. If the wound becomes hot to touch, red in appearance or more swollen as days go by this might be an indication that the wound is infected. You should contact your GP or the Drayton Vasectomy Service for further advice.

• There is a small possibility of post vasectomy pain, which can be chronic. There is also a small possibility of testicular atrophy.[12]"

The consent form

15. The Defendant's case is that a consent form was sent together with the Booklet. The material part of that form is:

"**Statement of healthcare professional**

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits: **Permanent Contraception**

Serious or frequently occurring risks:

Infection/haematoma ☐

1:1000 early failure rate ☐

1:2000 late failure rate ☐

[12] This is on page 8 of the Booklet.

Chronic testicular pain ☐

Testicular atrophy ☐”

The Claimant’s evidence

16. Mr Ollosson works as a care support worker for the Norfolk and Suffolk Foundation Trust. The Ollossons have a grown-up daughter who was born in 1991.

17. In 2012 Mrs Ollosson was told by her doctor that he recommended that she came off the pill as it would pose a health risk. She had previously found other methods of contraception to be painful. The Ollossons wanted to explore the option of vasectomy as a means of birth control.

18. On 7th August 2012 Mr Ollosson went to his general practitioner and saw Doctor Macris. He says there was a very short discussion with the doctor who said that they should see the procedure as being permanent. He briefly described that it would stop the sperm getting into the semen but did not go into detail. He said he would send out a referral letter.

19. In cross examination Mr Ollosson said that as a result of his wife’s problems with contraception and having discussed the options with her, vasectomy was his idea. When he went to his general practitioner he attended on his own and told him he wished to be referred for vasectomy. He had not looked up vasectomy on the internet. Work colleagues (not medical) had told him that it was simple and just a “snip/snip”. Before going to the GP it had occurred to him that there may be risks. The GP said it was a safe and simple procedure, though he should be sure that he wanted it because it was not reversible. The GP said that the surgery to which he would be referred would send out literature about the procedure. He then waited for the information.

20. Later the Ollossons received a “choose and book” letter listing different places that would do the vasectomy. Mr Ollosson chose the Drayton and St Faith’s Medical Practice. He said he was sent leaflets regarding the vasectomy which was to be carried out by a Doctor Lee on 15th November 2012. He did not see Doctor Lee or anyone to discuss the risks of the operation prior to the day of the procedure. The Ollossons read through the documentation which had been sent. They were reassured by the statement “there is no evidence of long term risks to men’s physical or mental health” from the vasectomy.

21. In cross examination Mr Ollosson clarified a number of matters. These were:

    a) he accepted he would have received a letter similar to the pro-forma letter in the bundle;

    b) he had no recollection of receiving the consent form with the Booklet. He was shown a number of passages about the consent form. He said that he tended to follow instructions and so if something was missing he would have noted it. If the consent form had been missing he would have done something about it. Therefore, he accepted it must be the case that the consent form was sent to him with the Booklet;

c) neither he nor his wife signed the consent form ahead of the appointment. His wife always intended to attend with him;

d) if, as must be the case, the consent form was with the Booklet, he would have taken that with him, along with the Booklet, on the day of the procedure. When shown the completed consent form, he said that would have been the form he received. Both his wife and he and Doctor Lee signed it on 15th November 2012. He also accepted that he was provided with a copy of the form he signed on 15th November 2012;

e) he was aware from the Booklet that if he had any concern, or wanted more information, he could call the practice. The number was provided;

f) from the statement in the Booklet that there was “no evidence of any long-term risk to men’s physical or mental health after vasectomy”, it sounded as though there were no long-term risks, but he was accepting that there may be short term pain; as regards the four risks/complications set out later in the Booklet:

   i) he realised that there was a small possibility of post-vasectomy pain which could be chronic. By chronic he understood that it could be long-term bad pain;
   ii) because there were figures given for the first two risks, and no figure given for the possibility of post-vasectomy pain, he thought that the risk of that was less than one in two thousand.[13]

g) Mr Ollosson thought that he initially read the Booklet on his own and then his wife read it (because they work different shifts). Then they would have looked at it together. They did discuss the difference between the suggestion that there were no long-term risks to health and the wording about the small risk of chronic pain. He recalled discussing that with his wife;

h) therefore, at the time he had finished reading the information and made his appointment[14], Mr Ollosson knew the risk of long-term bad pain which he thought was less than one in two thousand. However, he was going to ask the doctor about this. If the doctor had confirmed that there was such a risk, Mr Ollosson said he would then have asked further questions;

i) Mr Ollosson also said that he felt that they were not committed to anything, i.e. going ahead with the surgery, at any point up to the point of the surgery starting. He understood he could say no all the way up to that point.

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[13] Mr Ollosson accepted with the knowledge of what he now has that he was mistaken in that. He did not accept he was mistaken at the time in interpreting the words e.g. “rare cases”, “remote chance” and “small possibility” in the way he did.

[14] This would have been sometime between 25th September 2012 and 15th October 2012 on the evidence.

22. On 15th November 2012 Mrs Ollosson accompanied her husband. There was a discussion with Doctor Lee prior to the procedure. The main issue which Mr Ollosson recalls Doctor Lee saying, was that there was a one in two thousand chance of the procedure failing, and therefore future pregnancy. Mr Ollosson recalls Doctor Lee explaining the mechanics of this and that the tubes could re-connect. Mr Ollosson went through the vasectomy consent form with Nurse Keene and Doctor Lee. Mrs Ollosson was present throughout the discussions prior to signing the consent forms. Mr Ollosson recalls that it was discussed when he could return to work. He was told that he would need to be off work for a couple of days. Doctor Lee said he would need to take it easy after the procedure and should not have sex. He also warned that he should do only light duties after work when first going back. The failure rates were certainly discussed. This was the main point that Doctor Lee emphasised.

23. Mr Ollosson says that they asked Doctor Lee about the possibility of pain after the vasectomy as there was some mention of this in the paperwork. Doctor Lee replied to the effect that all men will get pain after vasectomy and some may have it worse than others, but this should be treatable with over the counter medication such as ibuprofen. There was no mention of long-term pain and the percentage risk of this. The Ollossons were reassured by Doctor Lee's comments that this supported the literature they had been given demonstrating no long-term risks.

24. In respect of 15th November 2012, in cross examination Mr Ollosson said:

    i) that he accepted that there was a discussion with Nurse Keene. He did not recall how long it was. He would not dispute it may have been 20 to 30 minutes. He was taken to Nurse Keene's note of the discussion which amongst other things records "long-term pain discussed" and the word "yes" is ringed. Mr Ollosson said he remembered discussing this with somebody on the day. It was possible that he discussed it with Nurse Keene and Doctor Lee. He said he recalled asking about long-term pain, but he could not recall to whom he put the question. However, he was confident that the answer came from Doctor Lee.

    ii) in relation to the consent form where all the boxes of "serious or frequently occurring risks" are ticked as having been explained to the patient, Mr Ollosson accepted that it would be logical that Doctor Lee ticked those boxes as he went through each risk. He said that he and his wife were sitting opposite Doctor Lee.

    iii) Mr Ollosson accepted that Doctor Lee did mention infection risk but said he did not go into it deeply. Mr Ollosson said there is always a risk of infection. It was pointed out that the risk of infection or haematoma is not mentioned in his witness statement. Mr Ollosson accepted that Doctor Lee did discuss everything on the list, including chronic testicular pain. He said that Doctor Lee mentioned the wording but did not go into it in depth. The Ollossons then asked him about how that stood with there being no long-term risks. They asked about the difference in the leaflet. He reiterated that Doctor Lee's response was that all men get pain after vasectomy, some worse than others but is usually treated by over the counter medication. He was reassured by this.

iv) Mr Ollosson was not able to answer why he was reassured if Doctor Lee had not provided a proper response to the question he says he put to him.

v) Mr Ollosson said that if Doctor Lee had suggested that the post-operative pain might affect quality of life, he would have asked what he meant by quality of life. He did not recall Doctor Lee saying that there was no consensus about the treatment of chronic pain.

25. Mr Ollosson said that he was not told that chronic pain can occur which may be severe enough to affect quality of life. He would have wanted to know about any significant risks, particularly risks which would have inhibited his ability to work or enjoy his social life. He says there was certainly no mention of any risks in the region of 5% of chronic testicular pain. He is certain that he would not have proceeded with the operation if he had been warned of a risk of that magnitude. For him, a risk of long-term pain which might affect his work, social and sex life was certainly a risk he would have wanted to be aware of. That risk to him would have been much more significant than a one in two thousand risk of the operation failure rate.

26. The Ollossons had discounted using the pill because of health risks. Mr Ollosson says he is sure he would have done the same if given correct information about the vasectomy. He proceeded with the operation on the basis of the reassurance he was given.

27. Mr Ollosson was questioned about what he would have done had the advice been different. The following matters arose from his oral evidence:

i) he had an operation namely a pleuradectomy in 2001. He had also had a gastroscopy in 2009 where the consent form showed that he had a very small risk of haemorrhage or perforation of the gut, following which surgery might be necessary. There was also an endorsement that he did not want to be resuscitated if the need arose. I do not attach any weight to these previous procedures. The first one was in circumstances where Mr Ollosson said that if he had not the surgery his condition was life threatening. In relation to the gastroscopy there was a possibility that he may have had cancer. As to the resuscitation endorsement, he said he had a fear that if anything goes wrong with surgery, he would not want to be left in a very bad state. Those two situations are far removed from the position in an elective vasectomy.

ii) Mr Ollosson had it pointed out to him that the urologists said that the risk of the level of pain and interference of quality of life which he has is much less than 1%. After some exploration from Ms Whittaker and myself, he said:

a) if the risk had been explained in terms of the risk of an aeroplane crash, he probably would have had the operation as he does travel on planes;

b) if, however it was a few in a thousand risk he would not have taken it. He said he and his wife would not have wanted to do anything which would jeopardise their sex life or their home life;

c) Mr Ollosson was very fair and accepted that in principle the pain which he suffers could possibly colour his view; however he did not accept that his decision would have been any different.

iii) In re-examination Doctor Lee's supplementary witness statement was put to Mr Ollosson. In that statement he says that if a patient asks further questions about chronic pain he explains that the pain ranges from mild to severe in nature, and would be likely to increase during intercourse. He also explained that the pain can occur on a daily or even hourly basis. He would want them to understand that the pain can affect their life and to make sure that they are prepared to live with such an outcome and the effect it will have on their life. Mr Ollosson said that had that been explained to him he would have cancelled the operation on the day. If it had been in the Booklet he would not have made the appointment in the first place with the practice. He would not have wanted to take the risk. As he understood it, vasectomy was a simple procedure.

28. Thereafter, in his witness statement Mr Ollosson describes the pain which he suffered and continues to suffer and which has a very substantial effect upon his life in a number of ways. I do not go into this as the case is listed on liability only.

29. Two extra points emerge from Mr Ollosson's statement namely:

a) after the operation and with the continuing pain Mr Ollosson saw his GP and Doctor Lee a few times. On or around 21st December 2012 Mr Ollosson says that Doctor Lee told him that they may have to consider that it was post-vasectomy pain syndrome. Mr Ollosson said this was a concern as they had not heard of this and Mr and Mrs Ollosson questioned what this was. They started to be given the impression that this could be a long-term problem which was a real concern, particularly in the light of the fact that they were not aware of any long term risks;

b) Mr Ollosson was referred to hospital and recalls seeing a specialist registrar, Ben Hughes, on or around 8th February 2013. The registrar indicated that he thought that Mr Ollosson did have chronic pain following the vasectomy and that this happened in about 5% of people. Mr Ollosson said he was very angry to find this out and felt that he had been misled regarding the risks of the procedure.

30. The letter from Mr Hughes to Doctor Lee is dated 8th February 2013. In that letter Mr Hughes wrote:

> "I have explained to him that I think he has chronic epididymal pain post vasectomy and I have explained that this is a recognised complication of the procedure that occurs in 5% of men. Mr Ollosson is very unhappy about this and says that he was not warned about the potential side effects at the time of counselling or at the time of surgery and he tells me that this is something that he is going to take further."

31. Mr Ollosson accepted that the paragraph was incorrect. He said that he did receive the warning in the leaflet and that Doctor Lee went through the checklist with the warning of chronic testicular pain. However, he had taken reassurance from Doctor Lee. He did become angry when told by Mr Hughes of the recognised complication. In re-examination he said he had understood from Mr Hughes that there was a 5% risk that men would end up like him. The additional information he received from Mr Hughes was that the pain was probably unmanageable and that the only ongoing treatment was medication. He was also told that erections and ejaculations would be greatly affected and that the problem was very long term.

32. A few weeks after seeing Mr Hughes, Mr Ollosson sent a complaint email to the practice manager. In that email he emphasised the sentence in the Booklet that "there is no evidence of long-term risk to men's physical or mental health". He adds "we were told similar verbally as well". Later he refers to the last page of the Booklet where it says there is "a small possibility of post-vasectomy pain." The email does not specifically mention that he asked a question about long-term risks of chronic pain[15].

Mrs Ollosson's evidence

33. Mrs Ollosson's statement corroborates Mr Ollosson's evidence in a number of ways. She says that she had been on the pill for many years and her GP urged her to come off it as she was told it was a health risk and there was an increased risk of getting pregnant. She saw several GPs. She tried a coil at one point but this was painful and one of the injections she had tried had not worked. Neither of the Ollossons was keen on using condoms and so began to look at different options. Mrs Ollosson was not keen on having a hysterectomy as this was very invasive and carried risks. Therefore, Mr Ollosson began to explore the option of a vasectomy around August 2012.

34. In cross examination Mrs Ollosson said she had ruled out the coil and injections as a means of contraception. Apart from vasectomy what was left was condoms or barrier methods such as the diaphragm. It was her husband who suggested a vasectomy.

35. Mrs Ollosson remembers the leaflet which her husband received prior to the procedure. She says that this was the main thing they used to help them make the decision and discuss things. The procedure seemed to be very straightforward. They were particularly heartened by the fact that the leaflet said there were no long-term risks of physical or mental health from the procedure. They discussed things in some detail as it was such a definite decision they were making. Whilst they realised there may be some pain after the procedure, they understood this was something which would only be short lived and even then, would be dealt with by over the counter pain killers. They were not told that the pain may be so severe as to interfere with quality of life.

36. Mrs Ollosson said she read the Booklet. She envisaged she and her husband read it together and also separately. She could not recall.

[15] Though he did so in a subsequent email dated 12th July 2013.

37. As regards to the consent form, she did not recall it. It might have been with the Booklet. She remembered reference to the consent form in the Booklet. She accepted that it was likely it was in the pack which was sent.

38. She and her husband discussed matters in detail. They looked at the inconsistency in the Booklet about chronic pain. She also understood chronic to be bad long-term pain. She noted that the small possibility of chronic pain appeared at the end of the list and therefore thought it was a small possibility. She said that she wanted it clarified. She and her husband believed at the time they would discuss it with the doctor on the day.

39. According to her statement on 15th November 2012 the Ollossons went to the GP surgery where Doctor Lee would carry out the operation. Mrs Ollosson remembers the nurse being with them when the consent form was signed. She remembers the nurse and the doctor both mentioning the possible failure rate with vasectomy and that the tubes could reconnect. This was the major point that was discussed prior to the consent form being signed.

40. It was said that Mr Ollosson would be able to return to work after a couple of days. He would need to take things easy and was told to go back onto light duties at the start.

41. As long-term pain was mentioned in the paperwork, they asked about this. They were told words to the effect that all men get some pain post vasectomy, some worse than others and that the pain should be treatable with over the counter medications. They were reassured by this. They both signed the consent form which was just seen as a formality at that stage as they felt as though they were committed to the decision at that point.

42. The operation then took place.

43. Mrs Ollosson was asked about how the part of the statement saying that they felt they were committed to the decision was consistent with her previous oral evidence that they were going to discuss matters with the doctor on the day. She accepted that it was a possibility that she had picked up on the inconsistency point having been affected by hearing her husband's evidence.

44. Mrs Ollosson could not remember whether the paperwork she was talking about in her witness statement was the consent form or the Booklet or both. She said she thought her husband asked the question of Doctor Lee. The question was about the pain he might experience post-vasectomy. She said she thought it was the long-term pain which concerned him. Her recollection was that the question was asked of both Doctor Lee and Nurse Keene, but she could not really recall. She thought that the response about the pain as recorded in her witness statement came from Doctor Lee. She could not recall if they asked what if the pain is not treatable by over the counter medication. She could not remember if Doctor Lee went through the consent form. She said she remembered signing the consent form.

45. In her statement Mrs Ollosson corroborates the symptomatology her husband has had following the operation and the effect upon his life. She then concludes with the following points:

• The Ollossons have subsequently discovered that there is a significant risk of long-term pain following vasectomy. They were not aware of this or any percentage risk of this prior to the procedure.

• If for example they had been told of a 5% risk of long-term pain, this would certainly have made them alter their thought processes and decision making.

• Mrs Ollosson had had time off for long-term pain with a back problem for many months a few years before. She had to have traction and physiotherapy. As a result, she was aware of the difficulties with long-term pain and neither of them would have wanted Mr Ollosson to risk being in long-term pain.

• If they had been informed of the risk they would not have gone ahead with the procedure and would have explored other options with less risk.

• Mrs Ollosson feels that they were given the impression there were no long-term risks to mental or physical health, that it was a very simple procedure and that they would be in safe hands. She said it is difficult to reconcile the fact that this was an elective procedure, and a very bad outcome could have been avoided if they had been properly informed of the risks.

46. In cross examination Mrs Ollosson was asked whether it would have made a difference if they had been told that there was a 3-5% chance risk of chronic pain. She said it would because of the effect on quality of life. She said if they had been given a percentage it would have caused them to walk away. I clarified this with her. She ended by saying that whether the risk had been conveyed by way of a percentage or in words, if they had been told that there was a risk, which could not be excluded, of the type of pain from which he now suffers, then they would have walked away.

47. Finally, in re-examination, Mrs Ollosson said:

    i) had Doctor Lee said what he says he would have responded in answer to a question about chronic pain,[16] they would not have proceeded;

    ii) if it had been explained that there was a 1-2% risk of chronic pain sufficient to have an impact on the quality of life, they would have walked away;

    iii) she cannot recall anything being said about possible effect on quality of life.

Doctor Lee's evidence

48. I shall deal first with Doctor Lee's witness statement dated 6th July 2018.

49. Doctor Lee qualified as a GP in 1999. He is a partner in the practice where he has worked for 19 years, 14 of them as partner. The practice held a contract with the PCT (then CCG) from the mid-1990s until March 2015. The duty was to provide a one-stop vasectomy service. Doctor Lee performed vasectomies from 2005 to 2015. He did about 250 to 300 a year.

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[16] Paragraph 14 of his supplemental witness statement.

50. Doctor Lee was a member of the British Association of No-Scalpel Vasectomy. In that capacity he completed a log book and submitted annual audits of all vasectomy cases for external validation. Mr Ollosson's case is the only case of chronic testicular pain of which he is aware in his 10 years of vasectomy practice. He always told patients to contact him if there were any problems arising from the vasectomy.

51. Doctor Lee said that the vasectomy referral process works such that the patient has a consultation with his own GP who will inform him about contraceptive options, and the risks and benefits of vasectomy. If the patient wishes to proceed referral is made to the clinic by the GP.

52. Doctor Macris referred Mr Ollosson on 9th August 2012. In the referral letter he states that Mr Ollosson had a grown-up daughter and his wife was unable to use contraception without significant side effects. As a couple they had decided collectively to proceed to vasectomy. Doctor Macris said he had discussed the nature of the operation and the Claimant was happy to proceed.

53. In cross examination Doctor Lee accepted that the referral letter from Doctor Macris was brief. He also accepted that the letter did not show that the general practitioner had discussed complications, though he assumed that most GPs would discuss risk and complications. He also thought that most GPs would point the patient to the NHS website on vasectomy. However, he could not know what had been discussed unless it had been set out in a letter.

54. Once the practice received the referral letter, the vasectomy administrator contacted the patient to discuss making an appointment for the procedure. If the patient was uncertain, the administrator arranged a discussion with Doctor Lee. The referral would be cancelled or delayed if the patient had doubts. Otherwise a mutually convenient appointment was agreed, following which the administrator sent an information pack to the patient. The information pack was sent to the Claimant on 25th September 2012. Mr Ollosson confirmed the appointment on 15th October 2012.

55. Apart from a map to the practice the information pack included:

- information Booklet;
- vasectomy complications[17];
- a copy of the consent form which also stated possible complications;
- a contact number for patients who required more information or who were having second thoughts.

56. The vasectomy Booklet was intended to be read in conjunction with advice from the patient's own GP, and from the practice's nurse counsellor and Doctor Lee.

57. In evidence Doctor Lee said the purpose of the pack was to make sure all patients had the information they needed, regardless of what had been discussed with the general practitioner. Patients would look at the option for vasectomy, and compare it with

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[17] In oral evidence Doctor Lee clarified that this is the section in the Booklet and the consent form. There was no separate information.

other types of contraception and the risks they entailed. They would look to compare risk against risk. It was therefore important that the information they received enabled them to make proper decisions, and that it would not be misleading. The Booklet was intended to be the primary source of information in layman's terms. The consent form was more technical and had to be completed prior to the operation. At the time of sending out the Booklet, the practice did not know the intelligence of the person receiving it. That is why the discussion at the consultation was important, so that the patient could ask any questions.

58. As to the statement on page 5 of the Booklet, Doctor Lee agreed it was not sufficient and, in the absence of what was said at page 8, it could convey the wrong impression to a lay person. However, he expected the patient to read the whole Booklet, though a patient reading the later stages of the Booklet might read it in the context of what he had already read and understood earlier.

59. Doctor Lee had had patients who had experienced infection/haematoma following vasectomy. The wording about a "small possibility" of post-vasectomy pain which could be chronic and also of testicular atrophy was the same. He only knew about the incidence of testicular atrophy because he had heard about it at a meeting, where he said a Doctor had mentioned having encountered it. Doctor Lee thought a small possibility was at least 1%. He did not check in the literature about the incidence of testicular atrophy. He did not dispute that atrophy is not widely accepted in the literature, though chronic pain is well reported and dealt with in the literature. He had not come across people who had thought chronic was bad pain, as opposed to long-term pain. He considered that the Booklet gave some guidance of pain and its chronicity. He said it was in simple English. Further, a patient could always ring if there were problems, as the Booklet made clear. There would also be discussion at consultation. He agreed that some patients would not want to ring up.

60. If somebody telephoned about the risk of chronic pain, Doctor Lee said he would offer them an appointment before the date of the operation. That would be so they could think about it after he gave the advice. At such consultation he would say that the risk of chronic pain ranged from 1-5%, but the statistics do not mean anything if it is the person themselves, because then it is 100%. He would ask whether they could live with that. He would explain that pain can range from mild aching intermittingly, or deep aching to severe pain. In order to treat such pain they would start with simple painkillers and if that did not work, prescribe stronger painkillers all the way sometimes up to morphine. If that did not deal with the pain then the patient could be referred to the pain clinic. If the pain became too much then there was the possibility of reversing the vasectomy, but he had only heard about that in meetings and therefore he would not be able to quote any figures of success.

61. Doctor Lee said that this explanation would also be the explanation he would give in response to a question about pain, if asked, on the day of the procedure. He could not explain why certain elements in that response were not present in his supplementary witness statement when dealing with that specific point. These elements in outline were (a) that there would be the possibility of pain killers potentially as strong as morphine; (b) possible referral to the pain clinic and (c) possible reversal of the vasectomy.

62. Finally, in relation to the Booklet, Doctor Lee's evidence was:

i) he did not accept that the order of risks/complications suggested a lesser risk than 1:2000. He put the risk and complications in the order of what concerned people the most;

ii) the detailed exposition of chronic pain was not in the Booklet. That is why the patient needed to see him. He said he had a low threshold for not proceeding with vasectomy. If a man was showing uncertainty, he would say why not go home and consider. If they had any questions then they could by all means contact him;

iii) he accepted that on reading the Booklet and the consent form, there was nothing about the severity of pain. It might be just mild or long-term aching.

63. Doctor Lee said that the patient and partner were initially seen by one of the two vasectomy counsellors. These were senior nurses of at least band 7 status. Their role was to explain the whole process of having a vasectomy including complications and post-operative care. Each assessment took 20-30 minutes. If the nurses had any concern they highlighted this to Doctor Lee immediately. Following the counselling process, the patient and partner had some time to reflect and consider any questions prior to seeing him.

64. On 15th November 2012 Mr Ollosson and his wife met Julie Keene, one of the vasectomy counsellors. Her records specifically mention long-term pain having been discussed with the Claimant. Doctor Lee says that if after counselling there was any hint of uncertainty he cancelled the procedure and suggested that the couple reconsider and come back to him.

65. Following counselling, Doctor Lee said he saw the patient and partner in order to consent them for the vasectomy. The consent process covered the following points:

a) discussion about the procedure itself;

b) possible failure of vasectomy in achieving the desired aim;

c) immediate complications;

d) late complications;

e) discussion of rarer complications in order to provide the patient with a balanced and non-biased understanding of the procedure;

f) follow-up care.

66. Doctor Lee says that opportunity was given to ask questions and address concerns. Uncertainties always led to him delaying the procedure until a later date or cancelling it completely. There was no pressure placed upon the patient to proceed with vasectomy, as it was imperative that he fully understood and accepted the risks and complications before proceeding with a potentially irreversible treatment.

67. As to chronic testicular pain, Doctor Lee said that the patients were informed about the risk of this by both himself and the counsellor. Both the nurse counsellor record and the practice consent forms mention long-term pain and chronic testicular pain as a

potential complication. Doctor Lee says he discussed with the patient and his partner how this pain might present and affect their lifestyle. The discussion involved the fact that there is no consensus about specific treatment and that the pain can be a long-term condition.

68. Only if the patient understood and accepted the risks of the procedure and has capacity was the consent form completed and the vasectomy proceeded with. Both patient and partner were asked to sign the consent paperwork. If there was any uncertainty by either party the procedure did not go ahead.

69. On 15th November 2012 Mr Ollosson and his wife had a separate appointment with Doctor Lee following the counselling process with Nurse Keene. This was to discuss in more detail the risks and benefits of the vasectomy. Following this the consent paperwork was completed. The appointment took place outside the operating room.

70. Following the consent procedure, the patient and his partner would be taken through to the operating room. The partner could stay with the patient throughout the operation. The nurse counsellor was also present at the start of the procedure.

71. Doctor Lee says that Mr Ollosson's operation proceeded without any immediate complication.

72. In summary, Doctor Lee says that the nurse counsellor, Julie Keene, and he took time separately to discuss all potential complications with Mr Ollosson and his wife, including the risk of chronic testicular pain. The Claimant was given time to digest this information and ask further questions. He was under no pressure to proceed with the vasectomy. He fully understood the risks and benefits. These risks, says Doctor Lee, are also clearly stated on the practice consent paperwork signed by Mr and Mrs Ollosson.

73. The remainder of Doctor Lee's first statement deals with post-operative complications.

74. On 11th July 2018, the Claimant served a Part 18 request for further information asking for clarification of paragraph 19 of his first witness statement. It asked specifically what, if anything, Doctor Lee recalled saying to the Ollossons regarding "what pain might present and the effect on their lifestyle". Doctor Lee said that he interpreted the question as asking him to clarify what he said about the possibility of pain after the vasectomy, and the effect that it might have on the patient's lifestyle.

75. He had also then read the witness statements of Mr and Mrs Ollosson. He noted that it appeared that they were both alleging that they asked him a specific question about pain after vasectomy, and that they received an answer along the lines of: "all men will get pain after vasectomy and some may have it worse than others, but this should be treatable with over the counter medications such as ibuprofen".

76. Doctor Lee said that since he had not previously been aware that the Claimant intended to allege that he was asked a question about pain, he needed to address this point also in his supplemental statement.[18]

77. When he was performing vasectomies he would carry them out once a day doing six vasectomies a week. This is about 250 to 300 per year, and over 10 years amounted to some 2,500 to 3,000 vasectomies.

78. Doctor Lee said that his practice when counselling a patient was firstly to tell them that the procedure is permanent and non-reversible. He then explained each risk on the consent form. He said that early and late failure were rare and remote risks. He explained the likelihood of chronic pain occurring was small, but greater than the rare and remote risks of early and late failure. Chronic pain was always the last risk about which he advised. There was a good reason for this. He was aware that most people were likely to pick up the last thing he said. He therefore mentioned it last because there was a small risk of pain which can be chronic. Chronic pain had been discussed and raised as an issue by vasectomy peer groups in the profession. Doctor Lee said he knew that he used to stress this in particular, because a few colleagues in his peer group had reported patients who had experienced it.

79. Testicular atrophy had been added to the list of risks because Doctor Feltbower had reported in one of the vasectomy peer group meetings that he had experienced a patient who had this complication. Though this is the last risk listed on the consent form, its position was determined by the fact that it was added to the list in a late amendment after hearing from Doctor Feltbower.

80. After explaining the risks and going through the consent form, Doctor Lee always asked the patient and his partner if they had any questions at all. If there were no questions, he turned the consent form towards the patient and partner, who normally sat opposite him. This was so that it could be signed.

81. As to Mr and Mrs Ollosson's statement that they asked about the possibility of pain after vasectomy and that Doctor Lee effectively said: "all men will get pain after vasectomy and some may have it worse than others, but this should be treatable with over the counter medication such as ibuprofen" – Doctor Lee said that after this period of time he was not able to say categorically if the Claimant did or did not ask such a question. He did not remember being asked a question about the possibility of chronic pain. He said it was unlikely that they asked the question, because whenever a patient asked further questions about chronic pain, he explained that the pain ranges from mild to severe in nature and would be likely to increase during intercourse; also, that the pain can occur on a daily or even hourly basis, and he would want them to understand that the pain could affect their life and to make sure that they are prepared to live with such an outcome and the effect it would have on their life.

82. About one patient a month asked a question about pain. When he gave his above explanation, most patients were satisfied and content to proceed with the surgery. If the patient probed further, then it was his practice to inform them that he did not

[18] In fact Mr Ollosson had, in a lengthy e-mail of 12th July 2013, said: "we enquired about PVP and were told …. that all men get pain post vasectomy surgery, some get it worse than others and it may go on for some time but is usually treatable by OTC medication such as ibuprofen …". Doctor Lee, in his response letter of 12th August 2013 did not comment on this.

consider that they were ready for the procedure, and asked them to go home and think about it. He had one patient who picked up on the risk of chronic pain and asked further questions. Doctor Lee concluded he was wavering and cancelled the procedure on the day. He asked him to go away and think about it. Doctor Lee was confident that he would remember had the Claimant fallen into the category of patients who had asked probing questions about pain.

83. Doctor Lee did not recall the Claimant asking him to clarify the meaning of a “small” risk. If he had been asked to do so, he would have said that in general people quote a risk of between 1% and 5% based on the medical literature and the experience among clinicians undertaking vasectomies. He would have added that he encouraged his patients to come back to him if they experience post-vasectomy pain, and that he had never experienced a patient complaining of chronic pain in his clinic.

84. Although Doctor Lee did not remember either of the Ollossons asking the questions they now say were asked, he remembered the Claimant talking about his new motorbike during the procedure[19]. His recollection of them as a couple was that they were smiley and happy. He did not recall them wavering or having any sense of deliberation. They were both in the room when he talked about the risks. Once he finished explaining the procedure and the risks, he always asked if they had any further questions or concerns. For the above reasons, he believes he would remember if either of the Ollossons actually asked any questions.

85. In cross examination Doctor Lee said:

i) some men, if they heard of the risk at the consultation, might think that they were already there and would go through with the procedure. However, he said that he had had people change their mind at the appointment, even up to getting on to the couch;

ii) the procedure at the practice was always the same. The only time Nurse Keene was in the room was when he was scrubbed up and she broke the anaesthetic bottle. If there were no problems then she left the room and went to see the next patient;

iii) in relation to his general procedure of giving information relating to chronic testicular pain, as recorded above, Doctor Lee’s statement at paragraph 19 said “I discussed with the patient and their partner how this pain might present and affect their lifestyle. We will discuss that there is no consensus about specific treatment and that the pain can be a long-term condition.” He said that he left that discussion of pain to the end because most patients pick up on the last sentence, that being relevant in relation to any questions they may have. As regards what he actually said, Doctor Lee’s evidence was that he told patients there was a risk of pain which could be chronic. It may be mild or severe. It may affect quality of life. The risk was small but greater than the failure rate;[20]

iv) Doctor Lee denied that he would have dealt with any question about chronic pain as a throwaway comment or in a way which belittled the pain. He said that referring to pain relief over the counter would only be part of his response. The fact that he had

[19] Mr Ollosson confirmed his interest in, and the conversation about, his motorbike.
[20] He accepted that this amplification was not in his statement at the important point dealing where he deals with the counselling he gave on chronic pain.

not had a patient who had had chronic pain would not have affected what he told a patient.

Assessment of Witnesses

86. All three witnesses who were called as to the relevant facts in this matter were honest, decent people. All were doing their best to recollect what did happen and, in some cases, what would have happened in hypothetical situations. Mrs Ollosson had real difficulty in recollection. That is not a criticism. Rather it is a testament to her honesty.

87. Nevertheless, honesty does not necessarily equate to reliability, especially when people are trying to recall facts through the prism of later events. I remind myself of the authorities relating to evaluation of oral evidence, in particular *Gestmin SGPS SA v Credit Suisse (UK) Ltd*[21]. I summarised the principles at [96] in the *Kimathi*[22] case, adding [97] which is also relevant to the present case, as follows:

"96……

i) • We believe memories to be more faithful than they are. Two common errors are to suppose (1) that the stronger and more vivid the recollection, the more likely it is to be accurate; (2) the more confident another person is in their recollection, the more likely it is to be accurate.

ii) • Memories are fluid and malleable, being constantly rewritten whenever they are retrieved. This is even true of "flash bulb" memories (a misleading term), i.e. memories of experiencing or learning of a particularly shocking or traumatic event.

iii) • Events can come to be recalled as memories which did not happen at all or which happened to somebody else.

iv) • The process of civil litigation itself subjects the memories of witnesses to powerful biases.

v) • Considerable interference with memory is introduced in civil litigation by the procedure of preparing for trial. Statements are often taken a long time after relevant events and drafted by a lawyer who is conscious of the significance for the issues in the case of what the witness does or does not say.

vi) • The best approach from a judge is to base factual findings on inferences drawn from documentary evidence and known or probable facts. "This does not mean that oral testimony serves no useful purpose… But its value lies largely… in the opportunity which cross-examination affords to subject the documentary record to critical scrutiny and to gauge the personality, motivations and working practices of a witness, rather than in testimony of what the witness recalls of particular conversations and events. Above all, it is important to avoid the fallacy of supposing that, because a witness has

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[21] [2013] EWHC 3560 (Comm)
[22] [2018] EWHC 2066 (QB)

> confidence in his or her recollection and is honest, evidence based on that recollection provides any reliable guide to the truth"…….
>
> 97. Of course, each case must depend on its facts and (a) this is not a commercial case (b) a central question is whether the core allegations happened at all, as well as the manner of the happening of an event and all the other material matters. Nevertheless, they are important as a helpful general guide to evaluating oral evidence and the accuracy/reliability of memory."

88. I also accept the Claimant's submission that Mr and Mrs Ollosson were a careful couple who would always consult each other before making important decisions which they would make jointly.

Evidence of Mrs Keene

89. Mrs Keene is a nurse practitioner who has worked at the practice since April 2003. She qualified as a nurse in 1986. She has a BSc (Hons) in nursing practice.

90. As a vasectomy nurse counsellor, she saw patients prior to their contact with Doctor Lee in order to complete a Vasectomy Service Treatment Record. Whilst doing this she always ensured that the patient and any relative/friend with them were fully informed about the procedure and aware of the potential risks or complications. She also ensured that the patient was thinking of it as a permanent form of contraception. In case of any doubt, she informed Doctor Lee.

91. After that counselling the patient would then see Doctor Lee separately. The consent form would be completed and signed by Doctor Lee and the patient.

92. Mrs Keene would again be present when Doctor Lee examined the patient prior to doing the procedure to ensure there was no reason why the vasectomy could not go ahead. Doctor Lee ensured that the patient was fully informed and happy to proceed. If there were any doubts in the patient's mind, however small, Doctor Lee would not proceed at any time even if the consent form had been signed. He would tell the patient to go away and think about it and, if they wanted to proceed at a later date, a further appointment could be arranged. If not then they would be removed from the waiting list.

Evidence of Gillian Moore

93. Mrs Moore's evidence was read as agreed. She worked as vasectomy administrator organising the appointments for vasectomy. From the records she can confirm that a letter was sent to the Claimant on 25th September 2012. This was after Mr Ollosson would have phoned the surgery with his choose and book reference number to arrange the appointment. She confirmed that she would send out a proforma and letter with accompanying literature namely, a map, a blank consent form and the Booklet.

GP experts

94. Doctor Feltbower has been a vasectomy surgeon in Coventry for over 20 years and has undertaken approximately 5000 vasectomies. His last clinic was in January 2019

involving both counselling and operations. In addition, being registered as a principal trainer with both the FSRH[23] and ASPC[24], he has trained many other GP surgeons in minimally invasive vasectomy, undertakes peer reviews, accreditations and re-accreditations of GP vasectomy services.

95. In cross examination Doctor Feltbower said he had done about 5000 vasectomies over 20 years. He counselled patients. His practice sends out leaflets. He trains other general practitioner specialists in vasectomy, including the full pathway of choosing patients, counselling, operating and follow up.

96. Doctor Feltbower lectures. His last lecture was in October 2018 in Oxford. He gave part of the training. He accepted that he may have said at the conference that the consent form should involve the risk of pain affecting quality of life. The specific matter of pain affecting quality of life had not been talked about much. The emphasis previously had been on the fact that chronic pain could be severe and potentially require further treatment. Prior to November 2018 his own leaflet did not refer to pain possibly affecting quality of life. He accepted that the change in his own leaflet may have flowed probably from his involvement in the present case.

97. In 2012 he may have said that the pain could be severe and chronic, but he would not have given more detail unless the patient had asked for it. He regarded the Claimant's understanding of long-term bad pain to be fairly synonymous with severe chronic pain.

98. In his report Doctor Feltbower had said that he believed it was mandatory for all vasectomy patients to be informed of the risk of developing a chronic post vasectomy scrotal pain, that could in some cases be severe. He understood that what the Defendant had said in evidence complied with that.

99. Doctor Hampton has been a GP vasectomy surgeon for 25 years and has undertaken approximately 3500 vasectomies. His last clinic was in January 2019, involving both counselling and operation.

100. In cross examination Doctor Hampton agreed with Doctor Lee that a vasectomy surgeon has to allow for different patients' interpretation and level of ability and understanding. That is why the literature sent to them cannot stand alone. He said that in the 1990s doctors were sued for failed vasectomies. That was why the risk of a failed vasectomy came top of the consent form. The way he operates in his area is that the GPs who refer vasectomies are trained to do the counselling. They are sent a standard pack and the general practitioner goes through it with their own patient. There are about 40 boxes to tick. All that information comes to him and he sees the patient on the day of the operation and goes through it. There are some GPs who say they are not confident to do counselling. In those cases, Doctor Hampton does it himself. He makes an appointment at the end of an operating list and counsels those prospective patients. If they agree to have a vasectomy it takes place on a subsequent day.

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[23] Faculty of Sexual and Reproductive Health;
[24] Association of Surgeons in Primary Care.

101. Both general practitioner experts agree that risks and complications following vasectomy include "serious-infected haematoma, post-vasectomy chronic scrotal pain syndrome and testicular atrophy, any of which might require further treatment, hospitalisation or surgery".

102. The experts further agree:

i) most patients will have some pain or discomfort for up to two weeks post-vasectomy. This is usually managed with over the counter analgesics.

ii) The AUA[25] Guidelines 2012 provide a good summary of the incidence of persisting chronic post-vasectomy pain in the recommendation that the incidence is 2.2-6 per cent.

iii) The AUA Guidelines 2012 provide a good summary and recommendation that the incidence of severe post-vasectomy pain is 1-2%. This is the same incidence as that for chronic post-vasectomy pain severe enough to interfere with quality of life and with daily activities and work.

iv) The above material risks involved in vasectomy should be known by all reasonably competent vasectomy practitioners.

v) Although personal audit data can be mentioned by a vasectomy practitioner in relation to counselling a patient as to their own experience of the incidence and/or magnitude of any material risks, such data should stand alongside published robust, high volume and peer reviewed data.

103. The GP experts also agree that the written information in the Booklet and the consent form stated that there was a small risk of chronic pain and that, if a patient was to ask for more detail regarding severity, it would be mandatory to mention that rarely it could be severe enough to affect quality of life. They agree that in 2012 most people would consider 1-2% to be a small risk.

104. Further:

i) As to the adequacy of what Mr and Mrs Ollosson state was discussed with them on the day of the procedure, the experts agree that if the Court prefers the Claimant's evidence in his witness statement (paragraph 15), then he was not made aware of the potential for pain to be severe enough to affect quality of life.

ii) As to the adequacy of what Nurse Julie Keene states was discussed by her with Mr and Mrs Ollosson, they agree that she counselled Mr Ollosson for vasectomy, and that it included an awareness of the potential for chronic pain.[26]

iii) The experts agree that if the Court prefers Doctor Lee's evidence from his supplementary witness statement that, if asked for more detail regarding

[25] American Urological Association
[26] They add: "we have no information regarding any detail of what was discussed".

chronic pain, in mentioning the potential severity of chronic pain and possible impact on lifestyle, he would have provided adequate information.

iv) When asked whether it was appropriate to describe the risk of long-term pain which could affect quality of life and require further treatment by use of the words "a small possibility of post-vasectomy pain which can be chronic", as opposed to providing percentages - the experts agree that in 2012 it was common practice and appropriate to describe the risk of long-term pain as being a small possibility, without mentioning percentages.

105. In oral evidence Doctor Feltbower added the following:

i) In 2012 he may have been more up to date than most GP vasectomists. Nevertheless, there is a baseline for all and he passes on that knowledge to colleagues. New evidence comes to light because of research papers and court decisions. In fact, at annual conferences he usually brings an update of the cases in which he has been involved;

ii) in 2012 when referring to the infection risk, he did not think he used a percentage. He thinks he used words like "a small risk" or that a complication could be severe. That was because there is evidence to show many lay people do not use percentages. A small risk can mean different things to different people. However, going back to 2012 and before, there were lots of discussions about what would go into a consent form and how it should be put. He had always refused to provide a template. The training is that there are things which GPs must mention; how they mention them is up to the GP individually;[27]

iii) there is an extremely rare risk of gangrene which has been reported. It can be fatal. Doctor Feltbower thought the risk was 1 in hundreds of thousands. He was not aware of any on his database of 70,000 to 80,000 people, but said it was reported in the literature. He said he would not mention that risk. If a patient wants a vasectomy, one has to be careful to give a balance of advantages and disadvantages. He accepted that this sounded a bit paternalistic, but the doctor was not there to put the patient off. If a patient asked then the doctor has to talk about it. It is very individual as to how much information a patient required;

iv) prior to *Montgomery,* Doctor Feltbower said he relied on the consent form and the Booklet and went through the tick box. Since *Montgomery* he asks if there is anything material or significant a patient wants to talk about. Prior to that he just asked the patient if he had any questions;

v) he was asked about Doctor Lee's evidence as to his routine advice as set out in his witness statement, namely that he would discuss long-term pain and chronic testicular pain as a potential complication and would "discuss with the patient and their partner how this pain might present and affect their lifestyle."

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[27] Doctor Feltbower said the only time they would use figures is for failure rates because the general feeling was that people coming to a vasectomy would never want more children. Therefore the main factor was the reliability of vasectomy compared with other contraception.

He said that he would be comfortable with that explanation as a matter of routine. In re-examination he was asked whether he was making any assumptions in saying this. He accepted that he was assuming that in discussing "how this pain might present," Doctor Lee would explain that it might be chronic or intermittent. Apart from that he was taking the statement at face value;

vi) he was also taken to Doctor Lee's supplemental statement and what Doctor Lee said he would have responded if asked a question. Doctor Feltbower considered that what was in Doctor Lee's statement was an adequate response to a question asked. He added that if a patient asked more, then a doctor could mention painkillers, pain clinics and other potential procedures;

vii) Doctor Feltbower said that in 2012 to describe a small risk of chronic pain would have been enough. If a question had been asked, it would have been sufficient to say that rarely it could affect the quality of life.

106. Doctor Hampton, when he gave evidence, said he agreed with everything Doctor Feltbower had said.

107. Finally, Doctor Feltbower and Doctor Hampton both said that in their combined personal experience of 8500 vasectomies, they do not recall any patient deciding against a vasectomy when counselled about risk associated with chronic pain.

108. Doctor Feltbower said he did not keep records of those who received the literature but did not turn up for the procedure.[28] Doctor Feltbower said that perhaps one in twenty of his patients asked a question about pain. After he had given his explanation they all said they wanted to get on with the operation. The ones who asked about severity of pain would have been given an answer by him along the lines of what Doctor Lee said in his witness statement. No patient of whom he was aware failed to carry on because of the pain risk.

109. Doctor Feltbower had also done his own survey. This was after the Keoghane and Sullivan BMJ paper in 2010. His methodology was to ask any practice that had referred three or more patients to him, and on whom he had operated five to ten years earlier. He asked them to check their GP records. They traced just over 200 patients. Four to five of them had come back. Only one patient had been referred to a specialist for further management of pain. A few had attended once with occasional pain and ache. This suggested that only one had had severe chronic pain.

110. Finally, Doctor Feltbower was asked about the patients to whom he had specifically mentioned the possible effect of severe chronic pain on quality of life in the consent form, since he had changed it after November 2018. He estimated that 50 to 60 patients had received such consent forms and not one had asked about it.

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[28] In the 2004 Guidelines from the Royal College of Obstetricians and Gynaecologists at pages 50-51 there is a recommendation that "men should be informed about the possibility of chronic testicular pain after vasectomy." In that document it says "the only study that tried to assess testicular pain in a controlled group of men without vasectomy found a prevalence of pain of any type to be present in 26%. However, while vasectomy was associated with a doubling of the rate of occasional testicular pain … severe testicular pain was reported in only 6% of cases and 2% of control. None of the vasectomised men expressed regret." Doctor Feltbower was not aware of any other reference in the literature to whether vasectomised men expressed regret or not.

111. Doctor Hampton further said:

i) in about 2012 he was suggesting there was perhaps a 5% risk of severe chronic pain. He said he thought he was "over-egging" it. It was a reasonable but defensive figure;

ii) when training general practitioners, he would go into figures on everything. This was more to reassure them that there was no increased risk of cancer or autoimmune disorder which some GPs thought there might be. He covered chronic pain as well. He says it is important to have peer-reviewed articles but also important to put to them into context. The figures in those articles are used as a bench mark for how a doctor is performing;

iii) he was not aware of patients who did not confirm an appointment after they had been through the leaflets with the GPs. For the patients who had come to him as a GP over the years, he would see them with their wife and the consent form would be signed. All of them had signed the form. He could not remember anybody who did not turn up for the operation. The numbers here would have been some 15 to 20 a year over the past 30 years, a total of some 500. He accepted that over the years the information given to them would have changed and evolved over that time.

Urology Experts

112. Mr Reynard's experience is that he carried out vasectomy on a regular basis as a trainee surgeon and in the early days of his consultant practice. He now does it only rarely, most vasectomies being done by local GPs. The last one he did was some 3 to 4 years ago. He does continue to counsel patients undergoing planned vasectomy, since the Oxford University Hospitals NHS Trust offers a vasectomy service in those cases unsuitable for local anaesthetic vasectomy in general practice. He therefore continues to advise patients on risks and outcomes.

113. Mr Reynard was a trainee from 1989 until he became a consultant in 1998. In those nine years he would have done several hundred vasectomies. From 1998 onwards, he did vasectomy clinics for a few years. From about 2003 to 2014 he had only done about one a year. He said he counsels patients because he frequently has referrals from primary care where a consultant needs to be seen. Such patients are seen very infrequently. He has probably seen two to three in the last five years, or perhaps ten in the last six years. The cases he performs are complicated. The dominant problem would be the inability to find the *vas deferens*. Of the people he has counselled and dealt with, nobody has failed to proceed with the operations. Mr Reynard accepted that his practice is based on other people's research and guidelines. His counselling for vasectomy is entirely based on what people tell him the risks are.

114. Mr Parkinson sees patients for counselling about vasectomy and also performs vasectomy under local and general anaesthetic. He sees about two patients per month. He has done this throughout his consultant career of some 10 years.

115. As regards the severity of pain from which Mr Ollosson suffers, Mr Reynard said that that incidence is substantially less than 1%. In the Leslie paper (2007) on which the AUA Guidelines are substantially based, only four men among the 443 with no pain

before vasectomy describe the pain after vasectomy as "severe and noticeably affects their quality of life". This equates to 0.9%.[29] Mr Reynard was asked about Mr Parkinson's opinion that the risk of very severe and unremitting and debilitating pain was much less, perhaps 1 in 5000. He responded that in the Leslie paper those who described a pain level of 10/10 was about 1 in 500. Nevertheless, the confidence intervals on that would be extremely wide, such that it was not statistically significant[30]. It was the only information he could go on. He also accepted that pain thresholds could vary especially when people were self-scoring.

116. Mr Reynard said that the BAUS consent forms are like a checklist. He would supplement that with more information. Part of the job is to interpret jargon on forms and to quantify and qualify risks. The task is to embellish the subject without trying to put the patient off. He said this was a very delicate balance. He routinely told people that the risk of very severe unremitting and debilitating pain was present. He had not had anybody who had failed to continue with the procedure after the warning. However, a colleague had told him two people had walked away because of the risk of pain. He was not able to provide any more detail on this.

117. Finally, he said it was interesting that there were four experts in court and all had different views about getting the information across. He personally used percentages.

118. Both experts agree that in 2012 urologists were consenting patients for vasectomy on the basis of BAUS consent information guidance, supplemented by other information. Before 2013 (when the consent forms were modified), consent form guidance from BAUS recommended discussion with patients prior to vasectomy, including "rare … chronic testicular pain (5%) …[31]" Mr Reynard's opinion is that this would been supplemented by other information providing a clearer indication of what was meant by "chronic testicular pain". For example two urologists[32] noted in the BMJ of 2010: "severe scrotal pain defined as a visual analogue pain score greater than 5 was found in 1 - 6% of men after vasectomy in a study that followed participants for 10 years"[33].

119. Mr Reynard's opinion was that the 2010 paper BMJ paper was something of which urologists and other doctors doing a vasectomy in 2012 would or should have been aware. In oral evidence Mr Reynard said that he thought that the statistics in that paper were the most accurate evidence and he would give patients those statistics. He accepted that none of the other experts in the case do in fact counsel patients in those terms. In relation to what Doctor Lee said in his supplemental statement that he told Mr Ollosson in response to his question, Mr Reynard accepted that if there was some indication of the severity of pain then Doctor Lee's advice would be acceptable. Therefore, because severe pain was, according to Doctor Lee, mentioned, then that was an adequate response.

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[29] Mr Reynard accepted that the total number of men taking part in the audit was 626 and suggested that the ones who had not responded (138) probably had had no pain. On that basis the percentage of men with that level of pain would be somewhat less than 0.9%.

[30] This is because, had that one not been present the incidence would have been zero. Had there been another, it would have doubled.

[31] Mr Reynard said that he would perhaps take issue with 5% being described as "rare" but agreed that was that the form said.

[32] Keoghane and Sullivan

[33] The article says: "when obtaining informed consent for a vasectomy, this potential complication should not be underplayed, particularly in the presence of existing scrotal discomfort."

120. Mr Parkinson said he would expect a patient to be informed that 15% of men having a vasectomy will develop scrotal pain afterwards. For most the pain is mild and not bothersome, but around 1% will develop a more severe pain that is bothersome and may require further treatment. Treatment of this pain is not always successful. Although this is a small risk, it is not so small it can be ignored and it should be taken into consideration[34]. It is not common practice to warn patients of very severe, unremitting and debilitating pain, as this is extremely rare. Mr Parkinson has never encountered it. He does not think that this is something about which a reasonable patient would be expected to be informed, unless there was a specific reason such as pre-existing problem with chronic pain. Mr Parkinson says that the risk of quite severe pain is less than 1%, but the risk of very severe unremitting and debilitating pain is much less (perhaps 1 in 5000). In his experience no patient has declined a vasectomy having been warned of the risk of chronic scrotal pain, even when the risk of problematic pain is specifically discussed.

121. Mr Parkinson explained how he had arrived at the 1 in 5000 risk of very severe unremitting and debilitating pain. He said that the published evidence was not sensitive enough to pick up this level of very severe pain. The 0.9% in the Leslie paper was less severe. What he had done was to think about the chronic scrotal pain patients he sees. Most of them have idiopathic pain, some of it is post-vasectomy pain. The majority have milder degrees of pain that can be managed with painkillers. He sees about one or two patients a week. About one in fifty require very strong painkillers, pain modulators or surgery. He can only think of two people in the last ten years who have had an operation for pain. It is based upon that that he estimates 1 in 5000. Another way he has tried to cross check is that there are about 10,000 vasectomies per year in the UK. In a 1 in 5000 incidence level of pain of the severity of Mr Ollosson's, that would equate to two a year. He said that felt about right on the evidence of the four experts in this case and his own experience. He had asked colleagues how they would estimate the risk and one had said 1 in 2000. Another, who is in an expert in reversal vasectomies, said he had seen about two or three over ten years. That second colleague would see more of the very severe pain outcomes than is normally the case.

122. Mr Parkinson accepted that one has to be careful about ancedotal evidence and that what he had based his estimate on was ancedotal. How men present with pain is quite variable. The design of the Leslie paper was to follow up men with pain post-vasectomy and it is the most robust paper available. It does not include only those who go to seek medical advice, as some patients would just put up with pain and would be unlikely to present at clinic. The paper is designed to pick out patients with pain and ask people to put themselves in a range.

123. Nevertheless, on looking at the data in the Leslie paper four men described their pain as "quite severe and noticeably affects their quality of life" (0.9%). However, looking at the other information, those four men scored their pain at 6, 7 (x2) and 8. However, the one person who had scored himself at 10 and two others who scored themselves as 8 had not described their pain in those terms. That description of pain was the most severe catered for in the study (figure 2). Therefore, their description of pain would have been no more than "moderate, require pain killers". The fact that three of the four who described themselves with the most severe pain self-scored as 6

[34] Mr Parkinson added in oral evidence that this information is pretty much what he says during counselling.

and 7, and that two who self-scored as 8 and one at 10 described their pain in lesser terms, demonstrates the difficulty of self assessment of pain.

124. The expert urologists were asked to what extent, if at all, it is appropriate for any vasectomy practitioner to rely upon and/or counsel a patient about their own experience of the incidence or magnitude of any material risks. Mr Reynard said it is reasonable for any surgeon to consent a patient according to his or her own outcomes and complications, but that the reference to nationally or internationally reported outcomes is nonetheless still important where a surgeon has not previously had a negative outcome. This is on the basis that no surgeon is immune from negative outcomes, no matter what his or her previous experience. A surgeon is potentially just an operation away from such a negative outcome. Mr Parkinson said that personal data is unreliable and should not be relied upon in consent, unless the clinician's personal data are robust, high volume and subject to peer review. He agrees with Mr Reynard.

125. In relation to the Booklet stating "there is a small possibility of post-vasectomy pain, which can be chronic":

i) Mr Reynard's opinion is that this did not provide an adequate explanation of what chronic testicular pain could mean in terms of its impact both clinically and on work and life in general;

ii) Mr Parkinson's opinion is that the consent form never records the full details of a discussion[35]. In this case the consent form indicates that chronic pain was discussed as an outcome.

126. The experts agree that if what Doctor Lee says he discussed with Mr and Mrs Ollosson included a discussion about the development of severe pain impacting on quality of life, then this would be adequate. If it did not include a discussion about the development of severe pain impacting on quality of life, then it would not be adequate.

127. Finally, the experts comment on the question as to whether the use of the words "a small possibility of post-vasectomy pain which can be chronic is appropriate, as opposed to percentages". Their opinions are:

i) Mr Reynard says "small" is open to variable interpretations. A doctor defined small risk may not be viewed as such by a patient. The word may be interpreted by a patient as meaning low in frequency or low in impact. Percentage risks give, as a minimum, an idea of frequency of an event;

ii) Mr Parkinson's opinion is that a 1-2% risk is a small risk, as understood in general usage. It is not a technical, medical or statistical term and is subjective. However, a reasonable person in the Claimant's position would accept that 1-2% is a small percentage. A small possibility does not imply a small impact.

128. In oral evidence Mr Parkinson added the following:

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[35] Mr Reynard agrees with this.

a) he believes it is preferable to provide a percentage risk wherever possible, though to some people statistics mean something and to others they do not. He counsels that the risk of post-operative pain is 15% and the risk of pain affecting quality of life is about 1%. He says it is up to the clinician whether they go into percentages;

b) he agrees with Mr Reynard that there are two elements namely the quantification of risk and qualifying it in terms of its effect if it does happen. However, he said one cannot go into the "… nth degree" in dealing with the possible consequences if a risk occurs;

c) the face to face discussion with the clinician puts the flesh on the bones of the key elements which need to be discussed. This is particularly the case in an elective procedure;

d) the risk of testicular atrophy is not known. He has not encountered it. It is mentioned in the report but there is no information, such as is found in the Leslie paper relating to post-operative pain. He said he did not think anybody had attempted to study it;

e) his clinic is not a bespoke vasectomy clinic. It is a general urology clinic. He talks patients through the risks. They go away and come back if they want surgery. That consent process would be slightly dubious if he proceeded straight to surgery. All the patients he has seen and counselled have come back, though the numbers he deals with are relatively low. About 1 in 10 of his patients ask more questions about the pain.

Core Findings of Fact/Discussion

General

129. It was common ground that the risk of chronic pain was a material risk for which a warning should be given. As Ms Whittaker said, this is a case in which it is clear that some warning was given. The question is whether it was adequate.

130. Mr Matthews submitted that a proper interpretation of *Montgomery*, as applied to this case, required information to be given to Mr Ollosson that gave a proper indication of the magnitude of the risk, i.e. the chances of it occurring, and also of the range of consequences if it did occur. He submitted that what was said in the Booklet was insufficient. That much is agreed. Further, he submitted that what Doctor Lee said he said in his statement was insufficient, though what he said in oral evidence would have been sufficient. The gist of what Mr Matthews submitted should have been communicated, if percentages were not used for the quantification of the risk, was that it was not uncommon for patients to have some long term persisting pain which can range from mild to severe.

Pre 15th November 2012

131. At the outset I accept that Mr Ollosson had not had counselling relevant to pain risks of vasectomy from his General Practitioner. I also accept that he had not done his own

researches on the Internet. Therefore any information relevant to this case was communicated to him by the literature sent, and by Doctor Lee and Nurse Keene on 15th November 2012.

132. I turn first to the literature sent to Mr Ollosson. It is not seriously contested that the Booklet and the blank consent form were sent. I therefore find that it was sent and read by Mr and Mrs Ollosson. The fact that they did not recall this, but accepted the Defendant's evidence on this point (a) indicates that they made reasonable and sensible concessions, (b) does not of itself particularly undermine their evidence. Mr Matthews rightly drew attention to the fact that Mr Ollosson's copy of the consent form would have been a photocopy of the completed one. This explains why he may not recall being sent a blank form with the Booklet. It is an example of how memory is likely to be patchy and how people unsurprisingly re-construct that memory from other sources.

133. There is some tension between the statement on Page 5 of the Booklet and the statement on Page 8. If page 5 had stood alone, it was capable of conveying to a layman that there were no long-term risks to health, including chronic pain, despite its intention and its interpretation by the doctors that it was aimed at dispelling concerns about cancer or autoimmune system sequelae. Doctor Lee accepted this.

134. Mr Ollosson's oral evidence was that he read the Booklet and he knew of the risk of chronic pain. He interpreted 'chronic' as long-term bad pain. I have considered whether this evidence is probably correct or whether it may be inaccurate and based merely on Mr Ollosson trying to work out what he would have assumed from the Booklet. I have come to the conclusion that it is probably correct for the following reasons: (a) reading the Booklet with a modicum of care would probably lead to this conclusion as a matter of the common interpretation of the wording; whether this was re-constructed memory or actual memory (more likely the former), in either event it is probably what happened; (b) as regards the meaning of the word 'chronic', although this does not convey anything about the severity of the pain, Mr Ollosson is likely to be accurate as to what the word means/meant to him;[36] (c) I have noted that in Mr Ollosson's first written complaint[37] he refers to the Booklet's reference to "a small possibility of post vasectomy pain", and says this, in conjunction with Page 5, indicates it is "actually a short term problem". However, the tone of that letter is of somebody who is very upset, and he omits to mention that page 8 says that the pain "can be chronic".

135. Mr Ollosson said that he thought that because there was no figure given for the risk of post vasectomy pain, he thought it was less than 1:2000 since figures were given for the first two stated risks. He mentions this also in his complaint e-mail of 15th March 2013. Nevertheless, I do not accept that this is probably what he believed at the time of reading the Booklet. I believe Mr Ollosson is mistaken in his memory. This point is not in his witness statement. Further, it does not fit well with the fact that there is no figure given for the risk of infection or haematoma, whereas Mr Ollosson said in evidence that he knew there was always a risk of infection. Nor do I consider it to be a

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[36] I doubt if he would be the only person to make this error

[37] E mail 15th March 2013

logical conclusion[38]; this does not mean that it was not possible that Mr Ollosson formed that view; it does make it less likely that he did.

136. The blank consent form is referred to in the Booklet and was sent with it. I have set out its terms earlier in this judgment. There again under the heading "Serious or frequently occurring risks" are Infection/haematoma, the 1:1000 early failure rate, the 1:2000 late failure rate, Chronic Testicular pain and Testicular atrophy".

137. Mr Matthews submitted that Mr Ollosson's state of mind when confirming his appointment after reading the Booklet was that he had a niggle in his mind about post vasectomy pain. That may have been the case, but what he did know was that there was a small risk of (in his words) long-term bad pain, described in the blank consent form as "Serious or frequently occurring[39]". The risk was unquantified, but had not been interpreted by him as less than 1:2000. I accept that he wanted some clarification face to face.

138. Was Mr Ollosson essentially committed when he arrived at the surgery on 15th November 2012? He said he was not. His wife had said in her statement that he was. I believe she is mistaken. It is correct some men would be psychologically committed. It may be that for a number of men it would be important to have face-to-face counselling on a day prior to the operation[40]. However, Mr Ollosson was not in that category. In addition, there was the unchallenged evidence for Nurse Keene and from Doctor Lee that if a patient exhibited any doubts, the operation would not proceed. This is not the same situation as in the *Thefaut* case. Further, some information had been already communicated in the Booklet and there is no evidence that Nurse Keene or Doctor Lee or the Claimant were under any pressure of time. There was adequate time and space for a sensible dialogue to occur and for free choice to be exercised. The question is whether there was a sensible and sufficient dialogue.

15th November 2012

139. An important first point is centred on some undisputed evidence. In his witness statement, Mr Olosson said that he went through the consent form with Nurse Keene and Doctor Lee. This was explored in cross examination, the detail of which I have already set out.[41] Importantly:

- Long-term pain was discussed with Nurse Keene. This Mr Ollosson accepted, based on Nurse Keene's contemporaneous note.
- It was logical, and essentially Mr Ollossson accepted, that Doctor Lee went through the consent form and ticked the boxes of "serious or frequently occurring risks", including "Chronic testicular pain" and discussed them all with him, though he said not in depth.

140. Pausing there, I note that there is nothing in Mr Ollosson's or Mrs Ollosson's statements in which they accept that either Nurse Keene or Doctor Lee discussed the risk of chronic testicular pain with them. In the complaint e mail of 15th March 2013,

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[38] If anything, the adjective 'small' would suggest a greater, not a lesser risk, than the adjectives 'rare' and 'remote'.

[39] I note that these are disjunctive

[40] Hence the evidence from the medical experts on that topic

[41] See [23] above

the emphasis is on the Booklet saying: "There is no evidence of long tem risk to men's physical or mental health", and being "told similar verbally as well". Nurse Keene's statement[42] says: "I would always ensure that the patient and relative/friend (if present) were fully informed of the procedure and were aware of the risks of the potential risks or complications of the procedure".

141. What Doctor Lee said his discussion would have been[43] when dealing with the consent form in relation to chronic testicular pain was: "I discuss with the patient and their partner how this pain might present and affect their lifestyle. We will discuss that there is no consensus about specific treatment and that the pain can be a long-term condition."

142. It is against that backdrop that Mr and Mrs Ollosson's recollection falls to be considered.

143. Given that (a) chronic testicular pain was discussed, (b) Mr Ollosson's understanding of 'chronic' was that it meant bad and long-term and (c) Mr Ollosson did have a concern, what is the most probable gist of the conversation between the Ollossons and Doctor Lee?

144. Mr Ollosson's witness statement account is that he asked a question about the possibility of pain after vasectomy. The reply was that all men will get pain after vasectomy and some may get it worse than others, but it should be treatable with over the counter medication such as Ibuprofen. There are a number of problems with this recollection, namely:

(i) It does not fit well with the acceptance in oral evidence that Doctor Lee went through the checklist on the consent form (which they had brought with them) and discussed the seriously or frequently occurring risks, including chronic testicular pain.

(ii) It does not fit well with the acceptance in oral evidence that, as Nurse Keene's note shows, she discussed 'long-term pain'. She saw Mr Ollosson first.

(iii) If Mr Ollosson arrived with a question to ask about post vasectomy pain, and if, as he said in evidence, he arrived knowing there was a risk of long-term pain, (though he said he thought the risk was less than 1: 2000), then Doctor Lee's alleged response did not answer his question. His oral evidence was that the question was about how the wording on Page 5 of the Booklet stood with the wording on Page 8. It is difficult to see how Mr Ollosson would have been reassured, given his recollection in oral evidence as to his frame of mind when he arrived.

(iv) Doctor Lee was an experienced vasectomy practitioner. He was aware of the risk, as is confirmed from the literature and the consent form. Is it likely that he would have given the sort of response attributed to him? On the one hand, Mr Matthews submits that it is, on the basis that it is consistent with a kindly doctor trying to reassure a patient and based on his own experience of never having had a patient suffer from chronic pain. On the other hand, knowing of the risks and going through

[42] It was not expanded upon or clarified as Mr Matthews agreed it, so Nurse Keene did not give oral evidence.
[43] Witness statement paragraph 19

them with the patient, the alleged response amounts, however uncritically one might seek to describe it, as a misleading answer.

145. In my judgment, if a question was asked, I do not accept that Doctor Lee's response was as recalled by Mr Ollosson. In particular I do not accept that Doctor Lee in any way conveyed to Mr Ollosson that nobody suffered from long-term pain. That is not consistent with the evidence as a whole, and it is not consistent with my assessment of Doctor Lee as a practitioner. It is to be recalled that, though Doctor Lee had not had a patient who had suffered from chronic pain, he said[44] that he would stress this potential outcome as a few colleagues in his peer group had experienced such patients. It may have been that during the conversation it was mentioned that for most men the pain would be treatable with over the counter medication. It may be that that is the sort of thing which would stick in Mr Ollosson's mind, precisely because that is the position for the majority.

146. The remaining questions at this stage of the analysis are: (1) Did Mr Ollosson in fact ask a question? (2) If so, what was the gist of Doctor Lee's reply?

147. Ms Whittaker submitted that probably no question was asked. It is true that Mr Ollosson is vague as to the terms of the question, but that is hardly surprising. I believe that he arrived at the surgery aware that there was a small risk of bad, long-term pain and that he wanted more information about this before finally deciding to proceed. Further, there was the discussion with Nurse Keene and Doctor Lee based on the consent form, and in the course of that discussion more information was given. Neither party suggested the consultation was in any way rushed. It is likely that there would have been some dialogue and discussion, which probably did incorporate questioning from Mr Ollosson about post vasectomy pain.

148. That being the case, what information did Doctor Lee probably provide? Based on my above summary of Doctor Lee's evidence my findings are:

(i) That Doctor Lee mentioned, as he always would when consenting a patient, chronic testicular pain as a potential complication. He explained how the pain might present and affect their lifestyle and that it could be long-term; also that there was no consensus about specific treatment. He referred to the risk in terms that conveyed that it was a small risk, but greater than the rare and remote risks of early and late failure[45].

(ii) In response to questioning about the risk he explained that the pain may range from mild to severe and would be likely to increase during intercourse. The pain could occur on a daily or even hourly basis, could affect their life and they should be sure that they were prepared to live with such an outcome and the effect it would have on their life.

(iii) Doctor Lee's evidence about the possibility of painkillers as strong as morphine, possible referral to a pain clinic or possible reversal of vasectomy[46] being mentioned is not in his witness statements. Although he may sometimes discuss these matters, I

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[44] See [78] above
[45] See above at [78]
[46] See above at [60]-[61]

am not persuaded that they were invariably said in response to a question about the risk of chronic pain, particularly in 2012. I do not find they were communicated to Mr Ollosson. I believe Doctor Lee's memory is wrong in this regard.

(iii) In discussion about possible treatment for post vasectomy pain in general, he said words to the effect that it would be treated by over the counter medication such as Ibuprofen. However, I accept Doctor Lee's evidence that this would only be part of his response.

(iv) Mr Ollosson probably did not ask Doctor Lee about percentages.

149. In coming to these conclusions I have taken into account:

(i) The point made in closing submissions by Mr Matthews. He says that there is a conflict between paragraph 9 of Doctor Lee's supplemental statement and paragraph 19 of his witness statement. Paragraph 9 does not refer to the potential effect on lifestyle of post vasectomy pain when setting out normal counselling, absent a question. Paragraph 19 does so, and this is pleaded in the Defence. I do not think this was put to Doctor Lee in cross examination. In any event I accept what is in paragraph 19. Paragraph 9 is not contradictory of this; it fails to repeat part of it.

(ii) The evidence as to Mr Ollosson's reaction after hearing about the discussion with Mr Hughes[47], and that Mr Ollosson's recollection at that time was that he had not been warned about the possible side effects of surgery. I would add that the context of this was that Mr Ollosson was already having severe symptoms, much worse than the vast majority of men who suffer from chronic post vasectomy pain; he also understood Mr Hughes to be telling him that there was a 5% risk of ending up with his level of symptoms, whereas in fact Mr Hughes would have been referring to the risk of chronic pain generally. It follows that I find that his memory was already defective by that stage.

(iii) The terms of the correspondence between 15th March 2013 and 12th August 2013. In the last letter, it is correct that Doctor Lee did not respond to Mr Ollosson's 12th July 2013 point, namely that he had enquired about post vasectomy pain and had been given the answer which later appeared in Mr Ollosson's statement. There are a number of specific points in the 12th July 2013 letter to which Doctor Lee does not respond. He does say: "The possibility of experiencing chronic pain is covered by me during the consent process prior to the Vasectomy procedure and I can therefore confirm that I did inform you of the possibility of experiencing chronic pain." The relative generality of Doctor Lee's response does not undermine my above findings.

150. The next question is whether the information given by Doctor Lee was adequate to comply with his duty to inform Mr Ollosson.

151. In terms of the quality of the risk, it was communicated to Mr Ollosson that it was a risk of long term persisting pain which could range from mild to severe. That is sufficient information. I understand Mr Matthews to accept that, if I made the above findings.

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[47] See [30] above

152. In terms of the magnitude or quantification of the risk, was it sufficient for Doctor Lee to say that it was small, adding that it was greater than the rare/remote risks of early or late failure? Mr Matthews rightly accepted that it would not be necessary to give percentages, though he said this could be done. His formulation was that the risk could properly have been described as 'not uncommon'. In fact there was in the literature a wide range of possible percentages of risk of chronic pain. The 2010 BMJ review paper[48] says "Retrospective case studies, prospective observational audits and follow-up studies suggest that chronic pain follows vasectomy in 1-15% of men". I would not criticise a medical practitioner for not giving percentages of the risk of chronic post vasectomy pain, unless asked.

153. I remind myself of the authorities which I have cited above in particular the relevant sections of *Montgomery* and *Duce* at [33]. The quantification of the risk is a matter for the experts. What should be told to a patient is a matter for the court. It is not, as *Montgomery* says at [83] "a matter of purely professional judgment or, *Duce* at [33(2)] "something that can be determined by expert evidence alone". It is right that the court listens to, and takes account of the expert evidence, but the effect of *Montgomery* that the *Bolam* test has no relevance on this topic should not be in any way undermined or watered down.

154. Looking at the expert evidence:

(i) Doctor Feltbower[49] said that in 2012[50] to describe a small risk of chronic pain would have been enough. He may have said that the pain could have been severe and chronic, but would not have given more detail unless the patient asked for it. Since 2018, and probably because of his involvement in this case, his consent form mentions that pain should involve the risk of pain affecting quality of life. He regarded what Doctor Lee had said in his statement (if accepted by the court) to be acceptable.

(ii) Doctor Hampton agreed with everything Doctor Feltbower had said, though he himself told patients in 2012 that there was a 5% risk of chronic pain

(iii) Mr Reynard said he personally used percentages to get the risk across to a patient. Mr Parkinson thought it preferable to use percentages. Both agreed that in 2012 urologists used the BAUS consent form which referred to a risk of "chronic testicular pain (5%)" under the heading 'Rare'.

155. A large number of statistics was discussed in evidence. In summary the risk of chronic pain appears to be about 5%. Once one tries to evaluate pain there is always difficulty, as there is a considerable subjective element in the appreciation of pain, and substantial variation in patients who try to describe or score levels of pain. In the Leslie paper (2007) 0.9% had pain at 7 months post operation which they described as quite severe and affecting their quality of life. The percentage who have pain at the level of Mr Ollosson cannot properly be assessed, though it is very much smaller than that. He was, it must be said, extremely unlucky.

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[48] Keoghane and Sullivan, citing 6 papers, including the Leslie paper (2007)
[49] See above paragraphs 94-96, 102(iii)-(iv), 103(v)-(vii)
[50] There is nothing in the medical literature since 2012 which materially changes knowledge as to the magnitude of risk or the character of the post vasectomy pain which may ensue.

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.

157. In the light of those findings Mr Ollosson's claim must fail. On the balance of probabilities he was adequately informed by being told of a small risk of chronic pain, and of the range of severity and possible effect on lifestyle if it did materialise. Though the Booklet was of itself insufficient, the information provided at the surgery was in an unpressurised situation, with time to reflect, and against a background where Mr Ollosson had arrived with some knowledge that there was a risk of bad long-term pain. He would have been psychologically prepared to go through with the operation, but his clear evidence was that had he been told of a risk which was unacceptable to him, he would have walked away. This is confirmed by Doctor Lee's evidence that he does not proceed if he senses any real doubt on the part of a patient.

158. It is not sensible to consider causation in the alternative since, by definition on my findings, Mr Ollosson did give properly informed consent. However, I do make the following points:

(i) If Doctor Lee had adopted Mr Matthews' suggested quantification of the risk of chronic pain as "not uncommon', or if a properly estimated percentage (say 5%) had been communicated to Mr Ollosson, in lieu of a 'small' risk, I do not consider that it would have made any difference. Mr Ollosson would have probably still proceeded.

(ii) This was an elective procedure where the choice was to take the concomitant risks or, for the Ollosons, to use barrier methods which they did not want to use, if possible. There was a substantial imperative for Mr Ollosson to find another means of contraception.

(iii) Every person is an individual but there are, on the evidence, about 10,000 vasectomies every year. Dr Feltbower has access to a database of 70,000-80,000 men who have had vasectomies. Criticisms can be made of the methodology of the experience of the four experts' evidence about men not refusing to go ahead with the procedure, despite the risk of chronic pain sometimes severe in nature and affecting lifestyle[52]. That said, it is of some significance that their evidence was to the effect that the risk of chronic pain is not a factor which any expert encountered personally as being off-putting to men considering vasectomy.[53]

Summary

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[51] Though not the 2017 BAUS consent form

[52] For example men counselled separately by their GP may not register in the first place for the procedure; also men may be put off by their own reaches e.g on the Internet. There is no study of men who considered vasectomy but decided against it because of the risks and so never arrived at the point of seeing a vasectomist.

[53] See evidence summarised above: Doctor Feltbower at paragraphs 92, 93, 105-108; Doctor Hampton at paragraphs 97, 109; Mr Reynard at paragraphs 110-111, 114; Mr Parkinson at paragraphs 112, 118, 126e.

159. Mr and Mrs Ollosson are decent, honest people. Mr Ollosson continues to suffer from extremely unpleasant consequences of his vasectomy operation in November 2012. His chances of sustaining this level of continuing pain were much less than 1%. The probabilities are (i) he was adequately informed of the risk of chronic pain and of its range of possible severity, (ii) his memory of what he was told, particularly in this regard, is imperfect, and critically so, (iii) this is perhaps unsurprising given how he would have prospectively regarded the risk pre-operation and how, even from a few months post operation, the circumstances then appeared to him.