Neutral Citation Number: [2020] EWHC 310 (QB)

Case No: QB-2017-003013

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
CLINICAL NEGLIGENCE

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: Tuesday, 25th February 2020

Before:

GEOFFREY TATTERSALL QC
(sitting as a Deputy Judge of the High Court)

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Between:

SARAH PEPPER	**Claimant**
- and -	
ROYAL FREE LONDON NHS FOUNDATION TRUST	**Defendant**

- -
- -

Helen Mulholland (instructed by **Messrs Bolt Burdon Kemp**) for the **Claimant**
Andrew Bershadski (instructed by **Bevan Brittan LLP**) for the **Defendant**

Hearing dates: 18-21 and 25 November 2019

- -

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.

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HUGH MERCER QC

Geoffrey Tattersall QC:

Introduction

1. In these proceedings Ms Sarah Elizabeth Pepper ['the Claimant'] brings a claim for damages against the Royal Free London NHS Foundation Trust ['the Defendant']. She alleges negligence on the part of the Defendant's employees or agents, and in particular Professor Massimo Malagò, a Professor in Hepato-Pancreatic-Biliary ['HPB'] and Liver Transplant surgery, in respect of his treatment of the Claimant from about September 2014 which resulted in her undergoing a pancreaticoduodenectomy ['a Whipple's procedure'] undertaken by him on 17 November 2014. Such a procedure involves removal of the head of the pancreas, part of the small intestine, the gallbladder and part of the bile duct and is performed to remove cancerous tumours off the head of the pancreas, sometimes known as a pancreatic resection.

2. Such surgery was undertaken because Professor Malagò believed that the Claimant was suffering from pancreatic cancer. In fact, tests after such surgery confirmed the absence of malignancy but disclosed that she had acute pancreatitis and cholecystitis.

3. It is contended by the Claimant, who was then aged 56 years and in full-time employment, that by reason of Professor Malagò's negligence she underwent an unnecessary laparotomy and Whipple's procedure. She is now aged 61 years and suffers from the effects of pancreatic resection in that she now suffers significant maldigestion and a pancreatic exocrine deficiency and has to take pancreatic enzyme supplements permanently, suffers from digestive malabsorption, has lost weight, has significant disturbance to her bowel function, has a 25-40% lifetime risk of developing diabetes and is currently only able to work part-time.

4. However, I am not concerned with the consequences of such surgery because the hearing before me was limited to the issue of liability. The question which I have to decide, put shortly, is whether the Claimant should have been advised by Professor Malagò to undergo such surgery at all and, in particular, whether she had given her consent for such surgery.

5. At the hearing before me Ms Helen Mulholland represented the Claimant and Mr Andrew Bershadski represented the Defendant.

6. At the hearing I heard factual evidence from the Claimant, her wife Eva Lewin ['Ms Lewin'], Professor Malagò and Gemma Keating ['Ms Keating'], an HPB clinical nurse specialist who worked alongside Professor Malagò.

7. I also heard expert evidence from Professor Colin Johnson [for the Claimant] and Professor Steve White [for the Defendant], both consultant general surgeons specialising in this field, albeit that Professor Johnson had retired from clinical practice in August 2014.

8. Although I did not hear oral evidence from either Professor Derrick Martin [for the Claimant] or Dr Stuart Roberts [for the Defendant], both consultant radiologists, the parties agreed that, since there was much agreement between such experts, I should

have regard to their evidence without either of them being called to give evidence or be cross examined.

9. The structure of this judgment is as follows. Firstly, I will give a brief overview of the Claimant's case and summarise the pleaded cases of the parties. Secondly, I will review the relevant authorities relied on by the parties. Thirdly, I will review the evidence in detail and will set out my findings of fact on the basis of such evidence. Fourthly, I will review the expert evidence and express my conclusions as to such expert evidence. Finally, I will determine the merits of the Claimant's case.

A brief overview of the case

10. Given the complexity of this case it is helpful at the outset of this judgment to set out a brief summary of events.

11. The Claimant attended the emergency department at Whittington Hospital on 12 June 2014 with right upper abdominal pain. An ultrasound was performed and computed tomography ['CT'] were performed on 13 June 2014 which showed an ill-defined area of low attenuation in the pancreatic head. A discussion at a multi-disciplinary team ['MDT'] meeting on 20 June 2014 recommended a magnetic resonance imaging ['MRI'] scan of the liver and magnetic resonance cholangiopancreatography ['MRCP']. These scans were performed on 22 July 2014 and the recommendation was a discussion at a specialist hospital MDT as underlying cancer ['malignancy'] needed exclusion with endoscopic ultrasound ['EUS']. The Claimant's care was thus transferred to the Defendant's hospital.

12. The specialist hepatobiliary MDT considered the Claimant's case on 2 September 2014 and concluded that there should be an EUS of the pancreas. An EUS performed on 30 September 2014 showed a 1.5cm irregular diffuse lesion. Biopsy material taken from the lesion showed normal tissue and the bloods taken were normal. A further CT scan and repeat EUS with fine needle aspiration ['FNA'] were recommended.

13. The second EUS was performed on 17 October 2014 which reported a 1.3cm hypoechoic [i.e. more dense or solid than normal] lesion. The headline diagnosis of the report stated 'Pancreas, Probably malignant tumour' and a core biopsy and FNA biopsy were also taken at this EUS.

14. The core biopsy report dated 21 October 2014 reported that 'no malignant cells are present'.

15. The cytology report dated 4 November 2014 noted that there were 'crowded clusters of atypical glandular cells' and that the 'appearances are suspicious of malignancy but an inflammatory lesion cannot be excluded'.

16. On 31 October 2014 Professor Malagò saw the Claimant for the third time and recommended surgery which the Claimant underwent on 17 November 2014.

17. During such surgery an intra-operative 'frozen section' biopsy [referred to hereafter as an 'intra-operative biopsy'] was negative for tumour but Professor Malagò adjudged that the head of the pancreas felt hard on examination and he proceeded to undertake a

Whipple's procedure. Histopathology results from tissue removed during surgery showed no malignancy but acute pancreatitis and cholecystitis.

18. Although the Claimant consented to surgery there is a factual dispute, which I will discuss below, as to the nature of such consent. Professor Malagò alleges that the Claimant consented to such surgery, during which there would be an intra-operative biopsy which would be reported on immediately, on the basis that in the event of a positive [i.e. malignant] biopsy or if Professor Malagò believed that the appearance of the pancreas was very suspicious, he would carry out a Whipple's procedure. By contrast, the Claimant alleges that her consent was given on the basis that Professor Malagò would *only* undertake a Whipple's procedure if there was evidence of malignancy from the intra-operative biopsy.

19. I should record at the outset that it is common ground that pancreatic cancer is a devastating disease which can be very aggressive, that it has a poor prognosis and that to undertake a period of observation of one to two months, rather than undertaking a resection, can potentially mean that ultimately surgery is undertaken too late to save the patient's life. So it was that the following general opinions were expressed by the parties' surgical experts.

20. Professor Johnson opined that the management of a lesion in the pancreas which is suspicious for malignancy but for which the radiological appearances are not diagnostic, is difficult and that until the advent of EUS it was accepted that 5-10% of pancreatic resections would turn out to have a non-malignant pathology although with the advent of EUS his experience was that the risk of a non-malignant pathology had fallen. In cross-examination he expressed the matter somewhat bluntly: the diagnosis of pancreatic cancer was a death sentence and the timing of treatment determined the duration of a patient's survival.

21. Professor White opined that pancreatic cancer is a devastating disease which spreads rapidly and has a poor prognosis with a 5-year survival of 5% even after surgery. It is important to diagnose it early and remove the cancer as soon as possible and the consequences of getting the diagnosis wrong is usually catastrophic. He believed that any patient presenting with symptoms such as abdominal pain, here right upper quadrant pain, and a mass in the pancreas should be regarded as having a pancreatic cancer until proven otherwise.

The Claimant's pleaded case

22. I turn to consider the Claimant's pleaded case.

23. The Particulars of Claim fully set out the facts relied upon and the pleaded allegations of breach of duty therein may conveniently be summarised in that Professor Malagò:

    (1) failed to heed the fact that the extensive investigations which the Claimant had undergone made it more likely that she was suffering from a benign disease;

    (2) failed to heed the radiological findings which because of the lack of a progression, possible regression, lack of change of size and lack of pancreatic and bile duct reduction were strongly suggestive of a benign disease;

(3) failed to proceed to a period of observation and further imaging when such would have avoided surgery;

(4) failed to heed that the two biopsies taken at EUS and blood test markers were all negative and that together with the absence of symptoms since June 2014 and the variable radiological findings made it much more likely that there was no malignancy;

(5) advised the Claimant to proceed to surgery when to do so was contrary to any responsible body of pancreatic surgeons and defied logical analysis;

(6) failed to explain to the Claimant the full clinical picture and the significance of the radiological findings, two negative blood biopsies and normal bloods so that she could weigh up the benefits of surgery adequately and in an informed way;

(7) failed to sufficiently inform the Claimant of the consequences of losing part of her pancreas;

(8) unduly and unreasonably turned the Claimant towards surgery;

(9) failed to allow the Claimant to make an informed decision about her treatment;

(10) failed to consent the Claimant properly either on the day of surgery or prior;

(11) planned to perform a Whipple's procedure when he knew or ought to have known that to do so was unnecessary and undesirable;

(12) caused, permitted or allowed the junior doctor who consented the Claimant to believe that the Claimant was going to undergo a Whipple's procedure when the Claimant's understanding was that she would only undergo such procedure if the intra-operative biopsy demonstrated evidence of cancer;

(13) concluded wrongly at the consultation on 31 October 2014 that the suspicion of adenocarcinoma was still high;

(14) proceeded to resect the pancreas when there was no or no convincing evidence of cancer and contrary to the Claimant's wishes;

(15) failed to record any or any satisfactory description of the status of the head of the pancreas;

(16) failed to appreciate that the appearance of the pancreas was entirely consistent with a resolving inflammatory process;

(17) no responsible body of pancreatic surgeons would support the decision to proceed to a Whipple's procedure in the light of the pre-operative clinical picture and the negative intraoperative biopsy; and

(18) failed to close following the negative intraoperative biopsy so as to explain the situation to the Claimant and allow her to make an informed decision about further surgery.

24. It may be noted from the above analysis that reference is made to the junior doctor who consented the Claimant and to the Claimant's understanding that she would undergo a Whipple's procedure *only* if the intra-operative biopsy demonstrated evidence of malignancy. Moreover, on causation it was expressly pleaded on the Claimant's behalf that the Claimant only consented to a Whipple's procedure if there was evidence of cancer of the pancreas. However, although paragraph 2.25 of the Particulars of Claim recounts the meeting with the junior doctor who consented her and a discussion about the basis on which she might undergo a Whipple's procedure, it is *not* pleaded that the Claimant had amended the consent form to surgery to expressly record such understanding. In such a detailed pleading, such is a surprising omission and I will return to this issue below.

25. As to causation, it was pleaded that had the Claimant received reasonable and appropriate advice and treatment she would not have undergone the Whipple's procedure on 17 November 2014, that she would have elected to have a further period of observation and that by the end of such period of observation the abnormality would have resolved further and the Claimant would not have undergone any surgical treatment.

26. The Defence denied any breach of duty or that any injury or loss was caused by any breach of duty. It contended that Professor Malagò had at all times acted in a manner that accorded with a practice accepted as proper by a responsible body of surgeons.

27. As to the consultation on 31 October 2014, it was alleged that:

    (1) Professor Malagò had recommended undergoing an operation rather than continuing to wait because waiting could lead to a more difficult/riskier procedure or the cancer becoming inoperable which was reasonable and correct advice;

    (2) Professor Malagò had specifically explained that he may continue with the Whipple procedure if the intra-operative biopsy was positive or if there was a very suspicious appearance and the Claimant had agreed to such a course;

    (3) Professor Malagò denied that a positive intra-operative biopsy was a pre-condition to him carrying out the Whipple's procedure because he knew that such biopsies were notoriously unreliable; and

    (4) the Claimant was made aware of the poor prognosis of pancreatic cancer and of the two options open to her of waiting to see whether a confirmed diagnosis could be made or undergoing surgery and opted to undergo surgery.

28. As to the surgery itself, it was alleged that:

    (1) although the intra-operative biopsy was negative, the mass at the head of the pancreas felt suspicious, hard and typical for carcinoma, appeared worse than at radiography and had no classic signs of pancreatitis. In such circumstances Professor Malagò suspected malignancy and carried out the Whipple's procedure. Such was in the Claimant's best interests to avoid the possibility of an aggressive cancer with a poor prognosis from developing; and

(2) it is common [i.e. between 5-11% of cases] for a Whipple's procedure to be performed for presumed cancer only for it to be found that the lesion was benign and such did not constitute a breach of duty.

The parties' reliance on authority

29. As appears below, the issue of consent has loomed large in this case. In this context, Ms Mulholland relied upon a number of authorities.

30. Firstly, Ms Mulholland relied upon the decision of the Supreme Court in *Chester v Ashfar* [2004] UKHL 41 where Lord Hope, in discussing whether on the unusual facts of that case, justice required a modification of the normal approach to causation, stated, at para 86-87:

> "86. I start with the proposition that the law which imposed the duty to warn on the doctor has at its heart the right of the patient to make an informed choice as to whether, and if so when and by whom, to be operated on. Patients may have, and are entitled to have, different views about these matters. All sorts of factors may be at work here - the patient's hopes and fears and personal circumstances, the nature of the condition that has to be treated and, above all, the patient's own views about whether the risk is worth running for the benefits that may come if the operation is carried out. For some the choice may be easy - simply to agree to or decline the operation. But for many the choice will be a difficult one, requiring time to think, to take advice and to weigh up the alternatives. The duty is owed as much to the patient who, if warned, would find the decision difficult as to the patient who would find it simple and could give a clear answer to the doctor one way or the other immediately.
>
> 87. To leave the patient who would find the decision difficult without a remedy, as the normal approach to causation would indicate, would render the duty useless in the cases where it may be needed most. This would discriminate against those who cannot honestly say that they would have declined the operation once and for all if they had been warned. I would find that result unacceptable. The function of the law is to enable rights to be vindicated and to provide remedies where duties have been breached. Unless this is done the duty is a hollow one, stripped of all practical force and devoid of all content. It will have lost its ability to protect the patient and thus to fulfil the only purpose which brought it into existence. On policy grounds therefore I would hold that the test of causation is satisfied in this case. The injury was intimately involved with the duty to warn. The duty was owed by the doctor who performed the surgery that Miss Chester consented to. It was the product of the very risk that she should have been warned about when she gave her consent. So, I would hold that it can be regarded as having been caused, in the legal sense, by the breach of that duty."

31. Secondly, Ms Mulholland relied upon the decision of the Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 as explained in the judgment of Hamblen LJ in *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307 as follows:

> "30. In *Montgomery* the Supreme Court highlighted the importance of patient autonomy and the patient's entitlement to make decisions as to whether to incur risks of injury inherent in treatment. That entitlement was held to 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]
>
> 31. The former role was said to be "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 the latter role was not so limited as one cannot leave "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)" [84].
>
> 32. The nature of the duty was held at [87] to be:
>
> > "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."
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> 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 [83].
>
> (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 [83]. This issue is not therefore the subject of the *Bolam* test and not something that can be determined by reference to expert evidence alone [84-85].
>
> 34. The test of materiality is:
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> > "…whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is

> or should reasonably be aware that the particular patient would be likely to attach significance to it." [87]
>
> 35. Factors of relevance to determining materiality may include: the odds of the risk materialising; the nature of the risk; the effect its occurrence would have on the life of the patient; the importance to the patient of the benefits sought to be achieved by the treatment; the alternatives available and the risks associated with them."

32. Finally, she relied upon particular passages in *Montgomery* itself relating to the role of a doctor who is obtaining consent to surgery.

33. Firstly, the general principle set out at paragraph 90:

> "… 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."

34. Secondly, the guidance given to doctors as to how to consent patients given by the General Medical Council which was an intervener in *Montgomery*, which is set out at paragraph 77:

> "Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patient's rights to reach decisions with you about their treatment and care."

35. Thirdly, some cautionary words that doctors and courts should be wary of substituting their judgment for that of a claimant:

> "45. [In *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1995] AC 871, at 885] Lord Scarman pointed out that the decision whether to consent to the treatment proposed did not depend solely on medical considerations:
>
> > 'The doctor's concern is with health and the relief of pain. These are the medical objectives. But a patient may well have in mind circumstances, objectives, and values which he may reasonably not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion'

> 46. This is an important point. The relative importance attached by patients to quality as against length of life, or to physical appearance or bodily integrity as against the relief of pain, will vary from one patient to another. Countless other examples could be given of the ways in which the views or circumstances of an individual patient may affect their attitude towards a proposed form of treatment and the reasonable alternatives. The doctor cannot form an objective, 'medical' view of these matters, and is therefore not in a position to take the 'right' decision as a matter of clinical judgment."

36. Fourthly, the relevance of a patient's failure to question the doctor:

> "58. The significance attached in *Sidaway* to a patient's failure to question the doctor is however profoundly unsatisfactory. In the first place, as Sedley LJ commented in *Wyatt v Curtis* [2003] EWCA Civ 1779, there is something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about. … Secondly, this approach leads to the drawing of excessively fine distinctions between questioning, on the one hand, and expressions of concern falling short of questioning, on the other hand, a problem illustrated by the present case. Thirdly, an approach which requires the patient to question the doctor disregards the social and psychological realities of the relationship between a patient and her doctor, whether in the time-pressured setting of a GP's surgery or in the setting of a hospital. Few patients do not feel intimidated or inhibited to some degree."

37. As my review of the evidence below will demonstrate, the Defendant's case is founded largely on contemporaneous documents, such as Professor Malagò's clinic letters and the consent form. By contrast, the Claimant's case is founded on her evidence, for the most part without reliance on contemporaneous documents and with the undoubted hindsight that she now knows that the surgery which she underwent was unnecessary because she did not have pancreatic cancer.

38. As to the importance of contemporaneous documents, Mr Bershadski cited the decision of the Supreme Court in *Regina (Bancoult) v Secretary of State for Foreign and Commonwealth Affairs (No 3)* [2018] 1 WLR 973, at 1014-1015, where Lord Kerr stated that case law emphasised the importance of documentary evidence in assessing the credibility of oral witnesses and in particular cited dicta of Robert Goff LJ in *Armagas Ltd v Mundogas SA (The Ocean Frost)* [1985] 1 Lloyds Rep 1, at 57 that:

> "It is frequently very difficult to tell whether a witness is telling the truth or not; and where there is a conflict of evidence ... reference to objective facts and documents, to the witnesses' motives and to the overall probabilities, can be of very great assistance to a judge in ascertaining the truth."

39. Although Lord Kerr also stated that observations of Leggatt J in *Gestmin SGPS SA v Credit Suisse (UK) Ltd* [2013] EWHC 3560 (Comm) to the effect that the best approach

for a judge to adopt was to place 'little if any reliance at all on witnesses recollections of what was said in meetings and conversations and to base factual findings on inferences drawn from the documentary evidence and known or probable facts' had much to commend them, I believe that such dicta, although appropriate to commercial litigation, are inappropriate here.

40. As to evidence given with the benefit of hindsight, Mr Bershadski cited dicta of Hutchinson J in *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med LR 285, at 289, namely:

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

41. Although not referred to in *Smith*, such dicta have echoes of the words of Megarry J in *Duchess of Argyll v Beuselinck* [1972] 2 Lloyd's Law Reports 172, at 185, a solicitor's negligence case, when he said:

> "In this world there are few things that could not have been better done if done with hindsight. The advantages of hindsight include the benefit of having a sufficient indication of which of the many factors present are important and which are unimportant. But hindsight is no touchstone of negligence. The standard of care to be expected of a professional man must be based on events as they occur, in prospect and not in retrospect."

42. I accept the relevance of all these citations of authority and will endeavour to apply them when I make my primary findings of fact, having reviewed the evidence which was adduced before me.

43. With that introduction I will turn to consider the relevant background facts as contended for by the parties. Whilst some of the history is common ground, as will become apparent, much of it is not.

The relevant background facts

44. It is common ground that, in about March 2014, the Claimant began to suffer with episodic right upper abdominal pain which increased in intensity. She consulted her general practitioner ['GP'] on both 19 March 2014 and 9 April 2014; attended the Accident and Emergency department at Whittington Hospital on 18 April 2014 because she was in severe pain; was advised to and underwent an ultrasound on 29 April 2014, which was normal; and was referred by her GP to a gastroenterologist but, by June 2014, the episodic pain was getting worse. Having consulted her GP again on 12 June 2014 she attended Whittington Hospital on the same day with a suspected diagnosis of appendicitis but such diagnosis was not confirmed. However, the Claimant was admitted for investigations, underwent ultrasound and CT scans on 13 June 2014, was given antibiotics and was then discharged.

45. The report of the ultrasound scan stated:

> "Findings: … No focal liver parenchymal lesions identified. … Difficult to accurately assess the pancreas due to overlying bowel gas, however within the body of the pancreas there is an apparent area of low echogenicity measuring 1.4cm. …
>
> Conclusion: Apparent low echogenicity lesion within the body of the pancreas. In view of the patient's symptoms further imaging with CT Pancreas protocol to assess further is recommended."

46. It should be noted that the Defence avers that such ultrasound scan raised the possibility of a 1.4cm hypoechoic lesion in the pancreatic body. This seems to me to be correct.

47. The report of the CT scan stated:

> "Within the head of the pancreas there is the impression of an ill-defined 1.2 x 1.1cm area of low attenuation which is only evident on the portal venous phase. There is no peripancreatic fat stranding, collections fluid or adenopathy. The pancreatic duct is not dilated. ...
>
> Impression: No abnormality identified at the site reported on the ultrasound however there is the impression of a small area of lower attenuation in the pancreatic head. This is only evident on the portal venous phase and there are no associated suspicious features. Although this could be due to artefact such as partial voluming discussion in the GI meeting and consideration of further or follow up imaging is recommended in the first instance."

48. It should be noted that the Defence avers that such CT scan raised a suspicion of a mass in the head of the pancreas and that the differential diagnosis included a small pancreatic tumour or focal pancreatitis. In his oral evidence Professor Malagò accepted that this scan showed an abnormality within the head of the pancreas and, although its

significance was not known at that time, stated that 'your first suspicion must be that you have a cancer'.

49. Having been given antibiotics the Claimant's abdominal pain settled and, apart from one incident of a sudden shooting pain she did not have any further severe epigastric pain. However, she attended an outpatient appointment on 26 June 2014 when she was told that there was something visible on the head of the pancreas and although the doctor did not believe that it was a lesion or anything sinister he recommended that the Claimant undergo an MRI scan to 'double-check' the pancreas as the results from the CT were not very clear.

50. MRI and MRCP scans were performed on 22 July 2014 and in relation to the pancreas the report stated:

> "Findings: … The body and tail of pancreas are normal. Within the head/neck of the pancreas there is a normal T2 signal on the unenhanced study but postcontrast the head of the pancreas shows some reduced signal measuring up to 2cm on arterial phase which persists in the delayed phase. The uncinate shows some increased T2 signal on the unenhanced study and this measures up to 3 x 1.8cm. …
>
> Opinion: Reduced signal post contrast with the head/neck of the pancreas. Further uncinate lesion which shows increased enhancement on the delayed phase. No duct dilation. Suggest discussion at GI MDT as underlying malignancy needs exclusion with EUS."

51. It should be noted that the Defence avers that these scans raised a suspicion of malignancy at the head of the pancreas and that in the portal venous phase at a site which corresponds with the abnormality seen in the earlier CT scan there was an area of hypointensity measuring 2cm where one would normally expect uniform enhancement. Although such finding was non-specific, it raised the possibility of a pancreatic tumour and it was reasonable to proceed to an EUS. Professor Malagò adopted these comments in his oral evidence.

52. The Claimant was told that these scans showed a 3cm lesion on the head of the pancreas and that her care was to be transferred to the Royal Free Hospital which was the regional centre for pancreatic care.

53. The recommended treatment plan from the MDT on 1 August 2014 included a recommendation that the Claimant be considered at the regional specialist MDT and a meeting of the latter on 2 September 2014 concluded that there ought to be a EUS of the pancreas.

54. So it was that the Claimant first saw Professor Malagò at the Royal Free Hospital on 12 September 2014.

55. At that first consultation the Claimant states that Professor Malagò seemed frustrated at the inconsistent results given by the previous scans. He seemed to her to be dismissive of her account that she had been relatively symptom free since being

prescribed antibiotics and said that the Claimant should have an EUS to ascertain what was really happening but that he was concerned about the possibility that the Claimant might have pancreatic cancer.

56. In cross-examination the Claimant agreed that:

(1) About this time, she undertook research on the internet about pancreatic cancer, became aware that there were different types of tumour with different outcomes and researched the Whipple's procedure. She realised that her condition was 'potentially really serious'.

(2) She had subsequently received from Ms Keating a document '*Information about having Pancreas Surgery*' which set out in some detail the most common procedures for pancreatic cancer, including the Whipple's procedure, and included the possible risks and complications of such surgery and that subsequently she had sought further information from Ms Keating.

(3) Given that Professor Malagò had said that the lesion was very close to her blood vessels, the last thing she would have wanted was for any tumour to increase in size and endanger those blood vessels.

57. In substance, Professor Malagò does not disagree with the Claimant's account. He was mindful of the earlier MRI which had shown a pancreatic mass and because of the Claimant's past history, including an absence of gallstones, any gallbladder pathology and her low alcohol consumption, he believed that a diagnosis of pancreatitis was less likely that one of pancreatic cancer.

58. In his letter dated 19 September 2014 to the Claimant's GP, which was copied to the Claimant and had been dictated in clinic on 12 September 2014, Professor Malagò had stated:

> "The patient had a CT scan which initially did not reveal specific pancreaticobiliary pathology; however, an MRI on 21st August 2014 raised the suspicion of a mass in the head of the pancreas at the uncinate process with a suspicion of pancreatic cancer. We reviewed these radiologic findings in our MFT and we concluded there is a 3cm mass at the uncinate process on MRI. The patient is aware of these findings and relays to me the possible confusion between the two discordant imaging modality.
>
> … I explained to Mrs Pepper our high suspicion of adenocarcinoma of the pancreas and since I cannot definitely give her the diagnoses, I advised her to have a CA 19-9 and CEA done today plus an EUS with FNA in order to confirm the diagnosis. We briefly spoke about the prognosis of pancreatic adenocarcinoma and I introduced the patient to the concept of surgery and the Whipple operation. We agree that she will have an EUS as soon as possible to confirm the diagnosis and we will proceed to surgery if our suspicion of pancreatic

> adenocarcinoma or pancreatic malignant lesion should be confirmed."

59. It is agreed that at this meeting Professor Malagò was not offering surgery but at most was alerting the Claimant to the possibility of such surgery in the future.

60. Although the Claimant has no recollection of any discussion about the prognosis for pancreatic cancer or surgery, including a Whipple's procedure at such first consultation, she conceded that she had received this letter. By contrast Ms Lewin agreed that the question of surgery, including the risks and benefits of a Whipple's procedure, was raised by Professor Malagò at such meeting and that it was possible that he had discussed the long-term risks of such surgery.

61. Ms Lewin recollects that Professor Malagò explained that the lesion was apparently on the uncinate area of the pancreas, stated that due its proximity to major blood vessels it was very difficult to operate in that area but that he had undertaken such surgery the preceding week and stated that cancers in such area had the worst outcomes. Moreover, he referred to Steve Jobs dying from pancreatic cancer because he did not have surgery at the earliest opportunity.

62. This prompted Ms Lewin too to research pancreatic cancer online. Both she and the Claimant knew that the diagnosis of pancreatic cancer was 'extremely serious' and of the mortality rates of people suffering with this condition.

63. The Claimant's GP records show that on 17 September 2014 the Claimant had a telephone consultation with her GP in which the Claimant said that she was attempting to bring the EUS forward because she 'does not feel coping at work with stress of lesion / worried about capability at work' and was 'worried about prognosis'.

64. An EUS was performed on 30 September 2014 by Dr Pereira and he reported that 'there was an approximately 1.5cm irregular diffuse lesion which was very difficult to visualise from either the stomach or the duodenum'. Biopsy material was aspirated from the lesion. Histopathological examination reported unremarkable pancreatic acinar tissue. Notwithstanding such negative finding at EUS, Professor Malagò remained suspicious that the Claimant had pancreatic cancer and spoke with Dr Pereira about him performing a repeat EUS.

65. The Claimant saw Professor Malagò for the second time in early October 2014 but there is a dispute about the precise date of such meeting. The Claimant says that it took place on 8 October 2014 but Ms Lewin says only that it took place in early October 2014. By contrast, both Professor Malagò and Ms Keating say it took place on 3 October 2014 and both their clinic notes records such date and there was email traffic between the Claimant and Ms Keating between 5 and 7 October 2014 after such second meeting. Although nothing turns on the date of such meeting, I am sure that it took place on 3 October 2014. I fear that this dispute arises simply because the draft letter dictated by Professor Malagò when he saw the Claimant is incorrectly dated 8 October 2014.

66. The Claimant's account of that meeting is that Professor Malagò had explained that the EUS had been tricky to perform and that although there was a 1.5cm mass in the pancreas, the biopsy had shown normal pancreatic tissue with nothing of concern and that Professor Malagò wanted her to have a further EUS and CT scan. He made no

reference to the possibility of an intra-operative biopsy, that a negative report could not be regarded as definitive, that an exploratory laparotomy would be helpful or that he had advised her in detail of the risks of surgery.

67. Professor Malagò's account of such meeting was that he advised the Claimant that it was not unusual to have a negative finding at EUS and that although it is always better to have the presence of a tumour confirmed by biopsy, the suspicion of pancreatic tumour raised by the earlier imaging was sufficient to warrant surgery. Hence the conclusion of his clinic notes was 'still inclined for surgery but better to have tissue confirmation'. As to such surgery he explained that an intra-operative biopsy could be performed, that it should not be regarded as a definitive 'all clear' if reported as negative and that it would also be helpful to inspect the pancreas at an exploratory laparotomy. He also advised her of the risks of undergoing a surgical resection of a pancreatic tumour, namely pancreatic fistula formation, bleeding, pseudoaneurysm, bile leak, gastric leak and infection in the short term, pancreatic exocrine and endocrine insufficiency in the long term and death. Professor Malagò believed that the Claimant understood those risks and agreed to return for a pre-operative assessment.

68. Ms Keating recalls that at such meeting Professor Malagò advised the Claimant that he remained suspicious that she had pancreatic cancer and that surgery would be required and that she agreed to, and did, attend a pre-operative assessment on 15 October 2014. Ms Keating believed that it was at such meeting she provided the Claimant with a copy of the booklet *Information about having Pancreatic Surgery*. That booklet sets out considerable information about the most common procedures for pancreatic surgery, including a Whipple's procedure, what happens both before and during surgery, set out the possible risks of and complications from such surgery and what happens after surgery in the short-term and longer term. The Claimant was also given Ms Keating's contact details and, as hereinafter appears, subsequently contacted Ms Keating on a number of occasions.

69. Professor Malagò gave evidence that in clinic on 8 October 2014 he had dictated a letter to the Whittington Hospital, to be copied to the Claimant and her GP but, having seen the letter, he was satisfied that it was perfectly possible that such letter had not been sent because it was not dated and the transcribed letter contained gaps where the typist required Professor Malagò to correct/complete the text. However, such draft letter stated:

> "Diagnosis
>
> High suspicion of pancreatic head [malignancy]
>
> The EUS has been technically difficult and demonstrating the mass that is located at the uncinate process of the pancreas. The lesion is adjacent to the portal vein. Dr Pereira ... has struggled to visualise this lesion and indeed the biopsy has unfortunately come as normal pancreatic tissue. I have discussed this with Dr Pereira and I also have explained to the patient. My inclination is to repeat the EUS after speaking with Dr Pereira with hope that we will obtain pathological [diagnosis] GIST. In the meantime I will send the patient to pre-assessment and I will obtain a new arterial phase CT scan since the previous

> examination has been without good arterial contrast and has been performed on 21st August 2014. The patient understands the plan and is willing to undergo these further assessments. I will sit down with the patient and discuss the findings in my clinic hopefully we will be able to proceed to surgery."

70. In cross-examination, Professor Malagò added the word 'malignancy', which is inserted in the text set out above but which had been omitted by the typist who had left a blank, and accepted that the reference to a 'pathological GIST' was in error and should have referred to a 'pathological diagnosis'.

71. A further EUS was performed on 17 October 2014 by Dr Pereira. The report stated:

> "Diagnosis …
>
> PANCREAS. Probably malignant tumour
>
> Advice/comments
>
> … there appears to be a 1.3cm hypoechoic [i.e. more dense or solid than normal] lesion … The rest of pancreas normal. I thought 1.3cm lesion sup[*erior]* HOP [*head of pancreas*] likely pathological'."

72. A core biopsy and FNA biopsy were also taken at this EUS. The histopathology report from such two biopsies concluded that no malignant cells were present but Professor Malagò was aware that FNA pancreatic biopsies have a high rate of false negative results.

73. The cytology report from the biopsy on 17 October 2014 was dated 4 November 2014 and was thus only available *after* the Claimant saw Professor Malagò for the third time on 31 October 2014 and shortly before she underwent surgery. Professor Malagò conceded that he might have seen this only on the morning of the surgery on 17 November 2014 because he had been away the previous week. If he had seen it earlier, he agreed that he could and should have contacted the Claimant to discuss its findings, but he did not. Such report certainly increased Professor Malagò's suspicions that the Claimant had pancreatic cancer and if he had discussed the report with the Claimant, he believed that it was inevitable that she would have reaffirmed her consent to the proposed surgery. Such report stated:

> "Pancreas: probably malignant tumour
>
> Specimen Details
>
> FNA pancreas …
>
> Microscopic Description
>
> Moderately cellular direct smears from EUS guided fine needle aspiration of pancreas show crowded clusters of atypical glandular cells. The appearances are suspicious of malignancy but an inflammatory lesion cannot be excluded

> Advise correlation with radiology and clinical findings and repeat if necessary."

74. A further CT scan was performed on 18 October 2014 and the report thereon concluded that:

> "There is a subtle area of hypoattenuation within the pancreas head but this is less convincing than on the previous outside imaging. Pancreatic adenocarcinoma still needs to be considered and correlation with the findings from the EUS is required. The area of abnormality is in direct contact with the distal SMV, proximal portal vein and GDA"

75. At an MDT on 21 October 2014, taking into account the radiological findings, the visual findings on EUS and the Claimant's clinical presentation, Professor Malagò remained concerned that the Claimant had pancreatic cancer. The plan was for clinical follow up and then either surgical resection of what he believed was a worrying lesion on the pancreatic head or further imaging.

76. So it was that the Claimant saw Professor Malagò for the third time on 31 October 2014. This was a crucial meeting before surgery took place and it is thus appropriate to set out the accounts of such meeting given by each of those who were present, namely the Claimant, Ms Lewin, Professor Malagò and Ms Keating.

77. The Claimant's account was that although all the tests had come back negative for cancer, Professor Malagò was still very suspicious that the Claimant had cancer. He said that the Claimant could wait for 3 months and see what happened but confirmed that patients had died as a result of waiting. However, with surgery at least she would have a 'chance of life'. He explained the situation in dramatic language that if, after waiting three months, he would know whether the lesion had grown and would either offer the Claimant his congratulations because she did not have cancer or would say 'Bye Bye Sarah'.

78. The Claimant related that Professor Malagò explained that he could perform an intra-operative biopsy which would be reported on immediately and that if such biopsy was positive [i.e. malignant] he would perform a Whipple's procedure to remove the head of the pancreas but that if it was negative [i.e. not malignant] he would leave the pancreas untouched and would stitch her back up. The Claimant had consented to surgery on that basis.

79. At that meeting the Claimant says that Professor Malagò did not say:

    (1) that an intra-operative biopsy was notoriously unreliable and it is common ground that he did not;

    (2) what the long-term consequences would be for the Claimant in losing part of her pancreas, apart from the risk of diabetes and although malabsorption was mentioned, there was no reference to the long-term consequences of malabsorption such as vitamin deficiencies and osteoporosis.

80. The Claimant believed that Professor Malagò was impressing on her that any course of action other than immediate surgery might well lead to her death and that in reality she had no choice but to consent to such surgery on the basis set out above. 'Nothing was very balanced, it all felt very urgent.' Had the options been presented to her in a calm and more reasoned way, the Claimant believed that she would have elected to wait for 3 months, particularly since she was not a particularly risk-averse person and that she was not informed of the lifetime risk of serious recurring infection as well as other debilitating effects of the Whipple's procedure.

81. In cross-examination the Claimant:

(1) agreed that at this time the possibility that she might have pancreatic cancer was 'seriously negatively affecting her state of mind' and that she had been signed off work by her GP because of stress and worry;

(2) agreed that she knew from her internet research that differences of opinion would be addressed in MDT meetings. Although she had not been aware of any recommendation made following such a meeting, she had not asked Professor Malagò what such recommendation was;

(3) stated that it was not made clear to her by Professor Malagó that he might still perform a Whipple's procedure depending how the pancreas looked to him during surgery; and

(4) stated that she would have preferred the discussion with Professor Malagò to have been conducted in a calmer and more measured way. Referring to the agreed expert of the general surgeons that Professor Malagò should have given a percentage risk that the Claimant had pancreatic cancer, to which I will refer later, she stated that if there had been a 10% risk of such cancer she would have waited 3 months and not undergone surgery.

82. In her witness statement, Ms Lewin stated that Professor Malagò was concerned that the biopsy may have missed the malignant tumour and that although the Claimant could wait for 3 months to see whether the lesion had grown, he had had two patients who had decided to wait and had not survived. She confirmed that Professor Malagò had offered to undertake an intra-operative biopsy [described also as a 'Tru-Cut' test] which would be reported on immediately and that whether he would perform a Whipple's procedure would depend on whether malignancy was found and that if there was no malignancy he would not perform such procedure.

83. However, this was seemingly inconsistent with paragraph 26 of her witness statement where she expressly stated that:

> 'I understood from this whole conversation about his plan that Professor Malagó proposed to *make his diagnosis of malignancy based on his own assessment of the lesion* and the results of the Tru-Cut'.

84. However, she did not know that the results of the intra-operative biopsy were known to be unreliable and 'could only serve as a possible adjunct to his own assessment' and

that 'Professor Malagò did not discuss with Sarah what would happen if his assessment of the pancreatic lesion was different from the biopsy results.'

85. Although I note that in examination-in-chief, Ms Lewin had said that her impression as to what would happen if the intra-operative biopsy was negative was that Professor Malagò would *not* undertake a Whipple's procedure, in cross-examination she repeated her evidence that Professor Malagò proposed to make his diagnosis of malignancy based, inter alia, on 'his own assessment of the lesion' and she recalled him saying 'I know what these things look like'.

86. As to the relevance of Professor Malagò 'making his own assessment of the lesion', Ms Lewin said that she had understood that Professor Malagò would look at the Claimant's pancreas and decide from where to take the biopsies and that her understanding was that whether Professor Malagò would undertake a Whipple's procedure would depend simply on the results of the biopsy.

87. In this context it should be noted that at paragraph 30 of her witness statement, Ms Lewin recounted a conversation with a junior doctor the day after surgery as to whether Professor Malagò had undertaken an intra-operative biopsy before the Whipple surgery to which the junior doctor, whilst not answering that direct question, had said that Professor Malagò had 'felt the lesion with his fingers and that it did not feel right'.

88. In cross-examination Ms Lewin conceded that her witness statement did not suggest that the Claimant had not given her consent to a Whipple's procedure.

89. Professor Malagò's account of this meeting is that the repeat EUS was negative and that he explained the options of either continuing observations with CT and MRI scans or proceeding to surgery. He emphasised that the proximity of the suspected tumour to the mesenteric and portal vein and the current radiological findings were alarming, suggested the possibility of a malignant process and that to delay might result in the progression of the tumour beyond the pancreas such that the tumour would become inoperable and the Claimant would be left with a poor prognosis.

90. Professor Malagò again dictated a letter in clinic on 31 October 2014 to the Claimant's GP, copied to the Claimant and for the reasons set out in para 58 above I am satisfied that it was neither sent nor received by the Claimant's GP or the Claimant. Such draft letter stated:

> "Diagnosis
>
> Mass at the head of the pancreas suspicious for pancreatic cancer
>
> … The patient has received another EUS and has been discussed again at out MDT. The MDT discussion was to proceed with surgery. …We have a definite abnormality of the head body of the pancreas ... twice competent EUS Specialist has been providing negative biopsies. There is no positive CA 19-9 or CEA tumour markers. Nevertheless the images on CT and MRI are quite suggestive of changes in the head of the pancreas. Despite the fact that there has been no major change in the interval time, the suspicion of adenocarcinoma of the

> pancreas is still high. The tumour should not be NET since the arterial phase of the cross-sectional imaging is not prominently enhancing in this phases. I spoke to the patient and explained the difficulty we have in the diagnosis with the possibility of either indeed a pancreatic malignancy or local pancreatitis that is not sustained by history or risk factor in this patient.
>
> I have given the patient options of either proceeding nevertheless with a Whipple or on the contrary to wait and repeat imaging with an interval of time of two to three months. I proposed to her an intermediate solution and exploration with the possibility of Tru-cut or excisional biopsy at the suspicion region of the pancreas on top of my examination of the head of the pancreas. ... I explained Ms Pepper that I may still reserve with the possibility of performing a Whipple operation in case of positive biopsy or very suspicious appearance. I also explained that a pancreatic biopsy is bound with risks of pancreatitis or complications. I weigh this option versus the observational possibility and Ms Pepper agrees with my proposal to undergo an exploration and Tru-cut or excisional biopsy of suspicious lesions at the head of the pancreas ... possibility of the Whipple still remains. We will perform this operation on 17th November."

91. It is surprising that Professor Malagò does not mention intra-operative biopsy in this draft letter or in his witness statement, although in the latter he had already referred to the intra-operative biopsy in relation to the second meeting.

92. In cross-examination Professor Malagò conceded that the reference to the MDT discussion on 21 October 2014 was inaccurate because the treatment follow up was 'either resection or imaging': see above.

93. However, such draft letter made it crystal clear that Professor Malagò might still perform Whipple surgery in the case of a positive biopsy or very suspicious appearance and expressly stated that the Claimant had agreed to surgery being carried out on that basis. I appreciate that such draft letter was not received by the Claimant.

94. In cross examination Professor Malagó:

(1) admitted that he might have said to the Claimant words to the effect of 'I know what these things look like' but he said that this was not a determination of whether there was malignancy but whether there was suspicion of malignancy.

(2) it was put to him that he was a fairly formidable person, that the tone of the meeting on 31 October 2014 was that the Claimant absolutely should have surgery and that she should not delay and that he was concerned to not lose another patient to cancer as had happened in the past. He adamantly rejected these suggestions, saying that he only wanted to do the best for the Claimant. He was sorry if his comments about waiting and 'Bye Bye Sarah' had been seen to be sarcastic or lacking in compassion. That had not been his intention which

was to endeavour to bring home to the Claimant the realities of the seriousness of her situation in that without surgery she could well die.

(3) when it was put to him that his advice to the Claimant should have included a percentage chance of malignancy, he responded that this was probably inappropriate but that he had advised the Claimant to have a Whipple's procedure because this was 'way better than risking having a cancer' and that he conveyed to her that 'the likelihood of her having cancer was high', by which he meant, but did not say, that the likelihood of the Claimant having cancer was more than 50% but not 80% nor 10%.

(4) he agreed that for the Claimant to give an informed decision about surgery she needed to be told of the likely consequences of such surgery but he maintained that she had been so informed of both the short-term and long-term consequences. She did of course receive the booklet *Information about having Pancreatic Surgery* which identified such consequences.

(5) he agreed that there was nothing contained in the operation note which recorded that the pancreas looking as if it had a tumour. It was suggested to him that he must have given Dr Lurje, who assisted him with the operation and made the note 'a rocket'. When this colloquialism was explained to Professor Malagò, he said that by the time he had discovered this such person was already a consultant in Germany and he could not speak to him.

(6) he said that during surgery he had held the pancreas in his hand to inspect it, had looked for signs of pancreatitis but there was no sign of acute pancreatitis particularly because the gland of the pancreas was not hard or fibrotic as would usually be the case. However, there was definite bulk, enlarged, over the head of the pancreas and all of this suggested the possibility of a tumour and, taken with the findings of the cytology report referred to above, which was to the effect that there were cells suspicious of malignancy, led him to conclude that it was appropriate to undertake a Whipple's procedure.

(7) it was put to him that the email exchanges between the Claimant and Ms Keating supported the Claimant's case that she had consented to undergo a Whipple's procedure *only* in the event that the biopsy was positive. He did not agree and said that his practice was to see patients in clinic rather than responding by email.

(8) it was put to him that because of the unreliability of intra-operative biopsies, there was no utility in such a biopsy. He did not agree.

(9) asked about whether the head of the pancreas was enlarged with dimensions of 45mm x 60mm x 28mm, he thought that it was enlarged for a patient of the Claimant's size.

95. Ms Keating's account of this meeting was that Professor Malagò explained to the Claimant the options of immediate surgery and delaying surgery for further surveillance scans and that delaying might result in the cancer progressing and becoming inoperable. She recollects Professor Malagò explaining that a Whipple procedure would be advisable if the intra-operative biopsy was positive *or* the pancreas had a very

suspicious appearance on examination which suggested to him the presence of a carcinoma and that the Claimant agreed to proceed with such surgery if either of those circumstances arose. When in her email sent on 30 January 2015, set out below, the Claimant suggested that she had only agreed to a Whipple's procedure being undertaken if the intra-operative biopsy was malignant, Ms Keating said that that was not her recollection which is as set out above.

96. On 17 November 2014 Ms Keating received an email from the Claimant in which she said she was 'very hopeful re op either way really' which Ms Keating had understood to mean that she was optimistic about surgery whether it was limited to an exploratory laparotomy or included a Whipple's procedure.

97. In cross-examination Ms Keating:

(1) recollected that this was a long but not in her view a difficult meeting in which Professor Malagò had expressed the risk of pancreatic cancer as high. However, she conceded trying to explain to a patient that she might die was a difficult and lengthy conversation.

(2) although she conceded that she was unable to recall any discussion about the intra-operative biopsy, reaffirmed her belief that the Claimant had agreed to a Whipple's procedure taking place if either the intra-operative biopsy was positive or the pancreas had a very suspicious appearance on examination. She confirmed that saying that 'he knew what malignancy looked like' was the sort of thing that Professor Malagò might say and that he had said it previously. On receiving the Claimant's email sent on 30 January 2015 her response was simply to arrange a meeting with Professor Malagò. She did not believe it was appropriate for her to raise her recollection of events and that such matters were best discussed with Professor Malagò.

(3) conceded that her recollection of the meeting might not be reliable because her note simply recorded 'for surgery', there was nothing unusual about the meeting and she witnessed several discussions with patients each week.

(4) conceded that there might have been some medical students present.

(5) said that she would have remembered if she had felt that Professor Malagò was inappropriately pressurising a patient and that he did not do so.

98. The Claimant underwent surgery on 17 November 2014. On the morning of such surgery Professor Malagò first saw the cytology report referred to above and it deepened his suspicions of pancreatic cancer.

99. At such surgery Professor Malagò carried out the intra-operative biopsy. Although the result was negative, he did not find this reassuring because it is not unusual for a result to be negative where a carcinoma is present. However, having examined the pancreas, the mass at the head of the pancreas felt suspicious, hard and typical for a carcinoma. It appears worse than on any of the previous scans and it did not lead him to believe that the Claimant had pancreatitis rather than a malignant pancreatic tumour. He thus proceeded with a Whipple's procedure based on his judgment as set out above. He believed that the Claimant had consented to such procedure.

100. The operation notes record:

> "Tunnelling of pancreatic head / neck skidding on portal vein, transection with diathermy, no pancreatic duct visible / very small, pancreas quality hard after pancreatitis"

101. It is argued by Mr Bershadski that the fact that investigation confirmed the presence of a mass in the Claimant's pancreas but did not confirm the presence of cancer, did not mean that there was no cancer present. Moreover, Professor Malagò's view as to the likelihood of pancreatic cancer had been increased by reason of the EUS which was reported on by Dr Pereira on 4 November 2014 as set out above after his meeting with the Claimant on 31 October 2014.

102. The Claimant says that immediately before such surgery she gave her consent for surgery to a young doctor who simply said to her 'so you're having a Whipple?' and that the Claimant, being concerned about this, explained that she was having a Whipple's procedure only if there was evidence of cancer. Although not pleaded in the very full Particulars of Claim, the Claimant stated in her evidence [as referred to in para 41 of her witness statement dated 14 January 2019] that she had amended the consent form by adding words to the effect of 'I'm having a Whipple if there is evidence of cancer.' That was her evidence in examination-in-chief but in cross-examination she that she had amended another piece of paper. However, it may be noted that it is not suggested by the Claimant that she wrote words to the effect that she was only consenting to a Whipple's procedure being undertaken on the basis of a positive intra-operative biopsy, which is her case.

103. Any such amended consent form is not within the disclosed medical records.

104. The consent form signed by the Claimant that is within the medical records states:

> "*Name of proposed procedure or course of treatment*
>
> Exploratory Laparotomy +/- Whipple's procedure (Pancreaticoduodenectomy with distal gastrectomy) +/- proceed
>
> *Serious or frequently occurring risks*
>
> Bleeding, infection, scar, damage to surrounding structures (bowel, viscera, bile ducts, vessels), anastomotic leak, fistula formation, pancreatitis, haematoma collection, adhesions, hernia, recurrence, need for further procedures, inability to resect / incomplete resection, risks of general anaesthesia (pulmonary embolism, deep vein thrombosis, anaphylaxis, MI and death)."

105. In cross-examination the Claimant agreed that:

(1) the consent form as set out above was signed by her and that such document does not record the words which the Claimant contends that she added to the consent form. She seemed to suggest that there was another document signed by her which had not found its way in the Claimant's medical records. On being asked by me whether she had signed one consent document or two, she told me

that she had signed another 'piece of paper' given to her by this young doctor and that she remembered 'asking him for his pen and writing in 'if there is evidence of cancer'.

(2) the wording of the consent form authorised the undertaking of a Whipple's procedure depending on Professor Malagò's findings during surgery and that she well understood the risks of surgery.

106. Although para 2.25 of the Particulars of Claim pleaded that before she underwent surgery on 17 November 2014 she gave her consent to such surgery to a young doctor and told such doctor that she was only undergoing a Whipple's procedure if there was evidence of cancer, it was not pleaded that she had added to the consent form the words 'I'm having a Whipple's if there is evidence of cancer'. The doctor did not explain the long-term effects of losing part of the pancreas or explore with the Claimant the risks and benefits of proceeding with surgery in the event that there was no malignancy.

107. When cross-examined as to the consent to surgery given by the Claimant, Professor Malagò reaffirmed that the Claimant had agreed that he would carry out Whipple surgery in the case of a positive biopsy or very suspicious appearance of the pancreas. As to the consent form he did not know who had consented the Claimant and was unable to comment on her contention that she added words to the consent form and the substance of her contention had not been communicated to him.

108. Whilst in hospital none of the surgical or medical team told the Claimant that no malignancy had been found at surgery and that she did not have cancer, but when she was in intensive care her wife Eva was told that she was surgically free of cancer and had assumed that she had had a malignancy which had been removed. She was discharged from hospital on 25 November 2014. It was not until she saw Dr Sodergren, a senior registrar, some two weeks later, that she discovered that, at surgery, a necrotic area possibly caused by acute pancreatitis had been removed. When specifically asked by the Claimant, Dr Sodergren confirmed that she had not needed the Whipple's procedure because she was not suffering from pancreatic cancer.

109. On 15 December 2014 the Claimant sent an email to Claire Frier, copied to Ms Keating, thanking her for arranging a CT scan and blood tests for her, referred to seeing Dr Sodergren and reported on her continuing vomiting.

110. On 16 December 2014 the Claimant sent an email to Ms Keating, in response to an email sent by Ms Keating answering specific queries about her post-operative vomiting and asking how she was otherwise. After observing that her post-operative vomiting was settling, she stated:

> "We are very relieved that there was no sign of malignancy.
>
> I would like to know what made Prof Malagò proceed with a Whipple if the tumour was not malignant. (I know that even benign can cause problems). It would set our minds at rest to have an explanation. We didn't get to see him last Friday - saw medical senior registrar Dr Soden [sic]."

It may be noted that such email does not refer at all to an intra-operative biopsy.

111. There followed an exchange of emails between the Claimant and Ms Keating.

112. In answer to a request by the Claimant on 30 January 2015 for 'a clear understanding of why I needed to have the Whipple', Ms Keating replied the same day thus:

> "The abnormal area of the pancreas was, as Dr Sodergren outlined in his letter, found to be focal acute pancreatitis. Prof did explain before the surgery that there was an abnormality in the head of the pancreas but without an exact tissue diagnosis, we couldn't say for definite whether it was pancreatitis or a malignancy.
>
> The Whipple operation is the type of surgery we do if there is a suspicion of malignancy in the head of the pancreas. The option of waiting 2-3 months to have a repeat scan or going ahead with the Whipple was discussed with you in clinic and the agreed plan was to go ahead with the Whipple operation. (If it had been malignant, waiting 2-3 months might have resulted in the surgery not being possible).
>
> I hope this helps clarify things for you. Please let me know if anything is still unclear."

113. The Claimant's reply on 30 January 2015 stated:

> "What is still unclear is that Prof Malagò told me he would open me up and then do a frozen section & if it was malignant proceed with a Whipple. This is what I agreed to. Was a frozen section done or did something else convince Prof that it was suspicious? I just need to know the thinking. I have had major life altering surgery & want to know why it was felt necessary to do this. I am sorry to keep coming back to you as I feel it is the doctors who should be explaining their thinking & decisions to me."

114. It may be noted that in such exchange of emails the Claimant was not saying that she had amended the consent form she had signed to add words to the effect that she was only consenting to a Whipple procedure if there was evidence of cancer.

115. So it was that the Claimant saw Professor Malagò on 6 February 2015. Shortly before that meeting Professor Malagò became aware that the Claimant was contending that he had agreed to proceed with a Whipple procedure only if the intra-operative biopsy revealed that there was a malignancy. At that meeting Professor Malagò maintained that such was not correct and that the Claimant had expressly consented to an exploratory laparotomy and that if examination of the pancreas revealed any suggestion of pancreatic cancer he should proceed with the Whipple.

116. At such meeting Ms Lewin was also present but Ms Keating was not.

117. In her witness statement the Claimant said that Professor Malagò had removed the head of the pancreas despite the biopsies being negative. He had been trained in America and they were trained 'when in doubt, take it out'. She did not know whether to feel lucky about not having pancreatic cancer or angry about the long-term compromise to her health. She then felt very angry about such comments and thought Professor Malagò was being flippant about something which had affected the rest of her life.

118. In cross-examination the Claimant told me that Professor Malagò said that he was sorry that it had ended up the way it had but that, during the surgery, he had examined the pancreas and did not like the feel of it and had decided to proceed with the Whipple's procedure and resect the pancreas.

119. Ms Lewin echoed the evidence of the Claimant.

120. Finally, it should be noted that the Claimant sent an email to Ms Keating on 30 March 2015 in which she had stated:

> "I think I am just finding this all hard to deal with & expect to recover quickly. I do understand why the decision was made to do the Whipple in the circumstances - as does my GP."

121. The note in the Claimant's GP's medical records states that the Claimant has said on 30 March 2015:

> "Does feel that having the operation was not inappropriate with the information pre-op but not that happy with aftercare."

122. This email and note do not seem to me to be consistent with the Claimant's view that there was she had been subjected to an unnecessary Whipple's procedure to which she had not consented.

The parties' closing submissions

123. At the conclusion of the evidence both parties made closing submissions in writing and orally. I do not intend to set them out here but both counsel comprehensively addressed the material facts set out above and to a lesser extent the evidence of the consultant general surgeons. Neither addressed the evidence of the consultant radiologists, except fleetingly. I do not propose to add to the length of this judgment but rehearsing any of the submissions made but confirm that I have had regard to all such submissions in making my findings of fact, as set out below.

My findings of fact

124. For the avoidance of any doubt all my conclusions set out below are reached on the balance of probabilities, save where otherwise qualified.

125. Before I set out my primary findings of fact on the above evidence, it may be helpful to set out my overall impressions of the Claimant and Professor Malagò.

126. I have no doubt that the Claimant is a highly intelligent, confident and conscientious professional woman, as is Ms Lewin, who, when faced with the Claimant's possible diagnosis of pancreatic cancer, fully researched the topic and prognosis on the internet.

I gained the clear impression that [whatever the Claimant might say to the contrary and with the benefit of hindsight, knowing that she did not have pancreatic cancer but only pancreatitis and that it was unnecessary for a Whipple's procedure to be performed on her], she would have been risk-averse to waiting to see whether the pancreatic lesion grew to such an extent that cancer became inoperable rather than undergoing surgery which, if there was no cancer, as was the fact, would leave her with unnecessary disabilities as a result of such surgery. I believe that in the situation which the Claimant faced she did place great reliance on the undoubted skill and expertise of Professor Malagò as to whether it was appropriate that she should undergo surgery.

127. Professor Malagò is a very experienced HPB and Liver Transplant surgeon and inevitably in giving his evidence he is relying very substantially on contemporaneous documentation and what his practice would be. However, I am satisfied that he did have a clear recollection of this case from immediately after he had performed the Whipple's procedure because he discovered very soon thereafter that the Claimant on whom he had performed a Whipple's procedure did not in fact have pancreatic cancer.

128. I found Ms Keating's evidence persuasive. She had worked with Professor Malagò as a clinical nurse specialist since February 2013 and had thus sat with him seeing many patients with suspected pancreatic cancers. She did not pretend to have a perfect memory of events but her role was to perform a liaison role with patients who were having to make potentially life-changing decisions, to answer their queries and give them reassurance. Because of the subsequent email traffic between the Claimant and herself she would have good reason to remember the facts of this particular case, even if, as was the case, she made few notes of her own.

129. I need to say at the outset of my findings of fact that, because of the gravity of the potential diagnosis of pancreatic cancer, its poor prognosis and the need for pancreatic resection because a tumour grows and becomes inoperable, it is inevitable that pancreatic resections are undertaken in cases where it is subsequently determined that there has been non-malignant pathology. That is why Professor Malagò advised that the Claimant should undergo a Whipple's procedure.

130. It is uncontroversial that from about March 2014 the Claimant suffered abdominal pain, was referred to Whittington Hospital where she underwent various investigations and that the ultrasound and CT scans raised the possibility of a tumour in the pancreas. Quite properly she was referred to the Defendant hospital which was the regional centre for the treatment of pancreatic cancer. She thereby came into contact with Professor Malagò, saw him on three occasions before he undertook surgery on her which included a Whipple's procedure.

131. I have no doubt that the Claimant received a copy of Professor Malagò's letter dated 19 September 2014 following her first seeing Professor Malagò on 12 September 2014. It was copied to her and the Claimant conceded that she received a letter and I am certain, for reasons set out below, that she did not receive the subsequent two draft letters which Professor Malagò had intended should be sent or copied to her. Moreover, I am satisfied that if there had been any material inaccuracy in such letter dated 19 September 2014, the Claimant would have raised such inaccuracies with Professor Malagò at their next meeting, which no one suggests that she did. She struck me as a forthright woman who would want any inaccuracies explaining to her satisfaction, who would be unlikely

to be deterred by obviously unsatisfactory explanations and would have pressed Professor Malagò until she had received an explanation which she found satisfactory.

132. Although there is no significant disagreement about the first meeting on 12 September 2014, I am satisfied that Professor Malagò was frustrated, and it was understandable that he should be so, at the inconsistency of past investigations which had already been undertaken. Such notwithstanding, in my judgment it was wholly appropriate that at this stage Professor Malagò expressed concern that the Claimant might have pancreatic cancer, that there was discussion about the possible prognosis of pancreatic cancer, the fact of the proximity of the pancreatic lesion to the major blood vessels and the difficulty that such might cause and that he introduced the Claimant to the prospect of surgery, briefly setting out the risks and benefits of a Whipple's procedure. In my judgment it was entirely appropriate that the Claimant should be forewarned at this early stage about the overall position.

133. Notwithstanding that Ms Lewin recollects that at such meeting there was a reference to Steve Jobs, I think that this is unlikely to be the case and that this is a mistake on Ms Lewin's part, this having been referred to at a subsequent meeting. In any event this mistake has no significance.

134. From that first meeting I am satisfied that both the Claimant and Ms Lewin were well aware that the possible diagnosis of pancreatic cancer was very serious, that the Claimant was understandably worried about such possible diagnosis and would be anxious not to avoid such unnecessary delay as might render any pancreatic cancer inoperable.

135. I am also satisfied that Ms Keating provided the Claimant with a copy of the booklet *Information about having Pancreatic Surgery* either at or after the first or second meetings between the Claimant and Professor Malagò. I think that this probably happened after the first meeting.

136. I have no doubt each of the draft letters dictated by Professor Malagò in clinic when he saw the Claimant on 3 October 2014 and 31 October 2014, were dictated by him in clinic and confirmed what he had told the Claimant in clinic but I am equally sure that they were not sent to the Whittington Hospital, the Claimant or her GP. This is because the letters are obviously draft letters with gaps which Professor Malagò was intended to fill in, they bore no dates of when they were sent and do not appear in the GP's records as having been received. However, I can find no logical or persuasive reason why Professor Malagò would write to the Claimant and her GP in such terms if they were not an accurate record of the conversations he had had with the Claimant at these meetings and in my judgment they constitute compelling evidence as to what was said in those clinic meetings.

137. I have already concluded, for the reasons set out above, that second meeting between the Claimant and Professor Malagò took place on 3 October 2014 and not on 8 October 2014.

138. I do not think that the second meeting on 3 October 2014 takes matters much further in that Professor Malagò was still suspicious that the Claimant had pancreatic cancer and advised that she undertook further tests.

139. I have considered Professor Malagò's evidence that he first raised the possibility of an intra-operative biopsy at such meeting on 3 October 2014 but that he explained that, if it reported as negative, it could not be assumed that the Claimant did not have pancreatic cancer and that it would be advisable that the pancreas was inspected at an exploratory laparotomy. I note that such was not recorded in Professor Malagò's relatively brief clinic notes and does not appear in the draft unsent letter to the Claimant dictated immediately after the clinic. Moreover, neither the Claimant nor Ms Lewin refers to any such conversation and I am satisfied that, because that they had both researched pancreatic cancer on the internet and were very concerned that the Claimant's prognosis with pancreatic cancer was poor, they would have remembered such a conversation at that stage had it taken place.

140. On this issue I believe that Professor Malagò is incorrect in attributing this conversation to the second meeting, as opposed to the third meeting on 31 October 2014 where it is common ground that there was a reference by him to an intra-operative biopsy. In my judgment, he has simply made a mistake on this issue. Such mistake has no consequence.

141. As to the third meeting on 31 October 2014 a number of separate issues arise. By this time the Claimant had undergone a pre-operative assessment on 15 October 2014 and had received from Ms Keating and am sure had understood the contents of the booklet.

142. Firstly, I need to consider the general conduct of the meeting.

143. In this context it is important that in reaching any decisions on the facts I should have regard to the dicta set out above to the effect that a doctor's role is to ensure that a patient understands the serious consequences of her condition, her treatment options and the risks of undergoing or not undergoing such treatment and that it is a patient's right to make an informed decision as to whether to undergo the treatment which is offered to her. I bear in mind the inequality in the positions of doctor and patient, given that the former will be highly experienced and the latter may well have little or imperfect knowledge and that it may not be easy for a patient to question a doctor about what he proposes.

144. I thus have regard to Ms Mulholland's submission that the Claimant should have been provided with sufficient information and in an appropriate manner so that she was enabled to make an informed decision about her treatment. However, in my judgment the law does not require a court to micromanage the words used by a doctor to a patient provided that they do not involve putting a patient under pressure to accept a certain form of treatment.

145. It is said by the Claimant and Ms Lewin that she was put under considerable pressure to undergo surgery but on their account such pressure did not seem to have resulted in Professor Malagò being given carte blanche to undertake whatever surgery he thought fit because the Claimant's case is that it was only if the intra-operative biopsy was positive that Professor Malagò had the Claimant's consent to proceed with a Whipple's procedure. Per contra, I am satisfied that the Claimant was somewhat reluctant to undergo pancreatic surgery and Professor Malagò was concerned about her seeming inability to fully understand the gravity of her situation and that, although she could wait for 3 months to see whether the tumour grew, it was unwise to adopt such an approach because the tumour might then become inoperable. That was why he used

the somewhat emotive language which he did. However, I have no doubt that the Claimant was neither timid nor afraid to question Professor Malagò when she did not understand precisely what he was saying and we know that this meeting was not short.

146. This was without doubt a difficult meeting for all participants. The Claimant was facing a potentially devastating prognosis and struggling to make sense of it. Ms Lewin had similar concerns. Both must have been not only worried but frightened at the prospect of the Claimant undergoing such serious surgery. I am sure that Professor Malagò tried to explain to the Claimant that it had not been possible to exclude a diagnosis of pancreatic cancer and that waiting for further investigations carried the inevitable risk that any cancer might progress and become inoperable. It was his duty to inform the Claimant, if necessary, in stark language which might not at first sight seem to be appropriate, if she was to make an informed decision as to whether to undergo such surgery. Although in other situations it might be considered that the use of such language was inappropriate, I have no doubt that it was fully justified on the facts of this case to emphasise to the Claimant the gravity of her situation. Indeed, I believe that Professor Malagò would have been failing in his duty if he had not used such stark language when he believed that the Claimant did not fully appreciate the gravity of her situation.

147. I have carefully reflected on whether Professor Malagò exerted undue pressure on the Claimant to undergo a Whipple's procedure, but I do not find that there was any unreasonable pressure put on the Claimant to undergo surgery. I am satisfied that Professor Malagò knew that there was a line to be drawn between giving appropriate information to the Claimant to enable *her* to make an informed decision about surgery and pressuring the Claimant to agree to such surgery and I am satisfied that Professor Malagò did not cross such line. Moreover, I accept that Ms Keating would certainly have remembered if Professor Malagò had been inappropriately pressurising the Claimant and she was satisfied that he had not. If the Claimant had reflected on matters and did not wish to undertake such surgery, I do not believe that she would not have attended the pre-operative assessment or subjected herself to a Whipple's procedure.

148. I now need to address the nature of the consent to surgery given by the Claimant.

149. I am satisfied that it was probably the Claimant's initial reluctance/hesitation to undergo surgery which led Professor Malagò to suggest that he could perform an intra-operative biopsy and that if such was positive, he would perform a Whipple's procedure. It is common ground that Professor Malagò did not say that intra-operative biopsies were unreliable. As to whether he should have done so I am satisfied that from her past experience the Claimant well appreciated that EUS biopsies were unreliable.

150. However, I am satisfied that Professor Malagò explained to the Claimant that, even if the biopsy was reported as negative, it could not be assumed that the Claimant did not have pancreatic cancer, that it would be advisable that the pancreas was inspected at an exploratory laparotomy and that even in the event of a negative finding he reserved the right to perform a Whipple's procedure if the appearance of the pancreas suggested to him that it was malignant. I am satisfied that the Claimant gave her consent to a Whipple's procedure if the intra-operative biopsy was positive *or* Professor Malagò had found on examining the pancreas that it had a very suspicious appearance. The Claimant was thus trusting the judgment of Professor Malagò as to whether in such circumstances a Whipple's procedure would be undertaken.

151. In reaching this conclusion on the facts, I particularly on the following reasons:

(1) that is what Professor Malagò had said in his draft letter following the 31 October 2014 meeting which I am sure accurately records what he said.

(2) that is what Ms Lewin agrees was said: see paragraph 26 of her witness statement ['Professor Malagò proposed to make his diagnosis of malignancy based on his own assessment of the lesion **and** the results of the Tru-Cut']. I understand this to mean that, irrespective of the result of the intra-operative biopsy, Professor Malagò was to make his own assessment of lesion, which apparently he did, as was evidenced by the fact that after surgery a junior doctor had said that Professor Malagò had 'felt the lesion with his fingers and that it did not feel right'. Although Ms Lewin said in cross-examination, he was assessing the pancreas to determine from where to take the biopsies, I reject such evidence, as her simply correcting what was an obvious inconsistency between the accounts given by the Claimant and Ms Lewin.

(3) I accept Mr Bershadski's submission that the Claimant and Ms Lewin were enjoying life and did not want the Claimant to run the risk of dying from pancreatic cancer in circumstances where further investigations were causing the Claimant mental strain by having to continue to live with the suspicion of cancer, such that she felt she could no longer carry on working because of such mental strain.

(4) the express wording of the consent form '+/- Whipple's procedure +/- proceed' which had been signed by the Claimant.

(5) the Claimant and Ms Lewin having seen Professor Malagò on 6 February 2015 both the Claimant [in her email sent on 30 March 2015] and her GP [in the medical records] seemed satisfied with Professor Malagò's decision to perform a Whipple's procedure.

152. I have considered whether the agreement reached at the third meeting between the Claimant and Professor Malagò should have been reduced into writing at or immediately after that meeting or whether, as Ms Mulholland, submitted the question should have been revisited at some time before the Claimant underwent surgery. As to the former, I can see no reason why it should have been reduced into writing. Had a written consent form been signed at such meeting it could only have served to emphasise any feelings which the Claimant may have had that she was being somewhat coerced into surgery when I am sure that she would have known, as an intelligent woman, that no surgery could take place without her express consent. If no written consent was signed at such meeting, she knew that someone would in due course have to seek her consent and of course if she was going to undergo surgery, she would have to attend a pre-operative assessment. As to the latter, I cannot see what opportunity there was in reality for the issue of consent to have been revisited.

153. I have considered Ms Mulholland's submission that the offer of an intra-operative biopsy caused 'considerable confusion' and led the Claimant to believe that such biopsy would provide certainty but for the reasons set out above I reject this submission.

154. Finally, I need to refer to some other matters.

155. Firstly, the Claimant's evidence that she gave her consent for surgery to a young doctor by signing the consent form and adding words to the effect 'I'm having a Whipple if there is evidence of cancer'. Whilst I understand that there are two copies of such consent form: one for the patient and the other for the medical records, those words do not appear on the consent form signed by the Claimant and this seems inexplicable. Certainly, no one has explained to my satisfaction how a document bearing the Claimant's signature would not also contain the words which she says that she added to such consent form. Although the Claimant said that these words were written on another piece of paper given to her by the doctor, this makes no sense because she could easily have written on the consent form itself. There was no need for another piece of paper.

156. In so far as it is necessary to do so, I thus reject the Claimant's evidence on this issue. It seems to me highly unlikely that the Claimant's account about adding words to the consent form is accurate for three reasons. Firstly, there is no logical reason why any freestanding document in addition to the consent form containing words to the effect that she was only having the Whipple's procedure 'if there was evidence of cancer' did not find its way into the medical records, as did the consent form. Secondly, the consent form the Claimant agreed she had signed referred to above did consent to a Whipple's procedure and the Claimant does not say that signed two consent forms. Thirdly, the words 'if there was evidence of cancer' could well permit Professor Malagò undertaking a Whipple's procedure if, notwithstanding the biopsy being not indicative of cancer, he believed that his examination of the pancreas suggested evidence of cancer.

157. Secondly, the Claimant's email to Ms Keating on 30 January 2015 which indicated that in substance her consent to surgery was *only* if the intra-operative biopsy was malignant. By that time the Claimant knew that she did not have pancreatic cancer and that she had undergone an unnecessary Whipple's procedure. I am satisfied that there were good reasons why Ms Keating herself did not reply but instead arranged for the Claimant to see Professor Malagò. Indeed, the Claimant herself said that she felt it was the doctors who should be explaining their decisions.

158. I am satisfied that the Claimant is mis-remembering her detailed conversation with Professor Malagò in which she had consented to a Whipple's procedure if the biopsy was malignant *or* if on examination Professor Malagò believed that the pancreas was suspicious of cancer. Moreover, I note that her initial email some 6 weeks earlier was somewhat muted and did not say expressly that in the light of a non-malignant intra-operative biopsy she had not consented to the surgery she had undergone. Had she given her consent on that limited basis I am sure that she would have expressly said so. Further, having seen Professor Malagò on 6 February 2015, the Claimant's email sent to Ms Keating on 30 March 2015 suggests that both she and her GP now understood why Professor Malagò had performed a Whipple's procedure and does not suggest that there is any continuing issue about consent.

159. Thirdly, I accept that in advising the Claimant to have surgery Professor Malagò did not give the Claimant an indication of prospects of malignancy in percentage terms, although he told me that he believed that the risk was greater than 50%. The relevance of this issue must await consideration of the expert evidence of the general surgeons.

160. Fourthly, I reject the Claimant's evidence that Professor Malagò did not inform her of the long-term consequences of losing part of her pancreas. I unreservedly accept the evidence of Professor Malagò and Ms Keating that such consequences were explained and they were set out in the booklet which Ms Keating had given the Claimant.

161. Fifthly, although there was discussion during the trial about the presence of other doctors at the consultation, I note that Ms Keating conceded that there might have been some medical students present. However, I can see nothing of significance in their reactions to anything that Professor Malagò said to the Claimant.

162. Sixthly, it seems to me unfortunate and regrettable that the cytology report was not brought to the Claimant's attention before she underwent surgery, but such report merely reinforced Professor Malagò's suspicions of cancer. Professor Malagò accepts that the cytology report could and should have been discussed with the Claimant but it was his absence on leave which had prevented this happening. However, I am convinced, had such cytology report been brought to the Claimant's attention, it would have reinforced the Claimant's desire that surgery should take place because it would have reinforced the suspicion of cancer. I am thus satisfied that the failure to advise the Claimant of this report has no causative relevance.

163. Finally, having heard Professor Malagò's evidence at some length, I have no doubt that:

(1) he was concerned that, although there had been many investigations where the results were in part reassuring, the possibility of the diagnosis of pancreatic cancer had not been excluded, that the existence of such cancer carried with it a damning prognosis and that waiting for further investigations might mean that the opportunity for surgery might be forever lost.

(2) at the exploratory laparotomy carried out prior to the Whipple's procedure, he had been able to feel the pancreas and found that the whole head of the pancreas was hard to feel. Although he agreed that he would not have been able to tell from such examination whether the abnormality was malignant, he maintained strongly that he was entitled to suspect malignancy. I accept that he was.

(3) even though the intra-operative biopsy was not malignant, with the hard head of the pancreas and the suspicious cells on EUS, it would have been unwise *not* to undertake as Whipple's procedure on the Claimant.

164. Essentially what Professor Malagò is saying that it was a judgement call which he had to make about whether to proceed with a Whipple's procedure. He had her consent to do this if he believed it was appropriate. Of course, he could have elected to end the operation after the intra-operative biopsy and review the future with the Claimant again but he would have certainly have advised her that she should undergo a Whipple's procedure, in such circumstances I am sure that the Claimant would have accepted his advice. It should also be borne in mind that Professor White says, and I believe that it is common ground, that there is higher rate of morbidity if a second operation were undertaken.

165. Having made these detailed findings of fact it is necessary to consider the expert evidence which was put before me.

The expert evidence of the general surgeons

166. Professor Colin Johnson was a Professor of Surgical Sciences and a consultant surgeon in general, pancreas, biliary a GI surgery until his retirement in August 2014. Having reviewed the medical records, Professor Johnson's views in his report dated April 2019 may conveniently be summarised thus:

(1) The clinical history and varying abnormalities on imaging suggested an inflammatory cause for the Claimant's symptoms and were very much against a diagnosis of cancer. In such circumstances he opined that all reasonable pancreatic surgeons would advise the patient to repeat the CT after a further interval because at that time there was insufficient evidence to justify a diagnosis of pancreatic cancer.

(2) He conceded that the management of a lesion in the pancreas which is suspicious for malignancy, but for which the radiological appearances are not diagnostic, is difficult because, for example, chronic pancreatitis can cause similar appearances within the head of the pancreas. Before 2010 this resulted in 5-10% of pancreatic resections in fact having a non-malignant pathology. With the advent of EUS becoming more widely available with the ability to obtain samples from the pancreas by FNA, it was appropriate to undertake such and wait to see if any lesion increased in size. However, it had to be borne in mind that results which did not confirm malignancy, whilst supporting a diagnosis of benign disease, could not be completely relied upon because blood tests and EUS biopsy have a measurable false negative rate.

(3) In the light of the Claimant's post-operative emails to Ms Keating, he believed that the manner in which the options for surgery were presented by Professor Malagò were unbalanced and that he should have made the Claimant aware of how uncertain the diagnosis was and how likely it was that a further period of observation would have been likely to assist her. However, he rightly conceded that this was a matter of fact for the trial judge to determine.

(4) 'The correct course of action after review of the endoscopic biopsy (no malignancy), the EUS cytology (consistent with malignancy or pancreatitis) and CT scan in October (no progression and changes less obvious than on the June CT) should have been to advise a further period of observation'.

(5) In the absence of confirmation of malignancy, the uncertainty of diagnosis and the absence of features of malignancy at surgery, no reasonable pancreatic surgeon would support the decision to proceed with the pancreatic resection.

(6) The failure to pay proper attention to the clinical history and variable radiological findings led to Professor Malagò giving inappropriate advice to the Claimant that she should undergo a pancreatic resection.

167. Professor Steve White is a Professor of HPB and Liver Transplant surgery and a consultant general surgeon with a special interest in surgery of, inter alia, the pancreas. His opinions may conveniently be summarised thus:

(1) Any patient presenting with symptoms such as abdominal pain and a mass in the pancreas should be regarded as having pancreatic cancer until proven otherwise.

(2) A reasonable responsible body of surgeons would have performed a Whipple's procedure because a mass had been shown on abdominal ultrasound, abdominal MRI and EUS which suggested that the risk of cancer was very high and, given the proximity to the portal vein, there was a risk that any cancer might become inoperable even if the intra-operative biopsy was negative.

(3) In the circumstances Professor Malagò should himself have obtained consent and re-confirmed what was going to happen.

(4) Intra-operative frozen section biopsies are notoriously inaccurate for pancreatic cancer. Although they can be useful when they demonstrate malignancy, they can be unreliable and inaccurate when they do not.

(5) Although it is impossible to look at a mass and determine whether it is in fact cancer, a surgeon has to be guided by his experience and what he sees and it is impossible to get it right every time because it is easy to miss a very small cancer within an area of inflamed pancreatic tissue.

(6) Professor Malagò should have explained to the Claimant that there was a 5-10% chance that the lesion was benign.

(7) He personally would not have consented the Claimant for a Whipple's procedure dependent on the result of an intra-operative biopsy because pathologists find it extremely difficult to differentiate between pancreatitis and pancreatic cancer. In one such case, the pathologists subsequently changed their mind and he had to re-operate some three weeks later to remove the cancer which made the subsequent operation more difficult because of the risk of complications.

(8) Although it would be impossible and foolish to say that something looks like cancer, it is reasonable to say that it appears suspicious. On this basis he would support Professor Malagò decision to carry out the Whipple's procedure.

168. A joint report of Professor Johnson and Professor White following discussions between them revealed the following:

(1) It is agreed that there were no further pre-operative investigations that were not done which should have been done.

(2) The experts disagree as to whether the pancreatic lesion was more suggestive of malignancy. Professor Johnson opines that all the factors, when taken together, were more suggestive of benign disease. Professor White opines that the imaging, together with the cytology report, concluded that there was an abnormality on the heads of the pancreas with a biopsy suspicious for cancer. However, both experts agree that a malignant diagnosis could not be ruled out, albeit that Professor Johnson opined that the risk thereof was very low.

(3) It is agreed that the estimated percentage chance of benign disease should have been discussed with the Claimant but they disagree as to what such chance was. Professor Johnson opines that the chance of benign disease was in the region of 90% whereas Professor White believes that it was substantially less than 50% and likely to be approaching only 10%. However, the risk of a malignant diagnosis could not be excluded.

(4) It is agreed that a patient should be informed of the risks of a Whipple's procedure, usually with an indication of percentage risks. Although the risks were sufficiently identified, no percentage risks were recorded.

(5) It is agreed that a reasonable alternative to a Whipple's procedure would have been to discuss the uncertainties involved in diagnosis and to repeat the imaging after 2-3 months. However, it is agreed that, after pre-operative discussion with the patient, a reasonable body of surgeons would offer a Whipple's procedure and consent for that procedure. This is not something which Professor Johnson had conceded before.

(6) It is agreed that before the intra-operative biopsy Professor Malagò must have inspected the pancreas visually and by palpation between finger and thumb. Professor White adds that if pancreatitis is present it makes it very difficult to be sure whether any abnormality is benign or malignant. Both would expect findings at surgery to be recorded.

(7) It is agreed that although a positive finding on an intra-operative biopsy leads to a Whipple's procedure, it is difficult to rely on a negative finding because there is a risk of a false negative biopsy from inadequate sampling at the site of the tumour. It is further agreed that in the circumstances of this case there is no utility in an intra-operative biopsy and that a decision as to whether to perform a Whipple's procedure should be made pre-operatively.

(8) If an intra-operative biopsy was performed and a Whipple's procedure was not undertaken, it is agreed that a second operation would be more difficult because the needle biopsy would have created a small risk of cancer dissemination.

(9) The experts disagree as to whether the histological findings supported Professor Malagò's assertion that the appearance of the pancreas was highly suspicious of cancer.

My findings in relation to the expert evidence of the general surgeons

169. In my judgment it is sufficient to consider the evidence of Professor Johnson and Professor White in the context of their original reports, their Joint Statement and their cross-examination in respect of the five issues identified below.

170. Firstly, although the Joint Statement records that it was agreed that, after a pre-operative discussion with the patient, a reasonable body of surgeons would offer a Whipple's procedure in this case, towards the end of his cross-examination Professor Johnson agreed that it was the correct course of action, and not just reasonable, for Professor Malagò to offer a Whipple's procedure, notwithstanding that the previous day he had said that there was insufficient evidence to offer such a procedure. This already had

the support of the MDT which had concluded on 21 October 2014 that the Claimant should be offered 'resection or imaging'. I thus accept that, in the light of the findings of fact I have made, as set out above, Professor Malagò's advice that the Claimant should, if necessary, undergo a Whipple's procedure and him undertaking such surgery with the Claimant's consent was wholly appropriate and not negligent.

171. Secondly, given that both experts agree that an estimated chance of benign disease should have been discussed with the Claimant [albeit that each expert found it incredibly difficult to say in their oral evidence what that risk would be] it is important to assess what the Claimant should have been told. During his oral evidence Professor Johnson's estimate of the risk of malignancy changed from 10% to a percentage range of 10%-20% and then to 'around 20%'. By contrast Professor White said the risk was between 50 and 90%, more probably towards the latter. The obvious reluctance of both experts to put their opinions into practice suggests to me some doubt as to whether their agreed evidence should be accepted. However, because it remains agreed I am satisfied that I should accept that an estimated chance of benign disease should have been discussed with the Claimant.

172. Given the fundamental dispute between Professor Johnson and Professor White, I have to resolve this as best I can. In my judgment the opinions of Professor White are to be preferred to those of Professor Johnson for three principle reasons. Firstly, Professor White continues to have experience of undertaking Whipple's procedures whereas Professor Johnson, who retired over 5 years ago, does not. Secondly, all of the radiology in this case showed abnormalities and malignancy could not be excluded. Thirdly, and most importantly, in my judgment Professor Johnson made two fundamental errors in his evidence in that:

    (1) He had recorded in his report that there was no evidence of malignancy and had failed to record in his report the suspicions of malignancy reported in the cytology report on 4 November 2014, nor did he discuss the cytology report in his report. He could not explain these errors and omissions save to say that the former was an 'oversight'. I do not find this explanation credible, given that he had already referred to the cytology report earlier in his own report and that he conceded that the cytology report was quite obviously the most significant evidence supporting malignancy. Although he denied that he was not giving a balanced picture in his report, that was the effect of his 'oversight'. His assessment of risk of cancer at 10% thus failed to reflect the impact of such cytology report. In respect of his report, he declined to quantify in percentage terms the increased risk resulting from such cytology report which referred to appearances being 'suspicious of malignancy' but was referred to the *Papanicolaou Society of Cytopathology Guidelines* and agreed the category 'suspicious for malignancy' had 'a very high positive predictive value for malignancy' and that when a patient had a high clinical suspicion of pancreatic cancer and a pancreatic mass on imaging, the diagnosis of suspicious most likely indicates the presence of cancer. That explains why Professor Malagò had referred to a 96% risk of cancer. Such notwithstanding, he conceded, it seemed to me very reluctantly, that the overall risk was increased to 10-20% and then to in the region of 20%. That seemed to me to be an unjustifiable and unreal analysis.

(2) He confirmed that 5-10% of all pancreatic resections had non-malignant pathology. I asked him to quantify that risk after the advent of endoscopic ultrasound and he suggested it might be as low as 5%. When confronted with a paper *When to perform a pancreatoduodenectomy in the absence of positive histology* by *Asbun and Others* entitled published in 2014 he agreed that the risk was 5-13%, although he noted that the patients had been operated on until 2009.

173. Moreover, my impression was that Professor Johnson was a witness who, whilst certainly not deliberately seeking to mislead, had made significant errors in his report which he could not explain and was seeking to uphold at all costs the substance of his report. I am satisfied that his views were also clearly expressed with the benefit of hindsight.

174. I resolve this by determining that the Claimant should have been advised by Professor Malagò that the risk of a benign disease was no greater than 50% and probably significantly less: in other words, she should have been advised that the risk of a malignant pancreatic cancer was greater than 50% and probably significantly more.

175. In such circumstances I have to determine whether, in the light of such advice the Claimant will still have consented, if necessary, to a Whipple's procedure. There is no evidence before me from the Claimant as to whether she would have consented, having regard to such a degree of risk. The only evidence from the Claimant was that if there had been a 10% risk of cancer, she would have not have undergone immediate surgery. Having seen the Claimant give evidence before me and having noted already that she was risk-averse, I have absolutely no doubt that in these circumstances she would have consented to such surgery when faced with a risk of malignancy of 50% or greater.

176. Thirdly, I consider the significance, if any, of Professor Malagò's offer and agreement to undertake an intra-operative biopsy. I understand why both experts are agreed that there is no utility in an intra-operative [and per Professor White merely 'muddied the waters'] because a positive malignant biopsy inevitably prompts surgery whereas a negative non-malignant biopsy may justify surgery and that the decision as to whether to undertake a resection should be taken pre-operatively. However, I am satisfied that on the facts of this case Professor Malagò believed that the offer an intra-operative biopsy would be, as it was, reassuring to the Claimant in that in the event of a negative biopsy Professor Malagò had agreed that he would only undertake a Whipple's procedure if the pancreas looked suspicious for cancer.

177. Fourthly, the experts agree that a patient should be informed of the percentage risks of a Whipple's procedure and Professor Malagò concedes that he did not give such percentage risks. However, I have already found that Professor Malagò explained the risks to the Claimant and I am satisfied that on the facts of this case no further explanation in percentage terms as to each risk of such procedure would have assisted the Claimant or might have persuaded her not to consent to the procedure in the manner she did. Moreover, I note that at no stage during their reports or evidence did either of the experts say what percentages for what risks should have been given by Professor Malagò to the Claimant.

178. Fifthly, I consider the failure of the person making the operation note to record what Professor Malagò saw when examining the pancreas. This is in fact a criticism of the note taker, not Professor Malagò. I have already set out what Professor Malagò felt and

saw. I unreservedly accept his evidence on this issue. I note that in cross-examination Professor Johnson said that if Professor Malagò found that the head of the pancreas was hard at surgery, as he says that he did, and the operation note does refer to the pancreas being 'hard', and it was not possible to exclude malignancy, it was correct to remove the head of the pancreas. Equally, Professor White says that if the pancreas felt hard it was reasonable for Professor Malagò to perform a Whipple's procedure.

The evidence of the radiologists

179. I have read and considered the expert reports of the consultant radiologists Professor Derrick Martin dated 9 April 2019 and Dr Stuart Roberts dated 28 March 2019 instructed by the Claimant and Defendant respectively. There was no Joint Statement between them. For present purposes it suffices to set out their opinions, having reviewed the imaging.

180. Professor Martin opined that:

(1) the imaging was correctly reported and concluded that pancreatic cancer could not be excluded. However, the lack of progression, possible regression, lack of change in size, lack of pancreatic and bile duct dilatation all argued on a balance of probabilities against a diagnosis of pancreatic cancer.

(2) given the lack of progression in the 4 months preceding mid October 2014 a 3-month period of observation would have been safe and would have avoided surgery.

181. Dr Roberts opined that:

(1) a diagnosis of pancreatic cancer often relies on the radiological detection of subtle small lesions and in this case subtle small abnormalities were reported on CT and MRI in an effort to confirm or exclude early pancreatic cancer.

(2) the CT report of July 2014 that there was a hypodense abnormality seen only during the portal venous phase correctly gave rise to the differential diagnosis thereof including a pancreatic tumour.

(3) the MRI report that there was a hypointense abnormality on the post contrast imaging correctly gave rise to the differential diagnosis thereof including a pancreatic tumour.

(4) the CT report of October 2014 that there was persistent hypodense abnormality meant that it would be unsafe to rule out cancer purely due to lack of progression or development of pancreatic and/or biliary dilatation.

My conclusions as to the expert evidence of the radiologists

182. Given that there is no significant reliance by either party on such evidence and I have not seen either expert give oral evidence or be cross-examined, I have concluded that this evidence does not take the issues in this case any further.

Conclusion

183. It thus follows that for the reasons set out above I am satisfied that there was no breach of duty by Professor Malagò and that any injury or loss was not caused by any such breach of duty, as alleged or at all, and that the Claimant's claim should be, and is, dismissed.

184. At the conclusion of the hearing I agreed with both counsel that, after an opportunity given for the parties' counsel to suggest any correction of typographical errors and other obvious errors of fact:

(1) this judgment would be handed down without the necessity for either party to attend;

(2) within 14 days of judgment being handed down either party should indicate to the other party any application which it proposed to make against that other party;

(3) if the parties agreed any consequential orders, I would be minded to make them; and

(4) in the event of any dispute the parties should have a further 14 days in which to make submissions in writing in relation to any such application.

185. I will thereafter determine any application by either party on the basis of such written submissions and without a further hearing.

186. I should add my sincere thanks to both Ms Mulholland and Mr Bershadski, together with their respective instructing solicitors. This case involved the consideration of much complex evidence and involved the making of very detailed opening and closing submissions. They bore the brunt of ensuring that I fully understood this case and I express my appreciation to both of them for all the assistance that they gave to me.