

Neutral Citation Number: [2019] EWHC 936 (QB)

Claim No: HQ18C00995

IN THE HIGH COURT OF JUSTICE QUEEN'S BENCH DIVISION

Royal Courts of Justice Strand, London, WC2A 2LL

Date: 12 April 2019

Before :

KAREN STEYN QC (sitting as a Deputy High Court Judge)

Between:

ADRIAN MILLS (by MARIA MILLS his wife and litigation friend)

Claimant

- and -

OXFORD UNIVERSITY HOSPITALS NHS TRUST

Defendant

Charlotte Jones (instructed by Thompsons) for the Claimant John de Bono QC (instructed by Beachcroft) for the Defendant

Hearing dates: $4^{th} - 8^{th}$ March 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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Karen Steyn QC:

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A. Introduction

- 1. The Claimant in this case is Mr Adrian Mills. He was born on 11 April 1967 and is currently 52 years old. On 4 December 2012, Mr Mills underwent brain surgery at the John Radcliffe Hospital, specifically, a resection (otherwise known as de-bulking) of a left frontal glioma (i.e. a tumour). He suffered a haemorrhage during the course of the operation which caused him to suffer a stroke in the left anterior cerebral artery territory.
- 2. Prior to the surgery, Mr Mills worked as a Firefighter, employed by the London Fire Brigade. As a consequence of the haemorrhage and stroke, he has been left with a very significant physical and cognitive disability. He was medically retired in 2013.
- 3. Mr Mills has brought a claim for damages against Oxford University Hospitals NHS Trust ("the Trust") for alleged negligence. He alleges that Mr Puneet Plaha, a Consultant Neurosurgeon employed by the Trust:
 - i) Performed the surgery negligently; and/or
 - ii) Failed to take reasonable care to ensure that Mr Mills was aware of the material risks involved in the proposed procedure and/or of any reasonable alternative or variant treatments.
- 4. Mr Mills lacks capacity to litigate and/or manage his financial affairs. He has brought this litigation by his wife, and litigation friend, Mrs Maria Mills. Both Mr and Mrs Mills were present in court throughout the hearing. As Mr John de Bono QC (Counsel for the Trust) rightly acknowledged, Mr and Mrs Mills both demonstrated immense dignity and courage in the manner in which they sat and listened throughout the trial and, in Mrs Mills' case, in giving evidence.
- 5. I have summarised the issues in paragraphs 6 to 23 and my conclusions in paragraph 29 below. My overall conclusion is that the claim against the Trust (which accepts vicarious liability) based on lack of informed consent succeeds, whereas the claim based on clinical negligence fails.

B. The Issues

6. The hearing addressed issues of liability only. In broad terms, as I have said, the allegations of negligence break down into two parts (a) negligence in the performance of the operation and (b) failure to obtain informed consent. I shall address the performance of the operation first because the allegations under that head go not only to the actual performance of the surgery on the day, but also more fundamentally to the question whether the technique used by Mr Plaha was negligent.

(a) Alleged negligence in the performance of the operation

- 7. There are two distinct allegations under this head, and it is common ground that the standard of care in respect of them is to be judged by applying the well-known *Bolam* test.
- 8. <u>Issue 1</u>: In performing the resection Mr Plaha used a minimally invasive endoscopically-assisted open craniotomy technique. In 2012, the conventional

- technique involved using a microscope (rather than an endoscope) for the purpose of visualising the tumour site and required a larger craniotomy than the technique used by Mr Plaha in operating on Mr Mills.
- 9. Mr Mills alleges that using this endoscopically-assisted technique was itself negligent. Specifically, the particulars of claim allege negligence in failing "to use a technique that allowed direct line of sight of the vessels [Mr Plaha] injured and the ability to control bleeding if and when it happened" (PoC §19(i)). The Trust denies that the technique used was negligent.
- 10. <u>Issue 2</u>: Mr Mills alleges that, in the course of the operation, Mr Plaha unintentionally and negligently "migrated into the midline structures and directly damaged vessels causing life threatening haemorrhage" (PoC §19(h)). The Trust denies this.
- 11. It is clear that, when removing the tumour, Mr Plaha unintentionally transected a vessel causing a torrential bleed. The key question in respect of this allegation is where the vessel was located when it was transected. When the transected vessel was found, it was about 3-4cms from the deepest part of the tumour. It is common ground that if the transection of the vessel occurred where it was found that would signify that Mr Plaha had negligently migrated into the midline structures. To put it colloquially, it would mean he was lost "very far" from the tumour site. On the other hand, if the vessel was within the tumour when it was transected, then Mr Plaha was de-bulking the tumour in the correct area and the haemorrhage was a very unfortunate, but non-negligent, occurrence.

(b) Alleged failure to obtain informed consent

- 12. The allegations under this head concern the advice given by Mr Plaha to Mr Mills during the consultation on 8 November 2012. It is common ground that when assessing these allegations, I should apply *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] AC 1430.
- 13. <u>Issue 3</u>: It is alleged that Mr Plaha failed to advise Mr Mills that there were three treatment options available to him, namely, (i) surveillance (i.e. wait and watch, by means of repeat scans); (ii) biopsy; and (iii) resection (PoC §19(d) and (f)). The Defendant acknowledges that failing to offer all three options would be negligent but denies there was any such failure.
- 14. More broadly, Mr Mills contends that, even if Mr Plaha offered these three treatment options, he failed to provide adequate pre-operative advice in respect of each option (leaving aside the matters that are the subject of issue 4), (PoC §19(a), (b), (c) and (e). The Trust denies any failing in this regard.
- 15. <u>Issue 4</u>: Mr Mills alleges that Mr Plaha "wholly failed to advise that a minimally invasive endoscopic technique using a rigid endoscope was a novel technique and not a standard well tested technique for resection of a brain tumour; that the use of an endoscope would involve more limited access than would otherwise be the case and consequently greater risk to vessels that could not be directly visualised" (PoC §19(g)).
- 16. The Trust makes an admission in respect of this allegation in these terms: "in advising the patient of the surgical debulking option, Mr Plaha provided advice regarding the surgical approach, intended benefits and risks that were associated with a minimally

invasive endoscopically assisted open craniotomy technique and did not discuss the alternative approach of a microscopically assisted open craniotomy technique and the intended benefits and risks that were associated with this alternative approach to visualising the operative field" (Defence §13).

17. This admission narrows the issue, but there remains a question as to what advice and information Mr Plaha should have provided about the differences between the endoscopically-assisted technique compared to the microscopically-assisted technique.

(c) Causation

- 18. If Mr Mills succeeds in establishing that Mr Plaha negligently migrated into the midline structures, the Trust accepts that a finding of causation of damage would inevitably follow. If any other breach is found, the Trust raises issues of causation by way of defence.
- 19. <u>Issue 5</u>: If Mr Mills had received such additional advice and information from Mr Plaha as I find he should have done, would Mr Mills (on the balance of probabilities) still have opted for a minimally invasive endoscopically-assisted resection procedure? Or would he have opted for surveillance, a biopsy alone, or a microscopically-assisted resection procedure?
- 20. If I find Mr Mills would have declined surgery altogether, the Trust acknowledges that causation would be established. If I find that he would have opted for precisely the same procedure as he had, Mr Mills acknowledges that he would not have established that the failure to obtain informed consent was causative of any damage.
- 21. Further issues arise if I find that Mr Mills would have opted for a microscopically-assisted resection procedure.
- 22. <u>Issue 6</u>: The Trust contends that, on the facts, the choice of technique did not make it more difficult to control the bleeding. The Trust's argument is that once Mr Plaha sought the assistance of Mr Tom Cadoux-Hudson, a senior Consultant Neurosurgeon, the latter extended the craniotomy and from then on a microscope was used rather than an endoscope. It is contended that the fact that Mr Plaha initially made a smaller craniotomy, and used an endoscope, had no causative impact on the efforts to control the bleeding once Mr Cadoux-Hudson became involved. Mr Mills relies on the views expressed by the experts to counter this argument.
- 23. <u>Issue 7</u>: If I find that (i) Mr Mills would have opted for a microscopically-assisted resection procedure, whether on 4 December 2012 or another date (see Issue 5) and (ii) the choice of technique did not make it more difficult to control the bleeding (see Issue 6), the Trust contends that the complication suffered falls outside the scope of the duty to warn, applying *Khan v Meadows* [2019] EWCA Civ 152, [2019] 4 WLR 3. Whereas Mr Mills contends that he suffered the very injury that was the focus of the duty to warn and causation would be established.

(d) Issues that do not arise or have fallen away

24. The Particulars of Claim also alleged that Mr Plaha "failed to call for assistance as soon as it became apparent that he was in difficulties controlling the haemorrhage". However, in her closing submissions, Ms Charlotte Jones, Counsel for Mr Mills, made clear that this allegation is not pursued.

- 25. The allegation of delay was made because it was unclear from Mr Plaha's manuscript note of the operation when the bleeding began and a stray arrow on that note might have suggested it began when Mr Plaha took the biopsy. If the bleeding had begun at the outset of the operation, then Mr Mills contended there was negligent delay in calling for assistance.
- 26. However, it was clear from the evidence of Mr Plaha and Dr Sally Anne Wheatley, a Consultant Anaesthetist, together with the anaesthetic record, that for the first two hours the operation proceeded as expected. The bleeding began at about 4.15pm. Mr Plaha tried to control the bleeding using standard materials to pack the wound. Within about 10-15 minutes of the bleeding starting, Mr Plaha requested assistance from Mr Cadoux-Hudson. After Mr Cadoux-Hudson had left and the bleeding re-started, Mr Plaha called again for assistance from a senior colleague, and he received assistance from Mr Stewart Griffiths, another senior Consultant Neurosurgeon based at the John Radcliffe Hospital. Mr Kirkpatrick and Mr Grundy were in agreement that "if the torrential haemorrhage occurred at two hours", as I find it did, "then Mr Plaha seemed to have called for assistance quite quickly".
- 27. The Claimant makes no criticism of Mr Cadoux-Hudson or Mr Griffiths. Indeed, no criticism is now made of Mr Plaha either in respect of the period <u>after</u> the bleeding began.
- 28. In their joint report, Mr Kirkpatrick and Mr Grundy were asked to address a question whether the technique used by Mr Plaha required "formal trial and/or approval" and so they expressed a view (very briefly) regarding the Trust's governance systems and the question whether the technique required registration. There is no pleaded allegation regarding these matters, and I heard very little evidence about them. I have no doubt that if an allegation of any failure in respect of their governance systems had been made in the Particulars of Claim, the Trust would have wished to respond to it with evidence. In the circumstances, it would be unfair to address the question of registration or compliance with governance systems and I have not done so.

C. Summary of my Conclusions

- 29. In summary, I have reached the following conclusions:
 - i) The use of a minimally invasive endoscopically-assisted open craniotomy technique to resect Mr Mills' glioma was not negligent.
 - ii) Mr Mills has not proved, on the balance of probabilities, that Mr Plaha performed the surgery negligently by migrating into the midline structures (or otherwise).
 - iii) Mr Plaha discussed three treatment options (surveillance, biopsy and resection), and the risks and benefits of each of them, with Mr Mills during the consultation in his clinic on 8 November 2012. In this respect, he complied with his duty to obtain informed consent, save to the extent that Mr Plaha should have advised that the glioma was an incidental finding and it was unlikely that it was the cause of Mr Mills' headaches.

- iv) Mr Plaha breached his duty of care by (a) not offering a microscopically-assisted resection procedure as an alternative to a minimally invasive endoscopically-assisted resection and (b) not explaining the comparative risks and benefits of these alternative surgical techniques.
- v) The failure to advise the glioma was incidental and unlikely to be the cause of Mr Mills' headaches had no causative impact. However, if Mr Mills had been advised, as he should have been, with respect to the alternative surgical technique and the comparative risks and benefits, it is probable that he would have opted for resection using the standard microscopically-assisted technique.
- vi) If Mr Mills had undergone a resection operation using the microscopically-assisted technique (as he would have done if he had been properly advised), it is probable that if torrential bleeding had occurred it would have been controlled successfully much earlier and Mr Mills probably would not have suffered a stroke.
- vii) In any event, as Mr Mills should have been advised of the possibility that using the endoscopically-assisted technique could pose a greater risk to structures and vessels that were not within the surgeon's direct line of sight, and the risk of damage to a vessel that was not within Mr Plaha's direct line of sight eventuated, the damage which occurred was within the scope of Mr Plaha's duty to warn.

D. The Evidence

- 30. I heard oral evidence on behalf of Mr Mills from: Mrs Mills; Mr Peter Kirkpatrick, a Consultant Neurosurgeon who gave expert evidence; and Dr Jeremy Rees, a Consultant Neurologist who gave expert evidence. In view of his physical and cognitive disabilities, Mr Mills did not give evidence.
- 31. I heard oral evidence on behalf of the Trust from: Mr Plaha, the Consultant Neurosurgeon who carried out the operation; Mr Cadoux-Hudson, one of the two senior Consultant Neurosurgeons who assisted Mr Plaha after the bleeding began; Mr Griffiths, the other senior Consultant Neurosurgeon who assisted Mr Plaha to control the bleeding; and Mr Paul Grundy, a Consultant Neurosurgeon who gave expert evidence. I read the witness statement of Dr Wheatley, a Consultant Anaesthetist who was present during the operation, and whose evidence was not challenged.
- 32. I also read the witness statements of each of the witnesses, and the reports of each of the expert witnesses, who gave oral evidence. Mr Kirkpatrick provided two reports, one dated 31 May 2016 and one dated January 2019. Mr Kirkpatrick and Mr Grundy also produced a joint report. Mr Grundy produced a very brief additional statement during the hearing, clarifying his evidence on two points in light of the factual evidence, and Ms Jones agreed to its admission.
- 33. In addition, the trial bundle contained the expert report of Dr Richard Orrell, a Consultant Neurologist. However, the Trust chose to call Mr Grundy only to respond to the evidence of both Mr Kirkpatrick and Mr Rees, therefore I have not taken into account Dr Orrell's report.
- 34. The matters set out below represent my findings of fact unless I have stated otherwise.

E. The Facts

(a) Discovery of Mr Mills' tumour

- 35. Mrs Mills recalled that her husband began to experience headaches in early 2012. He was prescribed reading glasses, but he continued to suffer headaches. Bright lights caused him pain. His head would hurt if he watched television or from the light of his mobile phone. He found the pain was worse when he was lying down. In around October 2012, Mr Mills attended a routine Fire Service health check and it was noted that his blood pressure was high. He made an appointment to see his GP and was prescribed medication to address his high blood pressure. Mr and Mrs Mills assumed that the headaches were a result of his high blood pressure.
- 36. On 31 October 2012, Mr Mills came home from a night shift complaining of chest pains. Mrs Mills telephoned 111 and they were advised to go to Wexham Park Hospital. Mr Mills was admitted to Wexham Park Hospital on 31 October 2012 and discharged on 2 November 2012.
- 37. The "hospital leaving letter" sent to Mr Mills' GP records:

"Mr Mills was admitted with a 6-8 month history of headaches. He was found to be hypertensive with a BP pf 187/105 on admission. His creatinine was 180 on admission and the patient was reviewed by the renal team who started him on diltiazem. Systolic was 160 on discharge."

- 38. Although the letter from the hospital does not mention chest pains, I note there is reference to some history of chest pain in the preoperative assessment dated 27 November 2012. And I accept Mrs Mills' evidence that it was chest pains which initially prompted Mr Mills to go to the hospital. He explained his history of headaches while he was there.
- 39. On 31 October 2012, while Mr Mills was in Wexham Park Hospital, magnetic resonance imaging (MRI) and computerised tomography (CT) scans were taken. The hospital leaving letter records that the CT (head) scan was "normal". The letter stated that the MRI scan of Mr Mills' brain "identified a lesion in the left frontal lobe ?cause. Discussion and referral was made to neurosurgeons [at] John Radcliffe hospital, Oxford who will be reviewing the patient in MDT meeting and following him up as an outpatient".

(b) The MDT's assessment and plan

- 40. As the hospital leaving letter indicated, Wexham Park Hospital referred Mr Mills to the Trust's Central Nervous System Multidisciplinary Team ("the MDT").
- 41. The MDT discussed Mr Mills' case at a meeting on 6 November 2012. The brief meeting note records those present at the MDT meeting: six neurosurgeons (including Mr Cadoux-Hudson and Mr Simon Cudlip), three clinicians from neuro-oncology, one neuroradiologist, one neuropathologist and two nurse specialists.

- 42. In the box marked "Question for MDT", the hospital had recorded: "Verifying cause of left frontal lobe lesion. Possible low grade Glioma/DNET. Currently presenting with headaches and epigastric pain".
- 43. The MDT's assessment is recorded in these terms: "31.10.12 Left frontal intrinsic lesion Glial ?Grade3". The grade refers to the World Health Organization (WHO) classification. High-grade tumours are grades 3 and 4 and low-grade tumours are grades 1 and 2. A higher grade correlates with a more aggressive and rapidly growing tumour, and a worse prognosis; a lower grade indicates a slower growing tumour with a better prognosis. Over time, an untreated low-grade glioma will become a high-grade glioma and (as Mr Grundy explained) in patients over the age of 40, low-grade gliomas behave more aggressively. Mr Cadoux-Hudson explained, by reference to the note, that the MDT assessed the tumour as "query grade 3" because the scan suggested the tumour sat somewhere between the transition from a low-grade to a high-grade tumour. Although not formally classified as such, he said neurosurgeons sometimes referred to this as a grade "2.5".
- 44. The MDT's entry in the box marked "MDT discussion and plan" stated: "For outpatients appointment with Mr Plaha and offer resection". Mr Plaha is also identified in the MDT's note as the "Consultant surgeon".
- 45. It is clear the MDT decided to refer Mr Mills to Mr Plaha for an outpatient's appointment at which Mr Mills should be offered the option of resection (i.e. an operation to remove the glioma, to the extent possible). Mr Plaha was not present at the MDT meeting. Mr Plaha recalled that he was informed by Mr Cudlip after the meeting that the MDT had referred Mr Mills to him, and that the MDT considered Mr Mills should be offered a resection.
- 46. The MDT note does not specify that Mr Mills could or should be offered a resection using the minimally invasive endoscopically-assisted open craniotomy technique. Mr Plaha's evidence was that Mr Cudlip said that given Mr Mills' age and the size of the tumour it would be reasonable to offer resection and that this could be done using the endoscopically-assisted technique. Mr Cadoux-Hudson could not recall the MDT meeting, but he confirmed that he was aware of the study Mr Plaha was undertaking. Whatever the precise content of the conversation between Mr Cudlip and Mr Plaha, I accept that Mr Plaha's colleagues, and in particular the MDT, were well aware of the series of endoscopically-assisted resections he was undertaking and agreed the technique could be used in this case.

(c) Consultation with Mr Plaha on 8 November 2012

47. Mr Mills, accompanied by Mrs Mills, attended an appointment with Mr Plaha on 8 November 2012. Anne May, a specialist oncology nurse was also present. There is a dispute between the parties as to what information and options Mr Plaha gave Mr Mills during this appointment which I address in Section I (see especially paragraphs 158-166 and 183-194) below.

(d) Letter of 8 November 2012 from Mr Plaha to Mr Mills' GP

48. Following the appointment, on the same day, Mr Plaha wrote a letter to Mr Mills' GP. The letter states:

"Diagnosis:

Left frontal likely low-grade glioma.

Plan:

Offered endoscopic resection and Mr Mills is keen to proceed.

It was a pleasure to see Mr Mills and his wife in the neuro-oncology outpatient clinic today. Anne May, our Oncology Nurse Specialist was also present.

Mr Mills presents with a long-standing history of headaches especially when lying down. He has had this for a number of years. As he felt the pressure symptoms in his headaches has got worse recently and he was taken to Wexham Park Hospital where he was diagnosed as having hypertension and is presently on Diltiazem. For the past couple of weeks he has noticed numbness and tingling in his left finger. He has no long-standing nausea, vomiting or visual disturbance. Although he says his vision is funny when he watches television nor sees bright light. He has had no seizures. His gait function is unchanged.

He works as a fire-fighter He had operation on his knee three years ago.

On examination he has no motor deficits.

He had a CT and MRI scan of the brain performed on 31st October at Wexham Park Hospital. I showed him the scan images and explained that the lesion in the medial part of the left frontal cortex is likely a low-grade glioma. Although other possibilities like inflammation cannot be completely explored excluded.

I went through the natural history of gliomas and treatment options which are (imaging surveillance, biopsy and endoscopic resection). I went through the risks and benefits of each in detail. Given the likely possibility he is quite keen to have this debulked and I went through the risk of a craniotomy and endoscopic debulking including a small risk to his life, severe disability including paralysis/stroke, cognitive and memory disturbance, speech disturbance, infection, bleeding, CSF leak, seizures, loss of smell on the left side, DVT, PE, pneumonia and other undefined risks. I have put these risks at 2-3%.

He has mentioned problem with his short-term memory which is long-standing and I offered him an objective neuropsychology assessment which he is unkeen to have at the moment.

I have advised him not to drive and inform the DVLA.

I have added his name to the waiting list and I will bring him in for surgery soon."

49. This letter was copied to Mr Mills. There was no suggestion that he did not receive it.

(e) Pre-operative assessment

- 50. Shortly after the consultation, the resection was planned for 4 December 2012. On 27 November 2012, Mr Mills attended a pre-operative assessment with a nurse. Mr Plaha was not present on this occasion.
 - (f) Mr Mills' admission to the John Radcliffe Hospital on 3 December 2012

- 51. On 3 December 2012, Mr Mills was admitted into the John Radcliffe Hospital, to stay overnight before the resection was due to be undertaken the following afternoon.
- 52. Mr Plaha met with Mr Mills, as his manuscript note records, at about 6pm on 3 December 2012. Mrs Mills was not present during this meeting. She remained at home on the evening before Mr Mills' surgery, with their young son, going into the John Radcliffe Hospital the following morning to see her husband before his operation.
- 53. Mr Plaha's contemporaneous note records: "Still has headaches. Not worse. [Glasgow Coma Scale] 15/no deficits". The diagnosis was, as before, a left frontal low-grade glioma. Mr Plaha noted: "Rediscussed Treatment Options". Arrows then point to three options, namely, "Imaging surveillance", " B_x " (i.e. biopsy), and "Debulking \rightarrow keen to proceed". Mr Plaha's note also records "Risks/Benefits of Each", "Consented \rightarrow Copy to Pt" (i.e. patient).
- 54. I accept (and it was not disputed) that Mr Plaha discussed these three treatment options, explaining the risks and benefits of each, with Mr Mills on 3 December 2012. The question is whether these options were "rediscussed", as the note recorded, or discussed for the first time (i.e. had all three options been discussed in consultation on 8 November?), as to which see Section I below. It was not disputed that if the options had all been discussed on 8 November, it was good practice to go through the options again the evening before surgery, but discussing them for the first time on the eve of surgery would not have remedied any failure to discuss them during the earlier consultation.
- 55. During the course of their discussion in hospital on 3 December, both Mr Mills and Mr Plaha signed the consent form. On the form, the proposed procedure was described as "Endoscopic debulking of left frontal tumour". Mr Plaha signed to indicate that he had explained the procedure to the patient. In particular, he had explained the "intended benefits", which he described as "1 Reduce Mass Effect 2 Obtain tissue for histopathology"; and the "serious or frequently occurring risks", which he described as "Risk to life, Severe disability including paralysis / stroke / cognitive / memory impairment / speech disturbance / infection / bleeding / CSF leak / seizure".

(g) The resection operation on 4 December 2012

- 56. The operation took place on 4 December 2012. Mr Plaha was assisted by a Consultant Anaesthetist, Dr Wheatley, and by a Registrar, Dr Wright. A junior anaesthetist was also present in theatre. Dr Wheatley explained, by reference to the notes on the Anaesthetic Chart, that the general anaesthetic was administered at about 1.45pm, following which, at about 2.05pm, Mr Mills was transferred to the operating theatre.
- 57. Mr Plaha used a computer guidance system called "*Brainlab*". This is a navigation system which enabled Mr Plaha to plan the optimal access route for the surgery, based upon imaging of the location of the tumour in relation to the other structures of the brain. The route was mapped and the location and accuracy of key structures was confirmed prior to starting the surgery. Mr Plaha described it as being similar in concept to satellite navigation systems commonly used in cars.
- 58. The procedure began at around 2.15pm. Mr Plaha made a coronial incision just above Mr Mills' hairline on the left and took away the flap of bone to be replaced at the end of the procedure. He then performed a cruciate durotomy, which involves cutting through the outer firm covering of the brain to allow access to the brain matter. Mr

Plaha used a microscope initially and then, as planned, used an endoscope to visualise the operative field.

- 59. Mr Plaha undertook a biopsy, removing a sample of the suspected tumour which he sent to a neuropathologist for analysis. Within about 15 minutes of receiving the sample, the neuropathologist confirmed that it was a low-grade glioma. Once the presence of a low-grade glioma had been confirmed, Mr Plaha proceeded to debulk the tumour. This involved removing as much of the tumour as possible, and so reducing the size of the tumour, using a tool called a Cavitron Ultrasonic Surgical Aspirator ("CUSA") at low setting. The CUSA generates high frequency or ultrasonic sound waves to erode a cavity in the tumour. Mr Plaha described it as being similar in concept to sandblasting or coastal erosion. The CUSA has an in-built aspiration system which sucks away the tumour matter once it has been destroyed.
- 60. For the first two hours, the operation proceeded as expected. At about 4.15pm, a complication occurred: Mr Plaha encountered what he described in his manuscript operation note as a "torrential bleed". The bleeding appeared to be coming from the middle of the tumour. Mr Plaha sought to control the bleeding by packing the wound, using standard materials such as Surgicel (a cloth like material designed to stem bleeding) and patties (which are similar to cotton wool). Within about 10-15 minutes of trying, unsuccessfully, to control the bleeding, Mr Plaha asked Dr Wheatley to request assistance from Mr Cadoux-Hudson, a Consultant Neurosurgeon (described by Dr Wheatley as "one of the most experienced surgeons in the department"), who was operating in an adjoining theatre.
- 61. Mr Cadoux-Hudson found that the tumour site started to bleed again when he pulled the packing off, so he re-packed it. He then fashioned a small extension of the craniotomy. When the Surgicel and patties were again removed, using the theatre stereoscopic microscope (which was draped and ready), Mr Cadoux-Hudson could see no evidence of active bleeding. Mr Cadoux-Hudson was not able to identify the source of the bleeding, but haemostasis appeared to have been achieved. He advised Mr Plaha to wait for five minutes or so and check again for any further bleeding (i.e. to take a "haemostatic break") before proceeding, and he then returned to his own patient.
- When Mr Plaha resumed closing the dura, there was further bleeding from the cavity. As Mr Cadoux-Hudson had left the hospital by this point, at about 7pm Mr Plaha asked Dr Wheatley to request the assistance of another senior Consultant Neurosurgeon, Mr Stewart Griffiths. Mr Griffiths recalled "we decided to enlarge the craniotomy bone flap for increased access and due to the presence of swelling which would place additional pressure on the brain". A further attempt to control the bleeding with packing slowed the bleeding but did not offer a permanent solution. In order to find the source of the bleeding they decided to remove the gyrus rectus. This involved having to remove some healthy brain tissue. Having removed the gyrus rectus, Mr Griffiths "noted the retracted stump of what appeared to be a branch of the left frontopolar artery". The transected vessel was diathermised (i.e. sealed), which stopped the bleeding. They then proceeded to close the craniotomy. They finished the operation at about 9pm. Mr Mills was transferred out of theatre to the intensive care unit ("ICU") at about 11pm.
- 63. During the course of the operation, Mr Mills lost (and received by way of transfusion) about 5 litres of blood.

(h) Did Mr Cadoux-Hudson assist Mr Plaha once or twice?

- 64. A factual issue which I have not addressed in the narrative above is whether Mr Cadoux-Hudson attended theatre to assist Mr Plaha once or twice during the operation. Mr Plaha's evidence was that Mr Cadoux-Hudson assisted him twice. In cross-examination, Mr Cadoux-Hudson thought it likely he had only attended once. On the other hand, in his witness statement Mr Cadoux-Hudson had made clear that he could not recall whether he returned to assist Mr Plaha a second time. Mr Cadoux-Hudson said that it is "human nature that we recall our own personal complications in great detail" and, for that reason, he deferred to Mr Plaha as to the precise sequence of events and any timings regarding Mr Mills' operation.
- 65. Mr Plaha was not challenged on his evidence that Mr Cadoux-Hudson assisted twice. In the circumstances, as no allegation of negligence is maintained against the Trust in respect of the period after the bleeding began, it is unnecessary for me to determine whether Mr Cadoux-Hudson assisted once or twice.

(i) Mrs Mills' telephone calls to the hospital

- 66. Mrs Mills had returned home while her husband was in surgery, having been told he would not be back in the ward until about 5pm. She telephoned the hospital between about 5 and 5.30pm. She was told Mr Mills was not yet in recovery or back from theatre. She was reassured that it was likely his surgery may have been pushed back due to a medical emergency and advised to call back in a couple of hours. Mrs Mills telephoned the hospital again at about 7pm. She was again advised to call back in a couple of hours, as the person she spoke to thought Mr Mills was still in surgery, but was unsure.
- 67. Mrs Mills telephoned the hospital again at about 9pm, by which stage she was, naturally, very worried. She was told Mr Mills was still in theatre. Mrs Mills asked for someone to call her back to let her know what was happening. A short while later, a member of the hospital staff telephoned Mrs Mills and informed her that the operation had not gone to plan. She was told Mr Mills was still in theatre, that he had lost a lot of blood and had required a transfusion. Mrs Mills said that she was advised not to go to the hospital that evening as it might not be possible to speak to Mr Plaha. However, she wanted to be at the hospital so Mrs Mills called a friend to accompany her and went to the hospital that evening.

(j) After the operation

- 68. Mrs Mills arrived at the John Radcliffe Hospital at about 10.30pm. As I have said, Mr Mills was transferred out of theatre into the ICU at about 11pm. Also at about 11pm, Mr Plaha met with and spoke to Mrs Mills (and her friend, Rachael).
- 69. Mr Plaha's clinical note records the discussion in these terms:
 - "- Explained sequence of events in theatre
 - \rightarrow Blood vessel within tumour retracted at time of debulking tumour
 - Blood loss requiring transfusions
 - Bleeding controlled by finding retracted blood vessel originating from wall of major artery (Pericallosal)

- Assisted by Mr Cadoux Hudson/Griffiths
- At closure major artery (Pericallosal) flowing well and pulsating
- At closure [normal] brain pressure
- \rightarrow Presently plan to keep asleep overnight on ventilator
- Plan for angiogram in the morning
- Difficult to predict outcome
- → Could have a stroke paralysis / speech / cognitive / memory disturbance
- May require further interventions tonight / tomorrow
- Will update her on Mr Mills' progress"
- 70. Mrs Mills then went to see her husband in the ICU. Although the hospital staff had tried to prepare her for this, she said the warning was insufficient and she "broke down" when she saw her husband.
- 71. A CT scan taken shortly after midnight in the hours following the operation (specifically, at 00.13 on 5 December 2012) showed a cavity where the left frontal tumour had been removed, extensive sub-arachnoid and intra-ventricular haemorrhage and an infarct (i.e. a stroke) in the region of the left anterior cerebral artery.
- 72. At about 1am on 5 December 2012, Mr Plaha had a further discussion with Mrs Mills and her friend. His clinical note records that he explained the CT scan showed a subarachnoid haemorrhage and there was an "early suggestion" of an infarct/stroke in the left anterior cerebral artery territory.
- 73. Mrs Mills' evidence was that when she spoke to Mr Plaha at about 1am he told her that an artery had been connected to the last part of the tumour. He had not realised this until he removed that part of the tumour and heavy bleeding began. She said Mr Plaha told her the artery (or vessel) retracted and so it had been difficult to see and stop the bleeding. Other consultants had been brought into theatre and eventually they had managed to stop the bleeding, but it had taken hours to do so. Mr Plaha told her that Mr Mills had lost a lot of blood during surgery, he was now in a stable condition and the next 24 hours would be critical. He said he did not know how Mr Mills would be if he survived. I accept that Mr Plaha probably did explain to Mrs Mills what had happened (and what he understood to have happened) in these terms, although it seems probable (having regard to Mr Plaha's notes) that he said much of this during their conversation at about 11pm, rather than when he spoke to Mrs Mills again at 1am about the CT scan.
- 74. Mr Plaha had a further discussion with Mrs Mills at about 9.30am and then, again, between about 4 and 4.40pm on 5 December 2012, when he spoke with Mrs Mills, her friend and two family members. I address the evidence regarding the latter discussion in paragraphs 158, 161, 166 and 187 below. Mrs Mills continued to speak to Mr Plaha about Mr Mills' progress almost every day over the course of the following month.

- 75. On 12 December 2012, as a result of raised intracranial pressure, and having obtained Mr Mills' consent, Mr Plaha performed a surgical decompression and debridement of necrotic herniated brain tissue.
- 76. The neuropathology of the tumour was identified in a biopsy report dated 13 December 2012 as a WHO grade 2 oligodendroglioma with an IDH mutation.
- 77. On 27 December 2012, Mr Mills was transferred from the ICU to a general ward. Mr Plaha took a close interest in Mr Mills' progress and helped to arrange his admission, on 23 January 2013, to the Oxford Centre for Enablement, where he underwent intensive rehabilitation.
- 78. On 2 March 2013, Mr Mills had a further operation to insert a left parietal ventricular peritoneal shunt. Mr Mills was initially resistant to having this operation, but consented to it following further discussion. The surgery was, again, performed by Mr Plaha.
- 79. On 3 April 2013, with Mr Plaha's assistance, Mr Mills transferred from the Oxford Centre for Enablement to the Royal Hospital for Neuro Disability in Putney. He was discharged and returned home in December 2013.

F. <u>Clinical Negligence - Issue 1: Was the use of a minimally invasive endoscopically-assisted open craniotomy technique negligent?</u>

(a) The law

80. There was no dispute between the parties with regard to the law applicable to this part of the case. A doctor owes a duty to act with reasonable skill and care in performing an operation. This being a case in which clinical negligence is alleged, the starting point for the correct approach to the assessment of liability is the case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583, in which McNair J gave a direction to the jury at 587 in these terms:

"I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. ... Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view."

81. As Green J put it in *C v North Cumbria University Hospital Trust* [2014] EWHC 61 (QB) at [22]:

"It is therefore insufficient for a Claimant to demonstrate only that there exists a body of competent expert opinion which disagrees with the judgment which was taken upon the facts of the present case. This is no more than a recognition of the fact that in an area where professionals exercise a high degree of technical and medical expertise that there may be a range of different views all of which might quite legitimately be held about the same matter. Accordingly, if there exists a body of competent professional expert opinion which supports the decision as reasonable in the circumstances it matters not that other experts might disagree."

82. As Lord Scarman observed in *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634 at 638E:

"Differences of opinion and practice exist, and will always exist, in the medical as in other professions. There is seldom any one answer exclusive of all others to problems of professional judgment. A court may prefer one body of opinion to the other: but that is no basis for a conclusion of negligence."

83. However, as was made clear by the House of Lords in *Bolitho v City and Hackney Health Authority* [1997] UKHL 46, [1998] AC 232, as it is ultimately the court which has to determine the issue of negligence, it is necessary for the court to be satisfied that the responsible body of medical opinion relied upon by a clinician has a sufficiently logical basis. In *Bolitho*, Lord Browne-Wilkinson expressed the view of the House, explaining at 243A-E:

"...in cases of diagnosis and treatment there are cases where, despite a body of professional opinion sanctioning the defendant's conduct, the defendant can properly be held liable for negligence (I am not here considering questions of disclosure of risk). In my judgment that is because, in some cases, it cannot be demonstrated to the judge's satisfaction that the body of opinion relied upon is reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.

I emphasise that in my view it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgment which a judge would not normally be able to make without expert evidence. As the quotation from Lord Scarman makes clear, it would be wrong to allow such assessment to deteriorate into seeking to persuade the judge to prefer one of two views both of which are capable of being logically supported. It is only where a judge can be satisfied that the body of expert opinion cannot be logically supported at all that such opinion will not provide the benchmark by reference to which the defendant's conduct falls to be assessed."

- 84. I have also had regard to the helpful summary and analysis of the principles and considerations applicable in assessing expert evidence in a case such as this, given by Green J in *C v North Cumbria University Hospital Trust* at [25].
- 85. In the present case, the first question is whether, in choosing to undertake the resection using a minimally invasive endoscopically-assisted open craniotomy technique, Mr Plaha acted in accordance with a practice accepted as proper by his peers in the same speciality.

(b) Mr Plaha

- 86. Mr Plaha undertook his neurosurgical training, as a neurosurgery trainee with a national training number in the South West rotation, from 2005-2010. He learned the basics of neuro-endoscopy with Mr James Palmer, while training at Derriford Hospital in Plymouth, from September 2005 to February 2008. From February 2008 to August 2010, Mr Plaha continued his neurosurgery training at Frenchay Hospital in Bristol, working with Mr Ian Pople, Mr Richard Edwards and Mr Mike Carter. Mr Plaha's evidence was that all three consultants, but especially Mr Pople, have vast experience in neuro-endoscopy and he consolidated his neuro-endoscopy training during this period.
- 87. From September 2010 to August 2011 Mr Plaha was employed by the Trust as an Endoscopy and Pituitary Surgery Fellow. Mr Plaha took this one year fellowship because, given his experience in neuro-endoscopy, he was keen to consolidate it with advanced training with Mr Simon Cudlip. Mr Cudlip has performed the highest number of endoscopic pituitary cases in the UK.
- 88. From September 2011 until August 2013, Mr Plaha was employed by the Trust as a locum Consultant Neurosurgeon and he was also a Skull Base Fellow from 2011 to 2012. Mr Plaha's specialism is neuro-oncology and, alongside Mr Cudlip, he was given the role of leading the neuro-oncology MDT. Mr Plaha has been employed by the Trust in the substantive role of Consultant Neurosurgeon since August 2013.

(c) The standard technique

- 89. In 2012, the standard technique for a resection of a frontal glioma involved performing a craniotomy and using a surgical microscope to visualise the operative field. The tumour would be resected using the CUSA.
- 90. The size of the craniotomy, using the standard technique, would ordinarily be about 4-5 cms. The size would vary to a degree according to the pathology of the tumour (in particular its size and location), but as Mr Mills' tumour was described by Mr Grundy as being of "moderate size" and by Mr Kirkpatrick as "small to moderate", it is likely that a craniotomy performed using the standard technique would have been about 4-5cms in size.
- 91. With the standard technique, the size of the craniotomy would also vary somewhat, as Mr Kirkpatrick put it, "from surgeon to surgeon". Mr Kirkpatrick said when he was operating (and I bear in mind he is not a specialist neuro-oncologist) the size of the craniotomy he would create would be about 6 x 3 or 5 x 3 cms. Mr Cadoux-Hudson gave evidence that the operation had evolved over the years, with image guidance technology enabling surgeons to make smaller craniotomies. Mr Cadoux-Hudson used the standard technique and said the size of the craniotomies he would make had come down to about 3-4cms.
- 92. Using a microscope, only that which is in the neurosurgeon's straight line of sight can be seen. For this reason, the craniotomy must be large enough to give the neurosurgeon direct sight of the operative field, so that the tumour can be resected without damaging other structures.

(d) The endoscopically-assisted technique

- 93. The technique used by Mr Plaha to resect Mr Mills' tumour differed from the standard technique in that it involved (i) using an endoscope rather than a microscope to visualise the operative field and (ii) making a smaller craniotomy. The endoscope was used only to assist with vision. The actual resection of the tumour was performed using the CUSA, in the same way as it would be used with the standard technique.
- 94. This technique involves using a 30 degree endoscope which allows the neurosurgeon to look 30 degrees in any direction, rather than only being able to see in straight lines. The 30 degree angulation of the endoscopic view enables the neurosurgeon to visualise and resect the tumour through a smaller ("minimally invasive") craniotomy, of about 2-2.5cm in size.

(e) Mr Plaha's evidence, series and paper

- 95. Mr Plaha's evidence was that endoscopes have been used in brain surgery for 20-30 years. During his advanced endoscopy fellowship, he had performed around a hundred endoscopy-assisted pituitary cases, with Mr Cudlip. This is an established technique for tumours in the base of the skull, where the anatomy is different, and access to the tumour is via the nostrils rather than a craniotomy.
- 96. Mr Plaha acknowledged that, in 2012, so far as he was aware, no other neurosurgeon in the UK used the minimally invasive endoscopically-assisted technique to resect frontal gliomas. However, there were some other neurosurgeons around the world undertaking endoscopically-assisted resection procedures on such gliomas. In particular, Mr Plaha referred to a paper published in the Journal of Neurosurgery in 2009, by Kassam et al of the University of Pittsburgh, entitled *Completely endoscopic resection of intra-parenchymal brain tumours*, describing the authors' use of this technique in surgery on 21 patients. Mr Plaha discussed this technique with Mr Kassam when he attended an advanced endoscopic skull base course in Pittsburgh, in May 2011.
- 97. In December 2014, Mr Plaha published a paper in World Neurosurgery entitled "Minimally Invasive Endoscopic Resection of Intraparenchymal Brain Tumors". Mr Plaha was the lead author. The other authors included two senior registrars, a research scientist specialising in brain imaging, and Mr Cudlip. The paper reported that in a "21-month period between December 2011 and August 2013, 50 consecutive endoscopic resections of intraparenchymal brain tumors were performed on 48 patients".
- 98. Mr Plaha confirmed in evidence that all of these operations were performed by him, and Mr Mills was the 27th patient in this series of 48. He said, and I accept, that he did not begin the series without telling others within the department. It was done with the knowledge of the MDT and was the subject of open discussion. Mr Cudlip, who was appointed by the Trust to act as Mr Plaha's mentor while he was a locum, said when informing Mr Plaha that Mr Mills' case had been referred to him that Mr Plaha could use the endoscopically-assisted technique.
- 99. The objective of the paper was described in these terms:

"To report a minimally invasive, nontubular endoscopic technique to resent intraparenchymal brain tumours and assess the feasibility, safety, and surgical resection margins achievable by this novel technique." 100. In cross-examination, Mr Plaha explained that the novel aspect of the technique described in the paper was that he used a <u>non-tubular</u> endoscope, whereas Kassam, and others, had used a tubular conduit. I accept that is what Mr Plaha meant in describing the technique as novel in his paper. I also accept that, from the perspective of a medical journal, the application of an endoscopically-assisted technique in the resection of gliomas was not itself entirely novel, given the previous published papers on the topic. What Mr Plaha meant by describing his technique as novel is reflected in his paper, which states:

"Our technique is significantly different from techniques described in previously published series because we do not use a rigid tubular conduit. A tubular conduit maintains the access corridor but exerts constant circumferential pressure on the adjacent, already swollen white matter fascicles in the vicinity of the tumour. ... Our nontubular technique allows one to exert dynamic rather than constant pressure on the surrounding brain tissue, which continues to pulsate freely and maintain adequate perfusion. An access corridor not limited by a conduit increases flexibility and allows better manipulation of surgical instruments."

101. A number of criticisms were made of the description of Mr Mills' case which appears (in anonymised form) in Mr Plaha's paper. Ms Jones submitted the errors were evidence of Mr Plaha underplaying the risks, in his enthusiasm for the technique; and so supporting her case that Mr Mills had been persuaded into surgery using the endoscopically-assisted technique without anything approaching a full description of the risk. Accordingly, I have addressed those criticisms in the context of the informed consent part of the case: see paragraphs 167-173 below. Although I have found that there were some factual errors and omissions in the description of Mr Mills' case in the paper, I do not consider that this has any impact on this part of the case or my overall assessment of Mr Plaha, who I found to be an honest and reliable witness. It was clear that he was distressed by what had happened to Mr Mills and has reflected deeply on what went wrong on this occasion.

102. Mr Plaha's evidence was that:

"The advantage of using an endoscope is that it allows me to operate through a standard mini-craniotomy, a relatively smaller opening in the skull, rather than having to perform a full craniotomy — cutting and removing a larger section of bone. This is preferable both cosmetically and in facilitating a reduced recovery time given the less invasive approach. There is inherent morbidity associated with a larger incision but each neurosurgeon will have his preferred extent of access and technique.

The alternative to using an endoscope would have been to use a surgical microscope combined with a more extensive craniotomy. The advantage of this option is that a microscope produces a stereo or three dimensional image whereas an endoscope, which only has one lens, necessarily produces a mono, two dimensional image but like the microscope this is a HD (high definition) image and has a better illumination than the microscope. However, with advanced endoscopy training experience, the difference in quality of visualisation between these approaches is, in practice, not relevant to an experienced and trained endoscopic surgeon. It would be similar to the choice between a telescope and binoculars; both

enable you to have a clear view of the object that you want to see but the way your brain receives the image is different and the object itself does not change."

103. The difference between the 3D image produced by a stereoscopic microscope and the 2D image obtained by an endoscope was also addressed in Mr Plaha's paper:

"The substantially enhanced illumination from the divergent endoscopic light source, the proprioceptive feedback during bimanual resection, and the dynamic movement of the endoscope compensate for the loss of binocular visions. As suggested by Kassam et al, with experience, one develops a 3D perception relying on tactile feedback."

104. Mr Plaha explained that he has undertaken about 175 to 180 operations using this technique, with a low complication rate (there having been no complications before or since Mr Mills' case) and published two further peer-reviewed papers demonstrating that it is a safe technique. However, I bear in mind that I have to address the position as it was in 2012.

(f) The expert evidence regarding the endoscopically-assisted technique

- 105. It is clear, as Mr Kirkpatrick and Mr Grundy agreed, that the use of a minimally invasive endoscopically-assisted technique in the resection of gliomas was "still in its evolution and not well established". It was "not an approach that as yet was used by many neurosurgeons other than [Mr Plaha]".
- 106. Mr Kirkpatrick's view was that "the use of endoscopically-assisted resection by means of such a small craniotomy does not ... meet the criteria for safe resection as it would be very difficult if not impossible to control vessels, aberrant or not, which lie outside the direct scope of vision, i.e., the direct line of sight". The joint report records:

"Mr Kirkpatrick has great difficulty in understanding how this technique can afford any gain whatsoever. He feels that the technique would only increase the operative risk over and above the standard surgical method. ... He did not feel it was a reasonable approach to what traditionally is a very simple operation easily achievable in 1 to 2 hours. His concerns have been voiced by others in the literature (see commentary on Plaha's publication: Is there a place for endoscopy in glioma surgery; Duffau. World Surgery 2014; 82: 1020-1022) where the high complication rate arising from Plaha's series is discussed, and the cited claims in favour of the endoscopy method challenged."

107. Mr Grundy considered, although it is not a technique he himself uses, that it was "a reasonable thing to do" (subject to his concern that the patient should be properly informed). In his report, he said,

"I was unable to identify any good evidence to suggest that an endoscopic-assisted technique would have a higher risk than any other form of glioma resection, such as an operation assisted by an operating microscope or with the use of surgical loupes or indeed with the naked eye. ...

There are different surgical techniques, each of which have pros and cons. ... Indeed, a surgeon with perhaps the most extensive experience of operating on low-grade gliomas in the world, Professor Hugues Duffau, in Montpelier, France ...

has published extensively on his surgical series, with incredibly low rate of morbidity and he uses no form of additional magnification or illumination whatsoever....

...a proposal to remove a tumour such as this through a smaller craniotomy, at the hairline and using an operative microscope and endoscope-assistance in the hands of an experienced endoscopic surgeon, would seem reasonable to me. Furthermore, endoscopic surgery has now become commonplace (standard practice) for many other brain tumours, particularly those affecting the base of the skull and those within the ventricles."

- 108. Both experts agreed that for "all endoscopic methods throughout the body, if complications occur, such as bleeding, they are significantly more difficult to control and this may result in the need to extend the opening. ... In the case of cranial surgery, increasing exposure does delay ultimate control of the bleed quite considerably leading to complications of brain swelling with poorer access to the culprit vessels even when exposure is now appropriate".
- 109. Mr Kirkpatrick was dismissive of the cosmetic advantage of having a smaller craniotomy. His view was that "for operations involving the cranium, the vast majority of patients declare little regard for the size of the incision as they are far more preoccupied with a) the outcome following such a procedure, and b) the pathological diagnosis". Whereas Mr Grundy, while acknowledging that the most important consideration for patients would be the outcome, said that he was regularly asked about cosmesis and that it was often a concern for patients. He observed that "many patients now ask if it is possible to have 'keyhole' surgery having heard of the potential benefits". Mr Grundy's view accorded with Mr Plaha's evidence that cosmesis "does matter to patients" and with Mr Cadoux-Hudson's view that the evolution of smaller craniotomies, with the introduction of image guidance systems, had come with advantages for the patient (as well as challenges for the surgeon).
- 110. Mr Grundy also felt that a smaller craniotomy "may have gained a patient some reduction in morbidity over the short term" (a point that Mr Plaha also made, explaining that it causes less swelling around the ears), although he agreed that the benefits were not currently clearly established.

(g) Conclusion on Issue 1

- 111. In my judgment, the claim that Mr Plaha acted negligently in using a minimally invasive endoscopically-assisted open craniotomy technique to resect Mr Mills' tumour fails for the reasons I set out below.
- 112. First, I attach substantial weight to the opinion of Mr Grundy that this was a reasonable technique to adopt. I have no reservations about Mr Grundy's expertise or his impartiality. His expertise as a neuro-oncologist was readily apparent. His practice is dedicated entirely to patients who have brain tumours. He was not an experienced expert witness; giving evidence as an expert was a novel experience for him. His evidence was measured and came across as non-partisan. From the outset, and throughout his evidence, where he considered that there had been any breach of duty, he said so. It was clear that if he had taken the view it was not reasonable to use this technique he would have said so.

- 113. I find that Mr Grundy's opinion reflects a responsible, competent and respectable body of expert opinion. That is so even if Mr Kirkpatrick's condemnation of the technique as negligent represents another body of appropriate opinion.
- 114. Secondly, I consider that the reasonableness of using the technique falls to be judged by reference to the views of Mr Plaha's peers in neuro-oncological neurosurgery.
- 115. Mr de Bono challenged Mr Kirkpatrick's expertise on the basis that he is not a neurooncologist. In June 2006, the National Institute for Health and Clinical Excellence (NICE) gave guidance, entitled Improving Outcomes for People with Brain and Other CNS Tumours. The guidance set out the requirements for core membership of the neuroscience brain and other CNS tumours MDT. It involved a reorganisation to ensure that services were provided by specialists. Neurosurgeons on such MDTs were expected to fulfil this definition: "A specialist neurosurgeon who spends at least 50% of his or her clinical programmed activities in neuro-oncological surgery and is regularly involved in dedicated specialty clinics caring for these patients." Mr Kirkpatrick is not a neuro-oncologist and he does not fulfil this definition. He accepted in cross-examination, when published literature was put to him, that the reorganisation at Addenbrooke's Hospital, where he is a Consultant Neurosurgeon, was completed in 2007-2008, although he had earlier in his evidence sought to suggest the reorganisation occurred later. Mr Kirkpatrick acknowledged that he does not engage in any current education or learning in respect of neuro-oncology, beyond attending MDT meetings from time to time, and he has never attended a neuro-oncology scientific meeting.
- 116. In determining whether the technique adopted was itself a negligent act, I accept Mr de Bono's submission that it is significant that Mr Kirkpatrick is not a neuro-oncologist. Although Mr Kirkpatrick has considerable experience of removing low-grade gliomas, for more than a decade this has been a specialist field. Given the specialisation that occurred following the publication of the NICE 2006 guidance, in my judgment, the question is whether, in using a minimally invasive endoscopically-assisted open craniotomy resection technique, Mr Plaha acted in accordance with a practice accepted as proper by his peers in neuro-oncological neurosurgery.
- 117. I note that although Dr Rees is a neuro-oncologist, he is not a neurosurgeon and he did not seek to give an opinion on this aspect of the case.
- 118. Thirdly, it is clear that the Trust's MDT, which was attended by six neurosurgeons when Mr Mills' case was discussed, were aware of the technique that Mr Plaha was using. It is apparent that they, and particularly Mr Cudlip who was Mr Plaha's mentor and one of the authors of the paper, regarded it as reasonable to use this technique in Mr Mills' case.
- 119. Fourthly, the use of an endoscope in performing such resections had been discussed in reputable medical journals by neuro-oncologists based abroad, and Mr Plaha's paper covering his series of 48 patients was itself published in a reputable medical journal.
- 120. Mr Kirkpatrick referred to a commentary on Mr Plaha's paper, by Professor Duffau, in support of his view that the technique was not reasonable. In his commentary, Professor Duffau wrote:

"In this issue of WORLD NEUROSURGERY, Plaha et al, (18) report a series with 50 consecutive fully endoscopic intraparenchymal tumor resections — most of them being a glioma. More than 95% resection was performed in 70% of patients with total resection in 48% of cases. The investigators conclude that minimally invasive endoscopic resection is technically feasible and allows the achievement of good tumour removal. They have to be congratulated for their favorable results. It is important to add new tools to the armamentarium against gliomas. However, a few issues should be extensively discussed before to claim that endoscopy has some advantages versus a traditional technique."

- 121. Although Professor Duffau's commentary is cautious and somewhat critical, as is apparent from the passage cited above, it does not give the impression that Professor Duffau was suggesting this was a negligent technique to use. I also bear in mind Mr Grundy's evidence that "Professor Duffau's results are amongst the best ever reported in neurosurgery", although he does not use any visual aid, and "Professor Duffau is critical of every other neurosurgeon in the rest of the world!"
- 122. Another commentary on Mr Plaha's paper was published in World Surgery in February 2015: The Endoscopic Technique for Removal of Intraparenchymal Lesions: A Smooth Passage in Between Brain Fascicles, Luigi M. Cavallo, Domenico Solari, Paolo Cappabianca. The authors, who are based in the Department of Neurological Sciences in Naples, describe Mr Plaha's technique as "very innovative because it creates a corridor that does not require any conduit. On one hand, this technique raises major concerns in regard to the possible injuries caused by the maneuvers to create the corridor. On the other hand, the technical advancement is praiseworthy because the technique appears favorable in terms of maneuvrability and tumor angle of attack". Cavallo et al noted that "endoscopic visualization, especially in the case of deep-seated tumors, may be superior to microscopic visualization because the endoscope, with its inverted cone of light, allows a closer, wider, and orientable view of the lesion, supported by unrestricted illumination"; and they expressed the "hope that the advent of new techniques and multiple or combined treatments will result in significant improvement of surgical outcomes and ultimately longer patient survival and better quality of life." This commentary is broadly positive about the development of this technique.

G. <u>Clinical Negligence - Issue 2: Did Mr Plaha stray into the midline structures and transect a vessel there?</u>

(a) The law

123. The law applicable to this issue is the same as for issue 1: see paragraphs 80-85 above. However, issue 2 raises a factual question. There is no dispute that if Mr Plaha strayed into the midline structures and transected a vessel there, then the operation was performed negligently.

(b) The factual evidence

- 124. I have referred to the contemporaneous accounts that Mr Plaha gave of what appeared to have happened in paragraph 69 above.
- 125. Mr Plaha said in evidence that "this is a case which has happened only once... It is not one I have forgotten. I can distinctly recollect what happened in the operating theatre". He said:

"I did not cross the midline to the right side of the brain at any point during my surgery to access the tumour as my approach was along the superior frontal gyrus down to the anterior cranial fossa floor as set out in my operation note, ie to approach the tumour from the direction of the patient's forehead towards the tumour. If I had crossed the midline, my neurosurgical colleagues would have been aware of this when they came in to assist me when surgical complications arose. Also, by this stage of the operation I had got confirmation from the neuropathologist that the sample of brain I had sent them was in fact tumour which was on the left side of the brain, indicating that I had performed the correct trajectory to reach the tumour.

...

Around two hours into the operation, and whilst using the CUSA to debulk the tumour, I encountered bleeding from the medial part (middle) of the tumour. ... Having reflected on the reason for the continual bleeding, I can only surmise that there was a blood vessel going through the middle of the tumour itself, something which could not have been identified in advance as it was not visible. I reach this conclusion owing to the source of the bleeding appearing to be the tumour itself. If I had somehow 'nicked' a blood vessel before getting to the tumour, the bleeding would have started earlier, not midway through the debulking part of the surgery.

. . .

I was unable to visual the bleeding blood vessel precisely. I suspected that it may have retracted deeper into the brain as blood vessels can do as they are elastic."

- 126. Mr Plaha said that when Mr Cadoux-Hudson attended and could not identify any source for the bleed, they "discussed whether the bleeding was from deep in the brain from major blood vessels (called the anterior cerebral artery complex) close to the midline which may have retracted but Mr Cadoux Hudson felt given the area of the brain covering this region looked fine it was probably not likely and therefore to remove normal brain to inspect this area was not required".
- 127. Mr Plaha's evidence is that later on, after Mr Griffiths had joined him, extended the craniotomy to give space to the swelling brain, explored the surgical cavity, re-packed the area and, following a haemostatic break, found there was further bleeding,
 - "...Mr Griffiths felt we should explore the deep blood vessels in the midline brain (the anterior cerebral artery complex) given the repeated bleeding. The brain covering these deep blood vessels is called the gyrus rectus. This was intact and another indicator that the midline of the brain had not been breached during the initial part of the operation when I was approaching the tumour. Mr Griffiths removed the gyrus rectus and we saw the anterior cerebral artery complex...

Mr Griffiths was able to visualise the retracted stump of a branch of the left frontopolar artery (this artery originates from the anterior cerebral artery complex) which was bleeding."

128. Mr Plaha suggested three possibilities for the cause of the stroke: (i) chemical agents such as floseal may have been absorbed into the retracted bleeding stump of the blood vessel and clotted the pericallosal artery; (ii) the artery may have gone into spasm, narrowing the calibre of the vessel so that not enough blood was able to pass through; or (iii) pressure being applied on and off to the artery.

- 129. In cross-examination, Mr Plaha maintained that if the vessel had been injured where it was subsequently found then that area of the brain would have been visibly damaged.
- 130. Mr Cadoux-Hudson was clear in both his written and oral evidence that he could find "no evidence that the midline structures had been transgressed". He visualised the interhemispheric fissure and its blood vessels, using the theatre stereoscopic microscope. At this stage there was no evidence of active bleeding and he "could see that there was no visible or obvious puncturing of the midline or evidence of midline haemorrhage".
- 131. Similarly, Mr Griffiths could recall "nothing to suggest that he had crossed the midline", describing it as "new territory we were exploring". When asked about a diagram showing the vessels of the brain, Mr Griffiths emphasised that it was a generic diagram and there is "huge variation in vascular anatomy in individual patients".

(c) The expert evidence

132. In his January 2019 report, Mr Kirkpatrick wrote:

"Having reviewed the original pre-operative MRI scans, I have estimated that the pericallosal origins in the region of the anterior communicating artery, are approximately 3 cms away from the deepest portion of the tumour. It is difficult to envisage that this vessel has been damaged by means of tumour debulk within the anatomical confines of the tumour as displayed on the MRI scan. In other words, the plane of dissection was likely to have been significantly outside the anatomical confines of the tumour.

...

As an individual dealing with vascular pathology on a day-to-day basis, the overwhelming likelihood of Mr Mills' anterior cerebral territory infarcts was a consequence of direct manipulation of those vessels, or high pressure caused by the haematoma secondary to the bleed, the secondary swelling within the frontal lobes which required salvage surgery, and the direct attempts to abate the frontopolar artery. It would be physiologically impossible for Flowseal or any other agents to migrate their way into the pericallosal as suggested by Mr Plaha in his witness statement, but I do accept the possibility of vascular spasm and the influence of mechanical distortion of the left pericallosal artery during the attempts to stop it bleeding. According to the witness statements, the pericallosal arteries were not involved in the salvage surgery, and the midline was not transgressed. If the Court accept this to have been the case, the only explanation for infarcts affecting that territory would have been indirect pressure to the pericallosal arteries caused by the haematoma and subsequent brain swelling. On balance, this would have been avoided with timely control of the avulsed fronto-polar artery."

133. In their joint report, Mr Kirkpatrick and Mr Grundy were asked to "discuss and agree or disagree whether or not Mr Plaha probably 'migrated' in the way suggested [in para 19(h) of the Particulars of Claim] and whether if he did so this was negligent". In response they wrote:

"The experts had considerable difficulty understanding the exact mechanism. Their discussions are of course speculative. We both agreed that the descriptions would be in keeping with a branch coming off the pericallosal artery which is in the midline. The description with Mr Griffiths' involvement is that the avulsed fronto-

polar branch must have originated from the pericallosal artery very close to the anterior communicating complex where the hole in the side of the pericallosal artery was found. This was a considerable distance away from the posterior limits of the tumour. The experts had difficulty in envisaging this happening if the dissection remained within the confines of the tumour but Mr Grundy felt it possibly resulted from damaging a branch in a sulcus within or at the margins of the tumour."

- 134. In his oral evidence Mr Kirkpatrick said that the stump was 3-4cms from the deepest confines of the tumour. In this context, that meant it was "an artery which was very far away from the deepest aspect of the tumour". Mr Kirkpatrick's evidence was that a vessel "may regress a millimetre or two", but it is not so elastic that it could retract 3cms. He also explained that the vessels remain in place because they are "plastered down with arachnoid membrane". When he was re-called following Mr Grundy's evidence, Mr Kirkpatrick agreed that it is possible to see evidence of branches being pushed aside, but he said it is not possible for an artery to be pushed down the length of its valley because of the tethering mechanisms.
- 135. Mr Kirkpatrick suggested that Mr Plaha's angle of attack was correct but that he had made "a very significant error of depth perception". In answer to the question whether, if Mr Plaha had been using the CUSA 3cms away from the deepest part of the tumour, he would have expected the brain matter in that area to have been damaged, Mr Kirkpatrick said that it is "difficult to find where your track has been when the brain starts to swell".
- 136. In his oral evidence, Mr Grundy said that it is possible to become disorientated, but "to become this disorientated seems to me to be completely implausible". His evidence was that the "angle of approach was tangential" and, using Brainlab navigation, which can be used repeatedly during surgery, "we know he headed in the right direction"; "we know he reached the tumour". He said that it is well established that an experienced endoscopy surgeon is used to interpreting images on a screen, including depth, and Mr Plaha also had the benefit of the navigation system.
- 137. Mr Grundy explained that the CUSA is used to remove brain and tissue, which it shatters and sucks away. It can injure blood vessels, but "what is injured most easily is the brain tissue". Whilst appreciating that there was swelling, Mr Grundy said that he struggled with the concept of there being no evidence of the pathway. "If he had gone there, it would to my mind have left some evidence." Mr Grundy explained that the CUSA would not create a narrow channel that might not be visible once the brain swelled because it is not used by working in a channel: the CUSA is used in a circular motion.
- 138. Mr Grundy considered that all the explanations of what had happened were "speculative". He thought movement of the vessel, perhaps as a result of the considerable time that had been spent packing the site in order to try to gain haemostasis, was the more likely possibility. He accepted that movement of a vessel over this distance seemed "particularly unusual". His view was that "both theories are imperfect and difficult to understand". Mr Grundy agreed that "parts of the vessel are tethered down, but parts are more mobile depending on the branching pattern".

(d) Conclusion on Issue 2

- 139. In view of the considerable uncertainty about precisely how Mr Mills' brain injury occurred, I have not found this part of the case easy. Nevertheless, I have reached the clear view that Mr Mills has not proved, on the balance of probabilities, that Mr Plaha migrated into the midline structures. I conclude that the stroke was caused indirectly by the haemorrhage and the pressure applied to bring it under control. Accordingly, this aspect of the negligence claim fails. My reasons for reaching this conclusion are these.
- 140. First, both Mr Cadoux-Hudson and Mr Griffiths gave compelling evidence, which I accept, that they saw no evidence that Mr Plaha had crossed the midline structures. They are both very experienced Consultant Neurosurgeons who were trying to discover the source of the bleeding. It is clear that if there had been any visible damage to the midline structures, they would have seen it. In particular, Mr Cadoux-Hudson gave clear evidence that, having extended the craniotomy, and using the theatre stereoscopic microscope, he visualised the interhemispheric fissure and its blood vessels.
- Secondly, I consider it highly likely that there would have been visible damage if Mr 141. Plaha had crossed the midline structures. In reaching this view, I accept Mr Grundy's evidence about the way in which the CUSA is used. I found his view that, if Mr Plaha had transgressed that would have been evident, cogent and persuasive. Although I consider that Mr Kirkpatrick was expressing his genuine and firmly held view as to how the damage occurred, in general, and this is one example, I found that Mr Kirkpatrick was less willing to acknowledge the difficulties with his theory than Mr Grundy. I accept that the swelling of the brain could have some effect on the ability to visualise what had occurred, but if Mr Plaha had been using the CUSA at such a distance from the tumour, that area would not have appeared to be fine and untouched to the three neurosurgeons involved. It is particularly likely that Mr Cadoux-Hudson would have seen any such damage as he was involved shortly after the bleeding began, before it became necessary to extend the craniotomy to relieve the pressure caused by the brain swelling, and he was able to view the tumour site and surrounding structures at a point when there was no active bleeding.
- 142. Thirdly, it is clear that Mr Plaha was operating in the correct area because (i) the brain matter he sent to be biopsied at the outset of the procedure was found to be tumorous; and (ii) the scans taken after the operation showed that Mr Plaha had resected the tumour.
- 143. Fourthly, I accept Mr Plaha's evidence, which is reflected in the contemporaneous notes, that the bleeding began when he was debulking and appeared to be coming from the middle of the tumour.
- 144. Fifthly, it appears probable (having regard to the evidence of Mr Grundy and Mr Plaha) that Mr Plaha's trajectory was such that if he was on course (as the biopsy and evidence that he resected the tumour demonstrates was the case) then even if he had gone too deep he would not have been in line to transgress the midline structures.
- 145. Sixthly, it was readily apparent that both Mr Grundy and Mr Kirkpatrick found it hard to understand how, not least using Brainlab guidance, any surgeon could have been so very lost. This is a lesser point than those I have referred to above because it is, of course, *possible* that Mr Plaha did become as disorientated as Mr Kirkpatrick's theory would suggest, and I bear in mind that Mr Plaha was still a locum consultant in 2012. Nevertheless, I found Mr Grundy's view compelling as to the implausibility of a

surgeon becoming so very disorientated, particularly with the navigational guidance Mr Plaha was using, and bearing in mind that he was obviously in the right place for the purpose of biopsying and resecting the tumour.

- 146. Seventhly, against all of these points, I recognise that the transected vessel was found about 3cms from the deepest part of the tumour and Mr Kirkpatrick, whose expertise as a neurovascular specialist is not in any doubt, did not find it credible that a vessel would have retracted 3cms down its valley. Mr Grundy also made clear that this would be very unusual and was not something he had seen happen.
- 147. Nevertheless, Mr Grundy considered it more plausible, given the matters I have referred to above, that the vessel had moved than that Mr Plaha migrated into the midline structures. It is also significant that in his report (although not in his oral evidence), Mr Kirkpatrick recognised that indirect pressure was the possible and plausible explanation, if the court accepted the evidence of the witnesses as I have that the pericallosal arteries were not involved in the salvage surgery, and the midline had not been transgressed. Mr Griffiths' evidence that there is "huge variation in vascular anatomy" was not disputed and I accept Mr Grundy's evidence that although parts of the vessel are tethered down, parts of the vessel may be more mobile depending on the branching pattern. It is apparent that in an attempt to control the bleeding the tumour site was packed repeatedly, and so subject to pressure, over a period of about four hours, and such pressure could cause movement of the vessels.
- 148. In Thefaut v Johnston [2017] EWHC 497 (QB), Green J observed at [7]:

"Liability in cases such as this depends upon the Court being satisfied on a balance of probabilities that the defendant fell below the requisite standard and that the negligence was causative of the damage sustained. In the overwhelming preponderance of cases the facts involve a number of singular events which enable the Court with confidence to come to a clear conclusion about causation and breach of duty. However, if the evidence is equivocal, uncertain or inadequate or leaves too many loose ends, then it is no part of the judicial function to decide a case upon the basis of a hunch, educated guess or gut feel. In such cases the only correct result is that the Claimant has not proven the case to the required standard and the claim necessarily fails."

149. The theories as to what occurred put forward by both parties' experts had their difficulties, as Mr Grundy readily acknowledged, and it was, as they both agreed in their joint report, difficult to understand the exact mechanism. Even so, in my judgment, for the reasons I have given, it is clear that the Claimant has not proved that Mr Plaha performed the surgery negligently and this aspect of the claim fails.

H. <u>Informed Consent - Issues 3 and 4: The Law</u>

150. The test to be applied in determining whether Mr Plaha negligently failed to obtain Mr Mills' informed consent to the procedure is not the *Bolam* test. It is the test laid down by the Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] AC 1430. In a judgment endorsed by all members of the Court, Lord Kerr and Lord Reed said at [87]:

"The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in <u>Sidaway</u> by Lord Scarman, and by Lord Woolf MR in <u>Pearce</u>, subject to the refinement made by the High Court of Australia in <u>Rogers v Whitaker</u>, which we have discussed at paras 77-73. An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

- 151. The Supreme Court's discussion: of Lord Scarman's approach in *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871 is at [43]-[49]; of Lord Woolf's approach in *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P53 is at [64]-[66]; and of the High Court of Australia's refinement in *Rogers v Whitaker* 175 CLR 479 is at [71]-[73].
- 152. The duty is subject to a proviso expressed in [88]. It is what is referred to in [91] of *Montgomery* (quoted below) as "the therapeutic exception". I do not set it out as it is common ground that it was not applicable in this case.
- 153. Lord Kerr and Lord Reed continued:
 - "89. Three further points should be made. First, it follows from this approach that the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.
 - 90. Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.
 - 91. Thirdly, it is important that the therapeutic exception should not be abused. It is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests."

154. Alongside the references in [90] to "dialogue" and the provision of "comprehensible information", the Trust also emphasised these observations at [85]:

"A person can of course decide that she does not wish to be informed of risks of injury (just as a person may choose to ignore the information leaflet enclosed with her medicine); and a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter."

I. <u>Informed Consent - Issue 3: Advice regarding the three alternative treatment options</u>

(a) The allegations

- 155. There is no dispute that Mr Plaha's duty encompassed advising Mr Mills during the consultation on 8 November 2012 that there were three treatment options available to him, namely (i) surveillance, (ii) biopsy and (iii) resection, and of the risks and benefits of each option. The issue is a factual question whether he did so. In particular, did Mr Plaha advise that surveillance in the form of a "wait and watch" plan, with a repeat scan in three/six months, was an option?
- 156. More broadly, Mr Mills contends that the pre-operative advice given by Mr Plaha was negligent in these respects:
 - i) Mr Plaha should have advised that this was a low-grade tumour that would probably in time become symptomatic but on the basis of a single scan it was impossible to know how long it had been there and how quickly it would grow.
 - ii) Mr Plaha should have advised that the management of low-grade asymptomatic glioma was a matter of controversy; the prevailing practice in the UK would be to offer surveillance in the first instance and that proceeding straight to surgical resection would be regarded by the majority of UK neurosurgeons at the time as at the more aggressive end of the spectrum of management options. Deciding to opt for an en bloc resection was reasonable only if all the options had been discussed and a good reason demonstrated for not preferring the less invasive options namely surveillance or biopsy.
 - iii) Mr Plaha should have advised that it was unlikely the glioma was the cause of Mr Mills' headaches and that they were much more likely to be associated with hypertension.
- 157. In respect of the latter allegations, there is a dispute both as to what advice should have been given and with regard to what advice was given.

(b) The contemporaneous documentary evidence

- 158. Four contemporaneous documents provide evidence of the discussion on 8 November 2012:
 - i) Mr Plaha's manuscript clinical note of the consultation on 8 November 2012 records the diagnosis as a left frontal likely low-grade glioma. Mr Plaha noted that Mr Mills and his wife attended, and Anne May (a specialist nurse) was present. His note records "Scans shown". Then he wrote "Options" with arrows leading to three identified options, namely, "Imaging surveillance", "Biopsy"

and " S_x [i.e. surgical] *Debulking*". The note continues "*Risks / Benefits of each discussed*"; "*Pt keen on debulking*". From this last statement Mr Plaha drew two arrows, one led to the words "*Name on Waiting list*" and the other to "*Risks discussed* \rightarrow *detailed in letter*".

- ii) Mr Plaha sent a letter to Mr Mills' GP, copied to Mr Mills, on the day of the consultation, explaining what he had discussed with Mr and Mrs Mills. I have set out the contents of this letter in paragraph 48 above.
- iii) On 3 December 2012, a little less than a month after the consultation, Mr Plaha had a further discussion with Mr Mills in the John Radcliffe Hospital on the evening before the operation. Mr Plaha recorded in a manuscript note their discussion on 3 December. I have described the contents of this note in paragraph 53 above. Although this note focuses on the discussion on 3 December, not 8 November, it is relevant because it describes the three treatment options as having been "*Rediscussed*".
- iv) Finally, Mr Plaha's note of his discussion with Mrs Mills, Mr Mills' mother and sister, and Mrs Mills' friend, on the afternoon of 5 December 2012 describes a conversation the day after the operation about the advice and information Mr Plaha had given Mr and Mrs Mills in consultation the previous month. Mr Plaha's note records, amongst other matters that they "Re-discussed need for operation. Mrs Mills remembered and agreed the discussion we had in clinic regarding treatment options". The options are noted as "Conservative", "Biopsy" and "Surgery". The note continues, "Explained material history of gliomas (Grade 1-4)"; "Explained risks of craniotomy for tumour 2-3% stroke / disability".

(c) Mrs Mills' evidence

159. Mrs Mills gave the following evidence regarding the consultation on 8 November 2012:

"Mr Plaha discussed the results of the scan with us. He advised that a tumour had been found in the front of Adrian's brain. He explained that it was a slow growing tumour and had probably been growing for a couple of years. Mr Plaha asked if Adrian had suffered any seizures or blackouts. We both confirmed that he had not. Mr Plaha seemed surprised that Adrian had not experienced any seizures or blackouts and said that due to the location of the tumour he thought that Adrian would have been experiencing seizures and/or blackouts.

Mr Plaha brought up the scan results on his computer and pointed to the scan to show Adrian and I the location of the tumour. He explained that the tumour was in the frontal lobe and said that the location of the tumour meant that it needed to be removed.

Adrian and I were both extremely concerned that the tumour was cancerous. We asked Mr Plaha if the tumour was cancerous. Mr Plaha said that he would not know if it was cancerous until a biopsy had been taken. I recall Adrian saying that he would like a biopsy to be taken. Mr Plaha said that a biopsy could be undertaken to ascertain whether the tumour was cancerous but he said words to the effect that the tumour would still have to be removed at a later date regardless of whether it

was cancerous or not so he might as well remove the tumour at the same time as taking a biopsy.

At no point did Mr Plaha offer surveillance. There was no suggestion at all that we could simply watch and wait. My impression was that the tumour must be removed and a resection was necessary.

Adrian was not given any option regarding surgery. I recall that Mr Plaha discussed the debulking procedure with us and told us that an endoscope would be used. Not being medically aware neither of us knew what an endoscope was. Mr Plaha explained that he would open up the front part of Adrian's skull to remove the tumour.

Mr Plaha did not tell us that there were different ways to perform the surgery nor did he say anything about the surgical technique being new, novel or exploratory in nature. Adrian was not given any option about how he would like the surgery performed. He was simply told how it would be done. Mr Plaha told us that the tumour was accessible because it was at the front of the brain. He said the surgery was straightforward and should only take two hours. He told us that Adrian would be in recovery for 4 to 5 hours after the surgery because the surgery would be performed under general anaesthetic.

Adrian asked Mr Plaha how long he would be off work. Mr Plaha said that he would be off for no more than 6 to 8 weeks. I recall that he advised Adrian not to drive for a period of time after the surgery.

Mr Plaha mentioned risks. He said that there is always a risk with any kind of surgery but I remember him saying because of the location of the tumour, it was easily accessible and so the risks were low."

- 160. Giving oral evidence, Mrs Mills was taken to the contemporaneous documents I have referred to in paragraph 158 above. Mrs Mills maintained that during the consultation on 8 November there was "no talk about surveillance. Definitely not". She could not recall whether a nurse had been in the consultation room, whether Mr Plaha had used the word "glioma" or whether he had referred to it as "low-grade". Mrs Mills agreed that her husband's biggest concern was whether the tumour was cancerous. She agreed it was fair to say that for her and her husband surveillance was not an option because it would not have answered the question whether the tumour was cancerous, which was what Mr Mills was most concerned about. Mrs Mills recalled that Mr Plaha had "talked about risks", but said that "apart from biopsy, it was just the one option". Mrs Mills recalled that Mr Plaha had put the risks as being 1-2%.
- 161. Regarding the discussion at the John Radcliffe Hospital on the afternoon of 5 December 2012, Mrs Mills recalled that on the evening of 4 December, after her telephone call with the hospital at about 9pm (see paragraph 67 above), she called Mr Mills' mother and sister (as well as her friend Rachael) to make them aware that there was a problem. Mrs Mills described going to the ICU at about midnight with Rachael, whilst Mr Mills' mother and sister were outside the ICU. Mrs Mills said that when she came out of the ICU, Mr Mills' mother and sister were in a discussion with Mr Plaha which she and Rachael joined. Mrs Mills said that Mr Mills' mother and sister were "not happy with

how the operation went". Mr Plaha "made a point that Adrian signed a consent form", while Mrs Mills "thought what does this have to do with anything right now".

(d) Mr Plaha's evidence

162. Mr Plaha gave the following evidence:

"I met Mr and Mrs Mills in my outpatient clinic on 8 November 2012, together with neuro-oncology nurse Anne May. My out-patient appointments for new patients are 45 minutes long. ... I explained the nature and prognosis of gliomas. I then outlined three alternative management solutions, namely:

1 A conservative approach combined with regular imaging surveillance;

2 A biopsy;

3 Craniotomy and endoscopically assisted resection (also referred to as 'debulking') of the tumour.

I outlined the risks and benefits of each option in some detail. Mr Mills said that he was keen on debulking. I was careful to explain the risks.

I recommended proceeding with craniotomy and endoscopically assisted resection, but explained that it was a procedure which carried significant risks... [Mr Plaha then specified the same list of risks as recorded in his letter to Mr Mills' GP]

I explained to Mr Mills that the alternative to surgery was surveillance. Mr Mills was keen to proceed with surgery as I had recommended and I recorded this in my clinic letter and notes.

When discussing the proposed surgery I focussed on what I considered to be the key issues. Specifically, I explained that there was a choice of surveillance or surgery. I explained the natural history of the tumour and MDT discussions. As is my practice, I explained what the surgery would involve and explained the risks of surgery. I was content that Mr Mills appreciated the risks of the surgery and was nonetheless happy to proceed. With Mr Mills, as with most other patients, I did not go into the technical detail of how the procedure is performed apart from broadly explaining the basic relevant steps of surgery. So for example, I did not explain to him that I used an endoscope for vision and that this was a technique that some surgeons used but that there would be other surgeons who would not use the endoscope."

- 163. On 8 November 2012, Mr Plaha offered Mr Mills a pre-operative assessment and consultation with a Neuropsychologist, which Mr Mills declined.
- 164. Mr Plaha referred to seeing Mr Mills on the evening before surgery and said: "As is my unvarying practice, I was careful to discuss the treatment options with Mr Mills again together with the risks and benefits of each".
- 165. In cross-examination, Mr Plaha's evidence was that he has an independent recollection of the consultation on 8 November 2012. Mr Plaha maintained that he discussed all three treatment options. He said that he explained that a biopsy would not take the tumour out; if Mr Mills opted for a biopsy, he would then go under surveillance and

wait. If it was necessary to take the tumour out that would involve a second operation. Mr Plaha said he would never recommend that a patient should have an operation just because a biopsy was being done. Mr Plaha said that when explaining the natural history he always explains that a grade 2 always becomes a grade 3 or 4; and he always explains the three options, namely, surveillance, biopsy and surgery. Mr Plaha said that he explained there is a variation in practice, that was why the three options were discussed, and he explained that some surgeons will operate early. He said that he did not say that Mr Mills' symptoms were not attributable to the tumour but nor did he suggest they were.

166. In relation to the conversation on the afternoon of 5 December 2012, Mr Plaha said that he would not voluntarily have started talking about the past at that point. The discussion arose because he was being questioned by members of Mr Mills' family. They were shocked by what had happened. He said it was only reasonable for them to question him about why the operation had taken place and he had been responding to those questions. He denied that his note was covering for the possibility that someone might subsequently challenge the advice he had given.

(e) Errors in Mr Plaha's paper

- 167. As I noted in paragraph 101 above, Ms Jones relied on errors in Mr Plaha's 2014 paper as evidence of Mr Plaha underplaying the risks. She submitted that these matters go to my assessment of the advice and information he provided in consultation.
- 168. In their joint report, Mr Kirkpatrick and Mr Grundy drew attention to three passages in Mr Plaha's paper and suggested that "if these entries represent Mr Mills, this is in stark contrast with what actually happened".
- 169. First, they queried the statement "no cases of haemorrhage were seen along the operative corridor or contusion in the surrounding parenchyma on postoperative CT scanning". Mr Plaha explained that the paper was here focusing on the operative corridor. Although the questioning of this passage was understandable, when read in context, and bearing in mind that the novelty of the approach was using a rigid endoscope without a tubular conduit, I accept that this passage did not misrepresent the position. The paper made clear in the following paragraph that in the series of operations described, there had been "I intraoperative hemorrhage, which resulted in an anterior circulation (A2) infarct".
- 170. Secondly, both experts accepted that their criticism of the passage "none of these patients required intraoperative or postoperative blood transfusion" was mistaken, as the sentence began "In 49 of 50 cases" and so clearly excluded Mr Mills' case.
- 171. The third criticism was, as Mr Plaha accepted, well-founded. The paper said the "the blood loss was calculated to be 800ml". That was a serious error: in fact, Mr Mills lost about 5 litres of blood. Mr Plaha explained that he believes the error occurred as a result of reading the figure from the first page of the anaesthetic chart, rather than the second page. In my judgment, I cannot draw any inferences about Mr Plaha's approach to giving advice about the risks and benefits of the various treatment options from this error in a journal article.

- Ms Jones also made two further criticisms of the description of Mr Mills' case in the paper. First, she suggested that the references in the paper to an "evolving infarct" and to the patient having "developed a left ACA infarct on the third postoperative day" do not accurately reflect the fact that the CT scan taken a few hours after surgery had shown an infarct. Mr Plaha explained that this was the point at which there was firm evidence of the infarct. I note that this is consistent with his contemporaneous note recording that the CT scan taken on 5 December 2012 showed an "early suggestion" of an infarct. It is also consistent with the view expressed by Mr Kirkpatrick and Mr Grundy in their joint report that the CT scan taken on 5 December 2012 demonstrated "early signs of infarction in the pericallosal areas more on the left side, but also evolving on the right side". It would have been more accurate to say that the infarct began to develop within a few hours of surgery, but given the clear statement that the patient had an intraoperative haemorrhage and then developed an infarct I do not read this as underplaying the risks.
- 173. Secondly, Ms Jones drew attention to the fact that the paper refers to the patient (Mr Mills) being "mobile despite a right leg monoparesis", but makes no reference to the cognitive impact of the surgery. Mr Plaha's evidence was that, in the context of a journal article of this kind, the key point was that there had been a complication as a result of which a patient had suffered a stroke, which the paper clearly stated. He also explained that he had initially put in more detail regarding Mr Mills which came out as a result of the journal's editorial process. Although I accept both Mr Plaha's points, in my judgment, even bearing in mind the context in which Mr Plaha was writing, Ms Jones' criticism of the paper is fair: the paper does not give a fair impression of the impact of the operation in Mr Mills' case. I have borne this in mind in reaching an overall assessment of the evidence.

(f) Mr Cadoux-Hudson's evidence

174. Mr Cadoux-Hudson said that "not to offer surgery would not have been appropriate". The alternatives to surgery also need to be offered. Asked whether the MDT was aware this was an incidental tumour, he said: "We were aware there were headaches. It would have to be established whether they were due to pressure. ... I sometimes wonder how many of the tumours we label as incidental are in fact so. I hear this expression incidental has been used quite often. He presented with symptoms, including headaches."

(g) The expert evidence

- 175. In their joint report, Mr Kirkpatrick and Mr Grundy answered questions regarding preoperative advice:
 - "2 In terms of the advice that a responsible neurosurgeon would or should in late 2012 have given in relation to the treatment options for this tumour, are you able to agree that in accordance with a reasonable standard of care this would or should have included any/all of the following:
 - 2.1 the likely diagnosis was that of a low grade glioma, although other more benign medical conditions could not be excluded?

The experts agree, although Mr Grundy would point out that he felt that other diagnoses, although cannot be excluded, were most unlikely, say 1-2% chance in this particular case. Mr Kirkpatrick would not disagree with this but nonetheless

they represent an important consideration in the investigational and treatment pathway.

2.2 the tumour would probably become symptomatic in time but on the basis of a single scan it could not be determined how long it had been there?

Agreed. The experts acknowledge that the period of time before a lesion of this type becomes symptomatic, can be highly variable, but usually measured in years. Mr Grundy felt this was most likely to be 2-5 years (before progression is identified and treatment offered; consistent with recent publications on progression of incidental glioma at average time of 43 months, range 3-105 months, Opoku-Darko et al JNS 2018), in Mr Kirkpatrick's experience this would be somewhat longer, usually over a decade.

2.3 the tumour was an incidental finding and was unlikely to be the cause of the headaches reported by Mr Mills?

Agreed.

2.4 there were three options to be considered, namely regular surveillance with imaging, a biopsy and resection of the tumour?

The experts agree that the three options available to an individual patient would be 1) observation with regular surveillance; 2) a biopsy to confirm the diagnosis and exclude medical causes and; 3) resection of the tumour.

2.5 the management of such low grade gliomas which were asymptomatic and found incidentally was still a matter of controversy among neurosurgeons?

This is agreed.

2.6 proceeding to resection at this stage would be the approach of only a minority, the majority of neurosurgeons regarding this as at the aggressive end of the spectrum of reasonable management options?

Both experts agree that the three options covered in 2.4 above should be discussed in totality for each patient. Age and patient preferences are usually the dominant factors determining which avenue is chose. The experts agree that in the past, the balance was towards a non-surgical approach whereas contemporaneous practice is towards more invasive procedures including biopsy and resection. The balance is highly variable according to individual practices and personal preference."

2.7 In the case such as this of an incidental asymptomatic low grade glioma, in the first instance surveillance with regular imaging would be the prevailing practice?

This has been answered under 2.6 above."

176. In their joint report Mr Kirkpatrick and Mr Grundy identified the advice that a responsible neurosurgeon should have given about the main risks and benefits of the three treatment options in these terms:

- "1) Surveillance: Both experts agree that although there are no immediate risks to surveillance, in a small proportion of patients, the diagnosis may be incorrect, and these will usually manifest with early tumour progression. Provided surveillance is timely, this will not usually compromise the patient's prognosis with respect to that particular pathology. In some instances, inappropriately long intervals may allow a low grade tumour to progress to a level where they can start to cause neurological compromise. Again, accurate and timely surveillance should avoid this. The theoretical concern that a low grade tumour will be allowed to progress to a higher grade tumour is evidenced from the answers above. There are, of course, the psychological consequences for a patient not knowing exactly what they have.
- 2) Biopsy: This holds the advantage of tissue diagnosis, but sampling errors are recognised leading to occasional misdiagnosis. There is also a very low chance that a patient may suffer from intra-operative adverse events such as a bleed which is uncontrolled. Experts would expect that risk to be no greater than 1 to 2%. Biopsy alone will be followed by surveillance in order to pick up any misdiagnosis or tumour progression for a low grade glioma, or treatment with radiotherapy or chemotherapy for higher grade tumours. The experts note that the tumour for MR Mills was probably a WHO grade II oligodendroglioma with favourable mutation histological subtype confirming better prognosis than is average for this grade of tumour. Mr Grundy noted that biopsy clearly carries no potential to improve prognosis in its own right, whilst resection possibly would.
- 3) Tumour excision: The advantage of a tumour excision is that it provides the most robust way of diagnosing, histologically, the nature of the tumour. The operation also offers the greatest chance of removing the majority of the neoplastic tissues. The experts agree that the prognostic benefit of surgery has not been demonstrated in randomised trials and the evidence is variable, however, Mr Grundy noted it was of sufficient quality for NICE to recently recommend surgery as a first-choice therapeutic option for low grade gliomas and recent evidence has suggested it to be beneficial for incidental tumours (see references).

The experts again reiterate the importance that there is a significant degree of uncertainty and debate as to which is the preferred option, and hence discussion with individual patients is of critical importance citing all available options, and expression clearly that there is uncertainty as to the extent of survival gain of one approach over another."

- 177. Mr Kirkpatrick observed in his January 2019 report that a reasonable standard of care in the advice to be given would require a comprehensive discussion of the various alternative approaches to management of a low-grade glioma. He noted that Mr Plaha's documented account "provides a comprehensive account of alternatives in relation to surveillance, biopsy alone or open resecting surgery" and there was a difference in the factual evidence for the court to consider.
- 178. Dr Rees, who is a Consultant Neurologist, and who specialises in neuro-oncology, acknowledged that as he is not a neurosurgeon it was not his role to report on breach of duty, but rather to address the likely progression of the glioma. In his report, Dr Rees said that in a case such as Mr Mills', he would not recommend proceeding directly to resection. He would offer a period of surveillance initially with the second scan being

done three months after the initial scan, and his evidence was that the "prevailing practice in the UK would be to offer surveillance in the first instance". He agreed that it was not unreasonable to offer a resection and, if he had opted for a "wait and see" approach, it was always likely he would have had to have a resection at some point.

- 179. In his report, Mr Grundy said (and Mr Kirkpatrick agreed in cross-examination) it would have been "mandatory" to discuss all three treatment options (surveillance, biopsy and resection). It would have been unreasonable not to offer the patient an option of resection. He observed (and Mr Kirkpatrick agreed) that if Mr Mills had "embarked upon surveillance with imaging alone, it was absolutely inevitable that this tumour would have progressed". Mr Grundy's view was that given Mr Mills' age and the size of the tumour, with accurate measurements, growth of the tumour would have been detected "most commonly within a year or two of the original diagnosis". Mr Kirkpatrick suggested in cross-examination that it would be longer ("several years") to progression. Mr Grundy commented that it was uncertain how long it would take for the lesion to become symptomatic, but most neuro-oncology specialists, and most patients on a surveillance imaging pathway would not wait for it to become symptomatic before opting for surgery.
- 180. The risk level of 2-3% given in Mr Plaha's letter to the GP, in Mr Grundy's opinion, "would represent a realistic estimate of the risks of a very serious complication, such as a stroke or a haemorrhage or a risk to life".

(h) Evidence based on recollection

- 181. In *Gestmin SGPS S.A. v Credit Suisse (UK) Ltd* [2013] EWHC 3560 (Comm) Leggatt J addressed the unreliability of human memory at [15] to [23]. He observed:
 - "16. While everyone knows that memory is fallible, I do not believe that the legal system has sufficiently absorbed the lessons of a century of psychological research into the nature of memory and the unreliability of eyewitness testimony. One of the most important lessons of such research is that in everyday life we are not aware of the extent to which our own and other people's memories are unreliable and believe our memories to be more faithful than they are. Two common (and related) errors are to suppose: (1) that the stronger and more vivid is our feeling or experience of recollection, the more likely the recollection is to be accurate; and (2) that the more confident another person is in their recollection, the more likely their recollection is to be accurate.
 - 17. Underlying both these errors is a faulty model of memory as a mental record which is fixed at the time of experience of an event and then fades (more or less slowly) over time. In fact, psychological research has demonstrated that memories are fluid and malleable, being constantly rewritten whenever they are retrieved. This is true even of so-called 'flashbulb' memories, that is memories of experiencing or learning of a particularly shocking or traumatic event. (The very description 'flashbulb' memory is in fact misleading, reflecting as it does the misconception that memory operates like a camera or other device that makes a fixed record of an experience.) External information can intrude into a witness's memory, as can his or her own thoughts and beliefs, and both can cause dramatic changes in recollection. Events can come to be recalled as memories which did not happen at all or which happened to someone else (referred to in the literature as a failure of source memory).

- 18. Memory is especially unreliable when it comes to recalling past beliefs. Our memories of past beliefs are revised to make them more consistent with our present beliefs. Studies have also shown that memory is particularly vulnerable to interference and alteration when a person is presented with new information or suggestions about an event in circumstances where his or her memory of it is already weak due to the passage of time."
- 182. Leggatt J emphasised that "all remembering of distant events involves reconstructive processes". Such processes are largely unconscious and the strength, vividness and apparent authenticity of memories is not a reliable measure of their truth: Gestmin at [21]. He also drew attention to the "considerable interference with memory" introduced in civil litigation by the procedure of preparing for trial: Gestmin at [19]-[20].

(i) Conclusion on Issue 3

- 183. I have reached the conclusion that Mr Mills' allegation of breach of duty succeeds to the limited extent explained in paragraphs 191 to 194 below, but otherwise this aspect of Mr Mills' claim fails for the reasons given below.
- 184. First, in my judgment, it is clear that Mr Plaha discussed all three treatment options, and the risks and benefits of each of them, with Mr Mills during the consultation in his clinic on 8 November 2012.
- 185. In reaching this conclusion, I emphasise that Mrs Mills was an entirely honest witness. And I do not doubt the strength of her belief that Mr Plaha did not advise her husband on 8 November 2012 that surveillance, with a repeat scan in a few months, was an option. But as Leggatt J observed in *Gestmin* at [22], "it is important to avoid the fallacy of supposing that, because a witness has confidence in his or her recollection and is honest, evidence based on that recollection provides any reliable guide to the truth". I apply the same caution in placing reliance on Mr Plaha's recollection of what he said on this particular occasion, although he too was an honest witness. (I do not have the same hesitation in accepting Mr Plaha's evidence about the nature of the information that he would *ordinarily* give to a patient during such a consultation, for example about the way in which gliomas progress over time.)
- 186. The contemporaneous documentary evidence provides a far more reliable guide to what was discussed in consultation on 8 November 2012 than the recollection of either Mrs Mills or Mr Plaha. In particular, the letter to Mr Mills' GP and Mr Plaha's clinical note, both written on the day of the consultation, provide strong evidence that Mr Plaha fulfilled his duty of care by discussing all three treatment options and explaining the risks and benefits of each of them. I accept that Mr Plaha described the level of risk as being about 2-3% (as stated in the letter to the GP) and that this was an accurate assessment of the risk to life or of a serious complication such as haemorrhage or stroke.
- 187. The notes of 3 and 5 December 2012 are of secondary importance, but given their proximity to the consultation, they provide some additional support for this conclusion. In respect of the discussion on the afternoon of 5 December 2012, I accept Mr Plaha's evidence that the discussion about what he had advised in consultation arose only because Mr Mills' mother and sister questioned him about why the operation had taken place.

- 188. Secondly, I reject the contention that Mr Plaha failed to advise that this was likely to be a *low-grade* glioma. Mrs Mills could not recall the term "*low-grade*" being used, but the documentary evidence is clear that Mr Plaha gave that diagnosis. I also find that the explanation he gave Mr Mills of how tumours develop over time what Mr Plaha referred to as "*the natural history*" was consistent with the views of Mr Grundy and Mr Kirkpatrick, and there was no failure in this respect, either.
- 189. Thirdly, the expert evidence, particularly the joint report of Mr Grundy and Mr Kirkpatrick, as well as the evidence of Mr Cadoux-Hudson, did not support the proposition that, in 2012, the majority of neurosurgeons in the UK would have recommended surveillance in the first instance and regarded proceeding straight to resection as at the more aggressive end of the spectrum of treatment options. The MDT concluded that Mr Mills should be offered resection and it would have been unreasonable not to have offered that option. All three options had to be (and were) offered.
- 190. I also accept Mr Plaha's evidence that the essence of the discussion involved explaining the uncertainty about the natural history of gliomas (albeit he was clear, as were Mr Grundy and Mr Kirkpatrick, that a low-grade glioma would develop into a high-grade glioma); explaining the alternative treatment options; and explaining that in view of the uncertainty some neurosurgeons would recommend surgical intervention earlier than others. It is probable that he did not use the term "controversy" to describe the variations in practice between neurosurgeons. Nevertheless, in my judgment, the advice and information Mr Plaha gave about the three options (subject to Issue 4) fulfilled his duty to take reasonable care to ensure Mr Mills was aware of each of the reasonable alternative treatments, and of the material risks and benefits of each option, in accordance with *Montgomery*.
- 191. The final allegation under this head is that Mr Plaha should have advised (and failed to advise) that the glioma was an incidental finding and it was unlikely that it was the cause of Mr Mills' headaches. In respect of this allegation, I find a breach of duty.
- 192. First, Mr Plaha probably did not give such advice. Although Mrs Mills could not recall whether or not he did so, Mr Plaha thought, and the documentary evidence supports this, that he had neither suggested that the glioma was the cause of Mr Mills' headaches or that it was not.
- 193. Secondly, should he have done so? Mr Kirkpatrick and Mr Grundy were in agreement that one of the matters that a responsible neurosurgeon should have advised was that the tumour was an incidental finding and was unlikely to be the cause of Mr Mills' headaches. In this context, I have to apply the *Montgomery* (not *Bolam*) test. Nevertheless, in determining whether this was material information of which Mr Mills should have been advised, their agreement on this point is highly significant.
- 194. This information was material to the risks and benefits of the various treatment options. Knowledge that the tumour was an incidental finding was relevant in understanding that it was uncertain how long it had been there, or how fast it was growing, and in considering the alternatives to surgery. Knowledge that the tumour was unlikely to be the cause of Mr Mills' headaches was relevant in understanding that a resection operation was unlikely to relieve his presenting symptoms. I have borne in mind Mr Cadoux-Hudson's evidence on this point, to which I have referred in paragraph 174

above. However, the *likelihood* was that the headaches were not caused by the glioma and for the reasons I have given I consider that it was a breach of duty not to explain that to Mr Mills.

J. <u>Informed Consent - Issue 4: Advice regarding the alternative surgical techniques</u>

(a) The scope of the Trust's admission

- 195. There is no dispute between the parties that Mr Plaha did not offer Mr Mills the option of resection using the microscopically-assisted technique or advise that there were alternative surgical techniques. I have set out the terms of the Trust's admission in paragraph 16 above. Mrs Mills' and Mr Plaha's evidence on this point is set out in paragraphs 159 and 162 above, respectively.
- 196. In broad terms, it is accepted by the Trust that Mr Plaha had a duty to advise Mr Mills of the risks and benefits of these two alternative surgical techniques. There is a question as to the scope and content of the information Mr Mills should have been given. The Trust accepted Mr Grundy's explanation, in his oral evidence, of the sort of information that he would have expected to have been given.

(b) The expert evidence

- 197. Both Mr Kirkpatrick and Mr Grundy identified this breach of duty in their reports. In their joint report, at paragraph 4.2, they agreed that the advice to Mr Mills should have included the information that, in the resection of gliomas, the minimally-invasive endoscopically assisted technique:
 - i) Was a novel technique, still in its evolution and not well established;
 - ii) Was not an approach that, as yet, was used by many neurosurgeons other than Mr Plaha:
 - iii) The standard open resection technique which was adopted by other neurosurgeons involved using a microscope;
 - iv) The endoscopic technique would involve a smaller craniotomy;
 - v) The standard open craniotomy using a microscope would give the surgeon direct line of sight, which the endoscopic technique would not;
 - vi) The endoscopic technique would give more limited access and it is possible that this could pose a greater risk to structures and vessels that were not within the surgeon's direct line of sight;
 - vii) If untoward bleeding were to occur, the endoscopic technique would make visualisation and controlling the bleeding more difficult and may result in the need to extend the opening; and
 - viii) The risks and benefits of using the endoscopic technique were unclear.
- 198. In cross-examination, Mr Grundy made clear that he was not going back on paragraph 4.2 of the joint report. He added that in advising that this was a "newer technique, not in widespread use", Mr Plaha could have quoted his own experience of using the technique in 26 cases without any complication. But it would have been fair to draw

attention to the fact that how this would look in a larger series in due course was uncertain. And it "should have been made clear it was not a conventional approach used in that manner"

(c) Conclusion on Issue 4

- 199. It is clear (and accepted by the Trust) that Mr Plaha breached his duty of care by (a) not offering microscopically-assisted resection as an alternative option and (b) not explaining the comparative risks and benefits of these alternative surgical techniques.
- 200. In my judgment, Mr Plaha should have advised Mr Mills that the surgical technique he usually used involved making a small craniotomy of about 2-2.5cm behind the hairline and using a tool called an "endoscope" to see the tumour and surrounding structures during the operation. An alternative technique that he or another neurosurgeon at the John Radcliffe could use, to perform the same operation, involved making a larger craniotomy, of about 4-5cms, also behind the hairline, and using a microscope (instead of an endoscope) for vision.
- 201. In 2012, Mr Plaha also should have explained each of the points identified in paragraph 197 above, all of which meet the *Montgomery* test of materiality. The test is not, of course, what advice the experts consider is required. The focus is on what a reasonable person in the patient's position would be likely to attach significance to in deciding on his or own treatment. In addition, a risk is material if the doctor is or should be aware that the particular patient would be likely to attach significance to it, as for example in *Rogers v Whitaker* where "the risk was of blindness in one eye; but the plaintiff was already blind in the other eye, giving the risk a greater significance than it would otherwise have had" (Montgomery at [73]). The Trust did not contend that any of the matters identified by the experts were not material and, in my judgment, they are clearly all matters that a reasonable patient in Mr Mills' position would have considered significant in determining what treatment to opt for.
- 202. Mr de Bono emphasised that there should be a dialogue between the doctor and the patient, and it is important the advice should be comprehensible (*Montgomery* at [90]). I accept that submission, but each of the points identified in paragraph 197 above is capable of being explained in non-technical language without difficulty. Mr de Bono also emphasised paragraph 85 of *Montgomery* where the Court addresses the position when a patient does not want to hear the doctor's advice. As there was no evidence that Mr Mills declined to listen to any of the advice and information Mr Plaha provided, paragraph 85 does not affect the scope of the advice that should have been provided in this case.
- 203. It would have been open to Mr Plaha to have described the technique as, for example, "new" "newer" or "innovative", rather than "novel", as long as he explained that it was not well established and that other neurosurgeons in the UK used the microscopically-assisted technique, which was the "standard" or "conventional" approach to resection of such a tumour.
- 204. It would also have been open to Mr Plaha to have explained his considerable experience of endoscopic neurosurgery, and that he had (at that point) undertaken 26 resections using the minimally invasive endoscopically-assisted open craniotomy technique, without any complications. However, if he had referred to the series he had undertaken up to that point, it would have been important to emphasise that it was uncertain what

the complication rate for a longer series would be and, as with any new technique, the risks and benefits were not yet clear.

K. Causation - Issue 5: What treatment would Mr Mills have opted for?

(a) Impact of failure to advise the glioma was incidental and not the likely cause of headaches

- 205. Mr Mills succeeded to a limited extent on Issue 3. That gives rise to the question: what would have happened if Mr Plaha had advised Mr Mills that finding the glioma had been incidental and it was not the likely cause of his headaches?
- 206. In my judgment, this breach had no causative impact. Mrs Mills could not recall whether Mr Plaha had given such advice, but she did recall that when hypertension had been diagnosed she and her husband believed the headaches were caused by hypertension. There is no evidence to suggest that Mr Mills was under the misapprehension that the tumour was the likely cause of his headaches. In any event, I have found that Mr Mills was keen to have the tumour taken out having been advised that he had the alternative options of surveillance or biopsy. It is highly likely that if he had been given this limited additional advice it would have made no difference to his decision.

(b) Impact of failure to advise about the alternative surgical techniques

- 207. If Mr Mills had received the advice and information identified in paragraphs 199 to 204 above would Mr Mills still have opted for a minimally invasive endoscopically-assisted resection procedure? Or would he have opted for surveillance, a biopsy alone, or a microscopically-assisted resection procedure?
- 208. Mrs Mills' evidence was that before the operation she and her husband had complete confidence in Mr Plaha. She said they had a good relationship with Mr Plaha and "we trusted him 100%". When she was asked what her husband would have done if Mr Plaha had explained that the way he did this operation was new, involved making a smaller hole, but it was a technique he had confidence in, Mrs Mills said, "Adrian would have run a mile". She said that he was averse to running any unnecessary risks. Mrs Mills gave her husband's reaction to her giving blood as an example, explaining that he was annoyed with her for doing so because it was not a risk she needed to take. Mrs Mills said that if her husband had known the technique was not "tried and tested" he would not have agreed to it. She said he would not have wanted to be a "guinea pig". She agreed that he did not want to delay taking the tumour out. She said that it was playing on his mind and having been advised it would need to come out, his reaction was 'why delay something that has to happen?' Mrs Mills' evidence was that when told that Mr Mills would be put on the waiting list she assumed that the procedure was not urgent because, if it was urgent he would have been seen straight away.
- 209. In re-examination, Mrs Mills was taken to a document indicating that on 13 August 1992 Mr Mills "declined an X-ray for fear of radiation" and on 5 March 2013 two attempts to persuade Mr Mills to agree to an operation to insert a ventricular peritoneal shunt were rejected before he agreed to the operation. The note records him saying "I don't want to be an experiment".
- 210. Mr Plaha's evidence was that in his experience "the majority, but not all, of patients who have a brain tumour simply 'want it out' and opt for surgery". From his experience

- of Mr Mills and the way he followed his advice, Mr Plaha said he "would be very surprised if he would have asked for a different surgeon or a different technique had I gone into the differences between the endoscopically assisted approach that I use and any other technique".
- 211. Mr Grundy said in his report, and reiterated in cross-examination, that he considered it highly likely that Mr Mills would have proceeded with the same operative strategy. He said that he had found this to be the case with patients in circumstances where he had explained that his own proposal was novel or innovative. Mr Grundy gave evidence that "patients have a distinct tendency to opt for the most invasive aggressive option". Having talked through the options, in his experience, the "vast majority opt for the most invasive" option.
- 212. In my judgment, it is probable that Mr Mills would have opted for resection using the standard microscopically-assisted technique. I have reached this conclusion for the following reasons.
- 213. First, it is improbable that Mr Mills would have opted for surveillance or a biopsy if he was offered an additional surgical option. I have found that Mr Mills was offered surveillance or biopsy, but he was keen to have the tumour removed without delay. There is no reason to believe that if he had been offered an additional option of resection using the microscopically-assisted technique that would have prompted him to opt for one of the less invasive options that he did not in fact prefer to surgery. Mr Plaha's evidence was that most patients opt for surgery and Mr Grundy's evidence was that most opt for the most invasive option. That is what Mr Mills did. I consider it clear that he would have opted for surgery.
- 214. Secondly, it is probable that Mr Mills would have opted for the standard technique if he was advised in the way that he should have been. Mr Grundy's evidence that it was highly likely that Mr Mills would have opted for resection using the endoscopically-assisted technique appeared to be predicated on his experience that patients tend to opt for the most aggressive and invasive option. However, the two surgical techniques that would have been offered are equally aggressive in the sense that both resect the tumour using the same tool. Mr Plaha's view was predicated on the way in which Mr Mills had followed his advice. Mr Mills clearly trusted Mr Plaha and that would have been a factor in considering whether to opt for the technique that he used. But there is an important difference because Mr Mills would have been given comparative information about two ways of performing the same operation, giving him the opportunity to consider the relative risks and benefits of each technique.
- 215. The principal advantage of the endoscopically-assisted technique is that it involves having a smaller craniotomy. Although another possible benefit was reduction in morbidity, that was not demonstrated by November 2012. So Mr Mills would have been weighing the limited cosmetic benefit of a smaller craniotomy, bearing in mind that the conventional technique would also be behind his hairline, against the increased risks and increased level of uncertainty of the newer technique. Although I have accepted that many patients are concerned about cosmesis, there is nothing in the evidence to suggest that it was a factor that would have weighed significantly with Mr Mills. Whereas there was clear evidence from Mrs Mills that her husband has always been naturally risk-averse. I bear in mind that he had accepted the 2-3% risk to his life or of a serious disability, in agreeing to surgery in November 2012. However, those were

risks he knew he would have to run at some point, as it was inevitable that the tumour would progress and have to be excised. Whereas the additional risks and uncertainties of the endoscopically-assisted technique could be avoided by choosing the conventional approach, and I find that he would have opted for the latter.

216. In reaching this conclusion, I have not placed any weight on the evidence referred to in paragraph 209 above as I accept Mr de Bono's submission that as these matters were only raised in re-examination he was not able to put to Mrs Mills other operations that Mr Mills had consented to over the years, or the circumstances in which he initially refused his consent to the operation in March 2013.

L. <u>Causation - Issue 6: Did the choice of technique make it more difficult to control the bleeding?</u>

(a) The expert evidence

217. In their joint report, Mr Kirkpatrick and Mr Grundy agreed that had the torrential bleeding occurred with a conventional technique the source of the bleeding would have been detectable and/or the bleeding could have been successfully controlled earlier. In answer to the question whether Mr Mills would still have suffered a stroke if the torrential bleeding occurred using a conventional technique, they observed:

"The experts cannot wholly discount the possibility of a stroke with standard methods, but they agree that this is extremely rare and would usually complicate a much more complicated tumour anatomy."

218. They were also in agreement that: "With open operations, breaches of vessels can occur, but due to the improved access, they usually prove very simple to control". In the brief additional statement he submitted having heard the evidence, Mr Grundy qualified the latter statement by adding:

"However, in this case, even with a conventional medial craniotomy, it may still have proven very difficult to achieve rapid haemostasis if the mechanism was retraction of the frontopolar branch of the pre-callosal back to its origin. An additional extension of craniotomy and/or further brain resection may still have been required."

- 219. When writing their joint report, Mr Kirkpatrick and Mr Grundy had understood that "the craniotomy was not extended until Mr Griffiths attended" (para 15 of the joint report). In fact, after trying to control the bleeding by packing the site, Mr Cadoux-Hudson fashioned a small extension of the craniotomy, which was later extended further by Mr Griffiths (see paragraphs 61 to 62 above).
- 220. It was suggested to Mr Kirkpatrick in cross-examination that the initial choice of technique made no difference because once Mr Cadoux-Hudson's assistance was sought, he extended the craniotomy and used a microscope. Mr Kirkpatrick disagreed. He explained that using a microscope, if the surgeon hits a vessel it is usually controlled directly. He said there was a window of opportunity (which he described as minutes) to deal with it very quickly. He said in his experience, and Mr Grundy's experience, as they had said in their joint report, using the conventional approach it is very straightforward to control bleeding when resecting a tumour in this location.

(b) Conclusion on Issue 6

- 221. In my judgment, Mr Mills has succeeded in establishing that the breach of duty caused the damaged that he suffered. I accept the joint view expressed by Mr Kirkpatrick and Mr Grundy that if such torrential bleeding had occurred using the conventional technique, it is probable that it would have been controlled successfully much earlier and Mr Mills probably would not have suffered a stroke.
- 222. In reaching this conclusion, I accept the logic of the Trust's argument that once Mr Cadoux-Hudson extended the craniotomy, the procedure from that point onwards was the same as it would have been using the conventional technique.
- 223. However, although Mr Cadoux-Hudson was called promptly, there was a period of time from the start of the torrential bleeding when first Mr Plaha and then Mr Cadoux-Hudson sought to control the bleeding whilst only having the access permitted by a minimally-invasive craniotomy. It is probable that this period was at least 30 minutes, given Dr Wheatley conveyed the request for Mr Cadoux-Hudson to assist about 15 minutes after the bleeding began, and allowing time for Mr Cadoux-Hudson to leave his own patient, scrub up, inspect the wound site and re-pack it, before extending the craniotomy. I accept Mr Kirkpatrick's evidence that the bleeding probably would have been controlled in the immediate period after it began if a conventional technique had been used, giving greater access and better ability to visualise the area once bleeding began than the minimally-invasive endoscopic technique.
- 224. I accept that even using the conventional technique the bleeding that Mr Mills suffered *may*, as Mr Grundy said, still have proved very difficult to control. Clearly, that is a possibility. But Mr Grundy did not seek to depart from his evidence that it was probable the bleeding would have been readily controlled and the stroke would not have occurred if the conventional technique had been used.
- 225. Accordingly, I find that the breach of duty was causative of the stroke that Mr Mills suffered.

M. Causation - Issue 7: Scope of Duty

- 226. The Trust contends that if the choice of surgical technique was not causative of the difficulty in controlling the bleeding, then the complication suffered falls outside the scope of the duty to warn, applying *Khan v Meadows* [2019] EWCA Civ 152, [2019] 4 WLR 3. Given my conclusion on Issue 6, the premise for the Trust's contention that the complication Mr Mills suffered falls outside the scope of the duty to warn does not arise. The increased risk that it would be difficulty to control bleeding if it occurred, of which Mr Mills should have been warned, was one which eventuated.
- 227. However, even if I had reached the conclusion that, in view of the extension of the craniotomy made by Mr Cadoux-Hudson, the surgical technique used at the outset of the operation did not affect the ability to control the bleeding, I would find causation is established on the basis that the damage suffered falls within the scope of the duty. In view of my finding on Issue 6, I can address this point briefly.
- 228. I do not accept the Trust's contention that the increased risk of difficulty controlling bleeding was the only relevant risk. I have also found that Mr Mills should have been advised of the possibility that using the endoscopically-assisted technique could pose a

greater risk to structures and vessels that were not within the surgeon's direct line of sight. The risk of damage to a vessel that was not within Mr Plaha's direct line of sight is one which eventuated. This is a case where "the misfortune which befell the claimant was the very misfortune which was the focus of the surgeon's duty to warn": Chester v Afshar [2005] 1 AC 134, per Lord Walker at [94].

N. Conclusion

229. For all the above reasons the claim based on alleged clinical negligence in the performance of the surgery fails; the claim succeeds on the basis of informed consent.