Neutral Citation Number: **[2022] EWHC 949 (QB)**

Claim number: G90BM052

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
BIRMINGHAM DISTRICT REGISTRY

Birmingham Civil Justice Centre
The Priory Courts, 33 Bull Street
Birmingham, B4 6DS

Date: 26 April 2022

Before:

MR STEVEN GASZTOWICZ QC

sitting as a Deputy High Court Judge

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BETWEEN:

MARK ADRIAN CRITCHLOW **Claimant**

-and-

UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST **Defendant**

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Miss Catherine Ewins (instructed by **Hugh James**, solicitors) for the **Claimant**

Mr Jeremy Roussak (instructed by **Weightmans**, solicitors) for the **Defendant**

Hearing dates: 10 – 11 October 2021, 1-4 March, 17 – 18 March and 24 March 2022

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Judgment Approved

MR STEVEN GASZTOWICZ QC:

1. The claim in this case is one of alleged clinical negligence by the Defendant in relation to the diagnosis and treatment of the Claimant at the Royal Stoke University Hospital (formerly known as the City General Hospital) in Stoke-on-Trent ('the Hospital') in 2015.

2. A split trial has been ordered and the issues currently before the court are those of breach of duty and causation.

3. The Claimant, Mr Mark Critchlow, was born on 22nd April 1967.

4. Prior to autumn 2014 he was in employment as a lorry driver and was fit and well.

Terminology

5. It is appropriate at the outset to provide an explanation of some of the terms used in evidence in relation to the medical assessment of whether a person has a venous thromboembolism ('VTE'), that is to say a deep vein thrombosis ('DVT') or a pulmonary embolism ('PE') (which will probably have been preceded by a DVT).

6. References to a person's 'Wells score' are to the total number of points awarded by doctors in respect of specific factors set out in the Wells tables which are used to estimate the clinical probability of either a DVT or a PE.

7. The applicable tables for the purpose of this case are set out in the National Institute for Health and Clinical Excellence ('NICE') clinical guideline 144 of June 2012, which is before the court. A total of two points in the DVT table indicates a DVT is "likely". A total of more than 4 points in the PE table indicates that a PE is "likely".

8. What is there meant by "likely" is (on the evidence, and as agreed by the parties) that "there is such a degree of chance the person is suffering from the relevant condition to require further medical investigation". It is not intended to convey that on the balance of probabilities the person actually has the condition.

9. A person's d-dimer score is a laboratory test of the person's blood, which indicates whether or not there is a higher level of d-dimer in the blood than normal. Clotting increases the amount of d-dimer in the blood, so a higher than normal level may indicate a VTE.

10. A CT Pulmonary Angiogram ('CTPA') is a radiological scan which, though not necessarily 100% accurate in all cases, when it evidences a PE gives the highest possible degree of probability that a PE is present. It means that almost certainly the person has a PE.

11. A Dopler ultrasound scan is used to detect a DVT and gives an equally high degree of probability in relation to that on the same basis.

Background to the Claim

12. The background to the occasions in 2015 on which negligence by the Defendant's medical staff is alleged to have occurred is as follows.

13. On 14th November 2014 the Claimant attended the Accident & Emergency Department of the Hospital complaining of pain in his right calf, difficulty in mobilising normally, shortness of breath and chest pain. On examination his right lower leg had slight redness over the calf and was tender to touch. Both legs were recorded as measuring 39cm in circumference. He had a PE Wells score of 6 (the Wells scoring system being one which will I will explain further later). His D-dimer score was 501 ng ml. This was above the acceptable range of up to 230 specified in the d-dimer test kit insert and of 350 laid by the Defendant Trust based on its own research and judgment, which has not been criticised.

14. Having been admitted as an in-patient, on 15th November 2014 the Claimant's right calf was described as erythematous and very tender to touch. He underwent a CTPA and was found to have bilateral pulmonary emboli.

15. He was discharged on 18th November 2014, on warfarin, an anticoagulant. He returned to A&E later the same day complaining of severe pain, inability to weight bear and episodes of haemoptysis (ie of coughing up blood) and was discharged again with further painkillers and reassurance. He subsequently returned again on 25th November 2014, when he was anxious and was reassured, and on 7th December 2014, having suffered a heavy nosebleed that would not stop (having previously spoken to his GP about nosebleeds he was suffering). He complained of shortness of breath and other symptoms but was discharged following tests.

16. The Claimant had a 13 week course of warfarin, which ended on 14th February 2015.

17. No complaint is made about his diagnosis and treatment up to that time.

The First Occasion of alleged Negligence

18. On 15th March 2015 the Claimant again attended the Hospital's A&E Department, with shortness of breath, chest pain, and left calf pain. His left calf was measured at 2cm larger than the right calf. He had a normal d-dimer test result (at 225) and was discharged.

19. The first allegation of negligence in the case relates to the Hospital's failure on that occasion to calculate a Wells score for DVT or PE and to carry out imaging by way of a CTPA or at the very least an ultrasound. As a result, it is alleged in the Amended Particulars of Claim that he was not diagnosed with a DVT or a PE, which it is alleged he then had, which failure in diagnosis was causative of injury.

20. It is admitted in the Amended Defence that the failure to estimate a Wells score and to undertake imaging on this occasion was in breach of the Defendant's duty to the Claimant.

21. However, it is denied that the Claimant was at that time experiencing either a DVT or PE. Accordingly, it is said that that even had imaging been undertaken (ie a CTPA or ultrasound), no such condition would have been diagnosed and no treatment for it would have been prescribed, so that the breach of duty was of no causative effect.

The Second Occasion of Alleged Negligence

22. On 25th March 2015 the Claimant attended an out-patient appointment in the respiratory clinic of the Hospital. He was seen by Dr Muhammad Iqbal, a consultant physician in acute and respiratory medicine.

23. The Claimant gave a history of breathlessness and calf pain. It is alleged in the Amended Particulars of Claim that the Claimant's left leg was not examined, as it should have been, and only a d-dimer test was carried out, and not imaging, which should have been done. As a result of this alleged breach of duty, again it is said neither a DVT or PE were detected, as they should have been, with causative effect.

24. It is denied in the Amended Defence that there was a failure to examine the Claimant's left leg, and said that there was no swelling or tenderness apparent in the leg. It is said that it was appropriate to carry out a d-dimer test, as was done, which, when found to be normal (at 165), meant that it was reasonable to do nothing further by way of testing or treatment. Breach of duty on this occasion is accordingly denied.

25. Again, it is denied that the Claimant was in any event suffering from a DVT or PE at that time, so that had there been a breach of duty it is denied it would have been causative of injury anyway.

Events of 13th April 2015 and Resultant Anticoagulation

26. On 13th April 2015, the Claimant attended the A&E Department of the Hospital with shortness of breath which had recently increased in severity, and caused him to leave his job, tightness across his chest, tingling in the left calf and describing coughing up blood. His left leg was measured at 2cm larger than the right leg. A d-dimer test was carried out, the result for which was above the normal level (at 485) and as a result he underwent a CTPA, which was positive for PE. He was therefore commenced again on warfarin.

27. On 8th September 2015 his medication was changed from warfarin to apixaban (another anticoagulant), to be taken at a dose of 5mg twice a day.

28. No complaint is made about the way the Claimant was dealt with on either of these occasions.

The Third Occasion of Alleged Negligence

29. The third occasion on which breach of duty is alleged is 8th December 2015.
30. On 8th December 2015 the Claimant attended the haematology clinic of the Hospital and saw Dr Deepak Chandra, a consultant haematologist.

31. It was noted that he had had two nosebleeds. The dose of apixaban was reduced by Dr Chandra to 2.5mg twice per day.

32. It is alleged in the Amended Particulars of Claim that this was negligent in that the dose could not reasonably have been reduced to 2.5mg twice per day. Regardless of what had previously occurred, the Claimant's case is that this breach of duty meant the extension of the leg DVT and recurrent PE the Claimant subsequently suffered in April 2016 was not avoided, as it otherwise would have been, contributing to the development by him of post-thrombotic syndrome.

33. The Amended Defence denies that it was a breach of duty to reduce the dose in the way that was done, which it is contended was a reasonable and proper decision in the circumstances, following some 8 months of anti-coagulation, and not causative of any injury.

Factual Witnesses and Expert Evidence

34. I will refer in a moment to the evidence before the court which, when assessed as a whole, leads to the conclusions I make in the case. However, it is appropriate to note here that oral evidence was heard on oath from the following people:

For the Claimant

- The Claimant himself

- Mrs Betty Critchlow (the Claimant's mother)

-Dr Simon Taggart (consultant respiratory physician), who provided an expert report dated December 2020

-Dr K K Hampton (consultant haematologist), who provided an expert report dated December 2020, a letter dated 15th September 2021 and an addendum report dated 29th September 2021.

-Professor Linda Hands (consultant vascular surgeon), who provided an expert report dated July 2019 and addenda dated December 2020 and 29th September 2021.

For the Defendant

-Dr Muhammad Iqbal

-Dr Deepak Chandra

-Dr Adrian Draper (consultant respiratory physician), who provided an expert report dated October 2020

-Dr Keith Gomez (consultant haematologist), who provided an expert report dated 9th October 2020

-Professor Francesco Torella (consultant vascular surgeon), who provided an expert report dated 10th October 2020.

35. Joint statements were prepared by the two experts in each specialty.

36. The fact that I do not recite in this judgment the whole of the expert and other evidence in the case, which would be impractical, does not mean, of course, that I have not considered the whole of that evidence, both written and oral, in coming to my conclusions, which I have done in detail. I have also taken into account the legal authorities briefly referred to at trial.

Factual Evidence and Findings

37. The Claimant's witness statement of 23rd September 2020 stood as his evidence in chief, along with a small amount of supplemental oral evidence. He initially gave evidence by CVP video link from bed at home on the first day of the trial on 10th October 2021, where he was resting because of unrelated fractures of his vertebrae. However, fairly early on in cross-examination, he got up and fell, causing the hearing to be adjourned. He was later taken by ambulance to hospital and the hearing was unable to resume the next day. The trial, and his cross-examination, resumed on the 1st March 2022.

38. Both in his evidence in chief and under cross-examination the Claimant was clear that his legs were not examined at all by Dr Iqbal on 25th March 2015. In his witness statement he referred only to Dr Iqbal asking him to lift his shirt and listening to his chest and back using a stethoscope. However, he mentioned in his oral evidence that Dr Iqbal also used a finger to check his stomach for tenderness. Other than this, he was sure there had been no examination at all. He said he was also sure that he had gone in on crutches to see Dr Iqbal. His evidence was that he told Dr Iqbal he was suffering with shortness of breath, had some chest pain and had pain and swelling in his left lower leg.

39. The witness statement of Mrs Critchlow (the Claimant's mother), dated 23rd September 2020, stood as her evidence in chief.

40. Mrs Critchlow is 83 years of age. She confirmed under cross-examination that she thought her son went in to see Dr Iqbal on 25th March 2015 on crutches. Her recollection was that it was cold on the occasion she was thinking of so that she did not think this could have been the separate occasion in August 2015 when he saw Dr Iqbal and he referred in his clinical letter to the Claimant's use of crutches.

41. However, notwithstanding her witness statement (presented, she said, by lawyers for signature over 5 years after the event, following telephone discussions in disjointed sessions) containing brief reference to Dr Iqbal not examining her son's legs on 25th March 2015, she very fairly and properly said in oral evidence that she was not sure she was present at the start of that consultation or throughout it all. Furthermore, she specifically said that she could not remember whether or not her son's legs were examined on that occasion. As she put it, there has been a lot going on in the past, and lots of appointments, as well as the passage of time. This is understandable but obviously limits the weight to be attached to her evidence in relation to the events of 25th March 2015.

42. Similar considerations apply to her evidence that the Claimant attended on crutches. She said she that she had attended many appointments with her son over the years, and could remember so little of anything else associated with this occasion, that, although I am in no doubt that Mrs Critchlow was doing her best to assist the court, I cannot be satisfied that it is this occasion she is thinking of here.

43. On the Defendant's side, Dr Iqbal's evidence, as set out in his witness statement, which stood as his evidence in chief, was that his notes of the consultation on 25th March 2015, as supplemented by the clinical letter he dictated following it, would be correct. He agreed the Claimant's noted history included pain in the left calf and breathlessness.

44. Under cross-examination, he was confident that, as well as listening to the Claimant's chest, he had examined his left leg which had no swelling or tenderness (which may be symptoms of DVT).

45. The Claimant had not come into the room using crutches or he said he would have noted that fact. He said that he had measured the calf, which may have been with his hands, to see how it compared with the other leg, rather than with a tape measure.

46. He said he would not always document normal, as opposed to abnormal, findings.

47. He did not do Wells scoring as such, but his judgment based on the factors within the Wells tables was that a DVT was not clinically indicated. He said that by reference to the Wells tables the Claimant would have scored zero for everything other than the previous DVT/PE (for which 1 point was accorded in the DVT table and 1.5 in the PE table). He considered the breathlessness could have been due to deconditioning following the previous DVT.

48. Accordingly, he said he considered on the basis of his clinical judgment that a DVT/PE was unlikely and in accordance with the applicable NICE guidelines ordered a d-dimer test of the Claimant's blood. It came out in the normal range at 165. In addition, he recalled speaking to Dr Chandra and was aware the Claimant had also had a normal d-dimer score 10 days before, on 15th March, when it had been 225 meaning it had actually dropped. On this basis, and again in accordance with the NICE guidelines, no further investigation was done.

49. I must decide whether the Claimant's evidence or that of Dr Iqbal is most likely correct in relation to the examination of the Claimant's left leg in particular, though also in relation the use of crutches.

50. I say at once that I did not gain the impression that the Claimant was deliberately trying to mislead the court. Furthermore, I must bear in mind that Dr Iqbal presently has no direct recollection of the consultation on 25th March 2015 and is reliant on his notes and the clinical letter which was written following it.

51. However, there are a number of pieces of evidence that lead me to the conclusion that Dr Iqbal probably did examine the Claimant's left leg at the clinic on 25th March 2015 and found no swelling or tenderness in it.

52. First, Dr Iqbal's handwritten notes were entirely contemporaneous, having been written up during the consultation that day, and it was not challenged, and I accept, that the clinical letter to the GP was dictated immediately after it. Dr Taggart, the consultant respiratory physician called by the Claimant, confirmed in his evidence in chief that putting more information in the letter than was in the notes was entirely acceptable and did not suggest it was in any way unusual.

53. Both are documents of a type any doctor would understand the importance of getting right and given they were written at the time appear likely to be reliable as to what was done and discovered. This is not dependent on memory years later but is the physical record made at the time for the purpose of accurately recording important matters.

54. There is an accepted and obvious transcription error in the letter where "left calf" is written as "left cough" but this is understandable from voice dictation, as Dr Taggart, instructed by the Claimant, fairly pointed out. This is particularly so when the person dictating has a heavy accent, as Dr Iqbal does. It does not therefore undermine the general accuracy of the document, nor, in fairness, was it suggested it did so.

55. Though items may have been omitted from the documents where findings were normal, it seems unlikely something would be recorded as having been done without that having occurred. Similarly, it seems unlikely something would be recorded as positively found or not found unless that had been the case.

56. It is clear that the history section of Dr Iqbal's note on 25th March 2015 ends with the entry "No family H/o DVT/PE" and that what follows were his examination findings (as Dr Taggart, in his oral evidence accepted to be the position). That section of the notes records

> "C0, C0, J0, P0, N0
> [which is not disputed to mean "no cyanosis, no clubbing, no jaundice, no pallor, no abnormal nodes]
>
> S1 +S2 +0
>
> [which it is not disputed means heart sounds and closure of heart valves were normal and there were no additional sounds were found]
>
> No leg/calf swelling".

57. The clinical letter recorded,

> "On examination he seems comfortable. Oxygen saturation 95% room air. No evidence of clubbing, jaundice, pallors or nodes. Heart sounds are normal and there is no [calf] swelling or tenderness".

58. It appears to me from this that the overwhelming likelihood is that Dr Iqbal did on 25th March 2015 carry out more than a physical examination of the Claimant's chest, and that this probably included his left calf, which is described in the note and the letter along with everything else, and that it was not swollen or tender. These things would only be apparent from an examination of the relevant parts of the body, and the contemporaneous note and letter read together make clear that the left calf was examined and was not found to have swelling or tenderness.

59. I do not consider Dr Iqbal would have been likely to have recorded this, in what was plainly the examination section of the notes and was expressly stated in the letter to be on examination, unless the leg had been examined and found not to have these things.

60. I should add for completeness that the point was made by Miss Ewins for the Claimant that the left leg was recorded as swollen on 15th March 2015 (though by 2cm rather than the 3 cm or more referred to as of relevance in Wells Table 1) and subsequently on 14th April 2015. However, this does not preclude the swelling having gone down between times, and I accept that, as Dr Gomez pointed out, swelling of the leg could come and go depending on what was done with it. This also ties in with Mrs Critchlow's evidence (without being taken as specific to the appointment on 25th March 2015) that "the swelling came on at different times – it was not 24 hours".

61. In relation to the question of whether the Claimant attended the appointment on crutches, I would expect this to have been recorded were it so. The Claimant's use of crutches was recorded in Dr Iqbal's clinical letter following the Claimant's August appointment with him

and I would expect it to appear in the March letter were he to have been using crutches at that time. Dr Iqbal's reference to the Claimant's use of crutches in his August letter suggests he saw it as relevant to record this when he was aware of it. In fact, in contrast to it, the clinical letter records "his exercise tolerance is reduced to a couple of hundred yards". It seems inconceivable that note would have been made had the Claimant been using crutches to get into or out of the consultation room.

62. I am not satisfied on the balance of probabilities that the Claimant's left leg was not examined on 25th March 2015 and found on proper examination not to be swollen, or that he attended Dr Iqbal's clinic on that date on crutches.

Findings in relation to alleged breach of duty on 25th March 2015

63. Dr Taggart, a consultant respiratory physician, was called by the Claimant to give expert evidence on the question of breach of duty on the 25th March 2015. He provided an expert report dated December 2020. He also signed a joint statement with the Defendant's respiratory expert, Dr Draper, dated 9th April 2021.

64. Dr Taggart acknowledged in his oral evidence to the court that his December 2020 report focused on the Claimant's version of events that his left leg was not examined on 25th March 2015 but was in fact swollen, and that he attended the appointment on crutches. On this basis, he considered in his report that there was a sufficient degree of risk of a DVT/PE for Dr Iqbal to require the Claimant to undergo a CTPA, which he did not do.

65. The whole of the joint statement of the experts, like each of their respective reports, can be read for itself, but they indicated in it that if the Claimant had signs of DVT on 25th March 2015, the Wells tables would have given a score of at least 4.5 (being 3 for those signs and 1.5 because of the history of DVT/PE) and they in that case questioned Dr Iqbal's clinical judgment in stating the risk for DVT/PE was low. If the Court was to consider no other diagnosis seemed likely, then an additional 3 points would, they said, fall to be added for that, taking the score up to 7.5. They considered that in the circumstances a usual body of responsible physicians would have risk-assessed the Claimant as moderate or high risk. Such an assessment would require an urgent CTPA, which was not undertaken.

66. These assessments were based on the papers. Dr Taggart had the advantage, however, of hearing Dr Iqbal give oral evidence. Dr Draper did not, but did have the advantage of hearing Dr Taggart's oral evidence.

67. Dr Taggart said at the beginning of his oral evidence to the court that it depends on the circumstances to what extent reliance can be placed on scores. He pointed out that, unlike in A&E departments, scoring systems are not actually used in respiratory clinics and that Wells (whose name the tables bear) himself said clinical acumen and judgment were the most important things, trumping any "Wells scores".

68. In the early part of cross-examination Dr Taggart acknowledged that Dr Iqbal did appear to have given some consideration to whether the Claimant might have PE by reference to the handwritten note "?Request CTPA". He also agreed that so far as the 'symptom' of breathlessness was concerned, it is common in patients after an earlier PE and many clinicians would acceptably regard it as "unexplained breathlessness"; also that the recording of 'no chest pain' might make a PE less likely in some patients, and that there

was no coughing up of blood indicated which would be an indicator of PE. He agreed that the "No leg/calf swelling" entry was in the *examination* section of the notes, in accordance with the way in which from medical student days onwards all doctors are taught to make their notes, and that it clearly recorded a finding made on examination.

69. Not very long into cross-examination, the court adjourned for the evening. The next day, Dr Taggart said that he had thought carefully about all the evidence that was now before the court. He indicated he wanted to make a statement based on all that was now known. He said "I now feel quite strongly I accept Dr Iqbal examined the leg", that there was no swelling and tenderness found and that he was "now convinced that whatever assessment he [Dr Iqbal] undertook he came to the right conclusion that there was a low probability risk for DVT and PE and I believe he acted accordingly in requesting a d-dimer to refute a diagnosis of PE or DVT", and said that he now understood why Dr Iqbal did not request a CTPA. Common disorders, Dr Taggart said, were more common than pulmonary emboli, and more likely to be the diagnosis than his original contention using Wells scores. If a d-dimer was ordered and was low, as it was, it would have reinforced the view there was nothing to worry about.

70. Dr Taggart expressly confirmed that he now had no real criticism of Dr Iqbal's conduct.

71. In re-examination, Dr Taggart said that the absence of any note about erythema, veins and the like did not mean there had been no examination for those, as a majority of chest physicians would not record negative findings in relation to those in the notes, but that even if there had been no examination for them Dr Iqbal's examination was still adequate, as they would usually accompany tenderness and swelling, which had been excluded by him.

72. Despite counsel for the Claimant enabling him to state otherwise, he was also firm in his view that an examination with hands, without using a tape measure and without taking and noting measurements, was entirely acceptable and normal in a clinic (as opposed to A&E Departments), and that in any event a 2cm difference in size (as recorded in A&E notes on the different date of 15th March 2015), as opposed to a 3 cm difference would not be regarded as significant. He said that a 3cm swelling was what clinicians looked for, notwithstanding that 2cm might be regarded as significant by a patient.

73. Even had there been pain described in the leg as well as breathlessness, the absence (which I have found) of swelling would, he said, in his professional view properly swing a physician such as Dr Iqbal against a DVT being the cause of the pain and the breathlessness (which breathlessness might itself be caused in fact by such pain). Pain would be compatible with a DVT but not necessarily diagnostic of it.

74. Dr Draper, the consultant respiratory physician instructed by the Defendant, also gave oral evidence. He agreed with Dr Taggart's oral evidence. If there had been swelling of the left leg on 25th March 2015 Dr Iqbal should have had further investigations carried out beyond a d-dimer, but otherwise there was no criticism to be made of the carrying out simply of a d-dimer test.

75. In his report, Dr Draper stated a Wells score was a tool used for patients presenting in an emergency context (as opposed to in clinic), and said breach of duty should be denied and that he considered the Claimant did not actually have a DVT or PE when he presented to Dr Iqbal on 25th March 2015 because the d-dimer was low.

76. In the joint statement of respiratory experts he had agreed with Dr Taggart that there appeared to have been a limited consideration of the possibility of DVT by Dr Iqbal, and that he should have risk assessed the Claimant as at moderate or high risk and requested a CTPA. However, he said in his oral evidence that he felt he had been swayed by the strength of Dr Taggart's views at that time, since withdrawn, and placed too much emphasis on the Wells scoring system, which was not directly used in clinics, and on coming up with hypothetical scores as opposed to focusing on Dr Iqbal's clinical judgment in the circumstances actually presented to him, which was what was most important.

77. Dr Draper agreed with the evidence of Dr Taggart withdrawing earlier criticisms of Dr Iqbal. He emphasised there was a difference between what happens in A&E and what can reasonably be expected to happen at a regular appointment in a respiratory clinic such as that held by Dr Iqbal on 25th March 2015. He said that it was very unusual to see a patient walk into a clinic with a DVT – he had not seen it in over 30 years in practice. Clinical intuition on the day was, he said, more important than technical scoring systems.

78. Breathlessness, about which he was asked in cross-examination, could have been due to other factors, he said, particularly after a previous PE. The d-dimer test required by Dr Iqbal having returned with a score of 165 on 25th March 2015, having previously been 225 on 15th March 2015, meant that, in his view it was inconceivable that the Claimant was having a DVT then.

79. Both doctors gave evidence in what I regard as a reasonable, measured and convincing way. Both departed to an extent from earlier written views, most notably Dr Taggart, but having heard the oral evidence of Dr Iqbal he had clearly thought very carefully about matters overnight during the break in his evidence, conscious of his overriding duty to the court, and made clear that he now had no criticism whatever of Dr Iqbal's conduct on 25th March 2015.

80. In my judgment, based on the Claimant's own expert evidence of Dr Taggart - a consultant respiratory physician like Dr Iqbal – as well as that of Dr Draper, there was no breach of duty by Dr Iqbal on 25th March 2015.

<u>Findings in Relation to alleged breach of duty on 8th December 2015</u>

81. The Claimant was diagnosed with a thrombosis on 13th April 2015. Both parties are agreed that he had, appropriately, been prescribed the anti-coagulant warfarin, which was then, appropriately, changed in September 2015 to Apixaban, another anti-coagulant. Lifetime anticoagulation is agreed to be appropriate following a second PE with a view to preventing recurrence.
82. By 8th December 2015 the Claimant had been on anti-coagulation for almost 8 months. When he attended Dr Chandra's clinic on that date, he reported two episodes of problematic nose bleeds.

83. Dr Chandra reduced the dose of Apixaban at that time from 5mg twice daily to 2.5mg twice daily. His evidence was that he did this because that was the manufacturer's applicable dose after a period of 6 months following an episode of VTE and also the level of dose recommended after that period in the relevant NICE guidance. Both the manufacturer's sheet and the NICE guidance on the use of apixaban for the treatment and secondary prevention of DVT and PE dated 4th June 2015 are before the court. Dr Chandra was also

aware of the underlying Amplify-Extend study which was published in February 2013, which formed exhibit DC6 to his first witness statement, which confirmed that a dose of 2.5mg twice a day was as effective in reducing recurrent VTE as 5mg twice a day, but resulted in a lower incidence of bleeding.

84. The professional opinion of Dr Hampton, consultant haematologist called by the Claimant, was that the dose of Apixaban should not have been reduced on 8th December 2015 from 5mg twice daily to 2.5mg twice daily, and that it was not in keeping with the practice of a reasonable haematologist.

85. The basis for this view was in essence that the lesser 2.5mg dose was the appropriate preventative dose for a patient who had had just one PE, not two, as the Claimant is agreed to have had prior to 8th December 2015.

86. This was a view he maintained in cross-examination, saying that the guidance did not really cover those who had had two episodes of DVT (referring as they did to a dose to prevent recurrence of DVT following an "initial" VTE) and that a high chance of recurrence meant reasonable clinicians should and would have given a higher 5mg twice daily dose. He conceded, however, that the NICE guidelines before the court did not say the dose should not be reduced on account of two previous DVTs, which he said was his view although he could point to no other evidence to support it. He suggested at one point that other guidelines may offer support to his view, but accepted that neither he nor anyone else had produced anything which actually showed this. He went on to say that though it was his own view he had no evidence to support it.

87. Dr Hampton said that the Amplify-Extend study was not shown to include those who had had two episodes of DVT so that it showed merely that 2.5mg twice daily was as effective as 5mg twice daily in those with just one previous episode. It only included those who were considered to be at clinical equipoise, that is to say in whom there was uncertainty about the balance of risks and benefits of continued anticoagulation (as set out in paragraph 4.5 of the NICE guidelines), and someone who had had two episodes of VTE was not in an area of any doubt because it was known they would need anticoagulation for life.

88. He considered that the risk of recurrence was higher so that a higher preventative dose should be given.

89. As Dr Hampton said, if a person had a second episode whilst on anti-coagulation that would obviously not mean the dose should be reduced. However, it is agreed that the Claimant was not on anticoagulation at the time of the second episode and the question is whether it was reasonable to reduce the dose at the time in those circumstances.

90. The Claimant's treatment for the first episode (in November 2014) had ended and only after a second episode is someone put on lifetime anticoagulation to prevent recurrence. The question is whether after that second episode had itself been treated at 5mg twice daily a reduction to 2.5mg twice daily could properly have been made by Dr Chandra.

91. The professional view of Dr Gomez, the consultant haematologist instructed by the Defendant, was that 2.5mg twice daily was the appropriate level of dose of Apixaban to prevent recurrence of DVT. Here there was a VTE treated in April 2015. After a treatment period of 6 months at the treatment dose of 5mg twice daily it was appropriate to reduce the dose to 2.5mg twice daily. This was because the Amplify-Extend study showed such a

2.5mg dose to be just as effective in preventing recurrent thrombosis as 5mg, as well as being as specified in the manufacturer's instructions in accordance with the drug licence. Whether someone like the Claimant had had multiple episodes of DVT previously or not (when not on anti-coagulation), it was, he said, still to prevent a recurrence following the ending of the treatment dose. As it was shown to be just as effective for that purpose at 2.5mg twice daily as at 5mg twice daily it was entirely proper to reduce the ongoing medication to that dose, which also had the benefit of reducing the risk of bleeding. Indeed, put another way, you would otherwise be increasing the risk of bleeding with no corresponding benefit.

92. The applicable NICE guidelines referred to a twice daily dose of 5mg Apixaban being given in respect of an initial event, followed after 6 months of such *treatment* by a 2.5mg *preventative* dose. The "initial event" in the NICE guidelines was considered by both Dr Chandra and Dr Gomez to refer to that which was being treated (by the 5mg dose). Here, the "initial event" was that diagnosed in April 2015 which resulted in the 5mg treatment dose, to then be followed by the 2.5mg dose.

93. It is fair to say that drilling down into the Appendix to the relevant paper it was indicated at paragraph 1.1.2(2)(c) that "subjects with indications for long-term treatment with a VKA such as ….Multiple episodes of unprovoked DVT or PE" were excluded from the study.

94. However, I accept the evidence of Dr Gomez on this issue, and by reference to that evidence, the NICE guidelines, the manufacturer's information sheet, and the apparent basis for the recommendations, I do not consider Dr Chandra fell beneath the standard of care reasonably to be expected of a competent consultant haematologist in the situation that existed when the Claimant presented in his clinic on 8th December 2015 when he reduced the Apixaban dose to 2.5mg twice per day.

95. First, I cannot see why the fact that someone is at increased risk of a DVT means the appropriate preventative, therapeutic, dose needs to be increased from the level considered effective in preventing recurrence to a higher dose. Following a second episode of DVT whilst not on anti-coagulants, a proper *treatment* dose of 5mg twice daily should be given for 6 months to treat the DVT, but I see no logical evidence-based reason why, as Dr Hampton suggested, the appropriate dose aimed at *preventing recurrence* in the future must be kept at that higher *treatment* dose amount. If 2.5mg twice daily is shown to have the same *preventative* effect as 5mg twice daily there is no reason why, when that DVT has been treated, the *preventative* dose has to be increased to (ie maintained at) that different level.

96. Second, Dr Hampton could not point to any evidence to show the lower dose of 2.5mg twice daily is not as effective in patients who have had more than one DVT whilst off anti-coagulation previously.

97. The fact that those who were at the time of the study not in the category of 'clinical equipoise' (ie who obviously needed anti-coagulation without any uncertainty about risks and benefits of it, as referred to in paragraph 4.5 of the NICE guidelines, and whom it was at that time not known would not suffer medically by a reduction in the dose to 2.5mg – the whole point of the study being to discover whether that was as effective in preventing recurrence of DVT as a 5mg dose or not) does not appear to me to mean it is not as effective in reducing the risk of recurrence in them.

98. Third, to reduce the dose to 2.5mg twice daily is in line with the manufacturer's information sheet.

99. Fourth, it is in line with the applicable NICE guidelines before the court.

100. Each of these documents specified as at 8th December 2015 that, following the completion of 6 months of Apixaban treatment at 5mg twice daily, 2.5mg twice daily should be given to prevent recurrent DVT and PE. Neither of them anywhere state that this reduced dose is not appropriate where the uncoagulated patient has previously had more than one DVT or PE, which one would expect to see if that was the case. The manufacturer's sheet, which is also referred to in the NICE guidance, does refer to a lower dose of 2.5mg twice daily being used for secondary purposes 6 months after an "initial" VTE, but I accept Dr Gomez's view that this is a reference to the treatment dose being the applicable one for the 6 month period after the VTE in question and does not mean it is inapplicable merely because there was a previous DVT for which a treatment dose had been given. Had it not been intended for patients who had had more than one off-coagulation DVT I would expect that to be clearly spelt out.

101. At paragraph 4.5 of the NICE guidelines it was stated that the NICE Appraisal Committee concluded that, "the AMPLIFY trials had informed the market authorisation for apixaban, and as such were appropriate to make a recommendation *for the whole population* covered by the marketing authorisation". My emphasis.

102. Without qualification, the NICE Appraisal Committee expressly said at the end of paragraph 4.6 of the Guidance that it, "concluded that over the long term the lower dose [of 2.5mg] was as effective as the higher dose in preventing VTE, with a lower risk of bleeding".

103. In all the circumstances, it is not possible on the balance of probabilities to find the Defendant to have been in breach of its duty by Dr Chandra reducing the Claimant's Apixaban to a 2.5mg twice daily preventive dose on 8th December 2015 in place of the higher, treatment, dose, and I do not do so.

<u>Causation in relation to the Failures on the 15th March 2015</u>

104. As noted in paragraph 21 above, it is admitted in the Amended Defence – as it has been from the start – that the medical staff's failure to estimate a Wells score and undertake imaging on the Claimant's presentation at the A&E Department of the Hospital on 15th March 2015 was in breach of the Defendant's duty to the Claimant.

105. The question that has to be determined in relation to this is whether it has been proved on the balance of probabilities that it was causative of any injury – that is to say, whether the Claimant's suffering has, or will be, increased by reason of those failures.

106. In order to determine this, it has first to be decided whether the Claimant was suffering a DVT/PE on 15th March 2015, so that had imaging been carried out he would have been diagnosed as suffering that at that time and treated for it. If he should have been so treated, I must then go on to determine whether the failure to give such treatment at that stage would have made a difference to his suffering or prognosis.

107. As with other issues, these questions have to be determined by the court on the balance of probabilities. Sympathetic though I, of course, am to the Claimant in relation to his suffering, particularly in the light of the admission of breach of duty on 15th March 2015 which must obviously raise concerns in the Claimant's mind, as well as in that of the court, I must nonetheless be careful to determine these distinct questions only on the basis of the evidence relating to them that is before me.

108. The triage notes for the 15th March 2015 record the Claimant presenting in A&E on that date complaining of shortness of breath and pain behind the left knee/leg, and he was noted to have stopped warfarin the previous week, following a PE in November 2014. The handwritten note of the same date records him as complaining of left calf pain and also left-sided chest pain, but with no cough or haemoptysis (coughing up of blood). In A&E (unlike normal practice, on the evidence, in regular clinic appointments) his legs were measured using a tape-measure and the left calf was at that time found to be 2cm larger in circumference than the right calf. It was also recorded as tender on palpation.

109. The NICE clinical guideline 144, applicable on 15th March 2015, which it is agreed should have been followed at that time, meant that if a DVT was suspected on presentation of a patient in A&E his Wells score should have been calculated. This fell to be calculated in that event by the use of the scoring tables at pages 13 (table 1 - for DVT) and 14 (table 2 - for PE) of the guideline. These tables in each case gave a specified number of scored points to be awarded for particular factors that were present. The detail of this can be seen from the tables themselves, which are before the court.

110. This score was not calculated in A&E on 15th March, which, as I have indicated, is an admitted breach of duty. The evidence of Dr Hampton, consultant haematologist called by the Claimant, was (as set out in his part of the joint statement based on the Claimant's agenda) that retrospectively calculating the score now – as part of the evidence going to whether the Claimant was suffering a DVT/PE then – the position is as follows.

111. On the DVT table a score of 2 points was in his view appropriate, because the Claimant scored 1 point for tenderness of the leg and 1 point for a "previously documented DVT" (a 2cm swelling of it not adding anything because it was less than the 3cm swelling referred to in the table). On the PE table a score of 7.5 was in his view appropriate because there were clinical signs and symptoms of DVT resulting in 3 points, a "previous DVT/PE" giving 1.5 points, and 3 points for an alternative diagnosis being less likely than PE.

112. Dr Gomez, consultant haematologist called by the Defendant, considered that on the DVT table only 1 point should be awarded because there was no "previously documented DVT", which meant it had to have been radiologically confirmed, which it was not here.

113. However, so far as that goes, it is accepted the Claimant had had a PE in November 2014 which was in all likelihood caused by a DVT. The fact the position was not *radiologically* confirmed (which is not referred to in the table) does not in my judgment mean a point should not be added for this in the current exercise, the previous PE being clearly documented in clinical notes, and indeed a fact, notwithstanding the absence of radiographical results which would add nothing. The table scores are here being used to inform the court not as to breach of duty on 15th March (which is admitted) but on the question of whether a DVT/PE was actually suffered at that time. Though not radiologically confirmed, there is accepted to have been a previous PE (likely caused by DVT) in November 2014.

114. Dr Gomez accepted that in the PE table 3 points were to be given for clinical signs and symptoms of DVT and 1.5 points for "a DVT/PE" previously, but did not accept an alternative diagnosis was less likely than PE, making therefore 4.5 points in all.

115. The question of whether an alternative diagnosis was less likely than PE leads back, of course, to the question the court must, on all the evidence, determine, of whether the Claimant was suffering from a PE/DVT on 15th March 2015. Dr Gomez agreed, however, that on any basis the Claimant would have had a PE Wells score of at least 4.5.

116. All this means that a DVT and PE was on 15th March 'likely' in the sense of representing a sufficient risk to require further investigation, the threshold for this in the DVT table 1 being 2 points, and the threshold for this in the PE table being more than 4 points. However, it does not of course mean 'likely' in the sense that the Claimant was on the balance of probabilities actually suffering a DVT or PE at that time, though it is part of the evidence to be considered.

117. I bear carefully in mind of course that the Claimant did on 15th March 2015 have apparent left calf swelling of 2cm (though below the 3cm threshold of the DVT Wells table for swelling to be scored for), and left calf pain.

118. He also had shortness of breath (recorded in the triage notes as being for a "few days"), and had just come off warfarin.

119. This is notwithstanding that Dr Taggart considered the shortness of breath and calf pain might equally be explained by something else when the Claimant presented on 25th March, as referred to above.

120. Dr Hampton accepted that the Claimant's d-dimer was normal when tested on 15th March 2015. The reading was 225, which was normal on any view. As stated above, a d-dimer test involves testing a person's blood and a higher d-dimer level than normal would suggest the presence of a blood clot, but it was normal here.

121. He also accepted that the false negative rate for a d-dimer was on the papers (which were primarily those by Wells and by Gibson) shown to be only around 10%, as Dr Gomez stated.

122. Dr Hampton suggested, however, in his oral evidence that despite the statistical 90% accuracy of the d-dimer test result being normal indicating there was no such condition (a false negative being recorded in research in only around 10% of cases), the clinical features the Claimant had presented with on 15th March made a DVT/PE more likely than not in his case.

123. He relied on the shortness of breath, the left calf pain/tenderness and apparent swelling, which were otherwise unexplained and the fact the Claimant had recently come off warfarin, which he considered may mean the risk of a DVT was increased in a short period after coming off that anti-coagulation on the basis of the normal level of blood coagulation having been supressed and then bouncing up above its normal level.

124. However, he accepted that around 30% of patients who had previously had a PE may have breathlessness still from that and that it may get worse over time. He also had to accept that

risk bounce-back following anti-coagulation drugs being discontinued had not been demonstrated anywhere.

125. Obviously, anyone presenting at A&E with the symptoms the Claimant had may have a DVT/PE – and that is the reason why a d-dimer test or (as would have been appropriate here), imaging is carried out, to either rule out or confirm it. The question for the court is whether it is probable it was in fact the case here on 15th March 2015 or not.

126. The Claimant's d-dimer was normal at 225. Even though imaging should have been done, that is an important factor.

127. Statistical evidence in the papers before the court indicates, as is accepted, that only about 10% of people with a normal d-dimer in fact have a DVT, as I have said.

128. The defence suggest this therefore in itself means that on the balance of probabilities the Claimant, with such a d-dimer result, did not have a DVT on 15th March.

129. On the face of it, that is an attractive proposition. However, that seems to me to somewhat over-state the position. Though the d-dimer being normal is one part of the evidence before the court it does not seem to me to in itself be wholly determinative here. The true question seems to me to be whether on the balance of probabilities the Claimant was one of the 10% of those in the statistics who have a DVT notwithstanding a normal d-dimer result.

130. I do not accept the idea of 'bounce-back' increased risk of coagulation following the discontinuation of warfarin has been reliably demonstrated and discount that as a relevant factor.

131. The Claimant's symptoms and history on 15th March 2015, and his Wells score as retrospectively assessed, are relevant, as potentially is the fact that it is not disputed the Claimant did have a DVT by 15th April 2015.

132. The Wells score is only a basis for further investigation being warranted, however.

133. Breathlessness may on the evidence occur as a result of deconditioning or otherwise following a DVT/PE and not be indicative of another one, as both the Claimant's expert witnesses Dr Taggart (who was clear that this may have been the case even at the later date of 25th March 2015) and Dr Hampton accepted. Dr Hampton believed the Claimant had made a good recovery from the November 2014 DVT, including in relation to his breathing. However, the Claimant had in fact previously attended A&E on 25th November 2014 and 7th December 2014 with symptoms (although nothing untoward was found, about which no complaint is made), his GP notes in January 2015 referred to him being "still not right" and on 6th March 2015 the GP notes stated that he was "*still* struggling with SOB" (emphasis added), not that it was something entirely new.

134. In relation to the measurement of the Claimant's left calf, Dr Taggart also pointed out that in 2008 the left leg was recorded as being 2cm larger than the right leg when nothing abnormal was found. The left leg being larger than the right leg may well accordingly in fact have been normal.

135. So one is left in essence with the pain/tenderness in the left calf, though in conjunction with the breathlessness from some cause which could have been from a further DVT/PE, the fact that he previously had a PE, and that one had occurred again by 13th April 2015.

136. In relation to the latter point, the vascular surgeons - Prof Hands instructed by the Claimant and Prof Torella by the Defendant - are agreed that a DVT probably developed at any time within the period of 3-4 weeks preceding diagnosis on 13th April 2015. The extremity of that bracket, working backwards, comes close to 15th March, in which case, taking this as not a completely precise bracket, it could have occurred by then. Of course, that does not mean it had done, and it also means that it could have occurred after 15th March, which comprises the bulk of the window.

137. I should note at this point that in her report of July 2019 Prof Hands said that on 15th March 2015, on the basis of her understanding, "A 2 level Wells score would have been at least 2, making a DVT 'probable'. On the balance of probabilities the DVT was present at this time". However, the parties are agreed (on the basis of the relevant expert evidence) that whilst a Wells score above a certain level would make a DVT "likely" (which is the phrase used in the NICE clinical guideline 144) that does not mean "probable", but "requiring further investigation". Aside from this comment and her reference to Wells scores (though not herself a respiratory or haematological expert), Prof Hands referred in her reports, like Dr Hampton, to the Claimant's history and to the symptoms that were present on 15th March 2015.

138. However, there is another important factor. On 25th March the Claimant's d-dimer was again tested and found to be just 165. This was not only still normal, but it had actually fallen, though he had not received any anti-coagulation in the meantime.

139. Dr Hampton described the normal d-dimer results as "problematical" in the context of the Claimant having a DVT/PE. He conceded that, as is the case, when the Claimant was indisputably found to have a DVT/PE on 13th April 2015 his d-dimer was raised to an abnormal level (of 485), even though not as high as he might have expected. It is also to be noted in passing that when the Claimant had his first PE in November 2014 his d-dimer was abnormal at 501. The force of this is not affected by the fact that it was lower when he had a subsequent DVT/PE in April 2016, as he was at that time on anticoagulation.

140. However, not only was the Claimant's d-dimer normal on 15th and 25th March 2015, but it had actually fallen between those dates. It was, as I have noted, 225 on 15th March and 165 on 25th March.

141. As Dr Gomez said, if the Claimant had a recurrent PE or DVT on 15th March, which, of course was untreated, it is difficult to see how the d-dimer could thereafter have been falling given that, had there been a clot on 15th March, there would be more d-dimer in the blood as the clot burden increased over time.

142. Dr Gomez's clear and firm evidence was that the falling of the d-dimer was completely inconsistent with an untreated DVT for the reasons he stated. Dr Hampton said that he did not know whether this was so or not.

143. Under cross-examination Dr Gomez stated that there was no way that the d-dimer could have gone down with an untreated acute thrombosis for the reasons he gave.

144. This evidence was clear and logically based and was not shaken under test. I accept it.

145. I should add for completeness that this was also the view of Dr Draper who stated in cross-examination that with the d-dimer falling from 225 on 15th March 2015 to 165 on 25th March 2015 it was inconceivable the Claimant had had a DVT by then.

146. Prof Hands, though asked about it in oral evidence, was unable to express a view, it being outside her area of expertise. She, as a vascular surgeon, was called essentially as a causation expert, though I have taken all her evidence into account (as I have also that of Prof Torella).

147. It is true that the Claimant presented at A&E on 15th March 2015 with breathlessness, calf pain and apparent swelling, having had a PE before. It is completely understandable the Claimant should have been concerned that he was having another PE on that occasion (as he had been before when all was found well). His concern, as well as that of others, retrospectively that this was so is no doubt added to, equally understandably, by the fact that everyone agrees there was a PE detected in April 2015 when he underwent a CTPA.

148. However, I am not satisfied on the balance of probabilities that the Claimant did have a DVT/PE on 15th March 2015.

149. Symptoms such as breathlessness could on the evidence commonly occur following a PE such as the Claimant had in November 2015, and indeed could increase, as Dr Hampton said. Though the triage notes for 15.3.15 say "SOB few days", *continuing* breathlessness was previously recorded in the GP notes for 6th March 2015. Pain in the leg can be due to various causes, as Dr Taggart pointed out. The Claimant was understandably anxious and had returned to A&E previously when a further DVT/PE was properly ruled out.

150. I have taken the Claimant's presentation and history on 15th March 2015 fully into account, but do not consider that, considering all the evidence, including the normal d-dimer, which had fallen even lower in the 'normal' band by 25th March 2015, it is likely he was suffering from a DVT or PE on 15th March 2015 (or on 25th March).

<u>Conclusion</u>

151. It is not in the circumstances necessary to go on to consider other issues of causation on the basis of a number of possible permutations, given my conclusions on the above issues based on the evidence before me.

152. For the reasons I have given, despite the considerable sympathy I feel for the Claimant, the claim must be dismissed.