Neutral Citation Number: [2021] EWHC 643 (QB)

Case No: QB-2017-003152

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 19/03/2021

Before :

MRS JUSTICE EADY

- -

Between :

TRACEY ANNE NEGUS (1)
DEBORAH BAMBRIDGE (2)
(executors of the estate of MRS TRACY ANN NEILL deceased) **Claimants**

- and –

GUY'S AND ST THOMAS' NHS FOUNDATION TRUST **Defendant**

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Mr David Tyack of counsel (instructed by **Girlings Personal Injury Claims Ltd**) for the **Claimants**
Mr Matthew Barnes of counsel (instructed by **Bevan Brittan**) for the **Defendant**

Hearing dates: 1-9 March 2021

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Approved Judgment

This judgment was handed down by the Judge remotely by circulation to the parties' representatives by email and release to Bailii. The date and time for hand-down is deemed to be 10.30 am on Friday 15 March 2021

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MRS JUSTICE EADY DBE

The Honourable Mrs Justice Eady:

Introduction

1. This is a clinical negligence claim relating to aortic valve replacement surgery performed on Mrs Tracy Ann Neill ("TN"), at St Thomas' Hospital, London, on 5 March 2014. Proceedings were commenced by TN in 2017 but, after her death on 29 January 2020, the claim has been pursued by the Claimants as executors of TN's estate.

2. The Defendant is the NHS Trust responsible for the control and management of St Thomas' Hospital; it is vicariously liable for the acts and omissions of its clinical staff. The operation on 5 March 2014 was performed by Mr Sabetai, a Consultant Cardiothoracic Surgeon employed by the Defendant; it involved the implantation of a 19mm mechanical valve. The Claimants say that was negligent as a larger sized valve should have been implanted, albeit that would have required an aortic root enlargement ("ARE"); they further contend there was a failure to properly advise TN as to the risks arising from the implantation of a smaller valve, alternatively in performing an ARE.

3. Subsequently, on 18 March 2015, TN underwent re-do surgery at King's College Hospital, during which an ARE was undertaken and a larger, 23 mm, valve inserted. There were difficulties during the re-do operation and complications during TN's post-operative recovery; after her discharge, TN's condition continued to deteriorate and she died of heart failure on 29 January 2020. The Claimants say the re-do operation, and TN's subsequent deterioration and death, would have been avoided had an ARE been performed on 5 March 2014 and a larger valve implanted.

4. Quantum has been agreed between the parties, subject to questions of breach of duty and causation, which remain in dispute. Specifically, the parties agree that the issues I have to determine are as follows:

    i) Was it negligent to implant a 19mm mechanical reduced valve during TN's surgery on 5 March 2014?

    ii) Alternatively, was there a negligent failure to explain, as part of the consent process, that the largest possible valve should be implanted to avoid the risk of cardiac dysfunction (although this would involve an ARE, which was more complicated and involved higher risk)? If so, would TN have opted to undergo ARE?

    iii) If an attempt had been made to implant a larger valve, would TN have suffered the same complications that she did during surgery on 18 March 2015?

    iv) Did the failure to implant a 21mm valve cause the cardiac dysfunction requiring re-do surgery on 18 March 2015, with associated complications, and TN's subsequent death on 29 January 2020?

5. Due to the continuing need to reduce transmission of the coronavirus, during the trial of this matter the in-person days were kept to a minimum, with the remainder of the hearing taking place remotely by MS Teams. Public access to the hearing, whether in-person or remote, was enabled by video-link and details for that access were published in the cause-list each day, thus securing the principle of open justice. No significant

issues of connectivity or audibility were experienced; such minor issues as arose were addressed during the course of the hearing.

Evidence

6. In support of the Claimants' case, I read the statements of TN and of her mother, Mrs Irene Lodge (adduced pursuant to Civil Evidence Act Notices as both had died since making their statements) and of Ms Lucy Neill, TN's daughter, who was not required to attend for cross-examination. I also heard from the Claimants, Ms Tracy Negus and Ms Deborah Bambridge (both friends of TN and executors of her estate), and from TN's husband, Mr Leslie Neill, and her son Mr Toby Neill; all confirmed their witness statements and were asked questions by counsel for the Defendant. For the Defendant, evidence was adduced from Mr Michael Sabetai, and from Mr Ian Cummings, Speciality Trainee in cardiothoracic surgery (who completed the consent form with TN prior to her 5 March 2014 operation), and Mr James Roxburgh, Consultant Cardiac Surgeon employed by the Defendant (now retired from clinical practice); each confirmed their written statements and answered questions by counsel for the Claimant.

7. Both sides also relied on expert opinion evidence. Although expert reports had been obtained from other specialisms, all agreed that the issues between the parties were to be determined by reference to the evidence of the cardiothoracic experts: for the Claimant, that evidence was adduced from Professor Wallwork, Emeritus Professor in Cardiothoracic Surgery and Chairman of Royal Papworth Hospital NHS Trust; for the Defendant, from Mr Lawrence, Consultant Cardiothoracic Surgeon, UCL Hospitals NHS Trust and St Barts NHS Trust. In advance of the hearing, I had read the reports from Professor Wallwork and Mr Lawrence, together with Professor Wallwork's answers to CPR Part 35 questions, and their Joint Statement, and both experts attended to give oral evidence at trial.

8. The trial bundle comprised some 3,611 pages and additional documents were adduced by the experts during the course of the hearing (for which permission was given at the time).

The Facts

9. At the time of the operation on 5 March 2014, TN, who was born on 6 December 1966, was 47. She was a qualified nurse but worked for Macmillan Cancer Support in a public information role. TN was married to Leslie Neill and they had two children, Lucy, then 19, and Toby, then 15. By all accounts, prior to the events with which I am concerned, TN was an active and sociable woman, who enjoyed life and had good relationships with her family and friends. Her later deterioration was plainly very difficult for both TN and for those close to her; on any view, TN's death was very sad and I do not lose sight of the personal tragedy that lies behind this case.

10. In her teens, TN had suffered from Hodgkin's Lymphoma and she underwent mediastinal radiotherapy for this when she was 17. This treatment had been successful in that TN had then been in remission, with no further relapses. In 2003, however, investigations revealed problems with her aortic valve, related to TN's early radiotherapy, and she was thereafter monitored, having an echocardiogram every two years.

11. Between 2008 to early 2014, TN underwent various surgical procedures, including risk reducing mastectomies and subsequent breast reconstruction surgery, during which she had suffered an infection of her wound. TN had also had gastric band surgery and had later required re-do breast reconstruction surgery.

12. In January 2014, TN suffered a heart attack. She was diagnosed as having significant aortic stenosis and was referred to St Thomas' Hospital and to the care of Mr Sabetai.

13. Aortic stenosis describes the situation where the aortic valve does not function properly, leading to a narrowing of the valve and, thereby, reduced blood flow through the valve. It is common ground that, when aortic stenosis becomes symptomatic, there is a 2-year survival rate of below 50% and an aortic valve replacement is therefore indicated.

14. Mr Sabetai met with TN on 7 February 2014. As well as the information forwarded to him on referral and from an echocardiogram undertaken a few days earlier, he took a full history from TN. Mr Sabetai concluded that the aortic valve stenosis had progressed to a stage where it was necessary for TN to undergo aortic valve replacement surgery. This was because TN's aortic valve had become fibrotic, as a result of the radiotherapy she had undergone in her teens, and had increasingly calcified over the years, such that the valve leaflets, which open and close during heart function to let blood flow through, were not functioning correctly. The result was that blood flow through the valve was impeded, which was reflected in a peak gradient (which reflects the amount of resistance there is to the blood flow through the valve) of 97mmHg; that showed that the pressure on the ventricular side of the valve was significantly higher than on the aortic side of the valve.

15. Mr Sabetai advised TN that if she did not undergo surgery she would continue to experience symptoms of shortness of breath and chest pain and would eventually suffer heart failure and death; the benefits of surgery would be to reduce her symptoms and prolong her life. Mr Sabetai also advised TN of various risks associated with aortic valve replacement surgery, in particular given her past medical history. Although his normal practice would be to quote a risk of mortality and morbidity for this procedure of between 1% and 2%, he considered TN's history of mediastinal radiotherapy and previous experience of wound infection increased the risk of surgery in her case and therefore advised of a mortality risk of 2% and a morbidity risk of 2%.

16. Having been advised as to the risks and benefits of surgery, TN said that she wished to proceed with an aortic valve replacement. Mr Sabetai then discussed with her the type of valve he would insert.

17. In an aortic valve replacement, a surgeon removes a patient's native valve and implants either a mechanical or a tissue prosthetic valve. Mechanical valves are made with synthetic materials and have a long lifespan but require the patient to take blood thinning medication for life, to prevent blood clotting. Tissue valves are made from animal tissue and do not require the patient to take blood thinning medication, but they have a shorter lifespan and are likely to require replacement if implanted in younger patients. In TN's case, given her relatively young age, Mr Sabetai recommended that a mechanical valve be used. He recalled that TN, having been a nurse, had some knowledge of the different types of valve and agreed this recommendation.

18. Prosthetic valves come in different sizes; the smallest available for an adult is a 19mm, the largest 29mm. The size of valve that can be implanted depends, in principle, on the size of the annulus (the aperture at the root of the aorta). It is, however, possible to implant a larger valve by enlarging the aortic root. To perform an ARE, a surgeon would make an incision into the aortic root and then suture in a patch, resulting in an increase in the diameter of the annulus. An ARE is, however, a relatively rare procedure. As Mr Roxburgh – who was involved in the collection of national data for the Society for Cardiothoracic Surgery from 2003 to 2018 – explained, ARE surgery was not included in any of the datasets in which he was involved because it was so rarely performed.

19. The apparent rarity of an ARE is also evinced by the anecdotal evidence of the witnesses at trial. For example, in his 27 years' of clinical experience, Mr Roxburgh had only performed one ARE (when the patient's aortic root was too small for the smallest prosthesis), which would approximate to around 0.1% of the aortic valve replacement operations undertaken by Mr Roxburgh. For the Defendant, Mr Lawrence had looked at the figures for Barts Heart Centre over the past 10 years and had found only 8 ARE operations (of the type relevant to this case) had been performed, none of which had been carried out by surgeons under the age of 50. Given the number of aortic valve replacements carried out at Barts (for the years 2018 and 2019, there were an average of 251.5), this would equate to ARE operations being undertaken in only 0.32% of cases. Although the Claimant's expert, Prof Wallwork, had more experience of undertaking AREs, over his entire clinical career he had only performed around 20. Given that Prof Wallwork can be estimated to have undertaken some 4,000 aortic valve replacements in his career, that would suggest AREs were limited to 0.5% of his cases.

20. In TN's case, the pre-operative echocardiogram indicated that she had a small aortic annulus, with a diameter of around 18mm, and that the valve surface area was $0.7cm^2$. Mr Sabetai also noted that TN was of short stature (1.56m) but had a body mass index of 32.9 and a body surface area ("BSA") of $1.8m^2$.

21. As was common ground before me, the size of prosthetic valve to be used is not something that can be determined prior to surgery. As Mr Sabetai explained (and it was not in dispute), it is standard practice to ascertain the size of valve which can be inserted in the aortic root once it has been decalcified and is ready to take the replacement valve. The surgeon will then use a sizer to find the size of valve which fits the aortic root at the level of the annulus, and try the next size up, and the next size down, to see which is the best possible fit. As was volunteered by Mr Sabetai, and agreed by both Prof Wallwork and Mr Lawrence, it is also standard practice to insert the largest size of valve which can safely be inserted at operation.

22. There are, further, different brands of mechanical valves and different designs. Relevant for present purposes is the distinction between valves that are placed just above the annulus in the aortic root – so called "top hat" or "supra-annular" valves – and valves that are placed within the annulus – "intra-annular" valves. An important difference is that, owing to their positioning, where the ostia are situated close to the annulus, top hat valves can entail an increased risk of blocking the beginning of the coronary arteries (the coronary ostia) and thus causing a heart attack.

23. I accept Mr Sabetai's evidence that, pre-operatively, he considered it most likely that he would be able to implant a 21mm valve in TN's case. This was because, although

the estimated size of the aortic annulus was 18mm, once the native valve was excised and the aortic root decalcified, the annulus is often larger than that predicted by a pre-operative echocardiogram. If he was unable to insert a 21mm valve, however, Mr Sabetai had in mind that he would be able to insert a 19mm valve. As for the make and design of valve, he was aware of the models available and would make that decision during surgery.

24. I have already described how the surgeon uses a sizer to determine the best fit, but regard would also be had to the *effective orifice area* ("the EOA") produced by the particular prosthetic valve under consideration. Mr Sabetai described the EOA as "*a complex calculation based on the geometric orifice area and the blood flow patterns through the valve*" (the geometric orifice area being the space provided by the leaflets of the valve when open). That calculation was detailed by Mr Lawrence, who explained that to calculate the EOA of a valve, one has to measure three things: the radius of the channel of the left ventricle leading to the aortic annulus (the left ventricular outflow tract or "LVOT" – thus the "*LVOT Radius*"); the velocity of the blood passing through the LVOT ("*LVOT Velocity*"); and the velocity of the blood passing through the aortic valve ("*Valve Velocity*"). The EOA of a valve is then calculated as follows:

$$EOA = \frac{\pi\ (LVOT\ Radius)^2\ (LVOT\ Velocity)}{Valve\ Velocity}$$

25. In practice, as Mr Sabetai explained, there are sources of information to which a surgeon can (and will) refer to check the EOA achieved by a particular valve. In 2014, it was Mr Sabetai's practice to use an application (or "app") on his 'phone called *Cardiovalve*.

26. In any event, prior to the operation, Mr Sabetai did not discuss with TN the size, particular brand or design of the valve to be implanted. As he explained, he would not do so as the decision as to the particular size and make of valve would have to be determined intra-operatively.

27. Mr Sabetai agrees that, prior to surgery, he did not discuss with TN the possibility of undertaking an ARE to permit the insertion of a larger prosthetic valve. I accept his evidence that this was not because he was incapable of performing such a procedure but, whilst he had in mind the possibility that he might need to undertake an ARE, this would only be something he would do if he found it was necessary intra-operatively. In making this finding, I note that whilst Mr Sabetai had been appointed to his Consultant post at St Thomas' on 1 February 2012, he had been undertaking aortic valve replacements since 2003 and had previously performed two AREs (once due to infection of the aortic root, and once because the annulus was too small for the smallest size of valve (19mm) to be fitted). Given his comparative experience (and see my earlier observations on the relative rarity of the procedure), I accept that Mr Sabetai had both the skill and experience to carry out an ARE if he considered it was appropriate to do so. What is at issue in this case is not Mr Sabetai's ability but his judgement.

28. Following the discussion on 7 February 2014, Mr Sabetai referred TN for a cardiac CT scan, which took place on 10 February 2014. The results of the CT scan did not cause Mr Sabetai to change his advice and TN was duly booked in for surgery on 5 March 2014.

29. On 4 March 2014, Mr Cummings, working at St Thomas' hospital as a Specialist Registrar, completed the consent form with TN. This recorded the advice as to risks as previously communicated by Mr Sabetai, and included the following statements:

> "I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.
>
> I have been told about additional procedures which may become necessary during my treatment."

TN raised no concerns and signed the consent form.

30. Surgery took place on 5 March 2014. Having excised TN's native valve, Mr Sabetai was able to de-calcify the aortic root, which he found to be small and heavily fibrotic. The pericardium (the sac containing the heart and the roots of the great vessels supplying the heart) was also fibrotic and the calcification extended into the coronary ostia, which were very close to the aortic valve annulus. Given the position of the coronary ostia, Mr Sabetai took the view that he could not insert a top hat valve but would need to use an intra-annular valve. Having used a sizer, he further concluded that he would be unable to fit a 21mm valve but would, instead, have to implant a 19mm valve. Mr Sabetai considered that the best option would be a 19mm *Carbomedics Reduced* valve, which is what he proceeded to fit.

31. It was Mr Sabetai's evidence that he would have considered, intra-operatively, whether it was appropriate to perform an ARE in these circumstances. Had he concluded this was necessary, he would have taken the view that – for consent purposes - it amounted to a procedure necessary to save a patient's life or prevent serious harm to their health. Mr Sabetai stated, however, that he did not consider it would be appropriate to undertake an ARE in TN's case, explaining (I take these passages from his witness statement but his responses in cross-examination were to similar effect):

> "77. … the small size of the aortic annulus and the fact that the calcification extended in and around the rather small coronary ostia were both contra-indications to performing aortic root enlargement, rendering the enlargement very challenging and of high risk. In order to enlarge the aortic root I would need to use a segment of pericardium to bridge the gap where incisions had been made in the aortic root to widen it, to allow it to take a larger valve. Where the aortic root is densely fibrotic it makes it very difficult to safely enlarge the root, because the tissue is not supple and accepting of a large valve.
>
> 78. In addition, the closeness of the origin of both the coronary arteries to the annulus would have created an additional risk factor. A large valve sitting close to the origin of the coronary arteries creates a risk of blocking the coronary arteries causing a heart attack. Attempting to insert a large size aortic valve into a small size aortic root also creates a risk that the aorta could tear, which could cause a risk of substantial damage to the aorta and bleeding as a result.

> 79. Taking into account all these factors, it was necessary to weigh the risk of performing aortic root enlargement, set against a risk of PPM resulting from having to insert a 19mm valve which was smaller than I had expected to be able to insert. Taking into account the risks identified both pre and intra-operatively in connection with aortic root enlargement, and taking into account the fact that I expected Tracy Neill to have a good outcome with a 19mm Carbomedics Reduced prosthesis, I concluded that this was the safest and most appropriate option. The 19mm Carbomedics Reduced prosthesis represented a significant improvement in EOA compared to Tracy Neill's native valve and was the largest valve I could safely insert."

32. The reference to "PPM" is to a concept known as "*patient-prosthesis mismatch*". While there was a dispute between the parties as to its clinical relevance, it was not in dispute that there exists in the literature the concept of PPM. PPM refers to the situation where the prosthetic valve used is too small for the patient's size. As mechanical prosthetic valves include a case that has to be inserted into the annulus (the actual operative part of the valve will thus tend to be smaller than the native valve), PPM is not uncommon (in studies its prevalence ranges from 8% to 80%, but an estimated overall prevalence of 44% has been cited, based on a meta-analysis of 34 observational studies in 2012; see *R. Bilkhu et al 'Patient-prosthesis mismatch following aortic valve replacement*' *Heart 2019;105:s28-s33*). PPM is defined by what is known as the *indexed effective orifice area* of a valve (the "iEOA"), which is determined by dividing the EOA of the valve (in cm^2) by the BSA of the patient (in m^2). In the literature, PPM is standardly described as severe where a valve has an iEOA below 0.65; as moderate where a valve has an iEOA between 0.65 and 0.85; and as absent where a valve has an iEOA greater than 0.85.

33. There is a dispute between the parties as to what extent the presence of PPM is relevant to clinical outcomes and, therefore, whether the additional risk of an ARE (in order to be able to insert a larger valve) ought to be taken to avoid at least severe PPM (and whether this should be discussed with a patient pre-operatively). At this stage, however, I am concerned with the circumstances facing Mr Sabetai on 5 March 2014, and the factors that informed the decisions he made.

34. For the reasons I have already explained, I again accept Mr Sabetai's evidence that he had in mind the possibility of undertaking an ARE during TN's surgery: although AREs are rarely performed, he had experience of the procedure and had previously demonstrated that he could, and would, undertake an ARE if he considered it necessary. The fact that he had not raised this possibility with TN does not undermine my conclusion in this regard; I accept Mr Sabetai's evidence that he did not see this as an elective procedure but one that would need to be undertaken if necessary to save life or prevent harm, and thus covered by the general consent given by TN. As for his decision not to undertake an ARE, I find that Mr Sabetai was particularly concerned about the potential uncertainties of embarking upon this procedure in TN's case, given the fibrotic nature the aortic root, and was unconvinced that an ARE would actually allow for a larger valve, explaining as follows:

> "… A fibrotic root … is tougher and by definition less pliable. Even by doing an aortic root enlargement, the root may enlarge

> in unpredictable ways. It does not necessarily mean it is going to be a symmetrical enlargement which may not necessarily lead to the desirable result. …" (transcript day2/140)

35. I also accept Mr Sabetai's evidence that he considered that the 19mm *Carbomedics Reduced* valve achieved a significant improvement over TN's natural valve. Using the *Cardiovalve* app, he understood the valve could achieve an EOA of 1.2cm^2, which he calculated to be an improvement on TN's natural valve of 71%. Moreover, if that was correct then, given his calculation of TN's BSA, the iEOA would be 0.67cm^2/m^2 (falling within the moderate category of PPM). I further accept Mr Sabetai's evidence that he saw this in the context of the more general benefit provided by the prosthetic valve: whilst the stenosis afflicting TN's natural valve would only get worse, the leaflets in the prosthesis should allow for an unimpeded flow of blood through the valve.

36. There is a dispute between the parties as to whether, in fact, Mr Sabetai should have taken the EOA of the 19mm *Carbomedics Reduced* valve to be 1.2cm^2. Although initially accepting this figure in the joint statement, shortly before trial, Prof Wallwork drew attention to the manufacturer's own literature, which gave an EOA for this model of only 1cm^2 and questioned the reliability of the figure of 1.2cm^2. Some time was spent during the hearing, tracing through the sources cited for these figures. What is, however, clear to me is that it was entirely reasonable for Mr Sabetai to work on the basis that he was implanting a valve that gave an EOA of 1.2cm^2. That was the figure given on the entirely reputable app he was using; it was also the figure cited in the publication *Echopedia* and was based on a reputable study published in 2003. An EOA of 1.2cm^2 for the 19mm *Carbomedics Reduced* valve was also given by another app – *Echocalc* – which was developed on behalf of the British Society of Echocardiography. There was a competent and reasonable body of opinion that supported Mr Sabetai's understanding in this regard.

37. The 19mm valve having been successfully implanted, TN's surgery was uneventful; she made an uncomplicated recovery and was discharged home on 11 March 2014.

38. On 28 March 2014, TN was admitted to her local hospital with an episode of atrial fibrillation. An echocardiogram was performed, which showed a peak gradient across the aortic valve of 72mmHg. Mr Sabetai did not consider this was of particular concern as atrial fibrillation is not uncommon after surgery (and could explain the peak gradient) and generally resolves with time.

39. In any event, TN was referred back to St Thomas' and a further echocardiogram was undertaken on 6 May 2014. At that time, TN was not experiencing any symptoms and the echocardiogram showed a peak gradient of 61mmHg and a mean gradient of 39mmHg; an EOA of 0.8 was also noted. Mr Sabetai saw TN again on 10 June 2014, noting that, although she had gained almost 3kg in weight, she was entirely asymptomatic and seemed to have recovered well. Referring to the results of the May echocardiogram, Mr Sabetai considered the 39mmHg mean gradient was consistent with a 19mm mechanical prosthesis and the peak gradient of 61mmHg was a significant improvement on the 97mmHg recorded on the pre-operative echocardiogram of February 2014. Happy with TN's progress, Mr Sabetai discharged her from his clinic and had no further involvement in TN's treatment.

40. Towards the end of the summer of 2014, however, TN began to again suffer from shortness of breath. In her statement, TN explained that her renewed symptoms had started after a walking holiday in September; in her Particulars of Claim, her difficulties were attributed to climbing the stairs (albeit, also in September 2014). Although TN had returned to work in early June 2014, her job was largely sedentary in nature and I accept she may have been less active for some time after her surgery. TN would, however, have had to climb the stairs in her home since her discharge from hospital and it is apparent that she was largely symptom-free for the spring and summer after her operation.

41. On 1 October 2014, TN was reviewed at King's College Hospital and a further echocardiogram was performed, which showed a peak gradient of 83mmHg and a mean gradient of 49mmHg; a significant deterioration from May. In his witness statement, Mr Sabetai hypothesised that something must have occurred since he had met with TN on 10 June 2014 to cause the functioning of the aortic valve to deteriorate:

> "I consider this was possibly due to either tissue beginning to grow across the valve, which can happen from three months post-operatively. Alternatively it is possible that the valve leaflets were not opening properly, which was impeding blood flow across the valve."

42. In any event, TN was referred to Prof Olaf Wendler, Professor of Cardiothoracic Surgery at King's College Hospital and a further echocardiogram was undertaken on 5 December 2014, which recorded a peak gradient of 80mmHg, noting that the prosthetic valve was "*well seated and opens well*" and that "*No obvious thrombus or pannus [was] visualised*" (meaning that no obvious blood clots or tissue could be seen on the valve).

43. TN was seen by Prof Wendler in clinic on 16 January 2015; he considered she was suffering patient-prosthetic mismatch and needed a re-do aortic valve replacement, as a larger valve was required for her heart to function properly. In his post-clinic letter, Prof Wendler advised:

> "I totally agree that this lady suffers from symptoms of prosthetic-patient mismatch. I have discussed this with her today and explained that the aim of the next time surgery will be to implant a larger heart valve. This may only be possible by enlarging the aortic root or even replacing the aortic root using a mechanical composite. I quoted her a risk of 2-3% for this operation and she is keen to go ahead with surgery."

44. On 18 March 2015, Prof Wendler performed the re-do operation. He explanted the valve Mr Sabetai had inserted and then decalcified the annulus and performed an ARE. Prof Wendler first sought to insert a 23mm top hat mechanical valve but, whilst her coronary ostia had appeared not to be obstructed, it was not possible to successfully wean TN off bypass and Prof Wendler therefore decided to replace the 23mm top hat valve with a 23mm tissue valve. TN was then taken off bypass but her left ventricular function was severely reduced and she had to be placed on a life support machine.

45. TN was unconscious and in intensive care for around four weeks. During that time she had to have further open heart surgery; first to remove a large amount of blood that had

collected around her heart, second to resuscitate her following cardiac arrest. TN was discharged from King's College Hospital on 8 May 2015 and admitted to a local hospital for rehabilitation. She eventually returned home on 28 August 2015.

46. TN's progress after her return home was very slow and she had a number of further admissions to hospital and continued to experience serious health problems. TN ultimately developed progressive heart failure and died on 29 January 2020.

The Relevant Legal Principles

47. In determining the issues that arise in this case, there is no dispute as to the approach I am to take as a matter of law. Where treatment of a patient by a medical practitioner is in question, the test is as expressed by McNair J in *Bolam v Friern Hospital Management Committee* [1957] 1 W.L.R. 582 at p. 587 ("the *Bolam* test"):

> "… [a medical practitioner] 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. …"

At p. 589, McNair J summarised the question to be asked as being whether the practitioner had:

> "… fallen below a standard of practice recognised as proper by a competent reasonable body of opinion?"

48. In *Bolitho v City and Hackney Health Authority* [1998] A.C. 232, however, Lord Browne-Wilkinson highlighted the references in the *Bolam* test to "a *responsible* body of medical men" and "a competent *reasonable* body of medical opinion" (emphases added), making clear that it would not be sufficient merely to show there was a genuine belief amongst experts that the practitioner had acted in accordance with respectable medical practice:

> "… the court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis. In particular in cases involving, as they so often do, the weighing of risks against benefits, the judge before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter." (see pp. 241-242)

49. Thus, whilst respect is to be afforded to the views of experts in a particular field, the determination of breach of duty in clinical negligence cases remains firmly a matter for the court. Negligence will only be established if the treatment undertaken was outside the range of professional opinion, *but* that is subject to the court being satisfied that the views within that range are capable of withstanding logical analysis.

50. The *Bolam* test does not apply to the issue of consent, where a different approach is adopted. Where a medical practitioner is advising a patient as to the risks or benefits of a form of treatment, the test is as articulated by the Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; [2015] A.C. 1430, see the Judgment of Lords Kerr and Reid (with whom Lords Neuberger, Clarke, Wilson and Hodge agreed), at paragraph 87:

> "An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

51. At paragraph 89, Lords Kerr and Reid further explained that the materiality of a particular risk will not be something that can 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."

52. At paragraph 90, Lords Kerr and Reid also reflected upon the nature of the dialogue between doctor and patient as part of the doctor's advisory role:

> "… 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."

53. Turning to causation, where allegedly negligent medical treatment is concerned, standard principles apply and the starting position will be the ordinary "*but for*" test: the claimant must establish on balance of probability that *but for* the defendant's negligence, she would not have suffered the loss complained of. As Lord Bingham observed in *Chester v Afshar* [2004] UKHL 41; [2005] 1 A.C. 134:

> "8. … in the ordinary run of cases, satisfying the "but for" test is a necessary if not a sufficient condition of establishing causation."

54. The more difficult cases are those in which there are multiple causes for the injury; as Lord Toulson JSC observed in *Williams v Bermuda Hospitals Board* [2016] UKPC 4; [2016] A.C. 888:

> "40. A claim will fail if the most that can be said is that the claimant's injury is likely to have been caused by one or more of a number of disparate factors, one of which was attributable to a wrongful act or omission of the defendant: *Wilsher v Essex Area Health Authority* [1988] AC 1074. In such a case the claimant will not have shown as a matter of probability that the factor attributable to the defendant caused the injury, or was one of two or more factors which operated cumulatively to cause it. …"

55. Where, however, a claimant can establish that the act of negligence contributed to her injury in a manner that was more than negligible – where it is found to be a material contribution to the injury – the *but for* test will be satisfied (see per Lord Toulson JSC in *Williams* at paragraph 47).

56. Where alleged negligent medical advice is concerned, the law has recognised a narrow departure from standard causation principles. The case of *Chester v Afshar* concerned the question whether causation was made out where a claimant would have delayed a procedure, had they received the appropriate advice; the House of Lords held that causation was made out in such a situation, even though the likelihood of the harm occurring at a later stage was no different (see paragraph 87 in the speech of Lord Hope). The ratio of *Chester v Afshar* was explained by Simon LJ in *Correia v University Hospital of North Staffordshire NHS Trust* [2017] EWCA Civ 356, as follows:

> "24. ... If there has been a negligent failure to warn of a particular risk from an operation and the injury is intimately connected to the duty to warn, then the injury is to be regarded as being caused by the breach of the duty to warn; and this to be regarded as a modest departure from established principle of causation."

57. *Chester v Afshar* will not apply where the court concludes, on the facts, that it is probable that, even if warned about the risks, the claimant would have proceeded with the operation as and when she did, see *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307; [2018] P.I.Q.R. P18. Moreover, as Simon LJ went on to observe in *Correia*:

> "28. … The crucial finding in *Chester v. Afshar* was that, if warned of the risk, the claimant would have deferred the operation. In contrast, in the present case, it was not the appellant's case that she would not have had the operation, or would have deferred it or have gone to another surgeon. There was no such contention in either her Protocol Letter, the appellant's pleading or her witness statement. Nor was it part of

> her evidence. To some extent, the reason for this omission is the artificial nature of the appellant's argument on this part of the case. Nevertheless, it seems to me that if a claimant is to rely on the exceptional principle of causation established by *Chester v. Afshar*, it is necessary to plead the point and support it by evidence. In the event, the material evidence, such as it was, did not support the appellant's case on this aspect of the causation argument. … the appellant did not say she would not have had the surgery if advised differently."

The Expert Evidence

58. Given the nature of the allegations made in this claim and the legal tests I am to apply, it is unsurprising that the parties' focus was on the expert cardiothoracic evidence. Before turning to the detail, I make the following observations relating to the testimony of the expert witnesses in this case.

59. First, both Prof Wallwork (for the Claimant) and Mr Lawrence (for the Defendant) are acknowledged experts, who have enjoyed considerable success in their careers and are to be afforded due respect. Although Prof Wallwork retired from clinical practice as a Consultant Cardiothoracic Surgeon in 2011 (and last performed an aortic valve replacement in June 2011), I have no doubt that he continues to be aware of the standards appropriate to his specialism, not least given his role as Chairman of the Royal Papworth Hospital. And, whilst Mr Lawrence does not recall having personally undertaken an ARE, I have no doubt as to his understanding of that procedure, still less as to his skill and experience relating to aortic valve replacement surgery more generally.

60. It was, furthermore, apparent that both experts hold themselves to very high standards and are (not without justification) confident as to the professional judgements they make. At times, however, this was a characteristic that was unhelpful in this case, leading the expert witnesses to lose sight of the test that is to be applied in these proceedings.

61. For instance, at paragraph 5.1 of his report, Mr Lawrence spoke of ARE as a "*procedure now relegated to the history books*", a view that I do not find is shared by all reasonable bodies of opinion (as demonstrated not only by the evidence of Prof Wallwork, but also by the view plainly taken by Prof Wendler and by the testimony of Mr Sabetai in these proceedings). ARE may be a relative rarity, and there may be competing views as to the risks and benefits of the procedure, but I do not find that it can properly be characterised as "*relegated to the history books*". Similarly, in stating (at paragraph 6.2 of his report) that "*The issue of PPM was effectively resolved in a landmark paper by Tirone David (Is Prosthesis-Patient Mismatch a Clinically Relevant Entity? Tirone E. David. Circulation. 2005;111 :3186-3187, Originally published June 20, 2005 (Reference 2))*", Mr Lawrence may have been stating his own opinion on the subject, but the literature does not suggest that all reasonable bodies of opinion in this area would agree (see, e.g., *Philippe Pibarot and Jean G. Dumesnil* '*The Relevance of Prosthesis-patient Mismatch After Aortic Valve Replacement*' *Nat Clin Pract Cardiovasc Med. 2008;5(12):764-765*; and *R. Bilkhu et al* '*Patient-prosthesis mismatch following aortic valve replacement*' *Heart 2019;105:s28-s33*).

62. More significantly, however, the Claimant's case was founded upon a number of allegations of negligence that, upon exploration with Prof Wallwork in cross-examination, were demonstrated to be based upon a particular opinion as to how things should be done, rather than allowing for possible alternative views that might still be recognised as proper by a competent, reasonable body of opinion. Whilst experts should, of course, make concessions where it is appropriate to do so, the concern in this case is that so many of the allegations levied against Mr Sabetai appear to have been based on the application of the wrong test. I have already referred to the challenge taken (late in the day) to Mr Sabetai's reliance on the EOA figure given for the 19mm *Carbomedics Reduced* valve by an entirely reputable app regularly used by surgeons undertaking aortic valve replacements. Prof Wallwork had, however, initially also criticised the suturing technique used by Mr Sabetai (in the pre-action protocol letter of 22 July 2016 this was characterised as giving rise to a breach of duty in the failure to recognise this as "*likely to constrict the valve area for insertion of the prosthetic valve*."), explaining (in cross-examination, see transcript day 3/203-204) that this was because it was not a technique that *he* would use, albeit that he acknowledged it was "*perfectly acceptable*". Whilst this was not a point pursued in the Particulars of Claim, this was an allegation of breach of duty that should never properly have been made.

63. Having sought to provide a general insight into the expert testimony in this case, I will return to that evidence in my discussion of the issues I am required to determine, below. Ultimately, however, the testing of the expert evidence at trial has made my task easier in that it has demonstrated that the real issues between the parties were far narrower than originally appeared to be the case.

Discussion and Conclusions

Issue i): Was it negligent to implant a 19mm mechanical reduced valve during TN's surgery on 5 March 2014?

64. Although the Particulars of Claim suggested that issue was taken with the implantation of a *mechanical*, rather than a *tissue*, valve (see sub-paragraphs 55 (i) (l),(m) and (n)) , that was not an allegation pursued at trial. Indeed, given TN's age, there were obvious reasons for not using a tissue valve in her case and it is both troubling that this allegation appeared in the particulars of negligence and that Prof Wallwork was unable to explain why that should have occurred. By the hearing, the Claimant's case had also moved to allow that it was *not* negligent for Mr Sabetai not to implant a 23mm valve (contrary to the suggestion made at sub-paragraph 55(i) (l) of the Particulars of Claim). Indeed, by trial, it was clear that the real issue between the parties was whether Mr Sabetai had acted in breach of the duty he owed to TN in failing to carry out an ARE so as to accommodate a valve that was larger than the 19mm valve implanted (whether the alternative valve was 21mm or 23mm). As the Claimants had acknowledged in the Particulars of Claim, however, that was a procedure that could "*give rise to complications*" (sub-paragraph 55(i) (m)).

65. Allowing that an ARE might lead to increased risks (in cross-examination, Prof Wallwork accepted it would be reasonable to double the risks associated with TN's aortic valve replacement if an ARE was to be undertaken; see transcript day 3/262), it is necessary to consider the nature of those risks when weighed against the potential benefits. Specifically, given those risks and benefits, did Mr Sabetai reach a view that

both accorded with sound medical practice and can be seen to have had a logical basis in TN's case?

66. For the Claimant it is said that the benefits of an ARE were obvious. By implanting a 19mm valve, Mr Sabetai put TN at risk of PPM and the likelihood of a re-do operation (which would itself give rise to increased risks). As the only way of implanting a larger valve would be to undertake an ARE, this should have been done and the factors identified by Mr Sabetai were not, in reality, contraindications to an ARE and did not provide a rational basis for choosing, instead, to implant a smaller valve.

67. There was considerable debate between the parties at trial as to the clinical relevance of PPM. Having reviewed the literature to which I was taken, I conclude as follows:

(1) PPM is a calculation not a condition. There is evidence to suggest that it occurs in a large number of patients after an aortic valve replacement. The issue is not whether PPM exists, but whether it is clinically significant.

(2) There is evidence of a correlation between severe PPM and poor outcomes. It is unclear whether PPM is itself a cause or merely a surrogate marker of such outcomes, but there is a body of opinion to the effect that efforts should be made to prevent severe PPM.

(3) There is, further, a view expressed in the literature that PPM (even if moderate) might be prevented by undertaking an ARE (in order to insert a larger valve). It is recognised, however, that an ARE is a more complex procedure and will add extra operative time (in particular, cardiopulmonary bypass and aortic cross clamp times), which might negatively impact outcomes during surgery.

68. Although questioning the particular utility of PPM as a concept, Mr Lawrence accepted that all surgeons would seek to insert the valve that would give the best cardiac output – the flow through the valve – for the patient. Expressing the point that way, it seems to me that the difference between the parties reduces: achieving the best EOA in TN's case would mitigate the risk of PPM and would be likely to result in better cardiac output.

69. Returning to the decision that Mr Sabetai had to take, accepting (as I do) that he was able to reasonably conclude that, by using a *Carbomedics Reduced* 19mm valve, he could implant a valve that would achieve an EOA of 1.2cm^2, this was a case falling towards the higher end of the moderate category of PPM; it was not a case of severe PPM. Moreover, whilst the implantation of a 21mm valve might have had a better EOA, as Prof Wallwork accepted in cross-examination (transcript day 3/249-250), Mr Sabetai was entitled to conclude that the 19mm *Carbomedics Reduced* valve would be a significant improvement on TN's natural valve. Indeed, having regard to the various ways in which he accepted it would amount to an improvement over the natural valve, and applying the test of what a reasonable body of surgeons might do, Prof Wallwork conceded that it was, in those circumstances, reasonable to implant the 19mm reduced valve (transcript day 3/252).

70. Accepting (as Prof Wallwork thus did) that a reasonable body of surgeons might determine that it was reasonable to implant a 19mm valve, was it logical for Mr Sabetai to choose to take this course rather than opt to undertake an ARE, and seek to implant

a larger valve, in TN's case? Although it was agreed that an ARE would double the risks associated with the surgery, Mr Sabetai accepted this would have been necessary if any larger sized valve was to have been implanted. Moreover, whilst an ARE is not a common procedure, that does not mean it is something that will never need to be undertaken. Even if the comparative rarity of the operation might suggest that most surgeons would consider that the risks of an ARE will generally outweigh the possible benefits, the question for me must be whether a rational decision was taken in this particular case.

71. As I have already found, the reason Mr Sabetai did not undertake an ARE in TN's case was because he was concerned about the greater risks involved and was not satisfied that he could thereby achieve the implantation of a larger valve with any greater benefit for TN. As Prof Wallwork accepted, the radiation damage TN had suffered had left her with a thicker, fibrotic aortic root, which lacked flexibility. The disagreement between the experts was as to the clinical implication of this for a possible ARE. Mr Lawrence agreed with Mr Sabetai that the fibrosis of the root would have made root surgery more difficult; Prof Wallwork considered that "*Fibrosis of the root may not necessarily have made the operation more difficult*", observing that it might in fact have made the insertion of the patch and the sutures easier (Joint Statement, Question 6). That said, when asked, in cross-examination, whether it might have been reasonable for Mr Sabetai to conclude that the fibrotic nature of the root might have made it more difficult to get stitches through and to get them to hold, Prof Wallwork agreed that, whilst this might not have been his view, this would have been reasonable (transcript day 3/274-5).

72. Returning to the view Mr Sabetai said he had reached at the time, I am satisfied this was a reasonable exercise of his professional judgement in the circumstances. Whilst some surgeons (perhaps Prof Wallwork) might have concluded that the risk was worth taking, I am satisfied that a responsible body of cardiothoracic surgeons faced with those circumstances, would have taken the same view as Mr Sabetai. That was, moreover, an entirely logical view, balancing the benefits and risks in TN's case. Mr Sabetai reasonably concluded that it was doubtful whether performing an ARE would allow him to insert a larger valve (and the extent to which this would be of benefit to TN) and, given the increased risks it would involve, it was rational for him to adopt the alternative, entirely reasonable course, of inserting the 19mm valve that could be implanted without such risks.

73. The answer to the first question is, therefore, that it was not negligent for Mr Sabetai to implant a 19mm mechanical reduced valve during TN's surgery on 5 March 2014.

Issue ii): Was there a negligent failure to explain, as part of the consent process, that the largest possible valve should be implanted to avoid the risk of cardiac dysfunction, although this would involve an ARE, which was more complicated and involved higher risk. If so, would TN have opted to undergo ARE?

74. The test I am to apply to the issue of consent requires me to look beyond the opinion of a reasonable body of surgeons and to ask whether, in the relevant circumstances, a reasonable person in TN's position would be likely to attach significance to the risk, or whether Mr Sabetai was, or should reasonably have been, aware that TN would be likely to attach significance to it. In answering that question, however, I do not consider it irrelevant to remind myself of that which is common ground between the experts. As

Prof Wallwork and Mr Lawrence agreed, it would not be standard practice for cardiothoracic surgeons to discuss with patients the size of the prosthetic valve or the risk of PPM before surgery (Joint Statement, Questions 4, 5, 8 and 9). That is largely because these are matters that can only be decided during the operation, but it is also explicable because these are technical matters, which (per *Montgomery*) most patients could not reasonably be expected to grasp.

75. More than that, it was Prof Wallwork's view that the only omission in TN's case was in the failure to mention (as part of the consenting process) the risk of an ARE having to be carried out. Prof Wallwork stated that this should have been presented as a decision that would need to be taken by the surgeon during the operation; his evidence was that TN ought to have been warned of this risk (transcript day 3/283-4).

76. Mr Sabetai's view, in contrast, was that it was unnecessary to specifically warn TN of the risk that he might need to undertake an ARE as this was something that would be covered by the more general consent TN had given for procedures necessary to save life or prevent serious harm to health.

77. I take into account that there were certain unusual features to TN's case that might have been relevant when determining what was material when advising as to the risks involved in her surgery. TN had been a nurse and had previously undergone a number of surgical procedures; she might reasonably have been seen as someone with a greater appreciation of the potential risks and benefits of particular choices (certainly, that was something Mr Sabetai was aware of in his discussion with TN of the benefits of a mechanical, rather than a tissue valve). TN was also a woman of small stature with a higher than recommended body mass index. Although not a contra-indication for aortic root surgery, it did mean that the valve that might fit the aortic root in her case might give rise to a mismatch given her body size (a point that could be explained without using the more technical definition of PPM). More than that, although it would be unusual to undertake an ARE during aortic valve replacement surgery, it was Mr Sabetai's evidence that this was something he had in mind in TN's case, although it was something he would only do if he concluded – intra-operatively – that the circumstances required it.

78. Given the particular circumstances of TN's case, I am prepared to accept that Mr Sabetai was under a limited duty to warn her of the possible risk that he might need to undertake an ARE during the valve replacement operation, which would double the risks involved in that surgery. I do not, however, consider that duty extended to presenting TN with the various possible choices that might arise intra-operatively and could only properly be determined by the surgeon at that stage. The decision that Mr Sabetai had to make during surgery was not simply whether to implant a 19mm valve without undertaking an ARE, or to perform an ARE and then implant a larger valve; he had to exercise judgement at various stages of the surgery to determine what choices were open to him to achieve the best outcome for TN (what size of valve he could fit once he had de-calcified the root; what make and design of valve he should use; what outcome that could achieve; whether he could be assured of achieving a better outcome if he could insert a different, larger valve; whether any risks involved in doing so (in particular, if that involved undertaking an ARE) were justified; and so on). This involved highly technical decision-making, requiring a specialist-level of understanding and experience; it would be false to represent this as a simple or bilinear choice of treatment.

79. As for the question of causation in this regard, there is no proper evidential basis on which I could conclude that any breach of duty in terms of the advice given to TN would have made any difference. Had Mr Sabetai warned TN of the possible risk that he might need to perform an ARE, I consider it more likely than not that TN would still have consented to surgery. Even if, contrary to the conclusion I have reached, there was an obligation to, in some way, advise TN that an ARE was an alternative form of procedure, there is (contrary to what is required in such a case, see *Correia*) no evidential basis for thinking that TN would have done other than leave it to Mr Sabetai to exercise his professional judgement as required during the operation.

80. My answer to the second question is, therefore, that there was a negligent failure to warn TN, as part of the consent process, of the potential risk that an ARE might have to be undertaken, but there was no breach of duty in failing to go beyond that and to provide the explanation suggested by this question. Moreover, had Mr Sabetai advised TN as he should have done, I am satisfied (in either event) that it would have made no difference to the outcome.

81. Given my findings on breach of duty, it is strictly unnecessary for me to determine the third and fourth questions, which raise issues of causation. In case I am wrong on the first issue, however, I have proceeded to explain the conclusions I would otherwise have reached on causation.

Issue iii): If an attempt had been made to implant a larger valve, would TN have suffered the same complications that she did during surgery on 18 March 2015?

82. In addressing this first issue relating to causation, I bear in mind that I only have a limited amount of information regarding the March 2015 re-do operation and I have not heard from Prof Wendler. What is apparent, however, is that many of the concerns that Mr Sabetai considered to weigh against carrying out an ARE appear to have been borne out by what occurred during that later surgery.

83. Having undertaken an ARE, Prof Wendler was apparently still unable to fit a larger sized intra-annular valve (as Prof Wallwork accepted in cross-examination, the tissue annulus diameter achieved following the ARE was not much wider than it had been before, see transcript day 3/271). He initially sought to implant a 23mm mechanical top-hat valve, which would fit just above the annulus, but this appears to have led to an obstruction of the coronary ostia (hence the inability to take TN off bypass) and had to be replaced by a 23mm tissue valve. Although there is no criticism of Prof Wendler in this regard, it was common ground before me that the 23mm tissue valve was not an ideal replacement. First, because a tissue valve would not be recommended for a patient of TN's age. Second, because it could only be fitted by crimping the valve, thus losing the benefit of the larger size in any event.

84. For the Claimants it is said that the difficulties experienced by Prof Wendler can be attributed to the fact that this was a re-do operation, which is likely to give rise to greater difficulties. There is, however, no indication in Prof Wendler's notes of any particular issue arising from the fact that this was a re-do operation. The evidence before me suggests only that the ARE undertaken in TN's case was, as Mr Sabetai had feared, of little utility, providing no benefit (as Prof Wallwork conceded in cross-examination, it would still have been unlikely that a 21mm standard valve could have been implanted; transcript day 3/272), with substantially more risk.

85. In the circumstances, my answer to the third question would be that any attempt to implant a larger valve on 5 March 2014 (which would have necessitated undertaking an ARE) would most likely have caused TN to suffer the same complications as she did during surgery on 18 March 2015.

Issue iv): Did the failure to implant a 21mm valve cause the cardiac dysfunction requiring re-do surgery on 18 March 2015, with associated complications and TN's subsequent death on 29 January 2020?

86. The dispute between the parties in this regard really relates to the question whether the need for the re-do surgery arose from the PPM in this case or whether there was some other explanation for the apparent failure of the 19mm valve. Notwithstanding my answer to issue iii), this question assumes that it would have been possible to implant a 21mm valve, having safely undertaken an ARE, on 5 March 2014.

87. For the Claimants it is contended that TN's clinical course after the insertion of the 19mm valve was consistent with the poor outcomes associated with PPM. Although TN only reported becoming symptomatic in September 2014, this was consistent with her having been relatively inactive during her convalescent period and it cannot be assumed that the 19mm valve had ever provided an appropriate outcome. Certainly, when TN was reviewed by Prof Wendler, he considered this was a case of severe PPM, and there was no evidence of mechanical failure of the valve or of tissue overgrowth, which might otherwise explain the higher gradients. Indeed, the echocardiogram in December 2014, had reported that no tissue overgrowth was visible and the leaflets of the valve were working well, and Prof Wendler had recorded no issues in either respect during surgery on 18 March 2015.

88. In general, I can accept that the more likely explanation for the difficulties TN experienced might seem to arise from the fact that a smaller valve had been implanted than was right for her body size. She started experiencing the kind of outcome often associated with PPM and Mr Sabetai had not advised TN of the risks of mechanical failure or of tissue overgrowth pre-operatively, because he had not considered these likely outcomes. Without more, it might seem more likely than not that it was the small size of the valve that gave rise to the need for the re-do surgery.

89. In this case, however, there is more to the evidence than I have just described. First, there is the fact that TN was asymptomatic for nearly half a year after the implantation of the 19mm valve (the atrial fibrillation she had suffered was not unexpected after valve replacement surgery and she was asymptomatic when she saw Mr Sabetai in June 2014). Secondly, there is the fact that the echocardiogram in May 2014 recorded gradients that did not give rise to any concern. The difference between the position in May (mean gradient of 39mmHg and peak of 61mmHg) and in October and December 2014 (peak gradients of 83mmHg and 80mmHG respectively) is striking; as Mr Lawrence opined, it is consistent with a "*valve whose function has changed over time … the peak velocity gradient increased, so it does imply that there was some change*" (day 4/442). Although, as the Claimants postulated, the gradient might change with activity, the echocardiograms undertaken in TN's case were all taken at rest; in the circumstances, the change recorded in gradient would seem to be consistent with some change in the function of the valve.

90. That said, as the Claimants point out, the December 2014 echocardiogram recorded no visual tissue overgrowth or difficulty with the leaflets of the valve and there is nothing in the operation notes from 18 March 2015 that would suggest that either were observed at that stage. I accept Mr Lawrence's observations, however, that these facts do not tell me very much. Prof Wendler would have been unlikely to spend time investigating the valve that he was intent on removing and a relatively small amount of tissue overgrowth might still cause difficulties with the valve whilst being difficult to see on an echocardiogram (particularly one such as that undertaken in December 2014, which could not provide more accurate transgastric measurements (taken internally rather than externally) as TN had a gastric band fitted).

91. On this final question, therefore, I would not find the Claimants have made out their case. On the balance of probabilities, I cannot be satisfied that the difficulties that required TN's re-do surgery were caused by the size of the valve that had been fitted on 5 March 2014, as opposed to possible tissue overgrowth or mechanical failure, which would better explain the gap in time before TN began to experience adverse symptoms.

Disposal

92. For all the reasons provided, I dismiss this claim.

93. The parties should agree the terms of the order to be made on disposal of this claim. Should there be any outstanding issues requiring further determination by the court, these should be identified in writing within 7 days of the handing down of this Judgment.