Neutral Citation Number: [2021] EWHC 3266 (QB)

Case No: QB-2020-002812

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 07/12/2021

Before :

MASTER SULLIVAN

- -

Between :

FREDERICK HEATH PALING (a child proceeding by his Mother and Litigation Friend MICHELLE PALING)	**Claimant**
- and -	
SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST	**Defendant**

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Rachel Vickers QC (instructed by **Irwin Mitchell LLP**) for the **Claimant**
Charles Bagot QC (instructed by **Browne Jacobson LLP**) for the **Defendant**

Hearing dates: 18 October 2021

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Approved Judgment

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

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MASTER SULLIVAN

Master Sullivan :

1. The claimant brings a clinical negligence claim for serious brain injury said to have been caused due to hypoglycaemia following his birth. The claimant alleges the defendant failed to adequately treat the hypoglycaemia and that led to a brain injury. The defendant has made some limited admissions in respect of breach of duty but causation is in issue between the parties.

2. So far as it is relevant, the claimant's case on causation is that the cognitive, behavioural and emotional deficits from which he suffers were caused by damage to the brain caused by hypoglycaemia in the period shortly after his birth. There is no dispute that he suffered hypoglycaemia, the issue is whether the hypoglycaemia led to any brain injury. The defendant has not yet provided a defence but the letter of response states that "there is no clear evidence of a prolonged period of hypoglycaemia associated with neurological function and there is no evidence in the documents that the claimant suffered permanent brain injury as a result of hypoglycaemia. The claimant is put to proof."

3. The defendant has made an application for the court to order that the claimant, and both his parents, provide a blood sample for the purpose of genetic testing and in default that the claim be stayed. The defendant is of the view that there is possibly a genetic cause for the claimant's condition which is unrelated to the actions of the defendant. The defendant therefore contends that testing and expert evidence in the field of genetics is reasonably required in order for the Court to determine the issue of causation.

4. They seek to obtain evidence prior to service of the defence so that they can plead matters relating to any genetic cause of the claimant's condition in the defence, should it be relevant.

Genetic testing

5. It is not in dispute that in order to undergo genetic testing, a blood sample is needed. The testing proposed, including whole genome sequencing, is not a test looking for specific genes or abnormalities, it would examine the entire genetic sequence to identify any genetic abnormalities, relevant to the issues in this case or not. It would do so for the claimant and for both his parents – this is said to be required as the interpretation of any DNA change in a child relies on comparative analysis with the parents.

6. Before undergoing genetic testing, the claimant's parents would need counselling as to the testing. The testing proposed could identify unrelated matters such as the identification of positive mutations for an adult onset degenerative disease or early onset cancers. It is possible for people to decide to undergo the testing but to restrict what information they are given, so the claimant's parents, if they were to undergo testing, could elect not to be given any information about their own genetic sequencing or the claimant's insofar as it is not relevant to the claim.

The basis of the application

7. The defendant recognises that the claimant has expert evidence which supports his case that the brain injury is caused by the hypoglycaemia. Dr Connolly, Paediatric Neuroradiologist, is noted to be of the opinion that the appearances of the white matter

of the occipital lobes on MRI is, on the balance of probabilities, most likely due to damage to the occipital lobes from a period of neo-natal hypoglycaemia.

8. The defendant relies on and has served expert evidence in support of its application. I set out that evidence in summary. The claimant has not produced any evidence in reply.

9. An MRI scan of the claimant's brain was undertaken on 1 May 2019 for medicolegal purposes. Scans were taken earlier in the course of his treatment. Dr Halpin, Consultant Neuroradiologist, reviewed the scans in a report dated May 2021. He states in conclusion "both scans show no evidence of the sequalae of neonatal hypoglycaemia…the clues to clinically significant neonatal hypoglycaemia lie in focal atrophy, usually seen in the occipital and parietal lobes. There is no focal atrophy in this case…. There is no evidence on these scans of the sequalae of neonatal hypoglycaemia."

10. Dr Rennie, Consultant in Neonatal Medicine, has provided a letter dated 25 January 2021. She states "From the neonatal perspective, based on the information I have seen, Frederick does not have the typical outcome of a baby who sustained brain injury due to symptomatic neonatal hypoglycaemia, and it is clear there is a difference of opinion between experts about his MR brain imaging…In my opinion the court would be assisted in experts in paediatric neurology and genetics when considering the cause of his difficulties."

11. Dr Agrawal, Consultant Paediatric Neurologist, has provided a letter dated 8 June 2021. He states that the claimant clinically presents as someone with Asperger's syndrome, an autistic spectrum disorder. He states the exact cause of Asperger's is unknown and whilst it is largely inherited, the underlying genetics have not been determined conclusively. Environmental factors are also believed to play a role and brain imaging is often normal. He felt that the claimant's clinical profile could only be ascribed to neonatal hypoglycaemia if it is established in court that there is radiological evidence of brain injury. In his opinion, the claimant's clinical profile on the balance of probabilities is secondary to his IUGR[1] and unknown polygenic factors. He does not come across as a child with a specific neurogenic syndrome. He says in cases such as this it is commonplace in his clinical practice to perform whole exome sequencing (WES)[2] which looks at the entire exome of the individual and "has nearly an 85% chance of revealing a genetic diagnosis if one is present."

12. I pause to note here that there has been no genetic testing of the claimant by his treating clinicians, and I understand no suggestion that it should be done.

13. Dr Reardon is a Consultant Clinical Geneticist. He has provided a letter dated 20 May 2021. He starts by commenting on what he describes as several important points so as to put into context the potential role of genetic testing. The family history is normal, the claimant is not dysmorphic, he has no clinical neurological findings of significance, he has no history of ongoing epilepsy and no ongoing issues of recurring hypoglycaemia. Dr Reardon then considers first whether genetic testing would be helpful in determining whether the neonatal seizures the claimant suffered in the relevant neonatal period had a genetic cause, secondly whether the neonatal seizures

[1] Intra uterine growth retardation
[2] the exome is a part of the genome

were caused by hypoglycaemia, but the current problems are the result of a different genetically determined disorder and thirdly that the hypoglycaemia is genetically determined. He is of the opinion that:

i) Perhaps 40% of neonatal seizures have a genetic basis. Most, but not all such patients require ongoing treatment for such disorders. Characteristics of many of those conditions described as genetic forms of neonatal seizures involve significant developmental impairment, often severe mental retardation. In an unbiased population of babies presenting with neonatal seizures, genetic profiling can have a beneficial value in identifying underlying diagnosis and modifying management in about 20% of all cases, including seizure presentation. He was of the view that is not how this claimant presents and on the balance of probability it would be more likely than not to result in negative test results. He also notes that DNA changes can occasionally be found that are uninterpretable as they haven't previously been reported.

ii) If the seizures were caused by hypoglycaemia, the fact of normal family history, non dysmorphic presentation and absence of neurological signs would count against the hypothesis of another genetic disorder. But genetic investigation would offer the possibility of identifying a mild mutation in a known syndromic disorder. However, not many children with the sort of functional deficits the claimant presents with have been analysed and there are no publications to assist with the likelihood of a positive finding.

iii) There are estimates which suggest upwards of 50-60% of neonatal hypoglycaemia may be genetically attributable however the basic facts of this case tend to suggest this generalisation would not apply.

iv) Overall he is of the view that there is a 20-25% chance of identifying a causal mutation for his deficits. He says this is only an estimate but is one which is based on experience and published findings.

14. Dr Reardon states that samples would be required from the claimant and both his parents and he suggests investigations for fragile X expansion, for High Density Chromosomal microarray analysis and for Whole Genome Sequencing. There is no mention of WES testing as suggested by Dr Agrawal.

15. Dr Reardon states that he is of the view that more limited testing would not be appropriate given the somewhat obscure nature of the clinical sequalae claimed in this particular instance. I take that to mean that there is no suspicion of a particular mutation or particular genetic syndrome which would mean testing could be limited and directed to those mutations or syndromes.

16. It can be seen from the evidence that there is a view that the claimant's symptoms do not clearly fit with those expected from neonatal hypoglycaemia and it is thought possible there may be a genetic cause.

17. The defendant's case is that it is in the interests of justice to order the test. The defendant accepts that there is only a 20-25% chance that there will be a genetic cause found, but that is a sufficient chance in the context of a claim which, if successful, is likely to result in the payment of substantial damages and where the invasiveness of the

procedure is limited. It is argued that absent genetic testing, there is a real risk the defendant will be held liable and pay significant damages in circumstances where the defendant may not properly be liable in law.

18. The defendant argues that if there is a genetic diagnosis to be made, there is a nearly 85% probability of the proposed testing establishing it, a very high degree of accuracy and the test is likely to produce a definitive answer as to whether there is a genetic explanation to the cause of the claimant's condition.

19. It accepts that if I order the test to be undertaken, it is probably a novel exercise of the court's inherent jurisdiction. The defendant is not suggesting that such test should be ordered as a matter of routine in clinical negligence cases where causation is in dispute. But, as medical science progresses it is appropriate for the court to adapt to developments through incremental steps and this is an appropriate case to do so.

The claimant's position

20. The claimant, through his litigation friend, his mother, opposes the application. Neither of the claimant's parents wish him, or themselves to undergo genetic testing.

21. The claimant accepts that, in principle, I have jurisdiction to make an order that, unless they all undergo testing, the claim be stayed, but it is argued that the exercise of that jurisdiction would not be appropriate in this case.

22. On a procedural matter, the claimant's case is that the application, made as it is before the defence has been served, is premature. The decision on the need for expert evidence should not be made until the usual time, at a case management conference after close of pleadings. The defendant is able to plead its case that the claimant's condition is not caused by hypoglycaemia, and their experts have been able to put forward alterative possible causation. The events occurred in 2012. The letter of claim was sent in November 2015 and a letter of response in 2016. This application was not made until June 2021. It is time to get to close of pleadings and then determine the way forward in the light of what is pleaded.

23. In response to the substance of the application, the claimant's case is that the defendant's experts appear to have been able to form a view based on the imaging and the claimant's clinical course that the injuries were not caused by hypoglycaemia, and Dr Agrawal is able to attribute the symptoms to Asperger's syndrome. What is proposed is an exploratory exercise and likely to be negative.

24. The claimant questions Dr Reardon's estimate of a 20-25% chance of there being a genetic explanation given he states that in an unbiased population genetic profiling can have a beneficial value in identifying underlying diagnosis and modifying management in about 20% of cases. It is questioned why it is higher than that in this case, especially given the history of hypoglycaemia leading to seizures and the likelihood of the causal nexus between the two. It is stated that one would expect the risk to be lower therefore than in the unbiased population. Equally there is nothing in Dr Reardon's report to suggest that genetic testing will assist in proving or disproving that the claimant has Asperger's as proposed by Dr Agrawal.

25. The claimant points out that if the genetic testing is negative or inconclusive, the defendant's arguments on causation will remain the same. There will still be a dispute on the radiological evidence.

26. Additionally the litigation friend is concerned that for the claimant, having a blood test is an invasive procedure and there are real difficulties in explaining to the claimant and others why he would be going to London to undergo blood tests.

27. The claimant's parents would also rather not undergo test which could potentially reveal information about their and their son's future health.

28. The claimant's case is that therefore the interests of justice do not require the test. The issue in the case is whether the claimant's condition was caused by hypoglycaemia or not. It is not necessary for the defendant prove that the claimant's difficulties were caused by something other than glycaemia. Their case that it was not can be founded on the imaging and the claimant's clinical course. The defendant's evidence suggests a low possibility of a genetic cause being identified.

Should the evidence be allowed before a defence?

29. It seems to me to be a reasonable position for the defendant to take that the evidence should be obtained now rather than effectively adjourning the application to a later date. The issues will remain the same now or after a defence has been served and the claimant is not prejudiced by not yet having a defence. It is clear what the defence is likely to say.

Legal test

30. The defendant says there is no direct authority addressing the issue in this case, but that I should apply the test in *Nield-Moir v Freemen (Re Birtles Deceased) [2018] EWHC* 299 (Ch). The claim was a dispute over the estate of the deceased. The claimant and defendant were sisters. An application was made by the claimant for the defendant to submit to DNA testing to establish whether the defendant was the biological daughter of the deceased. The claimant asked for the defendant to be tested with the intention that she would also be tested and that their DNA would be compared.

31. HHJ Paul Matthews sitting as a judge of the High Court considered that there were three questions to be addressed – (i) whether the test would be sufficiently accurate, (ii) whether the court had jurisdiction, and (iii) whether it ought to make the order in all the circumstances of the case. The evidence was that there was a 97% to 98% chance of the test producing an accurate result as to whether the claimant and defendant were full sisters and, if not and were half sisters, a 50% chance of determining whether the defendant was the biological daughter of the deceased. That was thought to be high enough.

32. In respect of the second part of that test, the court looked by analogy to the common law jurisdiction in personal injury cases to stay a case if medical testing is not undergone. I note that one of the considerations was how severe the invasion of bodily integrity would be and what risks it would carry. In that case it was a mouth swab. No concern of a physical or mental health nature was raised. The value of the evidence to the resolution of the case was also considered.

33. In the third question, whether the court should make the order, matters such as whether it was a fishing expedition, the relevance of the evidence and its value to the case were taken into account.

34. The claimant says that the relevant test I should apply is that set out in *Laycock v Lagoe* [1997] PIQR 518 and is a two stage test. That was a case where the applicant, the defendant to a personal injury claim, applied for the claimant to undergo an MRI scan. The Court of Appeal held that the test applied was first whether the interests of justice require the test which the defendant proposed and second if the answer is yes, whether the claimant has advanced a substantial reason as to why the test should not be undertaken. I note that factors taken into account in these two questions were similar to those is *Birtles.*

35. I was also referred to *Y v Croydon LBC* [2016] 1 WLR 2895, but it seems to me that does not add to what I have to decide. It is a decision again in a slightly different context, considering similar issues and emphasises that the right of a defendant to be able to defend itself in litigation has to be balanced against a claimant's right to personal liberty. That is of course relevant to the issues I have to consider, but does not address the test I should apply.

36. It seems to me that the 2 stage test in *Laycock* is the correct approach. That was a case similar to this where a medical test was being proposed in an injury claim to assist with causation. The accuracy of the test considered in *Birtles* is clearly relevant but that falls to be considered in whether it is in the interest of justice that the test should be undertaken.

(i) *Do the interests of justice require that the claim be stayed if the tests are not undertaken*

37. The factors which are relevant to the question of the interest of justice seem to me to be the likelihood of the test assisting the court in determining the issue in dispute and the risk of injustice if it is not done.

38. This is not a case which is directly analogous to the *Birtles* case. In that case the parameters of the investigation were limited; were the parties full or half sisters, and if half sisters, was the deceased the father of the respondent. Three sets of DNA would be compared for familial ties. An equivalent to that in the genetic context might be where a particular genetic mutation or condition was in issue. This is a case where there is a view that there may be a genetic cause – and it is put no higher than that - which is said the tests would be highly likely to rule in or out.

39. I do not find the statistic provided by Dr Agrawal that if there is a genetic cause present there is an 85% change of it being identified in WES testing helpful. WES testing is not being proposed. The testing proposed by Dr Reardon is a wider set of tests. Dr Reardon does not give any evidence as to the accuracy of the testing proposed. The wider tests may have a greater than 85% chance of any causative genetic mutation present being identified, or they may throw up more subtle results which lead them to being seen as less accurate. I simply do not know.

40. What Dr Reardon does say is that in his opinion here is a 20-25% chance that a genetic cause will be found. There is some force to the criticisms put on behalf of the claimant

as to how that 20-25% estimate has been reached. There is no explanation in the report how that percentage figure has been come to; there were three matters considered. The first referred to a statistic of a 20% chance in an unbiased population of babies with seizures, but that statistic was said to be unlikely to apply to the claimant's presentation, the second issue had no literature which would assist with evaluating the chance of there being a genetic cause and the last was also said not to be applicable to the claimant's presentation. It is therefore difficult to see how the 20-25% chance has been reached.

41. I note Dr Reardon does not give any indication of whether there is likely to be any significant dispute in the field about that percentage chance.

42. Whilst I have sympathy with the claimant's criticism that the percentage estimate is not clearly reasoned, and concerns about how robust that evidence is, for the purposes of this application I accept that it is Dr Reardon's opinion based on his experience. It is the only expert evidence I have seen and the concerns are not so severe that I should reject it out of hand.

43. I take into account that if no causal genetic mutation is found, the defendant will still dispute causation, and argue that the cause of the claimant's symptoms is not the hypoglycaemia.

44. I accept that in principle, if a test has a 20 to 25% chance of ruling out any negligence as being causative, it is a test which has a significant chance of progressing the claim and it is in the interest of justice to carry out such a test in a claim such as this one where the value of a successful claim is likely to be high.

45. The extent to which it would progress the claim must be balanced against the claimant's right to personal integrity but that is matter for the second part of the test.

(ii) Has the claimant advanced a substantial reason as to why the test should not be undertaken?

46. As set out above, the claimant's parents do not wish to undergo the testing for themselves or the claimant. Although on one view, the invasiveness of a blood test is low, the testing which that blood will then undergo has potentially serious implications.

47. In my judgment, testing and sequencing of the whole genome does have more significant invasion into a person's private life than a simple blood test or even a genetic test which is looking for a specific syndrome or type of mutation, or to establish whether a particular person is a father. Such wide sequencing might bring to light mutations which indicate severe health consequences but might be irrelevant to the issue of causation – matters such as mutations of genes which indicate a predisposition to cancer or other disorders later in life.

48. In this case, that is the case not only for the claimant but also for each of his parents. I accept that in principle it would be perfectly proper for me to order a stay unless his parents took a test, although they have a right to a private life it is not unqualified and as discussed in *Birtles* such an order would not in principle be in breach of the Human Right Act. However in this case the impact on the claimant and his parents is not just

a simple blood test, it is the impact of the information the genetic sequencing would give and the choice they would have to make about what information to be given.

49. It is argued by the defendant that the counselling that would be given the parents would negate any real consequences of genetic testing. They can then choose whether to be told about matters not relevant to causation or not.

50. Whilst that is true, there seems to me to be a qualitative difference between never having to think about that issue and knowing that a test is being done and that choice has to be made. If they chose to find out the full results it might have profound implications for the way they live their lives. If not, they might question whether they are missing something they might be able to avoid if forewarned. The very fact that before testing is undertaken, counselling is given underlines that conclusion. I am of the view that is a significant adverse impact on them.

51. That is very different again to the *Birtles* situation where paternity was already in dispute, and also very different to the case of *Laycock* where although an MRI has the potential to throw up serious and non causally related matters, it would only be to the claimant.

52. Also relevant to the balance is what impact not having the testing would have on the Defendant's ability to defend the claim. The chance of proving a genetic non negligent cause is valuable, especially in a high value claim, but the Defendant would still be able to run the causation arguments it already has based on the imaging and the claimant's presentation. The chance of proving a genetic cause is of course not a likely outcome and therefore is on balance unlikely to progress the claim beyond those defences, which are not uncommon in this type of case, and which still remain.

53. The claimant also objected to the test on the basis that the litigation friend is concerned that travelling to London and having the tests would be stressful for the claimant. It is said that he would be very worried about the thought of someone putting a needle into his arm and taking blood and gave the example of the fact that he found having his fingernails and toenails cut intrusive and he had found recent treatment for a verruca frightening. The last time he had an injection was his pre-school booster and it was an extremely traumatic experience for him and his parents. He has never had a blood test that he has a recollection of so there was no reference point to talk to him about. The litigation friend was also concerned about how the purpose of the test would be explained to him as he knows nothing about the litigation.

54. The defendant points out that the pre school booster was some time ago and the claimant will have to see a number of experts and tests of a more conventional nature and his parents will have to, as all parents do in these sorts of cases, provide the best explanation they can to their child.

Conclusion

55. In those circumstances, in a case where it appears that the defendant's position that there may be a genetic cause has arisen more from the view that there is no other known cause than from a positive view that his symptoms fit with a particular genetic cause or indeed that there is an unknown but likely genetic cause, I am of the view the balance lies in not making the order. The effect of the testing on the claimant and his parents is

significant and in my judgment outweighs the potential benefit to the defendant in having a 1 in 4 or 5 chance of positively proving a genetic cause.

56. In respect of the objections about the claimant having a blood test itself, whilst I have great sympathy with the real and practical difficulties in dealing with a child who is fearful of needles and treatments which might seem non intrusive or trivial to the majority of adults, and accept that the claimant has greater vulnerability than many other children to being distressed by a blood test, the concerns raised would not have been sufficient to say the test should not go ahead without more. There is no recent evidence of any specific concern about needles or the trauma of the pre-school booster some years ago still being present. I am sure that the litigation friend would have, as all parents have to do at times, found an explanation which would have fit his understanding level, even if it were not a full or indeed entirely accurate explanation for the purpose of the tests. She will have to do so as the claim progresses with examinations by other experts.

57. The application is therefore dismissed and I invite the parties to seek to agree an order for the service of the defence and any other consequential orders.