

Neutral Citation Number: [2019] EWHC 2591 (QB)

Case No: HQ17C01861

# IN THE HIGH COURT OF JUSTICE QUEEN'S BENCH DIVISION

Royal Courts of Justice Strand, London, WC2A 2LL
Date: 08/10/2019
Before:
MR JUSTICE JAY
Between:
EDYTA EWELINA MORDEL Claimant
- and —
ROYAL BERKSHIRE NHS FOUNDATION TRUST  Defendant
Clodagh Bradley QC (instructed by Boyes Turner LLP) for the Claimant Michael de Navarro QC (instructed by Hempsons Solicitors) for the Defendant  Hearing dates: 2 <sup>nd</sup> – 5 <sup>th</sup> and 8 <sup>th</sup> - 9 <sup>th</sup> July 2019
Approved Judgment  I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.
MR JUSTICE JAY

#### MR JUSTICE JAY:

#### Introduction

- 1. Aleksander Mordel was born to the claimant on 25<sup>th</sup> January 2015 with Trisomy 21 or Down's syndrome. He had been her first pregnancy. It is her claim in these proceedings for damages for clinical negligence that, in essence, the defendant missed two opportunities to carry out screening for Down's syndrome which, if taken, would have led to a termination of the pregnancy. Damages are claimed on the basis of the principles explained in *Parkinson v St James and Seacroft University Hospital NHS Trust* [2002] QB 266. This trial is confined to the issue of liability.
- 2. As is well known, Down's syndrome is one of the commonest genetic disorders and is caused by the presence of all or part of an additional copy of chromosome 21. It does not run in families. For some time now pregnant mothers have been offered in the NHS routine screening for Down's syndrome in the first trimester, usually at around 11-13 weeks. This screening has two elements: first, an ultrasound scan of the foetal neck area this is what is known as the nuchal translucency test or "NT"; and, secondly, a blood serum test of the mother (a double test, i.e. of Beta hCG and PAPP-P) is carried out in this particular trust on the same day. The result from this combined test yields a statistical risk factor which serves to inform subsequent decision-making. Any result higher than 1:150 is regarded as "high risk" and the mother should then be offered diagnostic testing.
- 3. Second trimester screening can also be offered to the mother but only if the first trimester screening has not taken place. The precise circumstances which might trigger the offer are not agreed by the parties, but the test in question is not performed by ultrasound and is limited to blood serum. On this occasion four blood components are examined, and the procedure is known as the "quadruple test". As with the combined test, this is no more and no less than a screening procedure and cannot yield any certainty. The latter is attained only if the mother proceeds to diagnostic testing of DNA following the taking of foetal or placental blood and/or tissue via a needle placed through the abdominal wall, a procedure which entails a risk of miscarriage of up to 2%.
- 4. It is immediately apparent that screening and diagnostic testing of this sort generates differences of opinion amongst reasonable people, and for that reason in no sense is it regarded as obligatory. The NHS must *offer* screening for Down's syndrome but maternal informed choices must be respected. The majority of expectant mothers do accept first trimester screening although rates vary quite significantly throughout the country dependent no doubt on the make up of the catchment area. However, and as one of the witnesses explained to me, there is no profile or stereotype for those who tend to decline.
- 5. In the present case, the facts in the broadest outline are that on 23<sup>rd</sup> June 2014 the claimant attended the community midwife at her GP's surgery for her booking appointment and "accepted" all six of the standard screening tests, including combined screening. She was booked in for her NT scan on 22<sup>nd</sup> July. On that date she attended the Royal Berkshire Hospital for the scan to be carried out. There is a

dispute between her and the sonographer as to what happened, but it is clear that the latter completed the ultrasound report: "Down's screening declined". No NT scan was carried out but the overall condition of the foetus was checked by ultrasound and the due date was ascertained more precisely and then corrected in the records. The second part of the combined test – the taking of blood – was not carried out either, consistent of course with the claimant having declined Down's screening. On 11<sup>th</sup> August the claimant returned to see the same midwife and it is common ground that the quadruple test was not offered. The claimant did undergo a foetal abnormality scan at around 20 weeks' gestation but this was unremarkable. After a Caesarean section Aleksander was delivered safely.

- 6. In the light of the parties' submissions, the issues for my determination may be specified as follows:
  - (1) (a) Did the sonographer offer Down's Screening on 22<sup>nd</sup> July 2014; and, if she did, what exactly did she say? (b) did the claimant appear to decline the offer; and, if she did, what exactly did she say?
  - (2) Did the sonographer discharge her duty to the claimant in terms of obtaining the latter's informed consent?
  - (3) If the answer to (1)(a) and (b) is "yes" and (2) is "no", was it in fact the claimant's wish not to undergo Down's screening on this occasion?
  - (4) Did the midwife discharge her duty to the claimant on 11<sup>th</sup> August 2014 in not exploring why the combined test had not been carried out?
  - (5) If the answer to (4) is "no", would the claimant have informed the midwife pursuant to the exploration that *ex hypothesi* the latter should have conducted that she wanted Down's screening (i.e. the quadruple test)?
  - (6) In the event that the answer to (3) is "no" and/or to (5) is "yes" (on the assumption that either or both of these questions arise), would the claimant have consented to invasive testing and a termination of pregnancy?
- 7. Within these issues are embedded a number of sub-issues which I will address at the relevant time.

# Key Contemporaneous Records

8. The booking appointment took place on 23<sup>rd</sup> June 2014 under the auspices of Midwife Foley with a student midwife also in attendance. It was recorded that this was an unplanned pregnancy, that the claimant's mood was low, and that her first language was Polish. It is clear from the hand-held notes, and it is not in dispute, that a number of tests were discussed and "accepted" by the claimant, in particular "Dating scan 8 weeks onwards", "Combined screening 11-13+6 weeks (NT and serum)", "15-19 weeks serum testing after dating scan (if no combined screening)" and "foetal anomaly scan (18-21 weeks)". Midwife Foley and her student have signed the records at this juncture with the addition, "NHS screening booklet given". The word "unsure" has been written beside the invasive tests. Very little really turns on this particular uncertainty, because there is a broad measure of expert agreement that "unsure"

would be commonplace: many mothers would wish to know the level of the risk before contemplating the next stage. Either Midwife Foley or her student wrote "Nuch 22/7" on the hand-held notes.

9. On 22<sup>nd</sup> July 2014 a maternal ultrasound report was completed by Ms Lorraine Bracher, the reporting sonographer. This provided, insofar as is material:

# "Indication:

1<sup>st</sup> Trimester screening

# **History**

Maternal age: 28 years

. . .

**EDD by ultrasound**: 28.01.2015 (EDD by dates: 03.02.2015)

**Gestational age**: 12 weeks + 6 days ...

**First Trimester Ultrasound** 

. .

CRL [crown rump length]: 67 mm

# **Downs Screening Declined**

. . .

# **Diagnosis**

No obvious abnormal ultrasound appearances, results communicated to patient."

10. On 11<sup>th</sup> August the claimant was seen again by Midwife Foley. She completed in the hand-held notes the results of blood tests taken on 23<sup>rd</sup> June. The test for antibodies needed to be repeated and this was done on the same day. The following two boxes were left blank in the notes:

"Combined NT & Serum (11-13+6 weeks)

Serum only (if no combined test) (15-19 weeks)"

- 11. Foetal abnormality scans were carried out in September. It was recorded that all structures were normal.
- 12. Within ten hours of Aleksander's birth the claimant suspected Down's syndrome and her notes record her anger and disbelief once the diagnosis was confirmed:

"Incident Reporting form DIF2, 27<sup>th</sup> January 2015

Antenatal notes show antenatal screening accepted [a]nd screening booklet accepted. Documentation states pre-natal diagnosis/CVS/amnio as unsure. On scan report it states downs screening declined but pt disputes this as she was concerned about her baby's health. Bloods were taken but no letter with risk factor receive by pt and no result in hand-held notes/no reason documented for declining downs screening in USS. Baby was born with trisomy 21 and pt tells me she would not have continued with the pregnancy had she known.

# Note of Midwife Vicky Antonowicz on 27<sup>th</sup> January 2015

Edyta very upset + angry about baby having Down's syndrome as she had scans + bloods taken. Scan report state screening declined but Edyta denies she said this + she doesn't remember being asked about screening. She did not receive any letter stating blood results/risk factor and no documentation in notes re blood results. No documentation of any reason given for declining Down's screening at USS. Edyta tells me she would not have continued with pregnancy had she known baby had Down's syndrome. Apologies given ++.

# Clinical Note, 28th January 2015

Seen re missed [diagnosis] Tr 21

Condolences

Explained what is written in the notes & US report.

Agreed handover between M/W's & failure to f/u absence of screening result an 'issue'.

The couple are <u>very</u> upset to the point of irrationality re process & ability of screening to detect Tr 21.

Plan to 'sue' hospital. Advised against it."

#### Relevant Policies

13. National guidance is provided in the NHS document, *Antenatal Screening – Working Standards for Down's Syndrome Screening*, 2007. I will be referring to these subsequently as the 2007 National Standards. The twin philosophies underlying this policy document are that (i) screening tests for Down's Syndrome "should be offered to all pregnant women presenting for maternity care, before twenty weeks of gestation", and (ii) patient choice must be respected. The focus in this trial has been on sections 7 and 8, the relevant portions of which read as follows:

"7.0 Consent

**Standards** 

- 7.1 Women must be informed of the purposes, possible outcomes and the limitations of the screening test.
- 7.2 When women are offered a screening test for the detection of Down's syndrome they must not be made to feel that they should accept the screening tests as part of their antenatal care.
- 7.3 Only the woman has the right to consent to (or decline) the screening tests.
- 7.4 Consent must be obtained prior to any screening/diagnostic tests, and documented in the trust's clinical information system and/or in the woman's maternity notes.
- 7.5 The screening and diagnostic tests the woman accepts or declines must be documented in the Trust's clinical information system and/or the woman's maternity notes.
- 7.6 The right to decline tests or further investigations should be made clear and any such decision, including withdrawal of consent, must be respected.

. . .

#### 8.0 Informing Women

## **Standards**

- 8.1 All women must be given clear information about the choices available along the screening and diagnostic pathway.
- 8.2 All women must be informed of the tests available within the Trust for Down's syndrome screening, irrespective of any assumptions as to how individuals may choose to proceed along the screening pathway.
- 8.3 All professionals involved in the screening process must be impartial and supportive towards women, as they make decisions along the screening and diagnostic pathway.
- 8.4 All women must receive information about Down's syndrome and the availability of a screening test, as early as possible in pregnancy, and at least 24 hours before they are asked to make any decisions.

. . .

- 14. On 26<sup>th</sup> March 2008 NICE published its Clinical Guideline, *Antenatal Care for Uncomplicated Pregnancies*. The relevant portions of this Guideline are as follows:
  - "1.7.2.3 The 'combined test' ... should be offered to screen for Down's syndrome between 11 weeks 0 days and 13 weeks 6

days. For women who book later in pregnancy the most clinically and cost-effective serum screening test (triple or quadruple test) should be offered between 15 weeks 0 days and 20 weeks 0 days.

- 1.7.2.4 When it is not possible to measure NT, owing to foetal position or raised BMI, women should be offered serum screening (triple or quadruple test) between 15 weeks 0 days and 20 weeks 0 days.
- 1.7.2.5 Information about screening for Down's syndrome should be given to pregnant women at the first contact with a healthcare professional. This will provide the opportunity for further discussion before embarking on screening ... Specific information should include:
- \* the screening pathway for both screen-positive and screennegative results.
- \* the decisions that need to be made at each point along the pathway and their consequences.
- \* the fact that screening does not provide a definitive diagnosis and a full explanation of the risk score obtained following testing.
- \* information about CVS and amniocentesis
- \* balanced and accurate information about Down's syndrome.

. . .

# **Appendix D: Antenatal Appointments**

. . .

#### 16 weeks

The next appointment should be scheduled at 16 weeks to:

- review, discuss and record the results of all screening tests undertaken; reassess planned pattern of care for the pregnancy and identify women who need additional care
- ... [two further bullet points irrelevant for present purposes]
- give information, with an opportunity to discuss issues and ask questions, including discussion of the routine anomaly scan ..."
- 15. The defendant's *Down's syndrome Screening Policy*, November 2012 edition (and in place at the time of these events), provided in material part as follows:

### "3.1 The Offer of Screening

All women attending for antenatal care before 20 weeks gestation will be offered antenatal screening for Down's syndrome.

The offer of screening and the decision to accept or decline should be recorded in the hand-held notes.

. . .

At the booking appointment with the midwife she should be given the local test-specific leaflets 'The Combined Test' or 'The Quadruple Test' as appropriate to her wishes and gestation. These leaflets are available in other languages on request. The Community midwife should document in the hand-held notes that Downs screening has been discussed, what written information has been given, and whether the woman accepts, declines, or is undecided about the tests. Women declining Down's screening in the 2<sup>nd</sup> trimester should be notified to the Screening Coordinator for the purposes of audit.

. . .

#### 3.4 The Combined Test

This can be performed between 11 weeks and 3 days and 13 weeks and 6 days, and in this Trust the scan and bloods are done on the same day ...

. . .

If the sonographer cannot obtain a measurement (raised BMI, foetal position, gestation too advanced) she will date the pregnancy and the woman will be offered a quadruple test from 15 weeks.

. . .

### 3.5 The Quadruple Test

This is a blood test which can be taken between 15 weeks and 20 weeks gestation. This is available for women who book too late for the 1<sup>st</sup> trimester test, or in whom it has not been possible to get a measurement of the NT. ...

. .

# 3.6 Test Results

All women should receive the result of their test within two weeks of the date of the test. All women are informed when the

blood is taken to contact their named midwife if they haven't received a result within 2 weeks.

. . .

It is the responsibility of the Community midwife to ensure that all women have received their results, and document them in the hand-held notes when they attend their 16-week appointment.

. . .

#### 4.0 Flowchart

[I cannot do justice to this diagram in this narrative, but in my view the 'Decline Screening' box does not apply to the sonographer and probably does not apply to the midwife at the 16-week appointment. In any event, I would hold that the purposes of audit are separate from the duties which are germane to the present case.]"

16. The defendant's policy was amended following the birth of Aleksander and I draw the inference due to the circumstances leading up to it. Ms Lorraine Bracher assumed this to be so, and the defendant has elected to call no evidence to rebut the inference. There are established limitations, however, on the inferences to be drawn from changes to systems made after an incident such as this, including in particular the inference that the prior system was sub-standard: see, for example, *Jaguar Cars Ltd v Alan Gordon Coates* [2004] EWCA Civ 337. I have noted that the first draft of the revised document is dated January 2015, that it was published in April 2015, and that a number of "fail-safes" were specified including the requirement that all women with no result at the 16 week stage should be offered a quadruple test.

# Legal Framework

- 17. Recitation of the familiar *Bolam* test is not required for these purposes. Ms Clodagh Bradley QC reminded me that it is insufficient for a defendant merely to point to the *existence* of medical opinion which supports the act or omission perpetrated. As Lord Browne-Wilkinson made clear in *Bolitho v City and Hackney HA* [1998] AC 232, that opinion must be responsible, reasonable and respectable, and logically based (at 241G-242B). Even so, it will only "very seldom" be right for a court to hold that views genuinely held by a competent medical expert are unreasonable, because matters of clinical judgment are in play (at 243C-D). Mr Michael de Navarro QC for his part reminded me that, in the event that breach of duty is established, the burden is on the claimant to prove what would have happened on the balance of probabilities.
- 18. I have also taken time to re-read the joint judgment of Lords Kerr and Reed in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, in particular paras 89-93. This re-examines the concept of informed consent in a manner which is not central to the issues in the instant case, save to underscore that the issue of consent and the need for it to be truly informed is a question of right rather than discretion; and that the patient must be provided with sufficient information to make an informed decision.

- 19. In *ARB v IVF Hammersmith* [2018] EWCA Civ 2803, the Court of Appeal overturned a finding of mine that a fertility clinic was not in breach of its duty to take reasonable care to obtain the claimant's informed and written consent. I had preferred the clinic's expert evidence which was to the effect that a particular practice was commonplace in such clinics. Notwithstanding such evidence, this particular practice was held to be both illogical and prone to make a mockery of the whole process of obtaining informed consent which lies at the very heart of decision-making in the NHS. This authority is valuable to the extent that it vouches that a system which does not entail the taking of reasonable steps to ensure that relevant consent is informed may be regarded subject always to a host of other considerations as irresponsible, unreasonable and unrespectable even if there may exist expert evidence to support it.
- 20. My attention was also drawn to the decision of the Court of Appeal in *Goodman v Steel* [2013] EWCA Civ 153, in particular to the judgment of Moore-Bick LJ at para 17; and to *Ollosson v Lee* [2019] EWHC 784 (QB), in particular to the judgment of Stewart J at para 87. In making assessments of witness reliability, these decisions warn against placing too much weight on judicial impressions of witness credibility, especially those derived from perceptions of body language and demeanour, and recommend that greater attention be paid to contemporaneous evidence, especially that of a documentary nature.

#### My Impressions of the Lay Witnesses

- 21. The claimant was a transparently honest witness who did her best to assist and not to mislead the court. Her English is good but far from excellent, and there were occasional failures to understand what was being put to her by both counsel, particularly if the question or proposition had a degree of nuance or complexity. On reflection, and with respect to the claimant, I put that down not primarily to lack of competence in the English language (although it remains a significant factor) but to her general level of education and sophistication. Aside from the artificiality of the forensic environment, these observations are all the more relevant to the claimant's understanding of what occurred on 22<sup>nd</sup> July and 11<sup>th</sup> August, and to the very nature of the process she was going through at all material stages of her pregnancy. In emotionally charged situations experience informs us that people do not always take on board, process and understand what they are being told.
- 22. I have said that the claimant's competence in the English language remains a significant factor. From my experience, care needs to be taken in not assuming that because a person appears to be reasonably fluent in the English language her comprehension will be at the same level. For many people who are not linguistically gifted passive comprehension is harder than active communication. For obvious reasons, the latter is easier to assess by an outsider than the former, although during her evidence the claimant did make errors of grammar and syntax. Of course, none of these matters should be overstated: the claimant had been here for about six years before 2014, and although she doubtless spoke Polish at home with her partner, she must have spoken English at work and in many social settings.
- 23. Had the claimant been other than a straightforward witness she would not have volunteered that she had taken extra English lessons before coming to the UK, she would not have said that she was happy to receive the NHS booklet from the midwife in English rather than Polish, and she would not have freely accepted in answer to Mr

- de Navarro's questions in cross-examination that she understood the difference between screening and invasive testing and was aware of the essential elements of the screening and (potential) diagnostic pathway. In any case, the claimant's demeanour and overall comportment in the witness box left me in no real doubt as to her credibility. I defer for later consideration the submission that we all have the ability to convince ourselves that events in fact happened as we would have wished them.
- 24. Mr de Navarro was able to demonstrate through his sensitive cross-examination that the claimant was not a particularly reliable witness on matters which are not central to this case. For example, the claimant asserted in her witness statement that the student midwife was not taking notes, but an examination of the hand-held notes for 23<sup>rd</sup> June demonstrates that to be incorrect. The claimant also stated that she had her bloods taken at every GP appointment, but that is not right either.
- 25. The claimant's lack of reliability as a historian on some matters does not prove that she is unreliable across the board, particularly in connection with issues and matters which are more central to the case and/or she might well have a better chance of remembering accurately. Here, I have in mind the claimant's evidence that there was no discussion whatsoever with Ms Bracher regarding Down's screening; and in this regard she is supported by her partner, Lukasz Cieciura. I will need to continue to bear this in mind when reaching my conclusion as to whose evidence to accept. In relation to Mr Cieciura, I would add that there is a greater issue for me as to his reliability as a historian in circumstances where he did not attend the booking appointment and was not as apparently *au fait* as was his partner as to what would or might be taking place at the scan appointment.
- 26. One additional and obvious point may be made about the claimant. Her primary case is that there was no material exchange between her and Ms Bracher. If I were to reject that primary case, an alternative case is advanced on the pleadings and by way of submission that a misunderstanding developed between her and the sonographer during the course of what was undoubtedly a brief exchange such that, subject always to arguments as to the nature and extent of the latter's duty, the consent she gave was not informed. My point is this: the less able the claimant may be, the easier it may be for those representing her to persuade me of the correctness of her alternative case, other things being equal.
- 27. Midwife Suzanne Foley was another transparently honest witness who was perhaps too frank. She accepted on at least two occasions in cross-examination (Ms Bradley has counted two; I have counted three) that she should have discussed the claimant's scan appointment with her in order to ensure that her wishes had been respected; and also should have documented the claimant's declination of Down's screening in the relevant box in the hand-held notes. Doing so would have demonstrated that there had been a dialogue. Midwife Foley also accepted that the reason for taking the step she in fact failed to take was that it was important to make no assumptions about a patient's current wishes. In re-examination Ms Foley gave a different answer, reverting to the line she had taken in her witness statement, but as far as I am concerned the forensic damage had been done. Ms Bradley's cross-examination had been conducted in an entirely appropriate and moderate manner, and it cannot be said that the witness was somehow cajoled into saying something that did not represent her viewpoint, or was put under such pressure that she could not fight her corner if she had really wanted to: the reality is that part of her did not really want to. Even so, and in the defendant's

favour, this witness does not have the experience of the expert witnesses in this case, and in my view her admissions do not carry that much weight.

- 28. Ms Lorraine Bracher was a more difficult witness to assess, and Ms Bradley was critical of her evidence in a number of respects. She is clearly an experienced and competent sonographer (she is now retired) but I would not describe her as particularly communicative, forthcoming and outgoing. She has no recollection of the claimant and therefore can only assist me with her account of what she would routinely do in this situation – having been in it on countless occasions. Plainly, she could not assist the court as to whether she departed from her usual practice, but by way of commentary on her routine she freely accepted the possibility of human error. She was not as forthcoming as she might have been about the free text box on the scan report form, but ultimately I do not think that much turns on this. Ms Bracher was undoubtedly quite defensive and circumspect in the witness box, but many professionals are when their practice is placed under close public scrutiny and I did not feel that she was, to adopt Ms Bradley's terminology, evasive and obfuscating. Overall, although I do have some reservations about Ms Bracher's evidence, I am not driven to conclude that her credibility and reliability are in any real doubt.
- 29. Having set the scene in this way, I now propose to summarise the evidence of the claimant and of Ms Bracher. I judge that this exercise is unnecessary in relation to the other lay witnesses, although in due course I will be providing encapsulations of the expert evidence, focusing on the areas of dispute.

# The Evidence of the Claimant

- 30. In chief, the claimant said that her belief was that the sonographer on 22<sup>nd</sup> July did everything that "we" had asked for. She did not decline Down's screening on that appointment. According to her witness statement, she is 100% sure that there was no discussion about Down's screening. As for the 16-week appointment on 11<sup>th</sup> August, the claimant said that she believed that the test results showed a healthy baby. If asked, she would have wanted a blood test. If the result had been 1:150 or worse, she would have proceeded to amniocentesis and a termination. She had no religious and ethical objection to that course. Although a Roman Catholic, not that she described herself in that way, my sense of her evidence was that she was not particularly devout and in cross-examination she said that she attended Mass 3-4 times a year when she felt a need to. She has previously used contraception and has not married her partner.
- 31. In cross-examination, the claimant confirmed that she had a good command of English and that she was quite comfortable in dealing with medical professionals in English. She was happy to receive the information booklet in English. She understood that there were two possible tests for Down's syndrome: the combined and the quadruple, with the latter taking place later. She also understood that the quadruple test was normally only offered to a woman who had booked too late for the combined test.
- 32. The claimant agreed that Midwife Foley told her that the combined test involved the taking of blood and the measurement of neck fluid. The midwife also told her that this was only a screening tool and was not diagnostic.

- 33. In answer to my open question, the claimant said that her understanding was that the sonographer would know "automatically" or "already" if something was wrong with the baby. In that eventuality a further test would be offered. This would say whether the baby had Down's syndrome although it carried a risk of miscarriage. The claimant had said that she was "unsure" about these tests (on 23<sup>rd</sup> June) because of the miscarriage risk. She agreed in cross-examination that it was not an easy decision. Later in her evidence, the claimant agreed that she knew that the screening result would not be altogether reliable.
- 34. The claimant agreed that Midwife Foley told her that not everyone has screening, and that if the mother is happy to have a Down's syndrome baby, it was not necessary to have screening. She did not recall the midwife saying that with the combined test the bloods would be taken on the same day. I interpolate here that this was clearly the defendant's policy, although Midwife Foley's evidence has the unsatisfactory feature that this matter was not in her original witness statement and following prompting from a solicitor was included in a supplementary statement with unnecessary underlining for emphasis.
- 35. The claimant agreed that Midwife Foley told her that she would be informed of the results. If high risk, she would be contacted within a few days; if low risk, a letter would arrive within 2-3 weeks. Her understanding was that the letter would give the risk. In the event that she was high risk, the claimant accepted in cross-examination that she would be offered a further test by implication, a diagnostic test which could give a definite result.
- 36. The claimant said that she did not read the booklet she had been given: there was no need to, because she had gone on YouTube and understood the position.
- 37. Asked again about the events of 22<sup>nd</sup> July, the claimant said that she was sure that the sonographer was doing the Down's syndrome screening. She was always sure that she wanted it done. She was 100% sure that there was no discussion at all about Down's syndrome screening; this is not a case, she agreed, of any misunderstanding about it. The claimant denied that she declined the screening by saying "no". She agreed that she would not have understood the question as being about invasive screening (here, of course, the claimant was being asked to address something which was from her perspective counterfactual).
- 38. The claimant said that she did look at the ultrasound report which had been put in her hand-held notes. She did see "Downs screening declined". Her understanding of this was that the sonographer did undertake the test and that it was she who had declined Downs syndrome: that is to say, the baby was healthy and could not have Down's syndrome. This evidence had not been given in chief, nor was it in the claimant's witness statement, and I propose to ignore Ms Bradley's submission in her closing argument to the effect that the claimant had told her this, presumably in consultation, on a previous occasion. Although the claimant appreciated that the test was in two parts, she believed that this was the result. The claimant then agreed that the second part of the combined test was not performed and that she never got the results: her thinking was that the blood test was probably done at the GP practice. The absence of a letter meant that the baby was OK and healthy.

39. Ms Bradley relies in particular on the following answer given in cross-examination – I bear it in mind in the context of the claimant's evidence as a whole:

"I was always sure I wanted the Down's syndrome screening to be done, I wasn't sure for the other test with losing the baby but for the Down's syndrome screening I was sure I will never change my mind. Going for that scan I was 100% sure the sonographer done the test as I asked for it and it is in the notes I agree on that. And I booked that scan for myself. I was sure I wanted Down's screening."

40. In her oral evidence, when she was pressed by Mr de Navarro on the 1-2% risk of miscarriage, the claimant said this:

"To me it was not an option; I always go for screening. If the chances were big I would go for another diagnosis. I would probably agree on another test if I didn't know the risk."

- 41. The claimant agreed that she was angry after the event but denied bitterly regretting her decision.
- 42. As for 11<sup>th</sup> August, the claimant did not tell Midwife Foley that she had not received her results. The claimant said that it was for the midwife to give advice. The claimant denied that the reason she did not ask was because she no longer wanted to know.
- 43. In re-examination the claimant was asked about her being "unsure" on 23<sup>rd</sup> June of whether she might proceed to diagnostic testing. The claimant said that in the event that the result had come back as high risk she would have discussed it with her partner and reached a decision. If she had been given a pre-natal diagnosis of Down's syndrome, she would have chosen a termination. In answer to my question, she said that if there were a possibility that she was carrying a baby with a health problem she would have wanted to confirm it and be made more sure if there was something wrong (here, I am correcting the claimant's syntax, and am capturing the gist of what she said).
- 44. This evidence is at least consistent with what the claimant had stated at para 29 of her witness statement, which merits full citation:

"I knew someone from work with Down's syndrome. I saw how difficult his life is and I would not have continued my pregnancy. I would not have wanted a disabled child and I would not have wanted my child to suffer the way that disabled people suffer. I know how my colleague acts, speaks and what people say about him. I wouldn't want to have brought my child into the world like that."

45. Lukasz Cieciura's written evidence was on similar lines:

"If tests had been done which showed a greater than 1:150 chance of Down's syndrome we would have decided to undergo more tests, even if they carried a risk of miscarriage.

If, following these further tests, we'd found out that Aleksander had Down's syndrome, we would have terminated the pregnancy. We would have discussed it and thought that termination was right. We would have known that the problems that Aleksander has now he will have for the rest of his life."

The Evidence of Lorraine Bracher

46. According to para 6 of her witness statement:

"Having first called a patient into the scanning room I would have introduced myself. In the case of a first trimester screening scan I then asked the patient, "Do you want the screening for Down's syndrome?" If the answer was "No", I would then say something along the lines of "So we are not doing the screening then, we are just doing a dating scan and I will be checking the baby and making sure that the dates are correct". Provided I was satisfied that the patient understood this, I would then ask her to lie down on the table and before I started the scan I would select from the dropdown menu in Viewpoint: "Down's syndrome screening declined". There was no dropdown selection if the patient wanted to have screening for Down's syndrome."

- 47. In her evidence in chief, Ms Bracher said that if it seemed that the patient did not understand her question, she would then make sure that she did. Ms Bracher explained that in order to get the dropdown menu you would have to click on the relevant box. There is a screenshot of this in Mr Howe's report.
- 48. In cross-examination, Ms Bracher confirmed the sequence of para 6 of her witness statement (initially, there was some doubt as to the substance of her evidence on this issue in the light of the parties' conflicting notes, but the transcript has resolved this). Ms Bracher said that if she felt that the patient understood her question she would have no reason to test her understanding by further questioning or by probing her. On the other hand, she said that she would definitely have made sure that she understood the question that she asked her. Two particular answers in cross-examination and another in re-examination encapsulate her position on this:

"If I felt that she understood my question and she answered "no" I would have no reason to question her. If she asked any particular question relating to "no" I would have answered accordingly, but if she just said "no" I would have accepted her decision.

. . .

Well I would obviously be looking at the patient when I asked her the question. If it seemed as if she didn't understand or she spoke to her partner or asked me questions I would then make sure that she understood and if it was a language question I would – we would have an information leaflet in Polish, so I would have offered her the information leaflet for her to read.

. . .

[in re-examination] She would have understood what I was asking and would have – you know, if she declined there was no reason for me to then try and cross-examine her as to why she wouldn't want the screening. That was her decision."

- 49. Ms Bracher accepted, contrary to her witness statement, that there was room for free text on the computer menu to insert an additional comment but she said that none of the sonographers would have done so in these circumstances. For example, the practice in this clinic was not to deploy the free text box to record something along the lines of, "changed her mind; no longer wants Down's screening".
- 50. Although she fairly accepted the possibility of human error, Ms Bracher denied the proposition that in this particular instance she said nothing to the claimant and proceeded immediately to carry out the scan.
- 51. In answer to my question, Ms Bracher said that if the patient had informed the midwife at her booking appointment that she did not want Down's screening, her practice was to ask exactly the same question "Do you want the Down's screening?" and if the answer was "yes" and the patient appeared to understand, she would then proceed with the scan.

The First Issue: (a) did the sonographer offer Down's Screening on 22<sup>nd</sup> July 2014; and, if she did, what exactly did she say? (b) did the claimant appear to decline the offer; and, if she did, what exactly did she say?

- 52. The claimant and her partner have given a very clear account, apparently based on their recollection, that Ms Bracher proceeded to perform the scan without further ado. It is their evidence that all that Ms Bracher ever asked was whether they wanted a picture of the scan. It is said by Ms Bradley that they, and in particular the claimant, are in a far better position to assist the court as to what happened because this was a "first" for them and a life event; whereas Ms Bracher is constrained to resort to an account of her usual practice, which after all is susceptible to departure in specific circumstances and/or to human error.
- 53. I cannot accept Ms Bradley's submissions on this issue. The circumstantial and documentary evidence strongly militate against the claimant's primary case, notwithstanding my overall general assessment of her credibility. The proposition that nothing was said, beyond maybe opening courtesies and introductions, is very difficult to accept. Not merely would this have amounted to a gross breach of duty by the sonographer and a significant departure from her standard practice, the fact that she did select a particular option from the dropdown menu weighs very heavily in her favour. The fact remains that she would not have been using this menu at all if the claimant had answered "yes" to her question: the use of the menu presupposes both that the question was asked and answered in the negative. I have said that the claimant and her partner were honest witnesses, but to my mind the real issue here is not credibility but reliability of recollection. If this were a brief exchange which may not

have been understood (I will be coming to this in due course), the proposition that it has simply been forgotten is not merely plausible but probable. In these particular circumstances, the proposition does not reflect poorly on the credibility of either the claimant or her partner.

- 54. In the light of Ms Bradley's submissions, I have considered the possibility that Ms Bracher was guilty of some sort of mistake or human error but have concluded that this is highly unlikely to have occurred in relation to the dropdown menu for the reasons I have already given. Not merely would she have been nowhere near this part of the form had the answer been "yes", she had to make a specific selection. The possibility that Ms Bracher heard "no" when the claimant in fact said "yes" is also highly unlikely and has not been suggested by anyone. Whatever the claimant's actual wishes, my overall assessment of the evidence, the inherent probabilities and basic common sense points to Ms Bracher having adhered to her routine on this occasion.
- 55. I find that the sequence of events was as follows:
  - (1) Ms Bracher, having introduced herself, asked "Do you want the screening for Down's syndrome?"
  - (2) The claimant said "No"
  - (3) Ms Bracher said, "So we are not doing the screening then, we are just doing the dating scan and I will be checking the baby and making sure that the dates are correct".
  - (4) There was no response from the claimant.
  - (5) The claimant was asked to lie down on the table.
  - (6) Ms Bracher then clicked on the box in the dropdown menu, "Down's screening declined", and this was not a mistake the claimant had said "no" and nothing else. (According to para 6 of her witness statement, the relevant box was "Down's syndrome screening declined". The ultrasound report misses out the word "syndrome". Nothing turns on this, although it is a small discrepancy)
- 56. Items (2) and (4) are inferential findings inasmuch as there is no direct evidence either that the claimant said "no" or that there was no response or other relevant reaction from her after Ms Bracher had stated what was going to happen. The possibility that the claimant queried the question in some way cannot of course be eliminated, but there is no proper basis for inferring that she did. If, indulging for a moment in a piece of speculation, the claimant did query the question (I would emphasise that only item (1) is in fact a question), that would tend to suggest that some sort of dialogue ensued. I cannot sensibly proceed on the basis that it did, and no one has suggested that I should.

The Second Issue: Did the sonographer discharge her duty to the claimant in terms of obtaining the latter's informed consent?

# The Expert Evidence

- 57. Dr Trish Chudleigh PhD, DMU was the claimant's expert in ultrasound and sonography. It is clear from her *cv* that she is highly distinguished and experienced, amongst other things having held the position of Past President of the World Federation of Sonographers. Dr Chudleigh was also part of the UK National Screening Committee which produced the 2007 National Standards.
- 58. Asked to comment on Ms Bracher's question "Do you want the Down's screening?" Dr Chudleigh said that this was insufficient because she would want to make sure that the screening that was being performed was the screening the patient was expecting to have. If the patient had been booked for Down's screening and gave a negative answer to Ms Bracher's question, Dr Chudleigh told me that she would want to confirm that the former was aware of what the test involved. For example, some women come for scanning in the misapprehension that this was the "needle test": accordingly, Dr Chudleigh would want to know that the mother understood the difference between the combined test, which she would explain, and the diagnostic test. All of this was to ensure that the decision the patient was making was an informed choice based on the information she needed to know.
- 59. After Dr Chudleigh had concluded her evidence and the defendant's expert had also testified, she was at my request asked to deal with the second limb of Ms Bracher's account "So we are not doing the screening then, etc.". She had not been asked by either counsel about that. Dr Chudleigh said that this was insufficient follow-up because she would want to explore the patient's reasons, as she put it, including any possible misunderstanding as to the purpose of the test. Dr Chudleigh asked rhetorically, is this a question or a statement? What Ms Bracher said, assuming that she said it, did not help explain or give an adequate reason for the negative answer by the patient.
- 60. In cross-examination, Dr Chudleigh said that to ask someone almost immediately "Do you want the Downs screening?" would not be likely to elicit whether she had the necessary proper understanding of what she was being asked to accept or reject. This was the patient's first opportunity to express her views of whether she did consent to this procedure. In the event of a "no" answer, she would want to explore the issue further. In Dr Chudleigh's experience, not every woman fully understands the procedure, and not every woman has the body language which indicates either comprehension or the lack of it.
- 61. Asked what question she would ask in these circumstances, Dr Chudleigh explained that she would ask the woman if she has had a discussion with the midwife about combined screening. She would also explain the nature and implications of the test and that the result would give just a risk factor. Dr Chudleigh said that she appreciated that this was a sensitive area, but the failure to explore this any further was a breach of duty by the sonographer.
- 62. Mr Gerald Mason, FRCOG is a foetal-maternal expert who also gave evidence on behalf of the claimant. For reasons which are unclear, Mr Mason was not provided with a copy of Ms Bracher's witness statement for the purposes of preparing his report in these proceedings. On the other hand, and to be fair to him, he put the matter in the conditional mode in para 37 of his report: there would have been significantly sub-standard care *if* the claimant's decision were based on no or limited discussion. Mr Mason felt able to be less cautious by the time the experts discussed the parties'

agendas for the purposes of their joint report. In his oral evidence before me, Mr Mason made clear that it is very important that the sonographer satisfies herself that the lady knows why she has come and that the test is performed if the patient so desires it. Mr Mason added that the decision that the lady wants screening is usually made at a time remote from the screening test itself, and that he could not think of any occasion on which she declined on the day. At a slightly later point in his evidence in chief, Mr Mason stated more generally that it would be uncommon for patients to change their mind. Then in cross-examination, he said that this would be very unusual. The midwife at the booking appointment goes through the issues in significant detail, and effectively obtains consent at that moment in time when she refers to the patient to the NT. The sonographer's role is to confirm that consent is forthcoming on the day of the test.

- 63. Mr Mason agreed with Dr Chudleigh that there was a significant chance that Ms Bracher's opening question might be interpreted as being directed to an invasive test. He said that he has had personal experience of patients confusing the two tests. You could not be certain by posing this simple question whether you and the patient were on the same page.
- 64. Asked about the second limb of Ms Bracher's routine, Mr Mason said that in theory this would assist the sonographer in gaining a better understanding of the patient's wishes because, as he put it, the question was being asked in a more detailed way. But, if you got no response you would be asking yourself why, and querying whether the patient understood the question that you had asked and its implications. In short, in Mr Mason's view the sonographer could not obtain informed consent on the basis of the account given by Ms Bracher in para 6 of her witness statement.
- 65. Mr Mason was asked about the sort of questions that should be asked in these circumstances. Ideally, he said, you should ask open-ended questions, but these do not always yield the answers you want. He suggested the following:

"I understand that you have come today for me to measure the thickness on the back of the baby's neck to enable me to alter your age-related risk for Down's syndrome: is that correct?"

Mr Mason said that it was clear from this sort of question that the sonographer would be carrying out an ultrasound scan with a very specific objective. This avoided the risk of misapprehension. Mr Mason added that you would first wish to establish a rapport with the patient because she will be likely to be anxious. The interpretation of body language is not a safe strategy.

66. In cross-examination Mr Mason agreed that scanning in the private sector, where his recent experience lay, was different from the NHS in that the patient had already committed herself to a particular scan by having paid for it. He also accepted that many patients would need 24 hours to reflect before making a final decision. It was put to Mr Mason that on three occasions in his evidence he had said either that the claimant was "very keen" on having the NT or that her inclination was "strong": he said that this was based on his conversations with her. Mr Mason agreed that one possible interpretation of "Down's screening declined" was that the claimant told the sonographer that she did not want this screening.

- 67. Mr Mason added, although this was not a point pursued with his counterpart Mr Howe, that before he started any ultrasound procedure, even in an instance where the NT had been declined, he would point out to the patient that during the course of it he might find something which caused him concern. He would, accordingly, ask the patient whether in such circumstances she wished him to inform her of that.
- 68. The defendant's first expert on this topic was Dr Josephine McHugo, FRCR, who qualified as a doctor of medicine and is a radiologist with a specialism in all aspects of ultrasound. Her responsibility as head of department was to ensure safe practice in all aspects of radiology and obstetric ultrasound. It follows, she said, that she is very well placed to assist the court in relation to the routine practice of sonographers.
- 69. Dr McHugo's evidence was that Ms Bracher, who was aware that the claimant had been booked for a NT scan, needed to satisfy herself that the latter still consented to screening taking place, that she had been provided with the appropriate information at least 24 hours beforehand, and that her consent was informed consent: i.e. that the information provided had been understood. She and Dr Chudleigh were in agreement about this, and with the proposition that the 2007 National Standards (see paragraph 13 above) do not expressly require a sonographer to question a woman as to why she had declined screening or to organise any follow-up of that decision.
- 70. Asked about Ms Bracher's routine, Dr McHugo said that it amounted to the asking of the right questions in a succinct way: the mother's understanding could be ascertained by these means. Dr McHugo also pointed out that a lot is about body language. In particular, there was no need to go further and to explore the patient's state of mind. It was not the sonographer's role to re-counsel the patient or to provide further information.
- 71. In cross-examination, Dr McHugo agreed that open questions should be asked because they give more information than a single word. By asking closed questions, you are running the risk that any consent is not properly informed. It was put to Dr McHugo that Ms Bracher asked two closed questions. Her answer was that this needed to be placed in context: the sonographer will be observing the mother in order to detect if there are any misunderstandings this is relatively normal practice, she said, for sonographers across the country. There is a danger that even communication through dialogue can be misunderstood. Dr McHugo said that there is an ethical dimension about getting true informed consent and it is to that end that the process as a whole is directed.
- 72. Dr McHugo agreed that if Ms Bracher had just asked, "Do you want the Down's screening?", had received a negative answer and then proceeded simply with the dating scan, that would not have been sufficient for obtaining informed consent. She also agreed that body language is capable of being misinterpreted. The obligation on the sonographer is to follow up and ensure that you are doing with the woman what she would like you to do at the appointment. In this context, it was Ms Bracher's second utterance which in Dr McHugo's opinion made all the difference; and constituted good practice.
- 73. The defendant's foetal-maternal expert was Mr David Howe, FRCOG. He has an impressive *cv*, has written at least two papers which are relevant to the ethical and good practice issues raised by this case, and his report is in my view far superior to

- Mr Mason's in its detail, manner of expression and referencing. He also has more recent experience of ultrasound scanning although most of it would not be routine.
- 74. In Mr Howe's opinion, the patient at the booking appointment does not provide an informed consent but is given an informed offer. She is also given necessary written information to inform her thinking. In the vast majority of cases, the next meeting with a medical professional is at the scan appointment, and on that occasion the sonographer's duty is to obtain informed consent.
- 75. On the premise that Ms Bracher's evidence were accepted, Mr Howe said that this was acceptable practice because, and here I paraphrase, she could be confident that she was respecting the patient's wishes.
- 76. In cross-examination, Mr Howe said that in his experience a change of mind on the part of the patient would not be rare. He came across this quite regularly, and it was his practice to ask patients quite carefully whether they want to go ahead with the screening.
- 77. I asked Mr Howe to assist me as to his practice in this sort of situation. His evidence may fairly be summarised as follows:
  - (1) inform the patient words to the effect that his understanding is that she had come in for a screening scan. Mr Howe agreed that this, without more, would be insufficient owing to the possibility that the statement, or implied question, could be misconstrued.
  - (2) Ask the patient whether she has received information from the midwife about Down's screening.
  - (3) Ask the patient in terms, "do you want to have the screening done?"
  - (4) In the event that the answer to (3) is in the affirmative, say words to this effect: "fine, I am going to measure the NT and there will be blood tests to complete the screening process".
  - (5) In the event that the answer to (3) is in the negative, then say something broadly comparable to Ms Bracher's second utterance.
- 78. I explored item (5) with Mr Howe and he said that in the event that the patient said "no", he would want to ensure that she understood what she was saying "no" to. His form of words is similar to Ms Bracher's, and it is usually clear from the feedback what the patient wants.
- 79. Commenting specifically on Ms Bracher's practice, Mr Howe said that what I am calling her second utterance gives the patient a second opportunity to express her concern. He agreed that this was putting the responsibility on the patient. Immediately thereafter, however, Mr Howe agreed that it was the sonographer's responsibility to obtain informed consent or an informed decision to decline. In this same context, Mr Howe said that there was a danger in continuing to probe in a manner which made the patient feel that she was making the wrong decision.

80. Finally on this issue, Mr Howe stated that the sonographer should not rely on body language alone. There are occasions when closed questions are important, as he put it, but the sonographer must ensure that she and the patient are not at cross-purposes.

# Discussion and Conclusions on the Second Issue

- 81. Dr Chudleigh was an impressive witness who was clear, firm and not opinionated. Dr McHugo was a reasonable and competent expert who made a number of appropriate concessions in cross-examination. She conceded that had Ms Bracher asked "Do you want the Down's screening?" and said nothing else in reaction to a "no" answer, she would not have been obtaining an informed consent. Overall, I felt that she was not quite as authoritative and compelling as Dr Chudleigh.
- 82. The contest between Mr Mason and Mr Howe has proved more difficult to evaluate. I have already commented on the high quality of Mr Howe's report. He also gave a reasonably good account of himself and of his opinions in the witness box. Mr Mason's report was not particularly impressive. He gave no references for any opinions expressed, and he was quite brief on questions of breach of duty. On the other hand, in many respects he was a very good witness orally, notwithstanding the evident and regrettable difficulties consequent on the makeshift video-link which had to be deployed.
- 83. I did feel that some of the experts came too close to the line which separates the giving of opinion evidence from advocacy; and here I am not confining myself to the experts whose evidence I have reviewed thus far. Mr Mason, for example, should not have said that the claimant was "very keen" to have Down's screening, even if he had been told that in conference. I think that it is clear from the way in which I have already summarised, and will in due course summarise, the expert evidence in this case where the difficulties arise. I do not need to be explicit.
- 84. I remind myself that this cannot be a matter of simply preferring one side's witness or witnesses over another's. The *Bolam* test, as qualified by *Bolitho*, imposes a stringent burden on claimants; and one which very often cannot be overcome. The defendant has called two experts whose evidence, taken at its face value, supports Ms Bracher's practice. The issue for me is whether her practice was irresponsible, unreasonable and unrespectable, if not illogical, in the light of the duty to take reasonable steps to secure informed consent. To my mind, there is no real distinction between on the one hand consenting to and on the other declining a procedure in these circumstances because (a) the claimant still had to consent to the dating scan and understand what that entailed, (b) none of the experts identified any relevant distinction, and (c) she had either to accept or reject the defendant's "informed offer" on a basis which was properly informed.
- 85. I take Mr de Navarro's point that the process counselled by the claimant's experts is not specifically prescribed in the 2007 National Standards, the NICE Guidelines or local policy. However, informed consent is a fundamental principle of the modern NHS, and I would not expect documents of this sort to be prescriptive as to how it should be obtained. The obligation falls on the clinician to secure it; the obligation does not rest on the patient. On a related topic, I consider that the defendant has consistently overstated the difficulty in exploring the patient's level of understanding without at the same time appearing to undermine her right to choose. It is not the

patient's *reasons* for acceptance or rejection which need to be unpicked (*pace* Dr Chudleigh's choice of words, assuming that this is what she meant to say); rather, a gentle exploration is required of the patient's state of mind, conducted for the limited and specific purpose of checking that she understands what is entailed. Respect for patient autonomy is scarcely undermined by sensitive inquiry: indeed, it is enhanced because autonomy, properly understood, predicates full understanding. I discern nothing in sections 7 and 8 of the 2007 National Standards which suggests otherwise.

- 86. Thus, what informed consent means is not sensibly in dispute: the issue here is the nature of the steps which should be taken to secure it. I have previously referred to the taking of *reasonable* steps because I think that in the context of a human system it is impossible wholly to avoid misapprehensions persisting and misunderstandings arising despite the implementation of entirely proper practice by a sonographer. The NHS could not operate if the law required guarantees and complete "fail-safes", the latter term being interpreted literally. However, what is *reasonable* in this context must absorb consideration of the issues at stake here. Not merely is the birth of a child with Down's syndrome a life-changing event for most parents, the steps required to guard against parental choice not being respected are not onerous. What is at issue here is the asking of a limited number of questions to ensure that what may be an unwarranted outcome does not result.
- 87. What is reasonable cannot depend on the attributes and characteristics of any particular patient. An examination of the claimant's actual wishes is highly germane to causation (my third issue) but it has no relevance to the second. A reasonable process or system must take into account the fact that patients will naturally vary in terms of their ability, knowledge and capacity to understand.
- 88. Mr de Navarro submitted that the booking appointment is not the occasion on which informed consent is obtained, not least because the requisite 24 hours cannot have elapsed. I accept that submission. He further submitted that this is the occasion on which the patient is furnished with all relevant information so that an informed offer may properly be made by the midwife on behalf of the defendant. I also accept that submission. The point he was making was that all necessary information had already been provided to the patient by the midwife and it was not the sonographer's duty either to counsel (or re-counsel) the patient or provide anything more in terms of information. Mr de Navarro submitted that it was the sonographer's role to ascertain the patient's decision.
- 89. I agree with the submission that the system works on the basis that the midwife informs the patient, but I do not accept that the sonographer's role is limited to taking the patient's decision one way or another: i.e. hearing an acceptance or a declination of Down's screening. All relevant information may have been provided beforehand, but informed consent to the procedure in question still had to be provided. To the extent that the claimant's expert, Mr Mason, at one point suggested otherwise, I would disagree. I think that the point is more than a semantic one because the midwife has not, and cannot have, obtained informed consent from the patient, and in any case the focus must be on the patient's wishes and agreement to the procedure at the moment it is about to be performed. In my judgment, it is the sonographer's duty to satisfy herself that the patient is consenting to the procedure, either with or without the NT, before it is undertaken on the basis of proper information; and that her consent is informed. This in my view logically mandates: (i) checking that there has

been a discussion between patient and midwife, (ii) checking that the patient has been supplied with the NHS booklet, and (iii) ascertaining by brief questioning that the patient understands the essential elements and purposes of scanning for Down's syndrome. These conclusions are in line with the evidence of Dr Chudleigh and Mr Mason which I accept.

- 90. As I have said, I reject the contention that items (i)-(iii) above involve in some way prying inappropriately into the patient's reasons or reasoning and undermining her free choice. Mr Howe informed me that the 2007 National Standards were introduced to obviate these very risks, but there is no conflict between my conclusions and para 8 in particular of this guidance document. The risk only arises in the event of maladroit or insensitive interrogation, and NHS professionals are well habituated to avoid that.
- 91. As I pointed out in oral argument, the defendant may be caught between a rock and a hard place. If informed consent was effectively given at the booking appointment, with the decision communicated to the sonographer being something of a formality, the defendant's forensic difficulty would be that the claimant had accepted (i.e. given informed consent to) six tests including the NT on this very occasion. On that hypothesis, the sonographer ought to have been doing what the claimant had already consented to; or, at the very least, have explored that the claimant's apparent change of mind was genuine. In any case, even on this hypothesis (which I do not accept), the sonographer would remain under an obligation to ensure that the consent that had been given remained valid. On the other hand, if informed consent had not been given beforehand, which is my analysis, it would be incumbent on the sonographer to take reasonable steps to ensure that it was given before the procedure commenced.
- 92. I must say that I believe that Ms Bracher's opening question, without any preliminaries or preamble, was a somewhat abrupt way to begin an important exchange between a medical professional and a patient. I appreciate that sonographers are busy, are working under time-pressures and that their lists are full, but I am driven to conclude that she should have done more to lay the ground properly, if for no other reason than to preclude the real risk that she and her patient were at cross-purposes and/or that the latter was not listening to her properly. This would be all the more so in a situation such as the present in which the bald question might have confused or bewildered the claimant. Why ask "Do you want the Down's screening?" when the claimant would have been entitled to think that she had already told the midwife that she wanted this very procedure and that her wishes must have been recorded.
- 93. Mr Howe's practice is materially different from Ms Bracher's, and in my view probably goes far enough to ensure that informed consent is being obtained. Mr Mason's gentle question is preferable, as is Dr Chudleigh's suggested approach. Both would make clear that the procedure about to be performed is an ultrasound for screening purposes involving no more than the measurement of the thickness of the foetal neck: this information, together with a blood test, will lead to the acquisition of more accurate data as to the risk of Down's syndrome (here, I am paraphrasing heavily).
- 94. I appreciate that the modicum of exploration I am holding that the sonographer was duty-bound to perform could lead to the patient asking a series of questions about the procedure which the former might have felt unqualified to answer: a sonographer is not a midwife, and is not trained to provide advice. However, in such circumstances

- the obvious solution and requirement would be to refer the patient for further consultation with a midwife, preferably on the same day.
- 95. In my judgment, it is relevant that it was Ms Bracher's practice to ask exactly the same question regardless of what had been recorded at the booking appointment. At the very least, and I consider that she should have gone further, in a case where the patient had provisionally accepted screening for Down's syndrome, she should have asked whether she still wanted it; and in a case where she had rejected it, she should have sought confirmation that this was so. I was particularly concerned by Ms Bracher's evidence that if the patient had indicated at booking that she did not want Down's screening and then had answered "ves" to the standard question which is still asked in these circumstances, the sonographer would have proceeded to carry out the NT provided that she was satisfied that her question had been understood. To be fair to her, the way in which this evidence came out during the hearing did not readily facilitate an answer from Ms Bracher as to whether in such circumstances she would have gone on to state what she was going to do (presumably adapting what I have been calling the second limb of her routine to these notional facts); but even if it were her practice to do so there would still be a real risk that patients who did not want screening for Down's syndrome would end up having the NT.
- 96. It is also relevant in this case that the sonographer was not provided with a *tabula rasa*. She knew, or ought to have known, that the claimant had indicated provisionally that she wanted Down's screening; or, to use Mr Howe's terminology, had been made an informed offer to that effect. She knew, or ought to have known, that this was at the very least likely to be the claimant's expectation when she walked into the room. I do not have to decide how frequently patients do change their mind because on any view this must be uncommon. The sonographer should have been expecting a "yes" answer but instead she heard the opposite. Yet this on my findings prompted no further inquiry. As I have pointed out, Ms Bracher stated in cross-examination that she would not have asked any follow-up questions had she been of the opinion that her patient had understood the question. But the answer "no", without more, could provide insufficient enlightenment on this crucial issue. By definition almost, the sonographer could not be satisfied that this answer was correct without some further exploration; and to that extent the experts were in agreement.
- 97. The issue arises as to whether Ms Bracher's second limb uttered just before the patient is asked to lie down in preparation for the scan is sufficient for the purposes of ensuring that the patient has understood what is, and is not, about to happen. Although expressed as a proposition and not as a question, it is clear that Ms Bracher's second limb does constitute a further opportunity of sorts to ascertain the patient's wishes; but is it an adequate one? Dr Chudleigh and Mr Mason are firmly of the opinion that the second limb does not go far enough, and I accept their evidence on this point. A statement of this sort would attract an unacceptably high risk of being met with silence regardless of the patient's actual state of mind, even assuming, which will not be the position in too many cases, that it has been properly understood. Patients who have not been through this experience before may well assume that everything is still going according to plan and with their wishes: that would, or could, be their working hypothesis.
- 98. The fact remains that on Ms Bracher's account the taking of informed consent involves asking a short question and hearing the answer (maybe 3 seconds);

explaining briefly what is about to happen and inviting the patient to lie down (maybe 5-6 seconds); and then turning to the computer and selecting the appropriate dropdown menu (a few more seconds, but the patient will not know precisely what is happening). My overall assessment is that this is an inadequate process in all these circumstances because there remains an unacceptable risk that a patient perplexed by Ms Bracher's first question will not be properly informed.

99. I am reluctant to find against a sonographer or any medical professional for that matter who may well have been following the practice of her unit – I heard little or no evidence about this either way. However, I have come to the conclusion that I am driven to do so, for all the reasons I have given, in the face of what logic, common sense, and the preferable expert evidence have dictated.

The Third Issue: If the answer to (1)(a) and (b) is "yes" and (2) is "no", was it in fact the claimant's wish not to undergo Down's screening on this occasion?

- 100. Mr de Navarro made a number of powerful points in his closing submissions. He reminded me of the claimant's frank answers in cross-examination which demonstrated, or appeared to demonstrate, that she had a reasonably good understanding of the procedure from booking appointment to the 16-week appointment, that she appreciated the difference between screening and diagnosis, and that she knew that the results of the combined test would be provided separately and at a later date.
- 101. Maybe Mr de Navarro's strongest submission was that the claimant's explanation in cross-examination for "Down's screening declined", which she had not given previously, was "extraordinary". It was said that the claimant could not have interpreted this as the sonographer somehow ruling out Down's syndrome in the baby: she must have understood it for what it says, that the screening had been declined.
- 102. The defendant's case in written opening submissions, and in cross-examination, was the claimant now bitterly regretted her change of mind and that she has "persuaded herself that events happened as she would have wished". It was not put to the claimant in cross-examination, at least in terms, that she was lying, nor was it suggested that her explanation for "Downs screening declined" was a late invention designed to mislead. A suggestion along these latter lines would admittedly have been problematic in the light of the contemporaneous notes of what the claimant said shortly after her baby's birth. Viewing this issue more broadly, I have to say that in the circumstances of this case there was little opportunity for the claimant to have "persuaded herself" of anything. This sort of explanation for human behaviour and motivation works better when witnesses have had a good opportunity to reflect and ruminate.
- 103. Ms Bradley's submission was that on this topic there can be no room for equivocation or uncertainty. Had there been a change of mind after the booking appointment, it could not have been a spur of the moment decision made on hearing Ms Bracher's question. It must have been a considered decision following discussion between the claimant and her partner. Given the importance of this decision, it is inconceivable that the claimant could have forgotten or misremembered it. Accordingly, so the submission runs, the claimant is either being truthful or she is being dishonest. There

- is no room for the argument that the claimant might have persuaded herself of something which was not true.
- 104. I agree with Ms Bradley that the issue here is a binary one. In my opinion, at this stage of the case the claimant's lack of education is really beside the point. She will know in her heart or soul whether it was her wish to have Down's screening or not on 22<sup>nd</sup> July 2014. Either she is telling the truth about that or she is not.
- 105. Often, defendants prefer to finesse an issue such as this through fear that accusing a claimant of lying may not appeal to the court. The formulation that a witness has "persuaded herself" can be a polite or coded way of saying that she is not telling the truth. Judges often understand language of this sort as being euphemistic or toned down to avoid upsetting a witness and the risk of alienating the court. Moreover, experience teaches us that there are many situations where honest people do genuinely persuade themselves that something happened when it did not, or vice versa. As I have pointed out, however, this interpretation of the claimant's mindset is problematic in the light of the sequence of events with which I am confronted, as evidenced by the medical records.
- 106. Mr de Navarro is a very experienced and skilful advocate, and he tested the claimant's evidence both comprehensively and sensitively. The claimant's interpretation of the sonographer's report was an entirely new point. I consider that Mr de Navarro is entitled to submit that this was an "extraordinary" piece of evidence that I should reject. Even so, I revert to the difficulty that in relation to the claimant's evidence as a whole there is no real room for leeway. At no stage was it put to her that she was not telling the truth. Even so, had it been she would very likely have said that she was being truthful. At the end of the day, whether the matter was squarely put or not, I have to decide not whether the claimant is mistaken or has persuaded herself, but whether she has not been honest in the witness box on this particular issue.
- 107. In resolving this question, my point of departure is that there is a mass of evidence that tends to support the defendant's case, at least superficially. Mr de Navarro has listed all of this highly convincingly, and it relates to the claimant's understanding of the procedures. Taken at face value, it tends to suggest that by saying "no" to Ms Bracher's first question this is what the claimant actually meant. As I indicated in oral argument, this is the most difficult issue in the case to resolve.
- 108. Had she taken stock and thought carefully about what happened at her ultrasound appointment, and had she asked herself at the time whether it had truly proceeded in accordance with her expectations, I think that the claimant would have begun to wonder. The sonographer was apparently saying that there was no Down's syndrome, but the midwife had previously said that this was but one part of a combined screening test which could not yield a concrete result. Whatever her state of mind regarding the timing of the blood test, she had been told that the result would either be communicated rapidly or after 2-3 weeks. When she saw the midwife on 11<sup>th</sup> August there had been no letter and the issue was not raised by her on this occasion when there was ample opportunity to do so.
- 109. Even so, in a case such as this where the central issue is what did the claimant actually want? it must be incumbent on me to judge the claimant on the basis of how she appeared in the witness box and my overall assessment of her credibility, her

character and her ability. She should not be judged on the basis that the majority of expectant mothers up and down the country would not have thought and acted as she did. She should not be judged according to canons of how most reasonable people in her position would and should have thought and acted. I reiterate: the claimant was utterly guileless and disarmingly frank. I would be very slow to hold that the claimant and her partner had changed their mind before 22<sup>nd</sup> July and are now lying about it.

- 110. Although the defendant's strongest point is the late revelation that the claimant understood "Down's screening declined" as relating to the baby and not to any decision she may have taken, this must be considered in conjunction with the claimant's negative answer to Ms Bracher's question. What I am calling this central issue must be addressed in the round, and in the light of other evidence which tends to favour the claimant's case: in particular, her early, angry reaction to learning of the diagnosis (see para 12 above), and her prompt assertion to medical professionals that she had never declined Down's screening. Conversely, I place little weight on the fact that the claimant underwent foetal anomaly scanning in September in the light of the evidence that most patients who decline Down's screening have such scans.
- 111. The fact remains that the claimant answered "no" to Ms Bracher's question. It is not her case that she misunderstood that she was being offered invasive testing on this occasion. It follows that it cannot be the claimant's case that she answered "no" because she believed that she was declining an invasive test. In any event, a positive case along these lines would be difficult to run in view of the claimant's evidence that she did not say "no" at all. It seems to me that there are only two possibilities here: first, the claimant said "no" because she meant it; secondly, the claimant said "no" because she misunderstood the question in some other way.
- 112. Ms Bradley did not advance a positive case as to what this misunderstanding could have been about: she did not hypothesise as to what the "in some other way" could or might have pertained. Mr de Navarro did not make a submission about this either, but I have thought very carefully about how and why the claimant could have said "no" if she did not understand the question. True it is that few people would answer "yes" to a question which has not been understood, particularly in a medical setting, but an immediate "no" against the backdrop of incomprehension would seem, at the very least, to be unwise. Far safer, one would have thought, to ask the sonographer to repeat the question.
- 113. Ultimately, though, it is not the claimant's wisdom or good sense which is at stake here, but her credibility. Although I have not found this an easy issue to resolve, I have concluded that the claimant failed to understand Ms Bracher's question (in the sense that she failed to understand what it meant, not that she necessarily understood it to mean anything in particular), and that her unreflective response was to say "no". In the heat of the moment, the claimant did not process the question properly, and everything that ensued subsequently really resulted from that. From the claimant's perspective, Ms Bracher's subsequent actions were consistent with the NT being undertaken, and the claimant could have had no idea that only the crown rump length was being measured. Ms Bracher found nothing untoward, presumably said so, and according to her own lights the claimant was entitled to assume that everything was as it should be.

- 114. The claimant's case would obviously be stronger if the hand-held notes had said, "Down's *syndrome* declined", but no clinician would ever have written that. Further, the claimant did not pinpoint exactly when she read "Down's screening declined" in her notes but any reasonably curious patient, and in this particular regard I would include the claimant, would have done so at the time and certainly on the same day. A medical professional or any reasonably informed layperson would not have been troubled by the moderate degree of ellipsis, but such an individual would not have misunderstood Ms Bracher's question in the first place. If the claimant's mindset was that the sonographer had in fact carried out the test, this entry would have been confusing. On that premise I accept the claimant's evidence that she genuinely interpreted this as a reference not to any decision she may have made but to the condition of the child; and that she is not lying about this.
- 115. If this evidence had been untrue, and in this respect I repeat that there is virtually no room for judicial manoeuvre, I believe that I would have detected some change in tone or demeanour in the claimant at this important stage in her evidence. There was none. The claimant remained guileless, artless and devoid of sophistication.
- 116. I have referred to what probably would have happened had the claimant "taken stock" and reflected on the sequence of events occurring in the sonographer's room and the absence of any sort of communication confirming the result of the combined test. I have concluded that the claimant did not reflect on these events in this way. This, of course, is all of a piece. There is a consistent picture here of someone who genuinely believed that everything was still going according to plan but failed to process what was going on once that plan, judged objectively, had gone off course.
- 117. It follows that I must find for the claimant on this issue. It remained her wish to undergo Down's syndrome screening on 22<sup>nd</sup> July, and (I would add) she continued to believe at all material times thereafter that it had been carried out.

The Fourth Issue: Did the midwife discharge her duty to the claimant on 11<sup>th</sup> August 2014 in not exploring why the combined test had not been carried out?

# Midwife Foley's Evidence: One Matter Arising

118. It is clear that Midwife Foley must have seen the sonographer's report in the claimant's hand-held notes because she amended the EDD to reflect Ms Bracher's findings. It is less clear that she read the report in full, not that it would have taken her long to do so, and saw the entry "Down's screening declined". I find on the balance of probabilities that she did, although the upshot is that this does not really matter. It is common ground that the inference must be that Midwife Foley did not mention this to the claimant and did not make any entries in the boxes designated for the combined test and quadruple test results.

# Summary of the Expert Evidence

119. The claimant's midwifery expert was Ms Dawn Johnson, MRCM. She now works in a largely administrative capacity although it is clear that over the years she has accumulated considerable hands-on experience in midwifery. The essence of Ms Johnson's evidence was that the claimant had initially requested quadruple testing in the event that there was no combined test, that the opportunity to perform this test

subsisted, and that it was incumbent on the midwife to ensure that the claimant's apparent change of mind was an informed decision. Ms Johnson relied on para 1.7.2.5 of the NICE Clinical Guideline which required the midwife at the 16-week appointment "to review, discuss and record the results of all screening tests undertaken": she contended that this language was wide enough to accommodate all screening tests which the patient had requested be undertaken.

- 120. In her evidence in chief Ms Johnson was asked in particular about the NICE Clinical Guideline. She explained that the report at ultrasound, "Down's screening declined", did not mean that the midwife should steer clear of the subject. There had been an apparent change of mind which required gentle exploration with the patient along the lines of: "tell me about the scan?" and "did they ask you about Down's syndrome screening?". Ms Johnson emphasised that this was an unplanned pregnancy, the claimant was of low mood and English was not her first language, although in answer to my question she confirmed that the content of the defendant's duty in no way depended on these particular features. The point she was making was that some women exhibit these characteristics. Further, Ms Johnson stated that it would have been good practice for the midwife to record something in the relevant boxes on this page of the hand-held notes: maybe "not required" or "not requested". That would have evidenced a discussion.
- 121. In cross-examination, Ms Johnson agreed that a woman's choice should be respected, and she "absolutely agreed" that a midwife should not make a woman feel what her choice ought to be. She also agreed that sections 7 and 8 of the 2007 National Standards were fully in play, but did not accept that this was a difficult area. In particular, she did not accept that by asking a limited number of open questions there was a risk of impeding or interfering with a woman's autonomy and freedom to choose.
- 122. Mr Mason also gave relatively brief evidence about the 16-week appointment. From his perspective, the purpose of the 16-week appointment is to check that all booking investigations are available, that the results are normal, and that no further action is required. If at the booking visit there is a "strong desire" for Down's screening (I have already observed that this is Mr Mason's unwarranted gloss on the document, based no doubt on what the claimant had told him), the midwife is duty-bound to check that the lady has genuinely changed her mind when the test has not been performed. This can be achieved by asking the very simple question: "I understand that you have changed your mind, is that correct?" If the answer is in the affirmative, it is perfectly acceptable to record in the relevant box, "screening declined". If the answer is in the negative, the quadruple test can still be performed.
- 123. Mr Mason agreed in cross-examination that the combined test is preferable to the quadruple test. He did not accept that by carrying out the check he was suggesting there was a danger that the patient might think that the midwife was interfering with or influencing her decision. Mr Mason adhered to his written evidence that Midwife Foley did not read "Down's screening declined" in the ultrasound report. This point counts against him to the extent that he was both entering the arena at this point and coming to an inferential conclusion which is probably incorrect; but the forensic damage is limited.

- 124. The defendant's midwifery expert was Ms Susan Brydon, RGN, RM, BSc (Hons). Her experience certainly matches Ms Johnson's and my overall impression of her evidence is that her recent hands-on midwifery experience may be slightly greater. In my view, though, very little turns on this.
- 125. The essence of Ms Brydon's evidence, and I may take this from the joint reports as well as her evidence in chief, is that it is not incumbent on a midwife at the 16-week appointment to carry out the sort of follow-up suggested by Ms Johnson, that there is no need to check whether "Down's screening declined" is or may be a mistake, and that it is very difficult to be or at least appear to be non-judgmental. As she said in her evidence in chief, "it is terribly difficult to raise it and there are already some fail-safes in the system. It is not a breach of duty to fail to explore".
- 126. In cross-examination, Ms Brydon was pressed by Ms Bradley to address the NICE Clinical Guidelines. Ms Brydon's point was that the review obligation was triggered only if the relevant screening test was undertaken, and here the claimant declined it. She also said that if the guideline required a midwife to revisit the issue it would say so. In answer to the question, "if at the 16-week appointment you rely on the sonographer's record, this assumes that the patient is of the same mindset [approximately 3 weeks later]", Ms Brydon said, "no: the midwife is entitled to respect the woman's decision as recorded at the scan; there is nothing to investigate. You aren't making an assumption".
- 127. Ms Brydon also said that by revisiting the matter you are effectively asking the patient to consider whether she has made the right decision. The question would always be: "you have declined it but are you sure?" Furthermore, by declining Down's screening at the scan appointment, the claimant had effectively declined the quadruple test. This latter test is offered if for some reason the combined test has been missed, or no result is available; it is not for those who have declined the combined test and then changed their mind.
- 128. In re-examination, Ms Brydon accepted that the midwife might have written "declined" in the box recording the result of the combined test, but it was not incumbent on her to do so.
- 129. Mr Howe's evidence was similar to Ms Brydon's. He told me that there was no duty on the midwife to ask further questions. He added that it is one of the regular complaints of mothers that they are subjected to routine procedures they were not properly counselled about, and that they end up with invasive testing they did not want. When the 2007 National Standards were being formulated the emphasis was on respecting a mother's informed choice: if a mother declined a procedure, it was important that her wish be respected. If you revisit the issue, you run the risk that the mother will feel that she has made the wrong choice; and will therefore be pressurised into changing her decision.
- 130. Mr Howe stressed that offering the quadruple test is not mandatory. The patient has been for and declined the better test (i.e. the one with higher sensitivity and specificity). It is reasonable to leave it there.
- 131. In cross-examination, Mr Howe did not accept that the NICE Clinical Guideline was applicable. Given that no screening test was carried out, there was nothing to record.

- A quadruple test is reserved for those whose combined test has failed for technical reasons (later he clarified that he would include those who booked too late for that test, or for whom that test was not possible).
- 132. As far as the midwife was concerned, Down's screening had been declined. She would assume that the sonographer had discharged her duty. Attempts to ask non-judgmental questions often fail. Mr Howe agreed that offering the quadruple test would be a fail-safe.

# **Discussion and Conclusions**

- 133. Mr de Navarro's submissions on this issue proceeded as follows:
  - (1) Local policy did not require the midwife at the 16-week appointment to investigate what had occurred at the scan appointment.
  - (2) The NICE Clinical Guideline did not do so either: in terms, it is directed to the screening tests *undertaken*.
  - (3) If the patient declined Down's screening, it follows that she also impliedly declined the quadruple test for which she had been booked 8 weeks earlier. It was not therefore incumbent on the midwife either to discuss or to offer that test.
  - (4) Patient autonomy must be respected, and there is a real risk that any exploration will be seen as intrusive.
  - (5) The midwife was entitled to assume that the sonographer had discharged her duty and obtained informed consent (or, that the system had worked such that the claimant's decision was informed).
  - (6) In any event, the quadruple test is a backstop dedicated to situations where the combined test has either been missed or has failed for some technical reason. Further, it is less sensitive than the combined test, and this is relevant to the delicate balance that may have to be performed at a later stage in the context of whether or not to have a diagnostic test.
  - (7) Midwife Foley's practice is supported by a respectable and responsible body of medical opinion, namely that of Ms Brydon and Mr Howe.
- 134. In approaching this issue, I continue to remind myself that this cannot be a question merely of preferring the opinions of one party's experts. Lord Browne-Wilkinson's observations in *Bolitho* remain applicable.
- 135. The parties will have noticed that I have slightly reformulated this fourth issue. Originally, I had formulated it in terms of the midwife's duty to explore the reasons for the absence of results for the combined test. I have concluded that by referring to "reasons" the duty, if it arises, is capable of being misunderstood. I have substituted more neutral language.
- 136. It is clear from the NICE Clinical Guidelines that a mother will proceed through a number of clinical appointments and that each has a particular purpose or purposes. Under paragraph 14 above I listed those purposes which are potentially relevant to the

16-week appointment, although I have concluded that the last bullet point (which is the fourth in the guidelines themselves) is forward-looking and has no relevance to the instant case. Read entirely literally, the words "review, discuss and record the results of all screening tests undertaken" is concerned only with those tests which have in fact been carried out. However, I have little difficulty in accepting Ms Bradley's submission that this clause cannot be read in so restrictive a manner. There may be many reasons why tests were not undertaken, ranging from genuine changes of mind; patients missing appointments for no good reason and failing to rebook; illness; forgetfulness; to other misunderstandings and human error along the way. It cannot be incumbent on the midwife to undertake lengthy inquiry or to delve into the reasoning processes and motivations of the patient, but in my judgment in a situation where the patient was booked for the combined test and did not have it, the midwife should not leave the matter there. A simple and straightforward exploration and check that what has occurred, or not has occurred, was and is in accordance with the patient's wishes continues to place her at the centre of the decision-making process and amounts to the taking of reasonable steps to ensure that everything has gone and is continuing to proceed according to plan. Any working hypothesis that everything has happened properly and in accordance with the patient's wishes and expectations is unrealistic in relation to virtually any human system. All that was required, after all, was Mr Mason's single question; or, perhaps preferably, Ms Johnson's gentle and open-ended enquiry. I agree with Ms Johnson in particular that the failure to do this constituted sub-standard care.

- 137. It is not as if there was no screening undertaken at all. The foetal anatomy was recorded by Ms Bracher and everything appeared normal. Midwife Foley would surely have wanted to mention this if for no other reason than to reassure her patient. The entry "Downs screening declined" appears immediately above this.
- 138. In my view, nothing really turns on Midwife Foley's omission to complete the box for the result of the combined test. All that this demonstrates is that the matter was not discussed; or, rather, that there is no evidence that the matter was discussed. Had it been, it would have been good practice to insert a word or two to evidence the discussion. Plainly, it would have been sub-standard practice to have inserted "not applicable" or "declined" without such a discussion.
- 139. I appreciate that the quadruple test is less sensitive than the combined test, and that many would perceive it as designed for those who have missed the earlier test. However, it remains available at the 16-week point, and its accuracy and implications could be explained to any patient who now wanted it. I do not understand Mr de Navarro to submit that the quadruple test should not be offered if, for example, a patient says that she has changed her mind again (not this case) and now definitely wants Down's screening. The claimant's case is *a fortiori*, because it is her contention, which I have accepted, that she always wanted Down's screening.
- 140. I place no weight on the defendant's changes of practice after January 2015. After any event such as this, those providing medical services may go too far the other way. In fact, this defendant has not; but I have reached that conclusion on the basis of a purposive, common sense and reasonably fluid application of the NICE Clinical Guidelines in the context of the expert evidence.

141. It follows that I am constrained to hold that Midwife Foley failed to discharge her duty to the claimant on 11<sup>th</sup> August 2014 in not exploring why the combined test had not been carried out.

The Fifth Issue: If the answer to (4) is "no", would the claimant have informed the midwife pursuant to the exploration that <u>ex hypothesi</u> the latter should have conducted that she wanted Down's screening (i.e. the quadruple test)?

142. Given my findings in relation to the third issue, the answer to the question I have posed must be "yes". Ms Bradley does not advance the alternative case that the claimant genuinely declined Down's screening at the sonographer's appointment and then changed her mind again.

The Sixth Issue: In the event that the answer to (3) is "no" and/or to (5) is "yes" (on the assumption that either or both of these questions arise), would the claimant have consented to invasive testing and a termination of pregnancy?

- 143. I have found that the claimant did wish to undergo Down's screening on 22<sup>nd</sup> July 2014, that the sonographer did not discharge her duty on that occasion, and the midwife did not discharge her duty to her on 11<sup>th</sup> August. In these circumstances, even had I determined the fourth issue in the defendant's favour, the upshot would be the same; and this sixth issue would arise in the same way. Equally, if I had determined the second issue in the defendant's favour but my holdings were otherwise in place, the upshot would be the same.
- 144. I should make it clear that my finding in relation to the third issue is central to the claimant's success in this litigation, subject to the sixth issue. If I had found that the claimant's wish was not to have Down's screening on 22<sup>nd</sup> July 2014, her case would fail regardless of the defendant's breaches of duty.
- 145. Messrs Mason and Howe are in agreement in relation to medical causation. They are agreed that had a combined test or a quadruple test been carried out, it would have been determined that the claimant was in a high-risk category, i.e. the risk was more than 1:150. The claimant would have been offered invasive testing, either amniocentesis or CVS, and the result would have confirmed that the foetus had Down's syndrome. There would have been time for a termination.
- 146. Accordingly, the issue I have to resolve on the balance of probabilities is that of factual causation: whether the claimant, had there been no breach(es) of duty, would have (i) consented to invasive testing, and then (ii) sought a termination.
- 147. Mr de Navarro submitted that the claimant's evidence is obviously affected by the fact that she now has the certainty that Aleksander has Down's syndrome. The sixth issue entails the asking of a hypothetical question which should be answered without the benefit of hindsight. The claimant informed the midwife on 23<sup>rd</sup> June that she was unsure about invasive testing. Had she received a high-risk result, the experts are agreed that it would have been 1:150 or more but cannot be more precise than that. Mr de Navarro's point is that there is no evidence that Down's screening in this case would have produced a result which was worse than 1:50 (i.e. 2%), and "unless it did the risk of Down's and the risk of miscarriage would have been of the same order". He submitted that the claimant's answer in cross-examination (see para 39 above) was

somewhat equivocal, pointed out that a substantial number of women do not opt for an invasive diagnostic test, and even when Down's syndrome is confirmed a significant number do not proceed to termination. It is always a difficult decision, and the claimant's case should fail given that the burden of proof is on her.

- 148. I agree with Mr de Navarro that care is needed in evaluating retrospective assertions that a claimant would have acted in a certain way when the outcome is no longer a statistic but a certainty. I disagree with him that there is much if any utility in examining the statistical probabilities at any stage, either in terms of the risk of Down's versus the risk of miscarriage or of decision-making in general across the whole cohort of expectant mothers. This must be a case-specific evaluation tailored to this particular claimant. The notion that this particular claimant would have weighed up a 1:X risk of Down's syndrome (whatever X was) against a 1-2% risk of miscarriage is implausible. She would have made the assessment is a far less precise manner.
- 149. The claimant said that she was unsure about invasive screening on 23<sup>rd</sup> June at the 8-week appointment. I have already touched on this issue. Ms Brydon gave no weight to this answer, making the valid point that invasive testing is not offered at the booking appointment. For some mothers, the answer would always be a firm "yes" or "no" regardless of any screening result, but I think that the majority would want to wait and see. In these circumstances I can place virtually no weight on this particular answer.
- 150. It is quite true that the answer the claimant gave in cross-examination was somewhat garbled. This has availed her in the context of the third issue, but I do not think that it significantly harms her case on the sixth. Having accepted her case on the third issue, I have found that the claimant consistently wanted Down's screening of her baby. The claimant did not have a principled objection to termination, and Mr de Navarro did not suggest that she did. Had she been informed that her baby had Down's syndrome, I am satisfied that she would have proceeded to termination. So, the real issue is whether she would have declined invasive testing not because she did not want a termination but rather because she feared she might miscarry. The claimant's written and oral evidence accepted that she had this very concern.
- 151. Lucasz Cieciura stated at para 9 of his statement that had the risk been higher than 1:150 "we would have decided to undergo more tests, even if they carried a risk of miscarriage". He was not cross-examined about this, although I have to say that I do not hear Mr Cieciura's authentic speaking voice through this paragraph. Taken in isolation, I can give little weight to this assertion. Para 29 of the claimant's witness statement is more authentic, although it is really addressing the question whether she would have proceeded to a termination had she been given a definite diagnosis. Para 27 addresses the earlier point in her hypothetical decision-making in these terms:

"I understand a high risk is usually expressed as a greater than 1:150 risk. I would definitely have agreed to further tests had this been explained to me. I am aware that there is around a 1% risk of miscarriage from tests such as an amniocentesis but would definitely have agreed for further tests to be done."

This needs to be placed against her answer in cross examination which is much less clear. It is also noteworthy that the claimant appears to be adamant about this and I have wondered whether that is entirely accurate.

152. Deciding a hypothetical issue such as this on the balance of probabilities is a matter of inference which cannot purely depend on general assessments of witness credibility. On balance, and in the light of all the evidence and the inferences to be drawn from it, I have concluded that the claimant probably would have proceeded to invasive testing had she been told that there was a high risk of Down's syndrome. The claimant was a relatively young mother and I think that at the end of the day the fear that she might be carrying a child with Down's syndrome would, at least for her, have tipped the balance. It follows that this sixth issue must be resolved in the claimant's favour.

#### Conclusion

- 153. Nothing I have said in this judgment should be interpreted as suggesting that the birth of a child with Down's syndrome must be seen as unwelcome. Some parents have absolute ethical objections to termination of pregnancy, and for them the discussion begins and ends at that point. Other parents accept the possibility of having a baby with Down's syndrome without a shred of concern or reluctance. The State expresses no judgments either way, but it is the policy of the NHS that Down's screening must be offered to all expectant mothers, the premise being that many would wish to exercise their right to proceed to medical termination in the event of a diagnosis. These various wishes and decisions must be and are respected without comment.
- 154. There must be judgment for the claimant.