

29 November 2022

Baby F

+Prof Sally Kinsey on Babies A, B, E & F

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Tuesday, 29 November 2022

(11.00 am)

(Delay in proceedings)

(11.28 am)

(In the presence of the jury)

MR JUSTICE GOSS: I'm sorry we're late starting. We are in a position to proceed now. Mr Johnson.

MR JOHNSON: Thank you, my Lord. Professor Sally Kinsey, please.

Just while Professor Kinsey is coming in, my Lord, a word of introduction. This evidence relates to several cases. We'll start with the case of [Baby A], move on to his sister [Baby B], and then [Baby E].

MR JUSTICE GOSS: All right. You understand? This witness is going to give evidence in relation to a number of the babies, but each will obviously be identified as we go on through in turn.

MR JOHNSON: To help us all, not least to help myself, we'll go through the sequence of events dealing with events leading up to the material evidence.

MR JUSTICE GOSS: Yes.

PROFESSOR SALLY KINSEY (sworn)

Examination-in-chief by MR JOHNSON

MR JOHNSON: Could we start with your giving the jury your full name and your professional qualifications, please?

KINSEY: My name is Sally Elizabeth Kinsey. I am a retired paediatric haematologist and I am a fellow of the Royal College of Physicians, the Royal College of Pathologists, and also an honorary member of the Royal College of Paediatrics and Child Health.

JOHNSON: Thank you. Dr Kinsey, were you a professor of paediatric haematology at the University of Leeds from 2007 until very recently?

KINSEY: Yes, that's correct.

JOHNSON: And when did you formally retire from everyday practice?

KINSEY: At the end of April 2021.

JOHNSON: Thank you. Were you approached by Cheshire Police to look at several cases with which the jury are concerned in this trial?

KINSEY: Yes, that is the case.

JOHNSON: One of the cases, which is yet to come, is that of [Baby N]; is that right?

KINSEY: That's correct, yes.

JOHNSON: But the three that we're going to deal with most directly today are the [Surname of Babies A & B] twins, [Baby A] and [Baby B] --

KINSEY: Yes.

JOHNSON: -- and [Baby E]?

KINSEY: Yes.

JOHNSON: Just so that the jury have an idea of what you're going to deal with, in terms of the issues that arise with [Baby E], because he was an identical twin to his brother [Baby F], did you also look at his brother [Baby F]'s medical records for reasons that you will explain in due course?

KINSEY: Yes, I did.

JOHNSON: Thank you. So going back in time, for those of us in court, to the case of [Baby A], it involves a degree of what

I'll call recalibration because we've been concentrating on other cases. So if I may, I'm just going to go through some of the history of [Baby A] before we get to your professional opinion. All right?

KINSEY: Thank you, yes.

JOHNSON: Is it right to say that in each of these cases you have written reports?

KINSEY: Yes, that is the case.

JOHNSON: And in each of the reports, you set out the relevant factual background relating to each of the children individually?

KINSEY: Yes, that is correct.

JOHNSON: So the factual background and events leading up to the matters with which the jury are concerned all have a bearing on your opinion?

KINSEY: Yes, they do.

JOHNSON: Thank you. I'm going to start, if we may, Professor Kinsey, with your report of 4 March 2020, relating to [Baby A].

For your Lordship's note that's at page I781.

MR JUSTICE GOSS: Thank you.

MR JOHNSON: Did you start your report, having dealt with your professional qualifications, with what you headline as a brief outline of the case?

KINSEY: Yes, I did.

JOHNSON: Did you record the fact that [Baby A]'s mother, [Mother of Babies A & B], had been diagnosed with something called antiphospholipid syndrome?

KINSEY: Yes.

JOHNSON: That that was a longstanding medical condition that had originally been diagnosed back in 2011?

KINSEY: Yes, that's correct.

JOHNSON: And did you record the fact that when she became pregnant, [Mother of Babies A & B] was under fairly close medical supervision?

KINSEY: Yes, I did.

JOHNSON: Thank you. That original supervision was taking place in London?

KINSEY: Yes.

JOHNSON: And the original intention had been for [Mother of Babies A & B] to give birth in London under the supervision of her treating medical practitioners?

KINSEY: Yes, that was the plan.

JOHNSON: However, because at 29 weeks' gestation [Mother of Babies A & B] developed pre-eclampsia, she was admitted to the Countess of Chester Hospital?

KINSEY: Yes.

JOHNSON: And the remainder of her pregnancy was managed at that institution?

KINSEY: Yes, that was the case.

JOHNSON: Did you record at your paragraph 6 that on 20 May 2015, this is 3.6, when [Mother of Babies A & B] was at 28 weeks and 5 days gestation, she self-referred to the obstetric day assessment unit at the Countess of Chester with what she reported as reduced foetal movement?

KINSEY: Yes.

JOHNSON: She was reviewed by the physicians at Chester and, following discussions with Professor Cohen in London, she remained thereafter as an inpatient until she gave birth at Chester?

KINSEY: Yes, that's right.

JOHNSON: If we can go, just to aid the jury's recollection of the chronology, if Mr Murphy could take us to tile 1 in the [Baby A] sequence, please. Did you record the fact -- this is your paragraph 3.9, Professor Kinsey -- that on 7 June 2015 [Mother of Babies A & B] was significantly hypertensive, in other words with high blood pressure, and that a diagnosis was made that she had severe pre-eclampsia and therefore an elective C-section under general anaesthetic was undertaken?

KINSEY: Yes.

JOHNSON: Thank you. If we look at tiles 2 and 3 -- these are on the screen in front of you, professor -- we can see that, first, [Baby B] was born, followed quickly by [Baby A].

KINSEY: Yes.

JOHNSON: [Baby A], if we just click on the tile, please, to remind ourselves, was born at 31 weeks plus 2 days' gestation.

His Apgar scores are there recorded as is his birth weight at 1,660 grams.

KINSEY: Yes.

JOHNSON: I think you, looking at the medical records, reproduced what's there recorded in a rather shorter form, that on birth [Baby A] had good tone, was blue/pink in colour, his heart rate wasn't heard, initially there was minimal spontaneous respiratory effort, but his heart rate was brought up by five inflation breaths and he gradually became more pink, his heart rate rose to above 100 beats a minute, and by 4 minutes of age he had good spontaneous respiratory effort, his apnoeic episodes became fewer, his oxygen saturations varied between 95 and 100%, initially in oxygen, but then subsequently in air, and that by 10 minutes of age we can see there an Apgar score of 9.

KINSEY: Yes.

JOHNSON: Is that right?

KINSEY: That is right, yes.

JOHNSON: If we move on to, Mr Murphy, please, tile 24 -- and this is your paragraph 3.15, Professor Kinsey. There do we see the assessment of Dr Brunton later that evening?

And if we could click on, please. Thank you.

The jury are familiar with this medical shorthand now, professor, but we see there that [Baby A] was clinically stable on CPAP.

KINSEY: Yes.

JOHNSON: We see that the amount of additional oxygen he was receiving was such that he was breathing in between 25 and 30% oxygen.

KINSEY: Yes.

JOHNSON: His respiratory rate, I think you have recorded, albeit I'm not sure it's recorded on this particular tile, was 40 breaths a minute, with no increased work of breathing?

KINSEY: Yes.

JOHNSON: And that his oxygen saturations, as we see there in about the fifth line, were 100% in 26% oxygen?

KINSEY: Yes.

JOHNSON: Thank you.

Move on to tile 31, please, and your paragraph 3.16.

Again, if we could just click on that, please, Mr Murphy. Thank you.

Do we see that a chest X-ray was undertaken of [Baby A] at just before 00.30 on 8 June? This was 4 hours after he had been born. There was an observation about the position of the NG tube and there was some evidence of respiratory distress syndrome in the picture of his lungs.

KINSEY: Yes, that's the case.

JOHNSON: Thank you. As a matter of interest, and if this is outside your sphere of expertise -- we see there rather than RDS it is recorded as hyaline membrane disease. Is it the same thing or not?

KINSEY: I think it is the same thing but I'm not specifically a paediatric neonatologist.

JOHNSON: All right. Thank you. Can we move back to tile 84 now, please, and your paragraph 3.17, professor.

Here we have a medical review at 09.45 on the 8th.

That records [Baby A]'s problems as being preterm, RDS.

He was established on feeds, he was being treated for a suspected sepsis for reasons that we have already heard from the treating doctors, but he was being managed in air with CPAP; is that right?

KINSEY: That's right, yes.

JOHNSON: He was being given antibiotics, we know and you have recorded, and you record the fact that the clinical examination was what you describe as unremarkable; is that right?

KINSEY: That's right, yes.

JOHNSON: So that's 09.45 in the morning of the 8th. If we move on, please, to tile 143.

By just after 4 pm, here we have the notes of Dr Theresa MacCarrick. We see that a UVC was put into [Baby A] under sterile conditions, but it wasn't ideally placed, it was removed, another attempt was made, but again that had to be removed as well, and therefore the decision was taken, rather than having a UVC or a UAC, [Baby A] would be given a long line.

KINSEY: Yes.

JOHNSON: Thank you. If we move on now, please, Mr Murphy, to tile 154, we will come to Dr Harkness' insertion of a long line, one of, the jury will remember, three he was doing in room 1 that evening.

You have recorded this event, professor, at your paragraph 3.19; is that right?

KINSEY: Yes, it is, yes.

JOHNSON: Thank you. The next matter that you record in your statement or your report is at paragraph 3.20 where you refer to nursing notes made for the night shift; is that right?

KINSEY: That's right, yes.

JOHNSON: For the jury's information, we see those at tile 170, please. There is a summary there, but essentially you refer to these as having been written the following morning at 07.58 in the morning; is that right?

KINSEY: Yes, that's correct.

JOHNSON: That the observations at 8 pm were stable?

KINSEY: Yes.

JOHNSON: And that glucose infusions had commenced via the long line as directed by Dr Harkness?

KINSEY: Yes.

JOHNSON: You also refer in the subsequent paragraph to other matters recorded in the nursing notes, namely that [Baby A] was noted to be "jittery"; is that right?

KINSEY: Yes, that's right.

JOHNSON: Then at 20.20, that the person you describe as the nurse looking after [Baby A], who we know to be Lucy Letby, noticed that his hands were white, he was centrally pale with poor perfusion and had become apnoeic.

KINSEY: Yes.

JOHNSON: You then record the fact that Dr Harkness was called to assist, that the glucose infusion was disconnected, that [Baby A] then collapsed, and you record the fact that his death was recorded as having occurred at 20.58 that evening.

KINSEY: Yes.

JOHNSON: Thank you.

Do you then refer to what the jury has at tile 183?

If Mr Murphy would just find that for us, please. These are Dr Harkness' retrospective notes recording the fact that he was called to see [Baby A] at 20.26.

KINSEY: Yes.

JOHNSON: That respiratory support had been given to him and that there was good chest movement. If we just -- I'm not going to do this very often with you, Professor Kinsey, but it's really for the benefit of the rest of us who need to remind ourselves of the factual circumstances.

So if we could go to the underlying material, please, Mr Murphy, at 1065.

There we see the fact recorded by Dr Harkness that respiratory support with bagging had started via Neopuff immediately and that there was good chest movement from [Baby A].

KINSEY: Yes.

JOHNSON: You refer to evidence that we heard that Dr Harkness had got the impression that there might have been an issue relating to the long line which was removed?

KINSEY: Yes.

JOHNSON: That [Baby A] was intubated at 20.28?

KINSEY: Yes.

JOHNSON: His heart rate was between 60 and 70 beats a minute?

KINSEY: Yes.

JOHNSON: And that chest compressions then started at 20.28 and he was given a saline bolus and a bolus of adrenaline at 20.31 and 20.33 respectively?

KINSEY: Yes.

JOHNSON: You at your paragraph 3.29 record that Dr Jayaram then arrived.

KINSEY: Yes, the consultant on call. I didn't know it was Dr Jayaram.

JOHNSON: I don't think you knew his identity. I'm inserting the names for my own and the jury's benefit, really.

So Dr Jayaram arrived, the UVC was pulled back, there was no heart rate detected, there was pulseless electrical activity on the monitor, and there then followed full CPR with multiple doses of adrenaline, sodium bicarbonate and dextrose.

KINSEY: Yes.

JOHNSON: And those efforts, unhappily, had to be discontinued at 20.58?

KINSEY: Yes.

JOHNSON: At your paragraph 3.30, you then record what Dr Jayaram spoke of in a witness statement concerning an unusual skin discolouration that he had observed on [Baby A] at around this time.

KINSEY: Yes, that's correct.

JOHNSON: What you record him having recorded as being "flitting patches of pink areas on the background of a blue-y/grey skin, which appeared and disappeared"?

KINSEY: Yes.

JOHNSON: And which he said didn't fit with anything he had seen before?

KINSEY: Correct.

JOHNSON: Finally, so far as the background was concerned, at your paragraph 3.31, did you record the fact of a post-mortem

examination conducted by Dr Shukla of Alder Hey Hospital in Liverpool?

KINSEY: Yes, I did.

JOHNSON: The fact that no cause of death could be determined?

KINSEY: So I understand, yes.

JOHNSON: You record an anatomical variation of [Baby A]'s pulmonary arteries, which was thought unlikely to be significant?

KINSEY: Yes, I did.

JOHNSON: And you also record something called a patent foramen ovale. Have I pronounced it right, first of all?

KINSEY: Yes, you have and yes, I did.

JOHNSON: Can you explain to the jury what that is, please?

KINSEY: Yes, I can. I expect we may be coming on to this later because I have provided some diagrams for further discussion. In babies, before they are born, there is a bypass of the lungs' blood circulation, so the pulmonary circulation. And this circulation goes from the right side of the heart to the left side of the heart. Normally, when people are born, so in all of us sitting in this room now, the right side of the heart sends blood into the lungs for oxygenation and that comes back to the left side of the heart, once it's oxygenated, and the blood continues round the body to provide oxygen to all the organs to keep us going.

Because, when in the womb, a baby doesn't have use of their lungs, because they're swimming around in a pool of amniotic fluid, the placenta takes over the job of the lungs for oxygenation of the baby's blood supply, so the blood doesn't need to go through the lungs, apart from a tiny amount helping the lungs to grow.

So there's a bypass mechanism between the right atrium, which is the first chamber of the heart on the right-hand side of circulation, through to the left atrium, which is the first chamber on the left-hand side of the heart. That hole is the -- oh dear, foramen ovale. Foramen is a window and ovale is oval, so it's an oval window, which is really a flap. It's a bit of membrane that is pushed against by the greater side pressure levels so that in a preterm -- well, in a baby in utero, the circulation goes through the patent foramen ovale omitting to go through the lungs. This is normal.

Have I explained this sufficiently?

JOHNSON: Yes.

KINSEY: So the foramen ovale is between the right and left parts of the circulation, is normal in preterm babies and neonates, and it closes in most people.

JOHNSON: Thank you. That will become relevant at a later stage and we'll run through the diagram and your explanation as to how this mechanism works, how it changes between a baby that's in its mother's womb and a baby after birth.

KINSEY: Yes.

JOHNSON: Okay. Thank you.

I'm going to move on now, please, professor, to your section 4 of your report. Within the medical records relating to [Baby A], did you find the results of a full blood count test taken that had been undertaken on 6 July at just after 10 pm?

KINSEY: Yes, I did.

JOHNSON: Just to put that into context for the jury, that's about an hour and three quarters after he had been born?

KINSEY: Yes.

JOHNSON: Others can ask you if it's thought to be necessary, but putting it in a sentence, was [Baby A]'s full blood count normal or abnormal?

KINSEY: It was normal of a child of his gestational age, yes.

JOHNSON: Thank you. The jury will recall from the evidence that a cause for concern in relation to both [Baby A] and [Baby B] was the maternal antiphospholipid syndrome from which [Mother of Babies A & B] suffered.

KINSEY: Yes.

JOHNSON: Could we start, please, with you explaining to us what antiphospholipid syndrome is?

KINSEY: Yes. So antiphospholipid syndrome is a rare autoimmune disease which affects the general systemic situation in the mother and causes antibodies. This is a rare disease in approximately 50 per 100,000 people.

It often occurs in cases of other autoimmune disorders, but most commonly something called SLE, which is an abbreviation of systemic lupus erythematosus; again, a rare autoimmune condition.

The problem with people with antiphospholipid syndrome is they make antibodies against their own tissues and so these tissues tend to start to work badly or not normally and can be associated with increased blood clotting. As a result, part of the management is to be on anti-coagulation with drugs such as warfarin and with heparin and also aspirin.

It is well recognised in antiphospholipid syndrome that women who are pregnant can have problems both themselves during pregnancy and also that the unborn child may also have issues because of poor development of the placenta on the maternal side, and quite often mothers end up with very high blood pressure, which is hypertension, and is called pre-eclampsia in pregnancy.

This is because the antibodies in antiphospholipid syndrome target the placental tissues in particular.

Because of problems with the placenta it means that the baby or babies that are trying to grow in the womb don't get the same amount of nutrients and blood flow and oxygenation as one would hope to see and therefore this can cause foetal growth retardation and potential issues for the unborn child.

Quite a lot of pregnancies in women with APS tend to have to have intervention with caesarean section of young babies in order to save the mother's life as well as that of the unborn children.

JOHNSON: So would it be an oversimplification to say that antiphospholipid syndrome is likely to result in premature birth?

KINSEY: Yes.

JOHNSON: Results in clotting problems for the mother?

KINSEY: Yes.

JOHNSON: And therefore can endanger both mother and baby?

KINSEY: As a result of problems with the placenta, yes.

JOHNSON: Is antiphospholipid syndrome hereditary?

KINSEY: Not that I'm aware of, but I'm not an expert in antiphospholipid syndrome itself.

JOHNSON: Did the antiphospholipid syndrome pass to either [Baby A] or to [Baby B]?

KINSEY: No, that is not the case. I can explain that in a little bit more detail because if one looked at the blood results, it would show that there were antiphospholipid antibodies in the circulation of the babies and this is because there are two types of antibody: IgM, immunoglobulin M, and IgA, immunoglobulin A -- sorry, IgG and IgM, sorry.

MR JUSTICE GOSS: I was going to say, I don't think we really need --

KINSEY: Okay.

MR JUSTICE GOSS: Obviously it's very helpful of you to offer to do it, but the important thing is that neither [Baby A] or [Baby B] had this condition.

KINSEY: That is correct, yes, it is.

MR JUSTICE GOSS: Right.

MR JOHNSON: Right. I wasn't sure quite what was in issue and what wasn't.

MR JUSTICE GOSS: Anyway, if you need -- you can explain how you can tell that, but it's basically from the blood that's taken? You'd find the antibodies in the blood?

KINSEY: You would find the antibodies in the blood, one type, only the IgG, which is not significant in the children.

MR JOHNSON: All right.

We know, from the evidence that we heard, that the treating doctors at the time were concerned about this and were not sure that it hadn't passed, but you can say it didn't pass from mother to children?

KINSEY: No, it didn't.

JOHNSON: Thank you. You then at just before -- as part of your haematology results and interpretation section at the end of that section you deal with the question or the issue of air embolus.

KINSEY: Yes.

JOHNSON: And what remarks did you -- we'll come in more detail to air embolus in due course towards the end of your evidence, but what conclusions did you draw so far as air embolus was concerned?

KINSEY: Well, the only conclusions that I was able to get was from the description of the doctors who attended [Baby A] and the features of the blotchiness on the skin, particularly the commentary about pallor and pinkness and blueness in the skin. And so I was quite brought up short, really, by hearing -- reading about this and so that is -- that really cemented my concerns and the comments, particularly that Dr Jayaram had said about what was going on.

JOHNSON: Did his description -- was his description consistent with a particular phenomenon?

KINSEY: Yes. Having said that, seeing air embolus features in the skin is very rare. I have never seen it myself.

I have seen it in medical literature, but it was a pretty stark description of what sounded to be air embolus to me.

JOHNSON: That was a conclusion you drew. We'll deal with the mechanism by which these features exhibit themselves at the end of your evidence. Okay? So I will return to that in due course because it's an explanation that applies to several of these cases, isn't it?

KINSEY: It is, yes.

JOHNSON: Yes, all right. So just before we leave [Baby A]'s case behind, albeit we will return to it in the context of the air embolism issue, did you conclude that [Baby A]'s collapse on the evening of 8 June could not be attributed to any haematological abnormality, nor to maternal antiphospholipid syndrome?

KINSEY: Yes, I did.

JOHNSON: Thank you. So with the caveat that we will return to air embolus, can we move on to the case of his twin [Baby B], please, professor. I'm going to refer you, if I may, to the statement you made in her case, dated 4 March 2020.

KINSEY: Yes.

MR JOHNSON: For your Lordship's note, this statement appears at I874.

MR JUSTICE GOSS: Thank you.

MR JOHNSON: As with [Baby A], for all our benefits, I hope, I'm just going to deal with the background of [Baby B]'s progress so that we can put your opinion into its factual context. So if Mr Murphy would assist, please, by bringing up the [Baby B] carousel, tile 2 records that at 8.30 pm, [Baby B] was the first born of the twins. Her birth weight, I think, was 1.669 grams (sic).

KINSEY: Yes.

JOHNSON: You, professor, recorded the fact that at birth, [Baby B] was blue and floppy, required two sets of five inflation breaths and CPR when she was between 2 and 3 minutes of age, that her ventilation was supported by bagging, during which time her tone improved, as did her colour, and at 7 minutes of age her heart rate was greater than 100 beats per minute. At 13 minutes of age she was successfully intubated and stabilised, and then transferred to the neonatal intensive care unit, and we see there on the screen her Apgar scores recorded at 1, 5 and 10 minutes respectively.

KINSEY: Yes.

JOHNSON: As with her brother, did you record that on day 2 of life, in other words 8 June, her clinical problems were recorded as being preterm, respiratory distress syndrome, that there was a query as to whether or not she too had sepsis, and maternal antiphospholipid syndrome was recorded as a potential issue?

KINSEY: Yes.

JOHNSON: [Baby B] was started on TPN and antibiotics, had phototherapy, but also was being given some breast milk through the tube?

KINSEY: Yes.

JOHNSON: At your paragraph 3.6, and this is not long before the death of her brother [Baby A], did you record that there had also been unsuccessful attempts to insert a UVC line to [Baby B], followed by the successful insertion of a long line?

KINSEY: Yes.

JOHNSON: If we can move on, please, to tile 57. So on day 3 of [Baby B]'s life, this is the day after [Baby A]'s death, did you record at your paragraph 3.7 that [Baby B] was very active, crying, had normal tone, the clinical examination of her was unremarkable, blood cultures were negative for infection and that therefore antibiotics were stopped, as was phototherapy,

that she was allowed time off CPAP, and that a cranial ultrasound revealed a grade 2 intraventricular haemorrhage and the ECG was normal?

KINSEY: Yes.

JOHNSON: If Mr Murphy would move us on, please, to tile 210.

Did you record, professor, that in the early hours of 10 June, so day 4, there was a note in the nursing records that from 8 pm on the 9th to 00.20 on the 10th [Baby B] had continued on CPAP, that her observations were satisfactory, that she was active and handling well, but that shortly before midnight she had desaturated to 75%, and there was an issue about the positioning of the nasal CPAP prongs?

KINSEY: Yes.

JOHNSON: But following repositioning of the prongs, she had recovered?

KINSEY: Yes.

JOHNSON: Tile 218, please, Mr Murphy. The next event to which you referred was the nursing comment timed for events at 00.30, saying that there had been a sudden desaturation to 50%, that [Baby B] had been cyanosed. Is that blue --

KINSEY: Yes.

JOHNSON: -- in everyday language? Centrally shut down, limp, apnoeic, that ventilation was given via a Neopuff, resulting in observable chest movement, and that her colour had changed rapidly to purple blotchiness with white patches, she became bradycardic, and that the doctors had been called for?

KINSEY: Yes.

JOHNSON: We then go to tile 221, please, Mr Murphy. This is the note of Dr Lambie relating to events at 00.33.

Could we go to the actual document, please? Could we go to the note, please? Thank you.

Here we have a reminder for us. It's a retrospective note written by Dr Lambie at 02.30, but referring back to events that had happened from 00.33, where Dr Lambie had been called to the neonatal unit, a bag and mask ventilation was in progress, Dr Lambie had received a history of acute apnoea with no warning, widespread purple discolouration of the skin with white patches, gradual fall in the heart rate down to between 80 and 90 beats

per minute, and that [Baby B] was being ventilated with a Neopuff -- is that a Guedel airway?

KINSEY: Yes.

JOHNSON: With good chest movement. Was intubated, given fluid, she had a reduced capillary refill time, but within 10 minutes became active and was bleeding.

KINSEY: Breathing.

JOHNSON: Breathing, sorry. I beg your pardon, I was reading ahead to the next sentence.

Was a blood sample taken and sent for analysis at that stage?

KINSEY: Yes.

JOHNSON: I don't think we need to go into the details, but were the results of that blood analysis normal or abnormal?

KINSEY: They were normal.

JOHNSON: Thank you. Did [Baby B] then recover?

KINSEY: Yes, she did.

JOHNSON: And was a differential diagnosis made of sepsis or coagulopathy? What is coagulopathy?

KINSEY: Coagulopathy is an abnormality of the body's coagulation mechanism in the blood and this can be seen in severe infection, so the coagulation system doesn't clot properly.

JOHNSON: As a matter of fact, was that -- did the results of the blood tests support that as a potential diagnosis?

KINSEY: No, they didn't. The blood tests taken at that time on that day were normal for a child of her age.

JOHNSON: You then, in your report, refer to the on-call consultant attending, who the jury know was [Dr B].

And you refer, I think, professor, to [Dr B]'s record of a "purple blotching" of the right mid-abdomen and right hand?

KINSEY: Yes.

JOHNSON: Lest I misquote, can we go to tile 227, which has this information there recorded?

If we could go to the notes, please, Mr Murphy.

Here we see [Dr B]'s legible writing. We see about four lines down at the end of the line:

"Suddenly purple blotching of body all over with slowing of heart rate. Bagged then tubed by registrar. Heart rate came up. Adrenaline not required. 10ml/kilogram bolus of glucose."

Underneath that:

"Upon my arrival, purple blotchiness, right mid-abdomen and right hand."

So that is the note, I believe, to which you were referring, Professor Kinsey; is that right?

KINSEY: Yes, it is.

JOHNSON: Thank you. Later in the morning, so we're dealing with the early hours here, but later in the morning did you refer to Dr Saladi's note, made on the ward round?

KINSEY: Yes, I did.

JOHNSON: And the fact that he had recorded a purple rash around the chin?

KINSEY: Yes, I did.

JOHNSON: Thank you. I want to come to your section 4, if we may, please, professor.

KINSEY: Yes.

JOHNSON: So far as all the blood results that you have seen for [Baby B] are concerned, are they normal or abnormal?

KINSEY: All of the results that I have seen are normal for her age at the time that each of the individual tests were taken.

JOHNSON: And so far as any potential transfer of the antiphospholipid syndrome is concerned, is the position the same for [Baby B] as it was for [Baby A]?

KINSEY: Yes, it is, it's identical.

JOHNSON: Thank you.

In [Baby B]'s case did you also -- and I'm looking now at, at least in the version I have, page 6 of 13, which comes just

before the section 5, the summary and opinion section of your report -- did you also refer in passing to the question of air embolus?

KINSEY: Yes, I did.

JOHNSON: We will come to the specifics, but did you make similar observations to those made in the case of [Baby B]'s twin, [Baby A]?

KINSEY: Yes, they are.

JOHNSON: Thank you.

If I can just move on in the report, please, to your paragraph 5.6.

KINSEY: Yes.

JOHNSON: In the light of the evidence you have already given, was there any haematological abnormality which could have provoked [Baby B]'s collapse in the early hours of 10 June?

KINSEY: No, there's no evidence of that at all.

JOHNSON: In relation to the purple spots noted by Dr Saladi on his round during the day shift of 10 June, did you come to a potential view as to what might explain the small spots around -- purple spots around her chin at that stage?

KINSEY: Yes, I did. It was something that I wanted to draw attention to because my view is it's most likely to be a rash, in inverted commas, whilst the jaw was being held so she could have oxygen administered. This causes quite a tight squeeze on the underside of the jaw, which can sometimes cause some little compression bleeding spots called purpura.

JOHNSON: Thank you. Can we move on, please, to the case of [Baby E].

My Lord, I'm moving on to the report at 5.1.51 in the case papers.

MR JUSTICE GOSS: Thank you.

MR JOHNSON: So far as [Baby E] was concerned, Professor Kinsey, did you write a report, dated 19 July?

KINSEY: Yes, I did.

JOHNSON: I should say 2022.

KINSEY: Yes.

JOHNSON: Thank you. I'd like to move on to his sequence of events, please, Mr Murphy.

Did you record the following facts so far as the background of his case was concerned: starting with tile 5, your paragraph 3.2, that [Baby E] had been born on 29 July 2015 at 17.53?

KINSEY: Yes.

JOHNSON: At the time of his birth he was 29 weeks plus 5 days' gestation, his birth weight was 1.327 kilograms, and he received the routine dose of vitamin K shortly after his birth?

KINSEY: Yes, I did.

JOHNSON: What type of twin was [Baby E]?

KINSEY: He was a monochorionic and diamniotic identical twin with his brother. Just to explain that, this is where there is one placenta, which is shared by both twins, but in this situation each twin had their own amniotic sac.

JOHNSON: Thank you. What are the, if any, genetic differences between twins of that type?

KINSEY: The genetics will be identical in twins of that type because they have a monochorionic placenta.

JOHNSON: So in terms of researching or determining whether a dead twin, in this case [Baby E], had a blood disorder, is it legitimate to look at the results from the living twin?

KINSEY: Yes, absolutely. Looking for a potential hereditary abnormality, you could investigate the other twin.

JOHNSON: So lest there's any mystery about where we're going, in determining the issue of whether [Baby E] had a predisposition, a genetic predisposition to bleeding, is it legitimate to look at [Baby F]'s 7 years of life?

KINSEY: Yes, it is.

JOHNSON: Just returning to tile 5, [Baby E] was born in good condition, his heart rate was greater than 100 beats a minute. He had a reasonable tone but no respiratory effort. Did he receive resuscitation and was breathing spontaneously from 4 minutes of age?

KINSEY: Yes.

JOHNSON: And we can see there that by 5 minutes of age, his Apgar score was 9 out of 10?

KINSEY: Yes.

JOHNSON: Did you record the fact that [Baby E] was seen by the registrar at 22.40 on 29 July?

KINSEY: Yes.

JOHNSON: He was given respiratory support in the form of CPAP?

KINSEY: Yes.

JOHNSON: And he was, at that stage, very vigorous and active?

KINSEY: Yes.

JOHNSON: Was a full blood count undertaken on the evening of 29 July, so the same day of birth?

KINSEY: Yes, it was.

JOHNSON: How would you -- without going into the details, unless required, how would you categorise those results?

KINSEY: I'm just looking for those results at the minute.

JOHNSON: I don't think you reproduce them, at least not in the copy of the report I have, but you do attribute an adjective to them at paragraph 3.6.

KINSEY: Yes. Right, well, it says "see table at the end of the report", which doesn't seem to be there in my bundle, but yes, they were normal.

JOHNSON: Lest I lead you into saying something that you don't mean, I think the word you use is "satisfactory" at that stage.

KINSEY: Yes.

JOHNSON: The following day, on 30 June, you record the fact that [Baby E] was pink and active on CPAP in air, with no evidence of respiratory distress?

KINSEY: Yes.

JOHNSON: That his general examination was unremarkable and that the plan was to insert a long line for access to give him total parenteral nutrition and lipids?

KINSEY: Yes.

JOHNSON: Still on 30 June, the long line was inserted into the left saphenous vein; is that right?

KINSEY: Yes.

JOHNSON: His blood gas analysis was satisfactory at 18.21 that evening?

KINSEY: Yes.

JOHNSON: Moving on to 31 July, you record the fact that [Baby E]'s blood gases were described in the notes as "excellent"?

KINSEY: Yes.

JOHNSON: That he'd passed "a smear of meconium"?

KINSEY: Yes.

JOHNSON: That he had been on antibiotics, but those had been stopped at 36 hours of age?

KINSEY: Yes.

JOHNSON: There was an unremarkable examination of [Baby E] and the plan was to increase his fluid input?

KINSEY: Yes.

JOHNSON: He was started on expressed breast milk when he was 48 hours old?

KINSEY: Yes.

JOHNSON: Moving on to 1 August, at 11 am [Baby E] was reviewed and there were no concerns?

KINSEY: Yes.

JOHNSON: There was no abnormality revealed by a cranial ultrasound scan?

KINSEY: Yes.

JOHNSON: And his general examination was unremarkable, albeit he needed a small amount of insulin due to a relatively high glucose level?

KINSEY: Yes.

JOHNSON: By 2 August at 9.25 in the morning, [Baby E] was on 23% oxygen?

KINSEY: Yes.

JOHNSON: With a soft abdomen?

KINSEY: Yes.

JOHNSON: And by 3 August, which is tile 86, please, Mr Murphy, do we see there what you have recorded, albeit not under her name, as Dr Thomas' examination, which described [Baby E] as normal?

KINSEY: Yes.

JOHNSON: Albeit that a blood gas taken at 14.50 revealed he had elevated glucose?

KINSEY: Yes.

JOHNSON: And thus he was given a very small amount of insulin because of the fact that previously he had demonstrated himself as being very sensitive to insulin?

KINSEY: Yes.

JOHNSON: Can we move to tile 113, please, Mr Murphy. There do we see that [Baby E]'s blood sugar levels were settling?

KINSEY: Yes.

JOHNSON: There was a plan to repeat the blood gas analysis for glucose and sodium 4 hours later?

KINSEY: Yes.

JOHNSON: And also, a note that the blood cultures that had been taken were still negative?

KINSEY: Yes.

JOHNSON: Which of course is a positive finding in the sense of no bugs in his blood?

KINSEY: Exactly, yes.

JOHNSON: Could we go to tile 128, please, Mr Murphy.

Do we come next to Dr Harkness' notes of an examination of [Baby E] consequent on a report of a gastric bleed?

KINSEY: Yes.

JOHNSON: This is fairly recent evidence for those of us, those others of us in court. There'd been a sudden large vomit of fresh blood, a large aspirate, although [Baby E]'s observations at that time were satisfactory.

He was described as being alert, pink and well perfused, his abdomen soft and not distended, and bowel sounds present with normal blood pressure and normal femoral pulses?

KINSEY: Yes.

JOHNSON: You have recorded the fact that at [Baby E] was at risk of necrotising enterocolitis, he was started on ranitidine and metronidazole?

KINSEY: Yes.

JOHNSON: And that the plan had been to repeat the full blood count the following morning?

KINSEY: Yes.

JOHNSON: Tile 140, please, Mr Murphy.

Did you next record at your paragraph 3.17 the further episode of gastrointestinal blood loss at 23.00 hours?

KINSEY: Yes, I did.

JOHNSON: Did you also refer to the other findings that we can see recorded there on the screen and which are also in the notes?

KINSEY: Yes, I did.

JOHNSON: Thank you. Dealing with your report, please, professor, at your paragraph 3.19 and our tile 204, please, Mr Murphy. If we go to the notes themselves, it probably helps.

Do you then record much of the information contained in these notes made by Dr Harkness?

KINSEY: Yes, I did.

JOHNSON: The fact of the deterioration at 23.40 hours?

KINSEY: Yes.

JOHNSON: The fact that 5 minutes later, [Baby E] had had to be intubated?

KINSEY: Yes.

JOHNSON: There had been a good air entry and good chest movement and a consequent improvement in [Baby E]'s colour?

KINSEY: Yes.

JOHNSON: And that he, that is [Baby E], had then been put on to artificial ventilation, albeit his saturations were still low, being between 60 and 70%?

KINSEY: Yes.

JOHNSON: Do you refer again -- do you refer to Dr Harkness' reference to a purple discolouration of [Baby E]'s abdomen?

KINSEY: Yes, I did.

JOHNSON: Next, and I'm not asking to go to the tiles for this because I anticipate that the jury remember all this evidence pretty clearly, did you refer to [Dr C]'s notes of having attended at 01.30 hours?

KINSEY: Yes, I did.

JOHNSON: You then record [Baby E]'s unfortunate death?

KINSEY: Yes.

JOHNSON: The fact that his parents had been updated by [Dr C] and that [Dr C] had discussed [Baby E]'s case with the coroner?

KINSEY: Yes.

JOHNSON: Did you also look at the nursing notes, professor?

KINSEY: Yes, I did.

JOHNSON: What did you observe from the nursing notes, please?

I'm looking at your paragraph 3.27.

KINSEY: Yes. Well, I'll read what I put. So the nursing records between 30/07/2015 and 04/06/2015 (sic) show an entry each day that a nasogastric tube was present in [Baby E], and between 30 July 2015 and 3 August 2015, nasogastric tube aspirates were unremarkable.

Additionally, during these 3 days, the abdomen was described as being soft and not distended. And there was a comment of [Baby E] having his bowels open on 30 July 2015.

Would you like me to continue?

JOHNSON: Yes, or I can help you if you want, I don't mind.

KINSEY: Also on 3 August 2015 in the morning, at 10.44, that's the entry in the nursing notes which states that [Baby E] was pink and well perfused and that his CRP was less than 1, which is normal.

JOHNSON: Thank you. I think next you referred to an entry made on 4 August; is that right?

KINSEY: That's correct, yes.

JOHNSON: With Mr Murphy's help, I would like to put this on screen, please. It's J2592 to J2593, please.

This, as you referred to in your report, is a note made at 04.31 in the morning.

KINSEY: Yes.

JOHNSON: By somebody with the initials LL, who we know to be Lucy Letby.

KINSEY: Right.

JOHNSON: And refers to care given in retrospect -- are written in retrospect for care given from 20.00 hours on 3 August.

KINSEY: Yes.

JOHNSON: You record or repeat some of what's there set out, and I'm looking to the fourth line of the text now:

"Prior to 21.00 feed, 16ml mucky slightly bile-stained aspirate obtained and discarded. Abdomen soft and non-distended. Senior house officer informed to omit feed. At 22.00 large vomit of fresh blood. 14ml fresh blood aspirate obtained from NG tube. Registrar Harkness attended. Blood gas satisfactory. Blood sugar 10.7mmol. Metronidazole and IV ranitidine commenced and given."

And then a bolus of sodium chloride and the fact that the mean blood pressure and observations were stable and [Baby E] was, as we will see over on to 2593, please, handling well and active.

Then the balance of Nurse Letby's record recording [Baby E]'s decline: becoming bradycardic, a purple band of discolouration over his abdomen, with poor perfusion and a capillary refill time of 3 seconds --

KINSEY: Yes.

JOHNSON: -- and other detail, which we have seen recorded by other sources.

KINSEY: Yes.

JOHNSON: You record the fact at your paragraph 3.30 that [Baby E]'s -- what I should have -- sorry, there's one detail I have omitted. It's at the bottom of the page as we see it there.

Counting up five lines:

"Further decline. Resus recommenced at 01.15 and discontinued at 01.12 when [Baby E] was given to parents. [Baby E] was actively bleeding ++ from mouth and nose throughout the resus. 6ml blood was obtained from NG tube. [Baby E] passed away at 01.40 in parents' arms."

Did you refer also to a chest X-ray and abdominal X-rays that were taken at 00.27 on 4 August?

KINSEY: Yes, I did.

JOHNSON: There was a normal heart shadow, clear lungs, the ET tube was in a satisfactory position, and the NG tube was in the body of the stomach?

KINSEY: Yes.

JOHNSON: There was a bowel gas pattern within normal limits with no evidence of intramural or free peritoneal gas and no evidence of bowel dilation?

KINSEY: Yes, that's right.

JOHNSON: Finally, before we get to your interpretation, did you refer to the observation charts and the blood gas charts, which we can find at tiles 156 and 188 respectively, both of which in effect recorded a sudden change after 9 pm?

KINSEY: Yes, I did.

JOHNSON: So just taking those one by one, if we start with 156 and the document itself, please. So this is the observation chart where we see the heart rate at a consistent level somewhere north of 130 and --

KINSEY: Yes.

JOHNSON: -- possibly slightly south of 140, but jumping up to a significantly higher rate at 22.15?

KINSEY: Yes.

JOHNSON: The respiratory rate adopting a similar pattern to the heart rate?

KINSEY: At the same time.

JOHNSON: At the same time.

KINSEY: Yes.

JOHNSON: Thank you. And then the blood gases at 188, please, Mr Murphy.

If we scroll down, did you interpret that to show in effect a similar pattern of decline at about the same time?

KINSEY: Yes, it did.

JOHNSON: Moving on to [Baby E]'s blood results and your interpretation of those results, please, professor. Did you produce those in tabular form?

KINSEY: I did. I'm afraid they don't seem to be in this bundle that's been created for me.

JOHNSON: Don't worry about that. But perhaps we can deal with it in this way. Looking at your 4.3, what conclusions did you draw from the results as they were reproduced?

KINSEY: The striking thing was that there had been a big change in the haemoglobin. So initially the haemoglobin was 185.7 grams per litre, and 2.5 hours later had fallen to 156.6. So that's a fall of approximately 30 grams per litre.

JOHNSON: Yes. Just before you continue, we need a time for that if we can, please. Is the higher reading -- was that in the sample taken at 22.21 on 3 August?

KINSEY: Yes, it is.

JOHNSON: That's 185.7 at 22.21 on the 3rd?

KINSEY: Yes.

JOHNSON: And 156.6 at 01.05 on the 4th?

KINSEY: Yes.

JOHNSON: Why is that significant?

KINSEY: Well, that's significant because in the space of 2.5 hours, he has lost 30 -- well, he's lost the haemoglobin level has come down from 185 to 156. We know -- we have seen evidence of blood loss in the aspirates, so 14ml, 13ml and also 6ml, making 36ml of potential blood, maybe mixed up with other bodily fluids. But he, with a birth weight of 1.66 kilograms, would have had a total circulating volume of 142ml. So that's a considerable amount of his total blood volume that's been lost over that period of time. So that was what I thought was particularly significant and why his observations had deteriorated as they had seemed to be on the chart.

JOHNSON: Yes. So far as the results of the coagulation investigation were concerned, was the sample -- was that at just after 1 o'clock on the 4th, so during the course of what proved to be his fatal collapse?

KINSEY: Yes. Apologies, as the table is not here I'm just going to have to read...

(Pause)

So there has been a slight prolongation of the coagulation times, but these were within normal limits for a child as preterm as he was.

JOHNSON: Yes.

KINSEY: Yes.

JOHNSON: So far as your overall impression as to the blood count results was concerned, looking at your 4.6, what conclusion did you draw so far as whether or not he had some sort of predisposing condition which would have caused him to have a sudden spontaneous haemorrhage?

KINSEY: Well, the coagulation factors were within the expected normal range for a preterm baby. His full blood count

haemoglobin result had been normal and had fallen very rapidly, as I previously mentioned, and his platelet count was normal.

So bleeding can happen in the presence of a low platelet count, known as thrombocytopaenia, but there was no evidence of that. So this was spontaneous bleeding with no explanation.

JOHNSON: Yes. Now, in the context of determining whether or not [Baby E] did have some sort of condition which might predispose him to a spontaneous bleed, were you then asked to look at his identical twin?

KINSEY: Yes, I was.

JOHNSON: In that context, please, can we move on to your report on [Baby F], which for your Lordship's note is page I5657. For the record, this is the -- the date of this is 29 October 2022.

I'm not going to ask you, Professor Kinsey, to deal with the history of [Baby F] because his -- in the context of the issues that the jury has to determine, his relevance to his twin's case is simply on a comparative basis. So insofar as his -- for the reasons you've already explained to us, his history and circumstances can inform the conclusions that you draw in relation to [Baby E]?

KINSEY: Yes.

JOHNSON: Is that right?

KINSEY: That is right.

JOHNSON: So can we start then, please, so far as [Baby F] is concerned, with your section 5, which is our page I5657.

Were you given access to [Baby F]'s medical records?

KINSEY: Yes, I was.

JOHNSON: And for complete clarity, unless I have obscured the purpose, could you tell the jury what was your interest in looking at [Baby F]'s records in the context of the case of [Baby E]?

KINSEY: Having, as I explained earlier, agreed that [Baby F] was the identical twin of his brother [Baby E], looking at [Baby F]'s haematology is going to reflect what would have been [Baby E]'s haematological situation. The things I wanted to look for, both in the history -- within the total medical records for [Baby F] were important, and one or two things happened to [Baby F] which actually helped me specifically.

So as it happens, [Baby F] had a number of blood investigations, full blood count, particularly during the summer of 2015, when he was still a neonate, and subsequently, later that year, at Southport and Ormskirk Hospital, and 2.5 years later or 2 years later a blood investigation at Whiston Hospital. All of these have shown normal results for all the parameters that we look for in the full blood count. That is the haemoglobin, the white cell count, and the platelets.

The platelet count is important to make sure there isn't an inherited problem with low platelets which would cause a bleeding problem. The other thing to mention is that [Baby F] also had an accident with a car door banging on to his leg when he was quite a young child and there was no consequence to that. If there had been an inherent bleeding abnormality in [Baby F], I would have expected, because he was seen at the A&E department, that there would have been significant bruising and bleeding at that time and there wasn't any.

Looking specifically, he had a coagulation investigation in August 2015, which was completely normal. The only abnormality in [Baby F]'s haematology that I have identified was in 2017 when he was just 2 years of age, chronologically, and he was slightly iron deficient by looking at the size and haemoglobin content of his red cells, but that is virtually normal in children of his age, particularly those born preterm.

So my conclusion is that the haematology results in [Baby F] are completely normal.

JOHNSON: Yes. Therefore, so far as any suggestion that some haematological abnormality may have contributed to a spontaneous bleed, in other words a bleed for no reason, in [Baby E] the night he died, what conclusion did you draw?

KINSEY: That the bleeding in [Baby E] was not spontaneous.

JOHNSON: Returning to [Baby E]'s case, please, and your report on [Baby E], and I'm going back now, my Lord, to page 5157, and Professor Kinsey, to your paragraph 5.7, by coincidence.

KINSEY: Is this of the report of...?

JOHNSON: I'm sorry to jump about. I know it's confusing. It's your report of 19 July on [Baby E], section 5, paragraph 5.7.

KINSEY: Yes.

JOHNSON: So towards the bottom of the page, if it's in the same format as the version I have.

KINSEY: Yes.

JOHNSON: Did you record the fact that we have seen on the screen from Dr Harkness' contemporaneous notes that he had recorded purple discoloured patches during the resuscitation of [Baby E]?

KINSEY: Yes, I did.

JOHNSON: And that [Dr C] had made a similar record at about the same time?

KINSEY: Yes.

JOHNSON: I want to come to the issue of air embolus, please. I'm going to your Lordship's page 5632.

Were you asked to produce, for our understanding, some diagrams to explain how it is that the presence of air in the bloodstream can manifest itself in signs on the outside of somebody's body?

KINSEY: Yes.

JOHNSON: Thank you. In this context, did you produce some diagrams to which you have already referred at the beginning of your evidence?

KINSEY: Yes, I did.

JOHNSON: I'd like to put these on the screen now, please. Do we start with -- do these diagrams all contain as their references your initials, SK?

KINSEY: Yes.

JOHNSON: And are numbered sequentially 3 through to 7?

KINSEY: Yes.

JOHNSON: So it may be that the jury understood perfectly your explanation of the difference in circulation in utero in the mother's womb and after birth. It may be that, like me, they're not quite as quick as you and having a diagram to explain it might help --

KINSEY: Right.

JOHNSON: -- so we'll do that now.

KINSEY: Thank you.

JOHNSON: If we can deal with the first diagram, please, if we can move to the next page.

KINSEY: Hopefully --

JOHNSON: We're just going to enlarge it.

KINSEY: Thank you.

JOHNSON: Haemoglobin is a word that you've used on several occasions during your evidence. Assuming that we know nothing about it, can you explain what it is, please?

KINSEY: Yes. So haemoglobin, on this figure is the squiggly bit with the four bits that look like ping-pong balls in them. So this is a unit of haem. There are four groups of haem bound together and that is called haemoglobin, and each molecule of haemoglobin can bind oxygen.

The haemoglobin is within the red blood cells and the red blood cells are sent round the body by the pumping action of the heart and the circulation. Just to explain, you'll see on the bottom right-hand side the deoxygenated bit, which is blue, without the white bit, which is the ping-pong ball, which is indicating haemoglobin -- sorry, the oxygen.

So haemoglobin without any oxygen is a blue colour.

When you add oxygen to it by -- coming from the lungs, which we'll get on to, the haemoglobin changes to a red colour. So what's going to happen next is you're going to see features of slides where some of the blood is blue, that is low oxygenated blood, and some is red, which is oxygenated blood.

So it is haemoglobin's job within the red cells to transport oxygen around the body.

JOHNSON: So that in effect is a pictorial representation of what you are explaining?

KINSEY: Yes, that's right.

JOHNSON: Thank you. Can we move on to the next slide, please.

This is SK4.

KINSEY: Yes. This is a picture of the tiniest parts of the lungs, which are called alveoli, one alveolus. This is where the lungs have developed tiny, tiny little pockets which are only one cell thick and at the same time the blood supply to that area is only one cell thick as well. So if you look on the left-

hand side of the diagram here you'll see blue on the left-hand side, moving to pinker in the middle, and red to the right-hand side of that. So that is the tiniest blood vessel, called the arteriole, coming into contact with the small bit of the lung called the alveolus. It's obtaining the oxygen from the circulation, into the haemoglobin, making it turn pink, and then you can see that the pinkness becomes more, so that by the time we get to it right-hand side of the left-hand picture what's going out from the lungs is bright red.

JOHNSON: Can I just ask you a few questions about that then, please? We can see, just looking at the left-hand side of the page to start with, under where it says figure 11.2 in black type, it says:

"Inhaled air inflates alveolus."

As my diaphragm reduces the pressure in my lungs, the air goes in; is that right?

KINSEY: Yes. So when we breathe in, our chest expands, and when we breathe out our chest decreases. So it's like bellows, really.

JOHNSON: Yes. So as the air goes in, it goes -- follows that black arrow?

KINSEY: That's right, all the way down to the tiniest membranes in the bottom of the lungs.

JOHNSON: And as that is happening, blood is also flowing in an anti-clockwise direction on this diagram; is that right?

KINSEY: Yes, that's right.

JOHNSON: So the blood coming in from the heart; is that right?

KINSEY: Yes.

JOHNSON: Is being pumped out by the heart into the lungs?

KINSEY: Yes.

JOHNSON: And goes round that circuit and, as it goes round, it is picking up oxygen from the air that I have just breathed in?

KINSEY: Yes.

JOHNSON: The way that happens is it goes into those tiny capillary -- that capillary network that's like a honeycomb in the middle of the alveolus; is that right?

KINSEY: Yes, round the outside of the alveolus.

JOHNSON: And it transfers into the haemoglobin, the ping-pong ball, in effect, is picked up by the haemoglobin and it comes out with, hopefully, all four ping-pong balls in place in the haemoglobin? Is that correct?

KINSEY: Yes.

JOHNSON: That's my rather idiotic explanation.

KINSEY: No, it's very sensible.

JOHNSON: So what's the difference then between what we see on the left-hand side and what we see on the right-hand side?

KINSEY: The right-hand side is showing more clearly about the diffusion of the oxygen out of the alveolus. So if you take a deep breath in, there's more oxygen in the alveolus, and the red cells, as they are going back -- you see those little discs in the blood vessel running next to the alveolus -- and the oxygen moves across by diffusion. So there's a gradient of high oxygen in the lungs and low in the blood vessels, so the oxygen diffuses through into the bluish looking red cells to pinken up the haemoglobin and it comes out in the capillary.

JOHNSON: So does it come to this: the way these red cells are set up and the way the haemoglobin is set up is if it comes across oxygen, in effect it grabs the oxygen?

KINSEY: It does indeed, yes.

JOHNSON: And that makes the haemoglobin turn from blue to red --

KINSEY: Yes.

JOHNSON: -- or to pink?

KINSEY: It does.

JOHNSON: Okay. Right so far.

Now, the CO₂, the carbon dioxide, is that in the deoxygenated blood, so the blood that's gone round the system and is being sent into the lungs?

KINSEY: Exactly. So that's -- the situation here is that carbon dioxide, which is a waste product of metabolism, is taken out via the lungs in the opposite way: the relatively high CO₂ in

the tiny blood vessels diffuses into the lower CO₂ inside the lungs and then when you breathe out, the CO₂ comes out.

JOHNSON: So the proportion of carbon dioxide in normal air, there's oxygen in normal air?

KINSEY: Yes.

JOHNSON: But the proportion of gas that you breathe out has a high carbon dioxide content and lower oxygen content than what's gone in; is that right?

KINSEY: Yes, that's absolutely right.

JOHNSON: And that's reflective of this exchange of oxygen and carbon dioxide in the alveoli of the lungs?

KINSEY: Yes, it is, yes.

JOHNSON: We've heard some of the medical practitioners refer to a gas exchange; is that this concept of literally exchanging your waste carbon dioxide for your oxygen?

KINSEY: Yes.

JOHNSON: Okay. And this is how it happens?

KINSEY: Yes.

JOHNSON: Thank you. Can we move on to the next still, please.

I think we're moving -- if you could enlarge it, thank you.

This looks very much more complicated.

KINSEY: Well, it isn't, really, at all.

JOHNSON: Not to you.

KINSEY: It's showing the same thing and let me explain. So you now should see a diagram where there are some boxes on the lower side. Those are showing exactly what -- well, the ones, sorry, on the right-hand side -- the top of the two boxes are just showing exactly what we've seen now.

JOHNSON: So they're the alveoli?

KINSEY: They're the alveoli with the blue blood coming down one side and the pink going down the other way.

JOHNSON: Yes.

KINSEY: And below that, the rectangle on its side there, is showing exactly the same thing that we've just been talking about. So that's the gas exchange.

JOHNSON: Yes.

KINSEY: What I'm going to come on to next is the bottom box, which is the same thing happening but actually in the tissues of the body, so the red oxygenised haemoglobin is giving the oxygen, by diffusion, into the organ cells, exactly where the arrowhead is now.

JOHNSON: So dropping off ping-pong balls as it goes along?

KINSEY: Exactly. And the CO₂ comes out, it dissolves into the blood at that stage. But what I wanted to show specifically more in this diagram is actually about the right and left side of the heart.

JOHNSON: Can we see the heart there?

KINSEY: The heart's in the middle there, yes. So the heart is sort of heart-shaped. Blue blood in here, in this diagram, is deoxygenated, so it hasn't got the ping-pong balls. The red is oxygenated so it does have the ping-pong balls.

So if we start from the heart -- it's quite difficult without pointing.

JOHNSON: Mr Murphy is very good at following instructions, so if you --

KINSEY: Okay. If you just go slightly up and to the left. Stop now, thank you.

So what we're looking at now is the right atrium, that's the upper part of the right-hand side of the heart. Below it you can see two little flaps, there, and a little bit further down. Thank you. That is the right ventricle. So that's the most muscular part of the right side of the heart.

Now, what those chambers are doing is pumping the heart, but pumping the blood to go up through the pulmonary circulation.

JOHNSON: Pulmonary means through the lungs?

KINSEY: Yes. So as the little cursor is going up, you'll see there are now two blue branches going off. They are going to the lungs. So those two triangular things right at the outside are the right and left lungs that we're looking at. So in there, the

deoxygenated blood is going in as blue and then it's re-oxygenated with the ping-pong ball oxygen into the haemoglobin and that comes back to the heart, it goes behind the pulmonary vessels and into the top of the right -- sorry, the left atrium, then down through the valves there into the right ventricle, and then the heart pumps it round the rest of the body. So we can see the red blood going round to the head and neck and to both lungs because they also have non-respiratory activity, and the lowest one down at the bottom is to the entire circulation, sort of below the heart.

What you'll notice is that the vessels coming out of the heart are large and the nearer they get to the outer edges, the smaller they are. So you see a crisscross in between the red and the blue zone, in that area the blood vessels are really, really tiny, and by the time they are at the oxygen diffusion stage, they're only one cell thick, so absolutely minuscule blood vessels. So that's the important thing to know.

Then as the circulation goes from the left-hand side to the right-hand side, it's deoxygenated, goes back to the right side of the heart and is pushed again through the lungs, back into the heart, down to the organs and then back up to the heart again. So that's to explain the circulation.

Now, if we go down to the next slide, what I have been explaining to you is the adult or ex utero circulation in human beings. This is -- I'll just have to remind myself what this is. Could you tell me the reference number for this?

JOHNSON: This is SK6.

KINSEY: This is in utero. Thank you. What's happened here is we've got the heart there, right in the middle.

JOHNSON: This is the baby in the womb?

KINSEY: This is the baby in the womb, yes. So what has changed is that we can't see the lungs on here because the lungs aren't doing very much in a baby who is not yet born, apart from developing. So some blood goes there, so the lungs are able to grow.

So the circulation is different and the air -- well, the oxygen that the baby is receiving is via the placenta, so the placenta is taking on the work of the lungs until the baby is born. So at the bottom left-hand corner you can see that there's an arrow.

That's the coming-in side. So relatively red blood coming from the placental oxygenation of the red blood cells.

JOHNSON: Just so we can visualise this in a child, is that coming through the belly button?

KINSEY: Yes, it is. Down at the bottom left-hand side, those tubes there, the top one that's red is coming out and the two at the bottom are a sort of funny mixture, a sort of purple colour, and they are going back into the umbilical cord. So those three vessels and the umbilical cord.

JOHNSON: So when we've heard of the medic putting in UVCs and UACs, this is where they put them in?

KINSEY: Exactly, those are the vessels where they are put.

JOHNSON: And we've heard of one getting diverted into the liver would that go up that --

KINSEY: Yes. So up the reddish one there. That's going into there and can sometimes get too far.

The liver is also bypassed slightly, so that you can -- stop now, the arrow. That's great. So just to the left of the white arrow is a black arrow and that is the inferior vena cava, which is a very, very big venous system which takes all the returning blood flow from the lower limbs and the abdomen. That normally goes through the liver, but it's bypassed because the liver doesn't need to do quite so much work either because the placenta, or mother's liver, is actually doing the work for the child.

So what you can see here is that if we follow that red vessel past the liver and up, it's crossing the blue bit. So if you stop there. So the blue area here is the deoxygenated blood in the right atrium. So it's just going round because the lungs are not doing anything.

The blood flow is bypassing what would be going up into the lungs, up the blue bit, through a hole between the right atrium and the left atrium and -- yes, exactly there.

The tip of that black arrow that you can see is showing where there's a gap between those two parts, the right atrium and the left atrium, and that's called the foramen ovale. That's where it is.

JOHNSON: Just so that we can understand, the big figure where we have a blue top left-hand quarter, a pink bottom left-hand quarter and two corresponding right-hand quarters on the other side, that's the heart?

KINSEY: That's the heart, yes.

JOHNSON: Okay. So this patent foramen ovale is the gap there?

KINSEY: Yes. So if you just move the cursor away for a second, thank you, you see there's that little white flap coming up. And there's a corresponding bit, if you move the cursor left and then up, up, up, up. Left a bit, left a bit, there. There. If you move the cursor away now, you can see that there's a flap there, a smaller bit from the top, a larger bit from the bottom, and that allows the membrane to open so that the blood flows straight round to the arterial side of the circulation and is pumped round the rest of the body and back to the placenta.

JOHNSON: So the heart isn't doing the pumping, it's --

KINSEY: The heart is doing the pumping but it's not going through the lungs, so the lungs have been diverted here because the -- and can be because of the foramen ovale, which is open at this stage.

JOHNSON: Okay. The foramen ovale becomes important in explaining air embolus and how it performs in little children, is that right --

KINSEY: Yes, it is.

JOHNSON: -- or how it may perform?

KINSEY: Yes.

MR JOHNSON: My Lord, I see the time.

MR JUSTICE GOSS: I think this is a good point to break because I can see we're going to go on.

We're going to break off now until 2.05, an hour's break, just under an hour now. Members of the jury, could you be ready to be back in court for 2.05 when we will continue?

(In the absence of the jury)

MR JUSTICE GOSS: Professor Kinsey, if you can be back ready to continue at 2.05, please, thank you very much.

(1.08 pm)

(The short adjournment)

(2.05 pm)

(In the presence of the jury)

MR JUSTICE GOSS: Mr Johnson, there's a request from one of the jurors, asking if it's possible to have paper copies of the diagrams that they're looking at.

MR JOHNSON: It is.

MR JUSTICE GOSS: It is possible? Presumably, do they come from a textbook or a publication of some kind?

KINSEY: No, they came from the internet, actually.

MR JUSTICE GOSS: Oh right.

KINSEY: There's a picture in here that could be photocopied.

MR JOHNSON: I'm afraid the problem is colour copying.

We will do it. I can't, I'm afraid, just produce it straightaway.

MR JUSTICE GOSS: Yes. It's difficult to get colour copies.

Don't become -- all facts, as I have said, are entirely for you to decide. This is for illustrative purposes, these diagrams, so they are simply showing you the heart of a baby in utero and the heart of all of us who are alive or a person who is alive, outside the uterus obviously, after they've been born, and the circulatory system that goes on. It's all to do with the oxygenation of the blood --

KINSEY: Yes.

MR JUSTICE GOSS: -- and the different systems that there are. So if you want any of it to be gone over again, it can be gone over. Perhaps if you recap slightly on the image we have of the baby because that -- most people may be familiar with the heart in life outside the uterus and how it works with the ventricles and the atria, et cetera. We'll try and get them but it's difficult getting colour photocopies.

MR JOHNSON: Yes. On that subject, it may be -- I don't know if Mr Murphy can put up two pictures at the same time.

KINSEY: Yes, that'd be useful.

MR JUSTICE GOSS: Exactly, do comparisons. All right, we'll do that.

Perhaps just go over -- this flap, as it's described, was where we finished before lunch.

KINSEY: Yes.

MR JUSTICE GOSS: And we can see the black arrow leading up goes through that flap. We can see that the flap is orientated, it goes that way and then the flap shuts when blood is not pumping through?

KINSEY: Exactly.

MR JOHNSON: It may be that this is... If we leave this on the screen and put the next one up, SK7, which is your image of what goes on, what's going on with all of us now?

KINSEY: Yes.

JOHNSON: We can see the differences and then we can recap on the one that's on the screen at the moment. That may be the best way of dealing with it.

So we'll go back in a minute, if we may, to the right-hand image, Professor Kinsey, which is the baby in the womb.

KINSEY: Yes.

JOHNSON: The left-hand image, which is your next image, which is SK7, if anybody needs to refer to its reference, does this represent the position of the circulation in all of us now?

KINSEY: Yes. So this is what we'd call ex utero. And in people who haven't had problems with their own heart, so yes, this is what we see in normal circulatory function.

It's much clearer to see the red side of the circulation, which is the oxygenated side, going out from the left side of the heart, up through the top where there are three bits coming out of the top of the vessel and then down. That goes round to the smaller vessels and then comes back via the liver into the right side of the heart.

You can see if the arrow goes up a little bit further and slightly to the right now, you can see where those flaps that I showed you on the other diagram have actually shut. That's because the arterial pressure is much stronger, that's the red-sided pressure, it's stronger than the blue so it's actually physically closing that. Then in about 70% of people, it's permanently closed, but it is said to be the case that there are about 30% of the adult population who still have some patency of the foramen ovale.

MR JUSTICE GOSS: Of the flap?

KINSEY: So the flap, yes. So there's something happening still, allowing stuff to go through. If we go to the picture, I think you can see it now with the purple ring on the right-hand side there, you can see that that's open, and the black arrow is pushing it open, keeping it open, so the circulation is mostly going in that direction. So it's going past -- it's bypassing the lungs, but is moving from the deoxygenated side of the circulation into the oxygenated side without going through the lungs.

The lungs are a bit of a sieve and takes out stuff that shouldn't be there because they just get blocked up and then they get eaten by different cells called macrophages, which just tidy things up.

MR JOHNSON: So in terms of the pressure, in some modern office buildings, not so often in court buildings, the air conditioning will be on in one room and not another and you can't shut a door because the air pressure on one side is stronger. Is that the situation we have with this --

KINSEY: Yes.

JOHNSON: -- this foramen ovale?

KINSEY: Yes, that's a good way to describe it, yes.

JOHNSON: Well, I hope that's clear now.

Can we move on, please, in your most recent report to the issue of air embolus, and can you -- I'm at your page 3 of 5, I think, if you have the same version that I have.

KINSEY: Yes, thank you.

JOHNSON: Can you tell us what an embolus is, first, please?

KINSEY: Yes. So an embolus is something that shouldn't be there in the circulation. This does happen quite frequently in the human population. So the most common time that we see an embolus is from a blood clot when some of the clot breaks off and then travels round in the circulation. So it's a loose body travelling around in the circulation. And you can see and understand from the way I've described to you that the vessels on the venous side of the circulation, that's the right side of the circulation, get narrower and narrower and narrower until they're oxygenated and those little capillaries get bigger and bigger and bigger. You can see there are times where the vessels get narrower and so the embolus gets stuck in the vessel, and it

can't get through, the rest of the blood can't get through, and the oxygen within the blood cells can't get through either.

So anything beyond that stops flowing or, in fact, dies. So you may have heard of people who have had clots in their legs or in the pelvis, who have had a pulmonary embolus, to the lungs, and they've just dropped dead because that can happen. But that's a solid thing.

It is possible to have other things that can be embolic. So it's possible to have a fat embolus with multiple trauma with many fractured bones, where bone marrow, which contains a lot of fat, gets into the circulation, so you can get fatty emboli.

And I think I have got something else in here as well. Yes. So the other time that emboli are slightly different -- but in narrowing of arteries, such as in the neck going up to the brain, you can have thrombi there, which can cause stroke, and you can get little bits of plaque coming from the coronary arteries so you get a heart attack. These are the things, the embolic things, that happen in the normal course of being a human being.

Very rarely you can get amniotic fluid embolus during childbirth where, by accident, amniotic fluid gets into the maternal circulation and that is usually fatal.

So an embolus is something that's in the wrong place. The important thing about it is it can get lodged and so it stops the circulation behind it, which is what does the damage.

JOHNSON: Yes. Now, if air is injected into a vein, so into the venous circulation, with a syringe into a line, what might happen?

KINSEY: So what would happen is that -- well, a couple of things could happen. So the air will go in, if it's into the venous side, into the blue side of the diagram I showed you, and in an adult, where the foramen ovale is not open, so it will go from the right atrium into the right ventricle -- the heart is pumping at this time and you all will have seen when you turn the lid off a fizzy drink that the bubbles in it get bigger. But what happens in the situation in the heart is the heart is pumping, so the mass of air is being squished into ever-smaller pieces. So there are going to be some quite large bubbles of air and some very weeny, tiny bubbles of air.

These -- outside the uterus, so in people breathing air, this goes through the lungs. The lungs will cope with very tiny bubbles but not with big bubbles. So you can get air occluding one of the main vessels going to the lungs.

In a child, a young baby, particularly a preterm baby where the foramen ovale is still open, some of these little bubbles can get through the patent foramen ovale into the arterial circulation, so that you can then start to see bubbles -- well, bubbles will be going down the arterial system in the big vessels first, going right up to the smallest capillary until the air bubble is lodged, because it can't go any further because the blood vessel in front of it is smaller. So what that does is it blocks the arteriole, the space in front of it is then bloodless because no blood is getting through so it becomes pale.

The stagnant red cells behind the blockage will release their oxygen and then gradually will re-oxygenise. So you see when the red cells lose their oxygen they go a bluish colour and then because they're near a bubble with oxygen in it, they will absorb that oxygen and then turn pink again. That will then disappear into the tissues and it will go blue again.

So you can see in the skin a fluctuating colour distribution and pallor.

JOHNSON: So we have heard, and you have reproduced in your statement, some of the accounts of some of the witnesses relating to seeing what appeared to be flitting or moving patterns, that sort of thing. Is that what -- are you describing the mechanism, the physiological mechanism by which that happens?

KINSEY: Yes, that is what I tried to do.

JOHNSON: If we could just have the patent foramen ovale picture up again, I just wanted to clarify a couple of things that you just said.

So you referred, professor, to the fact that if air comes into the venous circulation, in other words coming in on that arrow from the top left, in the blue section -- is that right?

KINSEY: Yes, this is in utero, this one.

JOHNSON: Sorry. Yes, sorry, yes. I got them the wrong way round.

KINSEY: So this is -- now on the left-hand side this is the normal adult, let's call it that, circulation.

JOHNSON: Yes.

KINSEY: And on the right-hand side is the in utero, still attached to the placenta.

JOHNSON: Yes. So if air was injected, say, into my circulation, and assuming that my foramen ovale is no longer patent, it would come into the left-hand side of the heart, go out into the lungs --

KINSEY: Yes.

JOHNSON: -- via the blue route?

KINSEY: Yes, that's right.

JOHNSON: It may be absorbed in the lungs if the --

KINSEY: If it doesn't get blocked, yes.

JOHNSON: -- if I don't have the pulmonary embolism?

KINSEY: Yes.

JOHNSON: And that would be the end of it --

KINSEY: Yes.

JOHNSON: -- or the end of me, depending on which --

KINSEY: Which is bigger.

JOHNSON: Yes, exactly.

However, in a very small and often premature infant, looking at the right-hand diagram, even though they have been born, this foramen ovale may still be open --

KINSEY: Yes.

JOHNSON: -- as in that right-hand diagram, and therefore the air bubble or bubbles may pass straight from the venous circulation into the arterial circulation without having been filtered by the lungs?

KINSEY: Exactly.

JOHNSON: Is that it?

KINSEY: That's right.

JOHNSON: And that possibility would then send the air round the arterial circulation?

KINSEY: Yes.

JOHNSON: And at some stage has the potential for blocking, in various parts of the body, the passage of the circulation?

KINSEY: Yes.

JOHNSON: That would make parts of me go blue?

KINSEY: The visible bits, which is the skin, yes.

JOHNSON: But would also potentially have the consequence of the air in the embolus, the oxygen in the air, being absorbed by the -- so the golf balls in the embolus being absorbed by the golf ball carriers in the haemoglobin?

KINSEY: Yes.

JOHNSON: Turning from blue to red or pink?

KINSEY: Yes.

JOHNSON: And therefore having this flitting pattern of blue and pink?

KINSEY: Yes.

MR JOHNSON: Right, thank you.

Would you wait there, please? There may be some more questions for you.

Cross-examination by MR MYERS

MR MYERS: Professor Kinsey, you've given us evidence in relation to [Baby A], [Baby B] and [Baby E] and [Baby F] on haematology and the question of whether there were any blood abnormalities.

KINSEY: Yes.

MYERS: You dealt with that, haven't you?

KINSEY: Yes, I have.

MYERS: And then you've also given evidence about them and more generally on the question of air embolus?

KINSEY: Yes.

MYERS: Just so it's quite clear where my questioning lies, there's relatively little issue in what you say about haematology; that's not the issue.

KINSEY: Yes.

MYERS: The questions that I have for you primarily are to do with what you say about air embolus. That's just so you can understand and everyone understands what's in dispute or what's to be considered.

KINSEY: Yes.

MYERS: There's only a couple of points on the haematology, the bleeding aspects, that I would like to ask you about in relation to [Baby E].

Can I just ask, first, as a general point is it right that a premature baby hasn't normally developed the normal levels of blood clotting that you would see in an older child or an adult? As a general point.

KINSEY: Yes, that is the case, yes.

MYERS: Your evidence on [Baby E] is that you -- the way you put it was you were -- there was no explanation for spontaneous bleeding.

KINSEY: Yes.

MYERS: Can we be quite clear? When you say there was no explanation for spontaneous bleeding, what you mean, if I may say it, is in terms of his haematology his blood properties, there's no explanation for spontaneous bleeding?

KINSEY: Yes.

MYERS: That's what you were looking at in particular, wasn't it?

KINSEY: Yes.

MYERS: That doesn't mean that he might not have had a gastrointestinal haemorrhage for some other reason unconnected with blood clotting or haematology; do you agree?

KINSEY: I do agree, yes.

MYERS: And your assessment doesn't establish what the cause of the bleeding was, it simply establishes that the cause of the bleeding wasn't a blood abnormality?

KINSEY: Yes.

MYERS: Thank you.

KINSEY: Absolutely.

MYERS: And nor does it in fact assist us in establishing what the cause of death ultimately was, does it?

KINSEY: No.

MYERS: That's what I wanted to ask about haematology, Professor Kinsey.

I'm going to turn now to what's said about air embolus. Just some general questions first about your position as an expert here. You understand, it's important that experts stay firmly within their field of expertise and practice, don't you?

KINSEY: Yes.

MYERS: As an expert and as a doctor you adhere to the rules of practice provided by the General Medical Council, don't you?

KINSEY: Yes.

MYERS: And we've looked previously at rule 12, I'm not going to put it up on the screen, I'm going to read it so we have it in mind and you will be familiar. It deals with giving evidence as an expert witness and it says the following:

"You must only give expert testimony and opinions about issues that are within your professional competence or about which you have relevant knowledge, including, for example, knowledge of the standards and nature of the practice at the time of the incident or events that are the subject of proceedings. If a particular question or issue falls outside your area of expertise you should either refuse to answer or answer to the best of your ability, but make it clear that you consider the matter to be outside your competence."

You're familiar with that guidance and that rule, aren't you?

KINSEY: Yes.

MYERS: You are an expert in haematology, are you not, Professor Kinsey?

KINSEY: Yes.

MYERS: And I certainly raise no dispute that you are eminent in that field. That's not in issue. Your special interests lie in paediatric haematology; is that correct?

KINSEY: Yes.

MYERS: Blood disorders?

KINSEY: Yes.

MYERS: Acute leukaemia?

KINSEY: Yes.

MYERS: Stem cells?

KINSEY: Yes.

MYERS: Bone marrow failure syndromes?

KINSEY: Yes.

MYERS: And childhood leukaemia?

KINSEY: Yes.

MYERS: They're particular areas of interest. And you've, both as a practising medical practitioner and someone engaged in research, you've authored many papers in areas of your field, haven't you?

KINSEY: Yes.

MYERS: I looked on the University of Leeds website and found 164, there may be more, there may be less -- fewer, I don't know.

Now, in the papers that you have authored, there has been a focus on cancer, hasn't there --

KINSEY: Yes.

MYERS: -- and childhood blood disorders and aspects of genetics? Air embolus doesn't feature in your particular expertise, does it?

KINSEY: No.

MYERS: If a patient had an air embolus and there was time and facility to seek somebody to help with it, a specialist who would help with it may be, for example, what's called a decompression specialist, mightn't they, someone who deals with blood decompression, decompression sickness?

KINSEY: In the case of decompression, which means scuba diving or lower than that.

MR JUSTICE GOSS: Scuba diving or what, sorry?

KINSEY: Deeper than scuba divers go --

MR JUSTICE GOSS: Deep sea diving?

KINSEY: Deep sea diving, yes.

MR MYERS: Specialists in what's called barotrauma, which is to do with the effect of pressure on body tissue.

That's the sort of person who might deal with an air embolus, isn't it?

KINSEY: Yes, but -- yes, they would.

MYERS: Now, the questions that I'm asking may be asked critically but they're not asked disrespectfully or rudely, but you wouldn't ask for a haematologist, would you, if it was an air embolus that you were trying to deal with?

KINSEY: If you were trying to deal with an air embolus the minute it happened, you'd want an anaesthetist there with a needle to remove the air from the right ventricle if you had time.

MYERS: You may well ask for an anaesthetist to do that, but a haematologist and haematology generally does not make somebody an expert in air embolus or issues associated with air embolus, does it?

KINSEY: No, it doesn't.

MYERS: Again I'm not going to keep on saying I don't mean to be rude, please take it from me I mean to discourtesy in any critical questions, but you are not an expert in decompression of gas in the blood, are you?

KINSEY: No, but this isn't a decompression problem.

MYERS: No. And you have no expertise in dealing with air embolus, do you?

KINSEY: No. Very few people have.

MYERS: No. That may be a fact, but you don't, do you?

KINSEY: No, I don't.

MYERS: We've looked, with your assistance, at diagrams and explanations that set out aspects of the circulation.

We've just been looking at those, Professor Kinsey. I'm really picking up on something that was said soon after the lunchtime break. What we'd looked at were -- those diagrams of the circulation and gas exchange are, in many respects, standard images of the way the circulation or gas exchange works in the body, aren't they?

KINSEY: Yes.

MYERS: In no way are they designed to be or are they specific to explaining how an air embolus works? They are of general application, aren't they?

KINSEY: They were produced for that purpose only, to explain about the circulatory system --

MYERS: Yes.

KINSEY: -- and the exchange of oxygen on to haemoglobin.

MYERS: And haemoglobin. What you are doing in your evidence, or what you're seeking to do to assist, is to take that standard understanding of circulation and gas exchange and then look at how that might apply to what's alleged in this case in terms of air embolus. That's how you're taking them and using them, isn't it?

KINSEY: Yes.

MYERS: When you've been looking at the babies in this case with whom we have been dealing, I'm going to suggest your primary focus in your reports and your considerations, your primary focus has been the question of blood characteristics or disorders in terms of whether there is any haematology abnormality that's relevant to their case.

KINSEY: Yes.

MYERS: That's the primary focus, isn't it?

KINSEY: It is, yes.

MYERS: You have, at stages in the reports, commented on the evidence or things you may have to say about the suggestion of an air embolus; is that fair to say? I'm going to go to it in any event, but in the course of your reports you have commented at stages on the issue of air embolus, haven't you?

KINSEY: Only with respect to the changes in the skin, which are very impactful.

MYERS: Yes, I'm going to come to that. I'll turn to that now, in fact.

I'd like to start with what you say about [Baby A] and the changes in the skin of [Baby A]. Do you have a copy of the report that you prepared for [Baby A], Professor Kinsey? It's 10 pages.

My Lord, it starts at page 781 in our papers.

KINSEY: Could you give me a paragraph?

MYERS: Yes, of course. It's page 7 of 10. There isn't a paragraph -- well, it comes at the end of your section 4.

KINSEY: Right. End of section 4?

MYERS: Yes, page 7 of 10.

KINSEY: Yes.

MYERS: And you have a section that says "Air embolus". Can you see that halfway down the page?

KINSEY: Yes.

MYERS: In that report you go through the background relating to [Baby A], as you have done in your evidence today, and at the end of the report you can see, at the bottom of page 7, you set out your summary and opinion, which goes over the page in fact?

KINSEY: Yes.

MYERS: And your summary and opinion is focused on the question of whether or not there is any haematological abnormality or whether maternal antiphospholipid syndrome played a part in what happened to [Baby A].

KINSEY: Yes.

MYERS: And your conclusion in summary and opinion is that they didn't?

KINSEY: Yes.

MYERS: I am not disputing that or going into that.

What you say about air embolus occupies a couple of paragraphs just in your general comments, doesn't it?

KINSEY: Yes.

MYERS: That's what I meant earlier when I said that where you touched upon it in those reports it was part of the comment. You do prepare a report finally that deals with air embolus and I'll come to that, but on [Baby A] it forms part of the comment, doesn't it, in that report?

KINSEY: Yes.

MYERS: Because I want to ask you questions about it, I'm just going to read it to you so we can see what it is you said about it. You have it in front of you there.

This is page 7 of 10. You have dealt with the antiphospholipid syndrome and blood issues and you then say this:

"Air embolus. Other experts, Dr D Evans and Dr Bohin, have commented upon the clinical features described by the medical staff attending [Baby A] at the time of his cardiac arrest on 8 June 2015. Dr Jayaram gave a particularly clear account of the unusual skin features seen in [Baby A] which were consistent with those described in the medical literature [and you then cite] including the paper by Lee and Tanswell."

Which we are familiar with.

KINSEY: Yes.

MYERS: You then add:

"Injection of air into a vein will enter the right side of the heart, leading to a subsequent problem in the pulmonary lung vasculature."

That's what you have just been describing to us, isn't it?

KINSEY: Yes.

MYERS: And then you add:

"But in a newborn with a patent foramen ovale, as was the case with [Baby A], it is possible for air injected into a vein to cross from the venous circulation into the arterial circulation, leading to the features and changes in the skin described by Dr Jayaram."

That's what you say about it at that point with [Baby A], isn't it?

KINSEY: Yes.

MYERS: And so can we just make it clear, as a starting point in that report, which is dated 4 March 2020, you rely upon comments by Dr Evans and Dr Bohin, don't you, as to air embolus?

KINSEY: Yes.

MYERS: And in particular, the description given by Dr Jayaram and how it matches the description in the literature?

KINSEY: Yes.

MYERS: Again, I have no questions and no challenge to what you say about the patent foramen ovale or how that works.

That's not in issue, that's an anatomical fact.

Where you talk about the paper by Lee and Tanswell, we're familiar with the particular description in that paper of how an air embolus presents itself and I'm going to remind us. It won't be the first time we've seen it, but you're familiar with that description, aren't you, Professor Kinsey?

KINSEY: Yes.

MYERS: We've seen it before. I'll read the description. It's very short. Just so we have it in mind, the description was as follows:

"Blanching and migrating areas of cutaneous pallor were noted in several cases."

There had been analysis of 53 infants in this study:

"In sever cases, and in one of our own cases, we noted bright pink vessels against a generally cyanosed cutaneous background."

That was the description.

KINSEY: Yes.

MYERS: Cyanosed we know means a bluish colour?

KINSEY: Yes.

MYERS: So they're referring to one case where they noted bright pink vessels against a generally cyanosed cutaneous background (inaudible) no, the pink:

"Blanching and migrating areas of cutaneous pallor were noted in several cases and in one of our own cases we noted bright pink vessels against a generally cyanosed cutaneous background."

That's the description, isn't it, that you're familiar with?

KINSEY: Yes, it is.

MYERS: All right. We know, by the way, that there were 53 infants in that study, cutaneous signs, skin colours, were seen in 11% of the cases.

Would you like to see the entry from that paper?

You look a little confused.

KINSEY: No, I'm not confused by that.

MYERS: And there is one of them where bright pink vessels are noticed against a generally cyanosed cutaneous background, isn't there?

KINSEY: Yes.

MYERS: Yes. And when you were describing about the gas exchange and the oxygenation of cells at the surface of the skin and the bright pink that you've described, you draw a parallel between that and the type of description in Lee and Tanswell, don't you?

KINSEY: And in -- yes, I do.

MYERS: And that's the principal description which you are relying upon, isn't it, from the papers?

KINSEY: From the papers because it's a very rare phenomenon.

MYERS: Yes. Now, you, as you set out in the paper with [Baby A], were impressed by the way that Dr Jayaram's description was so consistent with that in the Lee and Tanswell paper, weren't you?

KINSEY: It was the other way round actually because when I was reading the notes that I was given, I was shocked by his description before I'd even considered air embolus in the case. It was the first case that I did and I was shocked because it is what I knew, not actually specifically from the Lee and Tanswell paper, but from my education in medicine, that this is -- this is what air embolus looks like in the skin. So I was shocked.

I actually remember me feeling an intake of breath, "This is an air embolus".

MYERS: From the description that he gave?

KINSEY: From the description that the doctors gave.

MYERS: Yes, well, Dr Jayaram, first of all, is who you mention in your statement, isn't it?

KINSEY: Yes.

MYERS: Is that a description you say that comes from his clinical notes or just from his statement? Do you recall?

KINSEY: I think it's from the clinical notes. Haven't we seen them today?

MYERS: Let me help. If we can go into the sequence of events, please, Mr Murphy, for [Baby A]. The carousel for [Baby A]. This is at tile 201. We've got Dr Jayaram's description as made at the time in his clinical notes. Thank you.

Just scroll down. We're familiar with these, Professor Kinsey, and will have seen them more recently than you have, so I won't read through everything.

If we continue to scroll down, we've got the background and descriptions of how [Baby A] presented.

Can we continue to scroll down, please, Mr Murphy? I'll take us to the description that appears in here.

Carry on over to the next page. The description, the sole description, in the medical notes, if we pause there, by Dr Jayaram was four lines down:

"Legs noted to look very white and pale before cardiac arrest."

Can you see that?

KINSEY: Yes.

MYERS: It's a while since we've looked at these notes, but that was the actual description in the clinical notes from Dr Jayaram.

The prosecution took the opportunity, quite properly, to reacquaint the jury with some of the relevant evidence when they went through your reports.

Perhaps I can reacquaint the ladies and gentlemen of the jury with the fact that that is the description in the notes. And when Dr Jayaram came to make a statement to the coroner in the case of [Baby A] on 24 July 2015, 6 weeks later, he said no more than we have in the notes here. That's the background.

The description that you read, Professor Kinsey, comes in a statement that he made about 2.5 years later.

First of all, you're satisfied, that what we see in the notes there is not the description you're thinking about, is it?

KINSEY: No, it isn't.

MYERS: No. The description you are referring to -- we have got on the screen what was said in the notes -- you put at page 5 of your report, the one you have in front of you.

And there you write, paragraph 3.30:

"Dr Jayaram was the consultant on call. When he saw [Baby A] at the time of his resuscitation he described seeing unusual skin discolouration and described it as:

"'An odd sort of discolouration where there were flitting patches of pink areas on the background of blue-grey skin. These patches appeared to appear and disappear. It wasn't like the rash seen with meningococcal sepsis. It didn't fit with anything I had ever seen before. I would describe the marks as blotches which were fairly ill-defined, 1 to 2 centimetres, not discreetly round but blotchy patches of brighter pinkness on a background of blue-grey.'"

Is that which you saw that struck you as reflecting an air embolus?

KINSEY: Yes.

MYERS: And again, just to remind us, that comes from a statement he made 2.5 years after the event, not from the notes.

Your position, Professor Kinsey, is, faced with that description, that struck you as characteristic of what you understood the discolouration of an air embolus to be?

KINSEY: Yes.

MYERS: And when in your report at page 7 you refer to it as matching or consistent with descriptions in the medical

literature, you specifically refer to the paper by Lee and Tanswell, don't you?

KINSEY: Yes.

MYERS: I'm going to ask you next about [Baby B], please, Professor Kinsey. That is at page 6 of your report into [Baby B]. The report is dated 4 March 2020. I'm going to ask you about what you say there. Have you got that?

KINSEY: Yes, I have.

MYERS: My Lord, page 879 of the statements, page 6 of 13.

Again, as with [Baby A], if we read on and look in your summary and opinion, the summary and opinion, your overall opinion is directed towards whether or not there is any blood disorder or, in particular, an antiphospholipid aspect --

KINSEY: Yes.

MYERS: -- that played a part in what happened? That's your principal opinion, isn't it, and it was that there wasn't?

KINSEY: Yes.

MYERS: Yes. What you said at that point about air embolus or embolus was part of the more general comment leading up to your final opinion, wasn't it? That's at page 6 at the end of the comment section.

KINSEY: Yes.

MYERS: What you said was this, and I'll read it so we have what you said:

"The clear account of the unusual skin features seen in [Baby B] were consistent with those described in the medical literature, including the paper by Lee and Tanswell."

The paper we've just talked about. Then you repeat that:

"Injection of air into a vein will enter the right side of the heart, leading to subsequent problems in the pulmonary lung vasculature."

And you go on to explain how the patent foramen ovale can lead to air crossing from the right to the left side of the heart.

KINSEY: Yes.

MYERS: All right. But in particular, you draw a comparison between the features in [Baby B] and those described in the medical literature, including the Lee and Tanswell paper, don't you?

KINSEY: Yes.

MYERS: Again, this afternoon you've explained to us how it is that if bubbles of air get to the surface of the body where the skin is, they can oxygenate cells in that area, can't they?

KINSEY: Yes.

MYERS: What's been described as the ping-pong balls passing from the blood into the skin cells; is that correct?

KINSEY: Yes, the subcutaneous tissue.

MYERS: And it's that which leads them to become pink or red?

KINSEY: Yes.

MYERS: And that's the distinctive factor, that we have the pink or the red against a cyanosed background, do you agree, or a pale background?

KINSEY: The two are slightly different, actually. So pale due to blockage of a vessel, so the blood doesn't get through so you wouldn't see the change. And pink and blue, as I have described, yes.

MYERS: All right. We've looked at the descriptions this morning. I'm just going to refresh us now in context with what we're asking. The first was from Dr Lambie and it's in the [Baby B] sequence of events at tile 221, please, Mr Murphy.

If we go behind that tile, please, and scroll down, please. Thank you.

So this is the note of Dr Rachel Lambie, who dealt with [Baby B], or one of the doctors who dealt with her, and we get the description of colour. Can you see:

"Widespread purple discolouration of skin with white patches"?

KINSEY: Yes.

MYERS: That's what Dr Lambie said. She repeats the purple discolouration elsewhere but that's the most specific description. Perhaps just scroll down, check there's no other

detail that I have missed. Can we scroll to the end of the notes, Mr Murphy?

Describing towards the end there a gradual improvement in perfusion over the next 50 minutes.

Scroll it down. Just to the end, please. All right.

We have reviewed the X-ray reviewed by [Dr B].

We've got [Dr B]'s note as well, which is at slide 233. Can we remind ourselves about that, please?

Start at the top and scroll down. We know that [Dr B] arrived after Dr Lambie was there and the first part of this report appears to be reporting what was reported to [Dr B]. We can see it refers to:

"Suddenly purple blotching over body, all over, with slowing of heart rate."

If we scroll down, please. Thank you. Just to there. In the centre of the page:

"Upon my arrival, purple blotchiness right mid-abdomen and right hand."

Do you see that, Professor Kinsey?

KINSEY: Yes.

MYERS: Just for completeness, can we scroll to the end, please?

Towards the end, a reference to:

"Purple discolouration, almost resolved."

That situation.

The final description we had was in the note of Lucy Letby, which is at slide 218. We can go into that and into the note behind it.

In fact, are we able to go to the page beforehand?

This is the second of two pages, I think. We need to start at page 1362 if possible. Thank you.

Enlarge the bottom right and go over the page when we've read this. It's here, in fact. 07.29, so written retrospectively:

"Cyanosed in appearance. Centrally shut down, limp, apnoeic. CMV via Neopuff commenced and chest movement seen. Colour changed rapidly to purple blotchiness with white patches."

So those are the descriptions we have there, Professor Kinsey.

KINSEY: Yes.

MYERS: There is reference to purple throughout. We can see, as it happens, in none of those is there any description of any bright pink or red feature, as we have, for instance, in the Lee and Tanswell article, is there?

KINSEY: No.

MYERS: I'm going to move to look more about what you said more generally about changes in skin colour, please. You've assisted this afternoon and this morning with an explanation of how the circulation works and how bubbles passing through the circulation may or can move to the skin and cause discolouration. That's what you've done this morning, isn't it?

KINSEY: Yes.

MYERS: And that is set out in a report that you prepared for this trial, dated 1 November 2022, isn't it? It's at page 5632 of our statements, my Lord. It's your final report to date, 1 November 2022.

KINSEY: Yes.

MYERS: Your first statement in the case, which is the one that dealt with [Baby A], I think, was back in March 2020, wasn't it?

KINSEY: Yes.

MYERS: But since that time you were asked to give further consideration to the mechanisms by which an air embolism could work, weren't you?

KINSEY: Yes. I was asked to be able to give an anatomical description about how air embolus would actually happen so people understood what it was.

MYERS: Your voice is quite quiet, if you could raise it, that would help to make sure everyone can hear what you say.

KINSEY: I was asked if I could make a bit more of an explanation about the features of an air embolus. I did say at the time that I was not an expert in this area, but I was asked if I could do it anyway.

MYERS: Right. And that was -- in fact, you'd come to give evidence in the trial at an earlier stage, hadn't you, and was that the time at which you were asked to assist with that?

KINSEY: Um... Well, no, it was before.

MYERS: All right.

KINSEY: No -- yes. I don't quite understand the question of which...

MYERS: This isn't the first time you have come to court to give evidence in this trial, is it?

KINSEY: It is the first time.

MYERS: It's the first time you have given evidence, but you attended earlier in the trial, didn't you?

KINSEY: My apologies, yes, I did.

MYERS: And was it on that occasion you were asked to consider, if you would, the anatomical basis and any further information you could provide to explain the mechanism of air embolism?

KINSEY: Yes, and at that meeting I said that I was not an expert in air embolus or in decompression.

MYERS: Right. But it's that which led to the report that you gave us, dated 1 November 2022, wasn't it?

KINSEY: That is the case, yes.

MYERS: In that report, and I'm looking at page 5 of 5 of the statements, which is page 5636, my Lord. In that report, really in the centre of that section, is where you deal with comments on changes in skin colour. You acknowledge, professor, that:

"It is important to note there is very little in the medical literature regarding the cutaneous features of air embolus in the skin."

KINSEY: Yes.

MYERS: That's a fact, isn't it?

KINSEY: It is an absolute fact.

MYERS: You've applied your knowledge of blood and circulation to the available research to assist with this; is that correct?

KINSEY: Yes.

MYERS: And that's involved, for example, the paper by Lee and Tanswell, hasn't it?

KINSEY: Yes.

MYERS: When it comes to the question of how bubbles operate in the blood, was that a paper by the authors Garcia and Mitchell that you relied upon to some extent?

KINSEY: Yes, it is.

MYERS: Right. Again, we recognise you're dealing with, as you say, a limited amount of material to work with in the literature.

KINSEY: Yes.

MYERS: Just so we understand, the paper by Garcia that you rely upon to assist in the model you have given us of bubbles in the blood deals with decompression sickness in deep sea divers, doesn't it?

KINSEY: It does, yes.

MYERS: And the way that bubbles of inert gas can form in the blood of a deep sea diver as a result of decompression, can't they?

KINSEY: Well, re-compression.

MYERS: Sorry, they're decompressed and when they re-compress the bubbles come out; is that correct?

KINSEY: No, it is decompression -- sorry, you were right first time. So the further up you come to the surface, the bigger the bubbles become.

MYERS: Yes. Is that what people call colloquially the bends?

KINSEY: Yes, it is.

MYERS: And the problem is that the gas in the blood is -- that will -- it'll contain 78% nitrogen; is that right?

KINSEY: Perhaps not quite as much as that, but in that ballpark yes.

MYERS: But nitrogen, which is roughly that proportion of air, is not readily soluble in blood, is it, or in the body tissue?

KINSEY: It doesn't disperse in the same way, no.

MYERS: It doesn't disperse. It stays around a lot longer, doesn't it?

KINSEY: Yes.

MYERS: So although oxygen gets taken up by way of the ping-pong ball mechanism --

KINSEY: We're talking now about non-decompressed people.

MYERS: But in any event, whatever the situation, nitrogen will remain in the blood in a gas form for much longer, won't it? Nitrogen bubbles will, won't they?

KINSEY: I don't know the answer to that question.

MYERS: In any event, the paper you looked at there deals with something that happens to divers and aviators and astronauts, doesn't it?

KINSEY: Yes.

MYERS: It's not a paper that deals specifically, perhaps quite obviously from what I have said, with premature babies or the systems in a premature baby, is it?

KINSEY: No, I was asked to provide a report about embolus.

MYERS: I'm not criticising you for that, Professor Kinsey, and I am simply looking at the limits or the extent to which it is applicable to what we're dealing with here.

The mechanism in that report that you've relied upon where you tell us about the bubbles is, as you've said, decompression. It's the effects of gas coming out into the blood when deep sea divers, having been to the deep, come back up the top?

KINSEY: As things expand.

MYERS: As it expands. So far as mechanisms go, that's quite a different mechanism from the exogenous introduction of air injected or that finds its way into the system of a baby, isn't it, by way of mechanism?

KINSEY: By way of mechanism it is, but bubbles will enlarge and will be in the circulation already and therefore you then end up with emboli causing the bends, the pain that comes with that.

MYERS: Again, the paper that we're dealing with focused on four adults, didn't it?

KINSEY: It did, yes.

MYERS: It seems one relevant feature in that case was they were also four overweight adults, they had raised BMIs, didn't they?

KINSEY: Yes. There were many limitations to their findings.

MYERS: And the reason I point that out is because their raised BMI is relevant because they had more subcutaneous fat and, from the paper, that affects the rate at which nitrogen might be released; is that correct?

KINSEY: Again, this is decompression stuff that I'm not an expert in.

MYERS: All right. In any event, whilst that paper certainly goes to show the relationship between bubbles coming to the skin and decompression in those divers --

KINSEY: Who had patent --

MYERS: Yes, who did have. It is very specific to them in terms of the base of people that it's based upon, isn't it?

KINSEY: Yes, it is, but also they did happen to have patent foramen ovale.

MYERS: Yes. And was that paper the first paper dealing with reports of bubbles in the skin after diving as far as we can tell?

KINSEY: Again, I've said I'm not an expert in this area and I don't know the entire literature.

MYERS: Do you agree that the paper, the research you have relied upon there, would be no basis for saying that bubbles in the blood would always cause a rash in deep sea divers?

KINSEY: No, I can't say that and I don't think that they can say that either.

MYERS: But that it always causes a rash, you can't say that?

KINSEY: Could you repeat the question again?

MYERS: Just so we understand what you've relied upon, this paper, informing your opinion about bubbles and air embolus, it doesn't give a basis for saying, for instance, that bubbles in the blood will always cause a rash in divers who are suffering from decompression sickness, does it?

KINSEY: No.

MYERS: Right. And nor can it form a basis for saying that air introduced exogenously in a baby will always, for example, produce bubbles that will come to the skin and cause discolouration? It doesn't do that, does it?

KINSEY: No, it doesn't.

MYERS: I just want to move away from the research basis for what you've had to said to some more general questions about air in the blood as far as you can help us, Professor Kinsey.

We've seen from the material you've given us how tissues and blood will absorb oxygen when it's carried around the body.

KINSEY: Yes.

MYERS: That's right, isn't it? And again, I repeat, that's illustrated by what was referred to as the ping-pong ball mechanism --

KINSEY: Yes.

MYERS: -- the exchange of oxygen? I touched on this earlier: a large part of air is formed by nitrogen, isn't it?

KINSEY: Yes.

MYERS: And what percentage did you say that was?

KINSEY: Well, it's about 71%.

MYERS: About 71%. All right. As we've established, nitrogen is not absorbed by the blood or body tissue in the way that oxygen is, is it?

KINSEY: No.

MYERS: And it will remain in bubble form in the blood for very much longer, won't it?

KINSEY: I expect so.

MYERS: And in fact, decompression sickness, when we're looking at that, can last for hours with divers, can't it?

KINSEY: This isn't decompression.

MYERS: No, but one of the reasons it lasts for hours is because the nitrogen stays in the blood for quite a long time, doesn't it?

KINSEY: I don't know the answer to that, but I'm not sure we can compare it with decompression either because the amount of -- the problem with decompression is the nitrogen is compressed and because it's a larger gas in air, as people come up to the surface the bubbles get larger.

It's not the same because at sea level the bubbles are not going to change just because of nitrogen. So I don't think that is the right thing to say.

MYERS: You agree, you can't simply take what happens in decompression sickness and apply that to an air embolus?

KINSEY: No, you can't.

MYERS: Which again is one of the limitations with the paper you went to, isn't it?

KINSEY: Well, it is. What I was -- I was explaining in using that was the fact that skin manifestations have been seen in deep sea divers on decompression who have patent foramen ovale.

MYERS: All right. If air is in the blood sufficient to cause a collapse, we're talking about air introduced exogenously, however that is, whether intentional or accidental, but air that's come in exogenously, that air will include the nitrogen and the oxygen, won't it?

KINSEY: Yes.

MYERS: If it's caused a collapse, the nitrogen will still remain in the blood for some time even after the oxygen has been absorbed, won't it?

KINSEY: If the circulation has stopped then that is the case.

But the oxygen -- the nitrogen is introduced by breathing.

MYERS: Yes.

KINSEY: Actually, that's not the case.

MYERS: No.

KINSEY: Nitrogen comes in exogenously, so it will stay around.

MYERS: It will, won't it?

KINSEY: Yes.

MYERS: So however it's entered the system, it will stay around.

And you've explained that the harm is done by blockages as the vessels get smaller?

KINSEY: Yes.

MYERS: So if nitrogen is in the system, even if the oxygen is absorbed, the nitrogen will continue to block vessels for however long it takes for the nitrogen to stop?

KINSEY: Yes.

MYERS: And if that's the case, you wouldn't expect there to be what could be described as a rapid recovery if there was sufficient air to cause a collapse because of an air embolism, would you?

KINSEY: It depends how big the embolism is.

MYERS: All right. But in principle, insofar as the blockage of vessels creates the harm, whatever that is, as long as there are nitrogen bubbles of sufficient size to create a blockage, that harm would continue?

KINSEY: Well, the harm really is in the size of the embolus and the size of the vessel it's in. So minuscule arterioles in the skin, it doesn't really matter if they get blocked up because there is a bypass circuit. But if you have a massive air bubble going into the arteries that lead to the brain then life will cease instantly.

MYERS: Thank you for explaining that. But save for acknowledging that nitrogen takes much longer to be cleared from the system than oxygen, the continuing effect of it depends on how much there was that went in; is that what you'd say?

KINSEY: I don't think I would say -- I don't think I have an opinion on that because I don't know enough about it.

MYERS: All right.

KINSEY: I'm not sure other people do either.

MR MYERS: Thank you for dealing with that, Professor Kinsey. Would you give me one moment, please?

(Pause)

Thank you for answering my questions.

MR JOHNSON: Does your Lordship have any questions?

Questions from THE JUDGE

MR JUSTICE GOSS: Just in relation to that very last answer that you gave, you won't give an opinion on that proposition that was put to you and you didn't think other people would have an opinion about it, if I understood your answer.

KINSEY: Well...

MR JUSTICE GOSS: Can you just explain why you said that?

KINSEY: Yes, my Lord. I have never encountered any discussion about nitrogen in the circulation except in deep sea divers. So the biggest effect of an air embolus would be the size of it, of course, and in the vessel that becomes blocked and what is beyond that vessel that then dies. Nobody has ever mentioned-- in the cases I have needed to talk to people about air embolus, nobody's talked about the different quantities of the gases contained in air. So that's why I made the comment I did.

MR JUSTICE GOSS: Right. 71% nitrogen, 21% oxygen, carbon dioxide?

KINSEY: And a few other things.

MR JUSTICE GOSS: And other smaller gases?

KINSEY: Yes, inert gases.

MR JUSTICE GOSS: Right.

MR JOHNSON: Thank you, professor.

MR JUSTICE GOSS: Thank you very much, Professor Kinsey.

That completes your evidence at this stage. But you will be coming back, is that right, Mr Johnson?

MR JOHNSON: Yes.

MR JUSTICE GOSS: You will be coming back at a future time to give evidence. Please do not discuss this case or anything to do with this case or your evidence and the areas of expertise about which you have given evidence with anyone else.

KINSEY: No.

MR JUSTICE GOSS: Just keep your thoughts to yourself until this case is all over, please.

KINSEY: Yes.

MR JUSTICE GOSS: Thank you very much.

(The witness withdrew)

MR DRIVER: My Lord, the next witness is Mr Ian Allen, who we hope and believe is just outside.

MR JUSTICE GOSS: Thank you.

MR IAN ALLEN (affirmed)

Examination-in-chief by MR DRIVER

MR DRIVER: Could I invite you to begin by stating your full naming for the record, please.

ALLEN: My name is Ian Christopher Allen.

DRIVER: And your current occupation?

ALLEN: I'm a regional quality assurance specialist pharmacist for the north-west of England.

DRIVER: And your occupation in May 2015?

ALLEN: I was the principal pharmacist for aseptic services at the Countess of Chester.

DRIVER: And for how long did you undertake that role?

ALLEN: So from May 2015 to December 2019.

DRIVER: Thank you. Could you tell us a little, please, about your academic qualifications that are relevant to that professional role that you undertook at the hospital?

ALLEN: Yes, certainly. I have a master's degree in pharmacy.

I have a postgraduate diploma in clinical pharmacy, and a postgraduate diploma in pharmaceutical technology and quality assurance.

DRIVER: Thank you. Could you describe, in a sentence or two, the primary function of the aseptic unit at a hospital such as the Countess of Chester Hospital?

ALLEN: Yes, certainly. The aseptic unit is a specialist area within the pharmacy for the preparation of injectable medicines. So the facility functions to ensure the quality and safety of the medicine that's prepared.

DRIVER: During your time within that unit at that hospital, what was the nature of the intravenous bags produced within the unit for use within the neonatal department?

ALLEN: Yes. So we produce a range of products for the neonatal unit. One of them was intravenous feed, commonly referred to as TPN, total parenteral nutrition. We also provided a range of other injectable medicines, including antibiotics and other pre-prepared injections to be supplied to the neonatal unit.

DRIVER: We'll come back to those latter items in due course, but if we could, please, for the time being, focus upon the total parenteral nutrition bags that you and your department would have handled and ultimately provided to the neonatal unit about which this jury have already heard a little and indeed watched a video demonstration recording, which I believe, could you confirm, that you too had the benefit of seeing in the recent past?

ALLEN: Yes. I have seen the video last week.

DRIVER: Thank you. How many types of TPN bags did you come across during your time within the aseptic unit?

ALLEN: So prepared from the aseptic unit we would make Babiven Maintenance, which we would add vitamins and trace elements to. We also supplied out to the ward itself, but not made within the pharmacy aseptic unit, Babiven Start-up and Babiven Maintenance, but the one that was supplied to the ward directly would have no vitamins and trace elements inside it.

DRIVER: So Babiven Start-up. We understand, could you confirm, if you agree, that that would be used for babies during the first day or two of life?

ALLEN: That's correct, yes: for the first 2 days of life, the baby received Babiven Start-up.

DRIVER: A second type of, if I might call it off-the-shelf TPN bag, you've already described as a Maintenance bag. And both of those, is this right, would be supplied to the unit through your department but without your department in any way adulterating the contents of the bag?

ALLEN: Yes. So Babiven Maintenance -- there would be Babiven Maintenance bags sent to stock, which we would not add anything to the bag. But also we would supply Babiven Maintenance with vitamins and trace elements.

The difference being that it takes a little time to process an order from the pharmacy, so the ward might use the Babiven Maintenance without the vitamins and trace elements to start, but then once they had sent the order to the pharmacy, the baby would move on to have the bag with the vitamins and trace elements from that point forward.

DRIVER: Thank you. Let's deal with the process by which an order for such a bag would be made by the NNU to the pharmacy department and the process by which it would be tailored to the specific requests and then supplied if you would.

Firstly, how would an initial order be received?

ALLEN: So the order would be received via fax from the neonatal unit. So a prescription would be written on to a card by a doctor and that'd be faxed down to the pharmacy aseptic unit.

DRIVER: Thank you. And upon receipt of that request, what would be the first stage in the process within the pharmacy unit?

ALLEN: So that would be handed to a pharmacist, such as myself.

The pharmacist would review the prescription, to ensure it's prescribed correctly against the standard protocol.

The pharmacist would then process that prescription into a worksheet, which is essentially an instruction for how to make the TPN bag.

DRIVER: So a clinician would effectively send a prescription, the content of that prescription would be transformed into a worksheet, which is a set of instructions, effectively; is that correct?

ALLEN: That's correct, yes. The worksheet itself would be instructions on how to make the bag but also a list of the ingredients which are used to prepare the bag, so a list of what would need to be gathered to make it.

DRIVER: So you have the menu and the instructions on how to introduce those ingredients into the bag and in what proportions?

ALLEN: That's correct.

DRIVER: Next please. Might I ask you about the next step in the manufacturing process?

ALLEN: Yes, certainly. So from that point forward, after the worksheet -- and a label would be generated at the same time for the bag -- the next step would be for a member of the pharmacy team, either a pharmacy assistant or technician, to gather the ingredients used to make the bag. So on the worksheet is a list of exactly what materials are needed and the quantities. They would gather from the shelves in the pharmacy those specific materials and quantities.

So it would be a bag of Babiven Maintenance, a vial of water, a vial of -- an ampoule of water, sorry, a vial of Solivito, and an ampoule of Peditrace. So they would gather those ingredients and then copy down the batch numbers from those ingredients -- so every medicine comes with a pre-printed batch number which is specific to it. They would be written down on to the work sheet to record what been used to make the bag. So we would call that process assembly because you're gathering together ingredients.

DRIVER: And this assembly element of the process, would that be done in a creative way or would it be done by way of adherence to strict and well-established protocols?

ALLEN: So every step in the whole process of making the bag has a -- what's called a standard operating procedure, so a standard step-by-step process, which staff have to follow. The idea is that that makes the process repeatable and of a high quality level. Staff would have to sign to read those procedures and they would be trained in how to follow them.

MR JUSTICE GOSS: Sorry to interrupt you, but you do speak very quickly. I'm conscious that someone who is transcribing what you're saying, even a speed writer, will have difficulty with keeping up with you. Could you just slow down a bit, please?

ALLEN: No problem, yes.

MR JUSTICE GOSS: You speak quickly naturally. I'm not being critical, but for the benefit of other people.

ALLEN: I'll slow down.

MR DRIVER: Mr Allen, I think the answer you just provided to me is a description of -- is it appropriate to describe it as a quality assurance protocol?

ALLEN: Yes, so that would be correct: it's a quality assured process. There are regulatory standards which have to be followed in terms of how we produce the bag, nationally recognised regulatory standards.

DRIVER: So those standards are set by a regulatory body outwith the hospital?

ALLEN: Yes, that's correct. So the part of EU law is called Good Manufacturing Practice which defines the standards for preparation of a medicine.

DRIVER: And were those standards adopted and embraced within the pharmacy unit whilst you worked there?

ALLEN: That's correct, yes, they were.

DRIVER: You described to us the process by which specifically prescribed elements might be gathered together and added to a manufactured bag that had been bought into the hospital. After that is done, what is the next step of the process?

ALLEN: So after the ingredients have been checked, they would then be passed into the aseptic clean rooms. So this is a specially designed room which has clean air blown into it through special filters, so it's controlling all the air in that environment.

What we would do is we would spray the exterior of those items with 70% alcohol. The idea is that kills any microorganisms which are present on the exterior of those items as they're transferred into this controlled environment.

So there's two steps of this, where they are sprayed and wiped with alcohol and a sporicidal. And through this process they make their way to a clean-air device, which we refer to as a laminar airflow cabinet. This is the place where the actual manipulations are going to take place.

So the rooms themselves have controlled air, then the cabinet or the laminar airflow cabinet has controlled clean air blown into it. It's all about reducing the amount of micro-organisms in the environment where the bag is going to be made.

DRIVER: All designed to ensure the sterility of the process and thereby the sterility of the product?

ALLEN: That's correct.

DRIVER: The bags, having been tailored to match the prescription, details of which had been transformed into a worksheet of instructions, I should say, what happens next?

ALLEN: So inside the clean air device, which was demonstrated on the video itself, there will be two operators who will actually make the bag. What they are going to do is take materials from the ampoules and vials which have been assembled. They will add from -- one of those ampoules gets pulled up and added directly to the bag.

Another of the manipulations is to take some water and add to that to a vial -- we call that staff(?) reconstitution because it has got a powder inside and you are adding water to the powder. That is then pulled up and added to the bag itself.

There's a series of checks in place so we always work with two operators who are confirming both the identity of the ingredients against the worksheet, but also the volume that has been withdrawn and added to the bag.

After that takes place, the bag will be mixed.

DRIVER: So you've just described to us in detail how the bag or its content, more accurately, are prepared and the environment within which those preparations take place.

And is it still within that same sterile environment that a second employee checks all that has just gone on before?

ALLEN: That's correct. So just to be clear, there's a check whilst the bag has been made, so there's always two operators who are making the bag. But then there's another check once it's passed out of that cabinet as well by an independent -- what we call a releasing pharmacist will check.

DRIVER: So the two pharmacy assistants or operatives work together and check each other's conduct --

ALLEN: That's correct.

DRIVER: -- professional conduct? And we saw from the video, and we'll watch it again in a moment, does the bag pass through a controlled out-hatch --

ALLEN: Correct.

DRIVER: -- into a different room or part of a room, and on the other side of there, does a pharmacist undertake something akin to a defect check?

ALLEN: Yes. That is the releasing process where the pharmacist is checking all aspects of the preparation and the worksheet. They also perform what's called reconciliation, where they take the used ampoules and vials and they check what's used, they check that back against the worksheet to make sure the correct items have been used during the actual preparation of the bag.

DRIVER: And how would that checking pharmacist satisfy him or herself that the correct items have been used?

ALLEN: So they would have access to the prescription to understand what had been prescribed, so they check against that. So they check the worksheet back against the prescription itself.

They then take each ampoule or vial, which would now be empty, which had been passed out, they would again check those against the list of ingredients on that worksheet and sign for that check.

DRIVER: Who is ultimately responsible?

ALLEN: The releasing pharmacist would be ultimately responsible for the product.

DRIVER: You made mention of a regulatory regime which dictates the process that you have us just described to us. Is the unit itself subject to regulatory monitoring?

ALLEN: It is. So the unit had -- operated under two regulatory frameworks. Under one of them it prepared items under section 10 of the Medicines Act. And that was a requirement from the HS that there would be inspections via a regional quality assurance auditor.

The unit also held a MHRA manufacturer's specials licence and was subject to inspection by the MHRA.

DRIVER: Forgive me if this is an invitation for you to state the obvious, but what is the underlying purpose of these regulatory protocols and this systematic approach to the production of these bags?

ALLEN: It is to ensure the quality, safety and efficacy of the medicine, to make sure that what is prescribed, the product that we actually make, meets the patient's needs and is both safe and effective and of the required level of quality.

MR DRIVER: Thank you.

My Lord, I now intend to replay the video the jury watched yesterday afternoon, to pause it in between each part and ask Mr Allen to pass such comment as he thinks appropriate, if I may --

MR JUSTICE GOSS: Yes.

MR DRIVER: -- and to confirm that these do accurately reflect the protocols that were in place under his management.

MR JUSTICE GOSS: Thank you.

Just before we start that, Mr Myers, I don't know whether you anticipate you will have questions for Mr Allen. I was going to say that when the video recording has stopped and you wish to ask any question about the recording up to that point, I think that would be helpful to have it there and then rather than wait to the end and we go back through it all and come back to it again.

MR DRIVER: Absolutely, because after this stage I'm going to take Mr Allen's attention to a specific prescription.

MR JUSTICE GOSS: Exactly. If you have any, that will be your moment, Mr Myers.

MR MYERS: Thank you, my Lord. Mr Allen falls into that category where we don't anticipate them, but it's not unknown sometimes for a question to come to mind as I see the evidence me, so I will deal with it then if it arises. Thank you.

MR JUSTICE GOSS: As you see the evidence and depending on anything Mr Allen may say about it.

MR MYERS: Thank you, my Lord.

MR JUSTICE GOSS: You understand that?

MR MYERS: Yes.

MR DRIVER: Mr Allen, I can see your eye running down the screen. Do you agree with this general description?

ALLEN: Yes.

(Slides displayed to the court)

(Video played to the court)

DRIVER: Pausing there, does that reflect the hygiene protocols or processes that were observed during your time at the hospital?

ALLEN: Yes. We described the process as transfer sanitisation.

DRIVER: Transfer sanitisation.

MR JUSTICE GOSS: Before we start again, that spray that's used quite liberally, as we see, because we've seen this before, that's the 70% alcohol?

ALLEN: That's the 70% alcohol, yes.

MR JUSTICE GOSS: The wipes, are they infused with the same --

ALLEN: Pre-impregnated with 70% alcohol. There would have been -- just to make clear, there is a stage before this, which wasn't captured in the video, which would happen in the room before, in which things would be sprayed with a sporicidal substance to kill any bacterial spores. So this video starts one step into then process.

MR DRIVER: So there's an earlier step?

ALLEN: With another level of sanitisation. What you have just seen looks exactly the same, effectively, but it is repeating the process with a different agent than the step before.

(Video playing continued)

DRIVER: Where has the kit been transferred to now?

ALLEN: This is the room with the clean air device in. So you can probably just see through the window there is a clean air device where the thing is going to be made -- where the product is going to be made in the next room.

So the next step now will be to transfer into the clean air device itself, to begin preparation of the products.

DRIVER: And why is the next stage done with the assistance of a background clean air device?

ALLEN: This creates what we call a grade A environment, which in layman's terms means it's free of bacteria. So the air being blown into that device goes through a large filter which filters out any contamination. So at the point where connections are being made, as the bag is being made and things are being transferred from syringe to bag, completely clean air that's free of bacteria is blowing over those connections.

DRIVER: Thank you.

(Video playing continued)

Those dishes, two of which have just been opened, what are they and what's their purpose?

ALLEN: They are agar plates. The simple way to think about those is they are a growth media for bacteria. So bacteria like to grow on those, so they're a way of us detecting if there are any bacteria in the environment of the cabinet while we're making the bag. They're sent away to a QC testing laboratory where they're intubated and we get the results back. They are part of the ongoing monitoring programme of the environment of the clean air device so that we are aware if there is any contamination present at the point where the medicines themselves are being made.

DRIVER: That's an element of the unit monitoring?

ALLEN: Yes, monitoring of the unit. So they are placed both in the clean air device and also weekly throughout the unit as well so we are constantly monitoring the environment to ensure it meets predefined levels of cleanliness.

DRIVER: Thank you.

(Video playing continued)

DRIVER: Pausing there. So the narrator said she was removing the safety cap from which port?

ALLEN: The additive port. So the additive port is a tamper-evident safety cap which is made of preformed plastic which you snap away. That then allows the person to add additions to the bag via that port.

DRIVER: So the safety cap having been snapped away, what lies below?

ALLEN: It is a bung or a septum, which you can insert a needle through. Once you push the needle through you can add to the bag, but then as you pull off that bung will self-seal over so the bag doesn't leak and the container is again closed.

DRIVER: So that central port is the additive port?

ALLEN: That's correct.

DRIVER: Are these bags uniform? Do they always come in the same format?

ALLEN: Yes, they would always have the same ports in the same format, that's correct.

DRIVER: Help us then: so we've got the central one is the additive port?

ALLEN: Yes.

DRIVER: The one nearest the pharmacist's gloved finger?

ALLEN: Um... Nearest the gloved finger, that is the port that was used to fill the bag via the manufacturer. So the person who originally made this bag filled the ingredients in it and then you can see, as you look towards the bag itself, there's a transparent clamp on that bag. So after the manufacturer's filled the bag they've placed a clamp on it and that clamp cannot be removed.

DRIVER: What title or tag would you give that port?

ALLEN: A port used to manufacture the bag, I guess.

DRIVER: And the clamp, does that create a seal?

ALLEN: It does, yes. The bag is already sealed by the white cap at the end that you can see, so that prevents any more ingress. But the clamp is just completely preventing that port from being used anymore because once you have pressed that clamp over, there is no way to easily remove it without breaking it and taking (inaudible: coughing).

DRIVER: So if I call that the manufacturer's port for convenience --

ALLEN: Yes.

DRIVER: -- is that impregnable?

ALLEN: Yes, I believe so, yes.

DRIVER: The additive port, obviously, things can be added through it in the way you have just described?

ALLEN: Yes, that's correct. Once the tamper-evident plastic has been snapped, as you saw.

DRIVER: Thank you. And the third port nearest the camera?

ALLEN: Is the administration port, which the nurse would use to administer the bag to the patient. They would insert a spike and a giving line into that bag. They first need to -- you can see there is a piece of plastic on the end. They would snap off that piece of plastic and insert the spike.

DRIVER: So that's output, as it were --

ALLEN: Yes, that's correct.

DRIVER: -- to administer the fluids to the patient?

ALLEN: That's correct.

DRIVER: Thank you, Mr Murphy.

(Video playing continued)

DRIVER: Pausing there, please, Mr Allen. We saw the operative or the pharmacist add ingredients through the additive port and then she covered it with what she described as a safety cap. That having been reapplied, is it fixed or can it be removed again?

ALLEN: When we tested on the bags subsequently, it can be removed and attached over that port.

DRIVER: Thank you. Could we continue, please?

(Video playing continued)

DRIVER: Do you agree with that?

ALLEN: No, I believe there's an error in the video. So this was made by the existing team at the Countess of Chester and they've described the ports the wrong way round.

MR JUSTICE GOSS: Yes, you said the other way?

MR DRIVER: So the longer port with the white filter or cap on the end, that is in fact the input for the manufacturer's fluid?

ALLEN: That's correct, yes.

DRIVER: Thank you.

(Video playing continued)

DRIVER: Pause there. So it's vice versa?

ALLEN: Yes, that's correct. That is the manufacturer's port that she's got in her hand.

DRIVER: Thank you.

(Video playing continued)

DRIVER: Pausing there. You agree that's the additive port?

ALLEN: That's correct, yes.

DRIVER: Do you agree it's tamper-proof?

ALLEN: That cap is not tamper-proof that's on there now. It could be removed when we test it.

DRIVER: If I were to give you a bag now, could you demonstrate that?

ALLEN: Yes.

DRIVER: Thank you.

(Pause)

ALLEN: So I'll try and hold it up. The additive port is in the middle. You can snap off the piece of plastic which is tamper-proof. We then add to the bag.

MR JUSTICE GOSS: Would you mind standing up so everyone can see?

ALLEN: I have just snapped off the tamper-proof small piece of plastic which exposes the additive port. This is the cap then, once the operators have added to the bag, they place it over the additive port. And it does click on, but it's possible to actually pull off when we tested it previously. It does come back off. It has small plastic ridges which hold it in place, but if you want to pull it off, it can be pulled off.

MR DRIVER: And beneath that lies something you described as a bung earlier, a self-sealing rubber stopper?

ALLEN: Yes, a self-sealing rubber stopper through which the additives have been inserted into the bag.

MR JUSTICE GOSS: I think it might be helpful just for that to be handed round the jury to look at now, and Mr Myers as well.

(Handed)

MR DRIVER: Yes. We have another bag so we can do a compare-and-contrast exercise. Can you confirm that's two identical --

ALLEN: Yes, that's correct.

(Pause)

MR JUSTICE GOSS: The first bag was the one that Mr Allen broke the cap off and the second one is as it's manufactured.

Can those be exhibited, please?

MR DRIVER: Certainly. Prosecution exhibits 2 and 3, Mr Astbury reminds me. We'll call the one Mr Allen touched and took out of the bag number 2.

MR JUSTICE GOSS: And the manufactured one is 3.

3 and 4 it is, in fact.

MR DRIVER: Mr Worthington's right, Mr Astbury's wrong.

So Mr Allen, there's just 30 seconds of this video left. So if we let that play out, please.

(Video playing continued)

Do you agree with all of that?

ALLEN: Just a second.

MR JUSTICE GOSS: Take your time to read through it carefully.

(Pause)

ALLEN: Yes, so the middle -- the additive port has been described as tamper-proof, which isn't technically correct because we've just seen that on the middle port the cap can be lifted back on and back off.

Tamper-evident normally means that there'd be some kind of clear evidence once you have broken it. So just a clarification there, I guess. There would be no way to add to either of the other two ports without some kind of significant damage to the port.

MR DRIVER: Thank you.

The process that we've just watched, when undertaken in practice, how long does it take from start to finish?

ALLEN: For the preparation of an entire bag?

DRIVER: Yes.

ALLEN: Approximately between 40 to 60 minutes, I would have thought, end to end.

DRIVER: We saw one of the operatives introduce liquid through the additive port, so the jury can gauge how long that took because they watched it. What sort of quantity of liquid was added in during that part of the demonstration?

ALLEN: I believe it said it was 3.76ml.

DRIVER: Thank you. The systemised process that we've just watched, was that observed for each and every bag that was produced under your watch, as it were, or was that just for the cameras?

ALLEN: No, that's correct: the same standard operating procedures are followed by the staff for every bag.

It's a standardised process they'd repeat day in, day out.

DRIVER: Thank you. You have been asked to consider documentation that was produced during the process of prescription manufacture and delivery for a specific bag in the Countess of Chester Hospital in August 2015; do you recall?

ALLEN: Yes, that's correct.

DRIVER: And Mr Murphy, if we go to the carousel, please, and look at tile 145 to begin with. We have the documents available to put them on screen, Mr Allen. If you want to see the originals, they're in court too.

ALLEN: Okay.

DRIVER: So this is a prescription document. Do you recognise it in its style?

ALLEN: Yes, in its style, yes.

DRIVER: Thank you. Is that the sort of document -- is that the format in which the fax would be sent to the pharmacy unit?

ALLEN: That's correct, that's what we'd receive -- to use to make the bag.

DRIVER: If we go to the next tile, please, Mr Murphy, and the document beneath, please.

Is this the corresponding document created within your unit to reflect the terms of the prescription?

ALLEN: Yes, that's one of the pages. There are multiple pages.

So this is not the page that would be used to assemble the ingredients against, there's a different page.

DRIVER: Thank you. Mr Murphy, could you put up the bundle of documents that I think Mr Allen's just referred to, which you have in the additional file at J2805?

That's an exhibit label that has your initials on, Mr Allen, ICA10. If we could look at the next page, please.

ALLEN: Okay, yes. This is the worksheet that would have been used for the assembly process to gather the materials.

DRIVER: Was this the worksheet used for a prescribed TPN bag for a baby known to you at that point in time as Twin 2 [Surname of Babies E & F]?

ALLEN: Yes, that's correct.

DRIVER: [Surname of Babies E & F] being the baby's surname.

ALLEN: That's correct.

DRIVER: Thank you. Have you considered each and every page of this bundle of documents?

ALLEN: Yes, that's correct.

DRIVER: And are you able to identify each of the operatives and each pair of hands and the controlling mind that directed this procedure?

ALLEN: Yes.

DRIVER: And did it follow the protocols we've just watched in the example?

ALLEN: Yes, it did.

DRIVER: And upon production of the corresponding bag, what's the final stage in terms of the pharmacy's system?

ALLEN: Sorry, could you ask that question again, please?

DRIVER: The bag having been completed, the overseeing pharmacist having satisfied himself or herself, in this case you satisfying

yourself that it was reflective of the prescription, what happens to the bag after that, once it leaves the pharmacy aseptic unit?

ALLEN: So the bag would be transferred to the neonatal unit refrigerator by staff from the pharmacy aseptic unit.

They would courier it out to the neonatal unit.

DRIVER: How many runs per day?

ALLEN: There'd be one run in the day at approximately 4 o'clock.

DRIVER: We can see on one of these documents that a time for delivery of the nutrition, a printed document has -- 12 o'clock has been crossed out and someone's written in the words 11.30. Would that have been you?

ALLEN: Can we just see that document?

DRIVER: Yes. We'll go through them one by one, I'm sure we'll get there. It's 8 pages, I think. They're the labels --

ALLEN: The labels. So a copy of the printed label that would have been put on to the bag and the manufacturer's label, which got taken off and replaced with our label.

So that's the label we would have put on to the bag. We take a copy for our records to keep.

DRIVER: Thank you. Just go back to that, Mr Murphy, sorry.

The bottom line:

"For administration for up to 48 hours commencing 12 midnight 04/08/2015."

ALLEN: Yes, that's correct.

DRIVER: The period for the administration, is that the standardised period?

ALLEN: Yes, so bags would have been run over a 48-hour period.

DRIVER: We see, a few lines above, a controlled temperature for storage and an expiry date, a use-by date effectively?

ALLEN: Yes, that's correct. That's the expiry date.

DRIVER: Which is 7 days after creation?

ALLEN: That's correct. The product is stable for 7 days.

Also, the regulatory framework this product was made under has a maximum expiry assigned to the product of 7 days.

DRIVER: Thank you. Look at the next page, please. What's the purpose of this page?

ALLEN: So this documents the operator's checks in the process, so the checks at various stages of manufacture, the in-process checks on the ingredients, so the section 7 ingredient reconciliation. Also checks on the number of labels produced and the number of products produced, so we very carefully track throughout the process how many labels were generated, where they went, so we know that one went on to the worksheet, one went on to the bag, so that we don't have any mix-up between labels. We do the same for products as well.

For this, one bag has been made but for some different items we might make 10 within a certain batch, so we want to be absolutely sure we know what happened to every product, we know what was destroyed, so it is a stage of tracking everything that was made throughout the process itself.

Then the final set of checks are the release checks.

So they've confirmed the product's stable, they've checked the ingredients that were used, that reconciliation check we talked about. They've checked the label reconciliation and that the product complies with the prescription, and there's a final release from the pharmacist.

So just to confirm, this bag was not released by myself, this was Jos Wickett who signed the release of this bag.

DRIVER: Thank you. Next page.

ALLEN: So that is just a list of the manufacturers so we have a record of which ingredients are made by which manufacturer.

DRIVER: Thank you. A single manufacturer seems to be responsible for the supply of Babiven Maintenance, which comes in both 500ml and litre bags; is that right?

ALLEN: That's correct, yes.

DRIVER: Were they the sole supplier to the Countess?

ALLEN: At the time they were the sole supplier to the Countess, yes.

DRIVER: Thank you. Next page.

ALLEN: That is a copy of the prescription, which would be stapled to the white sheet. So again we're linking -- we've got a record of the prescription used to make the bag.

DRIVER: Can we please look at that in magnified form, please.

Zoom in. We can see details of the baby, [Surname of Babies E & F] Twin 2., a male born on 29 July 2015. The jury will recognise this document, we've seen it in a different context previously.

Down to the bottom part of that page, please, Mr Murphy. Thank you. And the next page, please.

ALLEN: So this is the prescription confirmation sheet. This details the ingredients in the bag, as the computer system which it's been produced on, and this is used by the pharmacist to check the details of the bag back against the prescription.

DRIVER: Thank you. We see it seems to be endorsed on the existing document "no lipids prescribed".

ALLEN: Yes. We did not make -- for this there was no lipids linked to this product, it was made as what we call an aqueous bag, so there was no fat in the bag.

DRIVER: If lipids were prescribed, would they have been added to the bag or provided separately?

ALLEN: They would have been provided by separate syringes.

DRIVER: So nutrition delivered by these bags, in a bag, lipid through a separate syringe?

ALLEN: Yes.

DRIVER: What about insulin?

ALLEN: No, there would never be any insulin in these products.

Insulin would never be placed inside TPN.

DRIVER: If a baby were prescribed insulin for sound medical reasons, how would that be delivered?

ALLEN: There was a specific protocol for the delivery of insulin, which would be provided via separate syringes.

DRIVER: I think we have an example of the syringes you have exhibited. Pass that to Mr Allen. Thank you.

(Handed)

ALLEN: Yes. So this is in itself not an insulin syringe, but it would look the same as this.

DRIVER: So that's the type of syringe that prescribed lipids would be supplied through; is that right?

ALLEN: Yes, that's correct.

DRIVER: What is it about it that enables or causes you to say that's not the sort of syringe (overspeaking) --

ALLEN: It's got a label saying it has got glucose 10% inside it, so I was referring to the contents of -- this example syringe has glucose 10% inside.

DRIVER: Right. I'm going to exhibit that as well, please, Mr Allen.

Mr Murphy, could you take us down to the bottom part of this page?

MR JUSTICE GOSS: So this is exhibit 5. Syringe in which dextrose or lipids -- is that right, Mr Allen? Dextrose or lipids would that in that sort of syringe?

ALLEN: In that format of syringe.

MR DRIVER: What format of syringe would insulin be delivered in from the pharmacy unit?

ALLEN: In a similar format of syringe if it was going to be provided.

DRIVER: Thank you. So was it just the labelling on that syringe that caused you to say that this is not an insulin syringe?

ALLEN: Yes, sorry, I was referring to the contents of the syringe specifically, which contains glucose 10% in that example.

DRIVER: Thank you.

(Pause)

Looking at the document, we can see the words "prescription details entered by", and then a signature and then "pharmacist". Do you recognise the signature?

ALLEN: Yes, that's my signature.

DRIVER: The prescription details that you signed for, are they the entries above?

ALLEN: Yes, that's correct.

DRIVER: This is a phrase we heard you use before, this is an aqueous feed, that's to say no lipids?

ALLEN: That's correct, yes.

DRIVER: And then:

"For administration for up to 48 hours, commencing 12 midnight."

Which is dashed out and replaced by 11.30. Can you explain that?

ALLEN: Yes, there'd been feedback prior to me starting at the trust that 12 midnight could be interpreted as two points in the day: is it the first point of the 4th or at the end of the 4th? So we didn't have the facility the software was bespoke (sic) designed so we couldn't easily change that, so we manually amend the script to just make it to be 11.30 so it was more clear to the nurse it meant 11.30 on day -- this should say 11.30 pm, it's intended to be sort of 30 minutes before midnight.

MR DRIVER: Thank you. I have no further questions to ask you.

Cross-examination by MR MYERS

MR MYERS: Just one matter, please, my Lord.

Something that came up I'd like to ask you about, Mr Allen. We saw on the paperwork for -- we have just looked at now for Twin 2 [Surname of Babies E & F], the TPN bag that had been prepared said it had an expiry date 7 days after preparation.

ALLEN: That's correct.

MYERS: Just so that we can understand, the TPN bags when they arrive with you generally have a two-month expiry date, don't they, as a starting point?

ALLEN: That's correct.

MYERS: And they would normally expire, you would work on a basis of 6 to 8 weeks as it is when they first come to you?

ALLEN: Yes, that's correct.

MYERS: The reason that we see 7 days' expiry on that one is that once you add the extra items to the bag according to the prescription, that then gives it a much shorter shelf life, doesn't it?

ALLEN: That's correct. Adding the vitamins and trace elements reduces the stability of the bag so as soon as that is added, it only has a seven-day shelf life.

MYERS: And that is why we see the 7 days marked on it that way?

ALLEN: That's correct.

MR MYERS: Thank you, Mr Allen.

MR DRIVER: I have no re-examination. Does your Lordship have any questions for Mr Allen?

Questions from THE JUDGE

MR JUSTICE GOSS: Just two. I may have misunderstood some earlier evidence: you said dextrose would never be added to a TPN bag?

ALLEN: There would be no additions ever made to a TPN bag other than the vitamins and trace elements which are added.

MR JUSTICE GOSS: Do you know what the composition of a TPN bag is?

ALLEN: The bag in itself will contain dextrose or glucose as part of it. That's the carbohydrate element of the bag but there will be no extra or additional --

MR JUSTICE GOSS: Added by a pharmacist?

ALLEN: -- added by a pharmacist --

MR JUSTICE GOSS: Or at the pharmacy, so to speak, by you.

But there would be dextrose in the premade bag?

ALLEN: That's one of the constituents of the bag, so that the bags effectively have carbohydrate in the form of dextrose and they have protein inside as well in the form of amino acids.

MR JUSTICE GOSS: That was one thing. I hadn't misunderstood the evidence then. We have heard that from Professor Hindmarsh.

The other question is this: we've heard about -- these are prescribed bags that are then sent down from the neonatal unit. We have heard about ready made-up bags that are kept in stock --

ALLEN: Yes.

MR JUSTICE GOSS: -- in the fridge in the unit.

ALLEN: Yes.

MR JUSTICE GOSS: Right. Do they just get sent down at any time?

ALLEN: The ready made-up bags?

MR JUSTICE GOSS: Yes.

ALLEN: So they would have a stock level on the neonatal unit of a certain amount of bags. As they became low, because they've been used up, they would request some from the pharmacy and we would send them more as stock. So we would not manipulate those bags, they are just off the shelf from the manufacturer, sent to the neonatal unit, and placed into the fridge.

MR JUSTICE GOSS: You just store them until they request them basically?

ALLEN: Yes, we are simply kind of an intermediary: we receive them from the manufacturer, we have a big fridge to store them in, the bulk of the stock. Then we send them up in small amounts to the smaller fridge in the neonatal unit.

MR DRIVER: My Lord, if I may assist, Nurse Yvonne Griffiths will give evidence tomorrow --

MR JUSTICE GOSS: I didn't know whether we were --

MR DRIVER: -- on this topic and she'll produce, as an exhibit, the requisition sheets sent from the neonatal unit to the pharmacy unit for the relevant period.

MR JUSTICE GOSS: Right, she will deal with the other matter then about what happens to the bags afterwards and any unused bags and things like that. All right, good.

Thank you very much.

I don't have any more questions. Thank you very much, Mr Allen -- that will be it?

MR DRIVER: That's Mr Allen's only visit to the witness box.

MR JUSTICE GOSS: Good. Thank you very much for coming and giving your evidence this afternoon. That completes your evidence. You are free to go.

Should it be that you encounter anyone who is involved in this case, don't talk about anything to do with the case until it's all over.

ALLEN: Okay.

MR JUSTICE GOSS: Thank you very much indeed, Mr Allen.

(The witness withdrew)

MR JUSTICE GOSS: All right, members of the jury, that's it for today. Can I just say this: we have heard quite a lot of evidence today of an expert nature and indeed the witness herself, the professor, referred to the fact that she gleaned some of the material, namely those diagrams that she produced, from the internet, which raises the obvious point that it is very possible to gain information from the internet.

So I repeat what I have said to you many times before: do not conduct any research into anything to do with this case, so don't start going on to the internet to try and find these diagrams for yourselves. All right? If there is anything upon which you require further exposition, you can ask a question about it, but don't conduct any of your personal research. Whilst I'm saying that, I remind you of the other vital obligation of you as jurors not to speak to anyone about anything to do with this case or each other unless you are all together in the room outside this court. All right?

Please remember those obligations. But that's a timely opportunity to remind you of them because you've had a specific example of what can be gained on the internet and there's an awful lot more, as we know. I shall keep reminding you of that during the case. Thank you very much indeed.

10.30 tomorrow morning then. Thank you.

(4.29 pm)

(The court adjourned until 10.30 am on Wednesday, 30 November 2022)