

1 Thursday, 8 November 2012

2 (10.06 am)

3 THE CHAIRMAN: Good morning, ladies and gentlemen.

4 The stenographer is unwell today, so today's

5 proceedings are going to be recorded and we'll

6 get a transcript hopefully at some point

7 tomorrow, but for today we'll have to go back to

8 the old-fashioned method of writing down notes as

9 the evidence goes along. So you will not be

10 getting a live note as we go along today. I hope

11 you have all filled your pens. Mr Reid.

12 MR REID: Thank you, Mr Chairman. If I can call Ms

13 Sally Ramsay, please.

14 MRS SALLY RAMSAY (sworn)

15 Questions from MR REID

16 MR REID: Have a seat. Just to begin, is it Mrs

17 Ramsay or Ms Ramsay?

18 A. Mrs.

19 Q. Mrs Ramsay, thank you. Mrs Ramsay, you've made

20 one final report for the inquiry, which is dated

21 14th June 2012, and there's a reference 231-002-

22 001. Would you like to adopt that as your

23 evidence before the inquiry?

24 A. I would.

25 Q. Thank you. If we can move just to your CV and

1 your experience and bring up 231-002-038 and 039
2 alongside that, please. We can see there that
3 you've been a registered adult nurse since 1972,
4 a registered children's nurse from 1974, and you
5 were a nurse manager of the paediatric and
6 neonatal intensive care unit at Guy's Hospital,
7 London, from 1986, is that right?

8 A. I was.

9 Q. You've had various other nursing manager roles.
10 You became director of nursing at Great Ormond
11 Street Hospital for Children in 1994?

12 A. I did.

13 Q. You were in that job until 2002, and since 2003
14 you've been a self-employed children's nursing
15 advisor, is that right?

16 A. That's right.

17 Q. Thank you. Can you just explain for us what do
18 you do in your role as a self-employed children's
19 nursing advisor?

20 A. Varied things over the years. I suppose helping
21 people where they need some expertise in issues
22 to do with the care of children, and so that's
23 varied from -- and not always children. I have
24 done some things with adults as well. I've
25 helped implement clinical governance in a general

1 children's ward in a general hospital. I've
2 written several guidance documents and standards
3 documents for the Royal College of Nursing, and
4 latterly I've been part of the team that's been
5 reviewing the children's heart surgery centres.
6 So it's been giving advice to people.

7 Q. If we turn over to page 40 we can see a number of
8 your publications; the documents you've written
9 for the Royal College of Nursing.

10 A. Yes.

11 THE CHAIRMAN: So you're not retired at all?

12 A. Not yet. Getting there I think.

13 MR REID: Can I ask, we're obviously concerned with
14 nursing care in October 1996. How familiar are
15 you with nursing practice in 1996?

16 A. Well, at the time I was Director of Nursing at
17 Great Ormond Street and I had very close contact
18 with the clinical areas because that was the
19 major part of my role was to facilitate and, one
20 could say ensure good nursing practice.

21 So I also throughout my career have tried to
22 maintain some direct clinical expertise and so,
23 as Director of Nursing, I did spend some time a
24 couple of times a year actually as a staff nurse
25 on the ward; I tried to keep a feel of it because

1 I was conscious, and I did have something
2 published many years ago, called "up-to-date but
3 out of touch" whereby it's very easy for people
4 to talk about it and not really have a full
5 understanding of how it feels to be a staff
6 nurse.

7 So I tried to maintain some of that, but you
8 can never go back to being that staff nurse
9 really. So I feel that in 1996 I had a good feel
10 of what was going on in a clinical environment,
11 through some direct observation but also close
12 contact with ward sisters and clinical staff.

13 Q. Thank you. We've heard the evidence to the
14 inquiry of several of the nurses; that was mainly
15 on 29th October and 30th October. Have you had
16 the opportunity to see the transcripts of the
17 evidence that the nurses gave?

18 A. Yes, I've read the transcripts.

19 Q. Just as an overall question, what would be your
20 overall impression of the evidence that the
21 nurses gave? What, after reading the
22 transcripts, was your general impression?

23 A. My general impression was that although most of
24 them couldn't remember very much of the events I
25 felt there was some agreement with some of the

1 things that I'd said. When they'd been exposed
2 to the same sort of evidence as I had, I felt
3 that they'd seemed to me, in the main, to have
4 come to some of the same conclusions.

5 Q. We'll come to each of those conclusions in turn.
6 If I can also bring up 096-024-183, please. This
7 is the expert nursing advisor report, in the
8 circumstances surrounding the death of Claire
9 Roberts, prepared by Susan Chapman for the Police
10 Service of Northern Ireland, and this is dated
11 24th March 2008. As it says there, it's Ms
12 Chapman's report she was asked to produce by the
13 police. Have you had the opportunity to see that
14 report?

15 A. I have seen the report.

16 Q. You'll be aware, if you can turn to the
17 conclusions at page 191 of that document, her
18 overall conclusion was that she finds only minor
19 deficiencies in the nursing care given to Claire
20 Roberts, and she would consider none of those to
21 represent a failure in nursing care, given the
22 diagnosis and management prescribed by the
23 medical team. She goes on to note that it was an
24 overall lack of recognition of the seriousness of
25 Claire's clinical condition. Her level of

1 consciousness was monitored and recorded by the
2 nursing staff, and it was the role of the medical
3 staff to act on these results.

4 She was reviewed only seven occasions by
5 members of the medical team before her transfer
6 to intensive care, but at no time was additional
7 monitoring, observation or treatment requested
8 and, therefore, she found the care delivered by
9 the nursing staff acceptable by the standards
10 expected in 1996.

11 Would it be fair to say, having seen Sue
12 Chapman's report, that you may be a little more
13 critical in certain areas than Ms Chapman?

14 A. Yes. But I think that might be due to the
15 approach.

16 Q. Firstly, do you know Sue Chapman?

17 A. I do.

18 Q. And you're familiar with her work?

19 A. Yes, yes. I've known her since she was -- she's
20 a nurse consultant now but I've known her for a
21 long time.

22 Q. You're saying there might have been a difference
23 in approach. Can you explain that for us?

24 A. Well, her report was commissioned by somebody
25 different to my report. I did read her report in

1 the beginning, but what I tend to do is look
2 through all the papers to get my own view before
3 I'm biased by anybody else's and then perhaps do
4 a little bit of compare and contrast. And so her
5 approach presumably, because it was done by the
6 Police Service, may have been to see if there was
7 anything that stood out in terms of major
8 failings in nursing that could have contributed
9 to Claire's death.

10 My approach was to go through everything, I
11 suppose, with a critical eye, all the aspects of
12 care, to then see what that added up to at the
13 end, because there wasn't one major incident
14 which I needed to focus on; it was a series of
15 events so that was possibly a different approach.

16 Q. So if I can be clear from what you've said, do
17 you think there were no major failings, as Sue
18 Chapman has said in her report, but that you
19 might be critical of some other elements?

20 A. Well, major failings. I have a concern that a
21 child that was so sick was still in the middle of
22 a general children's ward, and so the failure to
23 notice that a child is sick in this case did have
24 a very, you know, disastrous outcome. So I would
25 say that was a failure, because I do have

1 concerns that she was still being nursed in the
2 middle of a general ward throughout the day.

3 Q. I think there are two points I have understood
4 from your report: (1) Claire should have been
5 moved to one-to-one nursing at an earlier stage
6 but is being nursed in the middle of a general
7 ward, is that a reference to that she should have
8 been moved to intensive care earlier or moved to
9 a side ward?

10 A. Well, I think it could have been either. I think
11 possibly at the time it was you're on a general
12 ward, or you're in a PICU, because facilities for
13 high dependency nursing weren't perhaps as
14 developed as they maybe now because lots of
15 general hospitals would have a high dependency
16 area where they could have all the sick children
17 together and have a few more staff looking after
18 them. I think that there was a failure to
19 recognise the level of dependency that she had,
20 so she was just being nursed along with everybody
21 else in a general ward. High dependency could
22 have been provided for her in a cubicle or in a
23 PICU environment.

24 THE CHAIRMAN: We'd better not jump ahead too much
25 because I think you're going to be coming to

1 that.

2 MR REID: I might actually jump to that now. If we
3 bring up your report at 231-002-031, it's
4 slightly out of sequence but I think you've
5 identified it as what you consider to be the
6 major failing; I think we should address it now.
7 You say there in the second paragraph, after
8 quoting the source, that a coma score of 8 or
9 below was generally accepted as a definition of
10 coma. You say that you think a score of 8,
11 combined with a need for complex intravenous
12 therapy, should have prompted discussion between
13 nursing and medical staff regarding admission to
14 PICU and, given Claire's level of consciousness,
15 diagnosed anti-epileptic treatment and level of
16 nursing dependency, you believe she should have
17 been admitted to an intensive care unit? This
18 should have been at around 3.00 pm, when the coma
19 score of 7, and midazolam infusion was planned to
20 start shortly afterwards. However, you say,
21 admission to PICU was usually a decision made by
22 senior doctors and, therefore, you were unable to
23 give an opinion on whether there was sufficient
24 medical grounds to require such an admission, and
25 you reiterate your opinion that her nursing care

1 needs at the time were above those that could be
2 reasonably provided on a busy general ward.
3 That's a fair summary of what you just said, is
4 that right?

5 A. That's right.

6 Q. In fact, Ward Sister Pollock seems to agree with
7 you, if we bring up her transcript of 30th
8 October 2012, page 182. I asked her:

9 "From your experience and your look at the
10 nursing and clinical notes, when would you have
11 expected Claire to have been admitted to PICU?"

12 And she said:

13 "It's difficult to say. I'm aware that Dr
14 Webb reviewed Claire on a number of occasions
15 during the afternoon of the Tuesday, but when I
16 look at a Glasgow Coma Scale of 9 at 1.00 pm, and
17 then it is 7, at I think around 2.30, I'd be very
18 concerned at that point. [Let me turn over the
19 page.] There is a discussion around what level
20 of care she did require, could that be delivered
21 at ward level or did she require to be nursed in
22 another area in the hospital or what should the
23 plan of care be?"

24 And she goes on to say, in answer to the
25 Chairman's question, that that would have been

1 intensive care.

2 First of all, can I ask you, what is the
3 difference in the level of care you would receive
4 in PICU compared to the general ward?

5 A. On a general ward one nurse would look after
6 several patients. In PICU there would be, in the
7 main, one-to-one nursing, or if the child is not
8 ventilated then it could be that two children,
9 with a high level of dependency, could be looked
10 after by one nurse. So there would be more
11 nursing and continuous nursing, so that even if
12 the child's care was being shared with another
13 child, there would be a nurse in that area all
14 the time. Whereas, on a general ward, the nurse
15 would possibly be off fetching, carrying,
16 answering the phone, going to another child in a
17 cubicle in the next bay, so the child wouldn't be
18 within their sight all the time. And the other
19 element would be there would be more
20 sophisticated monitoring, probably.

21 Q. So on our first point, are you saying that
22 physically there would always be a nurse in the
23 room?

24 A. Yes.

25 Q. While on the general ward I think we've heard

1 that the majority of nurses had a four-bed bay
2 and a two-bed bay; a maximum of six patients to
3 look after. You would have a maximum of two
4 patients to look after in paediatric intensive
5 care.

6 A. I would think that would be the maximum, yes.

7 THE CHAIRMAN: But it's not just as simple as the
8 nurses on a general ward looking after six
9 patients, because they're also helping each other
10 out from time-to-time.

11 A. Yes, yes.

12 THE CHAIRMAN: So the six is accurate but it's not as
13 limited as that. In the end, the nurse actually
14 does more than just look after six defined
15 patients on a general ward.

16 A. Yes, because there would be other things, like
17 phones ringing and people coming to the ward
18 asking them, distracting them.

19 THE CHAIRMAN: Or two nurses administering a drug?

20 A. Yes.

21 THE CHAIRMAN: Okay, thank you.

22 MR REID: Do things like phones going off, or having
23 to go and get a drug or administer a drug, does
24 that not also happen in paediatric intensive
25 care?

1 A. Yes, but the way that paediatric intensive care
2 would have worked would be that people didn't
3 usually leave the child. The child needed to be
4 looked at and observed, and so there would be
5 some additional help; a healthcare assistant or
6 some sort of non-registered professional whose
7 job it was to supply the people at the bedside
8 with what they needed.

9 Q. So the nurse would always physically be there and
10 then would seek assistance from someone to go off
11 and do the other jobs?

12 A. Yes, or if they were in an open area and had to
13 leave their child to go and get something, which
14 sometimes you might have to go and get medicines
15 and things, you would say to somebody nearby,
16 "Can you just keep an eye on my patient while I
17 go off to get X, Y and Z?"

18 Q. You also said the other thing, apart from just
19 the fact that a nurse would be physically there
20 all the time, was that more intensive monitoring
21 could be done. What sort of monitoring do you
22 mean?

23 A. Heart rate and respiratory rate monitor.

24 Q. Just vital signs or other ailments?

25 A. Well, vitals signs and blood -- probably blood

1 pressure.

2 Q. What about central nervous system observations?

3 A. Well, yes, they would be done, particularly for a
4 child with altered consciousness.

5 THE CHAIRMAN: Isn't the fundamental difference in
6 what's tragically lacking in Claire's case is
7 that, if she had been moved into intensive care,
8 it would have been a recognition that she was
9 very seriously ill and the fact that she wasn't
10 moved into an intensive care raises a major
11 question about whether the severity of her
12 illness was recognised?

13 A. Yes. I think that's fair.

14 MR REID: Can I ask you then about the criteria for
15 moving into paediatric intensive care? First of
16 all, you said at around 3.00 pm -- and Staff
17 Nurse Pollock has said around a similar time -- I
18 think you said the trigger for that really was
19 the combination of the Glasgow Coma Scale and the
20 medication being administered, the phenytoin and
21 the midazolam. Would the phenytoin alone or
22 midazolam be sufficient, in your opinion, to
23 warrant admission to PICU?

24 A. Some of that depends on what the nurses were used
25 to giving on that ward. So if they were

1 regularly looking after children who were in
2 status, who were having phenytoin, then it might
3 be that they could manage that, although I would
4 still suggest that the Glasgow Coma Score was
5 perhaps of a level whereby, if it had gone down
6 any further, she might have got it. They might
7 have known that she could need ventilating, and
8 so would be better placed in an area where that
9 could be facilitated.

10 So I think, depending on their previous
11 experience, giving a medicine to a child that's
12 fitting might have been within their area of
13 expertise. I think it unlikely that the use of
14 continuous midazolam was something that was done
15 regularly at that time outside an intensive care
16 environment.

17 Q. We will get to the medication later on, but I
18 think the nurses generally said that they
19 wouldn't have been that familiar, certainly, with
20 midazolam at the very least and the
21 administration of that. If we could bring up the
22 timeline of 310-001-001, please. If we can
23 highlight the time, in and around 3.00 pm please,
24 and just drag it up, please. Thank you. So we
25 can see there at around 3.00 pm there's been the

1 ward round, she's been differentially diagnosed
2 with non-fitting status epilepticus, and then an
3 additional diagnoses at some point of
4 encephalitis and encephalopathy. She's been
5 administered diazepam, phenytoin and then
6 midazolam at around 3.25 pm, and there's a
7 seizure at around 3.25 pm and she's been examined
8 by the consultant paediatric neurologist. Are
9 you saying that that's the key time, as far as
10 you're concerned, when it reached that criteria
11 for PICU admission?

12 A. Yes. Because my understanding is that there
13 wasn't anything that said, "Well, this is a point
14 in time but now it's going to get better", so it
15 wasn't a momentary or a short expected phase. It
16 was something where there wasn't an end in sight
17 at that particular time.

18 THE CHAIRMAN: But that's around the time you think
19 that she should have been moved to intensive care
20 but that is, in terms of the nurses, their input
21 into that is limited, isn't it?

22 A. Well ...

23 THE CHAIRMAN: I mean, they can raise flags or express
24 concerns but they cannot move Claire into
25 intensive care?

1 A. They can't physically remove her but they can
2 certainly express concerns about her being on
3 their ward. And there are means of escalating
4 that if you're particularly unhappy.

5 MR REID: To build on that, if we can bring up Staff
6 Nurse Field's transcript of 29th October 2012 at
7 page 93. She's asked at the bottom:

8 "Did you consider one-to-one nursing at any
9 stage?"

10 She says:

11 "I don't believe that I did, but that's not
12 something that I would have requested or had any
13 control over. That would have been something
14 that the medical staff would have asked for in
15 terms of closer observation for the child. That
16 would have been facilitated, if you like, by the
17 nurse in charge."

18 Have you seen that as a recurring theme
19 throughout the nurses' witness statements, the
20 fact that a doctor's intervention might have been
21 required for an escalation in nursing care?

22 A. Yes.

23 Q. You're aware of that?

24 A. Yes.

25 Q. If we just concentrate on the intensive care and

1 one-to-one nursing at the moment. What do you
2 think of the nurses general opinion that they
3 would have expected something like that -- indeed
4 required something like that -- to have been
5 directed by medical staff?

6 A. I have to say it is not my experience that that
7 is something that would be solely dependent on a
8 doctor to order. I think the amount of time that
9 we need to spend with a patient and how you
10 facilitate the observations falls to a nurse to
11 decide. I think there are times when you have
12 that debate with medical colleagues, and perhaps
13 there are times when somebody might express the
14 fact that they think it's not necessary, but I
15 would have said that that was a nursing judgment.

16 Q. In terms of that, is it a judgment of whether you
17 as the nurse speak directly to the doctor or is
18 the judgment that you decide, "Well, maybe I
19 should bring this to the nurse in charge of the
20 ward or the ward sister"?

21 A. Well, I think you would have to talk to the ward
22 sister, because it's about the allocation of
23 resources and the person in charge would have a
24 comment to make with regards to that.

25 Q. So is the ward sister the first port of call if

1 you think that your patient requires greater
2 resources, greater nursing care, is the ward
3 sister the first port of call for you as a nurse?

4 A. Yes, but it would also be the other way. If a
5 ward sister has got a child that is sick on their
6 ward, then they would be having a close look at
7 what was needed.

8 Q. I think Angela Pollock said in her evidence last
9 week that she would have wanted to have been
10 informed of any drops in Glasgow Coma Scale, any
11 changes in medication and so on, and in Claire's
12 case I think she says, if you bring up page
13 187 ...

14 THE CHAIRMAN: From the same day?

15 MR REID: Sorry, from 30th October 2012. I asked her:

16 "Have you ever been in a situation where a
17 nurse informs you of what's happening with a
18 patient and you decided you need to step in as
19 the senior nurse and take over the management of
20 that patient?"

21 And she said, "Yes, I have". She was asked
22 about 5.00 pm, when her GCS was 6, whether she
23 would have taken control of nursing at that
24 point, and she said, "It's quite likely I would
25 have done so". In those circumstances, what

1 would you expect of the ward sister?

2 A. Well, to be discussing with the nurse at the
3 bedside what her observations were and what had
4 been going on, so a bit of history about the
5 patient. Having some understanding of what the
6 plan of care, both medically and nursing, was
7 aiming to do. And making their own judgments of
8 what was going on, assuming that a ward sister
9 has got a lot more experience to bring to the
10 situation perhaps than the nurse at the bedside
11 and then consulting with whatever medical staff
12 there were. And also -- sorry, if I could also
13 add, and looking for any lack of understanding on
14 the part of the nurse with regards to the
15 parameters within which she was working, or what
16 she needed to observe or things that she needed
17 to do.

18 Q. So I think you said that the normal system would
19 have been that you, as a staff nurse, would have
20 contacted your ward sister and brought the
21 patient to their attention, and if they thought
22 it warranted it, then the ward sister would speak
23 to the doctor, is that correct?

24 A. Probably. I say probably because if there was a
25 doctor in the vicinity then the nurse could have

1 a dialogue with him, and some of it depends on
2 what the physical presence of the ward sister is
3 at that particular time.

4 I would have thought that if there was
5 somebody -- a ward sister -- in charge of that
6 ward at the time that they would have been, or
7 should have been, aware of who the sick children
8 were in order to pay attention to those sick
9 children and to periodically check up on them; go
10 and ask what was going on.

11 Q. Well, as you know, the difficulty we have in the
12 case is that Ward Sister Pollock doesn't recall
13 whether she was present that day and there's no
14 evidence of who the ward sister might have been
15 on that particular day. So say, the ward sister
16 is unavailable to the staff nurses, for whatever
17 reason, what responsibilities do you think the
18 staff nurses have to contact the doctors and
19 discuss resources with them?

20 A. Well, things shouldn't just stop when the ward
21 sister isn't there, and so it would have fallen
22 to either the staff nurse at the bedside or the
23 person who was in charge of the ward to talk to
24 the doctors.

25 THE CHAIRMAN: Am I right in putting this into the

1 overall context that, while you are to a degree
2 more critical than Ms Chapman was, you also refer
3 at least twice in your report to the fact, to put
4 it in terms, while there were some failures in
5 nursing care there were at least seven
6 opportunities for the doctors to act more
7 decisively than they did in Claire's interests?

8 A. Yes, I don't think that they were unaware of her
9 condition and I think some of the judgments about
10 what was going on, I think the nurses should,
11 from the observations, have known that she was
12 sick. But I don't think they were getting much
13 in the way of comment to indicate that from the
14 people who were doing the medical assessments.

15 MR REID: To go back to Sue Chapman's comment at 96-
16 24-191. We've already gone through paragraph 59
17 that it was the role of the medical staff to act
18 on these results, and she was reviewed on at
19 least seven occasions by members of the medical
20 team. If you turn to the timeline at 310-001-
21 001, we can see that there was a ward round with
22 a doctor; there's an examination by Dr Webb; the
23 re-examination is now in question but we know
24 that a doctor administered the phenytoin and the
25 midazolam. A doctor administered the sodium

1 valproate; Dr Webb attended and Dr Hughes
2 attended at 5.30 pm and at 9.30 pm, and then Dr
3 Stewart attended at 11.30 pm.

4 In those circumstances, do you think that the
5 nursing staff, knowing that the medical staff had
6 been on several occasions, could have come to the
7 conclusion that, "Well, the medical staff seemed
8 to think that the nursing care standard is fine
9 at present. Why should we do anything
10 different?"

11 THE CHAIRMAN: It's not quite that.

12 MR REID: Sorry.

13 THE CHAIRMAN: Surely the question is: could the
14 nurses have thought, "Because the doctors are
15 there so frequently that it's not the nursing
16 care of standard that's sufficient; it's that
17 Claire's condition is under control"?

18 A. I think they could have thought that. Yes,
19 definitely.

20 THE CHAIRMAN: And if the nurses get the message,
21 expressly or impliedly, from the doctors that,
22 "Although this girl is sick things are under
23 control" it becomes a bigger ask of the nurses to
24 become more proactive and to say to doctors, "Are
25 you sure she's being cared for properly? Are you

1 sure she's responding? Are you sure she's really
2 not very ill?"

3 A. Yes.

4 THE CHAIRMAN: There's a degree in it, isn't there? A
5 question of degree?

6 A. Yes, yes. And of course some of it is your past
7 experience helps you sometimes in situations like
8 that. So if you've seen something similar
9 before, or if you have a tendency to challenge
10 things, then maybe you would do that but I think
11 that in general, as you said -- and I think I
12 might have alluded to that in my report -- I
13 think they probably had a false sense of security
14 that all was okay even though, when you look back
15 on it, all was not okay.

16 THE CHAIRMAN: Yes, I mean, that's really drawing out
17 your point about the fact that the doctors were
18 coming and going so much.

19 A. Yes.

20 THE CHAIRMAN: The trouble is they were coming and
21 going so much but without effecting an
22 improvement in Claire's condition. I got the
23 impression, from what some of the nurses said,
24 that they might be a bit less deferential or
25 reserved now in 2012 than they would have been in

1 1996, and they said -- I think this is also
2 mentioned in your report -- that the system is
3 less hierarchical now. Is that accurate?

4 A. Yes. I think there's been a movement on both
5 fronts. I think doctors are more team players
6 these days along with the nurses, and nurses are
7 a bit more confident in challenging things.

8 THE CHAIRMAN: That's not much consolation that Mr and
9 Mrs Robert can take out of anything that's been
10 heard here over the last few weeks, but if there
11 was any consolation would it be that what
12 happened in Claire's case would be less likely to
13 happen now, at least from the nursing end,
14 because the nurses would be more likely to
15 express their concerns, if they had those
16 concerns?

17 A. I think so. But also I think possibly people
18 might be more willing to listen.

19 THE CHAIRMAN: We know from this case, and we know
20 also from Alan Strain's case that you also
21 reported that, to the extent that there was any
22 review or investigation afterwards, it entirely
23 excluded the nurses.

24 A. Yes.

25 THE CHAIRMAN: Is that likely to happen these days?

1 A. I think it's highly unlikely.

2 THE CHAIRMAN: Thank you.

3 MR REID: While we're still on the paediatric
4 intensive care point, Mrs Ramsay, would you say
5 that the resources available in PICU were the
6 same in 1996 as now or were less than now?

7 A. Less.

8 Q. Would you accept that it was more difficult to
9 get a PICU bed in October 1996 than it would be
10 now?

11 A. Not necessarily, but for different reasons. I
12 think in 1996 it wasn't a highly -- well, the
13 reports hadn't come out and been implemented. It
14 wasn't a highly recognised speciality and so I
15 think people struggled for resources in there. I
16 think probably now people recognise the value of
17 PICU and so there's a greater demand perhaps,
18 although there might be more resources in the
19 speciality. So I think it was under pressure
20 then and it's probably under pressure now but for
21 slightly different reasons.

22 Q. So both the supply and the demand have increased?

23 A. Yes.

24 Q. Several of the clinicians have said that, in
25 October 1996, one of the criteria for PICU

1 admission would have been artificial ventilation
2 and that, generally, it would be much more
3 difficult for a child who wasn't being
4 artificially ventilated to meet the criteria for
5 paediatric intensive care. What would you say
6 about that?

7 A. I think that's possibly a valid argument, and the
8 high dependency areas weren't particularly well
9 developed so it was either general ward or PICU.
10 But I would have thought there needed to be some
11 consideration of whether a child might be on the
12 verge of needing ventilation and, although it
13 isn't within my area of expertise to say at what
14 point she might have done with a Glasgow Coma
15 Score of 6, I think it remained a possibility
16 that she might be on the edge, particularly with
17 having midazolam of needing ventilation. So I
18 think do you do it proactively and put somebody
19 in an environment where everything's there if
20 that is needed, or do you wait until the child
21 collapses and then rush them into a PICU?

22 Q. We will return to midazolam because, as we'll
23 hear from Dr Aronson later, midazolam can reduce
24 the respiratory function, isn't that correct?

25 A. Yes, that's my understanding.

1 Q. So are you saying that, in the absence of
2 artificial ventilation, it would have been more
3 difficult to get someone admitted to PICU in
4 October 1996 but it would not have been
5 impossible?

6 A. I think it would have been possible, but it
7 required a discussion because it needed people to
8 prioritise the use of their resources at the
9 time. But also to then determine whether the
10 environment that the child was -- if they
11 couldn't go into PICU you then have to make a
12 judgment on whether the environment they're in is
13 being made as safe as it possibly can be.

14 Q. If I can change tack and ask you about
15 hyponatraemia in 1996. What, as far as you can
16 recall, would have been your awareness of
17 hyponatraemia and any dangers related to it in
18 October 1996?

19 A. Well, I suppose my difficulty is that I was
20 originally a sister in a PICU where we saw a fair
21 number of children with low sodiums, and I was
22 also personally aware of inappropriate ADH so I
23 had knowledge. But I think on a general ward,
24 and I know from -- I went back to some clinical
25 practice as a staff nurse in 2003, I don't think

1 general nurses on a general ward would have known
2 anything about it.

3 Q. Even in 2003, prior to the National Patients
4 Safety Alert, staff nurses on the ward would
5 still be generally not that aware of ...

6 A. Yes.

7 Q. Would they not be generally aware of
8 hyponatraemia itself or just the dangers related
9 to it?

10 A. Well, I suppose, most nurses would know what
11 hyponatraemia was but I don't think they would
12 have known what might cause it. They would know
13 because blood results come back and a child's got
14 a low sodium and somebody initiates some
15 treatment to correct that, and I don't think that
16 they would have known perhaps much more than
17 that.

18 Q. Would they have known to bring it to a doctor's
19 attention quickly, for example?

20 A. Well, if they were taking blood results over the
21 telephone then they would then inform the doctor
22 of those blood results. Whether they would make
23 a judgment that this sodium is low, I think is
24 possibly unlikely.

25 Q. Just on that subject, in terms of blood testing,

1 you might have seen from the transcripts I asked
2 several of the nurses whether they would ever
3 take the initiative and say to a doctor, "Do you
4 think we should have any blood tests?" for
5 example at the ward round. I think the
6 overwhelming majority said, "No, we wouldn't have
7 done that. It would have been a doctor's
8 decision to take the blood samples". Does that
9 reflect your knowledge of what was happening in
10 October 1996?

11 A. Yes, yes.

12 Q. So for example, at the ward round they had looked
13 at Claire and diagnosed some treatment but blood
14 samples hadn't been mentioned. You wouldn't have
15 thought it incumbent on the nurses to say, "Would
16 you like a new blood count, doctor?" or something
17 of that nature?

18 A. No, I don't think so. I think where the nurse
19 would possibly have prompted is where it was a
20 situation with a well-recognised, known protocol
21 for "this happens, that happens and that happens"
22 and they think that the houseman has forgotten.
23 So it's the "we usually do so-and-so". But I
24 think in a situation like this, which is a one-
25 off-type situation and not a standard problem

1 with a child then they wouldn't.

2 Q. So for example, if there was a ward round
3 protocol that said, "Make sure you check fluids,
4 bloods, electrolytes and things like that" the
5 nurse would have been making sure that those were
6 checked off?

7 A. Yes.

8 Q. And if something hadn't been done they would ask
9 about that?

10 A. Yes.

11 Q. In the absence of that you wouldn't expect them
12 to?

13 A. No.

14 Q. If I can ask you then about the nursing care
15 plan; if we bring up 090-043-145 and 146 please.
16 Those are two pages of Staff Nurse McRandal's
17 initial nursing care plan on Claire's admission
18 to Allen Ward. You're familiar with those
19 sheets?

20 A. Yes.

21 Q. First of all, can I ask you what in nursing is
22 the purpose of a nursing care plan?

23 A. Well, it has several dimensions to it. One of
24 them is guide the care that's going to be
25 delivered so it's a plan of what somebody's going

1 to do. Secondly, it's a way of seeing whether
2 things have been successful, but it's also a
3 communication tool so that anybody coming along
4 can see what care that that child is having and
5 then, retrospectively, you can see what care the
6 child received.

7 Q. In that way does it share many of the same
8 characteristics as the nursing notes themselves
9 or the clinical notes?

10 A. Well, the nursing notes would be part of the care
11 plan, because there's the bits that you see in
12 front of you that identify the problems and the
13 goals and then the written part is the evaluation
14 that's telling you whether these things worked,
15 tell you any variations in the child throughout
16 the course of that shift, and documents any
17 relevant events. So the evaluation is part of
18 that whole, what we call, nursing process,
19 assessment, planning, implementation and
20 evaluation.

21 Q. So it's almost inaccurate for us to separate the
22 nursing notes from the nursing care plan because,
23 effectively, they're one and the same?

24 A. They're all part of the same thing.

25 Q. You said that it's a communication tool to let

1 others know the care that the patient is
2 receiving. In general, is that referring to the
3 nurses who are coming on after that nurse, or
4 does it also refer to the nurses that are on at
5 the same time?

6 A. It's both, because a nurse could be going past
7 the bedside and notice something, or called upon
8 to do something, and so you need to have a quick
9 look at the care plan to see who the child is,
10 what's going on, and so it acts as an indicators
11 of that child's situation. And then it's for the
12 next people coming on the next shift because you
13 can't possibly hand over all the information
14 verbally. And people's ability to retain
15 information is sometimes limited, and so they
16 need something to go back to, to see what is
17 happening or what they should've been doing, and
18 the more junior you are then perhaps you need the
19 guidance of the care plan.

20 Q. How often would you review the care plan?

21 A. Well, people would say that you should try to do
22 it on a continuous basis, but sometimes that is
23 logistically quite difficult for people, because
24 they get caught up in the here and now. So I
25 think the practice has been, just before the end

1 of the shift, for people to write up their
2 evaluation and change the care plan, with people
3 often staying afterwards in order to complete the
4 paperwork.

5 Q. I was asking Staff Nurse McCann about that, and
6 we were looking at the priorities of things to be
7 done. And obviously there are the actions that a
8 nurse needs to do right at that time:
9 medications, bloods and so on. Does a nursing
10 care plan fall a little down that list, in terms
11 of the priorities that a nurse has?

12 A. I think on a day-to-day basis this has been a
13 longstanding problem with care planning, that
14 people do find it a chore sometimes, and perhaps
15 with nurses whose training didn't train them to
16 think in this way. So perhaps people, like
17 myself, where we did it differently. Years ago
18 it used to be that you just wrote a narrative of
19 what had happened during the day. You didn't
20 have to do all this planning. I think that
21 nurses who've trained since the 1990s would find
22 this easier to do, because that's the way they've
23 been taught to deliver nursing care, so ...

24 Q. I think that Staff Nurse McCann said -- as you
25 did -- that normally she would wait until things

1 quietened down, maybe over the shift, and that
2 was the opportunity they might have taken to
3 update the care plans then.

4 A. Yes.

5 Q. She said that was why she didn't get round to
6 reviewing the care plan on the evening of the
7 22nd and the 23rd October.

8 A. Yes, because while you're delivering care, you
9 don't really need to read what you're delivering,
10 because you've got it in your head and you know
11 what you're doing, so I would say that the
12 majority of people at the time were doing it in
13 the way that she described.

14 Q. Although, as you said earlier, that then leaves
15 the problem of those on the shift at the same
16 time as you don't have the opportunity to see
17 that updated care plan?

18 A. Yes.

19 Q. Is that a problem that's encountered then?

20 A. Yes.

21 THE CHAIRMAN: Is this an equivalent of the police
22 complaining they have to spend too much time
23 doing documents and not enough time out in the
24 streets?

25 A. I think so. There has been a lot of controversy

1 about nursing care planning, and in the main it
2 hasn't been done very well over the years.

3 MR REID: Well, let me ask you this, do you think the
4 importance of the care plan outweighs the effort
5 that's needed to draw it up and update it, or do
6 you think it is an unnecessary use of time during
7 a nurse's shift?

8 A. My view -- and I think the view of the regulator
9 as well -- is that care planning and evaluation
10 is an indicator of good nursing care. Now, I
11 think one of the difficulties is that the amount
12 of time that it takes to do it effectively has
13 not been taken account of, in working out how
14 many people you need to look after a group of
15 patients, so it then became an add-on as opposed
16 to an integral part of delivering care.

17 THE CHAIRMAN: Is that any closer to resolution or is
18 that an ongoing problem?

19 A. I think it is likely to be an ongoing problem. I
20 think also maybe the tools that people have for
21 care planning aren't meeting their needs. I
22 think there has been some development in terms of
23 computerised care planning, but I have some
24 personal criticisms of that. But I think people
25 are working on it.

1 THE CHAIRMAN: Thank you.

2 MR REID: Well, let's just look at the actual care
3 plans then in Claire's case. First of all, Staff
4 Nurse McRandal said in her evidence the care plan
5 would normally be completed within 12 hours of
6 admission. Would that reflect what you think the
7 position was in October 1996?

8 A. Well, the guidance said that it should be done
9 within 24 hours, so 12 hours is good going by
10 that standard.

11 Q. If we can bring up your report at 231-002-019,
12 please? If we go to the third paragraph there,
13 your general opinion is that:

14 "The care plans reflect the identified
15 problems associated with the diagnosis of
16 seizures and vomiting, and the nursing actions
17 listed were comprehensive and were prepared in a
18 timely manner."

19 And I presume that's still your position?

20 A. Yes.

21 Q. However, you add that you believe that more
22 frequent observation of some vital signs should
23 have been made, and you elaborate on that at page
24 3 of your report. If we just bring that up 231-
25 002-003. (Pause) It might be the wrong

1 reference. But I think you said that overnight
2 the temperature, pulse and respirations were
3 recorded four hourly, and initially these
4 observations were slightly elevated but, by 6.00
5 am, they were in normal limits, and you consider
6 that hourly recordings were indicated. Can you
7 just explain why you think that hourly recordings
8 were indicated?

9 A. Well, it's my understanding that they thought
10 that Claire had had a seizure and, okay, at night
11 time you would expect a child to be asleep, but
12 my understanding is that she wasn't communicating
13 normally. Four hourly observations just didn't
14 seem very frequent for a child who's had one fit,
15 supposedly, who possibly could have had another
16 fit, and so four hourly didn't seem to me very
17 often to be going and checking things.

18 Q. If we bring up Staff Nurse McRandal's note at
19 090-041-040. (Pause) See there she says:

20 "Nine-year-old girl. History of mental
21 handicap and severe learning difficulties,
22 admitted via casualty with a history of vomiting
23 this afternoon, slurred speech, drowsiness,
24 pallor and query seizure."

25 Is that what you're referring to?

1 A. Yes.

2 Q. And you think in those circumstances, because of
3 the possibility of the seizure, there should have
4 been more frequent observations?

5 A. Yes.

6 Q. Staff Nurse McRandal has replied to that to say
7 that, having vital sign observations on a more
8 frequent basis, again, would only have been done
9 if directed by medical staff. How would you
10 respond to that?

11 A. Well, I must say that it is not my experience to
12 have ever had vital signs directed by medical
13 staff.

14 Q. And why do you think that has been your
15 experience?

16 A. Because I felt that as a nurse I was best placed
17 to make judgments on how frequently I needed to
18 look at somebody and, in particular, my level of
19 expertise was probably far greater than the
20 houseman, and so I felt myself better able to
21 make the decision.

22 Q. Because you would be the one doing the
23 observations?

24 A. Yes.

25 Q. And that you'd be the one there with the patient

1 more often?

2 A. Yes.

3 Q. And you had more experience than the house
4 officer?

5 A. Yes.

6 Q. You feel you can make a better judgment call?

7 A. Yes.

8 Q. I think you've said that some of those vital
9 signs were a little slightly elevated, but by
10 6.00 am they were within normal limits. Is that,
11 to some extent, you saying that that should've
12 been done but it's really of little consequence?

13 A. Yes, I think it should've been done but it
14 doesn't appear to have made, to me, any
15 difference, the fact that they weren't done
16 because by 6 o'clock it seems that things were
17 reasonably okay.

18 Q. In general, in terms of Claire's vital signs,
19 removing the central nervous system observations
20 for the moment, in general her vital signs did
21 seem to be stable throughout her admission until
22 her arrest at 2.30 on 23rd October. Is that a
23 fair summary of her vital sign recordings?

24 A. Yes, I think so. They weren't anything that was
25 so glaring that you'd shout.

1 Q. (Pause) We've already touched upon it, but it
2 seems to be a recurring theme that different
3 elements of the nursing care were felt to require
4 medical direction. Do you have any comment, in
5 general, just about that? You've said some
6 things already. Do you have any comment, in
7 general, about the fact that the nurses seemed to
8 require so much medical direction for a variety
9 of different elements?

10 A. Well, it sounds to me as though that was the way
11 that things worked at the time, and I can't be
12 sure as to why that would be but possibly custom
13 and practice. That's how it's always been, that
14 this is what you asked the doctor or the doctor
15 had the last say.

16 THE CHAIRMAN: Speaking on a general level then,
17 you've heard that things have changed
18 significantly since then, and the local nurses
19 have said that in their evidence here over the
20 last week or two. But do I take it from your
21 last answer that you're expressing a little bit
22 of surprise that they were quite as dependent on
23 direction from doctors in 1996, as perhaps comes
24 over in the transcript?

25 A. Yes, I am, because nursing is always evolving,

1 and this was a children's hospital that
2 professionally has a good reputation, and the
3 nurses there were professionally -- in particular
4 the senior nurses, that I know from the past,
5 were very engaged in wider nursing circles, and
6 so I'm a little bit surprised, I suppose, that at
7 ward level people come across as being a bit more
8 dictated to by the doctors, or dependent on the
9 doctor's decision.

10 THE CHAIRMAN: Thank you.

11 MR REID: If I can then bring up the fluid balance
12 chart at 090-038-133, please. (Pause) First of
13 all, I think you've said in your report that you
14 think that the fluid balance charts appear to
15 generally show an accurate recording of fluid
16 intake, would that be correct?

17 A. Yes.

18 Q. Just while we're on the intake section, is there
19 anything you would note about anything to do with
20 the intake of fluids on those charts?

21 A. Well, apart from the fact that it's just a
22 continuous total, so that you haven't got written
23 down readily to see what the hourly volume was.
24 You've got to calculate it. But it does seem as
25 though that when the recordings were done they

1 weren't done on the actual hour, so it isn't a
2 consistent 64 ml each hour that is being
3 recorded. The volumes vary.

4 Q. If we bring up 135 as well, please.

5 THE CHAIRMAN: That is inevitable, Mrs Ramsay, that
6 you don't?

7 A. Yes, it is, but some of these -- well, I think I
8 did a little bit of sort of working it out --
9 seem to show quite a bit of variation.

10 THE CHAIRMAN: Yes.

11 A. But, yes, there is an inevitability because you
12 can't get to every patient on the hour.

13 MR REID: Two things on that. First of all, although
14 you say it is an accurate recording of fluid
15 intake, all you see is a cumulative total of the
16 fluids, is that what you mean?

17 A. Yes.

18 Q. And you would have liked to have seen the
19 individual fluid per hour?

20 A. Well, the common practice that I have experienced
21 is that you would put what the level started at,
22 and then what the level finished at after the
23 hour, and then what the difference was and then
24 have a cumulative total.

25 Q. Yes. So for example, if we bring up the PQ fluid

1 balance chart at 090-058-208. If you zoom into
2 the top left-hand corner of that, please. Thank
3 you. Is that what you mean, the fact that
4 there's a number that was ticking down and a
5 number ticking up?

6 A. Yes. And you wouldn't necessarily have separate
7 columns. You put one figure over the top of the
8 other.

9 Q. And the second point you were saying there was
10 that there obviously seemed to be some
11 discrepancy between the times of each hour.

12 A. Yes.

13 Q. The Chairman made the point, obviously, that if
14 you have several children receiving IV fluids and
15 it comes up to the hour, you can't check the
16 fluid balance of each and every one of those at
17 that time.

18 A. No.

19 Q. But what variance of time would you consider
20 reasonable?

21 A. Well, some of that depends on how many other
22 children you've got to look after and whether or
23 not they've got IVs, but probably sort of
24 five/ten minutes each side of the hour.

25 Q. Yes. If we then look at the output, and we will

1 leave this 135 up there, we can see urine is
2 noted as "PU", as in episode of urine. And
3 during Claire's care more than only once is an
4 indication of volume written as "large" at 11.05.
5 What would you say about the measurement of urine
6 on those fluid balance charts, as regards October
7 1996?

8 A. The way that it's described would have been
9 common practice at the time. The use of "large"
10 to indicate what the volume is would've been
11 common, or to use plus signs to indicate volume.
12 So I would say that this is probably the way that
13 urine output was indicated for the majority of
14 children.

15 Q. Would you consider that to be an accurate
16 measurement of urine?

17 A. No.

18 Q. And why is that?

19 THE CHAIRMAN: It doesn't tell you.

20 A. It doesn't tell you and it's guesswork, and it's
21 subjective.

22 MR REID: Yes. Let's look at now. Would you consider
23 that now to be acceptable customary practice?

24 A. I think probably some of it depends on what's
25 wrong with the child, but a child with an

1 intravenous infusion people have said for a very,
2 very long time accurate measurements. I think
3 what's happened is that people's definition of
4 "accurate" has got a little bit distorted over
5 the years, so I think a child for an intravenous
6 infusion then this chance recording is not
7 acceptable now.

8 Q. So you wouldn't expect it with every single
9 child, but a child who's receiving intravenous
10 fluids you would expect a measurement of urine?

11 A. Yes.

12 Q. And that would be by weighing nappies or
13 collecting urine, I presume?

14 A. Yes.

15 Q. Or if they have a catheter, then checking that?

16 A. Yes.

17 Q. You may have seen the evidence of Staff Nurse
18 McRandal and Mrs Pollock regarding practice on
19 Allen Ward in the children's hospital at present,
20 which is that in not every case of a child who is
21 receiving IV fluids would their urine be measured
22 in that way, and they would still maybe record
23 that as "PU". How would you assess that as
24 reasonable practice or otherwise?

25 A. I would say I would be surprised, in the light of

1 these events, in the light of the publicity. And
2 my understanding is that there are guidance. But
3 I also understand that the guidance indicates
4 that there's a clinical judgment in this, and so
5 it isn't an absolute. It isn't that every child
6 on an IV must have its urine measured. But I
7 would say that I would be surprised.

8 Q. Well, certainly, let's say in the hospitals that
9 you're familiar with, in wards where children are
10 receiving IV fluids, would you expect, of the
11 staff nurses there, that they measure the urinary
12 output of children on IV fluids?

13 A. Now I would.

14 Q. If we bring up 090-003-133. (Pause) I just ask
15 you just as a general point, something I asked
16 Staff Nurse McRandal. Claire's on IV fluids, and
17 it seems to be that there is one episode of
18 urination between 10.30 and the next episode at
19 around 11.05 pm the next night. Would you
20 consider that to be a common occurrence, or an
21 uncommon occurrence?

22 A. So the timeframe is 10.30 pm at night until ...?

23 Q. If we bring up 135, please. See on the left-hand
24 side that the IV fluids were begun at 10.30 pm.
25 There was an episode of urination at around 3.00

1 am, and the next episode of urination is at
2 11.05. Is that common or uncommon?

3 A. Well, bearing in mind that -- and I wouldn't be
4 able to describe the physiology -- a lot of
5 people don't pass urine at night, and so that
6 seems to be reasonable.

7 Q. And another query on the left-hand side. It
8 seems that Claire was vomiting on several
9 occasions or six recorded episodes of vomiting
10 there overnight. She's described the next
11 morning as having slept well. If a child was
12 vomiting on a regular occurrence, would you
13 consider that to have been sleeping well
14 overnight?

15 A. Well, not really, because she was disturbed six
16 times in order to have a small vomit. But she
17 presumably wasn't very awake when this happened
18 and she wasn't sitting up and vomiting into a
19 bowl, so she was having small vomits, which were
20 possibly while she was half asleep.

21 Q. Would you expect anybody to be notified about the
22 fact that there were several episodes of vomiting
23 overnight?

24 A. Yes. And I've thought about this and I think
25 probably, at least on the ward round, that would

1 be one of the things that you would say that:

2 "She's been vomiting overnight".

3 THE CHAIRMAN: This document, that we're looking at
4 now, that would be available on the ward round,
5 wouldn't it?

6 A. Yes.

7 THE CHAIRMAN: So it is something that should be
8 picked up?

9 A. Yes. They should all have been available at the
10 end of the bed for anybody to look at at any
11 time.

12 MR REID: (Pause) If I can move then to the ward
13 round the next morning. As you may have gathered
14 from the evidence, it is Staff Nurse Field that
15 says that Kate Linskey, who had been a full staff
16 nurse for only a short period of time, she
17 believes that she was the nurse on the ward
18 round. Staff Nurse Linskey can't recall whether
19 she was or not. In general, in your experience
20 of ward rounds in October 1996, what level of
21 nurse would normally be on the ward round?

22 A. The most senior person on duty.

23 Q. Would that be the ward sister if she was
24 available?

25 A. Yes, the ward sister or the person who was deemed

1 to be in charge.

2 Q. In terms of Staff Nurse Linskey's experience, she
3 seemed to be one of the less experienced members
4 who were on the ward at the time. Do you have
5 any comment to make about her level of experience
6 and being the nurse on the ward round?

7 A. My understanding is that she wasn't registered as
8 a children's nurse, and so she might have had
9 experience, through having been in that
10 environment for a while, to be able to pick up
11 things, pass on information, but not necessarily
12 have the knowledge and expertise to contribute to
13 the discussion.

14 THE CHAIRMAN: I think she appears to have been the
15 longest qualified nurse, in the sense that she
16 was a state enrolled nurse from 1981. But she
17 wasn't the most experienced children's nurse?

18 A. Yes.

19 THE CHAIRMAN: Again, is there a balance to be struck
20 there. Can you see why she went on the ward
21 round?

22 A. Well, yes, I can because when she was a
23 longstanding enrolled nurse, part of that team,
24 she would have been valued by her colleagues
25 because of the expertise that she'd developed

1 through being there for a long time.

2 THE CHAIRMAN: Okay.

3 MR REID: If we look at Staff Nurse Field's note of
4 the ward round. Bring up pages 090-040-140 and
5 141 together, please. (Pause) Thank you. It is
6 a little small, but you might be aware that the
7 diagnosis that was noted by Dr Stevenson of Dr
8 Sands' ward round was non-fitting status
9 epilepticus. Are you aware of that?

10 A. Yes.

11 Q. It seems at some point after that that Dr Sands
12 added the diagnosis in the note of encephalitis
13 and encephalopathy. Are you aware of that?

14 A. Yes.

15 Q. And there has been some debate about whether
16 encephalitis was actually mentioned on the ward
17 round, but Dr Sands certainly says it would have
18 been. Would you have expected the nurse, who is
19 making a note of the ward round, to have noted
20 either encephalitis or encephalopathy on the
21 nursing note?

22 A. I wouldn't have expected that person to have put
23 it into the care plan, because the person on the
24 ward round was not the person who ultimately had
25 the responsibility for writing the case plan.

1 But to pass on what the current thinking was,
2 then I think that would have been a reasonable
3 thing for her to have done

4 Q. As in to pass it on to the nurses caring for
5 Claire. And that nurse who is caring for Claire,
6 would you expect them to write that in the notes?

7 A. Yes, and if I could just add that I'm a little
8 bit surprised that the nurse caring for Claire
9 wasn't there when the doctors were looking at
10 her, because she was the one with the most
11 knowledge.

12 Q. On a general ward round there's a nurse, as you
13 say, a more senior nurse, accompanying the doctor
14 on the ward round. Would you generally expect
15 the nurse who is taking care of the patient to
16 then be present whenever her patients are being
17 seen?

18 A. Yes, but I think there's probably ... this has a
19 1996 element to it and so these days I think it
20 would be more common, perhaps, than it was then.

21 THE CHAIRMAN: So would that be in addition to the
22 sister?

23 A. Yes, because I think the sister's role would be
24 to oversee the lots, co-ordinate, but the
25 individual nurse would have the in-depth

1 knowledge of the child because she'd been looking
2 after them, and would nowadays be expected to
3 contributed but probably less so in 1996.

4 THE CHAIRMAN: Thank you.

5 MR REID: Now, you have said previously you would have
6 expected the care plan to be reviewed probably at
7 the end of each shift.

8 A. Yes.

9 Q. I think you have also said in your report
10 previously that you would expect it to be
11 reviewed if there was a change in diagnosis or a
12 change in condition. Is that right?

13 A. Yes.

14 Q. At the ward round then the diagnosis changes from
15 that of a viral illness to that of non-fitting
16 status epilepticus, with possible encephalitis
17 and encephalopathy. Would you expect then, on
18 the basis of that, that the care plan should be
19 reviewed?

20 A. Yes.

21 Q. If it had been reviewed at that stage, how would
22 you have expected it to have been changed?

23 A. The key nursing element was that Claire had
24 altered consciousness, and so that needed to be a
25 feature because, regardless of what her medical

1 diagnosis was, her nursing care needed to focus
2 on the fact that she had altered consciousness,
3 and what the possibilities were for that in terms
4 of: what would you look for if it was getting
5 worse? What would the indicators be? What
6 things should you be noting? So I think it was
7 the altered consciousness and what the potentials
8 are for a child with altered consciousness,
9 because you would also be looking at their
10 breathing, were they fading into unconsciousness
11 to the point whereby their breathing is affected.
12 And a child who is unconscious might not be able
13 to maintain their own airway, so you then have to
14 look at the way they're positioned in their bed
15 in order to make sure that their airway is clear.
16 So I think the altered consciousness is the
17 overriding nursing need.

18 Q. I think, indeed, in your report at page 21 --
19 that is 231-002-021, and 020 as well, bring that
20 up, please -- there you list a number of the
21 different problems and goals that you would've
22 liked to have seen changed in Claire's care plan.
23 First of all, what effect do you think not
24 changing the care plan, along those lines, may
25 have had?

1 A. Maybe it didn't emphasise the fact that she was
2 unconscious, because she could've looked as
3 though she was just asleep and justifying the
4 level of consciousness by the medicines that she
5 was having, or the fact that she was thought to
6 have had a fit and was, you know, post having had
7 the fit. So it didn't emphasise that this was a
8 child with altered consciousness and so it then
9 brought in all the other possible consequences,
10 or risks associated with your consciousness level
11 being reduced.

12 Q. Would it almost be fair to say that the fact the
13 unconsciousness wasn't noted in the care plan,
14 does that mean also then the seriousness might
15 not also be considered?

16 A. Yes, I think that's possible.

17 Q. One of the elements you say there in the final
18 section is:

19 "Possible aspiration due to reduced
20 consciousness. The nursing goal: prevent
21 aspiration, and the nursing intervention: pass
22 naso-gastric tube."

23 Staff Nurse Field in her evidence said that,
24 again, this would be another element where they
25 would not pass a naso-gastric tube unless the

1 medical staff had requested it. Would you have
2 any comment to make about that?

3 A. Yes, a naso-gastric tube needs to be sanctioned
4 by a doctor. It isn't something that nurses
5 would readily do unless it was part of some
6 protocol: you know, "Child admitted with X always
7 has a naso-gastric tube". But I think that,
8 bearing in mind that she had been vomiting, her
9 consciousness level was reduced, so she might not
10 have been able to forcibly vomit and so there was
11 the potential for her to aspirate. There needed
12 to be the discussion. Now, at the end of that
13 discussion, somebody might have decided that
14 passing a naso-gastric tube could have
15 compromised her airway, and so it was best not to
16 do it at that point. So the doctor would have
17 had the final decision, but I don't think anybody
18 had the discussion.

19 Q. Yes. So it's not that perhaps a naso-gastric
20 should definitely have been passed, it's that the
21 nurse should have discussed it with the doctor
22 and it should have been considered?

23 A. Yes.

24 THE CHAIRMAN: And this is exactly where you're
25 getting into the absence of the sister, the ward

1 round being done in conjunction with the nurse
2 who is there and not the nurse who does the care.
3 We're getting more removed from pinning down what
4 exactly should be done with Claire?

5 A. Yes.

6 THE CHAIRMAN: Thank you.

7 MR REID: You said that you think the care plan should
8 have been reviewed and amended at this stage
9 because of Claire's change in diagnosis and the
10 fact that she generally was unconscious, and
11 Staff Nurse Field, I think to be fair, has
12 accepted that she believes that she should've
13 maybe reviewed the care plan on the basis of the
14 change of condition. Unfortunately, of course,
15 we don't have any evidence from Staff Nurse
16 Ellison, and Staff Nurse McCann says that simply
17 it did not reach that stage where she had the
18 time to perhaps review the care plan. By that
19 time Claire had gone off to intensive care.

20 In terms of any other changes, changes of the
21 day of the care plan, if we bring up 310-001-001,
22 please. (Pause) Just by itself thank you. We
23 talked about at the ward round how the care plan
24 might have been changed after that. At what
25 other stages during the day do you think that the

1 care plan maybe should've been reviewed or
2 changed?

3 A. Possibly when she'd had that seizure, because
4 that then became something definite, whereas
5 before there was the possibility, so she had
6 actually had an actual seizure; when the various
7 medicines started, like the midazolam, when that
8 infusion started, because that brings with it
9 possible complications. So when the midazolam
10 started. I think they're the ones I can think of
11 at the moment.

12 Q. And then, as you say, at the change of shifts as
13 well.

14 A. Yes.

15 Q. I will go further into the areas of the seizures
16 and the medication after the break. One last
17 point just before we break.

18 THE CHAIRMAN: We don't need a break.

19 MR REID: Oh we don't need a break at this point.

20 A. Can I have a glass of water?

21 THE CHAIRMAN: Unless you particularly want one, Mrs
22 Ramsay.

23 A. No. I'm fine.

24 THE CHAIRMAN: We have been breaking for the
25 stenographer, but we don't need to.

1 MR REID: I will go to this point before I move on to
2 the medication. The neurological observations
3 were begun at 1 o'clock on 22nd October. I
4 presume you would have expected the care plan to
5 be amended to reflect that as well?

6 A. Yes.

7 Q. If we bring that page up. It's 090-039-137,
8 please. (Pause) And if we just look at the
9 respiratory rate section, please. It's just at
10 the bottom, "Respiratory rates". (Pause) If you
11 note there, there seem to be a few lines and dots
12 but there are certain areas where the readings
13 are missing. Would you have any comment to make
14 about the fact that some of the respiratory
15 observations are missing on that part of the
16 chart?

17 A. One is that it's fairly common for respiratory
18 observations not to be recorded, but respiratory
19 observations in a child who is unconscious are
20 particularly important. And so the fact that
21 there are long periods when no respiratory rate
22 was recorded is an omission in record keeping.

23 Q. If we just draw that up to the full form, please,
24 and zoom in on the GCS scores, please. (Pause)
25 Would you be quite familiar with taking central

1 nervous system observations for the purpose of
2 the Glasgow Coma Scale?

3 A. In the past, yes, not recently.

4 Q. First of all, in terms of the scores that were
5 taken on 22nd and 23rd October, how would you
6 consider the competence of how that was done in
7 that form?

8 A. Well, the questions are there and the ticks have
9 been put beside them, so ...

10 Q. So generally reasonable?

11 A. Yes.

12 Q. I presume that there would be different times
13 when you were taking a Glasgow Coma Scale result,
14 and you would be taking it maybe an hour after a
15 different nurse had taken a result. From your
16 experience, what did you find about the
17 differences between the subjective views of each
18 of the different nurses, when it came to
19 assessing someone for a GCS result?

20 A. I think some of it depends on the expertise of
21 the person that's doing it, and possibly you then
22 get more expertise of the individuals, then you
23 get greater consistency. But if your assessment
24 varies from the previous one, then you would
25 either re-check it to see which one of you is the

1 closest to it, or get somebody else to come and
2 check what you've observed, because there is some
3 subjectivity to these assessments, and some level
4 of expertise in terms of interpreting what you're
5 seeing in front of you.

6 Q. So you might double check it yourself; you might
7 bring another member of staff. Would the ideal
8 situation be to grab whoever it was who did the
9 previous reading and see if they thought there
10 had been a deterioration?

11 A. Yes, but also for some of these things you can
12 ask a parent's view as well, because the parents
13 are the constant, and so they might have been
14 there when the previous person did things, and so
15 asking, "How did Claire respond last time?" would
16 give you an indication of what the other person
17 was seeing when they recorded what they were
18 recording.

19 Q. Let me ask you about that. A child is on IV
20 fluids or is getting hourly observations. You
21 always have to come to that child once an hour.
22 Would it be regular any time you come to see a
23 child to check on anything that you as a nurse
24 would say to the parent, "Well, how is she at
25 this point?"

1 A. Yes.

2 Q. So you would be getting that feedback from them
3 on an hourly basis if you were doing hourly
4 observations?

5 A. Yes.

6 Q. And you said that if there's a difference in
7 score you would maybe go and check that with
8 someone?

9 A. Yes.

10 Q. Would that be any difference in score or just a
11 significant difference?

12 THE CHAIRMAN: Scores as low as this surely?

13 A. Pardon?

14 THE CHAIRMAN: When the scores are as low as this
15 you're going to be worried?

16 A. Yes.

17 THE CHAIRMAN: If the scores are higher and are not
18 causing concern?

19 A. Yes, if they're better then it's all to the good
20 and you probably wouldn't give it a second
21 thought. You'd think: "Oh this treatment is
22 working. Things are on the mend". But if the
23 scores were worse, then you would want to go and
24 check with somebody that you were reading it
25 correctly.

1 MR REID: (Pause) We can see there that there are
2 drops from 3.00 pm, from 9 to 7; 4.00 pm from 7
3 to 6; at 9.00 pm from 8 to 6, and then it stays
4 at 6 from then on. If you had seen a drop in the
5 GCS score, and you had maybe checked that with
6 someone else, but you were still satisfied that
7 there had been a drop, what would the next stage
8 be? Would you inform anyone, for example?

9 A. Well, assuming you'd had the discussion with
10 another staff member on the ward, then one of
11 those people should call the doctor to check that
12 that was okay, that they were happy that the
13 score was down to 6. Because if you don't do it
14 at 6, do you then do it at 5 or do you just wait
15 until things have got down the bottom?

16 Q. And let's say that you're the senior nurse and
17 you're told by someone else that the Glasgow Coma
18 Scale has dropped, firstly, do you go and see the
19 patient?

20 A. Yes.

21 Q. And if you're also satisfied that there's been a
22 deterioration in the condition do you inform a
23 doctor?

24 A. Yes.

25 Q. And would you then expect them to attend the

1 patient as soon as possible?

2 A. Yes.

3 Q. And would you expect any drop in the Glasgow Coma
4 Scale to be noted in the nursing notes?

5 A. Yes.

6 Q. And you've had an opportunity to see the nursing
7 notes. Would you say that each of those drops is
8 reflected in the nursing notes?

9 A. I can't remember offhand.

10 Q. Well, I'll bring them up for you then. If we can
11 go to 090-040-141, please. We can see there

12 Staff Nurse Ellison's note. She says:

13 "Continuous on hourly CNS obs, GNS 6 to 7."

14 I think later on she says:

15 "Very unresponsive, only to pain, remains
16 pale."

17 And then if we go to the next page, which is

18 at 138. (Pause) There is no note of the GCS

19 other than on the right-hand side. Staff Nurse

20 Lorraine McCann at 11.00 pm notes Glasgow Coma

21 Scale of 6. So if we bring back up the CNS chart

22 at 090-039-137, please. (Pause) So we have that

23 one note of Staff Nurse Ellison saying: "GCS 6/7"

24 and we have that one note of Lorraine McCann at

25 11.00 pm saying: "Glasgow Coma Scale 6". Would

1 you have expected the drops in the GCS to have
2 been further noted in the notes then, the notes
3 that were made?

4 A. I don't think I would've expected somebody to
5 have done the observations and immediately gone
6 and written it in the evaluation, because that
7 isn't how people tended to do things. They
8 tended to do a summary of things at the end of
9 the day. And, of course, the trouble with that
10 is it is a summary. It's not a blow by blow
11 account of what's gone on. But bearing in mind
12 there seemed to be references to other things,
13 like change in temperature, I think it's
14 surprising that there aren't other references to
15 the Glasgow Coma Score, considering being
16 unconscious was her main problem.

17 Q. Can I ask about that. If we look at the chart we
18 had before which also has her vital signs. If we
19 just zoom out of that. Several of the nurses and
20 doctors have described Claire's condition in the
21 evening of 22nd October as "stable". I think the
22 Chairman has asked them on that occasion: "Do you
23 mean stable per", but would you have considered
24 her condition to have been stable in the evening
25 of the 22nd?

1 A. (Pause) Well, she was stable but sick.

2 Q. And how sick would you have considered her to be?

3 A. Well, from the coma score and her lack of
4 responsiveness, then she was very sick. But I
5 think from a nursing perspective they could have
6 thought that she was sick but stable.

7 Q. So you think that --

8 THE CHAIRMAN: "Stable" doesn't actually communicate
9 anything very much here, does it?

10 A. No, no, but --

11 THE CHAIRMAN: For instance, you could be in intensive
12 care and in a stable condition, but so seriously
13 ill that you have to be in intensive care.

14 A. Yes.

15 THE CHAIRMAN: Yes.

16 A. But it is a term that is used, and I think it
17 perhaps indicates that somebody isn't considering
18 that within the next half an hour something
19 drastic might happen to you.

20 THE CHAIRMAN: Thank you.

21 MR REID: If we can bring up 090-026-075, please.

22 This is the original drugs prescription chart.

23 I'm just going to ask you a few things about
24 this. Firstly, we've heard that when it comes to
25 IV medication that the first dose would generally

1 be given by a doctor rather than a nurse. Does
2 that correlate with your understanding of
3 practice in October 1996?

4 A. In lots of places, yes.

5 Q. And that sometimes a second dose might be given,
6 an IV by a nurse, but with the stronger drugs it
7 would still be a doctor's responsibility to give
8 them, for example, phenytoin?

9 A. I think it's quite likely that some nurses might
10 only have been giving intravenous antibiotics,
11 from the second dose onwards.

12 Q. Because it is self-taxing(?), for example?

13 A. Yes.

14 Q. We have also heard a difference of opinion on
15 double signing of drugs. In that I think Staff
16 Nurse Pollock said that the practice at the time
17 was that either a doctor and a nurse signed it or
18 two registrants would sign off the drug, and we
19 heard Dr Hughes say that in a lot of cases it was
20 simply that a doctor signed alone. What would be
21 your experience of how drugs were signed off in
22 October 1996?

23 A. From a nursing perspective, it would've been
24 common practice for two people to have checked,
25 but not necessarily signed the drug. So there

1 might just have been one signature but usually
2 there had to be a second checker. My experience,
3 doctors did their own drawing up and giving of
4 drugs and didn't have them checked by a nurse.

5 Q. Was that simply what happened? Were there any
6 policies that said differently at the time, or
7 was that simply what happened?

8 A. I think that's what happened. I don't recall any
9 policies at the time that described what medical
10 practice should have been in relation to
11 administering and checking drugs.

12 Q. When you say in locations that double checking
13 was done. You said that somebody would check the
14 dose. Would that sometimes just be the nurse
15 drawing up the drug for the doctor who'd
16 prescribed it?

17 A. Sorry, can you repeat that?

18 Q. You said that sometimes there would be a second
19 person double checking the dose, on occasion.
20 Would that sometimes just be the nurse double
21 checking the doctor?

22 THE CHAIRMAN: No (overspeaking)

23 A. No, in my experience, I wouldn't have said that
24 nurses were regularly checking what the doctor
25 was giving if he was then going to give it.

1 MR REID: Okay.

2 THE CHAIRMAN: If the doctor was going to give it, the
3 practice was, I understand from you, he would
4 take responsibility or she would take
5 responsibility for administering that drug?

6 A. Yes.

7 THE CHAIRMAN: If it was to be administered by nurses,
8 it would be checked by a second nurse but not
9 necessarily signed for by a second nurse?

10 A. Yes.

11 THE CHAIRMAN: Thank you.

12 MR REID: If we can look at some of the individual
13 drugs that were administered to Claire on 22nd
14 October. If we start with phenytoin. How
15 familiar do you think that staff nurses on a
16 general ward, such as Allen Ward, would have been
17 with a drug such as phenytoin in October 1996?

18 A. I think that it depended on whether they
19 regularly admitted children with epilepsy. They
20 would probably know what phenytoin was because
21 it's been around a long time, and they would've
22 given it to children orally. So I think they
23 would have had some knowledge of the drug.

24 Q. And if you as a staff nurse were unfamiliar with
25 a drug, would you check anywhere to find out more

1 about the drug?

2 A. Yes, I would think that all wards had a British
3 national formulary there, for people to go and
4 look up what the drug was and what its side
5 effects were.

6 Q. In what circumstances would you, as a staff
7 nurse, check the formulary for a drug?

8 A. If this was something you weren't too sure about,
9 hadn't come across before, because you should
10 have an awareness and a knowledge of the things
11 that are happening to your patient, so that you
12 know what to look out for.

13 Q. So it is a case it's not just the dose, or
14 something of that nature you're checking, you're
15 checking to see what might happen as a result of
16 the administration of this drug?

17 A. Yes, and also to inform yourself, because parents
18 ask questions so you need to have some
19 information to impart.

20 Q. You don't want to look as if you don't know what
21 is going on?

22 A. No.

23 Q. So in terms of the phenytoin, what as a nurse
24 would you be considering you might have to do if
25 you knew a patient was receiving phenytoin?

1 A. Well, you'd want to know what it was being given
2 for and were there any immediate side effects to
3 it, which could affect you as a nurse and the
4 nursing care that you gave, and what the likely
5 outcome was.

6 Q. Would you want to have a cardiac monitor running
7 during phenytoin administration?

8 A. I think the guidance is quite clear on saying you
9 should have a monitor there. Yes, because my
10 understanding is that if you give it
11 intravenously then you can get cardiac
12 arrhythmias.

13 THE CHAIRMAN: That is for the initial dose, is it?

14 MR REID: Yes, and I think the --

15 THE CHAIRMAN: Preferably for it to continue but
16 essential for the initial administration?

17 A. Yes. I think that's what it says.

18 MR REID: Obviously all of these issues will be
19 canvassed this afternoon with Dr Aronson. Sorry
20 I'm asking you questions about it when we have Dr
21 Aronson waiting in the wings with it, but I'm
22 trying to get it from a nursing point of view.
23 Because, in terms of the cardiac monitor, we can
24 see at 090-040-138, that there does seem to have
25 been a cardiac monitor in situ at the

1 administration of the phenytoin at 11.00 pm or
2 11.30 pm, whenever it was administered. But
3 there is no note of the same at the
4 administration at 2.45 pm in the afternoon. If
5 there was no cardiac monitor in situ during that
6 infusion, would you be critical of that fact?

7 A. Yes, I would because it should have been there.
8 I have to say I don't know how critical I would
9 be of the nurses, because this was a medical
10 procedure and not something nurses would've
11 necessarily had experience of.

12 Q. Well, would you have expected it to be noted that
13 a cardiac monitor was in situ, as it's noted
14 there by Staff Nurse McCann?

15 A. Could you repeat that?

16 Q. Staff Nurse McCann notes that a cardiac monitor
17 was there for 11.00 pm. If one had been there
18 for 2.45 pm, would you have expected that to have
19 been noted in the notes?

20 A. Yes.

21 Q. If we go back then to the chart at 090-026-075,
22 the next drug that Claire receives. She has also
23 received diazepam at 12.15 but the next drug she
24 received was midazolam at 3.25, and we think that
25 dose may have been 12 ml. It is written as 120

1 ml there. As a nurse, what would you have
2 expected? Firstly, would nurses have been
3 familiar with midazolam in October 1996?

4 A. In a general ward environment I seem to think
5 that it would be unlikely.

6 Q. In those circumstances would you consider that
7 consulting the BNF would, at the very least,
8 advisable?

9 A. Yes.

10 Q. We know some of the possible side effects of
11 midazolam, and Dr Aronson will go into those
12 later on. In terms of the side effects what
13 would you as a nurse be looking out for in the
14 period after that?

15 A. Reduced level of consciousness and depressed
16 breathing.

17 Q. If you were unfamiliar with midazolam, would you
18 be expecting a doctor or a senior nurse to say to
19 you, "These are the side effects. Look out for
20 these things"?

21 A. Yes.

22 Q. Would that be the doctor or the senior nurse or
23 either?

24 A. I think it could be either but also you, as an
25 individual, if you've not come across it before

1 would want to seek out the information to enable
2 you to look after the child effectively.

3 Q. Finally then the sodium valproate, would that
4 have been familiar to nurses on general ward in
5 October 1996?

6 A. If they were used to looking after children who
7 were having seizures.

8 Q. Would there have been any particular side effects
9 you would be looking out for that these would
10 involve?

11 A. I'm afraid I can't remember off the top of my
12 head.

13 Q. As a nurse, if you were aware of all of these
14 different drugs, the fact that Claire is
15 receiving all these different drugs, would that
16 raise any concern or alarm with you?

17 A. Well, it's an indicator that this is a child
18 whose condition isn't under control, and that
19 various things are having to be tried because
20 she's not regaining consciousness or she's still
21 fitting.

22 THE CHAIRMAN: It raises your level of concern about
23 the child?

24 A. Yes.

25 THE CHAIRMAN: You would expect that to prompt the

1 nurse to keep that child under closer review?

2 A. Yes.

3 MR REID: One moment, Mr Chairman. (Pause) If we then
4 go to the record of attacks observed at
5 090-042-144 please? You're aware of the sheet of
6 attacks observed, Mrs Ramsay?

7 A. Yes.

8 Q. The first incident that's recorded on there is a
9 record written by Mrs Roberts of:

10 "Frequently strong seizure at 3.25, of
11 duration of five minutes."

12 She stated afterwards "sleeping". It seems
13 from the evidence that Mrs Roberts witnessed the
14 seizure and then mentioned it to the nursing
15 staff. The nursing staff asked her to fill in
16 this particular document.

17 If you had been the nursing staff on at that
18 time, at 3.25, and you heard about the seizure
19 from the mother, what do you think you, as a
20 nurse, would have done as a result?

21 A. I would have asked the mother to describe it, and
22 I would have recorded it noting that it was
23 observed by the mother and not observed by the
24 nurse.

25 Q. Would you have recorded it in the nursing notes?

1 A. Yes.

2 Q. It would have been recorded on this sheet in the
3 nursing notes?

4 A. Yes, because the nursing notes are the ongoing
5 permanent record and these charts have a habit of
6 getting lost over time. So that's not seen as
7 being the permanent record.

8 Q. Would you have informed a senior nurse or doctor?

9 A. Yes.

10 Q. Is it that you would inform the doctor if a
11 senior nurse was not available or would you
12 inform both?

13 A. I think, I think that it's best to go through the
14 senior person so that the doctors, the general
15 feeling, was you didn't want lots of nurses on a
16 ward bombarding the same doctor when he was only
17 next door or something. And so it was more
18 effective use of people's time if you could
19 channel it but also you would want to keep that
20 person informed of what was going.

21 I'm a believer in sharing information, not
22 keeping information to yourself, and then having
23 shared it somebody would decide who was going to
24 phone the doctor.

25 Q. That point is reflected in your report at

1 231-002-024, and if I can go to 231-002-030
2 please, at this point in your report you are
3 discussing the chain of command, I think is what
4 you've just said. You said in the second
5 paragraph of this the wards, in your experience:
6 "Operated with a chain of command. When a
7 nurse was concerned about a child she would share
8 this with the nurse in charge and/or the junior
9 doctor if he/she was present. In most cases, it
10 would be then for the junior doctor to contact
11 the registrar possibly prompted by the nurse, and
12 the registrar or junior doctor would contact the
13 consultant.
14 "However, if the nurses felt their concerns
15 were being inappropriately ignored then
16 contacting the consultant was an appropriate
17 action."
18 How often in your experience in the mid 1990s
19 would staff nurses contact the consultant
20 directly?
21 A. I would think rarely.
22 Q. How often would they contact the registrar
23 directly?
24 A. Probably quite frequently because the registrar
25 would have had a higher presence, and so have

1 developed a relationship possibly with them, but
2 it was usual to talk to the houseman first often
3 because they were the people who were most
4 readily available.

5 Q. In 1996, if there was a junior doctor you had to
6 book into, and you were unhappy with what they'd
7 said or if you thought they made a mistake, what
8 would be done then in the ward?

9 A. Well, you shared that with somebody and somebody
10 would talk to the registrar.

11 Q. Would it then reach the consultant?

12 A. I think it's unlikely that you would go straight
13 to a consultant. You would go through the
14 registrar.

15 Q. If we go on to the next paragraph in the report,
16 you say in the second sentence the nurse had a
17 duty, in your view, to ensure that a doctor was
18 aware of any changes in Claire's condition, and
19 you list there at the bottom the things you think
20 the doctor should have been aware of. The
21 numbers are 3.10 and 3.25 seizure we've
22 discussed, at 5.00 pm the failure to pass urine
23 for six hours, 7.00 pm when the blood pressure
24 was 130 over 70, at 9.00 pm when the coma score
25 was at 6, and at 9.00 pm the episode of screaming

1 and raised pulse rate.

2 You said that the nursing record shows the
3 doctor was informed of the episode at 9.00 pm.
4 This is not confirmed by an entry in the medical
5 record, and it seems that for some of others that
6 the doctor wasn't informed.

7 What would be your general opinion of the
8 nursing care, in terms of the fact that it seems
9 that maybe a doctor may not have been informed of
10 those particular incidents?

11 A. Well, it's not really very good if you've got
12 some significant events and they aren't being
13 passed on to somebody else, because it then means
14 people who are directing her care don't have the
15 full picture of what's happening.

16 THE CHAIRMAN: None of this is ever quite
17 straightforward, is it, because for instance the
18 5.00 pm failure to pass urine for six hours but
19 we know that Dr Webb saw Claire at about 5.00
20 pm-ish and I think Dr Sands as well. They were
21 there looking after Claire and Dr Webb was coming
22 back, for instance, for an update on the
23 information on Claire's condition, is that
24 particular point about failure to pass urine for
25 six hours something he would have picked up?

1 A. Well, he would have seen it from the fluid chart
2 if he looked at the fluid charts.

3 THE CHAIRMAN: Yes, that's right.

4 A. But then if there was a nurse present then you
5 would say, "She hasn't passed any urine for six
6 hours".

7 MR REID: Yes, okay, but we're a bit unsure about who
8 was where and when. The coma score of 6 and the
9 9.00 pm episode of screaming, it was Dr Hughes
10 who told us a few days ago that she was there at
11 about 9.30pm and she was called partly because of
12 Claire's condition, so that information was
13 available for her to pick up. In fact she was
14 specifically called to see Claire, wasn't she?

15 I think there's a belief she said she was
16 attending Claire to check the phenytoin levels,
17 for one thing, and to administer medication.

18 THE CHAIRMAN: I understand your point whether each of
19 these specific issues was referred individually
20 by a nurse to a doctor but, as it happened in
21 Claire's case, perhaps apart from the 3.10
22 seizure and the blood pressure at 7.00 pm, there
23 were doctors attending to Claire at about 5.00 pm
24 and soon after 9.00 pm.

25 A. Yes.

1 MR REID: Before we move on to the final topic which
2 is communication with Claire's family, can I ask
3 you about the issue of consultant responsibility?

4 I think in your report, I'll just bring it up,
5 it's at 231-002-018, you state at the top:

6 "The identity of a child's consultant was
7 usually recorded on the nursing records, and I
8 know that Claire's consultant was Dr Steen. It
9 would not have been usual to make a specific
10 reference to this during the nursing handover,
11 however I believe the nurses could have concluded
12 that Dr Webb had taken over her care. Claire had
13 neurological problems. Dr Webb was a consultant
14 neurologist and spent a length of time examining
15 Claire and interviewing her mother, whereas Dr
16 Steen did not visit Claire."

17 You'll have seen the evidence of the different
18 nurses and the doctors over the last few weeks of
19 the inquiry, and it seems that their general
20 impression was that Dr Steen was the named
21 consultant but that Dr Webb was certainly
22 providing advice at the very minimum.

23 Can I just ask you why you think that the
24 nurses could have concluded that Dr Webb might
25 have taken over her care?

1 A. Because, as I've said here, I think he was the
2 one that was visible and she had a neurological
3 problem.

4 Q. What would you have expected to have been done if
5 the consultant care had changed from Dr Steen to
6 Dr Webb, from a nursing point of view?

7 A. Well, good practice would have been that somebody
8 would tell you that that child was now being
9 cared for by Dr Webb. You would then change the
10 bit on the care plan that says who the child was
11 admitted under, and there would have to be
12 changes to the information system so that the
13 hospital record showed who was the child's
14 consultant.

15 Q. You would have expected not only for there to be
16 a note in the nursing notes but also for some of
17 the forms which the assigned consultant is noted
18 to have been changed formally?

19 A. Yes, but I think that it probably was a bit more
20 lax than that.

21 THE CHAIRMAN: Maybe you could comment on this, was it
22 a situation where the nurses would have been sure
23 that Dr Webb had taken over?

24 A. No.

25 THE CHAIRMAN: You wouldn't change the identity of the

1 responsible consultant on the nursing care plan
2 unless you were clear that there had been a
3 change in consultant responsibility?

4 A. No, and you'd probably do it following on from
5 something being written in the medical record.

6 THE CHAIRMAN: Yes.

7 A. So "Now under the care of Dr Webb" would prompt
8 the nurse to then change some nursing.

9 THE CHAIRMAN: Yes, but that was written in to the
10 record by Dr Webb or by a junior doctor to say
11 that fact.

12 A. Yes.

13 THE CHAIRMAN: There's a difference between you. The
14 comment which is highlighted on the screen at the
15 moment is your conclusion from the papers that
16 you could understand if the nurses had concluded
17 that Dr Webb had taken over Claire's care, but
18 that's something short of saying that they would
19 have known that he'd taken over and therefore
20 should have altered the documentation.

21 A. Yes, yes.

22 THE CHAIRMAN: Thank you.

23 MR REID: If a consultant neurologist had maybe taken
24 over the care of Claire, would you have expected,
25 in 1996, for Claire to have been transferred say

1 to the paediatric neurology ward?

2 A. If there was a bed available then that would seem
3 the logical place for her to have been.

4 Q. But it happened on occasion that a paediatric
5 neurology patient was on a general ward, because
6 there wasn't enough room in the paediatric
7 neurology ward?

8 A. Yes.

9 Q. If I can then move to communication with Claire's
10 parents and that's in your report at 231-002-032?

11 Can I ask you just in general, from your
12 reading of the nursing notes, do you think there
13 was sufficient notation in the nursing notes of
14 what was communicated to Claire's parents?

15 A. In retrospect probably not, but I think at the
16 time people didn't write very much about the
17 conversations they had with parents, other than
18 if there was something specific that was of
19 concern to the parents or concern to the nurse in
20 having had the discussion with them.

21 So I think it wasn't unusual to have comments
22 that the parents were there or the parents had
23 gone home or something but not much detail.

24 Q. I think you say that actually in your report
25 there, you say:

1 "The most entries in nursing evaluations are
2 just concerning whether Claire's parents were
3 attending or not, and one entry shows 'Parents
4 concerned as Claire is usually very active'.
5 [But you state] There are no records giving even
6 brief details of information shared with them and
7 any discussions they had with the doctor."

8 Are you saying that although the practice at
9 the time that not much was recorded, that there
10 was still an insufficient recording?

11 A. Yes, I think so. I don't know if --

12 THE CHAIRMAN: It's the next paragraph.

13 MR REID: Over the next one, yes, I was going onto the
14 next paragraph. You say:

15 "It is my opinion that as a minimum there
16 should have been a record of the information
17 given to Claire's parents, their understanding
18 and concerns."

19 You give a useful example:

20 "Parents anxious that Claire is not responding
21 as usual. Seen by Dr X who's advised them of
22 likely brain problems. Medicines have been
23 explained and parents appeared to understand."

24 You consider that to be the minimum?

25 A. Yes, because often there was a communication

1 record sheet where people could specifically
2 document communication issues predominantly with,
3 with parents, so yes, this is my view that,
4 although something was written, it wasn't enough.

5 Q. We've discussed already the fact that nurses
6 generally are on the front line of communication
7 with the family since they're there the most
8 often, though, of course, whenever the doctors
9 attend you would hope that they would explain
10 certain elements of the condition and the
11 treatment to the parents that would be fair to
12 say?

13 A. The doctor would explain.

14 Q. Yes, but the nurse would be the first point of
15 call but the doctors would explain things
16 whenever they are present.

17 A. Yes.

18 THE CHAIRMAN: Just one moment. Mr Fortune?

19 MR FORTUNE: Mrs Ramsay has just mentioned there
20 should be or may have been a communication sheet.

21 A. Yes.

22 THE CHAIRMAN: That's in her report. There is
23 sometimes a document of that nature.

24 A. Yes.

25 MR FORTUNE: Is there any particular example in the

1 records that would actually go under that title,
2 as opposed to nursing records or relative
3 counselling records?

4 THE CHAIRMAN: From my reading of it, the closest we
5 have is the relative counselling records but that
6 comes at a later stage after Claire's collapse.

7 A. Yes, it would have been a similar sheet to that
8 but usually labelled "Communication record".

9 THE CHAIRMAN: But it's not on the records we have. I
10 can build on that, and thank Mr Fortune for his
11 point. Would you have expected a pro forma
12 sheet, such as that to be present in the nursing
13 records?

14 A. Not necessarily. It was something that some
15 people had and others didn't.

16 MR FORTUNE: Thank you.

17 MR REID: Was it (overspeaking)

18 A. It wasn't regarded as an essential.

19 THE CHAIRMAN: Has it subsequently developed as an
20 essential or not?

21 A. Yes, I think, I think they're in fairly common
22 use these days.

23 THE CHAIRMAN: Let's make sure there aren't two
24 separate points here. Is one point that in some
25 hospitals there would have been a separate record

1 sheet for communications with the parents but,
2 even if that was not the position in the Royal,
3 you would have expected that the nursing records
4 would have recorded something along the lines,
5 which you have under the third paragraph under
6 section 4.3.4?

7 A. Yes.

8 THE CHAIRMAN: Thank you.

9 MR REID: One of the key events obviously in Claire's
10 case, it's just after 9.00 pm, Claire's parents
11 are about to leave Allen Ward, after speaking
12 briefly to the nursing staff to tell them that
13 they were leaving. That's at around 9.00/9.15
14 pm.

15 At that point, from your impression of the
16 notes, can you see any indication that the nurses
17 appreciated the seriousness of Claire's condition
18 at that stage?

19 A. No, because my understanding is that there wasn't
20 a discussion about "We're now thinking of going
21 home", it was a sort of chance good bye as they
22 passed somebody at the desk.

23 THE CHAIRMAN: No, it's a bit more than that. I think
24 Mrs Roberts went to the desk to say her husband
25 and their sons were there with her, but she went

1 to the desk to say specifically that she was
2 going home.

3 A. Right.

4 THE CHAIRMAN: I think that's right. So she went for
5 that purpose.

6 A. Yes, but I was thinking in terms of the nurse
7 picking up on it.

8 THE CHAIRMAN: Yes (overspeaking) what the nurse's
9 interpretation was?

10 A. Yes, yes.

11 THE CHAIRMAN: I see, but I'm not sure, just to check
12 you've picked this up, as it happened when she
13 was there a phone call came in from a relative in
14 Scotland asking about Claire's condition and in
15 essence Mrs Roberts was on the phone saying
16 "Well, look, you know, she's okay. We're about
17 to go home".

18 A. Yes.

19 THE CHAIRMAN: Now if that --

20 MR FORTUNE: The inquirer was a nurse, if you
21 remember, sir.

22 THE CHAIRMAN: Yes, sorry. The relative was a nurse
23 who was actually a --

24 A. Yes.

25 THE CHAIRMAN: If that exchange was overheard, even in

1 part, then that would confirm that the nurses in
2 the Royal were not conscious of the state that
3 Claire was in at that time.

4 A. Yes, so I think the answer to the question is
5 that they weren't sufficiently worried about her
6 to keep the parents there.

7 MR REID: Do you consider that they should have been?

8 A. Yes.

9 THE CHAIRMAN: That rather begs the question, but you
10 may or may not know this but one of the family's
11 big concerns is whether the doctors had picked up
12 on how ill Claire was, never mind the nurses.

13 I'm sure it shouldn't be as hierarchical as
14 this but if the doctors were not alert to how
15 serious ill Claire was, then the nurses would be
16 at a lower level of alertness themselves,
17 wouldn't they?

18 A. Absolutely.

19 THE CHAIRMAN: So even though the Glasgow Coma Scale
20 score is low, even though she's pretty much
21 unconscious -- and we now know what was just a
22 few hours away -- at that point the nurses would
23 not have been alert to the extent of the danger
24 that Claire was in.

25 A. No.

1 THE CHAIRMAN: Because if the doctors who see a
2 patient don't give you that strong indication
3 then the nurses are more likely to miss it too.
4 A. Yes.
5 THE CHAIRMAN: Yes.
6 A. Yes.
7 MR REID: Let me ask you it this way -- sorry.
8 THE CHAIRMAN: Sorry.
9 MR CAMPBELL: [inaudible: no microphone]
10 THE CHAIRMAN: Yes.
11 MR CAMPBELL: With reference to the evidence of Dr
12 Sands, transcript page 233, I think day 48.
13 THE CHAIRMAN: Okay. Do you have a date, Mr Campbell?
14 MR CAMPBELL: Sorry?
15 THE CHAIRMAN: Do you have a date? So it's Dr Sands
16 is it?
17 MR GREEN: 19 October.
18 THE CHAIRMAN: Thank you.
19 MR CAMPBELL: It's 233, line 18 and also 235, line 7.
20 THE CHAIRMAN: Okay.
21 MR CAMPBELL: In which he's talking about a gap and
22 his acceptance that he should have had a
23 conversation with the nurses to communicate the
24 extent of his concern.
25 THE CHAIRMAN: Yes, but that is slightly premised in

1 Dr Sands had left at around 5.00 pm, or between
2 5.00 pm and 6.00 pm, is that right?

3 MR CAMPBELL: But he was the main medic on the ground
4 in the ward. Dr Webb is in and out, I think on
5 two occasions through the day.

6 THE CHAIRMAN: Yes.

7 MR CAMPBELL: But Dr Sands was in effect in charge of
8 Claire's care in the ward that day.

9 THE CHAIRMAN: Right, so this was the point in the
10 transcript, Mr Campbell, is it, on page 233
11 is ...?

12 MR CAMPBELL: I think it's line 18.

13 MR GREEN: I have to say, I should put it on record
14 that I do not accept the proposition that Dr
15 Sands was in charge in the ward that day.

16 THE CHAIRMAN: I understand that, and I understand
17 this may be a slightly loose way of describing
18 what was going on. Yes. Okay, so do you get the
19 point that's been made, Mrs Ramsay? I'm not sure
20 I'm quite picking it up from the transcript.

21 The question at line 14 is was Claire actually
22 the sickest child in the ward and Dr Sands says:

23 "Yes. Looking back, and having seen now the
24 notes, that's my impression."

25 So this is Dr Sands looking backwards and

1 saying that Claire was actually the sickest child
2 on the ward.

3 MR REID: Mr Chairman, maybe Mr Campbell is relying on
4 the live note that transcends reference rather
5 than the official transcripts?

6 MR CAMPBELL: [inaudible: no microphone] I checked it
7 earlier on, on the laptop in front of me here.

8 MR GREEN: The official transcript reference is 233.
9 The relevant questioning begins at line 6:

10 "Then in relation to the other children on the
11 ward whose care you have had during the day,
12 where would you place Claire?

13 "A. I would have said at the top of the list in
14 terms of children who were unwell. That's to the
15 best of my knowledge having looked at Claire's
16 chart and looked at some of the other patients.
17 Bits of the other patients' charts that we've
18 seen."

19 THE CHAIRMAN: Yes.

20 MR GREEN: Then he goes on to accept, in answer to the
21 question:

22 "Was Claire actually the sickest child on the
23 wards throughout the day? [This is line 18 on
24 233] Again, looking back and having seen more of
25 the notes [then there's a pause] well, I suppose

1 that's unfair because I haven't seen all the
2 notes from the patients on the ward. That's my
3 impression".

4 THE CHAIRMAN: Yes. Do I take it, Mr Campbell, that
5 what you are doing here is emphasising the point
6 that I was asking Mrs Ramsay about, about the
7 level of awareness which the nurses would have
8 had of the extent of Claire's sickness?

9 MR CAMPBELL: That is the point I'm getting to, Mr
10 Chairman, however there is a difference in the
11 transcript section which has been referred to
12 just now and the section that I wish to draw the
13 attention towards.

14 THE CHAIRMAN: All right.

15 MR CAMPBELL: That is a question for Ms Danes.

16 THE CHAIRMAN: What page are you on now?

17 MR CAMPBELL: I'm on the live, the laptop version so
18 to speak.

19 THE CHAIRMAN: I think we're all on that. No? Sorry,
20 we're not, okay.

21 MR CAMPBELL: Page 233, line 8 was the question. The
22 second portion of that question reads as follows:

23 "Now for Dr Stevenson and the nurses, they are
24 the touch point or the contact point with the
25 parents, so if they don't fully understand it,

1 absent yourself or Dr Webb coming and
2 specifically discussing it with the parents, then
3 it's difficult to see how the parents will be
4 accurately informed about the condition of their
5 child. Would you accept that?

6 "A. I think there may have been that gap in
7 understanding."

8 Then slightly further on, it's 235, line 7 and
9 the question starts at line 5:

10 "What discussion do you think you should have
11 had with the nursing staff at that time before
12 you went off duty?

13 "A. As one of the clinicians there I think I
14 should have been part of the discussion with the
15 nursing staff to say that this is a girl we're
16 concerned about for these reasons."

17 Those are the points, Mr Chairman. In fact,
18 there was a gap, and Dr Sands was accepting that
19 there was a gap between his belief about Claire
20 and his communication of that to the nurses.

21 THE CHAIRMAN: All right, it's then -- sorry.

22 MR GREEN: Sorry, that's only a partial part of the
23 picture. If we go to page 238 on the transcript
24 for that day, and to line 17. I'm not going to
25 read out all the preamble, the context is whether

1 Dr Sands did enough to make sure the nurses
2 understood.

3 The question at line 17:

4 "Q. Did it not fall to you to make sure they
5 understood that?

6 "A. That's before Dr Webb's visit.

7 "Q. Yes.

8 "A. I think again I would have expressed my
9 concerns to the nursing staff and told them I
10 thought Claire was very neurologically unwell,
11 and said we needed a neurologist to see Claire
12 because I'm not sure what's going on here. I
13 suspect this may be but I don't know."

14 The question over the page is put and elicits
15 the answer that my learned friend, Mr Campbell,
16 has just put. I simply raise the point at this
17 stage because while it was accurately quoted by
18 Mr Campbell, that sort of partial quotation can
19 be apt to mislead unless the full picture is put.

20 THE CHAIRMAN: Okay. Your point is that there was a
21 run in to the question in the reference that Mr
22 Campbell made?

23 MR GREEN: Exactly. Where Dr Sands indicated that he
24 thought he had expressed to the nurses that
25 Claire was very neurologically unwell.

1 THE CHAIRMAN: Right, and in terms, that piece of Dr
2 Sands' evidence is him explaining to them why
3 he's going to look for Dr Webb?

4 MR GREEN: Yes.

5 THE CHAIRMAN: Let me pick that up with you, Mrs
6 Ramsay. Then Dr Webb, who would not normally be
7 around this ward, he is brought in and the nurses
8 would have seen him there at different points.
9 That in itself would indicate there was something
10 more that needed investigating with Claire, would
11 it?

12 A. Yes.

13 THE CHAIRMAN: The nurses would pick up on that, and
14 so you've got his intervention and you've got the
15 drugs he prescribed and you've got the Glasgow
16 Coma Scale, and you've got her unconsciousness.

17 Really what that feeds into is maybe resetting
18 the context for the question, "To what extent
19 should the nurses have been alert to how
20 seriously ill Claire was as Tuesday afternoon
21 moved into Tuesday evening and Tuesday night?"

22 A. I think they should have been alert to it because
23 there were all those indicators, but I think that
24 jointly between them and the medical staff nobody
25 was having that conversation and maybe they felt

1 she did go some long periods without seeing a
2 doctor, I think, and so that was interpreted that
3 she might be sick but things were jogging along.

4 THE CHAIRMAN: Another way to look at it is this, to
5 the extent that there could possibly be any
6 criticism of the nurses for not saying to Mr and
7 Mrs Roberts at about 9.00 pm, "We don't really
8 think you should go home without speaking to a
9 doctor", and for the doctor to explain how ill
10 Claire was, the doctors had been coming backwards
11 and forwards during the day.

12 There was Mrs Roberts there constantly, for
13 long periods Mr Roberts was there. The
14 grandparents were there. Let's set aside their
15 sons for the moment. There were many occasions
16 during the day when any one of a number of
17 doctors could have sat down with Mr and Mrs
18 Roberts to explain things.

19 A. Yes.

20 THE CHAIRMAN: If that hadn't been done, and it
21 appears not to have been done, then the question
22 is to what extent would it be fair to be critical
23 of the nurse at around 9.00 pm for letting the
24 Roberts' leave without advising them of the
25 seriousness of Claire's condition?

1 A. I think if there was situation where the nurses
2 knew something but the parents didn't, then they
3 had a responsibility to ensure that the parents
4 were in the picture. And so I think that would
5 have been the sort of conversation you've just
6 described of getting a doctor to come and see the
7 parents before, before they left and that would
8 have given them an opportunity to decide whether
9 or not they should leave.

10 So I think that they probably didn't know what
11 the parents knew and so couldn't have that
12 particular conversation. I think that there were
13 opportunities for nurses to find out what the
14 parents knew.

15 THE CHAIRMAN: Okay. Sorry, Mr Quinn, am I right in
16 understanding that Mr and Mrs Roberts hadn't
17 spoken to a doctor from about 5.00 pm?

18 MR QUINN: That's correct. Yes, that is correct.

19 THE CHAIRMAN: Thank you. (Pause)

20 MR QUINN: Just to remind everyone, and put it onto
21 the record, the purpose for Mrs Roberts going to
22 the nurses' station was twofold. One, that was
23 to say, "We're going to go now, is that okay?",
24 and check with the nurses. The second one was to
25 ensure that the nurses were aware that Claire's

1 bed sides were up, because she might have been in
2 the habit of getting out of bed. So that was
3 something specific that was said to the nurses.

4 From my recollection -- I haven't checked the
5 record -- Mrs Roberts I think may have spoken to
6 her cousin, or certainly said there was some
7 indirect conversation with the cousin in Scotland
8 who was on the phone who was also a nurse.

9 THE CHAIRMAN: As I remember the evidence that call
10 came in, and it happened it was taken by the
11 nurse at the station and who was able to hand the
12 phone straight to Mrs Roberts because she was
13 already there.

14 MR QUINN: That's correct. That is correct. The
15 nurse would have known what Mrs Roberts was
16 telling her cousin in that she was reassuring her
17 cousin in Scotland that Claire was fine.

18 THE CHAIRMAN: Yes, yes. Okay, thank you.

19 MR REID: Mr Chairman, there are a few things that
20 just arose with the transcript. Just to put on
21 record as a practical note, the Transcend(?) live
22 note uses different referencing from the official
23 transcripts which are available for bringing up,
24 and so it would be useful if any of my learned
25 friends are referring to the transcripts that

1 they refer to the official transcripts as much as
2 they can, because that's the version that we can
3 bring up and so hopefully we don't get the --

4 THE CHAIRMAN: Those are the transcripts which are
5 found on the inquiry website?

6 MR REID: Yes.

7 THE CHAIRMAN: Yes.

8 MR REID: Because the difficulty is that the Transcend
9 note has additional words and so on added to it
10 and so the page numbers and line numbers are
11 different. Normally the page numbers are higher
12 than those that appear on the Transcend software.

13 THE CHAIRMAN: Okay.

14 MR REID: It's just to put that on record.

15 THE CHAIRMAN: Thank you.

16 MR REID: I take your point, Mr Chairman, not to load
17 too much on Staff Nurse McCann and the night
18 nurses because there may have been communication
19 during the day but let's just finish off the
20 issue at around 9.00 pm.

21 At that point, the nurses who were caring for
22 Claire would have been aware of seizure 9.00 pm,
23 would have been aware of her Glasgow Coma Scales
24 and the medication she was receiving.

25 They would be aware of those things, is that

1 right, Mrs Ramsay?

2 A. Yes.

3 MR REID: Claire's mother then comes to the nursing
4 station and says, "We're thinking of going now.
5 Can you please make sure that the bed sides are
6 up because I don't want Claire falling out of
7 bed?" At that point, even if they hadn't been
8 made aware of the seriousness of Claire's
9 condition by the doctors, do you consider that
10 maybe the nurses with the knowledge that they had
11 might have realised of their own initiative that
12 Claire's condition was serious?

13 MR MCALINDEN: With this question I think it would be
14 appropriate for the witness to be made fully
15 aware of the description of the 9.00 pm event, as
16 given by Mrs Roberts, because it certainly
17 significantly differs from the cold written
18 description in the notes?

19 THE CHAIRMAN: (overspeaking) very short note on the
20 attack sheet, yes?

21 MALE SPEAKER: Yes.

22 MR REID: Yes, would it be fair Mrs Roberts described
23 it, if I recollect properly, that she thought it
24 was Claire trying to wake up out of her sleep
25 effectively? The note on the record of attacks

1 observed says, "An episode of screaming and
2 raising of arms."

3 Mrs Roberts considered it at the time as
4 Claire trying to wake up from her sleep and being
5 restless somewhat in her sleep.

6 Given that GCS score and the medication that
7 was being received, do you consider that the
8 nurses at around 9.00 pm should have been aware
9 of the seriousness of the condition regardless
10 perhaps of whatever they'd been told by the
11 doctors?

12 A. Well, they should have been aware that she was
13 sick and in all likelihood the sickest child on
14 the ward.

15 MR REID: In that situation, if the parent comes up
16 and says, "We're thinking of going now", do you
17 think that the nurse should have contacted a
18 doctor to say that the Roberts were leaving?

19 A. I'm not too sure whether informing people that
20 parents are leaving is something that you would
21 do. I think if you openly have a child that
22 everybody knows is sick and they're going, you
23 would check with the doctor that there isn't
24 something that he wants to say to them before
25 they go.

1 So I suppose I'm struggling to give you a
2 clear view on that one.

3 THE CHAIRMAN: If I can come back to your answer a few
4 moments, but your point was that you don't know
5 what the nurses might not have known the extent
6 of the Roberts' existing knowledge?

7 A. Yes.

8 THE CHAIRMAN: In other words, the nurses might not
9 have known to what extent, if any, the Roberts
10 had had been sat down at 5.00 pm by Dr Webb to
11 explain things?

12 A. Yes.

13 THE CHAIRMAN: Okay.

14 MR REID: If we can then look --

15 THE CHAIRMAN: Sorry, just to make a point. It's just
16 one of the many awful aspects of Claire's case
17 that her parents did go home in the circumstances
18 that they did, and it would be very, very easy to
19 write this bit of the report because that should
20 not have happened.

21 The question I'm struggling with a bit more at
22 the moment is whether, in fact, there's blame
23 attached to a particular nurse or nurses for
24 that.

25 It's a more defined aspect of the very obvious

1 and simple point, which is that Mr and Mrs
2 Roberts should not have left with an entirely
3 mistaken understanding about Claire's condition.

4 A. Yes.

5 MR REID: In terms of Claire's care in paediatric
6 intensive care, a note from your report that
7 you've no criticism of her care in paediatric
8 intensive care, is that correct?

9 A. Yes.

10 MR REID: We then move on to the aftermath of Claire's
11 death. I asked each of the nurses whether they
12 had been involved in any audit or investigation
13 or discussion following Claire's death, and none
14 of them could certainly recall any audit or
15 investigation or discussion.

16 Would you have expected any discussion among
17 nurses following a child's death in October 1996?

18 A. I think the situation was not unusual.

19 MR REID: I presume you mean the situation that there
20 was no discussion?

21 A. Yes.

22 MR REID: The situation that a child had died after
23 being on a general paediatric ward for just over
24 24 hours, was that unusual?

25 A. It, it would have been unusual but I think

1 possibly the elements that meant that there
2 wasn't any great discussion would be that there
3 doesn't appear to have been recognised error at
4 the time.

5 If a child had died as a result of a clear
6 untoward incident, then I think even in 1996
7 something would have happened to reflect on that.

8 A child dying and somebody giving an
9 explanation of that, where people aren't thought
10 to have failed, then wouldn't necessarily have
11 prompted any discussion amongst the nurses.

12 MR REID: If I can speculate for a moment, if say, for
13 example, it had been considered that it had been
14 thought in October 1996 that Claire had suffered
15 fluid overload, would that be something that
16 might be discussed among the nurses on the ward?

17 A. Only if the fluid overload has resulted from an
18 inaccurate administration of the IV. So if the
19 nurse had set the pump at the wrong level and so
20 too much had gone in over too short a period of
21 time then that would have led to a discussion.

22 Or not necessarily a discussion, I think the
23 person who had set the discipline.

24 Q. Effectively there would only have been a
25 discussion with nurses if there was a, so to

1 speak, definite iatrogenic reason for the death
2 of the child?

3 A. Yes, that is my opinion.

4 Q. Would there be discussions if there was a
5 possible iatrogenic reason for the death?

6 A. I think at the time, no.

7 Q. Only in definite circumstances?

8 A. Yes.

9 Q. What would you -- sorry, Mr Fortune has a point.

10 MR FORTUNE: Rather than have an exercise in
11 speculation, could my learned friend not go back
12 in time and indeed deal with the contents of the
13 relative counselling record which is 090-028-088
14 and use the contents of that now for a discussion
15 about any discussion between nurses after the
16 death, but in particular we would invite my
17 learned friend to ask Mrs Ramsay about the
18 contents of that document and whether there are
19 any similar records that are to be found in PICU
20 because during the day there must have been a
21 constant attendance by the parents and at least
22 one consultant in PICU at all times, whether that
23 was Dr McKaigue, Dr Taylor or indeed anybody
24 else, because these documents would form the
25 basis, surely, for any audit or discussion later

1 between nursing staff and clinicians.

2 MR REID: I think you have said, Mrs Ramsay, already
3 that the relative counselling record is the only
4 sheet that the inquiry or you have seen that
5 solely concerns communications with the family;
6 would that be fair to say?

7 A. Yes.

8 Q. Picking up with Mr Fortune's point that there may
9 have been some sort of constant communication
10 between the nursing staff in PICU and Claire's
11 parents throughout 23rd October would you expect
12 any record of that to have been taken in October
13 1996?

14 A. Where specific information had been imparted then
15 good practice would be that you would make a note
16 of that, but I do not think -- I wouldn't have
17 expected a sort of verbatim record of -- so --

18 THE CHAIRMAN: Surely that depends on the
19 circumstances in which you move into PICU? If
20 you are, let us suppose we have child who is
21 terribly injured in a car accident and that child
22 is taken into PICU and that is the point of the
23 treatment starting, then you would expect or
24 sorry would you expect then that the PICU record
25 would show discussions with the parents about

1 what the state of the child's health was, how
2 much at risk she was of dying and things of that
3 nature? I am asking for a contrast because in
4 this case when Claire went to PICU and her
5 parents were there and called to the hospital in
6 the early hours of the Wednesday morning they
7 were in effect told at that point that there was
8 nothing more that could be done. There wasn't
9 revealing(?) then was for the brainstem tests,
10 but there was no updating to be done or no, "We
11 will come back to you and tell you in a few hours
12 if there is a change in condition or see how she
13 responds to treatment". In fact when they
14 arrived in PICU they were told that Claire was in
15 real terms "dead"; is that not right? There is
16 not in fact the extant of any exchanges which a
17 parent has with the consultant or nurses in PICU?
18 A. I am not sure that I am fully understanding the
19 question in order to give a response.
20 THE CHAIRMAN: Yes, I am sorry. I understood the
21 intervention from the floor from Mr Fortune who
22 represented Dr Steen was to the affect that the
23 record that you have now in front of you is the
24 only record we have of discussions with Mr and Mr
25 Roberts through the, although it is dated 22nd it

1 is actually 23rd October, okay, and he was
2 raising a query about whether there might have
3 also been discussions in PICU with the consultant
4 in PICU or with the nurses in PICU, right,
5 because there do not appear to be any records of
6 such discussions?

7 A. Well, a record to show that the parents had been
8 spoken to by consultants I think most of the
9 information because it is very negative would
10 have had to have been imparted by a doctor and
11 then reinforced or nurses explaining things. So,
12 yes, some sort of record of what their
13 understanding was, although it says here that
14 they understand the explanation. There were
15 several hours, were there not, after she was
16 admitted and so their state at the time possibly
17 to have written that down, so there is not a lot
18 of detail there or any detail. So, yes, it would
19 have been good practice to have written some more
20 of it.

21 THE CHAIRMAN: Okay and when you say good practice to
22 have written more of it, is that in these
23 relative counselling notes or in PICU or both?

24 A. In the -- well, the relative counselling notes
25 that's from PICU, isn't it?

1 THE CHAIRMAN: It's not.

2 A. My understanding was that I thought that was an
3 attachment to the intensive care documents.
4 There should have been both because intensive
5 care was a totally separate environment with
6 totally separate records and the people looking
7 after her there, needed to keep their own ongoing
8 account of what happened during the day.

9 THE CHAIRMAN: Okay, Mr Quinn, could I ask you, could
10 you find out from Mr and Mrs Roberts if they had
11 any discussions with the consultant in PICU as
12 opposed to Dr Steen and Dr Webb?

13 MR QUINN: Yes.

14 THE CHAIRMAN: Thank you very much.

15 MR QUINN: I have consulted with Dr McKaigue, in
16 relation to that issue and his evidence would be
17 that he had no communications at all with Mr and
18 Mrs Roberts.

19 THE CHAIRMAN: Okay, sorry, Mr Ferguson, just --

20 MR QUINN: We will find out.

21 THE CHAIRMAN: Yes, if you found out, but just --

22 MR QUINN: My recollection, from my instructions, are
23 that they at least spoke to Drs Webb and Steen.

24 THE CHAIRMAN: Yes, just Mr Ferguson is going to ask
25 in case -- did you hear that Mr Ferguson?

1 MR FERGUSON: Yes.

2 THE CHAIRMAN: Thank you.

3 MR REID: Okay. I also seek guidance from Mr Fortune
4 as to whether he is making the point that the
5 note is part of the other(?) notes, or whether he
6 is saying that these occurrences actually
7 happened on the ward rather than in PICU.

8 (Pause)

9 MR FORTUNE: I'm not quite sure who goes first, but so
10 far as this note is concerned it is part of the
11 PICU records and clearly the entries were made at
12 a time when Claire was in PICU. What we have
13 asked is whether there are any other records
14 similar in nature, however described, that relate
15 to discussions between Mr and Mrs Roberts and any
16 other consultant during the course of the time
17 that Claire was in PICU.

18 THE CHAIRMAN: Okay, so this note that we have of the
19 relative counselling record is part of the PICU
20 record, as you understand it?

21 MR FORTUNE: Apparently so, sir.

22 THE CHAIRMAN: Okay, that's fine.

23 MR FORTUNE: As you look at the record it is clearly
24 an incomplete record on the right-hand side and
25 indeed it is difficult to work out whose writing

1 it is.

2 THE CHAIRMAN: Yes, okay.

3 MR QUINN: There was no other contact with any other
4 consultant other than Drs Webb and Steen.

5 THE CHAIRMAN: In a sense that's not unexpected
6 because of the state that Claire was in there is
7 in effect what the parents were being told
8 there's nothing more that could be done for her,
9 so it's the contrast between that situation and
10 the one I described of a child being brought into
11 PICU after a car crash where you do have direct
12 contact with the consultant?

13 MR QUINN: Yes.

14 THE CHAIRMAN: Okay, thank you.

15 MR REID: Can I just bring you, Mrs Ramsay, to
16 something in your report 231-002-033, please.
17 This is just about PICU and you write at that
18 section:

19 "The nursing care plan is of an appropriate
20 standard. There are records giving details of
21 the discussion between the doctors and Claire's
22 parents. I believe these are a satisfactory
23 record."

24 I think you've said perhaps would maybe have
25 liked a little bit more in the record; would that

1 be correct?

2 A. Yes, I'm sort of reflecting on what led me to say
3 this. The document we've just seen I saw in the
4 context of being a PICU record and I felt that
5 things had been described. What I can't recall
6 is whether throughout her stay in PICU there was
7 any record of discussions that nurses were having
8 with parents that maybe portrayed what
9 information had been given to them or what had
10 been said to them or what their fears and
11 anxieties were and I'm afraid I can't recall
12 that, but they would have been some expectations
13 that if there was a nurse looking after her,
14 which there would have been, and she was
15 interacting with the parents then there would be
16 some record to reflect that interaction.

17 Q. Would you expect that even if there wasn't a
18 sheet that had the purpose of recording that sort
19 of discussion?

20 A. Yes, yes.

21 Q. For example, would you have expected that in the
22 general PICU nursing notes?

23 A. Yes, because of the distress of the situation and
24 the fact that the parents would have been there
25 all the time and so it's just a part of the

1 totality of nursing care that you're looking
2 after the parents as well and so you would then
3 record some of that.

4 Q. If we can go back to the very first point of Mr
5 Fortune's intervention where he wanted me to put
6 some of the detail of 090-028-088 to you. I
7 think you said already that only in a definite
8 iatrogenic case that you would have considered an
9 order for discussion usual in October 1996. We
10 can see from this chart, and I'm not going to go
11 through everything, but there was an explanation
12 that Claire had swelling of the brain and could
13 possibly be brain dead and then the third
14 paragraph the brainstem tests showed Claire's
15 brain had died and that her brain had swollen and
16 when it was asked why the brain had swollen it
17 was explained that it was probably caused by a
18 virus. In those circumstances would you have
19 expected any sort of audit or discussion with
20 nurses?

21 A. No, because from a nursing perspective it would
22 have been assumed that she has just died of an
23 illness.

24 Q. You said that it was unusual that a child would
25 have died on a general ward and it wouldn't be a

1 usual occurrence anyway in October 1996. If
2 you're the ward sister of that ward and a child
3 died what would you expect of them following that
4 death?

5 A. Well, as the ward sister, if I hadn't been there
6 I would have expected somebody to have told me
7 when I got back and informed me of the
8 circumstances, and possibly if I'd understood
9 that if somebody had portrayed to me that a child
10 had been admitted and then died, but hadn't gone
11 on to say that there were thought to have been
12 any contributing factors to that, then I would
13 probably have just accepted that and left it.

14 Q. You might have gone back to the ward and found
15 out a child had died and maybe taken a nurse
16 aside and just asked what happened in that case?

17 A. Yes, you would hope or you would expect people to
18 give you some sort of feedback, and also having a
19 child die is a traumatic event for the people
20 caring for them and so you would want to pick up
21 on that and what the impact on people had been of
22 having had a child die.

23 THE CHAIRMAN: Can I ask you, that's what the ward
24 sister would do with the staff nurses?

25 A. Yes.

1 THE CHAIRMAN: Would you expect the ward sister to
2 make any inquiries of the doctors?

3 A. At the time?

4 THE CHAIRMAN: Yes.

5 A. No.

6 THE CHAIRMAN: No. Okay.

7 MR REID: Mr Chairman, I have nothing further for Mrs
8 Ramsay at present. Perhaps if we take a small --

9 MR QUINN: This may short circuit events rather than
10 canvass questions. There is just one issue that
11 I wanted to raise. If we could have up document
12 231-002-032 which is page 31 of Mrs Ramsay's
13 report. I just want to read out for the record
14 the penultimate paragraph on that page reads:

15 "Nurses should have ensured the parents
16 understood that the diagnosis, its implications
17 and treatment needed. They should have explained
18 the medicines, what they were used for and any
19 potential side effects. The parents should have
20 been told while the observations were being made
21 and given explanations on the ongoing process."

22 Could then go up the transcript from 31st
23 October, which is Mrs Roberts' evidence, and go
24 to page 128 of the transcript of the 31st and
25 then look at what Mrs Roberts has said and I

1 would like, through yourself, Mr Chairman, if the
2 witness could be asked about this so that it's
3 rounded up and on the record and I will read out
4 what Mrs Roberts' evidence is in relation to her
5 leaving at 9.15. She said --

6 MR FORTUNE: Can we have the documents up side by
7 side, Mr Quinn?

8 MR QUINN: Yes, we can do. I am going to put up the
9 next page as well, Mr Fortune, which is page 129,
10 so if those three pages can be put up together
11 and what Mrs Roberts has said is that:

12 "Obviously then around 9.15 explaining to the
13 boys that we'll have to get home and Claire is
14 sleeping; that is her settled. So we get
15 ourselves sorted and Alan and the boys go back
16 and I go up into the nurses' station. I can just
17 visualise popping my head in and saying, 'Nurses,
18 that's us away for the evening. Claire seems to
19 be settled and sleeping. I still have a picture
20 of Claire waking up and jumping out of bed', and
21 they just said that, as long as the bed sides are
22 up all very quickly, she'll be okay and between
23 the general chat, goodnight, a phone call came
24 through and I was handed the phone and it was my
25 cousin from Scotland who was a nurse herself and

1 a mother, but she had heard about Claire through
2 my auntie that day. Her mummy lives beside us
3 and I again said, 'Och, Claire is fine.
4 She's just had an unsettling few days and seems
5 to be sleeping and Alan and I and the boys are
6 going home'. 'Did the nurses say anything to
7 you?' Mrs Roberts, 'Not one thing. Just okay,
8 Mrs Roberts or just, okay, see you on the
9 morning'".

10 In the context of that exchange and what the
11 witness has said at page 31, the penultimate
12 paragraph, is that enough information to be
13 giving when parents are going home? I am asking
14 that through the tribunal?

15 MR REID: It's page 32, if that can be brought up.

16 THE CHAIRMAN: The discussion we've been having, Mrs
17 Ramsay, which has been taken up with you, is what
18 the nurses have said before the Roberts left,
19 particularly with Mrs Roberts going over
20 specifically to say that she was leaving and to
21 watch out for the bedside. Do I read the
22 highlighted paragraph on the right-hand side of
23 the screen as meaning well, although this is all
24 very unfortunate really the nurses should have
25 done more?

1 A. Well, the parents appear to have known very
2 little which suggests to me that there wasn't an
3 ongoing dialogue, as I've described here, whereby
4 nurses were giving them information and checking
5 up on their understanding. And it is my view
6 that, if you are caring for a patient with the
7 parents sitting there, you talk through the
8 things that you're doing and why you're doing
9 them and ensure they've got the understanding.
10 So, I think that that situation wouldn't have
11 just happened at 9.00 pm. It would have been an
12 ongoing issue throughout the whole of her time
13 there. The bit that does occur to me is who were
14 the people to whom Mrs Roberts said they were
15 going? Were they people who had been looking
16 after her during the day who hadn't gone off
17 duty, or were they people who had just on duty
18 and so might not be fully appreciative of what
19 was going on.

20 MR QUINN: The evidence on that, sir, would be and I
21 may stand contradicted on this, was that we seem
22 to have pinned that down to the nursing handover
23 when there were perhaps two or maybe three nurses
24 at the handover. So you may have had staff from
25 -- and the nurses have identified this -- you may

1 have one person giving the handover to two other
2 nurses coming on seems to be what the consensus
3 of opinion was in relation to that, and I'm just
4 rather concerned at someone saying, "Och,
5 Claire's had a few unsettled days" doesn't really
6 translate anything and the nurses should have
7 picked up and said to them, "Hold on a minute,
8 it's not just a few unsettled days. Here's the
9 picture. That's what we're concerned about".

10 THE CHAIRMAN: It's the nurses who are on, and we know
11 from 310-016-001 that the nurses who were on from
12 8.00 pm were nurses McCann, Murphy and Maxwell.
13 They had come on at 8.00 pm for the nightshift,
14 having taken over from nurses Ellison and Taylor
15 who were there from 2.00 until 8.00 pm, is that?

16 MR REID: Yes, that's correct.

17 THE CHAIRMAN: Having in turn taken on, so there's a
18 series of nurses through the day. So if the
19 nurses who were on duty at 9.00 pm, when the
20 Roberts were leaving, didn't know how serious
21 Claire's condition was then they may not have
22 been properly informed at an adequate handover at
23 8.00 pm?

24 A. Yes.

25 THE CHAIRMAN: Yes, but I mean there's also a general

1 point about the extent of which anybody was
2 really on top of what Claire's condition was?

3 A. Yes.

4 THE CHAIRMAN: We've heard evidence from Professor
5 Neville on that over the last few days, yes.

6 Okay, look you want to --

7 MR REID: Check if there are other questions, Mr
8 Chairman.

9 THE CHAIRMAN: Yes, I am going to rise in a few
10 moments. Mr Reid will check whether there are
11 any more questions from the floor to rounded up
12 and ask you, but just before I do, can I ask you
13 about one thing which has, maybe this would be
14 common knowledge to you from your experience over
15 many years in nursing, but one of the things
16 which has emerged from this hearing is that on
17 Monday night into Tuesday and Tuesday night into
18 Wednesday in the Children's Hospital in Belfast
19 there was a registrar and the senior house
20 officer with responsibility for the children who
21 were already in the hospital which would be about
22 114 or so and responsibility then for patients
23 coming into A&E, children coming into A&E to be
24 seen. Does that level of medical cover shock you
25 or is that just that's what happened in the mid-

1 1990s?

2 A. Yes, I thought that that seemed to be a low
3 level; well, a very low level actually.

4 THE CHAIRMAN: The doctor who told us a day or two
5 ago, Dr Stewart, I think said he was overwhelmed
6 by the amount of work he had to do through a
7 night and he was the SHO on this evening.

8 A. Yes, I was surprised when I read that the number
9 of patients that he'd had responsibility for,
10 because you can sometimes have a situation where
11 there's a resident registrar and a junior doctor
12 who pick up on things that have happened where
13 somebody else isn't available to deal with them,
14 but to have somebody having to rush around all
15 those patients I thought the number seemed very
16 low and I had been trying to think back in my
17 days when I was a manager for a similar situation
18 and I think there would have been more housemen
19 about and possibly one registrar resident
20 available and then registrars on call at home.

21 THE CHAIRMAN: We're told now that there are fewer
22 patients, but that there are three registrars. I
23 think it was Dr Bartholome who said that there
24 are now three registrars for about 90 children
25 overnight and A&E which is clearly much better

1 than one registrar and one houseman for
2 everybody?

3 A. Yes and the other thing that's changed over the
4 years is that the role of the night sister has
5 changed and so a lot of hospitals now have nurse
6 practitioners on at night working in a team with
7 a couple of doctors and between them they deal
8 with the issues throughout the hospital because
9 the nurses would be putting up drips and nurses
10 would be making assessments of patients. So
11 there has been a general drift towards having
12 more people available at night.

13 THE CHAIRMAN: Okay, thank you.

14 MR FORTUNE: Before we leave that can be take Mrs
15 Ramsay back to 1996, and to a reminder to her
16 that this is not just a district general
17 hospital, but the regional centre for treatment
18 here in the province. Are you saying that you
19 would have expected there to have been two
20 registrars and two senior house officers? You
21 talk about a resident registrar.

22 A. What I'm saying is that I think there should have
23 been more people onsite because although it
24 wasn't a standalone children's hospital, it was a
25 hospital within a hospital, but the other people,

1 the adult people, wouldn't have come in to
2 support the children's service, I wouldn't have
3 thought, and it does sound to me as though two, a
4 resident registrar and a resident houseman,
5 seemed to be a very thin covering of people for
6 the number of children that were in that
7 hospital; part of the hospital.

8 THE CHAIRMAN: I picked Mrs Ramsay up as saying
9 possibly a second registrar, but definitely more
10 house officers?

11 A. Yes, yes.

12 MR FORTUNE: This sounds as though we're about to move
13 into governance?

14 THE CHAIRMAN: It is, but Mrs Ramsay is here and I
15 just wanted to get her view on this, but this
16 will certainly go into governance. Mr McAlinden?

17 MR MCALINDEN: Mr Chairman, just in relation to the
18 number of SHOs present in the hospital, I think
19 we may have lost sight of the fact that there was
20 a surgical SHO as well as a medical SHO in the
21 children's hospital and there also was an SHO
22 assigned to the Accident and Emergency
23 Department.

24 THE CHAIRMAN: Are you saying three SHOs?

25 MR MCALINDEN: Yes, there definitely was a surgical

1 SHO and a medical SHO and an A&E SHO.

2 MR REID: Can I ask Mr McAlinden whether the surgical
3 SHO was present after 10.00 pm because according
4 to the rota that we have of the night it seems
5 there was a medical SHO between 5.00 and 10.00,
6 surgical SHO between 5.00 and 10.00 and then what
7 was deemed to be the overnight SHO and that was
8 Dr Stewart. From that rota it only seems that
9 the surgical SHO clocked off at 10.00 pm?

10 MR MCALINDEN: My recollection of Dr Stewart's
11 evidence is that he would not have been dealing
12 with surgical patients. That he would have been
13 dealing solely with medical patients and I will
14 take specific instructions, but my impression is
15 that there was a surgical SHO, a medical SHO and
16 one present in the Accident and Emergency
17 Department.

18 THE CHAIRMAN: Okay, well, maybe we'll definitely pick
19 it up at governance.

20 MR FORTUNE: It may also, sir, have been this
21 situation; registrar, second term SHO and first
22 term SHO. Does that make a difference if that was
23 the case?

24 A. I really don't think that I --

25 THE CHAIRMAN: Yes, it's an extra body at least, yes.

1 MR FORTUNE: It is an extra body, but of course you've
2 got to bear in mind the relative experience or
3 inexperience of a first term SHO.

4 THE CHAIRMAN: Yes, okay, are there more questions for
5 anyone to pick up or can we let Mrs Ramsay go?

6 MR REID: Mr Chairman, I do believe Ms Anyadike-Danes
7 is behind the scenes and may have a question or
8 two for Mrs Ramsay, so I would just like to check
9 with her --

10 THE CHAIRMAN: We will come back in five minutes and
11 we'll get lunch at about 1.15 pm. Thank you.

12 (1.04 pm)

13 (A short break)

14 (1.08 pm)

15 [inaudible: no microphone]

16 THE CHAIRMAN: Right. Mrs Ramsay, now that your
17 evidence has finished, thank you very much for
18 your time and you're free to leave.

19 A. Thank you. Thank you.

20 (The witness withdrew)

21 THE CHAIRMAN: We'll start at 2.10 pm, okay?

22 DAVID REID: Thank you, Mr Chairman.

23 (1.08 pm)

24 (The short adjournment)

25 (2.03 pm)

1 THE CHAIRMAN: Ms Danes.

2 MS ANYADIKE-DANES: Thank you very much. I wonder if

3 I could call Dr Aronson, please.

4 DR JEFFREY ARONSON (called)

5 Questions from MS ANYADIKE-DANES

6 THE WITNESS: I am Jeff Aronson.

7 THE CHAIRMAN: Have a seat, please, Doctor. Thank

8 you.

9 MS ANYADIKE-DANES: Thank you very much indeed. Dr

10 Aronson, can I ask you, do you have your

11 curriculum vitae there?

12 MR ARONSON: Not in front of me.

13 Q. I think we'll get you a copy then. I wonder, Mr

14 Chairman, if I could confirm whether everybody

15 else has a copy of Professor Aronson's curriculum

16 vitae? Thank you.

17 THE CHAIRMAN: Everybody but the author.

18 MS ANYADIKE-DANES: Yes.

19 A. It is imprinted on my mind. Okay.

20 Q. Here it comes now.

21 A. Thank you. Very useful, thank you very much.

22 Q. Before we turn to that, Dr Aronson, you have

23 provided one report for the inquiry, is that

24 correct?

25 A. That's right.

1 Q. That report starts at reference 237002001 -- not
2 to be pulled up, but that's its reference -- and
3 you provided a number of publications with it.
4 It's dated June and July of this year, is that
5 correct?

6 A. That is correct.

7 Q. Do you adopt that report, subject to anything
8 that you may say in oral hearing? Do you adopt
9 that report as your evidence?

10 A. I do.

11 Q. Thank you. Then I wonder if we could turn to
12 your curriculum vitae and we can see at --
13 perhaps we might pull this up -- 311035002,
14 that's the first page of it, and your current
15 appointment is as a reader in clinical
16 pharmacology.

17 A. Correct.

18 Q. That is at Oxford University, and you are also an
19 honorary consultant in clinical pharmacology and
20 an honorary consultant physician at the Oxford
21 University Hospital. Could you, just for the
22 laypeople, explain briefly the discipline of
23 clinical pharmacology?

24 A. It's a discipline that bridges between basic
25 pharmacology, which is the study of how drugs

1 work, what they do, often in cells or whole
2 animals on the one hand, and the actions and uses
3 of drugs in people on the other, encompassing
4 such matters as how the drug works; what
5 indications to use it for; how to determine doses
6 and dosage regimens; how to administer it, in
7 what forms and over what periods of time; what
8 adverse effects and reactions may occur; what
9 interactions with other drugs and extending also
10 to policy of use, drug regulation, cost-
11 effectiveness, advice and indeed anything to do
12 with medications.

13 Q. Thank you very much. When you say that you are
14 also an honorary consultant, does that mean you
15 have any clinical work at all, you attend the
16 ward?

17 A. Yes, yes. I have been a consultant physician now
18 for the last 30 years or so, specialising -- if
19 it is a specialty -- in what is called general
20 internal medicine, in addition to my more focused
21 speciality of clinical pharmacology.

22 General internal medicine involves the
23 management of patients who present to hospital
24 with a wide range of medical conditions, indeed
25 virtually anything that does not have surgical

1 intervention indicated, so cardiovascular
2 disease, such as heart attacks, cardiac
3 arrhythmias, respiratory disease such as
4 pneumonias and bronchitis, nervous system
5 disorders such as strokes, epilepsy, migraine --
6 the whole range -- gastrointestinal disorders
7 such as bleeding from the gut, inflammatory bowel
8 disease, the whole -- a very wide range of
9 general medical conditions, and I deal with them
10 in one of three ways. One is either to deal with
11 them myself if the case is sufficiently simple
12 for a general physician to handle or I deal with
13 it in collaboration with the specialist
14 consultant, whom I may -- whose advice I may ask,
15 or in the third case, I may hand over the care
16 completely to a specialist. There is a wide
17 range of problems to deal with.

18 Q. But in the light of your work as a general
19 physician in terms of internal medicine, are you
20 therefore also looking at the prescription
21 calculation and administration of drugs in
22 relation to some of those conditions?

23 A. Indeed. That is my main interest, if you like,
24 in the conditions. Although I am responsible for
25 taking care of a patient from history-taking,

1 examination, investigation, diagnosis and
2 management, my main specialty is in -- at the
3 management end and the monitoring end of therapy
4 rather than in the preliminary phases of the
5 whole management process.

6 Q. I understand. If we just go over that page to
7 003, it would seem that you first became a
8 consultant in 1980, would that be right, or
9 thereabouts?

10 A. That's right, yes.

11 Q. If we stay with that page and look at your
12 research interests and publications, we see that
13 you are a guest editor or were a guest editor of
14 the British Medical Journal, the issue on
15 Balancing Benefits and Harms in Healthcare, and
16 also the British Journal of Clinical
17 Pharmacology, and in relation to that in the
18 December 2004 Clinical Pharmacology: Past,
19 Present and Future, and that was dated 2006.
20 Then it goes on to deal with adverse drug
21 reactions, and that was February 2007, and
22 medication errors in June 2009. Before I go to
23 where you are editor-in-chief in relation to
24 other publications, because of when you became a
25 consultant, how familiar would you be with the

1 practices in 1996?

2 A. Well, I was a consultant from 1980 and in the
3 1990s -- 1996 specifically -- I was a busy ontake
4 physician on call, in those days one month in
5 three, taking sick patients, anything from 20 to
6 40 patients at a take 6 or 8 times a month. So
7 that would have been my experience at that time.

8 Q. Then if we go on down that list, where we see
9 that you are the co-editor-in-chief on the
10 Meyler's Side Effects of Drugs, and that is the
11 14th edition of that, and then you go on to be
12 the editor of the Side Effects of Drugs: the
13 International Encyclopaedia of Adverse Drug
14 Reactions and Interactions. Is that a particular
15 interest of yours?

16 A. It is. Well, in fact, at the moment we are
17 heavily involved in preparing the 16th edition,
18 which involves taking the 6-volume 15th edition
19 and adding material that has accrued in the
20 annual volumes, which are published every year
21 over the last ... last 5 years, so there is an
22 extra 5 volumes' worth, 5 years' worth of
23 material to be incorporated into the 15th
24 edition, and that's a major task in which we're
25 involved at the moment.

1 Q. Then to refer back to the point that you were
2 making about 1996, if we go over the page again,
3 we see that you were involved in the Adverse Drug
4 Reactions Bulletin for 1996, and that seems to be
5 continuing, so that's to present day?

6 A. Yes. Yes, in fact, I was having dinner with the
7 editor of the Adverse Drug Reactions Bulletin
8 only last week and talking about planning future
9 editions.

10 Q. Then in terms of your membership of committees
11 and learned societies, you are President Emeritus
12 of the British Pharmacological Society, and
13 that's 2010, and is that a position you hold
14 currently?

15 A. Yes. Well, it merely means that I was president,
16 so it's --

17 Q. You hold on as an honorary position, if I can put
18 it that way?

19 A. Yes.

20 Q. Yes, and then you're a member of the Advisory
21 Board of the British National Formulary --

22 A. Yeah.

23 Q. -- and that's something you're currently a member
24 of?

25 A. Yes. I was for some time a member of the Joint

1 Formulary Committees of both the British National
2 Formulary and the British National Formulary for
3 Children, and when I stepped down from those
4 committees, I was appointed a member of the
5 Advisory Board for the BN -- the British National
6 Formularies.

7 Q. You also were until, I think it is, 2010 a member
8 of the Advisory Board of the National Patient
9 Safety Agency.

10 A. That's right.

11 Q. With specific reference to medications.

12 A. Yes.

13 Q. Then in terms of the university, you're the
14 Associate Member of the Department of
15 Pharmacology, and I think that's a position you
16 still hold.

17 A. Yes.

18 Q. You have been Head of Department of Clinical
19 Pharmacology?

20 A. Correct.

21 Q. Then just finally to deal with your membership of
22 academic societies, that's to be found at 005.
23 You're a Fellow of the British Pharmacological
24 Society 2004, and then as you have said before,
25 you have been President and now currently

1 President Emeritus, and a Fellow of the Royal
2 College of Physicians, and you still are.

3 A. Yes.

4 Q. Then just finally in terms of teaching, which we
5 find at 006, you've engaged in undergraduate and
6 post-graduate teaching activities and that
7 includes lectures on drug therapy to clinical
8 students and also bedside and seminar-teaching on
9 drug therapy and clinical medicine to clinical
10 students and so forth, and also at weekly grand
11 rounds, and it says, "student grand rounds".

12 What are student grand rounds?

13 A. Well, the grand round is a meeting at which all
14 the physicians in the hospital meet to discuss
15 cases of interest to help diagnose, to learn, an
16 educative meeting, and it's held once a week.
17 Usually two or three cases are presented. A few
18 years ago, the Medical School decided to
19 institute a similar meeting for the students,
20 which is run in exactly the same way, but by the
21 students, and so instead of all the physicians
22 meeting, all the students meet, they present
23 cases and discuss them.

24 And each time a grand round is held, a senior
25 member of the hospital is invited to come along

1 to comment on the case, and I found that actually
2 a very useful way of teaching clinical
3 pharmacology and therapeutics to the students, to
4 go along to their grand round and comment,
5 because every case, whatever it is, in whatever
6 specialty, medicines are almost always involved,
7 and so this was a good opportunity for teaching.
8 And the student grand rounds actually are of a
9 very high standard. The students take great care
10 and they spend a lot of time preparing their case
11 presentations, and they are very educative for
12 seniors as well as the students.

13 Q. And to bring a multi-disciplinary approach to
14 particular cases?

15 A. Indeed.

16 Q. Is this something that's unique to your
17 university, or are you aware of it happening at
18 other universities?

19 A. I don't know. Students have meetings and
20 educative meetings everywhere. I don't know if
21 the grand round idea has been taken up elsewhere.

22 THE CHAIRMAN: Just before you move on, when did the
23 weekly grand rounds start in terms of how many
24 years ago?

25 A. Sorry?

1 THE CHAIRMAN: For how many years have you been doing
2 weekly grand rounds?

3 A. Oh, since I came to Oxford, 1973.

4 THE CHAIRMAN: Thank you.

5 MS ANYADIKE-DANES: It says on the final page of your
6 CV, before it goes into your publications list,
7 that your current research interests are:

8 "Methods of classifying, detecting and
9 reporting adverse drug reactions, including
10 systematic reviews, meta-analysis and the use of
11 anecdotal reports in collaboration with others."

12 A. Yes.

13 Q. So that's what you're engaged in at the moment?

14 A. That's what my main research is currently. I do
15 take part in other activities. We've just
16 published, for example, the results of a large
17 clinical trial in Sri Lanka on the prevention of
18 adverse reactions to anti-snake venom, for
19 example, with my colleagues there. And I am also
20 currently working with other members of my
21 department in Oxford, which is the Department of
22 Primary Care Health Sciences, on outcomes of
23 treating diabetes, for example. So there are
24 other interests, but my main research focus is on
25 adverse drug reactions.

1 Q. Thank you. I wonder if we can now move to this
2 case specifically, and if you can help us at the
3 outset with some of the drug administration
4 terminology, if I can put it that way, and the
5 first is as we look through the clinical notes
6 and also the drug prescriptions, we see, for
7 example, references to a "stat dose". What is a
8 stat dose?

9 A. "Stat" is a term that doctors use, short for the
10 Latin word "statim" which means "immediately".

11 Q. Immediately?

12 A. Immediately, forthwith. If I say, "Give this
13 drug stat" -- it's not a term I often use, but it
14 is used -- then I mean, "Give it now. Don't hang
15 about, give it straight away or as soon as you
16 can".

17 Q. Perhaps if we use an example, and we can see what
18 "forthwith" might mean in those circumstances.
19 The direction in the clinical notes and records
20 in relation to phenytoin, and one finds that from
21 Dr Webb at 090, 022, 054 -- this is just for the
22 sake of making sure we have understood what you
23 said -- and if you see his suggestions, the first
24 of those is starting, "IV phenytoin 18 milligrams
25 per kilo stat" and then it's going to be followed

1 by a subsequent infusion, but if we just leave
2 with that. So that is a direction that he makes,
3 having seen Claire. It's not entirely clear when
4 he is writing that. It's recorded at 1400 --
5 well, it is known to be 2.00 pm on the Tuesday,
6 but presumably he would have spent some time
7 actually examining the child, so we're not quite
8 sure what the 2.00 pm relates to. So we have
9 that piece of information.

10 We also know that it was administered at
11 14.45, so depending on what the 1400 hours
12 relates to, there's a period of something up to
13 45 minutes before it's actually administered.
14 Does stat encompass that?

15 A. Yes, I would that is "stat-ish". How soon is
16 soon?

17 Q. Yes.

18 A. Forty-five minutes, perhaps a little on the long
19 side, but not unreasonable. It takes time for
20 communication of instructions, for drugs to be
21 found, for solutions to be made up, for
22 arrangements to be made to deliver the dose and
23 so on. Yes, that's not unreasonable.

24 Q. And if the 2 o'clock had been when he actually
25 came to see the child, then there'll be a period

1 of time when he was examining the child and so on
2 before that direction or suggestion would have
3 gone out?

4 A. Indeed.

5 Q. So that's that. What about a "loading dose"?
6 What is that?

7 A. If you give a dose of a drug at regular
8 intervals, it takes time for the drug to build up
9 in the body to a therapeutic amount. If you
10 remember the old mathematical problems --

11 Q. Sorry, by "therapeutic amount", do you mean an
12 amount to be effective?

13 A. An amount to be beneficially effective.

14 Q. Yes.

15 A. If you remember the old mathematical problems
16 that many of us were given at school, you turn on
17 the tap in a bath and the tap runs at 1 litre per
18 minute and the drain drains the bath at 100
19 millilitres per minute. How long does it take
20 for the bath to fill? Well, if the bath is a
21 litre big, then it is going to take at least ten
22 minutes, because you're running it at 100
23 millilitres per minute, but you're also losing
24 fluid at the same time, so it's going to take
25 longer. In other words, it's going to take time

1 before the amount of water in the bath actually
2 reaches the top and starts to overflow.

3 I don't want to wait for that. I want a bath
4 stat, so I pour a litre of fluid straight into
5 the bath. That's the loading dose. It fills the
6 bath up immediately. Now, I have left the drain
7 open because I don't have a plug, so I will lose
8 fluid all the time, so I leave the tap on just to
9 top it up. That's the maintenance dose. So the
10 loading dose is filling up the system, the
11 maintenance dose is replacing losses as they
12 occur. I can do that continuously by leaving the
13 tap turned on or I can do it intermittently by
14 turning the tap on from time to time. Either
15 way, it's a maintenance dose, maintaining the
16 amount of drug, within limits.

17 Q. Yes. If you do it intermittently, depending on
18 how long it takes for the effectiveness of the
19 drug in the system to diminish, you can work out
20 whether you will have a fluctuating level --

21 A. Indeed.

22 Q. -- or whether you will have a continuous
23 effective amount.

24 A. That's correct, and the longer you leave between
25 maintenance doses, the more fluctuation there is

1 in the amount in the body. As you can see, you
2 will lose more of the fluid from the bath the
3 longer you wait, and you'll have to put more in.
4 So the ideal circumstance to maintain a constant
5 amount of water in the bath is to give a constant
6 infusion, leave the tap running. If the drug --
7 if the drain is very slowly draining, just a
8 trickle, then you can afford to wait and top it
9 up every so often.

10 So, for example, we're going to talk about
11 phenytoin, no doubt, phenytoin -- the drain for
12 phenytoin is very, very small. It's a trickle,
13 it disappears very slowly, so you only have to
14 put some in every so often. You don't have to
15 keep it infusing every minute or every hour. You
16 can wait 12 or 24 hours, but for a drug like
17 midazolam, the drain is quite big and it drains
18 quite quickly. It's much better to give a
19 continuous infusion to maintain the amount of
20 drug in the system, and that's exactly what you
21 see in the dosage regimens.

22 Q. And a "bolus", what is that?

23 A. Bolus, right. Well, bolus is the Latin word for
24 a ball and, for example, when you swallow, when
25 you're chewing your food, you form a ball of food

1 and it's called a bolus, and you swallow that
2 bolus. Over the back of the tongue, there is a
3 ball of food going down your gullet. An
4 embolism, pulmonary embolism, is a ball of clot
5 being flung into a pulmonary artery and blocking
6 it. So a bolus is a ball.

7 If I throw you a ball, I can throw it hard and
8 fast. If I inject a drug, I can inject hard and
9 fast. That's the bolus. It's the amount of drug
10 in the syringe that I'm injecting, as if I was
11 throwing you a ball. Now, I can throw the ball
12 up in the air very high and you might have to
13 wait a few seconds before you caught it, but
14 still it would happen quite quickly. So I can
15 give a bolus dose, zap, instantly, or over a few
16 seconds if I lob it in, as it were. That's a
17 bolus. It's done pretty much instantly.

18 Q. And is that the idea, because you want to have a
19 pretty quick reaction to that drug?

20 A. No, it's just easy to give it that way.

21 Generally there are very few, if any, drugs that
22 one wants to put in fast because you need to put
23 it in fast. There was one drug some years ago
24 for which that was a direction, and it's defunct.
25 One doesn't do it for the sake of speed, one does

1 it because it doesn't matter and get it in as
2 quickly as you like.

3 Q. Oh, I see. So it would be the other way round,
4 you'd have a contraindication to giving a drug
5 quickly?

6 A. That's right, so giving a drug slowly is because
7 you don't want to give it quickly. You don't
8 give it quickly because you don't want to give it
9 slowly, it's not that way round. So the
10 difficulty is for a drug that would cause adverse
11 reactions were you to give it quickly as a bolus
12 dose.

13 Q. So if you give it slowly, you can see what is
14 happening and adjust things if you're getting a
15 response that you don't particularly want?

16 A. It depends on the time course over which you give
17 the drug. Generally speaking, if you don't give
18 a bolus, you give it by what one can term loosely
19 as infusion, which means giving the drug
20 intravenously. We're talking all about
21 intravenous administration now, not other routes,
22 although you can infuse drugs in other ways, but
23 let's just stick to intravenous. By infusion, I
24 mean over some period of time. Most people by
25 infusion mean that you put it in bottle and let

1 the drug drip in but in-between that and a bolus
2 you can give a give a drug by syringe but slowly.
3 I would call that by slow injection rather than
4 infusion, just to distinguish it.

5 Q. Or a slow push? We've seen some of that in the
6 (overspeaking)

7 A. Yes. That's a term that's sometimes used. It
8 derives from American habits, slow push, but yes,
9 that describes what I am calling a slow injection
10 indeed and, of course, it's precisely what you're
11 doing. You're on the end of a syringe and you're
12 pushing the barrel of the syringe in so it's a
13 slow push. Usually you do that because you want
14 to avoid an adverse reaction.

15 There are some drugs, for example, if given
16 too quickly can cause release of histamine into
17 the system which causes your blood vessels to
18 dilate and your blood pressure to fall, a thing
19 called the Red Man Syndrome. You get vassal
20 delectation, blood vessels dilating, a lot of
21 blood comes to the skin, you turn red and your
22 blood pressure falls because the blood isn't
23 going elsewhere. You avoid that by giving the
24 drug slowly and there are other examples of that.

25 Q. Thank you.

1 A. But if you want to maintain an effect of a drug,
2 as I was describing before, a constant effect,
3 then that would be a reason for giving a drug
4 over a long period of time not because you're
5 worried about avoiding adverse reactions in this
6 case but because you want to maintain an action
7 for a long period of time and you, therefore,
8 give the drug by long infusion, slow infusion,
9 which then keeps the amount of drug in the body
10 up at a steady value.

11 Q. Keeping that amount at an effective level, a
12 therapeutic level, I think you said, is that
13 connected at all with the notion of a drug's half
14 life?

15 A. It is. The reason is that if you give a drug by
16 continuous infusion without giving a loading dose
17 it takes time to reach the steady state -- as I
18 described for filling the bath. You can
19 appreciate that the time it takes relates
20 primarily to the size of the drain. The faster
21 the fluid drains the longer it will take you to
22 get up to steady state while you're filling the
23 bath. So the time it takes during an infusion to
24 get to steady state when the amount of drug is
25 steady and at therapeutic level depends on the

1 half life of the drug. Conventionally, the
2 teaching is usually that it takes about four half
3 lives to reach a steady state.

4 So within one half life you reach half of
5 steady state, within two half lives you get
6 three-quarters of the way; that is 50 per cent
7 plus 25 per cent, a half of the difference. The
8 next half life you get another 12.5 per cent of
9 another half and so on. So after four half lives
10 you're at 93 per cent of the way to the maximum
11 and that's good enough. So with a drug that has
12 a long half life like phenytoin you want to give
13 a big loading dose to get you up to that value
14 and then maintain it because if you just give an
15 infusion or regular maintenance doses it'll take
16 four or five half lives and with a drug like
17 phenytoin that could be many days.

18 Q. In terms of the effects of combinations of drugs
19 is that is also influenced by whether those drugs
20 are at their therapeutic level, if I can put it
21 that way, or their half life?

22 A. Perhaps just to finish the story about half life
23 before I answer your question -- when you stop
24 giving a drug it disappears with a half life and
25 half of the drug in the body will disappear in

1 one half life so that half of the effect that you
2 have will disappear. It's not quite as simple as
3 that because the effect, concentration effect
4 relationship, is in fact logarithmic rather than
5 linear but you can see that if you're losing a
6 drug quickly you will lose its effect quickly.
7 If you're losing it slowly you will lose the
8 effect slowly. That's the basic principle. How
9 much of the actual effect you lose is more
10 difficult to calculate because of the logarithmic
11 nature of the effect concentration relationship
12 but the basic principle is that the half life
13 determines how soon the effect dissipates.

14 Q. Before I ask you then to answer the combination
15 question, if we stick with single drugs, apart
16 from just the chemical compounds of the drug and
17 the known research about what its therapeutic
18 levels are and what its half life is and so
19 forth, are there individual things in the
20 patients that affect the length of time the drug
21 remains at a therapeutic level?

22 A. Yes. Firstly, there is natural inter-individual
23 variation. We're all different. We're different
24 sizes, different weights, different ethnic
25 origins, different sexes; all of these things

1 cause variability in the individual response to a
2 single dose. If I gave everybody in this room
3 the same dose of drug and measure the plasma
4 concentration at the same time after that dose
5 they will be widely different. So there is
6 individual variation just because of the way we
7 are different from each other naturally. In
8 addition to that people who have impaired kidney
9 function or who have impaired liver function may
10 not clear the drug as quickly as somebody else.

11 So the size of the drain in these cases -- if
12 you have kidney failure, your drain is smaller,
13 you don't get rid of the drug as quickly as you
14 should and the drug will take longer to build up
15 and longer to disappear. Similarly for drugs
16 that are cleared by the liver, which many drugs
17 are -- impaired liver function. There are many
18 other susceptibility factors which alter people's
19 responses to drugs, how many receptors you have
20 for a particular drug. The receptor is a protein
21 usually in the tissue to which the drug binds and
22 on which it acts to produce its effect or it
23 might be an enzyme or a transport protein or some
24 mechanism, some intrinsic moiety in the body
25 which the drug targets for its mode of action.

1 So everybody may have different numbers of
2 receptors, different amounts of enzyme, genetic
3 differences play a part. Many different factors
4 lead to huge variability in the population.

5 Q. But what you're trying to do, I presume, is to
6 tailor the drug and its effects, therapeutic
7 effects, to the individual patient that you're
8 treating?

9 A. Ideally.

10 Q. So if that's what you're trying to do and there
11 can be these variations and you really can only
12 know what's going on, I presume, by testing. The
13 way that you said if you were to test us all,
14 even having given us the same drug, we would have
15 different concentrations of that drug if you were
16 to test our blood.

17 How important is it when you are embarking on
18 quite an extensive drug therapy to be testing the
19 child or the patient, as it may be, to see
20 exactly what is happening?

21 A. People are nowadays calling this personalised
22 medicine. I prefer to think of it as
23 individualising therapy. For every patient one
24 tries to choose a dose and a dosage regimen, in
25 other words the size of the dose, 100 milligrams,

1 say, and the frequency with which it's
2 administered, the route of administration, the
3 duration of therapy, the formulation that you
4 choose. One tries to choose these in order to
5 maximise the benefit to the patient and minimise
6 the harm or risk of harm.

7 This individualisation is actually quite
8 difficult because in many cases there are not
9 good ways of determining how effective a drug has
10 been. Ideally you want to measure the outcome of
11 interest. If you have asthma then you might
12 count up the number of attacks of asthma you have
13 in a month or a year before and after the
14 treatment and see if it's altered. If you have
15 epilepsy you might count up the number of
16 seizures you have. You might even go so far as
17 to note the intensity of the seizure, did it last
18 five minutes, one minute, did it happen at night,
19 during the day, and so on. One might try to make
20 an assessment of the outcome of interest.

21 If on the other hand you have depression it's
22 very difficult to judge how well a drug has
23 worked. We all feel depressed from time to time.
24 How do you judge that you're better or worse? It
25 can be done but it's much more subjective and

1 difficult. So if you have objective measures
2 that you can record then that's the ideal way of
3 monitoring therapy.

4 Q. For the kind of drug therapy that was being
5 administered to Claire, what are the objective
6 measures for how effective that is being for her
7 condition?

8 A. Let's assume, just for the sake of discussion,
9 that she did indeed have non-convulsive status
10 epilepticus then it is very difficult because
11 measuring brain function in those circumstances
12 is hard. We're laying aside the question of
13 whether she had encephalitis which might have
14 altered her brain function or some other
15 condition that we don't understand. Let us just
16 assume that she has status epilepticus and we
17 want to monitor it. If she's having fits we can
18 see her fits and if she's not fitting then we can
19 count that as a success but this is a condition,
20 uncommon, non-fitting status, how do you measure
21 it? Well, I think the best way of doing that is
22 an electroencephalogram, an EEG, and you should
23 do it before treatment and then sometime after
24 treatment to see whether it has been modified by
25 the treatment. So that is a way of measuring the

1 outcome of interest. It's difficult. It's not
2 ideal because EEG, electroencephalography is not
3 a straightforward process, it's subject to a lot
4 of variability and interpretative difficulty but
5 experts in it are very good at that kind of thing
6 and they could, if it were in place, use that as
7 a test of judgment whether the drug had had an
8 effect.

9 Q. That would be so, would it not, even if you had a
10 combination of drugs which might otherwise be
11 rather difficult to work out the interactions
12 between them but if you're looking at an EEG,
13 which is monitoring the activity in the brain,
14 irrespective of that combination you would,
15 presumably, be able to see whether it was having
16 any marked effect on that?

17 A. If the end point of using all of these drugs was
18 a common end point then, yes, they would add up
19 and you could get an overall measure of the
20 effect of a combination of drugs such as was used
21 in this case.

22 Q. I understand.

23 A. Now if you don't have such an end point the next
24 thing to do is to use what I would call a
25 pharmacodynamic end point rather than a

1 therapeutic end point. So measuring the number
2 of fits is a therapeutic end point. That's what
3 the patient is interested in; am I going to have
4 a fit and can you stop me from having a fit?
5 That's the therapeutic end point.

6 If you can't measure the therapeutic end point
7 then you want to measure, if you can, some
8 pharmacological end point that relates to the
9 therapeutic end point. If the drug works, for
10 example, by altering sodium in the body, sodium
11 transport across cells or potassium or whatever,
12 you might want to measure, if you could, the
13 activity of that system. That's not for fits but
14 it's a measure of what the drug is acting on. In
15 this case you can't do that, there are no tests
16 of pharmacodynamic measurement.

17 To give you an example in diabetes; people
18 with diabetes measure their blood sugar. That's
19 not the therapeutic end point, people think it
20 is, but it's not. The therapeutic end point of
21 treating diabetes is to reduce the risk of damage
22 to the eyes, damage to the kidneys, that's the
23 long term outcome. We believe nowadays, although
24 the data are difficult to interpret, that
25 controlling the blood sugar leads to such an end

1 point but controlling the blood sugar from day to
2 day is a pharmacodynamic measure of the action of
3 insulin or other drugs. That's an example of a
4 pharmacodynamic end point which is related to the
5 end point of interest, prevention of the
6 complications of diabetes but is not the true end
7 point itself; it's a means to an end. But in
8 these cases you don't have such a measure.

9 Q. That's what I was going to ask you. But for
10 these particular drugs that were being
11 administered there isn't a way of looking at the
12 means to the end so does that mean that the only
13 reliable way of seeing how effective they were
14 was to have carried out an EEG?

15 A. I think so. There are other, however, indirect
16 ways of doing this which are commonly used. So
17 if you can't measure the therapeutic end point
18 and you can't measure the pharmacodynamic end
19 point the next best thing is to measure how much
20 drug is there because at least --

21 Q. In the system?

22 A. In the system.

23 Q. How do you do that?

24 A. So at least you can say, "At least I know now
25 that there's a certain amount there and I can

1 predict from what I know about the drug that that
2 amount should be associated with the likelihood
3 of a therapeutic benefit". Ideally, again, you
4 would want to measure the concentration at the
5 site of action, which is the brain in this case,
6 but you can't do that so the next best thing is
7 to measure the amount of drug in the blood, the
8 plasma or serum concentration.

9 Q. Is this the sort of reason why, for example, they
10 wanted to know what the phenytoin levels were?

11 A. That's correct.

12 This is not available for all drugs and in the
13 case of the drugs that Claire was given the only
14 one for which it is regularly available is
15 phenytoin but it is the most important one for
16 which that measurement should be made and it is
17 despite the fact that it is at a distance from
18 the therapeutic effect. The amount of drug in
19 the blood and the actual outcome in the brain are
20 quite a long way away from each other despite
21 that actually measuring the plasma concentration,
22 or the serum concentration, is quite a good
23 measure of therapeutic outcome and is an even
24 better measure of the risk of toxicity or adverse
25 effects. There's a very good correlation between

1 high plasma phenytoin concentrations and specific
2 adverse reactions to the drug. So measuring the
3 phenytoin concentration in the blood, whether
4 it's plasma or serum, it varies from place to
5 place and it doesn't matter, is a useful way of
6 monitoring therapy and tailoring dosage
7 requirements.

8 Q. Thank you. I want to ask you in turn about the
9 drugs that were prescribed and administered to
10 Claire, particularly the anti-convulsant, so that
11 will be the diazepam, the phenytoin, the
12 midazolam and the sodium valproate, being the
13 four main ones. We have prepared a schedule to
14 look at the overlapping medication timeline,
15 which may be of assistance, to look and see what
16 was happening, and that is 310-020-001. I
17 understand that a version of this went up
18 yesterday, which was my error, because that was a
19 draft and this is actually the correct version.
20 I think it has now been substituted in the
21 system. The reason for that is because we didn't
22 have the information on the half life which is
23 the very characteristic of these drugs that you
24 have been describing and their significance.
25 Just if I quickly show what's on this, I mean

1 it's a timeline, so you can see the time across
2 the top and those balls, coloured balls, they're
3 the bolus and underneath them is the time when
4 that was administered. Then the dotted lines are
5 the half lives and if you've got a solid line
6 that's an infusion. Then just to try and keep
7 this correlated with what was happening -- those
8 red vertical lines they indicate the seizure or
9 those episodes that are recorded on the record of
10 "attacks observed". Then you have, towards the
11 right-hand side, two vertical lines which show
12 when the brain stem death tests were carried at
13 6.00 am and 6.25 pm. So that's what this is
14 showing.

15 But the purpose is, when I ask you about what
16 might be the interactions of this, so that you
17 can help guide us as to what's in the system, if
18 I can put it that way, and to look and see to
19 what extent that fits or doesn't with any other
20 presentation of Claire, predominantly these
21 episodes.

22 So I wonder if we could start first with
23 diazepam and you can see that that was
24 administered at 12.15 rectally. It was a dose of
25 5 milligrams and I think in your report you say

1 the onset of action is 10 to 30 minutes, and I
2 think that's at 237-002-008 -- you don't have to
3 pull it up -- but that's where I think you say
4 that. What exactly does that term mean "the
5 onset of action"?

6 A. The diazepam has been given rectally so it's been
7 inserted through the anus into the rectum in a
8 solution which is then absorbed through the
9 rectal wall into the rectal veins which drain
10 directly into the systemic circulation. If you
11 take a drug orally, swallow it, it goes in, down
12 your gullet into the stomach where it stays for a
13 variable period of time, 15-30 minutes, an hour,
14 2 hours, sometimes longer. It then has to pass
15 into the small bowel before it gets absorbed. It
16 then passes through the liver which may
17 metabolise it. All these things take a long
18 time. If you give the drug into the rectum it
19 gets rapidly absorbed into the rectal veins and
20 straight into the systemic circulation without
21 having to go through all that delay. Then it has
22 to pass across the blood-brain barrier from the
23 blood to the brain, attach itself to receptors
24 and have an action. So this takes a bit of time
25 but not nearly as long as it would if it was

1 being given orally.

2 If you give intravenous diazepam you bypass
3 the absorptive process altogether and you will
4 get a very rapid response, maybe ten minutes. If
5 you give it rectally it will probably take a bit
6 longer, maybe 20-30 minutes or a bit longer still
7 but that's the order of magnitude of the time it
8 takes for these processes to occur.

9 Q. When you say the "onset of action" do you mean
10 the reaching of a therapeutic level?

11 A. Not necessarily.

12 Q. So it may not yet be at its therapeutic level?

13 A. It may not be. It depends on whether the dose is
14 right.

15 Q. But it would be doing something?

16 A. It would be doing something. You don't know
17 whether the dose of 5 milligrams is right. A
18 dose of 5 milligrams is written in the book.
19 This is the BNF from September 1996, so this is
20 the relevant document. You'd look it up in the
21 book and the book says 5-10 milligrams, let us
22 say, well that's the dose that has been
23 determined during development of the drug and
24 clinical trials and other matters of that sort
25 and it's a ballpark figure, huge variability from

1 individual to individual. You never know what
2 the right dose is but you start in the
3 recommended range and you usually start at the
4 lower level of the recommended range because you
5 don't know what the patient's response will be.
6 So you don't know if it's going to have the
7 effect you're looking for but you expect it to
8 start to have some effect and you should then be
9 monitoring that effect, looking to see what
10 happens, and as best you can judge what the
11 response is if there are ways of doing that and,
12 as I said before, that can be very difficult.

13 Q. When you say you should be looking to see, who
14 are the persons, in your experience, who have
15 that responsibility?

16 A. For me it's the doctor who gives the drug and I
17 say "gives" very loosely. It might be the doctor
18 who prescribed the drug or it might be the doctor
19 who said, "Let's do this" or who actually writes
20 the prescription or the doctor who gives the
21 drug. In my view it's the doctor responsible for
22 the case who is in charge of looking after the
23 patient who should go back and see, "Did this
24 drug have an effect?"

25 Q. Should it be a doctor who is giving it and

1 watching?

2 A. If the doctor is the one who has prescribed the
3 drug, and that is usually the case, then it
4 should be the doctor responsible for prescribing
5 it or giving it. If, in the case of a nurse, who
6 is a prescriber, then it's the nurse prescriber
7 who's responsible in my view although a nurse may
8 want to defer to another specialist, a physician,
9 who is there, for help with that if she feels
10 uncomfortable or unconfident about it. In my
11 view the individual who has been responsible for
12 prescribing the drug is responsible for making
13 sure that the drug has had an effect or what
14 effect the drug has had or is responsible for
15 delegating that task to somebody in his or her
16 team. It might be a junior hospital doctor if
17 the consultant has recommended the prescription.

18 Q. It would seem, in this case, that it was actually
19 given by a nurse and we can see that and the
20 prescription sheet, 090-026-075.

21 A. All right, but it was prescribed by a doctor.

22 Q. It would seem so. It's right down at the bottom
23 -- perhaps just blow that up a little bit, see
24 just across there. Yes, and it does appear to
25 have been prescribed by a doctor but nonetheless

1 given by a nurse.

2 A. All right. I would expect the doctor to be
3 interested in whether that medication had worked
4 or not and to what extent, if it was possible to
5 determine, and in this case I think it's actually
6 very difficult to determine.

7 THE CHAIRMAN: Although there is a note but it comes
8 along to say that it is noted that -- well,
9 there's some dispute about this but it is noted
10 that there was some improvement.

11 MS ANYADIKE-DANES: Yes, that's in the medical notes
12 and records. It's at 090-022-053. This is Dr
13 Webb's note and there's a note:

14 "Appeared to improve following rectal diazepam
15 at 5 milligrams at 12.30 pm."

16 So somebody had observed and that's recorded.

17 A. Yes, it doesn't say in what way the improvement
18 occurred or why he thought that that was so.

19 THE CHAIRMAN: What would be the detectable sign of
20 improvement?

21 A. In this case I think it's rather difficult to
22 know. We don't know what the diagnosis was.
23 We're assuming, for the purposes of discussion,
24 that it was indeed non-convulsive status
25 epilepticus but we have no evidence of that. We

1 have no way of knowing whether that condition
2 changed in any way from the point of view of the
3 activity of the brain because something is
4 happening in the brain that is not being
5 transmitted to the body.

6 Normally what happens in epilepsy is there is
7 an abnormal electrical storm in a part of the
8 brain. It starts in one area, a little storm of
9 electricity, and then in the most common form of
10 epilepsy -- that I see at any rate, called
11 tonic-clonic seizures, it becomes generalised.
12 It spreads to the rest of the brain; the whole
13 storm affects the brain. This is translated into
14 jerking of the arms and legs, clenching of the
15 teeth, biting of the tongue, incontinence, losing
16 your urine, these are the manifestations of the
17 electrical storm in the brain. That you can see
18 and if the individual was having a fit of this
19 sort and no longer had a fit then that's good
20 news, you've observed what appears to be a
21 beneficial effect. Of course it might be
22 coincidental with the administration of the drug
23 but one assumes in such cases that it is due to
24 the medicine rather than coincidentally abating
25 but one doesn't know that for sure.

1 MS ANYADIKE-DANES: If it's non-fitting status
2 epilepticus you don't have that.

3 A. You don't have that in someone who is not fitting
4 so exactly what one measures in this case is not
5 clear to me and I think you'd have to ask the
6 individuals concerned and better actually asking
7 a paediatric neurologist what they think the
8 signs would be. As a general physician I find it
9 difficult to know what those signs might be.

10 THE CHAIRMAN: But, doctor, this note was written by
11 Dr Webb and this was the first time he had seen
12 Claire so he couldn't have had a before and after
13 perspective and so far as we know he was not
14 accompanied at 2.00-ish pm, when he examined
15 Claire, by the doctors who had seen Claire in the
16 ward round. So the only possible source of
17 information about an improvement would have been
18 a nurse who had been on the ward that morning and
19 had seen Claire, and was able to tell Dr Webb
20 somehow around 2.00 pm that there appeared to be
21 some improvement.

22 A. But he uses the past tense, "appeared" to improve
23 which suggests that someone has said, "We gave
24 her the drug and she improved, we thought",
25 rather than "appears to have improved" which

1 would imply that he had seen such an event but I
2 don't think I can comment really more than that.

3 THE CHAIRMAN: But the point you're making is, I
4 gather, that it's actually a bit hard to know
5 what the detectable improvement was?

6 A. Even, I think, and as I say, this is really a
7 question for a paediatric neurologist and the
8 people who are on the site but for me it's hard
9 to imagine what a nurse might have noted that
10 suggested an improvement in her state. Maybe she
11 was restless and became less restless, that's
12 possible, but that's not evidence of improvement
13 in state, that's evidence of sedation. So I am
14 speculating and I don't know.

15 THE CHAIRMAN: Thank you.

16 MS ANYADIKE-DANES: Just on the characteristics of
17 diazepam, what is the half life of diazepam?

18 A. Diazepam itself has a relatively short half live
19 but its action is mainly mediated through a
20 metabolite, a compound to which it is altered in
21 the liver, called desmethyldiazepam which
22 unusually, because usually metabolism results in
23 drugs that have shorter half lives, in this case
24 has a longer half life and is active. So the
25 main duration of action of the drug is mediated

1 by its active metabolite which has a half life
2 of, on average, of about 30 hours, something like
3 that, quite long.

4 Q. So that metabolising effect actually extends what
5 is otherwise a relatively short period?

6 A. Relatively short. In fact diazepam has many
7 metabolites that are active and various drugs
8 were discovered as a result of studying the
9 metabolites and some of the metabolites which
10 have shorter durations of action were
11 subsequently marketed as drugs in their own
12 right.

13 So diazepam is complicated but the overall
14 duration of action is related mainly to the
15 longest acting metabolite, and that has a half
16 life of around 30 hours on average. Pull back up
17 with that overlapping medication timeline of 310-
18 020-001 and we see this at the top there; that
19 broken line for rectal diazepam actually extends
20 right up until the second brainstem death test.

21 A. And that is at least 30 hours.

22 Q. Yes. Now, having a half-life of that length of
23 time, what does that actually mean in terms of
24 what it is doing in the body or what it could be
25 doing in the body?

1 A. It tells you that the drug is there, some drug is
2 there and for the first half-life, more than half
3 is still there. That doesn't tell you what it is
4 doing, as I said before. Maybe 5 milligrams
5 wasn't enough to have an effect; we don't know,
6 but it does tell you at least that some of the
7 drug is still there and, of course, the longer
8 you go on, the less drug is there and so the less
9 effect it's having. How much of an effect it's
10 having is impossible to say but clearly, the
11 higher the dose, the bigger the effect. Perhaps
12 it's worth noting at this point that doubling the
13 dose only increases the duration of action by one
14 half-life, so if you want to prolong action, you
15 are better to give repeated small doses than big
16 doses. That's just in passing.

17 Q. I think Professor Neville, who is the inquiries'
18 expert on paediatric neurology, has been asked
19 about the diazepam improvement. I think we could
20 find that at page 169 of the transcript on 1st
21 November. I am afraid that's one of those
22 documents that doesn't come up for you, Dr
23 Aronson; I am sorry about that. I think it
24 starts at line 17. So you can see when Dr Webb
25 says he is under the impression that there has

1 been some improvement as a result of the
2 administration of rectal diazepam, what is the
3 significance of that in terms of trying to work
4 out what was wrong with Clare and how best to
5 treat her; the answer is:

6 "I would say it wasn't dramatic. In other
7 words, she didn't drop off to sleep and wake up
8 and was talking again, so it wasn't as clear as
9 that."

10 If you go over the page:

11 "I think it was just an improvement in the
12 sort of level of responsiveness which I think
13 means that it didn't really help a whole lot."

14 Unfortunately, we put Professor Neville in the
15 position of trying to speculate also because he,
16 of course, knows no more than you do about what
17 the circumstances in which people are describing
18 an improvement but, doing the best he could, his
19 impression was it actually probably hadn't helped
20 very much at all. I'm not asking you to comment
21 because I'm not sure you can comment any further
22 yourself but that was just for the benefit of
23 those who wanted to know what he said.

24 A. I think he's saying pretty much what I said which
25 is that you can't really tell. Whether his

1 interpretation is correct or not, I don't want to
2 comment.

3 Q. No. Then in your own report when you're dealing
4 with diazepam at 237-002-008, this is to do with
5 prescribing diazepam at all in those
6 circumstances and you say, in a child, you might
7 prefer to choose benzodiazepine with a shorter
8 duration of action than diazepam. Why would that
9 be?

10 A. No. I say in an adult I would consider the use
11 of a benzodiazepine to be appropriate although
12 one might prefer to choose a benzodiazepine.
13 This is interesting because we're talking about
14 2012 and 1996.

15 Q. Exactly.

16 A. My feeling actually in 1996, as well as today,
17 but my strong feeling today is that it's
18 preferable in these circumstances to choose a
19 drug with a shorter duration of action if you can
20 because you're more in control of what's going
21 on. You can switch it on and off much more
22 quickly than if you give a drug that has a
23 duration of action that is very long and that's
24 it. You can't do anything about that. You have
25 to wait.

1 Q. Because it's in the system and you can't get rid
2 of it.

3 A. Because it's in the system and you just have to
4 wait for it to dissipate. My own view is that --
5 and nowadays, if you look in the current edition
6 of the BNF for Children, you will see that
7 midazolam is the recommended treatment for status
8 epilepticus even though it is not currently
9 licensed for that reason. If you look in the
10 British National Formulary for 1996, you will see
11 that diazepam is recommended and, in fact,
12 interestingly it says that lorazepam may also be
13 helpful because it has a longer duration of
14 action. That was the view in those days.

15 Now, my own view at that time, and I know
16 because I used to use quite a lot of this
17 particular drug, was that I would have tended to
18 use a drug called clomethiazole, which was also
19 listed in the 1996 edition as a shorter acting
20 drug and for the reasons that I have given, but
21 my experience was generally that patients with
22 difficult epilepsy who would come under my care
23 would already have been given diazepam as a first
24 measure and that is what the 1996 Formulary
25 recommends; diazepam as a first measure to treat

1 status epilepticus.

2 Q. So although your preference would've been for a
3 shorter acting drug, even in 1996, and although
4 there are indications currently that one wouldn't
5 perhaps use such a long acting drug, in 1996, you
6 couldn't say it wasn't appropriate to prescribe
7 diazepam in that dosage.

8 A. Indeed it was the recommended first line of
9 treatment, so not at all inappropriate. My own
10 preference, as I say, was in the context
11 generally of seeing patients in whom diazepam had
12 already been used and had proved ineffective. My
13 next choice would, in those days, have been
14 clomethiazole. Nowadays, I think, probably most
15 people's choice would be midazolam.

16 MR FORTUNE: Just picking up something Dr Aronson
17 said, diazepam in 1996 was licensed. Dr Aronson
18 has said that even in 2012, midazolam is not
19 licensed for status epilepticus in children.
20 Could Dr Aronson explain what the term "licensed"
21 means in these circumstances in case anybody else
22 thinks that using a drug non-licence or
23 off-licence is, in fact, anything other than
24 therapeutic?

25 A. Drugs are licensed in the UK by an authority

1 called the Medicines and Healthcare Products
2 Regulatory Agency, the MHRA. The process whereby
3 licences are issued involves the submission to
4 the MHRA by the drug company involved of large
5 amounts of data on the pharmacology actions,
6 uses, effects of the medication for which they
7 are seeking a licence and which will have accrued
8 generally, on average, over about ten years of
9 work.

10 The MHRA then looks at the data and if it
11 awards a licence, then the terms of that licence
12 are regulated by law and the licence has to
13 contain certain pieces of information about the
14 medication. Anybody who wants to read the
15 licence can access the licences in a system known
16 as the Summaries of Product Characteristics.
17 These are regulated by EU law and have a certain
18 format.

19 One of the sections is labelled "Indications"
20 and in each Summary of Product Characteristics,
21 or SMPC, that section details the licensed
22 indications. Diazepam for anxiety, for example,
23 is a licensed indication and so on. These are
24 indications for which the MHRA is convinced that
25 there is enough information to say, "You may use

1 this drug for this indication".

2 Now, I should also explain that there is a
3 term of "the label". This is an American term
4 but it has come to be used widely. "The label"
5 is a description given to the whole licence and
6 in addition to indications, the label, the whole
7 description includes information such as the
8 formulation to be used, the dosage to be given,
9 the dose form, the dose in which it's to be
10 given, the frequency and so on. If you go
11 outside of those instructions, then you are said
12 to go "off label", so you haven't changed the
13 indication but you've done something else that is
14 different from the way the drug is described in
15 the label.

16 Now, in children, this raises enormous
17 difficulties because the vast majority of studies
18 on new drugs are carried out in adults. When a
19 drug is licensed for the first time, there is
20 generally little or no information about its use
21 in children. If you look through the BNF for
22 Children, it is liberally studded with the
23 statement, "Not licensed for this indication".
24 Many of the uses of medications in children are
25 not licensed because the appropriate clinical

1 trials have not been carried out to satisfy the
2 regulatory authorities and indeed the drug
3 company has probably found it too difficult, time
4 consuming and expensive to go to the trouble of
5 applying to the authority for a licence in
6 children and just doesn't bother. It markets the
7 drug and the drug is not used by paediatricians
8 but, of course, paediatricians build up a lot of
9 experience. They carry out trials of their own,
10 they have observations in their own clinical
11 experience and even though the amount of
12 experience they have and the trials they've
13 carried out may not be sufficient to be presented
14 to the licensing authority to obtain a licence,
15 nonetheless, the paediatricians may be
16 sufficiently confident to use the drug unlicensed
17 for such an indication.

18 For midazolam, for example, that is the case.
19 It is recommended for status epilepticus but the
20 text says -- if I can find it:

21 "Licensed use; injection not licensed for use
22 in status epilepticus."

23 Yet, if you look at the section on the
24 treatment for the management of this condition,
25 it says that you can use buccal midazolam or

1 intravenous lorazepam. Now, it says "buccal
2 midazolam" because the intravenous formulation is
3 not licensed but, and you can ask a paediatrician
4 this, I would not be surprised if intravenous
5 midazolam was used nowadays, in some cases,
6 off-licence, to manage status epilepticus.

7 MS ANYADIKE-DANES: Doctor, the upshot of this is just
8 because it isn't licensed for children, doesn't
9 mean it's not a beneficial therapy and that many
10 paediatricians are using it to good effect. It
11 doesn't mean that.

12 A. That is correct. In fact, I suspect that, more
13 often than not, unlicensed indications are the
14 rule rather than the exception in paediatric
15 practice; very common at any rate.

16 Q. Yes. I am not going to take you to them but, for
17 the sake of reference, you have included,
18 attached to your report, the Summary of Product
19 Characteristics. The one for phenytoin can be
20 found starting at 237-002-038 and the one for
21 midazolam can be found at 237-002-045.

22 A. These are, of course, current SPCs and not 1996.

23 Q. Yes and that changes presumably over time.

24 A. It does. It changes regularly; year on year it
25 changes in sometimes very subtle ways.

1 Q. You then, I think, said that at page 237-002-008
2 of your report that, in your view, it's desirable
3 to obtain an EEG before treating suspected
4 non-convulsive status epilepticus. At all, do
5 you mean, by anti-convulsive medication?

6 A. Yes.

7 Q. Why is that?

8 A. I might have even said, "Highly desirable".

9 Q. Yes.

10 A. Some might say mandatory.

11 Q. Mandatory.

12 A. Some might say that. I wouldn't say that because
13 there might conceivably be circumstances in which
14 one would want to treat but could not get an EEG
15 and that would be a clinical decision that one
16 would make. That's another reason why one might
17 want to choose a short acting drug because if you
18 don't have an EEG on which to base your
19 diagnosis, you feel that, in the circumstances,
20 it is important to treat nonetheless, you might
21 give a short acting drug to hold the fort for the
22 time being and then, when the effect of that had
23 worn off, then at more greater leisure get the
24 EEG. So highly desirable might be the way to put
25 it.

1 Q. Why do you consider it to be desirable?

2 A. Because in this case, I don't think, and again
3 this is for a paediatric neurologist to state an
4 opinion, but my experience with non-convulsive
5 status epilepticus in adults, which is very
6 limited because it's not common, is that you
7 cannot make a diagnosis comfortably without an
8 EEG because there's no outward sign of the storm
9 that's going on in the brain in terms of physical
10 output as a fit.

11 THE CHAIRMAN: Professor Neville took the view that
12 this was a possible diagnosis but rather low on
13 the list of possibilities and that influenced him
14 in advising that an EEG should have been obtained
15 before that was taken as the condition being
16 treated.

17 A. That implies that this is not a case in which he
18 felt that urgent treatment was necessary. He
19 felt that was Possible but unlikely. There was
20 no rush to treat the putative diagnosis.
21 Therefore, wait until you can get an EEG that
22 would confirm or deny the diagnosis.

23 Q. But meanwhile, you could be testing other things
24 on a differential diagnosis?

25 A. Well, you could, indeed. If you had a

1 differential diagnosis, you could be instituting
2 other investigations such as a search for viruses
3 that might be causing encephalitis, for example.

4 Q. If then we could move on to phenytoin, the first
5 administration of phenytoin is at 1445. That's
6 635 milligrams and it's given by an IV stat so
7 that's a bolus dose. We see that at 092-022-054
8 in the clinical notes and it's, "Dr Webb has seen
9 the child", as we've just taken you to. Then he
10 suggests three things and the first relates to IV
11 phenytoin as (inaudible) there:

12 "Start on IV phenytoin 18 milligrams a kilo
13 stat, followed by 2.5 milligrams a kilo, 12-
14 hourly."

15 Then:

16 "Will need levels 6 hours after loading dose."

17 So that's how it comes to the SHO where you
18 can see his note just below. The first part of
19 it, if we stay with the loading dose part, is to
20 attempt to translate that. As is now known and
21 he recognises, he ended up with an arithmetical
22 error at 632.

23 But if I can first ask you the question I've
24 asked you in relation to the diazepam: the onset
25 of action I think you put in your report was 30

1 to 60 minutes. I think -- I advise that's not to
2 be pulled up -- at 237-002-009. This seems quite
3 a wide range of onset of action, particularly
4 when you say that:

5 "The onset of action doesn't necessarily mean
6 you've reached the therapeutic level."

7 So why is there such a wide range?

8 A. Well, this is from reported data in the
9 literature, and I suspect that it reflects the
10 intrinsic variability. The drug has to pass into
11 the brain. It has to attach to whatever
12 mechanism it acts on, something to do with ion
13 transport in the neurons, I suspect. And that
14 has to be translated into a downstream action and
15 the activity of the brain cells. And these
16 things do take time, and there will be
17 variability from individual to individual. And
18 so that estimate that I have written there is
19 based on a literature estimate of reports and
20 clinical trials and the like.

21 Q. Though you do later on in that page -- and maybe
22 this is worth pulling up -- at 237-002-009 as to
23 how to give a dose like that. You said:

24 "To give a dose of 635 [it's just under "(e)"
25 at the top] one would use 12.7 milligrams in such

1 a solution. You would give it intravenously.

2 [Then you say to get at the rate of it] In other
3 words, over no less than 9 minutes."

4 Why is it that you have to give it in that
5 way, so far as you're concerned?

6 A. Well, that's the -- that's based on the
7 recommended rate, as published in the British
8 National Formulary for 1996, and I don't think
9 that's changed. The reason it should be given
10 slowly is because there is a risk of abnormal
11 rhythms in the heart if it's given more quickly.
12 This drug acts on electrical tissue in places
13 other than the brain. And the main part of the
14 body in which there is important electrical
15 tissue is in the heart. The wiring of the heart
16 is electrical and, if you give phenytoin too
17 quickly, there is a risk that you may cause
18 abnormal rhythms in the heart.

19 Q. Is that why you need to manage it with an ECG
20 while you're doing it?

21 A. That's right.

22 Q. But when you say it should be "no less than 9
23 minutes", is that something that, if you are
24 having a very junior doctor prescribe it from
25 your direction, it should be stated so that

1 there's no error if it can have that sort of
2 effect?

3 A. Yes.

4 Q. That should be included in the note?

5 A. Yes.

6 MR COUNSELL: I wonder if Dr Aronson would be able
7 just to clarify that, the question and the answer
8 perhaps?

9 MS ANYADIKE-DANES: Yes.

10 MR COUNSELL: I wonder if Dr Aronson could deal with
11 this. If the instruction's coming from a more
12 senior doctor -- the note of course is recorded
13 here by a very junior doctor -- is Dr Aronson
14 saying that the instructions as to the speed with
15 which it should be given should be given by the
16 more senior doctor?

17 A. I think that whoever is making the decision about
18 the prescribing should give that instruction.

19 These words are ambiguous, "prescribing",
20 "prescription". "Prescribing" could refer to the
21 mental processes that lead to the instruction or
22 it could refer to writing the prescription.

23 "Prescription" could refer to the act of writing
24 the prescription, but it could also refer to the
25 prescription you take to the chemist. So these

1 terms are very vague and ambiguous in some ways.

2 To me, prescribing involves the act of

3 thinking about it and the act of writing it down.

4 Both of those things are prescribing. If I say

5 to my junior staff, "I want you to give this

6 patient 300 milligrams of phenytoin

7 intravenously" -- whatever the does is, doesn't

8 matter -- I would say, "And I want you to give it

9 over a period". I wouldn't say over "no less

10 than ...". I would say, "Give it intravenously

11 over 15 minutes", let us say, and that would be

12 my definitive instruction. I would then expect

13 them to write that down in the notes, "To be

14 given phenytoin X milligram per kilogram (or

15 whatever it is) over 15 minutes by intravenous

16 infusion".

17 MS ANYADIKE-DANES: If we pause there and we go to Mr

18 Counsell's question, does that mean, therefore,

19 that it was for Dr Webb to have included that

20 instruction in his note?

21 A. If he was the one who was recommending the

22 prescription, the prescribing of that drug, then

23 I would say yes, he should have either said that

24 or said something to the effect, "... and look it

25 up".

1 Q. Yes.

2 MR SEPHTON: And would that apply [inaudible: no
3 microphone] if Dr Webb thought he was giving the
4 instruction to a registrar rather than an SHO?

5 A. I think it would apply to whomever he was giving
6 the instruction.

7 MS ANYADIKE-DANES: This is in the interests of
8 clarity?

9 A. Indeed.

10 Q. Thank you. So then if we --

11 A. And precision actually --

12 Q. Exactly what I meant.

13 A. -- precision.

14 Q. Precision. Then if we stay with that loading
15 dose and to see how the direction "IV phenytoin
16 18 milligrams per kilo stat dose" turns into a
17 prescription, if I can put it that way, or a
18 written-up prescription for it to be
19 administered.

20 A. ... you might say.

21 Q. Yes. So the calculation is there at 090-022-054
22 but we don't want to pull it up. He simply
23 calculates 18 times 24 and gets the incorrect
24 answer. But where it gets prescribed is, if one
25 goes to 090-026-075, there at the bottom, "This

1 is the once only" because it's going to be a stat
2 dose so that would be once only. The second
3 line, you can see the "635". The time it's
4 administered is 2.45 pm by IV and the signature
5 bar of the SHO and his initials, indicating that
6 that has actually been given at that time.

7 I wonder if you can help then. Given the
8 half-life of phenytoin and given when it was
9 given, when does it reach a therapeutic
10 concentration in her system?

11 A. If you're giving a loading dose intravenously,
12 then the concentration -- and it's given over,
13 say, 10 or 15 minutes, then the concentration
14 will rise quite rapidly during the infusion. So
15 that may be quite a high concentration because
16 the drug is restricted to the blood at that
17 point. So it rises to a high concentration and
18 then starts to fall as the drug is distributed
19 throughout the tissues. And then it reaches a
20 phase when it is declining very slowly and that
21 is the half-life. So the shape of the curve is
22 rather like a nose with a tail on it. It goes up
23 like a nose like that, and then tails off and
24 disappears with the half-life we've discussed.
25 So within -- the distribution time probably --

1 the distribution time of the blood is one minute.
2 The cardiac output is 5 litres per minute. The
3 total blood volume is 5 litres. So within one
4 minute the drug is uniformly distributed through
5 the blood, and so the peak concentration will
6 occur for intravenous administration at that
7 point. And then depending on the time it takes
8 to distribute throughout the tissues, which may
9 be quite a long time, it will then fall from that
10 concentration to a steady disappearing
11 concentration. So it might be half an hour/an
12 hour, that sort of order.

13 Q. Claire's phenytoin levels were actually checked.
14 The blood for those levels seems to have been
15 taken at 9.30 pm that evening, although they
16 didn't come back to about 11.30 pm. But in any
17 event, the result of her phenytoin levels from
18 those bloods was 23.4, and I think elsewhere in
19 your report you said that's a rather high level.

20 A. It is.

21 Q. But bearing that mind and from what you've just
22 described as to the way the drug acts, can you
23 express any view at all as to what her likely
24 phenytoin levels would have been by 1525? I
25 should say the reason I am asking about that

1 particular time is that is the first seizure that
2 Claire is recorded as having, the first visible
3 one that she's recorded as having.

4 A. 1525/1530, that sort of time, is about three-
5 quarters of an hour after the intravenous
6 infusion. By that time, I would expect that we
7 would probably be in the terminal(?) phase that I
8 described. And since the drug has a very long
9 half-life, it wouldn't change much between 3.30
10 pm and nine o'clock when the sample was taken.
11 So if it was 23 milligrams per litre at 9.00/9.30
12 pm, I would reckon somewhere between 25 and 30 as
13 an approximation at 3.30 pm that afternoon. It's
14 about that figure but it wouldn't be far off that
15 sort of range.

16 Q. If it were at that level of concentration in her
17 body at that time, is it possible that it could
18 have contributed to that seizure?

19 A. Well, very occasionally -- and it isn't common --
20 it has been reported anticonvulsant drugs, anti-
21 epileptic drugs, including phenytoin, can cause
22 seizures rather than relieving them. These are
23 known as paradoxical seizures and the mechanism
24 is not understood. It is therefore possible --
25 although I couldn't be sure about it and if you

1 ask me to say on the balance of probabilities
2 what I thought, I couldn't say as much -- it is
3 possible that a seizure at 3.30 pm could have
4 been due to phenytoin toxicity.

5 THE CHAIRMAN: So it's possible but not probable?

6 A. I'd say that, yeah.

7 MS ANYADIKE-DANES: In fact, given the other things
8 that might have been going on with Claire, I
9 think Professor Neville's evidence is it's really
10 impossible to unpick those things and to see to
11 what extent this could have been the cause
12 because there were other factors that could have
13 brought it about. So you can say nothing further
14 than "It's possible"?

15 A. That's right, and I'm sure he's right. There are
16 so many other factors in this case that one can't
17 attribute individual events to individual
18 factors.

19 Q. Can I just ask: because phenytoin is one of those
20 drugs that you've described can produce
21 paradoxical effects -- and paradoxical,
22 presumably means precisely the opposite to what
23 you're intending to do. You're intending to
24 produce a sedating effect, if I can put it that
25 way, or a calming effect on their electrical

1 storm and in fact you've done precisely the
2 opposite. I presume that's what makes it
3 paradoxical?

4 A. Indeed.

5 Q. But was it known that it had those effects in
6 1996?

7 A. Yes, I think it was. I'm not entirely certain,
8 and I'm just looking to see if I referred to a
9 paper that some colleagues had written on the
10 subject. I see I haven't. I can't remember at
11 the moment whether that is so, but I think that
12 this has been described. I would want notice of
13 that question.

14 Q. If it were to be known in 1996 that, not by any
15 means commonly but it could produce those
16 effects, and you have a child who is under hourly
17 observation if that's a part of what you have
18 directed, should the possibility of paradoxical
19 or adverse effects be described or explained to
20 those who were carrying out the observations so
21 that they know to look for these or, if they see
22 it, be able perhaps to alert somebody more senior
23 to the fact that this might be happening?

24 A. Assuming that it was known at that time, I think
25 that that's a highly expert judgement and very

1 difficult to make. In other words, even if it
2 had been described and published at that time, I
3 don't think that it was common knowledge. This
4 is a very -- I consider this to be a very expert
5 opinion in the area.

6 Q. So it's not necessarily something that you would
7 expect somebody in the position of Dr Webb to
8 have been describing to the nurses, "This child
9 is going to have a drug that could produce
10 certain sort of effects. You should look out for
11 that and, if you see it, you should be alerting
12 somebody to the fact that that might be
13 happening". That's not something you would
14 expect?

15 A. I would not expect even an expert paediatric
16 neurologist, who might well know of the risk of
17 paradoxical seizures -- and I'm not saying that
18 he did or didn't -- but even if he did, I would
19 not expect him to explain that to the nurses in
20 these circumstances. It is so uncommon and
21 unlikely that it's not something that one would
22 state formally in the course of a routine
23 management of a patient with status epilepticus.

24 THE CHAIRMAN: Thank you.

25 MS ANYADIKE-DANES: When you mentioned earlier about

1 you would have continuous monitoring by an ECG --
2 in fact I think you regarded it as essential --
3 is that just for the stat dose at 1445 or is that
4 also for the infusion that takes place at 2300
5 hours or thereabouts?

6 A. I would be less concerned about the later
7 infusion if the earlier evidence had shown that
8 there was no cardiac effect of the loading dose.
9 If on the other hand no cardiac monitoring was
10 carried out during the loading dose, then I would
11 certainly want it to be carried out during the
12 next dose.

13 Q. Yes. I think the position is that one can't be
14 certain that was done during the loading dose.
15 But the nurse's note at 090-040-138 indicates
16 that it was done for the infusion of a
17 maintenance dose. If one turns that around, you
18 can see:

19 "IV phenytoin directed by a doctor and
20 1/1-hour cardiac monitor in situ throughout
21 infusion." There is no similar note when it is
22 administered later on. But in your view, that's
23 really essential; they should have done it for
24 the first dose?

25 A. Yes.

1 Q. All the more given the size of it?

2 A. Yes.

3 Q. Okay. I wonder if we can move on now to the
4 midazolam; sometimes it's referred to in the
5 notes as Hypnovel. That was "12 milligrams"
6 actually written down, but I think that none of
7 the experts and the clinicians think it was
8 actually given as "120 milligrams". That was an
9 IV stat dose at 1525. Can you help with what the
10 half-life is of this drug?

11 A. The half-life of midazolam is quite short, two to
12 three hours, and it's for that reason that it is
13 nowadays very commonly used, for example, for
14 relatively minor surgical procedures such as
15 endoscopy and for induction of anaesthesia; in
16 other words, bringing on anaesthesia because it
17 has such a short duration of action. You give
18 it, it has its effect, wears off very quickly.

19 Q. What's its onset of action?

20 A. After intravenous infusion, probably a few
21 minutes, again highly variable but not very long.

22 Q. Yes. I'm just seeing where the actual dose is
23 first described and it's first described in the
24 clinical notes at 090-022-055. You can see it
25 right up at the top, the stat dose there. Dr

1 Webb, who was the paediatric neurologist, his
2 third witness statement describes a little bit
3 about how that came about. We don't have to pull
4 it up, but it's his third witness statement,
5 038-3 at page 2, when he says that he believes
6 his communication with the medical staff in
7 relation to it was most likely to have been by
8 phone as he didn't attend the ward until some
9 time later and didn't write the dose himself in
10 Claire's notes.

11 Now, the first thing before one deals with the
12 dose and the way that was translated into the
13 prescription, at that stage would you have been
14 prescribing and administering midazolam. The "at
15 that stage" is: she's had her 5 milligrams of
16 rectal diazepam at 1215; she's had phenytoin at
17 1445; and quite a large dose -- I think you
18 described that as an overdose -- the 635
19 milligrams.

20 A. Yes.

21 Q. And now she's having her midazolam at 1525.
22 Would you have prescribed midazolam then?

23 A. I would have called for a paediatric neurologist
24 because you're in trouble. You're in difficulty.

25 Q. Why do you say that?

1 A. And think probably I wouldn't have given the
2 phenytoin at that stage for the reasons that I
3 explained before. You don't have a diagnosis,
4 it's a long-acting drug, you really don't know
5 where you are. This child looks very ill, and
6 when exactly it was appreciated that she was very
7 ill may not be clear. And this is probably
8 continuous deterioration or at least gradual
9 deterioration. And at some point or other, a
10 discontinuous decision is made, namely to take
11 her to the paediatric ICU. When you make that
12 decision is difficult. But the tipping point is
13 the decision to give midazolam, clearly, because
14 at that point she's had diazepam. Somebody
15 thought it worked but not well enough not to give
16 phenytoin. And presumably the decision to give
17 midazolam was based on the view that the -- this
18 condition was continuing and maybe even getting
19 more serious with a declining Glasgow coma scale,
20 for example.

21 So the time of giving midazolam was clearly a
22 turning point, the point at which it clicked,
23 "This child is not well and we are not succeeding
24 in improving her condition". And the truth is it
25 happened when midazolam was given and she was

1 transferred to the ICU.

2 THE CHAIRMAN: No.

3 MS ANYADIKE-DANES: Not immediately, no. She wasn't
4 transferred to the ICU until about three o'clock
5 in the morning of the next day, after she'd had a
6 respiratory arrest.

7 THE CHAIRMAN: In fact it's about a 24-hour gap. The
8 midazolam --

9 A. I'm sorry. I'm sorry, yes. Absolutely, yes ...

10 THE CHAIRMAN: The other point, doctor, is this: that
11 near the start of that answer you said that you
12 would have called a paediatric neurologist.

13 A. Well, I was speaking as a general physician.

14 THE CHAIRMAN: Yes, but it was the paediatric
15 neurologist who gave the midazolam.

16 A. Quite, yes.

17 THE CHAIRMAN: Or who decided on the midazolam.

18 A. That's to ask a paediatric neurologist. Were I
19 in that position at that stage, I would have been
20 asking for help because I would have been very
21 unhappy, I think, about this girl.

22 I'm sorry, you're quite right of course. The
23 respiratory arrest and transfer occurred later,
24 and no doubt you will want to discuss that.

25 THE CHAIRMAN: Yes.

1 MS ANYADIKE-DANES: Yes. You described the midazolam
2 as a turning point. To be fair to you, I'm not
3 sure whether you thought it was a turning point
4 because you've reached a stage where you felt you
5 needed midazolam or you thought it was a turning
6 point because you had believed shortly thereafter
7 she went to intensive care. But leaving that
8 aside and knowing as you do now that she didn't
9 actually go into intensive care until three
10 o'clock the following morning, this is all
11 happening at 3.25 pm or thereabouts --

12 THE CHAIRMAN: This is 12 hours earlier.

13 Q. Exactly.

14 A. My judgement was based on both of those
15 considerations, even leaving aside the later
16 transfer. I think from what I've heard -- and
17 people who were there at the time and those who
18 had been more closely involved in her care, we
19 need to judge that -- that given that she was
20 given diazepam and then given phenytoin, and then
21 it was decided that midazolam was needed, I would
22 -- at that point as a general physician, I would
23 think that there are difficulties in this case.
24 And I am seriously worried about the problems
25 that the treatment is providing here.

1 Q. In terms of the difficulties, are they such that
2 you wouldn't have been happy about her being
3 treated on a general ward and would have wanted
4 her, for example, to be transferred to intensive
5 care?

6 A. Well, as I say, as a general physician, I would
7 look for help from the paediatric neurologist.
8 And at that stage, I would at least have thought
9 that transfer to a paediatric neurology ward, if
10 such existed, or some specialised facility would
11 be indicated, if not necessarily transfer to an
12 ICU. I would certainly be calling for specialist
13 help at this point.

14 Q. Those transfers, either to the paediatric
15 neurologic ward or to paediatric intensive care,
16 are they because of the greater specialism and
17 attention of care that she might receive there?

18 A. Yes. I think it's a truism that, if you've had a
19 stroke, you're better on a stroke unit. If you
20 have acute severe diabetes, you're better in a
21 ward where people know about the management of
22 diabetes. If you are in this position of having
23 status epilepticus, as was presumed, or at least
24 some difficult neurological problem, then I think
25 you're better under the care of a neurologist in

1 an environment where the nursing staff and all
2 the junior staff are used to taking care of these
3 kinds of difficult problems.

4 It may be that of course that a bed's not
5 available, in which case one would ask for close
6 involvement of those individuals. But that would
7 be falling short of desirable; that if a bed were
8 available in a specialised place, then it does
9 seem to me that that's the time when one would
10 think about it.

11 Q. Thank you. Can I ask you then about the dose?
12 The dose itself is 12 milligrams and there is an
13 issue between the paediatric neurologist who
14 phoned it through. His evidence and his
15 statement is that what he said was, "0.15
16 milligrams per kilo". It says, you can see
17 written down here "0.5" so that has made a
18 difference.

19 But leaving aside that, and I know you said
20 you wouldn't be wanting to do it in these
21 circumstances, but if you were prescribing
22 midazolam, have you got any comment to make on
23 what an appropriate dose might be?

24 A. Currently, the dosage that is given in the
25 British National Formulary for children is 150

1 micrograms per kilogram. That's 0.15 milligrams
2 per kilogram, as originally ordered, not 0.5
3 milligrams per kilogram, which is at least
4 threefold more.

5 In the BNF for 1996 of course, it does not
6 give a dose because midazolam at that time was
7 not licensed - it still isn't - but was not even
8 recommended. And so there is no dosage written
9 in the BNF specifically for use in the treatment
10 of status epilepticus. What there is is
11 information about the use of midazolam by
12 intravenous infusion in a child over seven for
13 induction of anaesthesia.

14 Now, if I was going to use an unlicensed
15 product, I would choose a dose that had been
16 found to be appropriate in other circumstances,
17 although I might not know what the effect would
18 be. But that's the dose I would go for, and the
19 dose that's given there for a child over 7 years
20 is 150 micrograms per kilogram.

21 Q. So that would --

22 A. So it seems to me that 150 micrograms per
23 kilogram is the dose to choose. And you tell me
24 that the doctor ordered 0.15 milligram per
25 kilogram, which is 150 micrograms per kilogram.

1 Q. No, I say that's his evidence that that's what he
2 did. But in any event, it would have produced
3 3.6 and not 12?

4 A. Yes.

5 Q. How significant is that, the difference between
6 the 3.6 and the 12 in these circumstances?

7 A. Well, that's at least three times more than would
8 be recommended, and that would produce much
9 greater sedation than one would expect from the
10 appropriate dose.

11 Q. Then the product information that I think you
12 provided, 237-002-058, which was the Hameln(?)
13 product information, that's correct, I think it
14 says that:

15 "Midazolam should be titrated slowly to the
16 desired clinical effect, and the initial dose of
17 midazolam should be administered over 2 to 3
18 minutes."

19 It's just there under "Children". Does that
20 accord with how you think it should be
21 administered?

22 A. Yes, that's reasonable advice.

23 Q. If that is how it should be administered, then in
24 the same way as I had asked you before about the
25 phenytoin, is that something that should have

1 been directed?

2 A. I think it's less important than with the
3 phenytoin, and I wouldn't lay as much stress on
4 it. I think the counsel of perfection would be
5 to say, "Give it slowly". But I think if I were
6 ordering it I would say, "... and look it up in
7 the book. Make sure you get it right". The
8 phenytoin is much more important because the risk
9 of cardiac arrhythmias is really quite high.

10 Q. Yes.

11 MR COUNSELL: I just wonder if Dr Aronson could
12 indicate what he means by "look it up in the
13 book"? I don't know whether it would assist him
14 if we brought up on the screen the BNF, for which
15 I think the reference is 311-028-020.

16 MS ANYADIKE-DANES: That's it.

17 A. I do refer to the British National Formulary, and
18 this is the relevant volume of the British
19 National Formulary that I would expect the doctor
20 to look at. The section on midazolam does not, I
21 think, give this advice. And if you look at the
22 section later on, which you may not have, which
23 is appendix 6 to the British National
24 Formulary --

25 THE CHAIRMAN: Can you give us a page number ...

1 A. -- starting at page 598 --

2 THE CHAIRMAN: Thank you.

3 A. -- entitled "Appendix 6: Intravenous additives",
4 if you turn to page 606 where it says, "Phenytoin
5 sodium", there are strict instructions about how
6 phenytoin should be given. But if you turn to
7 the page in which you expect midazolam to be
8 listed, there are no instructions. And I take
9 that to mean that either it was not known that
10 one ought to give this drug slowly at that time,
11 or it was not considered to be very important and
12 I don't consider it to be hugely important. I do
13 consider the phenytoin rate of dosage to be very
14 important, and that is borne out by its inclusion
15 in that section in the British National
16 Formulary.

17 THE CHAIRMAN: Okay.

18 MS ANYADIKE-DANES: I take it from what you've just
19 said that it wouldn't concern you that the
20 midazolam was administered as a bolus?

21 A. No, I don't think I would be greatly concerned
22 about that.

23 Q. Although the same product information, at least
24 that from the manufacturer, specifically says
25 that it shouldn't be administered by a rapid or a

1 single bolus IV administration. One finds that
2 at 311-034-004. But is that one of those counsel
3 of perfection --

4 A. I think it probably is. I don't think this is
5 hugely important. One gives midazolam quite
6 quickly when one is injecting it intravenously
7 for endoscopy, for example, although less than
8 two to three minutes. And this may -- the SPCs,
9 these summaries of product characteristics, are
10 very defensive.

11 Q. Yes.

12 A. They fall on the side of caution and for obvious
13 reasons. So I wouldn't lay great stress on that,
14 no.

15 Q. Leaving aside the rapid or single bolus, which
16 comes under the "Precautions", there is some
17 other guidance which indicates the potentially
18 serious effects of this drug; that it's a serious
19 drug, midazolam.

20 A. Oh, yes.

21 Q. If you've got junior doctors who have never
22 prescribed it or administered it, which is the
23 evidence of the junior doctors in this case, and
24 nurses who are unfamiliar with it and may never
25 actually have come across it at all, which I

1 believe is also the evidence in this case, then
2 is there anything that the prescribing paediatric
3 neurologist should say to them? Not necessarily
4 about rapid or single boluses, but just to
5 impress upon them the potential characteristics
6 of this drug with which they may not be familiar?

7 A. I'm always reluctant to use drugs in those
8 circumstances because the possibility of things
9 going wrong is much higher than in the normal
10 course of events. But you're going to say, "But
11 they did give it, and given that they did give
12 it, what should they have done?"

13 Q. Yes.

14 A. And again I would say the counsel of perfection
15 is to say, "Let's look it up. Let's see what the
16 current indications for this drug are, what the
17 information on its administration is, and so on,
18 and let's stick as closely as we can to that
19 information". Of course 1996, difficult to find
20 that information perhaps. Nowadays, we go to the
21 computer on the ward, we press a button and the
22 sheet comes up, as it does in this courtroom.

23 Q. Well, sir, I --

24 THE CHAIRMAN: Mr Sephton?

25 MR SEPHTON: Perhaps the doctor could be taken to Dr

1 Webb's third witness statement, which is 138-3,
2 page 4?

3 MS ANYADIKE-DANES: Certainly.

4 MR SEPHTON: I beg your pardon, it must be the --

5 MS ANYADIKE-DANES: I think you might want page 5.

6 MR SEPHTON: Page 5.

7 MS ANYADIKE-DANES: Yes.

8 THE CHAIRMAN: I think you're going the wrong way. Is
9 it not --

10 MR SEPHTON: No, no, page 5 is the one I had in mind,
11 and then please could we have next to that page
12 6. And we can see on page 6 in the abstract the
13 indication that:

14 "0.15 milligrams per kilogram bolus [I
15 emphasise that] followed by an infusion."

16 Use of midazolam, which is the paper that Dr
17 Webb specifically said he'd refer to before he
18 told Dr Stevenson what to administer. I think
19 the doctor might give his comments on that.

20 MR COUNSELL: With respect, I'm not sure that's
21 advisable(?).

22 MS ANYADIKE-DANES: No.

23 MR COUNSELL: The paper that we've just highlighted --

24 MS ANYADIKE-DANES: Is 1997.

25 MR COUNSELL: -- is 1997.

1 MR SEPHTON: [inaudible: no microphone] in Vancouver
2 and the paper on the left is 1993.

3 MS ANYADIKE-DANES: Perhaps, Mr Chairman, if we may
4 got to what Dr Webb actually did say, which is
5 138-3, page 2. He starts immediately under (1),
6 which is something that I had read out before.
7 He believes he:

8 "... suggested midazolam as a next option for
9 Claire. But I would not have been certain of the
10 dose and would have had to check this by
11 reviewing papers kept in my office."

12 Then he says:

13 "I believe my communication with the medical
14 staff in relation to this was most likely to have
15 been by phone as I did not attend the ward until
16 sometime later and did not write the dose myself
17 in Claire's notes. Cannot recall for certain the
18 dose that I recommended, but I believe this would
19 have been a loading dose of 0.15 milligrams per
20 kilo. I believe this because this was the dose
21 recommended in the principal paper describing
22 midazolam use in this situation at the time."

23 He refers to the Critical Care Med paper,
24 which is 1993, and then he says that:

25 "There were several other shorter papers

1 recommending a similar bolus dose."

2 and then goes on to refer to a subsequent

3 paper, but he certainly doesn't say that a 1997

4 paper is what led him to prescribe the dose in

5 1996. If we pull that up and have the two things

6 side by side again, which is page 5 and page

7 6 ...

8 THE CHAIRMAN: So if we go back to 138-3, page 5, and

9 drop page 2.

10 MS ANYADIKE-DANES: Yes, thank you very much, Mr

11 Chairman (inaudible), yes. So it's the page 5

12 one that Dr Webb says that he used in order to

13 get the dose and to telephone through to the ward

14 what they should do. One of the things that I

15 wanted to, if you like, comment on is if you see

16 after it says "The objective" -- and this is, I

17 presume, a test to a trial or a test carried out

18 with a limited number of children for research

19 purposes -- then you see "The design", and then

20 you see "(inaudible) in the paediatric intensive

21 care unit". Does that indicate anything about at

22 that time, and this of course would be 1993 but

23 at that time what they thought about where you

24 were best placed administering this medication to

25 children?

1 Q. I don't think it -- you might infer that, but I
2 don't think it implies it necessarily. It's
3 merely the place where the trial was carried out.

4 THE CHAIRMAN: No, I understand but I'm lost about how
5 "I infer it but don't imply it" or "imply it but
6 don't infer it".

7 A. You might infer it from what is written, but what
8 is written does not necessarily imply it. The
9 direction is important, right?

10 MS ANYADIKE-DANES: Yes.

11 THE CHAIRMAN: It's very subtle.

12 MS ANYADIKE-DANES: But in any event, that is the
13 paper that Dr Webb referred to. Having read that
14 part out of his witness statement, whether it's
15 to be implied or inferred, it would appear that
16 he himself was not so familiar with the
17 medication. Because he had to go and check what
18 its dose was from the time when he had been in
19 Canada, and he then phones that dose through to
20 the SHOs. Their evidence, as I told you, was
21 that they certainly didn't know about it. At
22 least, Dr Stevenson who is a person who writes it
23 up, he didn't know about it at all. So that's
24 why I had asked you: in those circumstances, what
25 is the obligation of Dr Webb to make sure that

1 the junior doctors, and if necessary the nurses
2 who are going to be carrying out their
3 observations of Claire, understand about the drug
4 that is going to be administered to her.

5 A. There's something of Alexander Pope that says,
6 "Be not the first to try a new treatment, but
7 don't be the last either". Somebody has to take
8 up a new treatment when it appears, and what has
9 happened here is that Rivera et al, as we can
10 see, have carried out a small clinical trial, an
11 open but prospective trial, not strong evidence
12 but some evidence, that suggests that this
13 medication may be of benefit in patients who are
14 in paediatric intensive care units who have
15 status epilepticus, presumably convulsive status,
16 not non-convulsive status.

17 So the evidence for this is not very good
18 here, but nonetheless the doctor has decided that
19 he will try it because this is a difficult case
20 and thinks it might help. And his assessment is
21 that it's probably quite safe, and so the balance
22 of benefit to harm, the balance of possible
23 benefit, which he is inferring from the published
24 study, he is taking out from the published study,
25 is likely to outweigh the possible harm from this

1 drug. And that's fine. I don't have any problem
2 with that. A specialist in the field, who has
3 experience in -- experience of managing such
4 patients, does sometimes have to try new things
5 based on whatever evidence is available at the
6 time, even though the evidence may not be as
7 strong as one would want. That's the first
8 point. So I don't think there's anything to say
9 that this should not have been a possible way of
10 proceeding in these circumstances, given all the
11 caveats we've discussed before.

12 The second point then, which is what you're
13 asking about, is how to communicate the
14 uncertainty in this decision, and how to
15 communicate the way in which one should proceed.
16 And it's my view in such circumstances that, when
17 you are dealing with what is really quite an
18 experimental treatment - it's a small, open
19 study; it's not double-blind, placebo-controlled;
20 it's in patients who have different conditions,
21 not well described in the abstract but presumably
22 better described in the main paper - this really
23 -- it's an early use of this drug and one ought
24 to take great care when communicating to one's
25 staff that one wants to use this drug.

1 To do it over the phone creates difficulties.
2 Communication by phone is not ideal. And if
3 indeed the doctor said on the phone "0.15" and
4 the doctor at the end of the phone wrote "0.5",
5 that's merely an illustration of the difficulty
6 that can arise.

7 So yes, I do think that a doctor, who is in
8 this position, as we've described it, has a duty
9 to be careful about his or her communication of
10 how this drug should be used and the precautions
11 that need to be taken.

12 THE CHAIRMAN: Professor Neville's overall observation
13 of Dr Webb was that he's to be complimented and
14 praised for the efforts that he went to to help
15 Claire. Professor Neville's concern, however,
16 was that he was simply on the wrong track. And
17 the fact, if I take his statement that he did go
18 off and check some papers that he had access to
19 what the appropriate dosage was, that confirms
20 the first point anyway, doesn't it? That he did
21 go to some lengths to do whatever he could to
22 have a check?

23 A. Undoubtedly. Oh, I do agree. I think the fact
24 that he has seen this drug used when he was in
25 Canada, I think he said - although he didn't

1 think that he'd used it himself; he knows the
2 paper to look up; he's gone to the trouble of
3 looking it up, getting a copy, reading it,
4 thinking about it; all that confirms what you've
5 said. But if the diagnosis is wrong, then it
6 rather vitiates the -- that side of the action.

7 THE CHAIRMAN: We build into the equation also
8 presumably that Dr Webb was also the reason -- it
9 may be that the reason that he didn't come
10 himself to the ward at that time and see Claire
11 but did it over the phone to Dr Stevenson was
12 that he had his own list to deal with that day.
13 He had other children presumably he was looking
14 after whom he had to devote himself to as best he
15 could.

16 Q. It does happen, but nonetheless does not alter
17 the fact that communication by telephone is --
18 can be hazardous.

19 THE CHAIRMAN: Yes.

20 MS ANYADIKE-DANES: Thank you. Then if we go to --

21 MR FORTUNE: [inaudible: no microphone], looking at
22 page 5 under the heading "Measurement and main
23 results", the sentence that starts:
24 "None of the patients had clinically important
25 changes in blood pressure, heart rate, oxygen

1 saturation or respiratory (inaudible)
2 attributable to the use of midazolam."

3 Which instruments would be used to measure
4 those changes, bearing in mind that midazolam is
5 being administered by a junior doctor?

6 A. It varies and with time the instrumentation
7 improves, becomes more sophisticated. But blood
8 pressure cuffs, sphygmomanometers, to measure
9 blood pressure. In some cases, particularly
10 nowadays, in-dwelling cannulae in the artery can
11 measure blood pressure directly. But more likely
12 a cuff from a sphygmomanometer measuring blood
13 pressure. Heart rate: probably with a cardiac
14 monitor. Oxygen saturation: nowadays with a
15 little instrument that fits over the thumb or a
16 finger that measures the colour of the blood in
17 the finger. It gives you a measure of oxygen
18 saturation. And respiratory status would be
19 counting the respirations. So these are things
20 that would either be done automatically by
21 monitoring instruments -- I can't remember what
22 it was like in 1996 --

23 MS ANYADIKE-DANES: Well, that's exactly the point
24 that I was going to ask you, doctor, because --

25 A. -- or perhaps by direct measurement by the

1 nursing staff putting a blood pressure cuff on,
2 feeling the heart rate, counting the respiratory
3 rate.

4 Q. That is exactly the point that I was going to ask
5 you because although it's of intellectual
6 interest to know what is done now in the
7 prescription of midazolam, from the point of view
8 of this case and the clinicians who found
9 themselves in the position of having to treat
10 Claire in her condition, 1996 is what's
11 important.

12 A. True.

13 Q. And this is the paper for 1993, and is indicating
14 amongst other things these measurements that were
15 being taken. And I think what Mr Fortune was
16 asking you is: in the 1996 setting in Claire's
17 circumstances - I think that's what he was asking
18 - what should have been being tested then?

19 A. Well, this is --

20 MR FORTUNE: We are only talking about 1996.

21 MS ANYADIKE-DANES: Yes.

22 A. But the paper is 1993. It's what is described.
23 Well, vital signs; this is what we're talking
24 about. When the nurses are asked to make
25 observations, these are the observations that

1 they're being asked to make, in addition to
2 neurological observations.

3 Q. Well, that's what I was going to ask you. Are
4 not these observations that the nurses would be
5 making in any event?

6 A. Yes, indeed.

7 Q. And this paper doesn't suggest that the nurses
8 would have to do anything different in relation
9 to the administration of midazolam?

10 A. Not as stated here. But the clinician might say,
11 "Do it every hour", rather than whatever the
12 nurses were doing at the time. In other words,
13 the clinician might order a review of the
14 patient's status at a different time than the
15 nurses would normally be expecting to do that,
16 which might be four-hourly. But the actual
17 measurements would not be any different to what
18 they would normally be doing when observing vital
19 signs.

20 Q. Would you have thought it advisable that she's
21 connected to a heart monitor?

22 A. At this stage, probably not, as long as phenytoin
23 is not being administered, and there's no
24 indication here of problems with the heart. I
25 suppose that in an intensive care unit it would

1 be routine.

2 Q. Yes.

3 A. But in an ordinary ward, I think I wouldn't be
4 strongly advocating that.

5 Q. Thank you. Well, if we can move on to the
6 phenytoin and the subsequent administration of
7 phenytoin. That happens at 2300 hours, and you
8 have to go back to see what Dr Webb directed so
9 that one can see how that is translated into a
10 prescription that is written up by Dr Stevenson.
11 And what he directed is at 090-022-054, and you
12 can see there:

13 "After the stat dose followed by 2.5
14 milligrams per kilo, 12-hourly."

15 I think you'll find in the course of this that
16 I have left off the sodium valproate which
17 happened at 5.15 pm but I'll take you back to
18 that in a minute. Now that we're here, let's
19 deal with the phenytoin. So that's what he wants
20 to happen afterwards and then he says:

21 "Will need levels 6 hours after loading dose."

22 How do you interpret that direction to the
23 junior doctor? What should he have made of that?

24 A. Well, the directions there is give intravenous
25 phenytoin stat, a single dose, and we've

1 discussed the direction for doing that. And
2 "Will need levels 6 hours after loading dose"
3 means take blood to have the serum/phenytoin
4 concentration measured six hours after you give
5 the phenytoin. That, I think, is
6 straightforward.

7 The difficulty arises here, I think, in
8 interpreting the direction "2.5 milligram per
9 kilogram 12-hourly". That suggests that -- the
10 note "followed by 2.5 milligram per kilogram 12-
11 hourly", that suggests a maintenance dose of 2.5
12 milligram per kilogram, and when the second
13 maintenance dose is given, it should be given 12
14 hours after the first.

15 It might also imply that the first maintenance
16 dose should be given 12 hours after the loading
17 dose, but it doesn't actually say that, doesn't
18 say when the first maintenance dose should be
19 given. It merely says that the maintenance doses
20 should be given 12-hourly.

21 Q. Well, we can see what Dr Stevenson in fact made
22 of that. It's 090-026-075. If one looks up at
23 the top, you have 60 milligrams which he has
24 calculated it out as 60 and we see how he got to
25 60 from the left-hand side. He had 2.5

1 milligrams times the 24; that got him 60. See
2 that from the medical notes. That's his notation
3 there on the left-hand side. So he got 60
4 milligrams 12-hourly. Then if you look at the
5 actual prescription, he's got 60 milligrams and
6 he ticks 8.30 pm and 9.30 pm. So that's going to
7 be 9.30 pm that evening when a dose is going to
8 go on which is about seven hours or so after the
9 loading dose, and then another one at 8.30 pm
10 which is about 12 hours afterwards. So that's
11 what he made of that and that's his signature
12 there.

13 And then that prescription was rewritten and
14 it's changed in certain respects but not that
15 much(?) so that remains the same. And then if
16 one looks at the IV fluids to actually try and
17 see what did happen, you can see if you go to
18 090-038-135. Sorry, I beg your pardon.

19 A: Before you move on to that, can I just ask you a
20 question about the left-hand side.

21 Q. Yes.

22 A: Can we go back, thank you. It says "2.30 pm", is
23 that right, above you?

24 Q. Yes.

25 A: We were talking, I think about 2.45 pm before so

1 that's, I suppose, in the same ballpark:

2 "24 kilograms, 18 milligram per kilogram.

3 Loading dose wrongly calculated as 632.

4 Subsequently given as 635."

5 Right.

6 MS ANYADIKE-DANES: So where that is highlighted

7 yellow, I'm asking you about the dose that he

8 subsequently calculates ...

9 A. ... He's then suggesting that he's going at some
10 time to do it and this is the instruction he's
11 repeating:

12 "Phenytoin 60 milligrams 12-hourly either IV
13 or orally."

14 Right. And "... check levels [he says] at
15 9.00 pm", which is 6 1/2 hours, yes, all right,
16 after the note when he's going to give the
17 loading dose. Okay, good. And then he writes,
18 "Phenytoin 9.30 pm tonight" and retrospectively,
19 it looks like, but actually looking forward to
20 tomorrow, "8.30 am" tomorrow.

21 Q. Yes. Well, can I just pause there. What is the
22 purpose of him being directed to check the
23 phenytoin levels at nine o'clock?

24 A. My view is of that is, I would say, check the
25 plasma concentrations, the levels, if you like,

1 sometime this afternoon or this evening to see if
2 the dose was right, to see if the dose was
3 appropriate. There's no point in measuring the
4 plasma concentration unless you're going to use
5 the information.

6 Q. So then what happens afterwards is contingent.

7 A. Absolutely.

8 Q. So if that is an acceptable level of
9 concentration of the dose, then you move on and
10 you administer your 60 milligrams and 12 hours
11 thereafter you administer another lot of 60 mg.

12 A. Indeed, and this is the problem with advance
13 directives. I tell you, "Give the phenytoin now.
14 He is the dose. Give some more later as a
15 maintenance dose". And you take that and say,
16 "Right, I'll do that" then you stop thinking
17 about it.

18 THE CHAIRMAN: But sorry, the safeguard is to check
19 the level in between surely?

20 A. The safeguard is firstly to check the
21 concentration, the level, and then to decide what
22 dose to give, not to decide in advance that you
23 will give 60 mg 12-hourly. The decision to give
24 the maintenance dose is contingent upon the
25 plasma concentration measurement.

1 THE CHAIRMAN: But then can that be read to say, well,
2 "Check the level" or "Check the concentration",
3 and we know that the concentration came back in
4 excess of what one would expect at 23.4, I think.

5 A. Yes.

6 THE CHAIRMAN: So should that have prompted a
7 reconsideration of whether to go ahead and give
8 the second dose?

9 A. Indeed it should, but by then the second dose had
10 already been given, as I understand.

11 MS ANYADIKE-DANES: Well, that's not entirely clear.
12 There is some debate about whether the second
13 dose was given after the information came through
14 of the levels. It's just a difference in the
15 notation. But in any event, as I understand you
16 to be answering the Chairman, the purpose of
17 checking it is to make sure that you move on on
18 the basis of an appropriate level of phenytoin
19 concentration in her system.

20 A. Otherwise why measure the concentration at all if
21 you're not going to do that. Could I just go
22 back to the yellow on the left, the top yellow?

23 Q. Yes.

24 A. Because in a sense, the instruction is -- could
25 be better. It could say, "Give intravenous

1 phenytoin 18 mg per kg as a loading dose. Check
2 the plasma concentration 6 hours later. If
3 satisfactory, give a maintenance dose of 2.5 mg
4 12-hourly".

5 THE CHAIRMAN: Yes, but I think to be fair to Dr Webb
6 on this point, it wouldn't take a lot of
7 imagination to read into that; that if the level
8 is in excess of what one would expect, that that
9 should prompt a reconsideration.

10 A. Absolutely. I agree entirely with that. That's
11 what one would infer from reading that. If it
12 had been written differently, it would have been
13 clear.

14 THE CHAIRMAN: Yes, it could have been spelt out ...

15 A. Could have been spelt out more clearly. But
16 you're right that that's what one should perhaps
17 have thought from what he wrote.

18 Q. What about the timing? The levels are going to
19 be checked in six hours' time, which was about
20 9.00. In fact, the nurse had written up in the
21 nursing notes that they were to be checked, or at
22 least the bloods were to be drawn for them to be
23 checked, at 9.00. In fact, it happens at 9.30,
24 so there or thereabouts. So that's what's to
25 happen within the 6 hours, and is the 12-hourly

1 dose, then, to happen 12 hours after that stat
2 dose is given, if, in 6 hours' time her levels
3 are acceptable?

4 A. That's what I would direct. Whether that was
5 what was in the mind of the prescribing doctor, I
6 can't say.

7 Q. I understand.

8 A. But I think that is a reasonable strategy.

9 Q. Yes, and then when the actual levels come back,
10 they come back at 11.30 pm, and at that time it
11 would appear that the dose which was prescribed
12 is given. What should have been the response of
13 learning at 11.30 pm that bloods taken at 9.30 pm
14 produced a phenytoin concentration of 23.4? What
15 should have been the response to that?

16 A. That the loading dose was too high for that
17 patient. Even leaving aside the question of the
18 miscalculation, the dose was given; that was
19 done. Having received notice of the plasma
20 concentration or the sodium concentration,
21 whichever it was, which was 23, I would say that
22 is higher than I would have wanted it to be. The
23 target range that you're aiming for is somewhere
24 between 10 and 20, on average, and that's what
25 one goes for; it's the best one can do. Going

1 above that implies the possibility of toxicity.

2 Q. Doing the best you can with what you would have
3 expected one of your junior doctors to do in that
4 situation, if I can put it that way, what would
5 you have wanted to happen when that was received
6 at 11.30 pm and you're thinking, "Should I be
7 giving any more of this directed phenytoin?"

8 A. I'd expect him to phone me.

9 Q. To phone you?

10 A. Yes.

11 Q. As a consultant?

12 A. Yes.

13 Q. Not the registrar?

14 A. No. Well, he might, but I -- I was the one who
15 did the prescription, and I would -- if I came
16 round the next morning and found that this had
17 happened, I would be very angry, because I'm
18 presuming now that I had given clear
19 instructions, as we discussed before, but if he
20 had -- if he gave the -- the maintenance dose,
21 the first maintenance dose before getting the
22 plasma phenytoin concentration, that would be
23 wrong. If he knew the plasma concentration and
24 nonetheless gave the maintenance dose, that would
25 be wrong, and I would be very annoyed that if he

1 had -- if he had not consulted someone at least -
2 - and I would be delighted if he consulted me, I
3 would not mind in the slightest.

4 If he consulted the registrar and the
5 registrar said, "Oh, that's okay, go ahead", then
6 I'm not sure how I'd react, but --

7 Q. Actually I think that's what the junior doctor's
8 evidence was; that he consulted the registrar, Dr
9 Bartholomew and she said to continue. That is
10 his evidence.

11 A. I see, yeah.

12 Q. What's your reaction to that?

13 A. I'd be at least very disappointed.

14 MALE SPEAKER 1: Am I right in remembering that
15 Professor Neville said this was a bit high but it
16 was okay to go ahead?

17 MS ANYADIKE-DANES: Yes.

18 A. I'm sorry, I disagree with that.

19 MALE SPEAKER 1: Okay, don't apologise. It's not the
20 first disagreement.

21 MALE SPEAKER 2: Can I just make a point here and ask
22 while we're on this subject? If one did the
23 checking and came along later in the evening and
24 found that at page 56 of the notes we have "23.4"
25 and in brackets after it we have, "Between 10 and

1 20," which seems to be the doctor reminding he or
2 she that that was what range should be, as the
3 witness has said. Should someone not have
4 checked back to see why it's an overdose and look
5 back at the calculation at page 54 of the notes?
6 MS ANYADIKE-DANES: That was actually going to be my
7 next question. Once anybody had recognised that
8 they were over the target range, if I can put it
9 that way, and you said -- when I asked you the
10 question, you said, "Well, that would imply too
11 much had been given", then does somebody not go
12 back and look and see what was prescribed, what
13 is recorded as having been administered?
14 A. Yes, you might do that.
15 Q. Should you do it?
16 A. Ideally, yes. By that stage --
17 MALE SPEAKER 1: But that's less important.
18 A. I think at that stage the horse has bolted,
19 really.
20 MALE SPEAKER 1: That's less important than deciding
21 what to do next.
22 A. Absolutely.
23 MS ANYADIKE-DANES: Yes.
24 A. Which is why I'm saying, "Yes, you might do it;
25 ideally you would do it". But that horse has

1 bolted, it's done; you're not going to be able to
2 do anything about that.

3 Q. In a way, that's a teaching issue ...

4 A. To an extent.

5 Q. You might deal with your registrar or junior
6 doctor afterwards when you had ...

7 A. To an extent, yes, you might.

8 Q. ... addressed matters.

9 A. Indeed. But there is -- there is a point to this
10 question which I think is important, and that is
11 that the calculation of the maintenance dose does
12 depend on the relationship between the loading
13 dose and the plasma concentration, so in the cold
14 light of day I'm sure I would do that.

15 I would go back and I would draw the graphs,
16 actually, of concentration versus dose, and there
17 are ways of doing this. And I would certainly go
18 back and look at the loading dose, draw the
19 loading dose against the plasma concentration to
20 calculate the kinetics of the drug in that
21 individual, and from that information I would
22 predict the maintenance dose. I think that's a
23 difficult exercise to expect a junior hospital
24 doctor to do.

25 Q. But you as a prescribing consultant might do it?

1 A. I as a clinical pharmacologist could and would
2 certainly do it.

3 Q. Yes. Can I ask you, Dr Stevenson had originally
4 envisaged that the phenytoin would be given at
5 9.30.

6 A. I'm sorry, say that again.

7 Q. Sorry, I beg your pardon. Dr Stevenson, who is
8 the SHO, in his prescription which is still there
9 on the screen (you can see it), that that
10 phenytoin would be given at 9.30; that's what he
11 thought, and it may be because he thought that
12 the levels were going to be checked at 9.00, but
13 that doesn't equate to 12-hourly after the
14 loading dose.

15 A. No, well that's why I said it's not clear what
16 that instruction means in relation to the timing
17 of the first maintenance dose. It's clear about
18 the timing of the second maintenance dose; it
19 should be 12 hours after the first. It does not
20 specify that the first maintenance dose should be
21 12 hours after the loading dose. Now, clearly,
22 as you've just said, the doctor did not interpret
23 it in that way. He wrote down "9.30" which is
24 what, seven hours or so after.

25 Q. Well, in fairness to Dr Stevenson, he might have

1 worked that out subsequently because in fact
2 somebody knew, or decided to give it at 11.30.
3 If there was a change of that sort, would you
4 expect any kind of record to be made as to how we
5 get from Dr Stevenson's prescription that it
6 should be given at 9.30 to the administration by
7 Dr Stewart at 11.30?

8 A. Um ... if a nurse had been going to give it, I
9 would have expected it to be given at 9.30 or
10 thereabouts, because the nurses adhere to the
11 instructions in the prescription chart. If a
12 doctor were going to give it, I might expect the
13 difference between the written and the given time
14 to be greater because doctors are busy doing
15 things off the ward and may not get there in
16 time.

17 So it could be -- one explanation would be
18 that the doctor was busy and couldn't get there
19 in time to give the dose. Beyond that, it may be
20 that the other doctor wanted to wait for the
21 blood concentration to come back before making a
22 decision. I can only speculate, I don't know.

23 Q. Yes, if we then look at the fluid balance sheet
24 at 090-038-135, this is one of the places where
25 you get some guidance as to when these

1 intravenous drugs were actually being
2 administered. You can see there the midazolam,
3 which I'm going to have to come back to, adjusted
4 the stat dose of midazolam, but that's a
5 continuous dose of midazolam. You can see that
6 that is at 4.00. And then you see at -- it's
7 slightly obliterated, but in fact it's at 2300
8 hours; working across you can see, "3 ml per hour
9 [it looks like], phenytoin." Or maybe that's the
10 midazolam. Sorry, I beg your pardon; that is the
11 midazolam. Just ...

12 A. Is that -- is that ...

13 Q. Just -- just -- sorry, I beg pardon. Just above
14 that you see the 60, so that's the phenytoin
15 going in.

16 A. Yeah, okay, so at 2300 -- or 2200; do we know?

17 Q. Can you tell from looking at that fluid balance
18 sheet when the phenytoin is actually given and
19 how much of it is given?

20 A. Well what I see is that at 2300, obscured by the
21 hole in the paper but clearly 2300, 11.00 pm,
22 phenytoin is given.

23 Q. Yes.

24 A. That's what it appears to be saying. It doesn't
25 appear to be saying what dose is -- what dosage -

1 - what dose was given. There is a "60" written
2 above it, but that's at 2200; it's not clear that
3 it relates to the phenytoin.

4 Q. No, I think, in fairness, that's carrying down
5 the acyclovir figure, which is 60.

6 A. Right, okay.

7 Q. So that's not the phenytoin. Is it clear from
8 that record ...

9 A. Well in that case it just says -- it just says
10 "phenytoin."

11 Q. Yes, so there's no ...

12 A. Of course, the drug chart says 60 mg.

13 Q. Yes. So that would be given in what, just a push
14 through?

15 A. No, that again would have to be given by slow
16 intravenous infusion over at least a few minute
17 at any rate. Not as slowly as the 600 mg but
18 over a minute or two, perhaps.

19 Q. What would it be given in?

20 MALE SPEAKER 3: Can I help Dr Aronson, because in
21 fact in the nursing notes there is the answer at
22 090-040-138, because at 11.00 pm, in the
23 handwriting of Staff Nurse McCann it says:

24 "IV phenytoin erected by doctor and run over
25 one hour, cardiac monitor in situ throughout

1 infusion."

2 A. One hour, yeah, yes.

3 MS ANYADIKE-DANES: Yes, thank you.

4 A. Yes, thank you, we saw that before and thank you

5 for reminding me. I would expect it to be -- to

6 answer your question, I would expect it to be

7 made up in saline, 0.9 per cent saline, which is

8 always the default position for infusing drugs.

9 Q. If you look at the intravenous fluid prescription

10 chart at 090-038-136, you can see that that has

11 specified the normal saline for the midazolam and

12 underneath that it looks as if they had put

13 phenytoin there and crossed that out. I may be

14 wrong; it is difficult to see.

15 But in any event, it doesn't indicate what the

16 phenytoin should be put into to infuse it. Is

17 there any reason that you can think of why it

18 would specify what it is for midazolam and not

19 for phenytoin?

20 A. The only suggestion I can make is to return to

21 the British National Formulary in the appendix

22 that we were discussing before, where phenytoin

23 is specified quite clearly as to be given in --

24 in saline, and therefore one might think that

25 there was no need to specify it otherwise.

1 Whereas midazolam is not specified at all, and
2 one might therefore want to specify that saline
3 was to be used in that case.

4 Q. Just while we are here and you say that, how
5 would Dr Stevenson have known to use normal
6 saline for midazolam if it's not specified in the
7 BNF which is where he might have gone to look?

8 A. Because for intravenous infusion, saline, I would
9 say, is the default position. If you're not
10 sure, then saline is a safe medium in which to
11 infuse any drug.

12 Q. Thank you.

13 A. There are one or two minor exceptions, but that
14 is what one would do if one didn't know.

15 Q. Yes. I wonder if I then could just go back to do
16 the continuous infusion of midazolam. The
17 clinical note records that at 090-022-055, and
18 you can see it says, "2 mcg by kilogram per
19 minute." And then Dr Stevenson -- it's him doing
20 it, this is his note -- he calculates that out as
21 69 mg per 24 hours. There's nothing wrong with
22 that calculation?

23 A. I think that's right.

24 Q. And that then has to turn itself into a
25 prescription and one sees his prescription for

1 that. It's at 090-026-075. If we just blow up
2 the top one because that's at B. There we are.
3 That's his prescription, and then the
4 prescription gets rewritten. If one looks at
5 090-026-073 it's rewritten there.

6 It's a bit difficult to see, but it's the
7 second line, and it looks like:

8 "2 ml increased by 1 ml an hour to 3 ml an
9 hour every 5 minutes."

10 In fact I think the nursing note helps with
11 that; just to see that more clearly it's at
12 090-040-141. Then if you turn that round you can
13 see:

14 "Continuous infusion running at 2 ml per hour
15 of Hypnovel [that's the midazolam], to increase
16 by ..."

17 -- is it 0.1, or ...

18 A. Yes.

19 Q. Yes, 0.1, because it's now millilitres. 5
20 minutes until up to 3 ml an hour.

21 Is it possible to see from the clinical note
22 that he takes of what Dr Stevenson believes Dr
23 Webb has told him over the phone, or told him,
24 how he gets to that prescription?

25 A. Can we go back to ...

1 Q. Yes, if we go back to the clinical note again at
2 090-022-055.

3 A. Yes, I'd also actually like to go back to the
4 first prescription.

5 Q. Sorry, yes.

6 A. Not the one that was rewritten but the one -- the
7 open that was to be eventually rewritten.

8 Q. 090-026-075.

9 A. Can we just enlarge the top bit of that?

10 Q. Yes.

11 A. Actually, I'd like to talk about the whole thing,
12 in fact.

13 Q. Yes?

14 A. the first thing to say I that the British
15 National Formulary is very clear about
16 prescription writing for doses that are less than
17 1 mg, in other words, in micrograms; and this is
18 true of the 1996 BNF. It says:

19 "Quantities less than 1 mg should be written
20 in micrograms."

21 And elsewhere it says that the words:

22 "Micrograms and nanograms should not be
23 abbreviated."

24 Q. So not to "mcg"?

25 A. Correct. Because there is a danger that the

1 prescription will be misread as milligrams and
2 that something will be misinterpreted. A
3 thousand-fold difference, you might say, "Well,
4 that's unlikely", but I have seen errors arising
5 of ten-fold differences that were important when
6 prescription charts were misread. And I think
7 that this is very sound advice and there's a
8 lesson here that if you're writing doses of
9 micrograms, take the time to write it out in
10 full.

11 Q. Okay.

12 A. But it's clear "mcg" and it's unlikely that an
13 error would be made, but nonetheless, one likes
14 to see things done properly.

15 Below midazolam, you think says "120"; maybe
16 it does. It could be 130. I'm not sure what it
17 says, but it's certainly not 12. But that's the
18 previous loading dose.

19 Curiously, it's not signed off as having been
20 given and I don't know what that implies but it's
21 signed to be given but not as having been given.

22 Okay, so the dose to be given is 2 mcg per
23 kilogram per minute. If we go to the next page
24 which you brought up which is the calculation of
25 the dose ...

1 Q. Yes, 090-022-055.

2 A. At the top we've talked about the wrong
3 loading dose, but the maintenance dose is 2 mcg
4 per kilogram per minute; a 24 kg child, 48
5 micrograms per minute, multiplied by 60, 2,880,
6 2.88 milligrams per hour, 69 milligrams per 24
7 hours. That calculation, as far as I can see, is
8 correct.

9 Q. Yes.

10 A. But the arithmetic has not been done properly.
11 How are you going to give that? Well, it's going
12 to be given in 50 ml of normal saline I think you
13 said. Can we go to that page that says that?

14 Q. Yes, that's the IV fluids. It's at 090 038 136.

15 A. So here we have 69 milligrams. It looks as if
16 it's been changed from something. It could be 64
17 but that's not a major problem; 69 milligrams of
18 Midazolam to be given in 50 ml presumably, again
19 not clear, but one would infer that 50 ml of
20 normal saline, that's .9 per cent sodium chloride
21 so there's 69 milligrams in 50 ml. That's a
22 concentration of 1.4 roughly milligrams per
23 millilitre and that is to be infused at a rate of
24 1 ml or 2 ml per hour. So that's 2.8 milligrams
25 per hour multiplied by 24 gives you about 69

1 roughly milligrams in the day. So that is a
2 correct calculation.

3 Q. Yes but then the nurse notes that it is to be
4 increased and that's to carry on up till 3 ml an
5 hour and you see that at 090 041 41.

6 A. Then the instruction is to increase by it should
7 be 0.1. Again the BNF is very clear on this. If
8 you're writing fractions, you should put a
9 preliminary zero in case the dot is missed.

10 Q. Mm hmm.

11 A. It's unlikely that that instruction would be
12 misunderstood but nonetheless there is a
13 principle to be followed which would be 0.1 ml
14 every five minutes until up to 3 ml per hour. So
15 that means ten times .1 over 50 minutes the dose
16 is to be increased from 69 milligrams per 24
17 hours by 50 per cent so we add half of 69, 39.5,
18 that's about 109 milligrams per day, 50 per cent
19 more than was originally intended.

20 Q. Is it obvious to you from the notes and records
21 where that comes from? One can see potentially a
22 change in the rewritten prescription at 090 026
23 073. Although it's actually quite difficult to
24 see that but on that second line, that might be
25 where that's happening.

1 A. Yes, if you could just enlarge that because it is
2 difficult to see, yeah. So he, or somebody, I
3 don't recognise the signature, has said, and as
4 you say it is difficult to read in the photocopy,
5 Midazolam 2 ml per minute, I guess, is it?

6 Q. Well, then next per hour.

7 A. Two ml per hour.

8 Q. Think you can then see the .1 ml an hour to --

9 A. I can see the .1 ml per --

10 Q. -- 3 ml an hour and then underneath --

11 A. Every five minutes.

12 Q. Yes.

13 A. Yes so that's where that instruction has come
14 from as you said and I presume that that is what
15 it's saying.

16 Q. This is a different doctor who rewrote this and
17 signed this off. Given that all of this therapy
18 is actually being directed by the paediatric
19 neurologist and he is the person who has been
20 directing the Midazolam part of this, in fact,
21 all of it really, but certainly the Midazolam,
22 and his original instruction was correctly taken
23 down by Dr Stephenson(?) as you've seen in the
24 clinical note, what do you think should have led
25 to a change like that?

1 A. I suppose that the obvious inference from this is
2 that the prescribing doctor thought that the
3 clinical response was not adequate and that an
4 increased dose was required. Looking at your
5 very helpful diagram at --

6 Q. 310 020 001.

7 A. -- at 020 001.

8 Q. Yes.

9 A. What you see is that the increase -- whether the
10 prescription occurred at that time but the
11 increase in dose of Midazolam occurred just after
12 the episode of screaming and drawing up of the
13 arms at 9.00 pm. One might infer that that's why
14 the instruction to increase the dose of Midazolam
15 was given and she had already had two episodes
16 that could be interpreted as epileptic episodes,
17 having teeth tightened slightly, teeth clenched
18 and groaned. Whether one would interpret the
19 episode of screaming and drawing up of arms in
20 that same way I think you'd need to ask a
21 neurologist. To me, that suggests more that this
22 girl was perhaps in pain but it might be, I
23 suppose, interpreted that this was more evidence
24 of continuing epileptic activity.

25 Q. But given the view that you expressed earlier,

1 what are your comments on having increased the
2 Midazolam at this stage, as to the advisability
3 of that if I can put it that way?

4 A. Really that we still don't have a diagnosis that
5 shows that this medication is appropriate and so
6 we're in a hole and we're digging it deeper. It
7 might, had the diagnosis been correct, have been
8 appropriate or at least a reasonable strategy at
9 the time but in the absence of a diagnosis, I
10 feel very unhappy about it. As I say, in my
11 position as a general physician, I would have
12 been asking for help long before this. But given
13 that the diagnosis was not substantiated, you're
14 piling also Epilim here, you're adding drug to
15 increase the dose of a drug to treat a disease
16 that you haven't diagnosed.

17 Q. Yes and then if we just go finally in the set of
18 the anticonvulsants, if we just keep that up
19 there, there's the Epilim or the Sodium Valproate
20 and that was administered, as you can see there,
21 at 5.15 pm. Dr Webb's direction was to add IV
22 Sodium Valproate, sorry this is at 090 022 055,
23 you don't have to pull it up because this might
24 help you to answer, to add the IV Sodium
25 Valproate 20 ml per kilo IV bolus followed by an

1 infusion of 10 milligrams per kilo IV over 12
2 hours. That was the third part of his plan when
3 he came to examine Claire at 5.00 pm in the
4 afternoon. Can you give your view as to the
5 advisability of that?

6 A. We're adding another anti-epileptic drug again in
7 the absence of diagnosis so that the same
8 comments apply.

9 Q. There was to be I should say that -- if you see
10 under that Sodium Valproate you will see that
11 it's continued on as an infusion and that's
12 because that's what Dr Webb had wanted to happen
13 but it's far from clear, it should say that that
14 actually did happen, because if one goes to the
15 drugs and you can see at 090 026 075 right down
16 there at the bottom, yes, there you are you can
17 see the Sodium Valproate 400 milligrams 5.15 pm
18 time administered. You can see it's signed for
19 and the person giving it who is Dr Sands, the
20 Registrar, has initialled it. Then above that in
21 the regular prescriptions, you can see that there
22 is the prescription for the continuous infusion
23 of Sodium Valproate but that's struck out and
24 when that prescription is rewritten at 090 026
25 073, it simply doesn't appear.

1 A. So it wasn't given.

2 Q. It looks like it wasn't given and I think Dr
3 Hughes, who is the person who has signed on that
4 and, in fact, rewrote that prescription, I think
5 her evidence was that she didn't give it or at
6 least she thinks she might not have given it. I
7 think that's more accurate. I'm not entirely
8 sure that there's a full recollection of
9 everything that happened. But so far as you're
10 concerned, if we pull back at the timeline we had
11 of 310 020 001, what would have prompted that
12 decision not to carry out the infusion of Sodium
13 Valproate which otherwise would appear to have
14 carried on fairly proximate to the administration
15 of the bolus?

16 A. I'm having difficulty in deciding what prompted
17 the use of the drugs in the first place.

18 Q. I understand.

19 A. So it's hard to know why one would change one's
20 mind in the case of a drug that perhaps one would
21 not have given anyway. I can't speculate on
22 that.

23 Q. Thank you. I just have a few more questions at
24 least for my purposes to ask you. I know it has
25 been a very long afternoon but we are nearing the

1 end, at least from the point of view of the
2 things that I have to ask you. One question was
3 if one looks at the drugs singly or in
4 combination, could any of them have affected
5 Claire's white cell count, either by raising it
6 or lowering it? To help you, we have a schedule
7 that shows the blood cell count. It is 310 022
8 001. There you see them. Now, there is no
9 differential done so we can't help but this is
10 the information that was available so far as we
11 understand it.

12 A. I commented on these white cell counts in my -- I
13 mentioned them but didn't comment on them and the
14 first question I would ask, the count is 16,000,
15 units are slightly different nowadays, but that's
16 higher than the reference range as quoted above,
17 4 to 11.

18 Q. Yes.

19 A. My first question would be, "What's the
20 differential?" because white cells come in a
21 large variety. About 70 to 80 per cent of all
22 white cells in the blood are what are called
23 neutrophils because of the way they stain with
24 the particular kind of stain to which they are
25 completely neutral so they are called neutrophils

1 and they are indicative usually of bacterial
2 infection. Generally speaking, when a white cell
3 count rises to this level, it's usually because
4 of neutrophilia, an increase in neutrophils, and
5 one can say that that is consistent with a
6 bacterial infection. If, however, the increase
7 is predominantly in the number of lymphocytes,
8 which form about 15 to 20 per cent of the normal
9 count, then one makes other assumptions. One
10 says, "That is more like a viral infection" and
11 that is what was suspected in this case. So I
12 would really want to know the differential on
13 that count and I'm surprised that it's not
14 available. I would have thought that
15 laboratories should be giving that as a matter of
16 routine on the differential on a raised white
17 cell count in these circumstances. If they
18 didn't give it as routine, I would be phoning up
19 and saying, "Can you do a differential white cell
20 count please?"

21 Q. Would you be doing that because you want to see
22 if what is being administered has had any effect?

23 A. No, generally not. I would be using it as a
24 diagnostic question from the point of view of
25 bacterial or viral infection or some other effect

1 which I can come to later. But this was taken at
2 10.30 pm on the 21st which is before Claire -- is
3 that right, that's the --

4 Q. No, that's --

5 MALE SPEAKER: That's Monday night. She was admitted
6 on Monday night.

7 A. Yes, 10.30 pm on the 21st.

8 MALE SPEAKER: Yes.

9 A. Your chart shows that she received all the drugs
10 on the 22nd.

11 MS ANYADIKE-DANES: That's correct.

12 A. So it is not just unlikely but --

13 MALE SPEAKER: It can't be a reaction to the drugs.

14 A. It can't be a reaction to the drugs.

15 THE CHAIRMAN: Just before you move on, when Professor
16 Cartwright gave evidence yesterday, he was really
17 taken aback by the fact that the printout which
18 gave the white cell count did not include the
19 differential and he said -- there's perhaps
20 something of a difference between him and
21 Professor Neville(?) in this because Professor
22 Cartwright was saying yesterday that this was a
23 standard calculation to be given in a printout
24 and had been for decades.

25 MS ANYADIKE-DANES: Mr Chairman, we can call that up if

1 you wish to see some ...

2 THE CHAIRMAN: Yes, please.

3 MS ANYADIKE-DANES: It's 090 032 108.

4 A. While we're doing that, I should say that, as I
5 said, I would expect the differential to be
6 reported in a raised white cell count and if it
7 were not, I would be phoning the laboratory to
8 ask what it was.

9 THE CHAIRMAN: The difference between him and
10 Professor Neville is this. What Professor
11 Cartwright said yesterday was that below
12 platelets in the left-hand column, below that, he
13 would expect automatically for the differential
14 to be printed.

15 A. I would expect it above platelets and below
16 leukocytes but the point is the same.

17 THE CHAIRMAN: Right, okay. But you would expect it
18 as a standard part of this printout?

19 A. Yes.

20 THE CHAIRMAN: Right, and Professor Cartwright said
21 not just in 1996 but actually for some
22 considerable time before that?

23 A. Yes. Sir, I think that practices may vary from
24 hospital to hospital.

25 THE CHAIRMAN: Yes.

1 A. But in a case where the white cell count, the
2 leukocyte count, the white cell count is raised,
3 I would expect to be told what the differential
4 count was as a matter of routine.

5 THE CHAIRMAN: Right and I think Professor Neville's
6 only -- this wasn't quite explored in the same
7 way as Professor Neville but he said if he got
8 that result, he would immediately ask the
9 laboratory for the differential. So either/or
10 but both of them seemed to say that this was the
11 natural and inevitable reaction to getting this
12 reading.

13 A. The first question you ask when you see a count
14 of 16.5, "What's the differential?" It trips off
15 your tongue automatically.

16 THE CHAIRMAN: If that wasn't picked up on the Monday
17 night/Tuesday morning when the results came
18 through, it should certainly have been picked up
19 on the ward round on Tuesday morning?

20 A. Yes.

21 THE CHAIRMAN: Right.

22 A. There is a hint elsewhere of the differential
23 count here and it's from the lumbar puncture
24 result, the CSF, which I thought was rather
25 curious. I don't know if you can call it up.

1 THE CHAIRMAN: It's 090 022 ...

2 A. Very good. That's the cerebrospinal fluid
3 analysis on -- I'm not sure what the date is.

4 MS ANYADIKE-DANES: That would be the 23rd.

5 THE CHAIRMAN: Curiously, it's dated the 24th, which
6 also seems to be ...

7 A. It's post mortem.

8 MS ANYADIKE-DANES: Post mortem, sorry, yes.

9 A. Yes, it's post mortem. Now, what are
10 erythrocytes doing in the cerebrospinal fluid?
11 You don't normally expect to see erythrocytes in
12 the cerebrospinal fluid. If there has been a
13 subarachnoid haemorrhage, which we have no
14 evidence of in this case, there would be
15 erythrocytes but we have no evidence of that. So
16 why are there erythrocytes in this fluid? The
17 likeliest reason for that is what we call a
18 "bloody tap". When you take cerebrospinal fluid,
19 you stick a needle through one of the lumbar
20 spaces, the space between the two lumbar
21 vertebrae low down in the back and the needle
22 enters the space in which the cerebrospinal fluid
23 is to be found around the spinal cord. You do
24 that because at that point, the spinal cord runs
25 out and all you have are strands of nerves

1 hanging down from the end of the spinal cord. So
2 you're not going to go into the spinal cord
3 itself. You're going to be pushing aside the
4 fronds that hang down from the tip of the end of
5 the spinal cord, the cord itself. So you put
6 your needle in and you suck off spinal fluid.
7 Sometimes when the needle is going through on its
8 way to the spinal fluid, it hits a little blood
9 vessel and you suck up blood with it. That's
10 called a "bloody tap". I think that's what
11 happened here and you've got some leukocytes
12 roughly in proportion, as you would expect, to
13 the number of erythrocytes. I think this is a
14 bloody tap and you see that the 4,000 cells were
15 mostly lymphocytes. I can't prove it but I
16 suspect that this is telling us that the raised
17 white cell count was a lymphocytosis consistent
18 with a viral infection.

19 Q. Thank you. Just for the sake of completeness,
20 because I have been asked, could any of the
21 medication have affected her white cell counts
22 the other way, reduce them in any way?

23 A. All drugs can reduce the white cell count. There
24 is no drug in my knowledge -- well, there might
25 be a few but there are reports of low white cell

1 counts due to almost any drug you can mention and
2 indeed a low white cell count, neutropoenia as
3 it's called or sometimes agranulocytosis when the
4 count is very, very low, is known as a designated
5 medical event, that because you can't tell what
6 it means, but what it means is that so often when
7 you get a low white cell count with no obvious
8 cause, it's due to a drug. You can bet your
9 bottom dollar it's due to a drug. What drug it
10 is, you can't always tell. So, any drug can
11 lower the blood -- the white cell count, yes, and
12 one never knows what is doing it.

13 Q. Could it have had the effect of lowering what
14 might otherwise be an even higher white cell
15 count associated with the viral infection?

16 A. Unlikely.

17 Q. Thank you.

18 A. Unlikely, because when a drug does that it pretty
19 much reduces the white cell count dramatically.
20 It would be unlikely to reduce a count of 20 to
21 16. I mean, it's conceivable, but I think it's
22 highly unlikely.

23 Q. Thank you.

24 A. Just for the sake of completeness, to answer the
25 question that, I think, as you've suggested sir,

1 is probably irrelevant, because the drugs were
2 taken after the raised white cell count. In
3 cases of allergic reactions, you can get a rise
4 in the count of -- of the type of leukocyte
5 that's known as an eosinophil, but we have no
6 evidence in this case that that was relevant.
7 That's just for the sake of completeness in
8 answering your question.

9 Q. Thank you. And could the drug therapy have had
10 any effect on her serum sodium levels?

11 A. She had a low serum sodium concentration.

12 Q. She did?

13 A. Hyponatraemia, low sodium in the blood. The
14 commonest cause of that is sodium -- excess
15 sodium loss from the body. And the commonest
16 cause of that is the use of a diuretic drug, a
17 water tablet conventionally called, which causes
18 increased loss of sodium and water. And she
19 wasn't, as far as I'm aware, being given any
20 diuretics.

21 The other major cause of hyponatraemia is
22 dilution of the sodium concentration by too much
23 fluid. I most commonly see this when I'm called
24 to the surgical wards to consult on a patient who
25 has a low serum sodium. And what has happened is

1 that the surgeons have given too much dextrose
2 and not given any saline after an operation and
3 they have diluted, diluted, the sodium
4 concentration down. We stop the dextrose and
5 give saline and the problem resolves.

6 In this case, the dilution is thought to
7 have occurred in a different way. And it's
8 through the secretion of a hormone that is
9 produced in the pituitary gland in the brain,
10 little gland that hangs down at the base of the
11 brain, and it secretes a hormone called ADH,
12 anti-diuretic hormone.

13 Now, when we go to sleep at night, we secrete
14 anti-diuretic hormone. That's why we don't get
15 up to have to pass urine. However, the older
16 members of the -- the older members of the -- I
17 was going to say "audience", it's the wrong word
18 -- will know that they do get up at night to pass
19 urine, once, twice a night, maybe, sometimes
20 more. That's because you cease to secrete ADH at
21 night as you get older.

22 The circadian rhythm of AHD changes, as you
23 get older you start secreting it more during the
24 day and less at night. So, remember that when
25 you're wakened in the morning, it's your brain

1 that isn't working properly, it's not your
2 bladder. You have failed to secrete ADH. If, on
3 the other hand, you secrete too much ADH then you
4 reduce the amount of water output, you build up
5 water and you dilute your sodium.

6 And there are ways of distinguishing these
7 different types of hyponatraemia. And the tests
8 here suggest secretion of ADH. And it's called
9 inappropriate, because normally ADH is secreted
10 in response to a change in the osmolality of the
11 blood. That means -- difficult concept. That
12 means the amount of sodium in the blood,
13 basically. It's more complicated than that. But
14 to put it simply, the more sodium you have the
15 more osmotic your blood is and ADH will respond
16 to that.

17 So, if you have a high sodium, the pituitary
18 switches on ADH, you retain more fluid and your
19 sodium is diluted, falls back. If your sodium is
20 low, you should switch off ADH. So, here you
21 have a low sodium, but you have increased ADH.
22 So, it's inappropriate. That's why it's called
23 the syndrome of inappropriate ADH secretion.

24 So now your question is: could any of these
25 drugs have stimulated the secretion of ADH?

1 Because this does happen. There are reports of
2 this. And some drugs do. I believe that none of
3 these drugs does that. There have been reports
4 that valproate can do it, but they're few and
5 anecdotal. And I was learning only last week at
6 the International Society of Pharmacovigilance
7 that large study using the general practice
8 research database, as it used to be, showed that
9 there was no increased incidents of hyponatraemia
10 in patients taking valproate.

11 So, I'm pretty sure that none of the drugs
12 that we are talking about would have contributed
13 to the risk of hyponatraemia.

14 A. Thank you very much. I think I've probably just
15 got two more questions to ask.

16 THE CHAIRMAN: Sorry. Just one small point before we
17 leave that.

18 MS ANYADIKE-DANES: Yes.

19 THE CHAIRMAN: Claire's vomiting would have had some
20 affect on the --

21 A. Small affect, yes. Vomiting tends to affect the
22 potassium more, but it could affect the sodium as
23 well. You will lose salt and water, yes. So, it
24 might have had a bit of an affect. I wouldn't
25 count it as major though, in this setting.

1 THE CHAIRMAN: No, okay.

2 A. And certainly not, inappropriate ADH secretion,
3 because the tests do suggest that very strongly.
4 That that was the diagnosis.

5 MS ANYADIKE-DANES: Yes --

6 THE CHAIRMAN: What test is the doctor referring to?

7 A. Yes. You start with the serum test, serum sodium
8 potassium and urea. Normally if you have a low
9 sodium, you tend to have a high potassium. The
10 two go in opposite directions. If they're both
11 low and the urea is low as well, that suggests
12 dilution. Everything is low, because there's too
13 much water, simple. You then measure the
14 osmolality of the serum and the osmolality of the
15 urine, how much sodium tension there is, if you
16 like, in those two things. If they don't match
17 or if they match in a particular way then you can
18 diagnose what the cause of the low sodium is.

19 So, those are the test on which I would base
20 a diagnosis of inappropriate secretion.

21 THE CHAIRMAN: SIADH rather than fluid overload was
22 the cause.

23 A. Well, fluid overload is, of course, the secondary
24 effect of SIADH. It's fluid retention. But, if
25 by fluid overload you mean excess administration

1 of fluid --

2 THE CHAIRMAN: Yes.

3 A. Yes, then I would agree with what you said. That
4 it's -- that the test diagnose SIADH rather than
5 excess fluid administration.

6 THE CHAIRMAN: Why is that?

7 A. Because the osmolalities would be different in --
8 if there was overload, because the pituitary
9 would respond normally to the dilution whereas
10 here it's -- it's inappropriate.

11 THE CHAIRMAN: The only osmolality I can put my finger
12 on at the moment is 090-022-057. You can see in
13 the left-hand margin, there it is.

14 A. Can you enlarge that?

15 THE CHAIRMAN: Yes.

16 A. Yes, 249(?). It's low serum osmolality.

17 THE CHAIRMAN: That helps you to suggest that it's
18 SIADH rather than ...

19 A. Yes, but I would like to see the urine osmolality
20 as well. Now, you can -- you don't have to
21 measure the urine osmolality, you could calculate
22 it if you knew the urine, sodium and potassium.
23 But, I would like to see the urine osmolality
24 too.

25 THE CHAIRMAN: Thank you.

1 MS ANYADIKE-DANES: I think that's a difficulty. They
2 might not have done that earlier.

3 A. Right.

4 Q. There are only two records of her serum sodium
5 levels taken. One is the evening of her
6 admission and you see the result of that on 090-
7 022-052. See that's taken down there. We don't
8 exactly know who did it, but in any event that is
9 the details that come through. Then after that,
10 one sees it --

11 A. As for there, I would expect the osmolality to be
12 roughly normal, because the sodium is not -- it's
13 low, but not greatly low.

14 Q. Yes. Then we go to 090-022-056 and just at the
15 top there. Somebody correct me if I'm wrong, but
16 we have not been able to get the lab result that
17 relates to this. But, in any event, maybe it was
18 phoned through and it's just been mislaid. But,
19 that's the only detail that we have. This is
20 from the bloods taken earlier that evening.
21 Until you come to the one which Mr Sephton showed
22 you, that's really all that we have.

23 A. It says here: "Send urine for osmolality", which
24 is perfectly appropriate.

25 Q. Yes, it does.

1 A. And I had assumed that the subsequent diagnosis
2 was based on that result. You say there's no
3 urine osmolality measured?

4 Q. We've not been able to find the result of that.
5 It's not clear that any urine was actually taken
6 or measured after that time. So, that may be a
7 reason, but in any event we've not come across a
8 result that relates to that direction. Let me
9 put it that way.

10 A. In that case, my assumption is in doubt, in that
11 case, without the urine osmolality. I had
12 assumed that that was the basis on which it was
13 discovered. So, your question is very
14 appropriate.

15 Q. So, your point is, in that way you can't
16 distinguish between how the hyponatraemia arose?

17 A. I think, it could -- it could have been due to
18 fluid overload if there wasn't a matching urine
19 osmolality to confirm the diagnosis of SIADH.

20 Q. Yes. Well, as you see --

21 THE CHAIRMAN: Can you have combination of --

22 A. Sorry?

23 THE CHAIRMAN: Can you have a combination of SIADH --

24 A. Yes, you can. That can be difficult to diagnose,
25 of course. That complicates things.

1 MS ANYADIKE-DANES: But you can see from this note
2 that this is what the SHO in the evening was
3 querying?

4 A. Yes.

5 Q. The thoughts that he got hyponatraemia and his
6 first line query was fluid overload and low
7 sodium fluids and then he queried the SIADH and
8 then he had some suggestions for how one might
9 address that. But, that was largely based on his
10 feeling that it might be fluid overload.

11 A. Yes.

12 Q. But, in any event, what I was seeking to clarify
13 with you is that so far as you can tell and in
14 your experience none of these drugs that were
15 being produced would have affected that
16 hyponatraemia condition that Claire developed, if
17 I can put it that way?

18 A. Correct.

19 Q. Whichever route she developed it by?

20 A. Indeed.

21 Q. Thank you. Then the last question that I was
22 going to ask you related to the brainstem test.
23 If we can pull that up at 090-045-148. You can
24 see that the first one was carried out at 6.00 am
25 in the morning and that's what I want to draw you

1 attention to. If you just see the answer, so
2 perhaps if I can take you to where the answer is.

3 Firstly (c):

4 "Could other drugs affecting ventilation or
5 level of consciousness have been responsible for
6 the patient's condition?"

7 There you see the answer: "No." I was asked
8 to ask you whether you believed that any
9 combination of those drugs could have
10 precipitated or contributed to her respiratory
11 arrest, which is something that happened at about
12 3.00 am on the Wednesday morning?

13 A. I apologise again for mis-remembering the order
14 of events here. What I was recalling was the
15 association between the respiratory arrest and
16 the midazolam.

17 Q. Yes.

18 A. Not the start of the midazolam, as I expressed at
19 that time, but the end of the midazolam.

20 Q. Well, maybe we can pull that chart up again, 310-
21 020-001. You see the green is the midazolam and
22 you see the respiratory arrest is that last red
23 line down there.

24 A. Yes. Which coincides with the end of the
25 transfusion.

1 Q. That was the question: is it possible that the
2 midazolam could have contributed to the
3 respiratory arrest?

4 A. Yes. Indeed it is. Any benzodiazepine carries a
5 risk.

6 Q. Now, many things are possible, so it's a matter
7 of getting some guidance as to whether it's
8 probable.

9 A. Again, I'm finding it difficult. I think it is
10 certainly possible and more possible than the
11 possibility I was talking about before. And it
12 could be bordering on the probable. In other
13 words if we were on the cusp of the balance of
14 probability, I think it is possible that we are
15 close to it, if not actually over it. It is
16 difficult to be sure if the midazolam alone did
17 it. It increases the probability even more if
18 one considers that there's still phenytoin on
19 board.

20 Perhaps even a little diazepam, although I
21 would discount that by that time. As your dotted
22 lines helpfully show, these are the lines that
23 show one half-life and so at least half of the
24 drug is expected to be present at the end of that
25 dotted line. So, there is still some drug of

1 midazolam. That might not be hugely important.
2 But, there is still a fair bit of phenytoin,
3 given that we know that there was a toxic
4 concentration measured at the times we know
5 about.

6 Even, I think there was one phenytoin
7 concentrate of 19, which is within the target
8 range, but is nonetheless high.

9 Q. I was going to take you to that. Phenytoin
10 level, you can see that at 090-031-101. There we
11 are.

12 A. Yes.

13 Q. It's not entirely clear when the bloods were
14 taken for that test, but it's thought that they
15 would have been taken when she was admitted to
16 paediatric intensive care, when a number of
17 things were being put in --

18 A. That's at about 3.00 am, I think. Is that right?

19 Q. Round about then.

20 A. Yes. That makes -- that makes sense.

21 Q. At that stage phenytoin level is 19.2. But the
22 target range, as you have already said, in
23 brackets, is 10 to 20. So, the question is: what
24 is the effect, if I can put it that way, of that
25 having been the concentration of phenytoin in her

1 system at round about 3.00 am and when the first
2 brainstem death test was done, which was at 6.00
3 am?

4 A. Well, perhaps we can deal with the respiratory
5 arrest.

6 Q. Yes, of course. I'm sorry. Yes.

7 A. Because on it's own, I would say, "Well, it's
8 high, but it's in the target range and I wouldn't
9 be very concerned about that". But she's also
10 receiving midazolam in a very high dose,
11 actually. If you look at the current
12 recommendations for midazolam, it's something
13 like 1 mg per kg per minute rather than 2 mg,
14 which is the thin infusion line, or 3 mg, which
15 is the thick infusion line. So, she was getting
16 quite a high dose of midazolam, I believe.

17 THE CHAIRMAN: And an overdose of phenytoin?

18 A. Not at that stage, an overdose.

19 THE CHAIRMAN: But she had received an overdose.

20 A. But she had received an overdose of phenytoin.
21 By that stage we're down to 19, which is just in
22 the target range.

23 THE CHAIRMAN: Okay.

24 A. So, it's on its own, okay. But, in combination
25 with the high dose of midazolam one starts to

1 wonder whether those two drugs might in
2 combination have contributed to a respiratory
3 arrest. Now, given that this girl had other
4 things wrong with her, it appears, it's hard for
5 me to say that even on the balance of
6 probabilities those two drugs did it alone. But,
7 it is certainly possible and perhaps probable
8 that the combination of the two drugs plus
9 whatever else was going on contributed to the
10 respiratory arrest.

11 MS ANYADIKE-DANES: Thank you. Sorry. Can I just
12 pull that 310-020-001 up again. It's just a
13 follow on from what the chairman was putting to
14 you there. She had had that high dose of
15 phenytoin, but according to you, she's also had
16 much more midazolam to start off with than she
17 should have had.

18 A. Yes, I think so.

19 Q. Then she goes into, what you consider, even at
20 the first level of 2, was too high an infusion
21 rate and then that too high infusion rate is
22 increased yet further.

23 A. Yes. I think so. From consulting the doses that
24 are recommended for midazolam in patients with
25 status epilepticus.

1 Q. If we then go back to the brainstem death test or
2 the diagnosis of it, which is at 090-045-148 --

3 A. Just --

4 Q. I'm so sorry.

5 A. If I can just confirm that?

6 Q. Yes.

7 A. In -- again, in the current British National
8 Formulary for Children, again, nothing in the
9 1996 version, as far as I'm aware. But, in the
10 current edition it says: "Initially by
11 intravenous injection." And this is in a
12 neonate, so lower doses than one might want to
13 use:

14 "150 to 200 mg per kg followed by continuous
15 intravenous infusion of 60 mg per kg per hour."

16 That's 1 mg per kg per minute. I would
17 expect an older child -- well, it's hard to know,
18 but if that's the dose of a neonate, I think that
19 one suspects that 2 mg or even 3 mg is probably
20 too much. I can't -- again, I can't be sure
21 about that. But, according to the information
22 here -- oh, I'm sorry. I take that back. I was
23 looking at the wrong place:

24 "Child 1 month to 18 years, 60 mg per kg per
25 hour."

1 So, that is true for that age group as well.

2 Q. So, it is too much.

3 A. It is true, yes. I was -- I'm sorry, I was
4 reading the neonatal section. It's the child 1
5 month to 18 years, exactly the same instructions
6 are given. And continuous intravenous infusion
7 of 60 mg per kg per hour is the -- is the initial
8 dose that's -- that's recommended. But then it
9 says:

10 "Increase by the same amount every 15
11 minutes until the seizure is controlled."

12 So, on the basis of that information, it's
13 perhaps reasonable to increase the dose the way
14 they increased it.

15 THE CHAIRMAN: That's the current edition?

16 A. This is the current edition.

17 THE CHAIRMAN: Where would the doctor have got that
18 information in 1996?

19 A. Well, I don't know. I don't know. This is -- I
20 have to say, this is not a situation I find
21 myself in. Must make that clear. I'm not a
22 paediatric neurologist.

23 THE CHAIRMAN: Yes.

24 A. And I'm making inferences from what I can read in
25 the texts. So, you really need to get an opinion

1 about that from someone who is experienced in the
2 field. But, my reading of it is that that may be
3 a high dose, but according to what I've just read
4 it may be reasonable to have used those doses,
5 assuming that you had a way of knowing that the
6 patient was or was not responding, which in this
7 case is difficult.

8 MS ANYADIKE-DANES: Can you have a way of knowing that
9 without doing an EEG and when the patient is
10 essentially comatose?

11 A. Well, we've been there already and --

12 Q. Exactly.

13 A. By this time, unfortunately, there's so many
14 drugs on board that I'm not sure what an EEG
15 would show you. You'd need to talk to a
16 neurophysiologist about that.

17 Q. Then if we go to the particular part of the
18 brainstem death test, which is (c):

19 "Could other drugs affecting ventilation or
20 level of consciousness be responsible for the
21 patient's condition?"

22 Given what you have just said, which is a
23 sort of mixed picture about the possible effects
24 of the anticonvulsant therapy, would you have
25 considered it appropriate to have deferred the

1 test, not because anybody thinks it would
2 automatically make a difference to the
3 conclusion, but just for the priority of
4 commencing that test and answering in that way at
5 6.00 am in the morning?

6 A. You're talking about the question about could
7 other drugs affecting ventilation be responsible?

8 Q. Yes.

9 A. If there is evidence that there are drugs in the
10 body, then I think you should wait. It's some
11 time since I did one of these tests --

12 THE CHAIRMAN: On the basis of what you've just told
13 us over the last few minutes, doctor, you
14 couldn't probably answer no to that question,
15 could you?

16 A. I agree. If you look at the diagram 020-001, it
17 shows that there was still likely to be at least
18 phenytoin in the body at 6.00 am when the first
19 brainstem death test was carried out. We know
20 that at 0300, or we think that at 0300, the
21 plasma concentration or the serum concentration
22 of phenytoin was 19. This struck as a very long
23 half-life. That is confirmed by the fact that it
24 was 23 earlier on. Not much has changed,
25 although she's had an extra dose.

1 So that three hours later there's likely to
2 be quite a lot of phenytoin left in the body at
3 that point. Even 12 hours after that there may
4 well be phenytoin. Although I would now discount
5 the other drugs, including the diazepam, which I
6 think is now getting to be trivial. Even though
7 your diagram suggests there might be some there,
8 it's going to be very low and probably not
9 contributing in a major amount. But there is
10 still phenytoin and it's likely still to be
11 within the target range, even though no more has
12 been given.

13 MS ANYADIKE-DANES: Can I then just take you to the
14 clinic note that Dr Webb enters, 090-022-058.
15 This is at 6.00 am and the brainstem test is
16 going to be carried out or is being carried out.
17 If you just see there's a sort of a second block
18 of his hand, just above his signature, and the
19 second line in that --

20 THE CHAIRMAN: It starts CT?

21 MS ANYADIKE-DANES: Yes, exactly, Mr Chairman.

22 THE CHAIRMAN: Okay. Beside where the arrow is, we'll
23 highlight those four lines.

24 MS ANYADIKE-DANES: Yes, thank you very much. Could
25 you just enhance that a little bit: "CT

1 cerebral ..."

2 A. Herniation.

3 Q. Sorry, "Cerebral herniation." So, she's had the
4 CT scan: "Under no sedating / paralysing
5 medication." Would you consider, in the light of
6 what you've been saying and looking at, that to
7 be an accurate statement?

8 A. Well, I think that the presence of the phenytoin
9 would contradict that.

10 Q. If you were being asked for guidance on it, as a
11 clinical pharmacologist, when would you have
12 thought it would be better, from the point of
13 view of completing the form, not as I say, the
14 outcome, but for the point of view of completing
15 the form, when do you say it would have been
16 better to have started the first test?

17 A. Well, I think --

18 MR FORTUNE: (overspeaking)

19 A. More appropriate, given the answer that has to be
20 given to 3(c).

21 MR FORTUNE: Or clinically indicated.

22 A. Well, clinically indicated, of course, you can
23 carry out these tests at any time. But, the
24 answer you give to them depends on the clinical
25 condition, clearly. I would have wanted to have

1 repeated the phenytoin concentration. And I
2 would probably have said -- and this may be
3 erring on the side of caution, given that another
4 expert has suggested that a plasma concentration
5 of 23 is okay, with which I disagree, I would say
6 that I would want to see the plasma concentration
7 below 10 before I felt that the contribution of
8 phenytoin could be disregarded.

9 Q. Thank you.

10 MR FORTUNE: At what time, then rather than 6.00 am,
11 would Dr Aronson be considering carrying out the
12 first set of tests?

13 THE CHAIRMAN: When the reading's below 10.

14 A. Well, I'd measure the concentration that morning
15 and see what it was. And if it was whatever, I
16 could make some theoretical calculations, based
17 on now having three or more plasma concentration
18 measurements, very helpful information, now I can
19 model the plasma kinetics, the pharmacokinetics
20 of this drug, work out exactly how Claire is
21 handling the drug and predict, with a fair degree
22 of certainty now, when it would fall below 10.

23 MR FORTUNE: Would that information normally be within
24 the province of a consultant paediatric
25 neurologist?

1 A. I don't know. I think that if someone is used to
2 using phenytoin and uses it a lot, then yes it
3 should be. But, I can't say on behalf of
4 paediatric neurologists.

5 THE CHAIRMAN: But the prescribing paediatric
6 neurologist would know that the phenytoin and, I
7 think you said, the midazolam could have been
8 responsible -- should have said that it could
9 have been responsible for Claire's condition. I
10 think you're saying that the answer to that
11 question, 1(c), should not have been, "No".

12 A. I'm sorry?

13 THE CHAIRMAN: Okay. Let's bring out 090-045-148.
14 The question that's being asked at (c), which
15 precedes the brainstem test is: could other drugs
16 which affect ventilation or level of
17 consciousness have been responsible for Claire's
18 condition? Now, your answer to that is that this
19 was actually verging over from possibility into
20 probability?

21 A. Depends what you mean by the patient's condition.
22 I was talking before about the respiratory
23 arrest. Now, it is possible, and I don't know
24 exactly where the probabilities rest, but it
25 seems to me not unlikely -- and on the -- let me

1 say, "Okay, on the balance of probabilities, it
2 is likely that the combination of the midazolam
3 and the phenytoin, perhaps the diazepam as well,
4 plus whatever condition Claire had that was --
5 that caused her original admission, perhaps a
6 viral encephalitis, I don't know, would in
7 combination have led to a respiratory arrest at
8 that time.

9 It's possible. And perhaps even on the
10 balance of probabilities. I don't know. But, I
11 might be pushed to say that.

12 THE CHAIRMAN: All right.

13 A. So, she has a respiratory arrest and presumably
14 the next thing that happens as a result of that,
15 and here we have a chain of events, is that she
16 develops brainstem death. So, indirectly, yes,
17 we're talking about effective drugs plus the rest
18 of the condition. Whether she would have had a
19 respiratory arrest in despite of the drugs, I
20 can't say, I can't know.

21 At the time then that the first brainstem
22 death test occurs, I don't know whether I can
23 attribute the midazolam at this point, because
24 there probably isn't much midazolam left in the
25 body at that point. It has a fast half-life.

1 But, I can at least say that we know that there
2 is phenytoin in the body at that stage. So, even
3 if we're not talking about the respiratory
4 arrest, there is a drug there that could in some
5 way contribute to the presentation.

6 And it would be worthwhile waiting for the
7 phenytoin to disappear to see if the brainstem
8 death test was in anyway changed.

9 THE CHAIRMAN: Well, let me put it another way,
10 doctor, in order to answer that question, "No",
11 one would have to be pretty confident in
12 excluding the phenytoin and the midazolam as a
13 possible cause?

14 A. I think so, yes.

15 THE CHAIRMAN: That is difficult to do, is it not?

16 A. Yes. Well, you've seen me struggling.

17 THE CHAIRMAN: Yes. But, surely, that's the point
18 about doing the brainstem test, if you can't
19 explain the contribution of these drugs as being
20 relevant then should you answer question 1(c) in
21 the negative?

22 A. Your default position should not be the negative.

23 THE CHAIRMAN: Mr Sephton.

24 MR SEPHTON: Could I just ask how the doctor's
25 construing question 1(c), because it's not

1 grammatical? Is the question: could other drugs
2 have been responsible for the patient's condition
3 at the time of the terminal event? Or does it
4 mean: could other drugs be responsible for the
5 patient's present condition? I suggest that the
6 second must be the case, because if you've come -
7 - if the answer to the question is the first of
8 those possibilities, has some drug caused the
9 patient to be in an unconscious state and
10 remaining so, then the answer would be yes, not
11 only at 6.00 am in the morning but also at 6.00
12 pm in the evening. It would always be the case.

13 So, is not the issue: were the drugs at 6.00
14 am in the morning still effective to cause the
15 presentation of which the doctors are taking
16 cognisance?

17 THE CHAIRMAN: That is a very perceptive question.

18 A. The word "been" here is, as you point out,
19 ungrammatical. Does it mean: could other drugs
20 be responsible currently as you are doing the
21 test, now, here and now? Or does it mean: could
22 other drugs have been responsible, as you
23 suggest, three hours ago when she had a
24 respiratory arrest?

25 In which case, as you say, respiratory

1 arrest, leading to irreversible brain death, it
2 would always have been responsible, even if the
3 drug was not present 48 hours later or whatever.
4 And I don't think one can tell, actually. I
5 don't -- I think I disagree that you can
6 necessarily come down on one side or the other of
7 that question. I don't know the answer.

8 MS ANYADIKE-DANES: I think, Dr Aronson, just finally,
9 just to clarify that, when you were answering the
10 Chairman I think you expressed it in two ways.
11 Firstly, you couldn't exclude the possibility
12 that some combination of those drugs, possibly
13 the phenytoin, but perhaps with some contribution
14 of midazolam, contributed in some way to her
15 respiratory arrest.

16 A. Correct.

17 Q. So, from that point of view, there could be a
18 causal relationship. Perhaps in combination with
19 other factors, but there could be a causal
20 relationship. Then, when you were asked about
21 her presenting condition, you were of the view,
22 perhaps no longer the midazolam, because that
23 would have reduced, but certainly the phenytoin.
24 There may be sufficient levels of phenytoin in
25 her to be contributing to her present state. As

1 I understand your answer.

2 A. Do you mean the brainstem death or the
3 respiratory arrest?

4 Q. The respiratory arrest, you've already answered,
5 but her state as it presents itself at the time,
6 at 6.00 am.

7 A. Yes, I think if, taking this question on board,
8 the word is "be" rather than "been", then I would
9 say, "Well, at this time, while I am doing the
10 test, I know that there is phenytoin in the
11 patient's system. I would like to wait to see
12 what happens, to what her condition is like when
13 the phenytoin is no longer in the body". And I
14 would count that as a reasonable time to be below
15 10 mg per litre in the plasma.

16 Other might say, "Well, a more purist
17 approach might be to say, 'Wait until it's
18 disappeared'". But, somewhere in that region
19 would be -- would be reasonable.

20 MS ANYADIKE-DANES: Thank you very much. Mr Chairman,
21 I have no further questions. I'm just going
22 to (overspeaking)

23 MR QUINN: [inaudible - no microphone] I may make
24 them to my friend. But, the first point, if we
25 just set the scene. I'm aware of the time.

1 THE CHAIRMAN: I think you'll have to be. We've got a
2 taxi coming for you at 6.00 pm, doctor. So,
3 because of the circumstances you can do it
4 directly if you like.

5 MR QUINN: I'm obliged. We know that Claire's mother
6 was in the hospital between somewhere around 2.00
7 pm the rest of the day. And we know that she was
8 -- she saw Dr Webb there and we know that the
9 midazolam and the phenytoin was given during that
10 time.

11 THE CHAIRMAN: Sorry, this is 2.00 pm?

12 MR QUINN: This is the 22nd October between 2.00 pm
13 and say 9.00 pm that night.

14 THE CHAIRMAN: All right.

15 MR QUINN: We know that at some time in the
16 afternoon, some time between 3.00 pm and 3.30 pm
17 say, the phenytoin and the midazolam were given
18 to Claire. We know that.

19 A. Yes.

20 Q. We've heard you saying that midazolam is perhaps
21 an experimental drug and in this setting, in
22 1986, and that the phenytoin is something that
23 should be administered by using an EEG.

24 A. ECG.

25 Q. ECG, I apologise.

1 A. Making the diagnosis is the EEG. Giving the
2 phenytoin is the ECG.

3 Q. Yes. Two points arising out of that: should the
4 parents or Mrs Roberts have been told about the
5 risks of phenytoin, that is administering it at
6 all, given that it could create problems with the
7 heart?

8 A. I think that I would not normally say to
9 relatives that that was the case. I think what I
10 would say is, "Your daughter appears to have
11 status epilepticus (let's just assume that's the
12 diagnosis). It has been difficult to manage. We
13 have given her the first line drug, which hasn't
14 worked. I think that this second line drug might
15 be beneficial and we're going to administer it
16 with careful monitoring of her condition". I
17 think that's what I would say. I don't think I
18 would specify that there was a risk of a cardiac
19 arrhythmia.

20 Q. Would it be appropriate to say nothing at all?

21 A. If they were there and available for discussion,
22 I think that one would be duty bound to tell them
23 what you were doing.

24 Q. The second point is, you've used the description
25 of midazolam as "experimental".

1 A. It was certainly -- in 1996, it was not licensed
2 for this indication, not mentioned in the BNF and
3 the paper on which its use was based was a small
4 open perspective study in 24 patients. I call
5 that, yes, experimental, if you like, in an early
6 stage of its use.

7 Q. Then should the parents have been advised of that
8 fact?

9 A. Yes, that's -- I think that's a difficult
10 question to answer about informed consent. And I
11 was at one time chairman of the Oxford Research
12 Ethics Committee and this was a question we dealt
13 with not infrequently and I find it difficult to
14 answer. There are dual standards in healthcare.
15 If you're doing a clinical trial then you have to
16 ask for informed consent --

17 Q. Well, let me make it easy, should they have been
18 told -- never mind the experimental aspect of it,
19 should the parents have been told that they were
20 going to give midazolam?

21 A. Yes. If I can finish what I was going to say.

22 Q. Yes, sorry.

23 A. I was going to say that in the context of a
24 formal clinical trial, we have to ask for
25 informed consent. In the context of treating a

1 patient with a drug that we think might or might
2 not work, we're not required to do so. I think
3 this case falls in between those two. It's not a
4 clinical trial, but on the other hand it's not an
5 established treatment.

6 And so I would -- I think -- I would like to
7 think that what I would do is to speak to the
8 relatives and say, "I'm going to try -- I'm now
9 going to try a treatment that is in the early
10 stages, although it has been tried elsewhere,
11 that we haven't used ourselves, we think might be
12 beneficial and probably relatively safe".

13 Q. How appropriate is it to say nothing at all?

14 A. I think that if the relatives are there and you
15 have a chance to speak to them, you should tell
16 them these things.

17 Q. The last point on midazolam. Given what you've
18 said about it and given the points that have been
19 made today about it, was it appropriate to raise
20 the infusion rate later on in the evening?

21 A. Yes. I -- as I've said, I find that a difficult
22 -- difficult to answer. I really don't know. At
23 this -- in 1996, I don't know what the
24 appropriate dosage would have been. According to
25 current standards as we've just read, that seems

1 not unreasonable. Whether it would have been
2 reasonable in 1996 I'm unable to say.

3 Q. If I move to another subject very quickly. Could
4 we bring up 310-011-001 and with that bring up
5 page 090-022-055. Now, we know that, from the
6 left-hand chart, that the Glasgow Scale's
7 dropping from -- if we look at 1.00 pm we know
8 it's dropping from 9 and then Dr Webb saw the
9 patient at 5.00 pm, 1700 hours, on the right-hand
10 page, we know that it's down to 6.

11 Bearing that in mind, and someone who's
12 looking for what is wrong with a very ill child,
13 would the doctor not be duty bound to check
14 through the notes to see what drugs have been
15 given and whether or not those drugs had been
16 calculated properly?

17 A. Yes.

18 Q. Just before you answer, I want you to fix with
19 this point --

20 THE CHAIRMAN: Mr Quinn, you got a yes.

21 MR QUINN: Yes, I know that. But, I want to just fix
22 this point doctor's mind. When one looks at the
23 sheet on the right-hand side, and we know that
24 there's nothing below the upper entry, when Dr
25 Webb appears at 5.00 pm. The calculation is

1 jumping out at you. Is that correct?

2 A. Show me.

3 Q. The calculation of 0.5 mg per kg, three lines
4 from the top.

5 A. Yes. Yes, 0.5 mg per kg, multiply by 24 kg, 12
6 mg.

7 THE CHAIRMAN: Yes, but the point is Dr Webb did see
8 Claire at about 5.00 pm. The Glasgow Coma Scale
9 score was low. Mr Quinn's point, that you've
10 accepted is, that that should have prompted him
11 to look through the notes. If he'd looked
12 through the notes, surely he should have seen
13 that the prescription of midazolam witness
14 statement more than triple what he had
15 instructed. And that seems to have been entirely
16 missed.

17 A. That seems a reasonable inference to make. I
18 should say that in retrospect -- and you're
19 saying at the time, which is different. In
20 retrospect I think those changes in the Glasgow
21 Coma Scale score, which could be partly
22 attributed to the drugs, probably were not
23 entirely attributable. But, your question is: at
24 the time should one investigate with a view to
25 thinking, "Could the drugs have caused that?"

1 And the answer to that is, "Yes".

2 MS ANYADIKE-DANES: Could I ask one final point?

3 THE CHAIRMAN: That would be a final point would it.

4 MS ANYADIKE-DANES: Yes.

5 THE CHAIRMAN: Mr Fortune, you can go and then don't

6 worry I will come back to you, Mr Counsell.

7 MS ANYADIKE-DANES: Thank you.

8 MR FORTUNE: It may seem a long time ago, but back on

9 31st May --

10 THE CHAIRMAN: Sorry, just one second, if you're going

11 to raise another point Mr Fortune, I'm quite

12 happy for you to do that, but if anybody wants to

13 raise a follow on point about the question Mr

14 Quinn just asked. No?

15 MS ANYADIKE-DANES: Yes. I was --

16 THE CHAIRMAN: Okay. Let Ms Anyadike-Danes ask her

17 follow on and then I'll come back to any other

18 issues.

19 MS ANYADIKE-DANES: Sorry, Dr Aronson, it was one I

20 was asked to ask and it slipped my mind as I was

21 putting it. It is allied to Mr Quinn's point,

22 which is, if you had been not sufficiently

23 certain of this drug yourself, in the sense that

24 you've got to go back and check through your

25 notes and see what the dosage is and all that

1 sort of thing, which is what Dr Webb said he did,
2 if you had given that dose over the telephone to
3 a very junior doctor, which is who Dr Stevenson
4 was, when you had the opportunity thereafter, at
5 5.00 pm, to come to the ward and examine the
6 child and you actually are making your own note,
7 would it have been appropriate or prudent to have
8 just checked that the junior doctor had actually
9 done what you'd told him to do over the phone?

10 A. Yes.

11 MS ANYADIKE-DANES: Thank you.

12 THE CHAIRMAN: Okay. Mr Fortune.

13 MR FORTUNE: Back on 31 May, Dr Haynes was asked about
14 brainstem death. For the benefit of Dr Aronson,
15 Dr Haynes is a consultant paediatric anaesthetist
16 at Newcastle. I believe at the Freeman. He was
17 asked at page 114, line 7, in answer to a
18 question from my learned friend:

19 "Can you just very briefly because I'm
20 conscious of the time (so am I) explain why it is
21 in the protocol or, so far as you're concerned,
22 important to exclude these electrolyte
23 imbalances, if I can put it in that way, or to
24 rectify them?"

25 Answer:

1 "Brainstem death is a diagnosis made when a
2 patient is comatose, is on a ventilator and it is
3 important to exclude any reversible causes of
4 that coma. The first premise is that there has
5 to be an underlying demonstrated diagnosis, which
6 in Adam's case (this is Adam Strain) there most
7 certainly was. There has to be the knowledge,
8 and the wording is no stronger than that, that
9 there has to be a certainty that there is no
10 residual effect of any neuromuscular or sedative
11 drug or other intoxicating agents, which in
12 Adam's case none were present, then there has to
13 be the exclusion of metabolic and biochemical
14 causes of coma and that exclusion has to be made
15 before doctors making the test can go on and do
16 the test."

17 Firstly, having had it read to you, do you
18 understand what Dr Haynes was saying?

19 A. Yes, I understand and I agree with that. I think
20 that's perfectly appropriate. And the question
21 was: could the drugs present in Claire's body
22 have been -- have fallen under that rubric as you
23 just read it? I think they could.

24 THE CHAIRMAN: Thank you. Mr Counsell.

25 MR COUNSELL: Dr Aronson, I wonder if you could look

1 at, and it could be brought up on the screen,
2 page 14 of your report. So, that's reference
3 237-002-014. I wonder if you'd look towards the
4 bottom of the page. You begin a paragraph with
5 the words: "I have noted." You say:

6 "I have noted above that it is not clear
7 what dose of midazolam Claire was actually given.
8 Midazolam 120 mg, even if given over 24 hours, is
9 a very large dose and would have caused major
10 anaesthesia, coma, severe respiratory depression,
11 possibly death, as has been reported in adults."

12 I think that reference was a reference to an
13 alert by the National Patient Safety Agency,
14 isn't it? Can I just ask you this: knowing what
15 we know about Claire's condition, both at 3.25 pm
16 and in the hours that followed, can we
17 effectively rule out the possibility of her
18 having been given 120 mg?

19 A. Oh, yes. Oh, yes, absolutely. I answered that
20 question because the question was phrased -- and
21 the questions had been phrased to ask, "What
22 would 12 mg have done? What would 120 mg have
23 done?"

24 Q. I understand, doctor.

25 A. And that's why I --

1 Q. It's just been there in the background.

2 A. My own view is that it is highly unlikely that
3 Claire was ever given 120 mg of midazolam.

4 MR COUNSELL: Thank you very much.

5 THE CHAIRMAN: Is that everything? It's been a long
6 afternoon, doctor. Thank you very much for your
7 time. Your evidence is finished and you're free
8 to go.

9 (The witness withdrew)

10 THE CHAIRMAN: Now, ladies and gentlemen, we're going
11 to sit on Monday with Dr Scott-Jupp. He, I
12 understand, has to leave by 4.00 pm at the
13 latest. He's available to us only for Monday.
14 We're then going to take Dr McFall on Tuesday and
15 I think it's at least possible that he will run
16 into Wednesday.

17 To get through Dr Scott-Jupp and not have
18 him as another witness who we want to have to
19 bring back or bring up in a video link or
20 whatever, can we start at 9.00 am? I think
21 that's our best chance of getting Dr Scott-Jupp
22 concluded on Monday. We'll then do Dr McFall on
23 Tuesday. He may run into Wednesday. Beyond him,
24 on Wednesday, if he does run into Wednesday, I'm
25 not clear what witnesses we have. The pathology

1 witnesses were not asked to give evidence and I
2 expect that's not quite ready yet.

3 We've got four sitting days next week and I
4 don't want to lose any, because when we're
5 running behind already I don't want to lose a day
6 or a day and a half. So, we will try as best we
7 can over the next 24 hours to identify all the
8 witnesses who are available for Wednesday, 14th,
9 November after Dr McFall finishes, if he isn't
10 finished on Tuesday, and into Thursday, 15th
11 November.

12 The next thing I should say to you is that
13 will bring us into Monday, 19 November. We will
14 not be sitting in the week of Monday, 19
15 November.

16 MR QUINN: Did you say the whole week?

17 THE CHAIRMAN: There has been some discussion about
18 that in the chambers, Mr Quinn, was welcoming a
19 break between clinical and governance. We're
20 going to have a break, but we won't quite finish
21 clinical, I'm afraid. But, we'll have enough of
22 it finished that we will be able to distribute
23 the governance opening by Monday, 19th November,
24 so you would see the lines that we're picking p
25 for closer scrutiny in governance and the issues

1 that we want to address. We will circulate the
2 opening by 19th November.

3 Then on 26th November, we'll work on a
4 timetable for that, about the pathologists, any
5 opening addresses on governance and then sitting
6 on through. Okay?

7 MR FORTUNE: I thought previously you had indicated
8 that you would not be sitting on Monday, 26th
9 November and Tuesday, 27th November and perhaps
10 some of us have made arrangements, that are of a
11 personal nature or not, to be elsewhere.

12 THE CHAIRMAN: You might very well be right, Mr
13 Fortune. Let me see what we can do, because
14 there have been some change in circumstances at
15 our end and more information coming through on
16 various issues, so let me see. Sometimes what we
17 have been able to do, if one or two individuals
18 are not available, is to see how we can juggle
19 witnesses, so that witnesses who are called
20 during a day or two are less directly relevant to
21 one's particular client.

22 Sorry, it is your recollection that I said
23 we weren't sitting on 26th and 27th November?

24 MR FORTUNE: That was the information I received.
25 That you would be sitting on Wednesday, 28th

1 November, Thursday, 29th November and Friday,
2 30th November. I don't think I'm alone in that
3 recollection.

4 THE CHAIRMAN: No, sorry. I think that was maybe
5 given out towards the end of last week. Is that
6 right?

7 MR FORTUNE: Yes. In fact, it had been given out
8 previously, because I had already made some, I'll
9 be quite frank, personal arrangements for that
10 Monday and Tuesday.

11 THE CHAIRMAN: Well, I'll tell you what we'll do.
12 We'll liaise between now and the early part of
13 next week. We will be sitting, as I say, next
14 Monday, Tuesday. If anything that makes it all
15 the more urgent that we get through as many
16 witnesses as we can next week and identify all
17 the people who will attend. Ms Conlon will be
18 back with us on Monday and we'll pick that up at
19 that point. Okay?

20 MS ANYADIKE-DANES: I would ask, if we're going to sit
21 at 9.00 am and try and complete Dr Scott-Jupp's
22 evidence, of which there is quite a bit, if I
23 could just ask my learned friends if there are
24 any areas they specifically wish me to cover
25 there is now some time to do that. That they get

1 that to me, not in the early hours of Monday
2 morning, but sometime before then, so that I can
3 integrate those into the question, that would be
4 very helpful.

5 THE CHAIRMAN: I am tempted to say that a lesson from
6 today, is there much more evidence you can hear
7 without a stenographer? Anyway, thank you very
8 much.

9 MS ANYADIKE-DANES: Thank you very much, Mr Chairman.

10 THE CHAIRMAN: 9.00 am on Monday.

11 (5.56 pm)

12 (The hearing adjourned until Monday, 12th April at
13 9.00 am)

