

The Inquiry into Hyponatraemia Related Deaths

Chairman Mr Justice O'Hara

Closing Submissions - Claire Roberts

Introduction

This Public Inquiry is of course more than an Inquiry into hyponatraemia related deaths. For the families of each of the children involved in this Inquiry it is about finally providing answers and resolution to the most traumatic and challenging life experience any parent will face, the death and loss of a child. For Mr and Mrs Roberts Claire's death and their loss has been compounded and extended by the improper actions and failures of the Belfast Trust, the Royal Belfast Hospital for Sick Children and the doctors responsible for Claire's treatment and care management. It is unfortunate for everyone that it has taken the establishment of a Public Inquiry to investigate, examine and uncover the shortcomings, failures and lack of openness and transparency regarding Claire's death. Not only in 1996 but also in 2004 and following the Coroners Inquest in 2006.

Mr and Mrs Roberts have attended every day of the Inquiry hearings into Claire's death and have given oral evidence to share and support their views and concerns regarding Claire's care management and the actions of the doctors involved.

In October 1996 during the two days that Claire was a patient in the RBHSC Mr and Mrs Roberts put their trust in the doctors responsible for her care. Following Claire's death they did not question or query the explanations given by the treating clinicians for Claire's sudden and unexpected death. They now feel totally betrayed and misled by the doctors who they as parents had put their utmost trust in. There was a systemic failure by the RBHSC in almost every aspect of Claire's care and treatment, however it was primarily the actions of individual doctors who have attempted to misuse the system to their advantage, mislead Mr and Mrs Roberts and cover-up Claire's death.

Mr and Mrs Roberts left the hospital on Tuesday evening 22 October 1996 believing that Claire was sleeping and that her care management was under control. This Inquiry has finally exposed and revealed the truth that when the parents left the hospital Claire was only two hours away from catastrophe, without her parents being with her and that no doctor or nurse was aware of the seriousness of Claire's clinical condition.

1. A&E Admission note 21 October 1996 (090-012-014)

1.1 Dr Puthurcheary (SHO) WS 134, Dr O'Hare (Registrar) WS 135

a). Examination in A&E on Monday 21 October 1996 - Dr Puthurcheary 07:15pm and Dr O'Hare 08:00pm.

In October 1996 Dr Puthurcheary was three months into his first appointment as an SHO in the Royal Belfast Hospital for Sick Children. Dr Puthurcheary compiled the A&E admission note (090-012-014) which notes that Claire had no diarrhoea, no cough and no

pyrexia. Dr Puthurcheary queried a presumptive diagnosis of encephalitis. Dr O'Hare, paediatric registrar subsequently examined Claire in A&E and excluded encephalitis. WS135-1 page 3 Q4a Dr O'Hare

My working diagnosis was a viral illness. I appeared to have also written encephalitis and then deleted it. I presume my reason for deleting this as a differential diagnosis was the absence of a fever as infective encephalitis is usually associated with fever.

2. Clinical treatment Claire received Ref Medical Notes (090-022-050 to 061)

2.1 Admission to Allen Ward Monday 21 October 1996 - Dr O'Hare 08:00pm (090-022-050/052) and Dr Volprech 12:00pm

Dr O'Hare (Registrar) WS 135, Dr Volprech (SHO) WS 136

a). There were inadequacies regarding the initial examination, initial diagnosis, blood test results and the recognition of hyponatraemia at A&E and following admission to Allen Ward on Monday 21 October 1996.

Prof. Neville 232-002-003 (ii)(a) I think that hyponatraemia/cerebral oedema could have been thought of and tested for in a child with vomiting and reduced consciousness in A&E and onwards, i.e. on Claire's attendance at A&E on 21 October 1996, on admission to Allen ward, RBHSC, on receipt of the serum sodium result of 132mmol/L at or after midnight on 22 October 1996, at the ward round on 22 October 1996 and when Dr Webb first saw Claire on 22 October 1996 at about 14:00hrs.

T12-11-12 Dr Scott -Jupp

T12-11-12P28L1-L5

(Q) But you formed the view that her initial investigation was somewhat limited and that you would have expected more extensive biochemical tests.

(A) Yes

b). There was an inadequate review of No18 IV fluid management to change to a fluid with a higher sodium content following the U&E result at 22:30 on Monday 21 October.

Prof Neville 232-002-004 (ii)(c) On Claire's admission, many would have administered IV fluids of either 0.45% or 0.9% saline as a precautionary measure. The use of 0.18N saline in a drowsy child should have been with at least a warning for urgent review and it would be appropriate to use restricted fluids (i.e. 1000ml/M2/per day) and many would use a higher NaCl concentration containing fluid. I think a higher concentration of salt containing fluid regime should have been used when initial low sodium level came back at midnight. The management with 0.18N NaCl I have commented on as being potentially unwise and certainly requiring careful monitoring of consciousness and of the sodium level in the plasma.

Dr McFaul 238-002-018 Although use of 1/5th-Normal-Saline for IV maintenance-fluid was within the range of current practice for the time for management of ill children, at this time also ideal/high-quality practice for acute encephalopathy any causation should have led to choice of IV fluid with higher sodium concentration.

c). **Dr O'Hare did not repeat the blood tests following the 22:30 result within 6 to 8 hours of No18 IV fluid administration.**

Prof Neville 232-002-004 (ii)(c) The problem was there was no repeat serum sodium test 6 hours from the first test.

Prof Neville 232-002-005 (iii)(a) The sodium level of 132 was just below the normal range and needed to be urgently repeated and fluid regime altered to restrict fluids 1000ml/m²/24hrs and given as N saline until it is clear that the sodium is not dropping to levels that would cause cerebral oedema.

d). **There was inadequate communication and information at handover between night staff (Dr O'Hare) and day staff (Dr Steen and Dr Sands) to re-assess Claire's clinical condition on the morning of Tuesday 22 October.**

The adequacy of the communication and information shared at handover between the two registrars, Dr O'Hare and Dr Sands is curious. Dr O'Hare did not believe encephalitis was a likely differential diagnosis yet Dr Sands evidence is that encephalitis was discussed during the ward round and that he later included it in the medical notes.

T12-11-12 Dr Scott -Jupp

T12-11-12P40L21 to P42L2

(A) This leads on to the whole issue of handover, which I think has been discussed previously. But if there was any substantial handover of Claire to the daytime Allen Ward team, mentioning encephalitis, if only to dismiss it, if only to say that, "Actually I don't think it is encephalitis", would have been appropriate, yes.

2.2 Allen Ward Tuesday 22 October 1996 - Dr Steen consultant responsibilities Dr Steen (Consultant) WS 143

a). **Dr Steen failed to identify Claire's clinical condition during handover at 09:00 22 October. (If Dr Steen was on Allen Ward or in the hospital).**

The Inquiry has attempted to establish Dr Steen's attendance and availability in the RBHSC Allen Ward on Tuesday 22 October 1996. If Dr Steen was on Allen Ward on Tuesday 22 October 1996 the adequacy of the handover and Dr Steen's involvement in the handover regarding Claire's clinical condition and proposed treatment plan are areas which the Inquiry will recognise as important.

WS 143/2 page 2 Q1a Dr Steen.

(Q) Explain how and when you became "*aware that Claire was in the ward at 9am on the 22-10-1996*", identifying by name and job title the person who informed you of this.

(A) I have no recollection of events. I assume I was informed by medical staff and nursing staff when I attended the ward prior to the ward round at approximately 8:45am on the 22 October 1996.

It is noted that 139-131-001 email dated 08 February 2005 from Dr Steen to Mr Walby states "I did not actually see or examine her".

Dr McFaul 238-002-019 (91) Claire had a persistent reduction in level of consciousness and by the morning following her admission at latest Claire should have been seen by Dr Steen. Claire was significantly unwell and a diagnosis of causation had not been made.

Dr Steen did not see Claire until after the final and irreversible collapse some 33 hours following admission.

b). Dr Steen failed to conduct the ward round on Tuesday 22 October.

c). Dr Steen failed to review Claire who was a new patient admitted under her care on Tuesday 22 October.

d). Dr Steen failed to provide an input into or obtain an understanding of Claire's clinical condition before leaving Allen Ward on Tuesday 22 October.

(If Dr Steen was on Allen ward or in the hospital).

The Inquiry, while recognising the importance of patient confidentiality, have attempted to establish through appropriate methods, Dr Steen's attendance, role and input, if any, into the clinical care of all the patients on Allen Ward on Tuesday 22 October 1996 and how that input affected any understanding Dr Steen had of Claire's clinical care before she attended the Cupar street clinic. There is no evidence that Dr Steen discussed Claire's care with any of the medical team or nursing staff or that Dr Steen examined Claire on Tuesday 22 October 1996. Dr Steen's evidence is that she attended Allen ward on the morning of Tuesday 22 October 1996. Mr and Mrs Roberts evidence is that they arrived on Allen ward around 09:30am on Tuesday 22 October 1996 and did not see or have any discussion with Dr Steen at that time or at any time throughout Tuesday 22 October 1996.

T14-11-12 Dr McFaul

T14-11-12P74L9-L25

(Q) But leaving that aspect of it aside, whose responsibility, as between Dr Steen and Dr Sands, was it to make sure that, by the time she leaves for her clinic, she is aware that a child like Claire has been admitted under her care and the belief at that stage that she is neurologically very unwell, the differential diagnoses are for status epilepticus, encephalitis and encephalopathy?

(A) Well, I think it would have been Dr Steen's responsibility to find out what was happening to children admitted under her care and, in particular, to children who were unusually unwell. And Claire was clearly somebody who was significantly unwell. So it was her responsibility to determine whether there were any children like Claire because she may not have been the only one on the ward before she went off to her Clinic.

e). Dr Steen failed to review the IV fluid management plan from the previous evening Monday 21 October.

There is no evidence that Dr Steen had any discussion or review of Claire's clinical notes, her low sodium level result or her IV fluid management plan from the previous evening, Monday 21 October through to the morning of Tuesday 22 October.

WS 143/1 page 9 Q15c Dr Steen.

(Q) State whether you believe the clinicians and nurses ought to have been aware in October 1996 that Claire was at risk of electrolyte imbalance and explain the reasons for your answer.

(A) Any child with vomiting is at risk of electrolyte imbalance and clinicians and nurses ought to have been aware of this in October 1996.

Dr McFaul 238-002-020 (95) The IV fluid was chosen by the general paediatric team - without consultant involvement.

f). Adequacy of Dr Steen's awareness of the dangers of No18 IV fluid and hyponatraemia in October 1996.

Dr Steen was asked during oral evidence about her awareness of the IV fluids that Claire was prescribed and administered.

T17-10-12 Dr Steen

T17-10-12P40L8-L14

(Q) Did you have such an awareness?

(A) I can't remember. We're going back to 1996. I can't remember. There has been so much in between that how practice has changed -- I certainly know that by 2000 any child with an acute neurological condition was maintained on two-thirds maintenance when they came in, no matter what their sodium was.

Dr Steen's knowledge and awareness of the dangers of low sodium fluid in 1996 is not consistent with other clinicians understanding.

T18-10-12 Dr Bartholome (Registrar)

T18-10-12P6L10-L17

(Q) Would you have been aware in October 1996 of the Arieff article from 1992?

(A) It certainly was discussed in the ward as one of the points that was raised in the Inquiry or -- it wasn't an Inquiry at the moment.

(Q) And would you have been aware of the fact that fluid overload may lead to cerebral oedema?

(A) Yes, I would have been aware of that.

Dr Stewart a first term SHO on receipt of the blood test sodium level of 121mmol/L on Tuesday 22 October 1996 recorded hyponatraemia and queried fluid overload and low sodium fluids.

T06-11-12 Dr Stewart (Junior SHO)

T06-11-12P72L12-L22

(A) Well, I certainly tried to think along the lines of first principles, so when a patient's sodium drops, with the risk of oversimplification, you're either thinking: are they losing sodium or do they have too much water causing a relative dilution of the sodium concentration in their blood?

g). Dr Steen failed to establish consultant responsibility and ensure appropriate communication between consultants

T12-11-12 Dr Scott -Jupp

T12-11-12P79L12 to P80L1

(The Chairman) If your the consultant in this setting, which I know is slightly different to your own setting, and your registrar has brought in a neurologist and then talks to you about having brought in the neurologist, what do you expect the consultant paediatrician to do?

(A) I think that would vary from one hospital to another, so it's difficult to be too definite

about this. There has not been an agreement at this stage to hand over Claire's care to Dr Webb because it seems that at this point he might not have even seen her. So the general consultant, i.e. Dr Steen, if I had been in her situation, I would have wanted to discuss with Dr Webb, either before or after he had seen Claire, and I would have wanted to remain involved.

h). Dr Steen failed to ensure that Claire was seen by a consultant for more than 18 hours after admission.

**2.3 Allen Ward Tuesday 22 October 1996 - Ward round Dr Sands and Dr Stevenson
approx 11:00am (090-022-052/053)**

2.3.1 Dr Sands (Registrar) WS 137

a). Dr Sands failed to review Claire as a new admission on Allen Ward before the 11:00am ward round on Tuesday 22 October.

b). Dr Sands failed to identify Claire's clinical condition at handover at 09:00am and during the 11:00am ward round on Tuesday 22 October.

There was a failure to identify and record Claire's clinical condition during the morning handover and during review of the medical notes at the morning ward round. This is highlighted by the fact that Claire continued to vomit through Monday evening and into Tuesday morning. The fluid balance sheet 090-038-133 records that Claire had six vomits over an eight hour period and by the time of the ward round she was still retching. However when the parents attended the hospital at 09:30am on the Tuesday morning they were informed by nursing staff that Claire was comfortable. The nursing notes state "slept well" and "much more alert and brighter this morning". The parents were never informed and were not aware that Claire had been vomiting so frequently until they received and reviewed the medical notes in 2006.

By the time Dr Sands first examined Claire at around 11:00am she had been vomiting for a duration of twenty hours and was still retching at this time. Dr Sands failed to identify that the continuous vomiting and loss of electrolytes was putting Claire at a high risk of hyponatraemia and electrolyte imbalance.

T01-11-12 Professor Neville

T01-11-12P80L22 to P81-L11

(A) At the ward round stage, no. She's just not improved, really and you would have expected, if she had -- she would be already beginning to develop cerebral oedema in a mild form.

(Q) Just so that I'm clear, are you saying that that is a possibility that he (Dr Sands) should have retained, that that might be what's happening?

(A) Yes.

(Q) It would need to be confirmed, but he should have had that as a possibility?

(A) Sure

(Q) Even as a registrar?

(A) Yes.

(Q) And in 1996?

(A) Yes.

T08-11-12 Dr Aronson

T08-11-12P249L13-L20

(A) The first question you ask when you see a count of 16.5, "What's the differential?" It trips off your tongue automatically.

(Chairman) If that wasn't picked up on the Monday night/Tuesday morning when the results came through, it should certainly have been picked up on the ward round on Tuesday morning?

(A) Yes.

c). Dr Sands failed to review the fluid management plan from the previous evening Monday 21 October.

Prof Neville 232-002-004 (ii)(c) On Claire's admission, many would have administered IV fluids of either 0.45% or 0.9% saline as a precautionary measure. The use of 0.18N saline in a drowsy child should have been with at least a warning for urgent review and it would be appropriate to use restricted fluids (i.e. 1000ml/M2/per day) and many would use a higher NaCl concentration containing fluid. I think a higher concentration of salt containing fluid regime should have been used when initial low sodium level came back at midnight. The management with 0.18N NaCl I have commented on as being potentially unwise and certainly requiring careful monitoring of consciousness and of the sodium level in the plasma.

d). Dr Sands failed with his incorrect diagnosis of non fitting status without justification or test or review of that diagnosis.

Mr and Mrs Roberts believe that the diagnosis of non-fitting status made by Dr Sands at the ward round on the Tuesday morning 22 October was incorrect and one of many fundamental errors and mistakes that resulted in Claire receiving inappropriate clinical treatment and care management. The parents believe that Claire's lethargic and pale clinical condition on the Tuesday morning was the result of a restless night through which she continued to vomit, with at least six further recorded vomits having an impact on her falling sodium level and that the administration of No18 hypotonic IV fluid compounded the situation. Dr Sands failed in his initial examination of Claire and with his clinical impression and diagnosis which steered Dr Webb into an incorrect treatment and management plan.

Dr Sands experience of diagnosing non-fitting status epilepticus before examining Claire:

T19-10-12 Dr Sands

T19-10-12P114L6-L9

(Ms Anyadike -Danes) Had you any experience of that before?

(A) I believe I'd seen one patient perhaps with this condition at some time previously. So my experience would have been very limited in practical terms. I might have had some theoretical book-knowledge about it.

Dr Steen's experience of diagnosing non-fitting status epilepticus before Claire:

T17-10-12 Dr Steen

T17-10-12P53L20 to P54L10

(Q) And when you saw that non-fitting status, did it occur to you that this child should have an EEG?

(A) A non-fitting status -- I've only ever seen a -- I personally have seen and diagnosed one case in all my experience, and the diagnosis was made with the EEG and diazepam. And that was my understanding: an EEG would be required to make the diagnosis. It could be suspected clinically, but to be diagnosed, you needed an EEG.

(Q) And given that in your experience you'd only seen one case of it, did you not perhaps think that maybe more investigation ought to be carried out before one even had it as a differential diagnosis, because it's a fairly rare condition, is it not?

(A) I hadn't even seen the case. I was discussing this in 1996; the case I was discussing was subsequent to that.

Both Dr Sands and Dr Steen had little or no previous experience of non fitting status before 1996. It is remarkable that following Claire's death in October 1996 the RBHSC, as a major teaching hospital, did not openly or transparently investigate or review this uncommon condition and diagnosis or discuss and highlight it as a learning subject for consultants, registrars, junior doctors and nursing staff.

T12-11-12 Dr Scott -Jupp

T12-11-12P111L19 to P112L6

(Q) As for the status epilepticus, if we go back, but before the encephalitis and encephalopathy was added, what he actually thought, his impression, to be fair to him, it wasn't so much a diagnosis as an impression of what was happening, was non-fitting status. Given that he is a junior registrar, as Mr Green pointed out, was that an appropriate diagnosis on the available indications for him to be reaching?

(A) I'm slightly surprised that a relatively inexperienced registrar came to that conclusion so readily because it's a difficult diagnosis to make, clinically, and it's not common at all. So I think that was surprising to me.

Prof Neville 232-002-005 (iv)(a) I would not agree that non-convulsive status epilepticus was the likely diagnosis because it is not common and epilepsy was not prominent in this girl's recent history. In my opinion non-convulsive status epilepticus needed to be proved by an urgent EEG.

Prof Neville 232-002-006 (iv)(b) The problem with the diagnosis on non-convulsive status is that it leads to inappropriate treatment with anti-epilepsy drugs which could have further reduced her conscious level and her respiratory drive.

Prof Neville 232-002-015 (xvi)(d) There is no clear evidence of status epilepticus and I cannot understand why an early EEG was not performed, I do not agree that it was a contributory cause of death.

Dr McFaul 238-002-008 (7) Strikingly, no EEG was done to confirm or refute the proposed diagnosis. The diagnosis of non-convulsive status epilepticus was not a high likelihood in Claire.

Dr McFaul 238-002-020 (94) The proposed diagnosis of non-convulsive epileptic status, whilst a possibility amongst other causes of acute encephalopathy, was not of high, or even moderate likelihood.

e). Dr Sands failed to carry out a blood test following the ward round at 11:00am on Tuesday 22 October to check Claire's electrolyte levels and fluid balance.

Mr and Mrs Roberts believe that the failure by Dr Sands to do a simple blood test on the Tuesday morning 22 October was one of many fundamental errors and mistakes made by Dr Sands in Claire's clinical treatment, diagnosis and care management that resulted in the tragic but avoidable outcome. Dr Sands, a junior registrar, was the most senior paediatrician involved in the ward round. Therefore the onus was on him to request and ensure that a blood test was carried out. If Dr Sands had given a simple instruction to do a simple blood test that morning it would have highlighted a low sodium level and alerted doctors to review and change Claire's fluid management. It would have identified hyponatraemia at an early stage and prevented the onset of cerebral oedema.

Dr Sands, Dr Steen and Professor Young were asked about when and how many blood tests were carried out on Tuesday 22 October 1996 at a meeting with Mr and Mrs Roberts on 7 December 2004 and the parents were informed it was normal practice to monitor sodium level every **twenty-four hours**.

No evidence regarding the failure to carry out a blood test to check U&E on the morning or early afternoon of Tuesday 22 October 1996 was given by Dr Sands, Dr Steen, Dr Webb or Professor Young at the Coroner's Inquest in 2006.

It has been equally distressing for Mr and Mrs Roberts to read and listen to Dr Sands and Dr Steen's Inquiry evidence about when a blood test should have been done and their attempts to justify their actions on Tuesday 22 October 1996.

Dr Sands WS137/1 page 8 (5c) I believe this would have been part of the ward round discussion and planned to be carried out.

Dr Sands WS137/1 page 9 (5f) Repeat electrolytes would most likely have been requested with the intention of using the result as a guide to further fluid management.

Dr Sands WS137/1 page 12 (6l) A further sample for serum electrolytes including sodium is recorded in the evening. I am not certain at what time that sample was taken. The request was most likely made earlier in the day, probably as part of the ward round discussion. I do not know why it was not carried out until the evening time.

Dr Sands WS137/1 page 29 (12q)(vii) I do not recall if a further full blood count and electrolytes was discussed at 17:15. However I believe there would have been an expectation that this had been carried out already and the result awaited.

Dr Sands WS137/1 page 37 (17a)(i) Although not specified in the ward round notes, further electrolytes are likely to have been requested. This would often have been documented by a SHO on a separate piece of paper or book as "work to do".

Dr Sands WS137/1 page 37 (17a)(ii) Although not specified in the notes, further electrolytes and or a full blood count may have been requested later on 22.10.96.

Dr Sands WS137/1 page 41 (21b) I believe it is likely that a blood test for repeat electrolytes was requested during 22.10.96. This appears to have been carried out later that evening. Any electrolyte test would often have been planned during the ward round, perhaps without a definite time specified. However the sampling would usually have been between 9am and 5pm.

Dr Sands WS137/2 page 9 (7c) I do not recall what discussion took place regarding a further check of urea and electrolytes. However electrolytes were repeated later that evening. I therefore think it likely that a decision was made to repeat a test of electrolytes.

Dr Sands WS137/2 page 9 (7d) I am unable to recall whether such a discussion was recorded or who may have been responsible for this.

Dr Sands WS137/2 page 9 (7e) I am unable to say why the ward round note does not record any plan or decision for a further check of urea and electrolytes.

Dr Sands WS137/2 page 9 (7f) I cannot be sure why I did not take such action.

Dr Sands WS137/2 page 9 (7h) I cannot be sure that the reason electrolytes were repeated later was because of a discussion/decision on the ward round on the 22 October 1996.

Dr Sands WS137/2 page 16 (19d) I do not recall whether I checked that a sample for testing serum electrolytes had been taken, or the results looked for.

T19-10-12 Dr Sands

T19-10-12P109L12-L21

(The Chairman) Well, in hindsight, let's suppose for the moment that the evidence doesn't really support the suggestion that that was planned. Do you accept, with hindsight, that it should have been planned?

(A) Yes, I think it's something that should have been done during the day. If I may: after hearing of Claire's collapse, I believe it was from Dr Bartholome, I was surprised to hear that there wasn't a blood result available before that.

The Inquiry have put the question about a repeat blood test to Dr Sands numerous times without a satisfactory answer. It is clearly evident that Dr Sands failed to request, failed to document, failed to process and failed to carry out a simple blood test. The failure to carry out a blood test on the Tuesday morning does not support Dr Sands evidence that he considered and described Claire as having a major neurological problem, an infection affecting her brain, encephalitis/encephalopathy and was the sickest child on Allen ward.

T01-11-12 Professor Neville

T01-11-12P64L23-L25

(A) I think the problem about the -- well, if we're going to judge the current levels of 132, that could well have been a rapid drop down from 140.

Mr and Mrs Roberts have read many statements and reports regarding Claire's initial sodium level of 132mmol/L and some doctors lack of concern for a sodium level that is just below the lower range of 145mmol/L to 135mmol/L. Professor Neville however highlights a very significant point that there was **no baseline** from which to judge the initial fall in Claire's sodium level or the rate of that fall. For example, if a doctor is advised that a patient's sodium level had fallen from 145mmol/L to 132mmol/L within 12 hours would that doctor be concerned?

T01-11-12 Professor Neville

T01-11-12P75L4-L6

(A) I think it's absolutely clear they should have been repeated the following morning, early, not waiting for the ward round, but get on with doing it.

T01-11-12P75L10-L12

(The Chairman) So the onus for that is on the registrar coming on at about 9 o'clock or a little bit before 9 --

(A) Sure.

T01-11-12P77L6-L11

(A) Yes, that's simple sodium testing.

(The Chairman) Professor, you almost looked there as if this is depressingly simple and obvious. Is that --

(A) Yes. Well I think it is very surprising that it wasn't done that morning. I'm astonished really that it didn't occur.

T01-11-12P136L2-L7

(Q) Dr Scott-Jupp and you agree that Claire's electrolytes should have been tested by the time of the ward round

(A) Yes.

T12-11-12 Dr Scott -Jupp

T12-11-12P55L12 to P56L1

(Q) What about the result of 132, do you think that should have been repeated?

(A) Yes.

(The Chairman) When?

(A) Well, this is perhaps one of the major questions of this entire inquiry. I think I said in my original report it should have been done some time during the day of the 22nd, and I think other experts have been more specific on that. It would have been normal practice, I think, in the way that the ward routine happens, and I think it would have been acceptable for it to have been repeated probably late morning after the ward round, after decisions had been made on what investigations were required on Claire.

T12-11-12P132L8-L15

(The Chairman) That criticism is more importantly directed at the ward round, isn't it?

(A) It is, but given that it wasn't done after the ward round, then it is more the responsibility of the general team, who knew that the 132 result had been quite a long time previously, more the responsibility of them to repeat it than it was the responsibility of Dr Webb to advise them to repeat it.

Prof Neville 232-002-005 (iii)(b) Certainly the electrolytes should have been urgently repeated six hours after admission because of the reduced conscious level and the marginally reduced initial sodium level. I do not think it was reasonable to wait longer in this clinical situation, whatever the arrangements for biochemistry at night.

Dr Scott-Jupp 234-002-003 (iii)(b) It would have been reasonable to repeat it about twelve hours later. If as is likely a substantial fall had been noted then it may have been possible to intervene before the Cerebral Oedema became apparent.

Dr Scott-Jupp 234-003-005

(Q) If there had been a request for a repeat blood test of Claire's electrolytes made during the ward round, or later during the day on 22nd October 1996, whether you would have expected this request to have been recorded and, if so, where, and the reasons why.

Response: Yes, I would have expected a request from the registrar to repeat any tests to have been recorded by the SHO in the ward round note at the time. This would have been part of the management plan. A note would also serve as a reminder to the SHO to do the blood test after the round.

Dr McFaul 238-002-020 (93) The paediatric registrar Dr Sands reviewed Claire on the ward round in the morning but did not repeat the blood electrolytes which the previous evening had shown a slightly low sodium. Although there is little agreed guidance on the frequency with which children on intravenous fluid should have repeat sampling, a further sample was indicated specifically because Claire was significantly ill with, by then, persistent reduced level of consciousness and thus had a clear encephalopathy and had vomited even while on intravenous fluid.

f). Dr Sands failed to record an entry within the medical notes on Tuesday 22 October that a blood test was required.

g). Dr Sands failed in his erroneous understanding of the timing of the sodium reading from the previous evening of 132mmol/L at 11:00am on Tuesday 22 October.

Dr Sands failed to establish and was unaware of the time the blood U&E sodium result of 132mmol/L from the previous evening was rewritten and recorded in the medical notes during the ward round.

T19-10-12 Dr Sands

T19-10-12P98L10-L15

(Q) And you'd have known that that U&E result of sodium of 132 related to blood that was taken the previous evening. Sorry, would you have known that?

(A) Yes, I think that's a reasonable question. I would have... I may not have known the exact time that blood was taken, I think is my answer to that.

T30-11-12 Dr Webb

T30-11-12P175L11-L20

(Q) And what did he (Dr Sands) tell you?

(A) Her glucose was normal and her sodium was 132. And I remember saying to him, "Well, that would not explain Claire's presentation at the moment".

(Q) Did he tell you when the tests that produced those results had been carried out?

(A) No, he didn't.

(Q) What did you understand about when they had been done?

(A) My understanding was that they were done that day because my question related to her presentation today and he had just examined her.

WS138-1 page 36 (23b)(i) Dr Webb.

Claire's serum sodium should have been repeated during the day of 22 October but I did not think of this because I erroneously thought her serum sodium had been normal that morning.

Prof Neville 232-002-006(c) The lack of an urgent EEG, CT and electrolytes were major omissions and the need for these would normally have been discussed with a consultant.

h). Dr Sands failed to ensure that a blood test had been done before leaving Allen ward at around 01:30pm on Tuesday 22 October.

i). Dr Sands failed to recognise the dangers of No18 IV fluids, inappropriate fluid management, hyponatraemia and cerebral oedema.

Dr Sands failed in October 1996 to recognise the link between fluid management, electrolyte imbalance and hyponatraemia. The evidence given by Dr Sands in preparation for and during the Coroners Inquest into Claire's death in 2006 is contrary to the evidence he has given to this Inquiry.

Dr Sands draft Coroners statement dated 27 May 2005 (139-103-005) and Dr Sands email to Mr Walby (139-104-001)(139-106-001).

139-103-005 line 18 This was standard fluid therapy at the time. Although I did not prescribe the fluids, **I was not aware** of a contraindication to their use in this type of situation.

Dr Sands deposition to the Coroner dated 4 May 2006 (096-003-020) states :

I agree that the fluid regime for Claire between 8pm and 2am **was not** an important issue for what happened to Claire thereafter.

I had no issues then with Claire's fluid regime. **I have no recollection of knowing of a linkage between fluid management and hyponatraemia in relation to No 18 solution.**

Contrary to the above is Dr Sands Inquiry evidence:

T19-10-12 Dr Sands

T19-10-12P14L16-P15L6

(Q) So this is Dr Stewart's note, and this is a note that he's making at 11:30, so he has those results and he has hyponatraemia, so he has that as how to classify it. Then he's querying the causes. One is **fluid overload and low-sodium fluids**. That's one pathway, if I can put it that way, towards hyponatraemia. The other is SIADH. Would you have been aware of that yourself in 1996?

(A) Of those as causes of hyponatraemia?

(Q) Yes.

(A) I would have certainly been aware of this syndrome of inappropriate ADH, again probably more from a theoretical point of view rather than having practically dealt with it on a frequent basis. In terms of **fluid overload with low-sodium fluids**, I think at the time **I would have been aware** of that as a potential problem.

Prof Neville 232-002-007 (iv)(f) Although 0.18N saline was in common use, in the context of a low sodium level and reduced consciousness, it would have been more appropriate to give a reduced volume of a higher strength of sodium chloride and to carefully monitor the sodium level in the plasma and the conscious level.

j). Dr Sands failed when he continued with a fluid management plan of No18 IV fluids on Tuesday 22 October

Dr Sands was the paediatrician responsible for Claire's fluid management, the review of her fluid management from the previous evening and her reassessment on the Tuesday morning. It is clearly evident that Dr Sands failed to reassess Claire's fluid management plan during the ward round and throughout Tuesday 22 October.

T19-10-12 Dr Sands

T19-10-12P101L9-L17

(Q) If you were going to continue the IV fluids and you were aware that she'd been on them for some period of time, she had a slightly below normal serum sodium level, you think at that time, in 1996, it would be logical to have thought about what IV fluids she should continue to remain on?

(A) I think there would have been some discussion about IV fluids and whether to continue them and at the present rate.

Prof Neville 232-002-002 (line 5) Not recognising that the slight initial hyponatraemia might be part of a worsening trajectory and thus not realising that hypotonic fluids might be hazardous.

Prof Neville 232-002-008 (iv)(f) Claire's fluid management ought to have been reviewed throughout 22 October given her deteriorating level of consciousness/drop in GCS/CNS observations, the attacks as recorded, the lack of response to 4 types of anti-epileptic medication on 22 October 1996 and the lack of urine output between 11:00 and 19:00 on 22 October 1996.

T12-11-12 Dr Scott -Jupp

T12-11-12P131L9-L22

(Q) There's no specific reference to reviewing her fluid management in this note.

(A) No.

(Q) Is that something that you consider the neurologist might have given some guidance about?

(A) I think this comes largely to the crux of this case who's responsibility was it to manage Claire's fluids? It would have been entirely within the remit and reasonable of the consultant neurologist to advise on it. I think, as Claire was still under the general paediatric team, the primary responsibility for doing the tests and altering treatment on the basis of those tests still rested with the general paediatric team, Dr Steen's team.

k). Dr Sands failed to monitor Claire's fluid balance, input against output.

Dr Sands failed to request, check or monitor Claire's fluid balance. No urine tests were carried out to check Claire's fluid output or fluid composition and establish an accurate fluid balance.

l). Dr Sands failed to request a urine sample for urine osmolality testing.

m). Dr Sands failed in his initial diagnosis by placing too much emphasis on Claire's past history of epilepsy.

At the age of 6 months Claire did have an early infancy set back when she suffered from epileptic convulsions. This was assessed, monitored and controlled with medication. Over the following years Claire had very few convulsions and was seizure free for over 5 years before her admission to the RBHSC. Her medication had been reduced over that period and she was off all medication for 18 months prior to her admission to the RBHSC.

Prof Neville 232-002-002 (line 3) To my mind the errors were as follows, attributing

deterioration to uncorroborated sub-clinical seizure activity.

Prof Neville 232-002-001 (line 17) I also think that sub-clinical seizure activity is an unlikely cause of this clinical presentation in someone who is in remission from her epilepsy.

Prof Neville 232-002-001 (line 27) I would not have described Claire as currently a person with epilepsy before her final illness.

n). Dr Sands failed to consider other possible diagnoses including hyponatraemia.

Prof Neville 232-002-001 (line 21) No one appears to have looked for an alternative treatable condition until she was admitted to ICU on 23 October and was noted to have fixed dilated pupils and papilloedema.

Prof Neville 232-002-002 (line 1) However it is clear that the possibility of hyponatraemia/cerebral oedema was not considered until it was too late.

Prof Neville 232-002-005 (iv)(a) Another more likely cause of reduced conscious level and poorly reacting pupils would be cerebral oedema related to hyponatraemia and that should have been considered as a matter of urgency because in its early stages it is reversible by treatment.

o). Dr Sands failed to carry out an EEG on Tuesday 22 October.

T01-11-12 Professor Neville

T01-11-12P99L7-L19

(Q) I think where I had been asking you before was in relation to the tests that you think should have been carried out, and I think you had expressed the view that there should have been, so far as you're concerned-- we're now talking about at the ward round or ordered as a result of the ward round, there should have been the repeat U&E tests, there should have been a CT scan ordered and/or an EEG and some consideration should have been given to a lumbar puncture, would that summarise it?

(A) Yes. It's not and/or, really.

(Q) It's a CT scan and EEG?

(A) Yes.

T12-11-12 Dr Scott -Jupp

T12-11-12P115L22 to P116L1

(The Chairman) If we understand emergency and urgent to describe somehow the extent to which one is needed immediately or as soon as possible, how urgent was it after the ward round for Claire to get an EEG?

(a) I think it was same-day urgent.

p). Dr Sands failed to carry out a CT scan on Tuesday 22 October.

Prof Neville 232-002-006(c) The lack of an urgent EEG, CT and electrolytes were major omissions and the need for these would normally have been discussed with a consultant.

Prof Neville 232-002-007(c) The CT scan and EEG should have been arranged at the latest by the morning of 22 October 1996.

q). Dr Sands - The credibility and accuracy of the alleged communication and information given to Claire's parents during and following the ward round on

Tuesday 22 October.

Mr and Mrs Roberts strongly disagree with Dr Sands evidence on 19 October 2012 and would state the following:

- i). Fact: Dr Sands did not discuss an infection affecting Claire's brain with the parents during or following the ward round.
- ii). Fact: Dr Sands did not discuss encephalitis or encephalopathy with the parents during or following the ward round.
- iii). Fact: Dr Sands did not state to the parents during or following the ward round that he believed Claire had a major neurological problem.
- iv). Fact: No treatment for encephalitis was considered or started at or following the ward round.

If Dr Sands had advised Mr and Mrs Roberts that Claire may have a brain infection, encephalitis or a major neurological problem they would not have left the hospital at lunch time for a trip into Belfast, Mr Roberts would not have left the hospital at 02:45pm before returning at 06:15pm and both parents would have been alarmed and asking questions. This was simply not just a breakdown in communication or understanding between Dr Sands and Claire's parents, none of those issues were discussed with the parents or recorded in the medical notes or nursing notes. Mr and Mrs Roberts have found this part of Dr Sands evidence to be extremely hurtful and painful because the conversation they had with Dr Sands during and after the ward round lasted no more than ten minutes and during that time Dr Sands did not raise any concerns for Claire's wellbeing. They firmly believe that Dr Sands carried out a routine ward round and as a result of the information they gave him about Claire's past history of epilepsy and his limited experience, he decided to discuss Claire's prognosis with Dr Webb. Mr and Mrs Roberts believe Dr Sands evidence on 19 October 2012 is an attempt to conceal his actions in 2004 and justify his evidence at the Inquest in 2006. The parents once again emphasise that the ward round discussion with Dr Sands was the only discussion they had with him throughout Tuesday 22 October 1996.

T19-10-12 Dr Sands

T19-10-12P134L16-L17

(A) I wouldn't have wanted to take away their optimism that Claire was going to recover. (11:00am Tuesday 22 October).

This statement by Dr Sands must be put into context with Dr Webb's understanding at 05:00pm that he expected Claire to make a recovery. Dr Webb did not believe Claire's mortality risk was greater than 1%.

T19-10-12 Dr Sands

T19-10-12P134L21-24

(Q) Before we go to that specific question about her brightness and responsiveness and so forth, in-your-view, what-were-you-telling-them then?

(A) That I thought Claire had a major neurological problem.

T19-10-12P135L10-L16

(Q) Is there any thing else you think you would have been telling them?

(A) I think I would have raised the issue about possible infection causing some of Claire's problems, infection that might have -- I probably wouldn't have used the word "encephalitis", but may have felt there was an infection also playing a part.

T19-10-12P135L17 to P136L3

(Q) Encephalitis is a particular kind of infection. We're not talking about a more run-of-the-mill infection or a tummy bug, if we're talking about viral illness. Encephalitis and encephalopathy are in a completely different league, I would anticipate, from that. So even if you might not have used those terms because you might not have thought they would understand what those terms meant, did you try and interpret for them what that was?

(A) I think I did to some degree, yes, in terms of an infection that might be causing a problem with Claire's brain.

T19-10-12P136L5-L8

(Q) And if you were telling them that sort of thing, do you think that that is something that should have been recorded, whether it's by your SHO or by the nurses?

(A) I think it should have been recorded.

T19-10-12P239L5-L12

(Q) Now, for Dr Stevenson and the nurses, they are the touch point or the contact point with the parents. So if they don't fully understand it, absent yourself or Dr Webb coming and specifically discussing it with the parents, then it's difficult to see how the parents will be accurately informed about the condition of their child. Would you accept that?

(A) I think there may have been a gap in understanding.

r). Dr Sands additional diagnosis of encephalitis/encephalopathy and when this was added to the medical notes (090-022-053)

The addition of encephalitis/encephalopathy to the medical notes is an ongoing major issue for Mr and Mrs Roberts. They believe the medical notes and nursing notes read more coherently without the addition of encephalitis/encephalopathy to the ward round note at approximately 01:00pm and that the clinical treatment Claire received and the medications administered follow a course of treatment for non-fitting status rather than treatment for viral encephalitis. Following Claire's admission there is only one single entry within the medical notes and nursing notes were encephalitis is recorded and Mr and Mrs Roberts believe that this was added in 2004.

T13-12-12P127 Mr and Mrs Roberts

T13-12-12P127L7 to P128L24

(A) I think that raises another issue around -- and I don't want to go back to it too much, but when the actual note, the "encephalitis/encephalopathy" was added, because I do feel that when we did go back in 2004 and we were heading -- we had our meeting and we were heading for a Coroner's Inquest, that Dr Steen was asked by Dr McBride in the first instance to review the medical notes. I find that very difficult to accept, that a doctor who potentially is going to be asked a question about the treatment of a child is given, in the first instance, the opportunity to look at the medical notes.

(Q) Why?

(Mr Roberts) I think it's pretty obvious if a doctor looks at a medical note and she's about to face criticism, that she will want to go through the medical notes, scrutinise the

medical notes and perhaps see what their content is. I feel that if Dr Steen was reading through the medical notes, she would realise that there had to be -- well, if she looks at the definition, she is confident that she has brain infection within the post-mortem report. But the medical notes do not find encephalitis, I feel, by that stage. I feel that Dr Steen needed to close the circle within the medical notes.

(The Chariman) If I understand it rightly, in effect what you're querying is whether, when Dr Steen saw the notes and the issue had been raised on the back of the documentary, she then saw that there wasn't a reference to encephalitis, so she got Dr Sands to write it in? Bluntly, is that what you're saying?

(Mr Roberts) That's my belief.

(The Chairman) Which would mean that Dr Steen and Dr Sands didn't just make mistakes or have oversights in the way that Claire was treated, but that they subsequently conspired to fabricate notes in order to try to see off the queries which you raised some years later?

(Mr Roberts) Exactly, yes. I think Dr Steen, looking at the notes, would realise that there had to be a trigger for the status epilepticus, or as she had put down, the non-fitting status. There had to be a reason for that. That's why I believe the encephalitis was added into the medical notes, in and around the ward time.

Mr and Mrs Roberts believe that following their contact with the RBHSC in October 2004 Dr Steen considered that the post mortem report supported and secured her view that a viral encephalitis was the cause of Claire's death. However on reviewing the medical notes as instructed by Dr McBride, in the first instance, and **any reason to suggest that fluid and electrolyte management** may have been a factor in this case (Ref e-mail 141-003-001 dated 2 November 2004) Mr and Mrs Roberts believe Dr Steen realised that the medical notes did not capture encephalitis from the start or thereafter. Mr and Mrs Roberts believe Dr Steen and Dr Sands in 2004 fabricated the notes in an attempt to reinforce and secure a better definition of encephalitis from an early stage within the medical notes to add support and weight to a viral cause of death and detract from a fluid mismanagement problem.

The importance of securing medical notes for review is highlighted in a letter dated 28 October 2004 from Mr Clive Gowdy, Department of Health, Social Services and Public Safety to Mrs Ann Balmer, Royal Group of Hospitals (141-009-001) "to ensure that all relevant records and documents are secured so that, if necessary, they can be made available for **independent** examination".

It was not until August 2007 when Professor Harding compiled a neuropathology report for the PSNI and considered meningo-encephalitis excluded, both by microbiology and post mortem neuropathology that the original hospital post mortem report compiled by Dr Herron and Dr Mirakhur in 1997 was questioned.

Dr Steen's view has always been that a viral encephalitis was the starting point in Claire's diagnosis.

WS143-1 page-70 Q44e-Dr Steen.

(Q) Specify the basis and reasons for explaining to Mr and Mrs Roberts that Claire's cerebral oedema "was probably caused by a virus".

(A) The scenario of events for Claire was suffering from viral gastritis/gastroenteritis

leading to encephalitis/encephalopathy, which precipitated status epilepticus leading to SIADH -low sodium increasing cerebral oedema which in turn further impacted on the SIADH and cerebral oedema.

Evidence of Dr Steen to the Coroner on 4 May 2006 (096-014-102).

(Mr McCrea) Dr McBride wrote "Our medical case notes may have shown a care problem relating to hyponatraemia in Claire's case". Do you accept that view?

(A) Our view was "meningo-encephalitis going to status epilepticus and then to cerebral oedema" and this has not changed significantly since then.

A viral meningo-encephalitis cause was maintained by Dr Steen during and after her medical note review in 2004, during discussions with Professor Young in December 2004, at the meeting with Mr and Mrs Roberts on 7 December 2004, on compilation of her Coroner's statement 096-004-021/023 dated 16 March 2005 and during oral evidence to the Coroner in May 2006.

During and following the Coroners Inquest in 2006, Dr Steen, Dr Sands, Dr Webb and Professor Young were still attempting to put the emphasis on a viral cause of death (meningo-encephalitis) and distract from a fluid mismanagement problem. This is borne out in the Coroners verdict of hyponatraemia due to excess ADH. Mr and Mrs Roberts concerns about the Coroners verdict and the lack of definition regarding fluid mismanagement and hyponatraemia were raised in a letter to their solicitor Mr Nigel Barr dated 4 August 2006 (096-019-115). This letter highlights their concerns about hyponatraemia and the omission of fluid mismanagement from the Coroners verdict. The letter emphasises two references from Paediatrics 2004:

"To develop hyponatraemia (plasma sodium concentration P (Na) <136mmol/L, one needs a source of water input and antidiuretic hormone secretion release to diminish its excretion".

"There are two requirements for a fall in P (Na) the presence of ADH and a source of water input. Although it should not be surprising to find elevated ADH levels in acutely ill patients, this will not cause hyponatraemia in the absence of water input".

The addition of encephalitis/encephalopathy to the medical notes is an example of what has already been highlighted several times during the course of this Inquiry. When an error within the medical notes is captured it tends to be repeated again and again within follow on reports and evidence. That of course is the intention in Claire's case with the addition of encephalitis/encephalopathy to the medical notes.

Claire's case is much more than clinical mismanagement, failures, errors, mistakes, misdiagnoses and medical negligence. It is much more serious than that. Mr and Mrs Roberts believe their concerns and oral evidence during Thursday 13 December 2012 raise additional and very serious issues.

The forensic report by Dr Giles 241-001-001/023 dated 13 September 2013 examined as a comparatory test the entry "encephalitis/encephalopathy" and the prescription entry timed at 5:15pm "22-10-96, sodium valproate, 400mg, 5:15pm, IV, A Sands, AS". Both entries were made by Dr Sands and are the only 2 entries made by Dr Sands in

Claire's medical notes between 21 and 23 October 1996.

Dr Giles conclusion is that there is **positive**, albeit weak, evidence to support the view that the questioned entry "encephalitis/encephalopathy" was written using a pen different from that used for the writings made by Dr Sands on the prescription card. This is important evidence.

Dr Giles also noted that the entry "encephalitis/encephalopathy" is similar to that of BIC ballpoint pen inks from her laboratory collection and that the prescription card entries may be from this brand of ink but are less easily identifiable. Again this is important evidence which would agree with the questioned time differential (2004 v 1996).

s). Dr Sands failed to inform the parents of the alleged additional diagnosis of encephalitis/encephalopathy and that it had been included in the medical notes (when and why this was added).

Dr Sands evidence is that he added encephalitis/encephalopathy to the medical notes immediately after speaking to Dr Webb. Dr Sands evidence is that following his discussion with Dr Webb around 01:00pm on Tuesday 22 October 1996 he returned to Claire's medical notes and added the only two words he recorded in the medical notes throughout that day. A total of two words by a registrar who states that he believed Claire had non fitting status, encephalitis/encephalopathy, a brain infection, a major neurological problem and was the sickest child on Allen Ward. It is also noted that Dr Sands did not record in the medical notes any intention to inform or contact Dr Steen by telephone.

T19-10-12 Dr Sands

T19-10-12P167L24 to168L7

(Q) Did you at that time, in 1996, understand what these terms meant, how they would affect a patient's presentation and actually what the underlying causes of them might be?

(A) Dr Sands "My understanding of encephalitis would have been limited, **having not seen perhaps any cases of encephalitis**, of definite encephalitis. My understanding would have been limited at that time. And even more so of encephalopathy".

T12-11-12 Dr Scott -Jupp

T12-11-12P97L7-L15

(Q) Your first report, 234-002-004, was that Dr Sands' diagnosis was not unreasonable at the time, but that other differentials, including encephalitis and encephalopathy should have been considered.

(A) Yes.

(Q) Dr Sands' evidence was that he did discuss encephalitis during the ward round. If he had discussed that, would you have expected the SHO to have recorded that?

(A) Yes.

Dr Sands did not inform Mr and Mrs Roberts that he had added encephalitis/encephalopathy to the medical notes. Dr Sands states he had not seen a case of encephalitis or he had limited knowledge of encephalitis. Did this diagnosis not

heighten Dr Sands concern or urgency for further investigation or explanation to the parents?

Considering the Inquiry experts evidence on encephalopathy and fluid management and given Dr Sands limited knowledge of encephalitis or encephalopathy, if Dr Sands added encephalitis or encephalopathy shortly after the ward round he therefore failed to recognise potential fluid management problems and failed to inform the parents, SHO's and nursing staff of the need to review, change and monitor Claire's fluid management.

t). Dr Sands failed to recommend or implement a management plan to treat "encephalitis/encephalopathy" following the ward round and at 13:00 Tuesday 22 October.

T19-10-12 Dr Sands

T19-10-12P116L11-L15

Dr Sands evidence to the Inquiry is that encephalitis was discussed during the ward round but not noted in the medical notes. If encephalitis was considered as a possible cause of the non-fitting status epilepticus (WS 137/2 page 13 Question 14a) Dr Sands failed to suggest or implement a treatment plan during the ward round or following his discussion with Dr Webb. Dr Sands left Allen Ward for most of the afternoon on Tuesday 22 October to possibly attend a clinic and therefore failed to be in attendance when Dr Webb examined Claire at 02:00pm when a treatment plan for encephalitis could have been discussed. Mr and Mrs Roberts find it is very difficult to understand and accept that if Dr Sands had any major concerns for Claire's condition at the ward round, or following his discussion with Dr Webb, or if he had added encephalitis to the medical notes prior to Dr Webb's 02:00pm examination that he would have left Allen Ward for teaching duties or to attend what appears to be a non urgent clinic.

T12-11-12 Dr Scott -Jupp

T12-11-12P121L9 to P121L20

(The Chairman) What was being floated with you was the idea of whether Dr Sands might be criticised for not prescribing acyclovir at the end of the ward round as he went off to get Dr Webb. And you were saying, well, he might have left it to see what Dr Webb said. Do I take it then that the fact that Dr Webb didn't prescribe it at 2 o'clock means that it's pretty harsh to criticise Dr Sands for not prescribing it earlier?

(A) Yes, it would. Well, I'm not a neurologist, but I found it slightly surprising that Dr Webb didn't suggest acyclovir. I don't think I put that in my report; maybe I should have done with hindsight.

Any level of criticism of Dr Sands not prescribing acyclovir at the end of the ward round must be based on the assumption that Dr Sands did consider encephalitis during the ward round and that following his discussion with Dr Webb he added encephalitis/encephalopathy to the medical notes. If anything, the failure by Dr Sands not to prescribe acyclovir at the end of the ward round supports Mr and Mrs Roberts evidence that encephalitis was not discussed or considered at that time. It is noted that Dr Scott-Jupp was surprised that Dr Webb did not suggest or prescribe acyclovir at 02:00pm.

u). Dr Sands failed to provide adequate information to junior doctors and nursing

staff to treat his alleged additional diagnosis of "encephalitis/encephalopathy".

T16-10-12 Dr Stevenson

T16-10-12P165L6-L16

(Q) And thereafter, I think in Dr Sands' hand, is added "encephalopathy/encephalitis".

And that's added.

(A) Yes.

(Q) And that brings with it a notion of some viral effect going on.

(A) That's true.

(Q) Do you have any knowledge of when that got added to the medical notes?

(A) I've no memory.

(Q) Was that ever discussed with you?

(A) No, not to my knowledge.

T12-11-12 Dr Scott -Jupp

T12-11-12P207L20 to P208L3

(Q) Given that, what do you feel it is important that he does to communicate his views and what's happening to the SHOs and the nursing staff?

(A) Dr Sands, you mean?

(Q) Yes

(A) Well, one would expect that he would have been in communication with the SHOs and the nursing staff all the time. That's what a registrar should do and he should have made his concerns known to them.

v). Dr Sands failed to provide adequate information to the nursing staff to treat his alleged additional diagnosis of "encephalitis/encephalopathy" to ensure an update of the nursing notes and nursing care plan.

T19-10-12 Dr Sands

T19-10-12P237L1-L6

(Q) Are you aware of having that recorded for the benefit of the nurses so that when they change shift, they would appreciate that this is the condition of the child whose condition they are monitoring?

(A) I'm not sure to what extent the nurses fully understood the severity of Claire's condition.

T19-10-12P239L1-L12

(Q) The problem, frankly put, from the nurses' point of view -- and one can't speak for Dr Stewart, he hasn't given his evidence yet -- their impression is that they just didn't realise that Claire was as ill as that. Now, Dr Stevenson and the nurses, they are the touch point or the contact point with the parents. So if they don't fully understand it, absent yourself or Dr Webb coming and specifically discussing it with the parents, then it's difficult to see how the parents will be accurately informed about the condition of their child. Would you accept that?

(A) I think there may have been a gap in understanding.

T19-10-12P239L23 to P240L9 Dr Sands

(Ms Anyadike-Danes) I am putting to you issues that people have. If we stay with the nurses, when you formed that view of encephalitis/encephalopathy, albeit contributed to by your discussion with Dr Webb, did you think that that ought to be recorded in the

notes for the nurses anywhere?

(A) Again, those were only possible differential diagnosis. I'm not sure that the nurses would have necessarily adopted those in the nursing notes at that stage.

This is contrary to Dr Sands WS137/2 page 13 question 14a. "I do not recall who discussed encephalitis on the ward round. I believe this may well have been considered a possible cause of non-fitting status epilepticus".

The Inquiry will consider if encephalitis was discussed at or following the ward round as a possible cause of non-fitting status epilepticus. If it was then surely it would have been essential to treat the encephalitis.

The nursing notes or the nursing care plan make no reference to encephalitis/encephalopathy.

The nursing note by S/N Field (090-040-140) 08:00am - 2:00pm states seen by Dr Sands status epilepticus non-fitting.

Dr Sands states around 1:00pm would have been the time in which he added encephalitis/encephalopathy to the medical notes. However S/N Field makes no reference to encephalitis/encephalopathy in the nursing note or nursing care plan.

WS148/1 Page 6 Q15 S/N Field.

My understanding for Claire's admission was to manage her symptoms of vomiting and observe for possible seizure activity. I do not recall being informed of the primary diagnosis of encephalitis (090-012-014) or viral illness (090-022-052).

WS148/1 Page 19 Q25k S/N Field.

(Q) State the reasons why the Nursing Care Plan was not reviewed and changed: (i) When the diagnosis was changed to "*non fitting status (epilepticus) /encephalitis/encephalopathy*"

(A) I do not recall any reason why the care plan was not reviewed and changed.

Mr and Mrs Roberts firmly believe that on Tuesday 22 October 1996 no doctor or nurse had an understanding of Claire's clinical condition, the true diagnosis of a rapidly falling sodium level and dilutional hyponatraemia. The nurses or SHO's were not aware, Dr Webb was expecting Claire to recover, Dr Steen, if she contacted Allen Ward, was given a reassurance that she did not need to return to the hospital. Dr Sands is the only doctor who has stated that he believed Claire's clinical condition at the time was serious and that he considered her to be the sickest child on Allen Ward. Dr Sands understanding of Claire's clinical condition does not agree with and is inconsistent with the views of the other doctors and nurses.

It is also noted that there are no entries in the medical notes by the paediatric team over the critical 8 hour period between approximately 03:00pm and 11:30pm on Tuesday 22 October.

~~Dr McFaul 238-002-040 (187)~~

There was a senior house officer on the ward and either he or Dr Sands should have made an entry in the late afternoon especially as Dr Sands in his witness statement has indicated that Claire was significantly unwell. And again in the evening.

w). Dr Sands - The reliability and credibility of the information given by Dr Sands to Dr Steen on the afternoon of Tuesday 22 October 1996.

There is no recorded or documented evidence that Dr Sands contacted Dr Steen on Tuesday 22 October 1996.

T19-10-12 Dr Sands

T19-10-12P184-P185

Dr Sands evidence is that if he telephoned Dr Steen early in the afternoon he would have informed her of what Claire's sodium levels had been, what IV fluids she was on, that Dr Webb was to see Claire, what her initial observation was (GCS 9), that she might have non-fitting status and that other possibilities were encephalitis/encephalopathy. If Dr Steen had been given this clinical information by Dr Sands she therefore failed to attend Claire in the early afternoon and again if she contacted Allen Ward in the late afternoon failed to make any contact with Dr Sands or Dr Webb.

T19-10-12P189L12-L15

(Chairman) Do you recall what Dr Steen's reaction was to the information you were giving her about your own views and the involvement of Dr Webb?

(A) I don't recall, sir, what we discussed or what Dr Steen said to me".

Mr and Mrs Roberts are very concerned that Dr Sands has a recollection of his conversation with Claire's parents and his conversation with Dr Webb but cannot recall what was discussed with the paediatric consultant Dr Steen.

T01-11-12 Professor Neville

T01-11-12P98L6-L10

(Chairman) Does this illustrate the problem that Claire's case features, which is the fact that Dr Sands seems to have been working without reference to a paediatric consultant for whatever reasons?

(A) Yes.

x). Dr Sands failed to request that Dr Steen should attend Allen ward on Tuesday 22 October.

Given Dr Sands alleged clinical assessment of Claire as having a major neurological problem, encephalitis/encephalopathy, an infection affecting her brain and the sickest child on Allen ward Dr Sands failed to requested definitive guidance and input from his paediatric consultant Dr Steen.

y). Dr Sands failed to recognise the appropriateness of the use of anti-epilepsy drugs.

Prof Neville report 232-002-006 (b) The problem with the diagnosis of non-convulsive status is that it leads to inappropriate treatment with anti-epilepsy drugs which could have further reduced her conscious level and her respiratory drive. If a single dose of rectal diazepam was to be given it should have been backed up by an urgent EEG, so that the working diagnosis could have been confirmed or refuted before any further anti-epilepsy medication was given.

Prof Neville report 232-002-006 (b) I have said that one dose of diazepam would be

understandable but not more than this or the rest of the IV drugs without EEG, at least a CT scan and checking the electrolytes (i.e. Na).

Prof Neville report 232-002-006 (b) (Q) Whether it was competent practice in October 1996 to use anti-epilepsy drugs without having made further attempts to rule out primary hyponatraemia by rechecking her blood electrolytes.

(A) No, I think this should have been done.

T08-11-12 Dr Aronson

T08-11-12P182L15-L21

(Q) The wiring of the heart is electrical and, if you give phenytoin too quickly, there is a risk that you may cause abnormal rhythms in the heart.

(Q) Is that why you need to manage it with an ECG while you're doing it?

(A) That's right.

z). Dr Sands as registrar and senior paediatrician on Allen Ward failed to be in attendance or oversee the calculations for and the administration of drugs administered by Dr Stevenson a junior paediatric SHO who was unfamiliar with and had no experience of using the drugs phenytoin and midazolam.

2.3 Allen Ward Tuesday 22 October 1996 - Ward round Dr Sands and Dr Stevenson approx 11:00am (090-022-052/053)

2.3.2 Stevenson (SHO)WS 139

a). Dr Stevenson failed to review the IV fluid management plan from the previous evening Monday 21 October.

T15-10-12 Dr Stevenson

T15-10-12P150L21-P151L1

(The Chairman) Doctor, how can you have any idea what fluid regime to continue? How do you know that the fluid regime which applied before is the right regime to continue?

(A) I didn't at the time, I just continued on what someone else had started.

(Ms Anyadike-Danes) Well, did you not think that's potentially quite dangerous?

(A) Yes.

b). Dr Stevenson failed to review and continued with an IV fluid management of No18 fluids on Tuesday 22 October.

T15-10-12 Dr Stevenson

T15-10-12P152L20-L24

(Q) Were you aware of the dangers of too much low sodium fluid being administered?

(A) No.

c). Dr Stevenson failed to monitor Claire's fluid balance, input against output.

~~Dr Stevenson failed to request, check or monitor Claire's fluid balance. No urine tests were carried out to check Claire's fluid output or fluid composition and establish an accurate fluid balance.~~

d). Dr Stevenson failed to provide accurate record keeping (medical notes and prescription sheets).

T16-10-12 Dr Stevenson

T16-10-12P204L22-P205L6

(Q) That addition of "encephalitis/encephalopathy", as further differential diagnoses, is it possible that that actually wasn't added to the notes before you left the ward?

(A) That's a possibility

(Q) Because you don't refer to it anywhere in anything that you do or engage in.

(A) Yes, that would be true.

e). Dr Stevenson failed with numerous errors made in drug prescription doses, drug dose calculations and drug administration rates.

Dr Stevenson as a first year SHO was left unsupervised on Allen Ward and had no experience in the administration of drugs such as phenytoin and midazolam. The dose administered and rate of administration of powerful drugs such as midazolam has always been a major concern for Mr and Mrs Roberts.

T15-10-12 Dr Stevenson

T15-10-12P180L19-L21

(Q) Can I ask you this: how often before then had you actually written up a prescription for phenytoin?

(A) Never.

T16-10-12 Dr Stevenson

T16-10-12P134L1-L12

(Q) And I can't remember if I had asked you whether you had prescribed midazolam before. Had you?

(A) I don't recall if I've prescribed it.

(Q) If you had, it's not likely to be something that you commonly prescribed?

(A) In paediatrics or general medicine, in my experience, no.

(Q) In fact, you might not have prescribed it before at all.

(A) Yes, that's true.

Prof Neville report 232-002-009 (v)(c) I do not think that giving I.V. phenytoin was appropriate at that stage without proof that non-convulsive status epilepticus was present.

Prof Neville report 232-002-009 (v)(d) Similarly the I.V. valproate was inappropriate because there was no confirmation by EEG of the diagnosis.

Prof Neville report 232-002-009 (v)(d) For the same reason the giving of midazolam was inappropriate.

Prof Neville report 232-002-016 (xvii) Yes, it [midazolam] can reduce the conscious level and thus the GCS because it is a sedative.

f). Dr Stevenson failed to learn any lessons following Claire's death.

2.4 Allen Ward Tuesday 22 October 1996 - Dr Webb examination 02:00pm (090-022-053/054)

Dr Webb (Consultant) WS138

The Inquiry are aware that the note made by Dr Webb at 02:00pm is incorrectly timed as 4pm and that the 4pm entry is also in a different coloured pen (T16-01-13P178). It is noted that Mr Walby raised the issue of different coloured ink within Dr Webb's medical note during oral evidence on 12 December 2012 (T12-12-12P128). The 4pm time is entered in black ink. All other entries recorded by Dr Webb within the medical notes and the diagnosis of brain death form (090-045-148) are in green ink. Mr and Mrs Roberts are concerned that the 4pm entry in black ink is another example of note tampering.

Dr Webb has attempted to provide an explanation for his error in witness statement WS 138-4. Dr Webb states that he would often re-read his note to make sure he was happy with the content before returning it to the chart trolley. It is therefore a concern when Dr Webb states that he checks and reviews his notes and can identify a missing time but is unable to identify the large overdose of midazolam ($0.5 \times 24 = 12\text{mg}$) recorded in the medical notes.

It is also difficult to understand how a consultant neurologist was aware that the only thing missing from his note was the time, that the timing of the note should be 2:00pm, that he intended to write 14:00 but somehow recorded 4:00pm.

a). Dr Webb failed in his erroneous understanding and interpretation of the medical note electrolyte reading and Claire's sodium level at 11:00am on Tuesday 22 October.

Mr and Mrs Roberts believe the failure by Dr Webb when he erroneously understood Claire's sodium level of 132mmol/L was from a blood test carried out on the Tuesday morning 22 October was one of many fundamental errors and mistakes in Claire's clinical treatment, diagnosis and care management that resulted in the tragic but avoidable outcome. The fact that this error was not disclosed until Dr Webb compiled his statement for the Coroner's Inquest in 2005/2006 raises serious questions about the investigations and reviews into Claire's care management in the days following her death and the obvious failures of any mortality meetings, grand round meetings or medical audits. Mr and Mrs Roberts are extremely concerned at how and why this major error was not disclosed for nine years.

T30-11-12 Dr Webb

T30-11-12P176L1-L7

(A) In my experience in the hospitals that I worked in prior to the Royal, if a child was put on intravenous fluids on an evening, then the blood test was done the following morning. That would also have been my practice in the Royal. So my expectation would have been that there would have been a blood test done that morning.

T30-11-12P178L4-L9

(A) As I said, I understood that it was 132 that morning.

(Q) That's why I'm saying you might have wanted to know that because, had it been significantly lower, that might have made a difference to how you started to formulate your differential diagnoses.

(A) Absolutely.

WS138-1 page 36 (23b)(i) Dr Webb.

Claire's serum sodium should have been repeated during the day of 22 October but I did not think of this because I erroneously thought her serum sodium had been normal that morning.

WS138-1 page 88 (66d) Dr Webb.

If I had been aware that Claire's serum sodium was not undertaken that morning (22 October 1996) I believe I would have requested a repeat urea and electrolyte measurement earlier that day.

Webb WS138-1 page 88 (66e) Dr Webb.

I believe the sample obtained on the evening of admission should have prompted an earlier repeat sample given that Claire was on intravenous fluids.

Prof Neville report 232-002-008 (v)(b) I have stated that 6 hours after the first blood test the electrolytes should have been repeated - this was before Dr Webb was involved but he should have required an urgent Na level as part of his assessment because of the likely possibility of falling Na levels, cerebral oedema and fatal outcome which might be preventable by treatment with fluid restriction and higher sodium containing fluids, diuretics and hyperventilation.

b). Dr Webb failed to review the IV fluid management plan from previous evening Monday 21 October.

Dr Webb has always, for whatever reason, refused to accept that he had any knowledge of or input into Claire's fluid management. Mr and Mrs Roberts are shocked that Dr Webb as a consultant who was advising on a medical treatment plan did not discuss, question, review or have an input into the choice of the IV fluids administered. If Dr Webb had no input into Claire's fluid management and Dr Sands had left Allen Ward for most of Tuesday afternoon who was responsible for Claire's fluid management?

T30-11-12 Dr Webb

T30-11-12P230L17-L25 to P231L1-L7

(Q) At 2 o'clock, its not recorded, but did you suggest that her serum sodium levels were tested.

(A) No.

(Q) Did you indicate that any further blood tests might be useful?

(A) No.

(Q) Is that because you didn't think that was part of what you were dealing with or because you thought about it and discounted it?

(A) I can't recall, but I am likely to have thought about it and said further blood test wouldn't have been terribly helpful.

(Q) And you knew that she was on IV fluids. Did you know what she was on and what rate she was on?

(A) No, and I would have left that part of her care to the general paediatric team.

T03-12-12 Dr Webb

~~T03-12-12P70L16-L21~~

(A) No. No. And I would have had an expectation that a sodium would have been repeated that afternoon at some point because she was a child on fluids. So that would have been my expectation.

(The Chairman) At some point on Tuesday afternoon?

(A) Yes.

Dr Webb expected a blood test on the Tuesday afternoon. Mr and Mrs Roberts raised this question with Dr Steen, Dr Sands and Professor Young on 7 December 2004 and they were informed that it would have been normal practice to monitor sodium levels every twenty-four hours.

T03-12-12P72L12-L17

(A) I've just told you. I think if they were required, they were done first thing in the morning and, if necessary, they were done later in the evening before 5 o'clock.

(Q) And who is the person who exercises the judgement that it's necessary to do it later on in the afternoon?

(A) It's usually the registrar.

WS138-1 page 73 (52d) Dr Webb.

I was not involved in Claire's fluid management and would have left this to the general paediatric team.

WS138-1 page 82 (62b)(i-iii) Dr Webb.

I had no input into Claire's fluid management and cannot therefore comment on what consideration was given to choice of fluids, ongoing fluid management or timing of blood tests.

T01-11-12 Professor Neville

T01-11-12P161L16-L25 to P162L1-L4

(Q) Leaving aside the fact that you said there should have been an EEG, there should have been a CT scan, and that her electrolytes should have been tested, but if one focuses on her fluid management, as he (Dr Webb) is now making suggestions for what people should do, do you think there is any guidance that he could have given or any suggestion he could or should have made in relation to her fluid management?

(A) Well, yes, he could have reduced the amount of fluid that was going in, he could have raised the level of sodium, but really the primary test of doing the sodium level is paramount, really.

T14-11-12 Dr McFaul

T14-11-12P84L15-L24

(Q) The question is: to what extent should the neurologist, Dr Webb, have been involved or offered guidance and opinion on her fluid management?

(A) Well, in my view, and I've stated it in my report, I expect part of the neurological opinion and treatment plan in an acute encephalopathy is to encompass the management of the fluids. By that, I mean he should have advised on the fluid treatment plan because of the reasons we've discussed, of the need for fluid restriction and adjustment of the sodium.

T14-11-12P85L11-L18

(Q) Are you of the view that because of the particular role or implications of fluid

management in the treatment of her neurological condition, if I can put it that way, it is so integrally bound up with each other that that is something that the neurologist himself should have understood, appreciated and taken on board as part of his responsibility?
(A) That is my opinion on this matter, yes.

Prof Neville 232-002-009 (v)(e) Dr Webb should be aware of inappropriate ADH secretion in acute brain illness and the need to monitor sodium levels/conscious level and fluid balance.

Dr McFaul 238-002-025 (118) However by the time that Claire was seen by the paediatric neurologist she was known to have established encephalopathy and the IV fluid should have been changed and this should have been part of the advice provided by the paediatric neurologist irrespective of any serum sodium results.

Dr McFaul 238-002-026 (121) Dr Webb should have been well aware of the significance of the slightly reduced blood sodium in a child with acute encephalopathy (in which there is a high risk of SIADH) which had been reported the previous night and he should have advised changes in the intravenous fluid regime both in terms of reducing infused volume and changing to a fluid with higher sodium content. He should have ordered further monitoring of the blood sodium but instead erroneously recorded that electrolyte results were normal.

Dr McFaul 238-002-026 (121) Instead of advising a fluid regime, as he should have done, he left the fluid management to the general paediatric team.

c). Dr Webb failed with his diagnosis of non fitting status without justification or test or review of that diagnosis.

Mr and Mrs Roberts believe that the diagnosis of non-fitting status made by Dr Sands at the ward round on the Tuesday morning 22 October and continued on by Dr Webb was incorrect and one of many fundamental errors and mistakes that resulted in Claire receiving inappropriate clinical treatment and care management.

Dr Webb has attempted to suggest that via a nursing comment there was an improvement in Claire's response following the administration of diazepam and that that provided support for his diagnosis.

Mr and Mrs Roberts did not see any marked improvement in Claire's clinical condition around midday on Tuesday 22 October following the administration of diazepam. They believe any slight improvement would be attributable to the increase in the level of activity around Claire's bedside when four grandparents were visiting and interacting with her but that Claire remained very lethargic.

Dr Webb WS138-1 page 78 (58g)

I considered that the fact she had improved following rectal diazepam made it more likely that she had been suffering from a seizure.

T03-12-12 Dr Webb

T03-12-12P69L14-L21

(The Chairman) In a sense, doctor, that's right about any diagnosis, isn't it? If you identify her illness going in one direction, if you treat that and if that assessment is wrong, then there's always the danger that another problem which you have missed or

you haven't missed but you thought was a much lower risk could be getting worse at the same time? (A) That's correct, yes.

T03-12-12P107L2-L8

(Q) That goes back to the question the chairman put to you earlier that, if you're waiting, you must have formed the view that the risk of being incorrect and what might be wrong with her be being something that was therefore not being treated and causing her harm must be quite low, otherwise you would keep all Claire's options open?

(A) I thought that risk was low, yes.

T03-12-12P189L20-L25

(Q) Would you have thought it relevant to convey to her that her daughter was seriously ill?

(A) Certainly if I thought that Claire was going to get worse, absolutely. But my expectation, as I've said, was that Claire was going to respond to treatment and that she could make a full recovery from this.

T30-11-12 Dr Webb

T30-11-12P208L1-L15

Mr and Mrs Roberts are shocked at what they have heard during oral evidence regarding one of Dr Webb's reasons for not requesting or organising an EEG on Tuesday 22 October. Dr Webb stated that he did not contact the EEG service on Tuesday afternoon because the technician would have felt that she would have to do an EEG and that would likely lead to her being there after hours.

Dr Webb's clinical judgement was that he could treat Claire and then look for a response. Dr Webb continued to prescribe anti-convulsive drug treatment without any justification or test verification for his diagnosis.

T01-11-12 Professor Neville

T01-11-12P103L5-L17

(A) I think by doing an EEG, you'll be able to tell the difference between a localised area or a more generalised area of brain that is firing continuously, and the occasional episode that's happening, which may be the result of hyponatraemia.

(Q) So if you don't do the EEG and don't do the repeat sodium tests, if I'm understanding you, you actually can't properly attribute a cause to those things.

(A) No.

(Q) -- and therefore can't treat them appropriately.

(A) No, that's right.

(The Chairman) Or to put it another way, you are **just working in the dark**.

T01-11-12P119L2-L9

(The Chairman) This is your concern that he went too quickly and too strongly in favour of one diagnosis.

(A) Yes, indeed.

(The Chairman) -- and missed what you think was a more likely diagnosis?

(A) Sure. I don't deny that he worked hard at it and came back to see the child and did that sort of thing, **but it was the wrong direction**.

T01-11-12P129L19-L25

(The Chairman) But the more fundamental point is that you say Claire should not have

been started on these various treatments and this diagnosis should not have been made with the degree of confidence which Dr Webb seems to have made it on the basis of information which was available to him?

(A) Exactly, sir.

Prof Neville 232-002-002 (line 26) An EEG is the only method of confirming a diagnosis of non-convulsive status epilepticus.

Prof Neville 232-002-005 (iv)(a) I would not agree that non-convulsive status epilepticus was the likely diagnosis because it is not common and epilepsy was not prominent in this girl's recent history. In my opinion non-convulsive status epilepticus needed to be proved by an urgent EEG.

Prof Neville 232-002-006 (iv)(b) The problem with the diagnosis on non-convulsive status is that it leads to inappropriate treatment with anti-epilepsy drugs which could have further reduced her conscious level and her respiratory drive.

Prof Neville 232-002-015 (xvi)(d) There is no clear evidence of status epilepticus and I cannot understand why an early EEG was not performed, I do not agree that it was a contributory cause of death.

Dr McFaul 238-002-024 (112) The assessment of the paediatric neurologist on 22 October 1996 has a number of shortcomings. The investigation and management was not consistent with guidance at the time for investigation and management of acute encephalopathy including need for CT and EEG investigation and a range of blood test (see below). And in particular the fluid management for acute encephalopathy of any cause required a reduction in infusion volume and increase in strength of sodium in the infusion fluid.

d). Dr Webb failed in his diagnosis by placing too much emphasis on Claire's past history of epilepsy.

At the age of 6 months Claire did have an early infancy set back when she suffered from epileptic convulsions. This was assessed, monitored and controlled with medication. Over the following years Claire had very few convulsions and was seizure free for over 5 years before her admission to the RBHSC. Her medication had been reduced over that period and she was off all medication for 18 months prior to her admission to the RBHSC.

T03-12-12 Dr Webb

T03-12-12P45L8-L22

Dr Webb in evidence stated that Dr Sands would have informed him that Claire had suffered from multiple seizure types during early infancy and that that information may have come from Claire's parents. Mr and Mrs Roberts would not have had the knowledge to discuss seizure types with Dr Sands or Dr Webb and the parents are concerned that Dr Webb or Dr Sands have obtained this information following Claire's death by reviewing the medical notes from 1987 and not on 22 October 1996.

Prof Neville 232-002-002 (line 3) To my mind the errors were as follows, attributing deterioration to uncorroborated sub-clinical seizure activity.

Prof Neville 232-002-001 (line 17) I also think that sub-clinical seizure activity is an

unlikely cause of this clinical presentation in someone who is in remission from her epilepsy.

Prof Neville 232-002-001 (line 27) I would not have described Claire as currently a person with epilepsy before her final illness.

e). Dr Webb failed to consider other possible diagnoses including hyponatraemia.

Prof Neville 232-002-001 (line 21) No one appears to have looked for an alternative treatable condition until she was admitted to ICU on 23 October and was noted to have fixed dilated pupils and papilloedema.

Prof Neville 232-002-002 (line 1) However it is clear that the possibility of hyponatraemia/cerebral oedema was not considered until it was too late.

Prof Neville 232-002-005 (iv)(a) Another more likely cause of reduced conscious level and poorly reacting pupils would be cerebral oedema related to hyponatraemia and that should have been considered as a matter of urgency because in its early stages it is reversible by treatment.

Prof Neville 232-002-010 (v)(g) This state required a diagnostic assessment of the cause of her deterioration including electrolytes, EEG and head scan. I would have expected the differential diagnosis to include the items on the list given above and specifically this should have included the causes of raised intracranial pressure in this setting since they are quite common and potentially treatable.

f). Dr Webb failed to recognise the dangers of No18 IV fluids and hyponatraemia. Dr Webb failed to recognise that Claire's fluid management was central to her clinical condition.

Prof Neville 232-002-007 (iv)(f) Although 0.18N saline was in common use, in the context of a low sodium level and reduced consciousness, it would have been more appropriate to give a reduced volume of a higher strength of sodium chloride and to carefully monitor the sodium level in the plasma and the conscious level.

g). Dr Webb failed with his incorrect management plan for Claire's clinical condition.

Prof Neville 232-002-008 (v) Dr Webb's assessment on the afternoon of 22 October 1996 was a competent examination but the interpretation failed to include the possibility of rising intracranial pressure to explain her reduced conscious level and motor signs.

Prof Neville 232-002-010 (vii)(d) It is difficult to know if she would have been retrievable by the measures outlined above but it is quite possible. From my perspective the electrolytes should have been repeated much earlier and a scan performed and seems likely to have shown a low Na level and brain oedema, which could have been treated. Claire was certainly retrievable early-mid 22nd October 1996; thereafter it is more difficult to say.

h). Dr Webb failed with his incorrect management plan for anti epileptic drugs (AED).

Mr and Mrs Roberts firmly believe that both Dr Sands and Dr Webb were incorrect with their diagnosis of non-fitting status or non-convulsive status epilepticus and that the subsequent anti-convulsant medication administered was not justifiable. The parents also

believe that if the medication overdose errors had not been made it is highly likely that a reconsideration of Claire's clinical condition would have identified the fluid management and dilutional hyponatraemia issues.

T01-11-12 Professor Neville

T01-11-12P183L20-L25 to P184L1-L5

(Q) And if at the same time she's received an overdose in terms of 12 milligrams of the stat dose of midazolam and then has gone on to an IV midazolam, so she's continuing to have midazolam in her system, if I can put it that way, that of itself could have increased her PCO₂, which also has an effect on her intracranial pressure?

(A) Yes.

(Q) So the combined effect might have been to hasten the rise in intracranial pressure that could have arisen from her falling serum sodium levels?

(A) Yes that's right.

T08-11-12 Dr Aronson

T08-11-12P194L21 to P195-L5

(Q) And now she's having her midazolam at 15:25. Would you have prescribed midazolam then?

(A) I would have called for a paediatric neurologist because you're in trouble. You're in difficulty.

(Q) Why do you say that?

(A) And think probably I wouldn't have given the phenytoin at that stage for the reasons that I explained before. You don't have a diagnosis, it's a long-acting drug, you really don't know where you are.

T08-11-12P201L5-L10

(Q) How significant is that, the difference between the 3.6 and the 12 in these circumstances?

(A) Well, that's at least three times more than would be recommended, and that would produce much greater sedation than one would expect from the appropriate dose.

T08-11-12P241L25 to P242L10

(Q) But given the view that you expressed earlier, what are your comments on having increased the midazolam at this stage, as to the advisability of that if I can put it that way?

(A) Really that we still don't have a diagnosis that shows that this medication is appropriate and so we're in a hole and we're digging it deeper. It might, had the diagnosis been correct, have been appropriate or at least a reasonable strategy at the time but in the absence of a diagnosis, I feel very unhappy about it.

i). Dr Webb failed to check and recognise errors in drug prescription doses, drug dose calculations and drug administration rates.

Prof Neville 232-002-006 (b) The problem with the diagnosis of non-convulsive status is that it leads to inappropriate treatment with anti-epilepsy drugs which could have further reduced her conscious level and her respiratory drive. If a single dose of rectal diazepam was to be given it should have been backed up by an urgent EEG, so that the working diagnosis could have been confirmed or refuted before any further anti-epilepsy

medication was given.

Prof Neville 232-002-006 (b) I have said that one dose of diazepam would be understandable but not more than this or the rest of the IV drugs without EEG, at least a CT scan and checking the electrolytes (i.e. Na).

j). Dr Webb failed to write the midazolam prescription into the medical notes?

Dr Webb failed to write the midazolam medication dose and the infusion rate into the medical notes. Dr Webb's evidence is that this information was given by telephone to Dr Stevenson. This failure has resulted in a series of unknowns. Did Dr Webb state 0.15mg/kg or 0.5mg/kg? How did Dr Webb fail to miss the 12mg midazolam stat dose entry within the medical notes when he recorded his 17:00 entry?

T03-12-12 Dr Webb

T03-12-12P149L20 to P150L7

(Q) The evidence that you gave was that the loading dose of 0.15 was something that you got from a particular paper which you provided to the Inquiry.

(A) That's correct. That paper is the one paper that seems to inform the dosing, but--

(Q) Yes. Had you actually used that dosage yourself or come across it being used while you were in Canada?

(A) Yes

(Q) You had used it personally?

(A) I hadn't prescribed it, but I was involved in the care of children who had had it.

(Q) Sorry, what does that mean?

(A) I hadn't prescribed it myself.

T30-11-12 Dr Webb

T30-11-12P245L15-L20

(Q) When you went to check the dose of midazolam, that's because you needed to because it wasn't one of those things at the forefront of your mind. Had you used it in the Children's Hospital since your return from Canada?

(A) No.

T30-11-12P246L4-L7

(Q) Yes, but would it be fair to say-- in fairness, you yourself have said that you hadn't actually used it since you had come back from Canada--

(A) Yes.

This evidence is contrary to one of Dr Webb's other patients, W2 ref 150-016-005, where midazolam is prescribed by Dr Webb on 21 October 1996. Dr Webb has responded to this query in WS138/5 page 6 "I was referring to the use of midazolam to treat epilepsy. I had not prescribed or used intravenous midazolam for the treatment of epilepsy - in Belfast prior to Claire's case".

It must therefore be a major concern for the Inquiry that Dr Webb had never prescribed intravenous midazolam for the treatment of epilepsy prior to Claire's case, Dr Steen had never seen a case of non-fitting status epilepticus, Dr Sands had perhaps seen one patient with non fitting status epilepticus, yet there was a failure by each doctor to raise an adverse incident report, review Claire's treatment or question the type and dose of the medications administered.

T03-12-12 Dr Webb

T03-12-12P150L22-L25 to P151L1-L2

(Ms Anyadike-Danes) It's really under the precautions. The second sentence. This is from Roche, the manufactures of Hypnovel, which is a particular type of midazolam that was administered to Claire "Hypnovel should not be administered by a rapid or single bolus IV administration".

The Inquiry will be aware that it has always been a major concern for Mr and Mrs Roberts that a rapid infusion and overdose of midazolam was administered around 3:20pm on Tuesday 22 October and within minutes Claire had her first strong seizure timed at 03:25pm.

k). Dr Webb failed to review or investigate Claire's Glasgow Coma Scale (GCS) scores on Tuesday 22 October.

Prof Neville 232-002-012 (viii) Claire's reduced conscious level ought to have prompted medical action. GCS/CNS observations ought to have been commenced from the ward round. It seems that there were sufficient observations to prompt medical action on the basis of a deteriorating situation given the findings on the ward round early on 22 October e.g. "pupils sluggish to light" (Ref: 090-022-053) but the team were firmly sticking to non-convulsive status as the diagnosis which seems to have stopped other avenues being pursued until it was too late.

Prof Neville 232-002-016 (xix) A drop in GCS would cause concern. Scores of 9-12 require investigation and explanation and less than 9 require urgent investigation and management. This statement applies to Claire's case and is also of general application. The low GCS was unexplained and could signify raised intracranial pressure which might be treatable e.g., cerebral oedema. If a GCS score is of concern, very often the nurse will invite a more senior nurse e.g. ward sister/nurse in charge and/ or the SHO to assess the GSC. Any fall in GCS is noteworthy. The GCS trend is important.

l). Dr Webb failed to carry out an EEG on Tuesday 22 October.

The failure by Dr Webb to arrange or carry out an EEG on Tuesday 22 October was a major omission in Claire's care management and treatment plan.

T01-11-12 Professor Neville

T01-11-12P122L11-L20

(A) As I've said, I think she could have had the first dose of diazepam without it being tried, but after that she would have needed an EEG.

(Q) Before you did anything further?

(A) Before you did anything else.

(Q) And if you really felt the situation was such that you needed to be doing something, then how do you regard the need for an EEG?. Is it urgent, is it an emergency, how do you categorise it?

(A) I think it's critical that it's done.

Prof Neville 232-002-007(c) The CT scan and EEG should have been arranged at the

latest by the morning of 22 October 1996.

T12-11-12 Dr Scott -Jupp

T12-11-12P115L22 to P116L1

(The Chairman) If we understand emergency and urgent to describe somehow the extent to which one is needed immediately or as soon as possible, how urgent was it after the ward round for Claire to get an EEG?

(A) I think it was same-day urgent.

m). Dr Webb failed to carry out a CT scan on Tuesday 22 October. (Dr Webb medical note CT scan tomorrow if she does not wake up 090-022-054)

The fact that Dr Webb was prepared to wait until the next day for a CT scan highlights his level of urgency and concern for Claire's clinical condition and the disparity between Dr Webb and Dr Sands alleged understanding and evidence.

Prof Neville 232-002-006(c) The lack of an urgent EEG, CT and electrolytes were major omissions and the need for these would normally have been discussed with a consultant.

n). Dr Webb failed to recommend or implement a management plan to treat "encephalitis/encephalopathy" at 14:00 Tuesday 22 October. (If recorded)

Dr Webb examined Claire three hours after the ward round at which Dr Sands stated he had considered encephalitis and informed Mr and Mrs Roberts that an infection may be affecting Claire's brain. However, Dr Webb has stated that he thought encephalitis was less likely at this stage and did not consider treatment with acyclovir. The fact that Dr Webb makes no reference to encephalitis within his 02:00pm note supports Mr and Mrs Roberts evidence that encephalitis was not within the medical notes at that stage and was added at a later date.

T30-11-12 Dr Webb

T30-11-12P200L9-L14

(Q) So you carry out your examination and that's what you describe. We can pull up the next page. Let's keep 053 and put up 054. That's your complete record. Can you recall if that "encephalitis/encephalopathy" was there when you looked at his note?

(A) I can't

T30-11-12P205L6-L13

(Q) There's nothing in there that addresses the differential that you were formulating and which it seems that you raised with Dr Sands of encephalitis.

(A) No. I have referred to the pictures of acute encephalopathy.

(Q) Sorry?

(A) I referred to -- you're right, there's no mention of encephalitis, that's correct.

T30-11-12P207L4-L11

(Q) That's why I'm asking you why you didn't do it here. Either you think it is a differential diagnosis which has some credibility to it, some possibility, or you don't. If you think it is, why don't you seek to treat it? If you think it's not, why don't you make a note to that effect?

(A) I think you could make the case that I should have started acyclovir there.

T12-11-12 Dr Scott -Jupp

T12-11-12P122L15 to P123L6

(Q) But to pick up the chairman's point, if you thought that that was an appropriate thing to be doing just in that conversation between Dr Sands and Dr Webb, would you have considered it appropriate for Dr Webb to himself have addressed the issue in his plan or suggestion, if I can put it that way, for how the viral element of what was thought to be her differential diagnoses was going to be addressed?

(A) Yes. It would have been appropriate. He said, "I don't have a clear picture". The picture of acute encephalopathy was probably postictal in nature. So he was clearly, on that first consultation, **of the opinion that it wasn't encephalitis**. That seems to be the impression. He doesn't explicitly say that, but he thought her problem was seizure activity, that her abnormal neurological signs were related to that, without an underlying encephalitic picture.

2.5 Allen Ward Tuesday 22 October 1996 - Dr Stevenson medical note 02:30pm (090-022-054)

Dr Stevenson (SHO) WS 139

Dr Stevenson who accompanied Dr Sands on the earlier ward round calculated the bolus dose of phenytoin as 632mg. The correct dosage for Claire's weight should have been 432mg (18X24 = 432). This was a error that resulted in Claire being administered, at 02:45pm on Tuesday 22nd October 1996 an overdose of phenytoin which effectively put her in the toxic range for this drug. The administration rate at which the overdose of phenytoin was given is not documented within the medical notes. Also, there is no record that cardiac monitoring equipment was used during the infusion of phenytoin. The record of attacks sheet (090-042-144) states that Claire had her first witnessed seizure at 03:25pm 22 October 1996 within 40 minutes of receiving the overdose of phenytoin.

2.6 Allen Ward Tuesday 22 October 1996 - Dr Stevenson prescription sheet note 02:45pm (090-026-075)

Dr Stevenson (SHO) WS 139

Claire was administered phenytoin at 02:45pm 22 October 1996. The bolus dose of 635mg is a 203mg overdose. Any review or audit of the medical notes and prescription sheet in 1996, 1997, 2004 or 2006 failed to highlight this error.

2.7. Allen Ward Tuesday 22 October 1996 - Dr Stevenson medical note untimed approx 03:00pm (090-022-055)

Dr Stevenson (SHO) WS 139

Several different versions of evidence have been given by Dr Webb with regard to how and when he advised Dr Stevenson to administer midazolam and how many times he examined Claire, ranging from two to three. The critical error made by Dr Webb was that

he did not revisit the medical notes to write up the required plan for the administration and dosage of midazolam. This resulted in Claire receiving a large overdose (330%) of midazolam. The administration rate at which the overdose of midazolam was given is not documented within the medical notes and cannot be established. The recommended rate of administration for midazolam is slowly over 2 to 3 minutes. Dr Stevensons evidence (T16/10/12P134) is that midazolam was a drug that he had little or no experience of and he would have administered it slowly like any other similar drug. The rate of drug administration for midazolam is important and should be documented within the medical notes. If the midazolam was administered at a rate faster than the recommended rate i.e. over 30 seconds rather than 2 minutes it is therefore possible that Claire received over 3 times the recommended dose at 4 times the recommended rate. This has always been an area of extreme concern for Mr and Mrs Roberts and they believe that the phenytoin and midazolam overdoses when combined with Claire's clinical condition and falling sodium levels at that time caused the seizure recorded at 03:25pm on Tuesday 22 October.

Dr Webb's Coroners deposition (096-009-053) states "The next note reads "seen by Dr Webb, still in status" and then goes on to document the calculations undertaken to prescribe midazolam as a bolus and then as a low dose infusion". This again raises serious concerns regarding how Dr Webb failed to recognise the midazolam overdose in his written or oral evidence to the Coroner in 2006.

Dr McFaul 238-002-009 (8) Midazolam was advised for Claire by the paediatric neurologist both as a bolus IV dose and as a continuous infusion. This drug carries a significant risk of respiratory depression which itself can make brain swelling worse. It is not licensed for use in children for status epilepticus.

Dr McFaul 238-002-021 (98) If the dose intended or prescribed had been given then the dose was such that it could lead to a significant reduction in conscious level, to potential depression of respiration and associated rising carbon dioxide level in the blood and the latter itself leading to brain swelling or aggravating it on top of the hyponatraemia. This was a major significant dose error in the circumstances.

2.8 Allen Ward Tuesday 22 October 1996 - Dr Stevenson prescription sheet note

03:25pm (090-026-075)

Dr Stevenson (SHO) WS 139

Claire was administered midazolam at 03:25pm Tuesday 22 October 1996. The bolus dose of midazolam that Claire received is unclear, the medical note states 12mg while the prescription sheet states 120mg. The prescription sheet is unsigned therefore any review or audit of the medical notes and prescription sheet failed to highlight these two critical errors.

2.9 Allen Ward Tuesday 22 October 1996 - Dr Webb medical note 17:00 (090-022-055)

Dr Webb (Consultant) WS138

a). Dr Webb failed to inform Claire's mother of the additional diagnosis of encephalitis/encephalopathy at 17:00 Tuesday 22 October . (If recorded)

During his examination of Claire at 17:00, some six hours after Dr Sands alleged definition of encephalitis, Dr Webb did not discuss encephalitis/encephalopathy, meningo-encephalitis or any possibility that Claire may have an infection affecting her brain with Claire's mother. Mrs Roberts emphasises that this was the only discussion with Dr Webb throughout Tuesday 22 October and it did not raise any concerns or alarms about Claire's condition.

Mr and Mrs Roberts believe that Dr Webb at 17:00 22 October failed to re-evaluate or question Claire's clinical condition following a course of treatment which was incorrect and inappropriate and that he then continued with additional inappropriate anti-epileptic drug administration.

b). Implications of Dr Webb's diagnosis at 17:00 Tuesday 22 October "*I don't think meningoencephalitis is likely*".

T03-12-12 Dr Webb

T03-12-12P173L19-L23

(A) I thought it was her epilepsy at 2 o'clock. I think at 5 o'clock she had had some medication and hadn't responded and I was concerned that the possibility of meningoencephalitis should be raised higher and I started her then on treatment for that.

T03-12-12P178L17-L23

(The Chairman) So you're telling us that in fact what you wrote at the time was the view you still adhered to that you didn't think that encephalitis was very likely, it was a bit more likely than it had been when you saw her at about 1:30 or 2pm, but still your primary diagnosis was a recurrence of underlying epilepsy?

(A) That's correct.

Mr and Mrs Roberts believe Dr Webb's 17:00 note highlights that it was unlikely that Claire had encephalitis or meningoencephalitis and Dr Webb's plan was to provide overnight cover rather than treat that unlikely possibility.

c). Dr Webb failed to investigate the witnessed attacks at 15:25 and 16:30 on Tuesday 22 October (090-042-144)

Dr Webb failed to consider other possible causes, request or carry out any investigations into the witnessed attacks at 15:25 and 16:30. Mr and Mrs Roberts firmly believe that the first seizure Claire had at 15:25 was the result of the administration of an overdose of midazolam at around 15:25 and the rate at which the midazolam overdose was administered. If Dr Webb had been informed, attended and examined Claire immediately following the seizure at 15:25 it is very likely that he would have reviewed the medical notes and identified the midazolam overdose.

WS138-1 page 43 (25d) Dr Webb.

I was aware of the attacks and this would have influenced my decision to continue trying further anti-convulsant medication to try and stop the occasional break through "convulsive" seizures that Claire was experiencing.

d). Dr Webb failed with his incorrect management plan for AED medication.

T01-11-12 Professor Neville

T01-11-12P86L10-L18

(Q) How important did you regard it that she should have had a CT scan and should have had an EEG at that stage?

(A) They're both of considerable importance. The EEG situation seems to be that she was given one dose of diazepam, which I think was reasonable, just to see whether she showed marked improvement or not. But then she was on a regime of receiving a total of four drugs in different forms. That seems to me to be quite **inexcusable** without having an EEG performed.

e). Dr Webb failed to participate in the clinical hand over at 17:00 Tuesday 22 October.

Dr Webb failed to have any involvement in the clinical handover at 17:00 to the evening staff and deferred this responsibility to the paediatric team registrar Dr Sands who had had no input into Claire's treatment between the ward round at 11:00 and 17:00. Dr Sands states he left Allen ward for most of that afternoon and his only input before going of duty was an administration of sodium valproate at 17:15.

WS138-1 page 42 (24h) Dr Webb.

The review of patients after 5pm would have been communicated by the registrar on Dr Steen's team to the on-call registrar that evening.

f). Dr Webb failed to consider PICU at 17:00 Tuesday 22 October if he thought it was necessary.

Dr Webb failed to recognise, review or question Claire's clinical condition at 17:00 and before going of duty and leaving the hospital around 17:30. At that time Dr Webb did not feel that Claire's condition was life threatening [WS138-1 page 39(l)] or that her mortality risk was greater than 1% [WS138-1 page 74(i)], yet she was only hours away from catastrophe. Dr Webb [WS138-1 page 42(g)] did not plan to make any further routine visits to Claire that evening.

Mr and Mrs Roberts have always maintained the view that **no one** had an accurate awareness or understanding of Claire's clinical condition or diagnosis throughout Tuesday 22 October 1996.

T03-12-12 Dr Webb

T03-12-12P166L12-25 to P167L1-L7

(A) My understanding from the transcripts is that Claire's parents felt that she was opening her eyes and looking at them and at the brothers during that period.

(Q) But apart from that, is there any evidence -- I'm asking you for what's actually recorded in the medical notes and records.

(A) Well, it's very significant evidence. It's not on the chart, clearly, but it's very significant evidence if she was opening her eyes at that stage because it suggests that her eye opening GCS was probably 3.

(Q) Was that something that you found recorded in the notes?

(A) No, it's from the transcript.

(Q) We'll check the transcripts.

Mr and Mrs Roberts believe that the administration of diazepam, the overdose of phenytoin and the overdose of midazolam, over sedated, anaesthetised and put Claire to sleep between 03:30pm and around 06:30pm. From 06:30pm onwards when Claire did open her eyes the parents were encouraging Claire to rest and sleep. However they now know that Claire was drifting in and out of consciousness and any response she made at that time to recover from the drug overdoses was countered and compounded by the continuing fall in her sodium level, fluid mismanagement, dilutional hyponatraemia, increasing intracranial pressure and cerebral oedema.

The Inquiry is aware that in addition to the excessive bolus dose of midazolam, Claire also received a regular prescription of midazolam 2mcg/kg/minute or 2.88mg/hr (090-022-055). This was administered in a concentration of 50mls of fluid to 69mg of midazolam, a ratio of 1.38 (090-038-136). Therefore when Claire's regular prescription of midazolam was increased from 2mls/hr to 3mls/hr at around 09:30pm she was receiving 4.14mg/hr of midazolam, a 44% increase on the original prescription and another significant overdose. Claire received a total of 41.67mg of Midazolam over a ten hour period.

The Inquiry are aware of a RBHSC drug information sheet 063-030 which states "Midazolam infusion 125mg in 50mls DO NOT EXCEED 1 ml/hour MIDAZOLAM" (2.5mg/hr of midazolam).

WS138-1 page 74 (53d) Dr Webb.

I do not believe I took any steps to discuss Claire with a PICU Consultant after 17:00 on 22 Oct 1996 and in hindsight I believe this was a mistake.

WS138-2 page 23 (42) Dr Webb.

I have acknowledged in my previous statement that I think, with hindsight, it was a mistake not to have taken any steps to discuss Claire's case with a PICU consultant after 17:00 on 22 October 1996 and this is a mistake I will always regret.

T01-11-12 Professor Neville

T01-11-12P168L2-L23

(The Chairman) It all becomes a **very unhappy mess** during that Tuesday afternoon, professor, doesn't it?

(A) Yes, it does.

Prof Neville 232-002-012(x)(a) Admission to PICU was appropriate. It should have been done earlier. I would expect this to be done with reduced consciousness and a low sodium level if fluid restriction and inducing a diuresis was not effective in improving the child's condition. Thus this would I think have been considered early on 22nd if the repeat electrolytes and CT had been performed.

Prof Neville 232-002-013(x)(d) The outcome might have been better but only if the diagnosis was made and treatment urgently instituted.

T12-11-12 Dr Scott-Jupp

T12-11-12P167L9-L20

(Q) From your point of view, when do you think they should have at least been seriously

considering transferring Claire to paediatric intensive care?

(A) I actually think in the early afternoon, possibly after Dr Webb's initial examination because it was clear that her conscious level was abnormal, it wasn't responding. She needed probably closer observation in terms of nursing observations than is easy to do on a general ward. So had cerebral oedema been strongly suspected or diagnosed, then that would have been an absolute reason to admit to intensive care. But even before that, even without that awareness, I think she should have done.

T12-11-12P171L13-L20

(The Chairman) Doctor, is it wrong to look at what happened to Claire and think that her condition just drifted on that day and nobody really seized control of the situation and acted decisively?

(A) I think that's a fair comment, yes.

(The Chairman) There were any number or opportunities for somebody to do that.

(A) Yes.

In contrast to the above evidence Dr Steen informed Mr and Mrs Roberts in 1996 and 1997 that everything possible had been done for Claire and nothing more could have done. Dr Steen also advised Mr and Mrs Roberts in 2004 that Claire's condition was not under-estimated and she received intensive medical intervention (096-018-111).

T12-11-12P215L12 to P216L18

(The Chairman) Mr Roberts' concern, as he expressed it in the witness box, I think a week and a half ago, was that he's not sure that the seriousness of Claire's condition was actually appreciated and he wonders why -- that's part of the reason why he and his wife and his sons were allowed to leave.

(A) I don't know, I can't comment on to what extent it was the doctors not appreciating the seriousness of her condition or them failing to communicate it to the family. Either way, it clearly didn't go well, and I don't know which of those is the major contribution.

(The Chairman) It's now fairly clear to me from the evidence that Dr Hughes did not appreciate it.

(A) Yes

(The Chairman) She might have come along a little bit after they left and got the check done and the phenytoin level and the blood test, which later came back at 121. If she didn't know it, then that, to a degree, might be a failing on her part, but it might also reflect back on what she was told if there was any handover at 5 o'clock?

(A) Yes, that's true, how unwell Claire was quite possibly was not communicated adequately at the 5 o'clock handover.

(The Chairman) And if it wasn't being adequately communicated between doctors, it might also very well be the nurses weren't aware of it either?

(A) Yes, possibly.

(The Chairman) Which all fits into the unhappy picture of Claire slipping away and nobody grasping or identifying the problem and stepping in decisively to treat her.

(A) Yes I would agree with that.

Mr and Mrs Roberts again highlight to the Inquiry that throughout Tuesday 22 October

they had, in total, one ten minute discussion with Dr Sands during the ward round and Mrs Roberts had one ten minute discussion with Dr Webb at 05:00pm. No alarms or concerns for Claire's wellbeing were raised or communicated by Dr Sands or Dr Webb at any time.

g). Dr Webb failed to review or investigate Claire's GCS scores on Tuesday 22 October.

Mr and Mrs Roberts were never informed or advised of Claire's Glasgow Coma Scale (GCS) until they received a copy of the medical notes in 2005. They now have an understanding of this assessment method and find it deeply distressing and impossible to understand why more was not done for Claire throughout Tuesday 22 October when her GCS was 6 or 7.

T01-11-12 Professor Neville

T01-11-12P158L20-L24

(The Chairman) Sorry, I think you said that at the level of 8 to 9 it's marginal for urgent action.

(A) Yes, and that at 7/8 you really need to be doing something. But it's in the context of the child not getting better, and in fact getting marginally worse.

T12-11-12 Dr Scott-Jupp

T12-11-12P151L8-L18

(Q) I'd like to ask you about what can be interpreted about Claire's condition from that chart and, in case it makes it any easier, the schedule showing the Glasgow Coma Scales?

(A) Well, the first observation is done at 1pm, so we don't know what it was before then.

(Q) Yes.

(A) But a Glasgow Coma Scale score of 9 is significantly low and worrying even if there wasn't a demonstrable acute deterioration down to 9. If that's your starting point, I think that is significantly low.

h). Dr Webb failed to learn any lessons following Claire's death.

2.10 Allen Ward Tuesday 22 October 1996 - Dr Sands prescription sheet note

05:15pm (090-026-075)

Dr Sands (Registrar) WS 137

a). Dr Sands failed to review Claire's clinical condition and blood test results before and at 05:00pm Tuesday 22 October 1996.

Dr Sands not only failed to request a blood test during and following the morning ward round, he also failed to check that a blood test had been requested, recorded in the medical notes and was either available or was being processed when he returned to Allen Ward at approximately 05:00pm. Dr Sands then went of duty at around 05:30pm. Mr and Mrs Roberts find this failure very difficult to comprehend considering Dr Sands alleged clinical impression earlier that morning when he described Claire as having a major neurological problem, infection that may be affecting her brain,

encephalitis/encephalopathy and the sickest child on Allen Ward.

Prof Neville 232-002-010 (vii)(d) It is difficult to know if she would have been retrievable by the measures outlined above but it is quite possible. From my perspective the electrolytes should have been repeated much earlier and a scan performed and seems likely to have shown a low Na level and brain oedema, which could have been treated. Claire was certainly retrievable early-mid 22nd October 1996; thereafter it is more difficult to say.

Prof Neville 232-002-016 (xx) The overdose of 12 mg I.V. stat of midazolam administered at approximately 15.25 (Ref:090-026-075, 090-040-141) could have caused or contributed to this fall in Claire's GCS. The effect of this drug could have lasted at least 1-2 hours. There was no evidence that Claire needed this dose of medicine. It was a big dose. It was likely to have exacerbated her condition. It is possible that this medicine tipped her over to a higher PCO2 level which caused greater cerebral oedema. It is also possible that it just added to what was already happening. Most important is the failure to treat Claire's underlying condition which was treatable. The main point is that the clinicians missed what was wrong with her and had slender reasons for a diagnosis of non-convulsive status epilepticus. The midazolam did not treat her underlying condition or the cerebral oedema.

b). Dr Sands failed to ensure that a blood test had been requested, taken or processed before going of duty and leaving the hospital at approximately 05:30pm Tuesday 22 October.

c). Dr Sands failed to review, question or recognise errors in drug prescription doses, drug dose calculations and drug administration rates, or the unsigned prescription sheets.

T19-10-12 Dr Sands

T19-10-12P226L6-L18

(Q) Then I wonder if we might -- one question I've been asked is when you looked -- at whatever stage you did it -- at the drug sheet, which you would have to look at to sign off that you were giving the sodium valproate, whether you noticed any of the errors there in relation to the phenytoin and in relation to the midazolam.

(A) The answer to that is no, and that sounds strange at this stage because when you look at it in detail and look at it now, it does look quite obvious, but the answer is no.

(Q) Do you think you should have?

(A) Perhaps.

d). Dr Sands failed to investigate the witnessed seizure at 03:25pm and 04:30pm Tuesday 22 October (090-042-144)

Dr Sands failed to review, discuss or investigate the seizure recorded at 03:25pm or the entry described as "teeth tightened slightly" at 04:30pm on the record of attacks sheet (090-042-144) on Tuesday 22 October and states that he cannot recall if the medical team were informed. However, Dr Webb has stated that he was aware of the seizure and instructed Dr Stevenson the paediatric SHO to administer midazolam.

WS 137/1 page 49 Q36(a) Dr Sands

(Q) State whether you or any other member of the medical team were informed of this seizure at 15:10 (03:25) or at any time thereafter.

(A) I do not recall if I, or other members of the medical team were informed of the seizure at 15:10 (03:25).

WS 137/1 page 49 Q37(a) Dr Sands

(Q) State whether you or any other member of the medical team were informed of this seizure at 16:30 or at any time thereafter.

(A) I do not recall if I, or other members of the medical team were informed of this observation.

e). Dr Sands failed to review or investigate Claire's GCS scores on Tuesday 22 October.

Prof Neville 232-002-012 (viii) Claire's reduced conscious level ought to have prompted medical action. GCS/CNS observations ought to have been commenced from the ward round. It seems that there were sufficient observations to prompt medical action on the basis of a deteriorating situation given the findings on the ward round early on 22 October e.g. "pupils sluggish to light" (Ref: 090-022-053) but the team were firmly sticking to non-convulsive status as the diagnosis which seems to have stopped other avenues being pursued until it was too late.

Prof Neville 232-002-016 (xix) A drop in GCS would cause concern. Scores of 9-12 require investigation and explanation and less than 9 require urgent investigation and management. This statement applies to Claire's case and is also of general application. The low GCS was unexplained and could signify raised intracranial pressure which might be treatable e.g., cerebral oedema. If a GCS score is of concern, very often the nurse will invite a more senior nurse e.g. ward sister/nurse in charge and/ or the SHO to assess the GCS. Any fall in GCS is noteworthy. The GCS trend is important.

T12-11-12 Dr Scott-Jupp

T12-11-12P151L8-L18

(Q) I'd like to ask you about what can be interpreted about Claire's condition from that chart and, in case it makes it any easier, the schedule showing the Glasgow Coma Scales?

(A) Well, the first observation is done at 1pm, so we don't know what it was before then.

(Q) Yes.

(A) But a Glasgow Coma Scale score of 9 is significantly low and worrying even if there wasn't a demonstrable acute deterioration down to 9. If that's your starting point, I think that is significantly low.

f). Dr Sands failed to provide adequate supervision of junior SHO doctors or manage and monitor their actions during Tuesday 22 October.

Dr Sands evidence is that he attended a clinic on Tuesday afternoon 22 October and was not available on Allen Ward from 1:30pm to 05:00pm. Dr Sands was not in attendance when Dr Webb examined Claire at 02:00pm and failed to supervise, guide and oversee Dr Stevenson a junior SHO who was miscalculating medication dosages and administering drugs he was not familiar with.

Dr Sands administered sodium valproate at 5:15pm. Dr Stevenson, possibly in agreement

with his registrar Dr Sands, prescribed and agreed when the cover for encephalitis (acyclovir) was to be administered (9:30pm) (090-026-075). Dr Sands therefore had the opportunity to treat possible encephalitis at 5:15pm with acyclovir but it was decided to leave "routine" cover and preventative antibiotic and anti-viral treatment for the evening staff. There was a planned 4.5 hour delay between Dr Webb's prescription and the administration of acyclovir.

If Dr Sands had included encephalitis in the medical notes following the ward round, this would have been foremost in his mind, yet when Dr Sands completed his duty shift at around 05:30pm the treatment for encephalitis had not been started and was planned for 09:30pm, some ten hours after the ward round.

g). Dr Sands failed to be in attendance on Allen Ward from around 01:30pm to 05:00pm on Tuesday 22 October.

h). Dr Sands failed to provide an adequate hand over and inform the evening duty doctors of Claire's unresolved diagnosis at 17:30 Tuesday 22 October.

During Tuesday 22 October Dr Sands evidence is that he described Claire as having a major neurological problem, an infection affecting her brain, encephalitis/encephalopathy and was the sickest child on Allen Ward, yet he states he has no recollection of a handover to Dr Bartholome or Dr Hughes.

T19-10-12 Dr Sands

T19-10-12P227L17-L23

(Q) Can you remember if you actually did effect handover on the 22nd?

(A) I don't remember the details of the handover on this occasion. I don't remember that.

(The Chairman) Do you remember the fact of a handover as opposed to the details?

(A) I don't have a recollection of the handover.

Dr Sands states he regarded Claire as the sickest child on Allen Ward. No blood tests were carried out for 23 hours, no CT scan was requested, no MRI scan was requested, no EEG was requested and the paediatric registrar responsible for Claire's care left Allen Ward for most of the afternoon on Tuesday 22 October to possibly attend a clinic held on the fourth Tuesday of every month.

Dr Webb WS138-1 page 42 (24h)

The review of patients after 5pm would have been communicated by the Registrar on Dr Steen's team to the on-call Registrar that evening.

Dr McFaul 238-002-049 (234) It is noteworthy that in 1996 when Claire was admitted, only one middle grade doctor was responsible for the whole hospital out of hours between 5pm and 9am. Dr Sands who had been caring for Claire in the daytime was going off duty and the registrar on call was Dr Bartholome. By the 4pm and 5pm consultations with Dr Webb, Claire had a persisting low conscious level. Dr Sands had indentified Claire as suffering significant illness and I would have expected him to have handed over in some form even if this was by telephone. There is no evidence that Dr Bartholome knew about Claire on the evening before the low sodium result was available

nor whether she saw her after that until the collapse in the early hours of 23 October.

T12-11-12 Dr Scott-Jupp

T12-11-12 P220L14 to P221L3

(Q) So that's what Dr Sands might have been communicating to Dr Bartholome if she was there. Would it have been appropriate to express his view, which I believe was that she was the sickest child on the ward?

(A) Yes. I think that's a useful thing to hand over because it's all about prioritisation. When you're handing over a whole ward full of patients, the people coming on need to know which are the ones to worry about most, to devote their priorities to.

(The Chairman) And doctor, even though handovers were less structured and more informal in 1996, if there was ever a case to be handed over or ever a patient to be handed over from one shift on another, it was Claire, wasn't it?

(A) Yes, and there may have been others equally, but yes.

i). Dr Sands failed to review or reassess Claire's clinical condition at 05:00pm Tuesday 22 October.

Dr Sands administered 400mg of sodium valproate at 05:15pm but failed to examine or review Claire's clinical condition before going of duty. Again this level of involvement by Dr Sands is inconsistent with and contrary to his evidence and alleged clinical impression.

T08-11-12 Dr Aronson

T08-11-12P242L4-L16

Dr Aronson's view on the administration of sodium valproate at 05:00pm Tuesday 22 October by Dr Sands is:

(A) Really that we still don't have a diagnosis that shows that this medication is appropriate and so we're in a hole and we're digging it deeper. It might, had the diagnosis been correct, have been appropriate or at least a reasonable strategy at the time but in the absence of a diagnosis, I feel very unhappy about it. As I say, in my position as a general physician, I would have been asking for help long before this. But given that the diagnosis was not substantiated, you're piling also Epilim here, you're adding drug to increase the dose of a drug to treat a disease that you haven't diagnosed.

j). Dr Sands failed as the paediatric registrar to record an entry in the medical notes of any concerns he had for Claire's clinical condition before going of duty at 17:30 Tuesday 22 October.

k). Dr Sands failed to discuss Claire's clinical condition or treatment plan or communicate with Mrs Roberts before leaving the hospital at approximately 05:30pm Tuesday 22 October.

l). Dr Sands failed to learn any lessons following Claire's death.

m). Dr Sands failed to provide consistent factual evidence under oath during his oral evidence to the Public Inquiry. The evidence given by Dr Sands in preparation for and during the Coroners Inquest into Claire's death in 2006 is contrary to the

evidence he has given to this Inquiry.

2.11 Allen Ward Tuesday 22 October 1996 - Dr Steen's contact with the ward at approximately 05:15pm
Dr Steen (Consultant) WS 143

a). Reliability and credibility of Dr Steen's contact with Allen Ward.

There is no evidence that Dr Steen contacted Allen Ward at around 05:15pm on Tuesday 22 October to inquire about Claire's clinical condition, treatment plan or who was responsible for Claire's care and management.

Dr Steen's evidence to the Inquiry is that she contacted Allen Ward around 05:15pm on Tuesday 22 October and was somehow reassured that she did not need to return to the hospital. Mr and Mrs Roberts would again highlight the inconsistency between the evidence of Dr Steen and Dr Sands. Dr Sands evidence is that following the ward round he considered and described Claire as having a major neurological problem, an infection affecting her brain, encephalitis/encephalopathy and was the sickest child on Allen Ward. In contrast to what Dr Sands states as his clinical impression, Dr Steen's evidence is that whoever she spoke to and whatever questions she asked, she was somehow reassured that there was no need for her to return to the hospital. There is no evidence, no reference or note in the medical records that Dr Steen was contacted by telephone by Dr Sands on Tuesday afternoon or that Dr Steen contacted Allen Ward at any time on Tuesday 22 October. Neither Dr Steen or Dr Sands can recall any detail of the content of their alleged telephone conversation which Dr Steen would attribute to poor record keeping or an unsatisfactory medical note completion failure. Mr and Mrs Roberts are highly sceptical and remain very concerned about whether the professed telephone calls are fact or fabrication.

T15-10-12 Dr Steen

T15-10-12P95L10-L19

(Q) So you don't know exactly what that management means. What else did you know about Claire at that point when you phoned the ward?

(A) I have no recollection. I don't know what was said in that conversation. It was most likely the nurse in charge of Claire that I spoke to. That would be the normal process. And unfortunately, we don't have her evidence. But whatever was said to me when I telephoned, I felt reassured enough not to come back to the hospital.

T15-10-12P99L6-L21

(The Chairman) Right. Mr and Mrs Roberts didn't know it was serious. Mr and Mrs Roberts never knew that Claire's condition was serious. I understand you're doing the best you can to put together what happened on Tuesday the 22nd. But if I take your evidence as it is, it suggests that you were told by phone that her condition was serious, but it was sufficiently stable that you didn't need to come back in and Dr Webb was managing it and it was under Dr Webb's control, despite the fact that -- in other words, you were getting more information down the phone in Cupar Street than the Roberts family in the hospital were getting.

(A) Yes. And--

(The Chairman) That's appalling, isn't it?

(A) It is appalling, it's absolutely appalling, and there's no defence for it

T15-10-12P100L13-L18

(A) I think it's absolutely appalling that for nurses, doctors, everybody involved in this child's care, we never managed to get through to the parents how ill their child was. They went home thinking she would go to sleep and waken up the next morning and that's awful.

Mr and Mrs Roberts find this part of Dr Steen's evidence disingenuous but typical of her mind-set. The failure was not on the part of the nurses, doctors and everybody involved in Claire's care to get through to the parents how ill their child was. They did not know. The failure, as Dr Steen is well aware was not one of communication. It was the multiple failures by Dr Sands and Dr Webb, their misdiagnoses, mismanagement and incorrect treatment plan for Claire and Dr Steen's failure to be involved in Claire's care until it was too late, which then resulted in Dr Steen attempting to hide, conceal and cover-up all of those shortcomings, errors and failures.

T12-11-12 Dr Scott -Jupp

T12-11-12P85L13-L22

(The Chairman) I thought you suggested a moment ago about how she could have taken reassurance from what was said to her by Dr Webb, but it's what was said -- that question is if she did -- this is all hypothetical -- whether there was, in fact, any contact with the ward at about 5 o'clock. And the question, which is really unclear, is how could anybody in the ward have expressed a view about Claire's condition, which would have given Dr Steen the assurance that meant that she did not need to come back to see Claire?

T12-11-12P88L5-L20

(The Chairman) And if Dr Webb had not taken over Claire's care, but was assisting with it, then do I have it right in believing that Dr Steen should then have come to see Claire?

(A) I believe so, yes.

(The Chairman) When I say "then", I mean at the latest when she was leaving. Because she says on previous occasions she has gone back into the Children's Hospital after she leaves her clinic to see a patient who's causing concern. So if she received any level of accurate information and, in any event, since she knew that Dr Webb was contributing to Claire's care, but had not taken it over, should she have come back in at that point?

(A) Yes, or as a minimum have spoken to Dr Webb directly by phone.

T12-11-12P93L10 to P94L8

(Q) So if that's what she had learnt from a nurse or a doctor, whomsoever, in your view should she have come and seen Claire before she left for Cupar Street?

(A) Yes. I think she should, but if she had been reassured that Dr Webb was definitely going to see Claire and there was going to be some consultant involvement at that level, that might have made it less imperative for her to see Claire straightaway.

(The Chairman) But she would want to know what the outcome of Dr Webb's assistance was, and that would influence her in deciding whether she should then come back in because she would want to speak to Dr Webb. She'd also then presumably want to speak

to Dr Sands, she'd want an update from Cupar Street and then decide whether or not to come in at 5 o'clock.

(A) Yes.

(The Chairman) And if she's getting accurate information from any of these conversations, then the only possible course of action for her would have been to go and see Claire.

(A) Yes.

T14-11-12 Dr McFaul

T14-11-12P88L21 to P89-L1

(Q) Yes. So that's from his side. From Dr Steen, what do you think should have been happening at about that time?

(A) I think she should have seen Claire.

(Q) She should have come back at the end of the clinic to see Claire?

(A) Yes

T14-11-12P92L9-L14

(The Chairman) There's lots of options and hypotheses and possibilities, but the one thing that does not appear to have happened at any point is a consultant to consultant conversation about Claire.

(A) Yes, I think that is definitely really, in the circumstances, a major shortcoming.

b). Dr Steen failed to make contact with her paediatric registrar Dr Sands at approximately 05:15pm Tuesday 22 October.

c). Dr Steen failed to make contact with the paediatric neurologist Dr Webb at approximately 05:15pm Tuesday 22 October.

d). Dr Steen failed to ensure that a senior paediatric doctor examined Claire after 05:30pm.

2.12 Allen Ward Tuesday 22 October 1996 - Dr Hughes prescription sheet note 05:30pm and 09:30pm (090-026-073)

Dr Hughes (SHO) WS 140

a). Dr Hughes, Dr Stewart and Dr Bartholome failed to carry out part 2 of Dr Webbs 17:00 plan to check for viral cultures.

No samples were taken to check stool, urine, blood or throat swab. This failure again raises serious concerns about the extent of any handover between Dr Sands and Dr Bartholome and Dr Sands alleged understanding of Claire's clinical condition.

Dr Hughes a first year SHO administered anti-biotics at 05:30pm and antiviral medication at 09:30pm. Dr Hughes was the only doctor to see Claire between 05:30pm and 11:00pm when Dr Stewart erected additional phenytoin. A five to six hour period when Claire's condition was recoverable if appropriate action had been taken. It is however extremely difficult to be critical of Dr Hughes, a first term SHO who did not

appreciate the seriousness of Claire's clinical condition at that time. This lack of appreciation by Dr Hughes again highlights the inadequacy of the information given at the handover by Dr Sands and the understanding and appreciation of Claire's clinical condition by the doctors who had been treating Claire throughout Tuesday 22 October and were going of duty.

T05-11-12 Dr Hughes

T05-11-12 P159L8-L17

(Q) First of all, what do you think you would have considered Claire's condition to be at half past nine in the knowledge of that material?

(A) With hindsight, as I said earlier, looking back at it, it's very hard to not appreciate that she was a very sick child. However, looking at both Mr and Mrs Robert's statements and the other statements from the nurses, I'm not sure that there was an appreciation of how sick she was, and I'm not sure that I would have appreciated that at the time.

T15-12-12 Dr Stevenson

T15-10-12 P111L13-L17

(Q) So what I'm asking you is: did you appreciate that Claire was actually a sick child?

(A) At my level of experience, I don't think I was aware of how sick Claire was.

T12-11-12 Dr Scott-Jupp

T12-11-12P200L11-L19

(The Chairman) There's two things. First of all, Dr Hughes, who is this doctor we're talking about, she effectively conceded last week -- it rather looks as if she didn't appreciate the seriousness of Claire's condition.

(A) Yes

(The Chairman) And was reasonably clear about that, so that's an acknowledgement on her part that, despite what now seems to be obvious, she did not pick that up at the time.

2.13 Allen Ward Tuesday 22 October 1996 - Dr Stewart medical note 23:30 (090-022-056)

Dr Stewart (SHO) WS 141

The nursing note (090-040-138) states that Claire also received an additional dose of phenytoin 60mg at 11:00pm 22 October 1996, 8 hours after the bolus overdose, administered by Dr Stevenson. Therefore Claire received additional phenytoin while she was still in the toxic range for this drug. The additional phenytoin was administered before the blood test result was available at 11:30pm 22 October 1996 which recorded a phenytoin level of 23.4mg/L. The therapeutic range for phenytoin is 10-20mg/L. Good medical practice would be to analyse the bolus dosage impact (or in Claire's case the overdose) of phenytoin before administering the additional dosage

a). Dr Stewart failed to carry out a blood test during Tuesday 22 October.

Dr Stewart made a similar mistake to Dr Webb in that he believed the blood test result from the previous evening of 132mmol/L was from a sample taken on Tuesday morning.

This error again highlights the failure to discuss, investigate and review the clinical care provided to Claire.

T06-11-12 Dr Stewart

T06-11-12P68L24 to P69L3

(Q) So you record the sodium of 121. Were you aware of what her previous sodium had been?

(A) Yes, I believe I was. It was written in the morning ward round at 132, I believe, and I believe I assumed that was the morning's result at that time.

b). Dr Stewart failed to adequately recognise the dangers of No18 IV fluids and hyponatraemia.

T06-11-12 Dr Stewart

T06-11-12P72L12-L22

(Mr Reid) You have written, "Hyponatraemic, query fluid overload". What was your awareness of hyponatraemic fluid overload in October 1996?

(A) Well, I certainly tried to think along the lines of first principles, so when a patient's sodium drops, with the risk of oversimplification, you're either thinking: are they losing sodium or do they have too much water causing a relative dilution of the sodium concentration in their blood? And I imagine it was along the lines of those primordial references to first principles that I would have gone to.

T06-11-12P77L22 to P78L1

(Q) And would you have told her (Dr Bartholome) about what you thought was the drop - not only the fact that the sodium was 121, but that you thought it had dropped from 132 that morning?

(A) I believe I did, yes.

T06-11-12P79L1-L7

(A) And Dr Bartholome's suggestion of restricting the fluids was certainly more conservative than the suggestion I had made. That cued me into the fact that -- led me to assume that while this was very serious, **we had time on our hands** to make those corrections judiciously over several hours, and even over the course of the night.

c). Dr Stewart failed to re-assess Claire's clinical condition at 23:30 Tuesday 22 October.

Dr Stewart's evidence is that he examined Claire at 23:30 but did not make a record of his observations in the medical notes. Dr Stewart stated that he was aware that at 23:30 Claire was in a semi-comatose state or comatose state yet he failed to review or re-examine Claire after 23:30 or request a repeat blood test.

T06-11-12 Dr Stewart

T06-11-12P60L7-L19

(Q) Is it because of that that you attend Claire at 11:30, or are you given the sodium result? How does that come about?

(A) When I arrived on the ward, I'm given the U&E and the phenytoin and immediately see the sodium is an abnormal result. I go to examine Claire, I remember distinctly now trying to see her fundi with an ophthalmoscope, but her pupils were very small and her eyes kind of roved. She was obviously in a semi-comatose state or comatose state and was unable to keep her eyes still -- which is difficult for a child at the best of times -- and

I was unable to obtain a clear sight of the back of her fundus.

T06-11-12P79L16-L17

(Q) Did you discuss a repeat test?

(A) We did not.

T06-11-12P80L13 to P81L5

(The Chairman) During the subsequent hour or two, did you keep an eye on what was happening because of your concern about Claire and to make sure that Claire's condition was not deteriorating any further?

(A) It's a fair question. It's my recollection that I was essentially run off my feet the rest of the evening. I didn't stop until very, very much later on that night, really in the morning. Dr Bartholome was Germanic in her efficiency, she was the most senior of the senior registrars, she was revered in the hospital, I was on call with her many times, and I had never known her in my life to miss -- to not see a patient whenever she was asked to. In fact, I never knew that Dr Bartholome hadn't seen Claire until the precipitous deterioration later on in the morning. **I didn't realise that there'd been a gap** from my call and Dr Bartholome seeing Claire until actually I began to review the notes of the inquiry this year.

This failure by Dr Stewart again highlights the failure to discuss, investigate and review the clinical care provided to Claire after her death.

d). Dr Stewart failed to reduce Claire's total fluid input between 21:00 and 24:00 Tuesday 22 October.

Dr Stewart was directed by Dr Bartholome to reduce Claire's fluids to 2/3rds. No 18 hypotonic IV fluid was reduced to 41mls/hr at 23:40 however an additional 110mls of IV fluid with 60mg of phenytoin was prescribed by Dr Stewart at 23:00 and continued running until 24:00. The intravenous fluid prescription chart (090-038-136) does not record the type of fluid administered.

T06-11-12 Dr Stewart

T06-11-12P67L17-L24

(A) And that's when she (Dr Bartholome) bleeped me back to the ward and she said to me at that time-- we discussed the various issues facing Claire and I suggested, I said, "Do you think we need to give increased sodium in the fluids, that's a low sodium level", and she said, "Yes, we do need to normalise her sodium, but we need to do so in a controlled fashion. Reduce the fluids to two-thirds and I'll come and see her".

T06-11-12P88L5-L15

(Q) Given that, that meant that between half 11 and half 12, Claire was to receive 110 plus 41, which is 151ml in that time. Because of the administration of that phenytoin, does that mean that, in fact, Claire was receiving more fluid over that hour period rather than less fluid?

(A) That would seem to be correct, yes. I don't recall precisely how much fluid I used for the phenytoin, but it is marked, I think, at 110. I don't recall how much I used. That would seem to be a fair conclusion to make, yes.

e). Dr Stewart failed to take a urine sample to carry out a urine osmolality test at 23:30 Tuesday 22 October.

Dr Batholome requested that Dr Stewart carry out a urine osmolality test at 23:30 Tuesday 22 October. This was not done.

f). Dr Stewart failed to examine or review Claire's clinical condition after 23:30 Tuesday 22 October.

No doctor attended to Claire for over a three hour period between 23:30 Tuesday 22 October and 02:30 Wednesday 23 October.

g). The additional diagnosis of encephalitis/encephalopathy to the medical notes (090-022-053)

T06-11-12 Dr Stewart

T06-11-12P19L21 to P20L6

(Q) And do you recall any mention of encephalitis at that particular ward round?

(A) Yes, I believe that was the working diagnosis. As I understand it, Claire's seizures had stopped, she had epilepsy early in her life or seizure activity much earlier in her life, but they'd been settled for quite some time, and it was deemed that encephalitis -- I think she had a viral -- there was a question about a viral illness and maybe a history of diarrhoea or loose motions and it was mentioned the possibility of encephalitis being the, perhaps, cause of the seizures.

This evidence by Dr Stewart is contrary to Dr Sands evidence that encephalitis was not the working diagnosis.

2.14 Allen Ward Wednesday 23 October 1996 - Dr Bartholome medical note

03:00am (090-022-056)

Dr Bartholome (Registrar) WS 142

a). Dr Bartholome failed to identify Claire's clinical condition at handover at 17:00 Tuesday 22 October.

Dr Bartholome did not see or examine Claire at any time between 17:00 on the 22 October and 03:00 on the 23 October, over a 10 hour period. This highlights the inadequacy of the handover between Dr Sands and Dr Bartholome, the information discussed and the level of understanding of Claire's clinical condition. Dr Sands evidence is that following the morning ward round he considered and described Claire as having a major neurological problem, an infection affecting her brain, encephalitis/encephalopathy and was the sickest child on Allen Ward. If any of that information or description of Claire's clinical condition had been discussed at the handover by Dr Sands and Dr Bartholome surely Claire would have been one of the first patients Dr Bartholome would have inquired about or assessed.

T18-10-12 Dr Bartholome

T18-10-12P39L6-L16

(The Chairman) And what I'm trying to understand is whether Dr Hughes would have

had the same level of understanding that Claire was a patient of concern. But that depends on whether she was with you at the handover or whether she already knew, from working in Allen Ward, what Claire's general condition was.

(A) I have no doubt that Dr Hughes was aware that Claire was a patient that we were especially concerned about. Whether that was from the handover or from the fact that she worked there I have no doubt that she would have been aware of that.

T18-10-12P44L5-L12

(Q) And who should have known about the seriousness of Claire's condition within the overnight team?

(A) I would have expected everybody to know about the seriousness of Claire's condition. There's no doubt she was the sickest patient on the ward at that time.

(Q) So yourself, your junior house officer and the nursing staff?

(A) That is correct, yes.

The inquiry will note that Dr Bartholome's evidence is contrary to Dr Hughes and the nursing staff evidence regarding their understanding and appreciation of how sick Claire was at the time.

T18-10-12P74L7 to P75L1

(Mr Reid) If I can return just to the serum sodium result at 11:30. You had spoken to Dr Stewart on the phone, you advised the restriction of fluid to two-thirds and to send the urine for osmolality. You knew about Claire's condition as well. I think you might have referred to her as being maybe the sickest child on the ward, I think, at some point during your evidence. Did you consider or would you have considered admitting Claire to PICU at that stage because of the seriousness of her condition as the sickest child on the Ward?

(A) The situation I was in that evening, as the registrar, was that the child had been assessed three times by a consultant and he was aware of the degree of sickness of this little girl, and who was happy for Claire to remain in intensive care. He does not mention in his treatment plan "consider admission to PICU" and I would have regarded that as an indication that he was happy for her to remain on the ward on the treatment that had been instigated by him, to await the effect of that treatment on the ward.

WS142/1 page 5 Q6(a) Dr Bartholome

(A) I also instructed him (Dr Stewart) to check the urine osmolality of Claire Roberts as I was concerned that she might have inappropriate antidiuretic hormone secretion due to the severity of her illness (suspected viral meningitis/encephalitis).

Mr and Mrs Roberts are particularly concerned about Dr Bartholome's diagnosis of Claire's condition at 11:30pm being described as suspected viral meningitis/encephalitis and when this was established and discussed. The parents left the hospital at 09:30pm believing that Claire was in her night's sleep. It is extremely difficult to understand how Dr Bartholome can describe Claire as the sickest child on Allen Ward, have a sodium level of 121mmol/L, have suspected viral meningitis/encephalitis and then fail to examine Claire or instruct another doctor to examine her until it is too late.

It is also noted that Dr Stewart failed to take a urine sample for osmolality testing.

Dr Scott-Jupp 234-002-007 (vi)(c)

(Q) Who should have had responsibility for Claire's care after 5pm on 22.10.96?

(A) This should have been agreed by the teams but I would have expected the on-call Paediatric Team and either Dr Steen or her General Paediatric colleague who was on-call that evening. The General Paediatric Registrar on-call would then have had prime responsibility.

b). Dr Bartholome failed to review the IV fluid management of No18 IV fluids, recognise the dangers of No18 IV fluids, inappropriate fluid management, hyponatraemia and cerebral oedema on Tuesday 22 October.

Dr Bartholome failed to question, examine or review Claire's fluid management and fluid balance and carried on with the administration of No18 hypotonic fluids.

WS142/1 page 5 Q5(a) Dr Bartholome

(A) The Allen Ward team which looked after Claire from 09:00 - 17:00 prescribed Claire Roberts iv fluids.

The fluid prescription on 22 October 1996 (090-038-136) was prescribed by a doctor of the Allen Ward staff.

Prof Neville 232-002-008 (iv)(f) Claire's fluid management ought to have been reviewed throughout 22 October given her deteriorating level of consciousness/drop in GCS/CNS observations, the attacks as recorded, the lack of response to 4 types of anti-epileptic medication on 22 October 1996 and the lack of urine output between 11:00 and 19:00 on 22 October 1996.

e). Dr Bartholome failed to review or monitor Claire's fluid balance, input against output on Tuesday 22 October.

d). Dr Bartholome failed to re-assess Claire's clinical condition after 17:00 Tuesday 22 October.

Prof Neville 232-002-011 (vii)(b) On receipt of the serum sodium concentration result at 23:30 on 22nd October, I would have expected both action and a neurological examination. Dr Stewart's assessment of the significance of a low sodium/fluid overload was appropriate at SHO level. However I would have expected the registrar/consultant to have acted on the assumption of cerebral oedema by restricting fluid intake to 2/3 of normal requirements to avoid further water overload which might contribute to cerebral oedema by inducing a diuresis (by Mannitol or furosemide/frusemide) and ventilating her to reduce her partial pressure of carbon dioxide (PCO2) to reduce intracranial pressure. Following the line of management of non-convulsive status was inappropriate.

Dr Scott-Jupp 234-002-008 (vii)(a)

(Q) Was the assessment and reaction of the on-call paediatric team Dr Bartholome and Dr Stewart at 2100h on 22.10.96 appropriate?

(A) No. A further seizure in spite of having received a considerable amount of anti-convulsant medication should have prompted reassessment. Her blood tests were repeated but there is no record of a repeat neurological examination. There is no record in the notes that the Registrar on-call actually saw and re-examined the child which, given her deterioration, I believe would have been appropriate. Even in 1996 it would

not have been appropriate for a relatively inexperienced SHO to manage this child without a more senior doctor seeing her.

Dr Scott-Jupp 234-002-008 (vii)(b)

(Q) Was the action following receipt of the result of serum sodium 121 appropriate?

(A) It appears the SHO received telephone advice from the Registrar and was advised to restrict the fluids further. As above, I believe that the Registrar should have re-examined the child with such a rapid fall in serum sodium without any other cause.

e). Dr Bartholome failed to reduce Claire's total fluid input between 21:00 and 24:00 Tuesday 22 October.

Dr Bartholome failed to assess, monitor or review Claire's fluid balance when she became responsible for Claire's care at 17:30 or between 21:00 and 24:00 when Claire's fluid input was increased.

f). Dr Bartholome failed to investigate the witnessed seizures at 19:15 and 21:00 Tuesday 22 October (090-042-144).

T12-11-12 Dr Scott-Jupp

T12-11-12P197L20 to P198-L7

(The Chairman) But you're saying that the attack which is noted at about 9 o'clock should have led to a full reassessment in light of the fact that this came after she had received quite a lot of drugs?

(A) Yes, and she was having overt seizures, which she wasn't at 5 o'clock.

(Ms Anyadike-Danes) Who do you think should have been carrying out that kind of examination in those circumstances?

(A) At 9 o'clock?

(Q) Yes.

(A) I think it should have been the on-call paediatric registrar.

g). Dr Bartholome failed to review or investigate Claire's GCS scores on Tuesday 22 October.

Prof Neville 232-002-011 (vii)(a) The seizure at 21:00 on 22 October 1996 may not have prompted any further action by the SHO, but the drop in the GCS score should have prompted contact with the registrar and / or consultant.

h). Dr Bartholome failed to examine Claire at 23:30 Tuesday 22 October.

Dr Bartholome did not attend to Claire for some nine to ten hours following the 05:30pm handover between Dr Sands and herself and only attended at 03:00am on 23 October following an emergency crash call from the nurse. This evidence again highlights a severe lack of understanding and underestimation by the doctors and nurses of Claire's clinical condition and supports Mr and Mrs Roberts evidence that no one had a clear appreciation of how ill Claire was. This evidence also discredits Dr Sands evidence regarding his communication with Mr and Mrs Roberts during the morning ward round about Claire's clinical condition.

Mr and Mrs Roberts do not accept that Dr Bartholome's failure to see or examine Claire was a resources issue. Dr Bartholome may have been busy at 11:30pm 22 October when

she received a telephone call from Dr Stewart but she failed to attend to Claire for at least nine hours following the hand over and commencement of her duty. The question is, how was Dr Bartholome so busy for over nine hours that she had no time to attend and failed to attend to "the sickest child on Allen Ward".

i). Dr Bartholome failed to carry out blood test at 23:30 on Tuesday 22 October.

T12-11-12 Dr Scott-Jupp

T12-11-12P81L16-L25

(Q) Finally, just on the sodium result part, would you have been aware of how quickly the sodium had fallen, as in that there was a result of 132 the previous evening at about midnight and this result now was 121 at 11:30pm?

(A) No, the one result of 121 would not have given me an indication of how quickly it had fallen because it could have been that it was quite stable, but then as a result of Claire deteriorating, it dropped suddenly, or it could have been that it slowly deteriorated throughout the whole day.

j). Dr Bartholome failed to contact a consultant at 23:30 Tuesday 22 October.

Prof Neville 232-002-011 (vii)(c)

(Q) Whether either the SHO or registrar should have informed either Dr Steen or Dr Webb of these events, and if so, whom they should have informed.

(A) Certainly the consultant should have been informed.

Dr Scott-Jupp 234-002-008 (vii)(c)

(Q) Should the resident team have involved a consultant?

(A) Undoubtedly yes. This was a serious situation. Even though thresholds for calling a Consultant these days are considerably lower than they were in 1996, it is my view that this child was sufficiently ill, with a number of problems that were not improving, particularly as it was still relatively early in the night, informing a Consultant would have been appropriate. It is not clear whether this did not happen because the on-call team were uncertain whether to contact Dr Steen or Dr Webb, but in any event one of other should have been contacted.

Dr McFaul 238-002-023 (104) The on-call registrar Dr Bartholome should have consulted the on-call paediatric consultant about the low sodium level associated with reduced conscious level.

k). Dr Bartholome failed to contact Mr and Mrs Roberts at 23:30 Tuesday 22 October.

l). Dr Bartholome failed recognise that Claire clinical condition was critical at 23:30 Tuesday 22 October.

m). Dr Bartholome failed to carry appropriate action when informed about Claire's sodium level of 121mmol/L at 23:30 Tuesday 22 October.

n). Dr Bartholome failed to learn any lessons following Claire's death.

2.15 Allen Ward Wednesday 23 October 1996 - Dr Steen medical note 04:00am (090-022-057)

Dr Steen (Consultant) WS 143

a). **Dr Steen as the paediatric consultant under whom Claire was admitted failed to provide an input into Claire's clinical care, attend or be involved in Claire's care until her condition was irretrievable.**

This was Dr Steen's first contact and involvement with Claire, 33 hours after Claire's admission. Dr Steen had no input into the treatment and diagnosis made throughout Monday 21 or Tuesday 22 October 1996. Dr Steen examined Claire, reviewed the medical notes in PICU and recorded a note at 04:00am. It is noted that this is before Dr Webb arrived in PICU. Therefore Dr Steen reviewed Claire's medical notes before speaking to Dr Webb and making her 04:00am note.

T17-10-12 Dr Steen

T17-10-12P44-46

This is Inquiry Counsel confirming that Dr Steen had compiled a history at 04:00am and the history had been obtained by reviewing and looking through the medical notes.

T17-10-12P46L17-L20

Dr Steen would therefore have picked up detail such as an untimed, undated ward round notes or when the bloods were taken. However when Dr Steen compiles her 04:00am note which is very detailed she only refers to acute encephalopathy (Dr Webb 2pm) but makes no reference to encephalitis.

When Dr Steen reviewed the medical notes she would have read "encephalitis" (if there) and recorded it in her first note at 4:00am (090-022-057). However the note at 04:00am by Dr Steen only refers to the impression noted by Dr Webb of "acute encephalopathy" (2pm) **but not** encephalitis/encephalopathy.

WS143-1 page 62 Q36a Dr Steen.

(Q) State the source of the information upon which you based your note at 04:00 on 23rd October 1996 in Claire's medical notes?

(A) This would have been written following discussions with medical and nursing staff, **review of medical notes** and clinical assessment of Claire in PICU.

WS143-1 page 62 Q36b Dr Steen.

(Q) Explain what you meant by "acute encephalopathy? aetiology".

(A) Dr. Webb had made a diagnosis of acute encephalopathy in his note of 22-10-96 and the cause of this I believe I put as a query as there were still concerns if there was underlying viral encephalopathy as well as status epilepticus.

WS143-1 page 62 Q36c Dr Steen.

(Q) Explain why your note does not refer at all to the diagnoses of non convulsive status epilepticus and/or encephalitis, and attributes an unknown cause to the encephalopathy.

(A) I have no recollection but assume this reflects my initial thoughts **after review of notes** and prior to talking to Dr Webb.

T19-10-12 Dr Sands

T19-10-12P184-P185

Dr Sands evidence is that if he telephoned Dr Steen early on the Tuesday afternoon, 22 October, he would have informed her of Claire's sodium level, what IV fluids she was on, that Dr Webb was to see Claire, what her initial observation was (GCS 9), that she might have non-fitting status and that other possibilities were encephalitis/encephalopathy. If Dr Steen had been given this clinical information by Dr Sands she would have been aware of encephalitis and would have recorded it in her 04:00am medical note.

T17-10-12 Dr Steen

T17-10-12-P44L24 to P45L1 (Inquiry Counsel question Dr Steen about the content of and the addition of encephalitis/encephalopathy to the ward round note).

(A) And then Dr Sands has felt, after speaking to Dr Webb, he needed to add something to it.

Dr Steen in her Coroners Deposition dated 16 March 2005 (096-004-022 Line 11) is aware that Dr Sands has added encephalitis/encephalopathy to the medical notes. Dr Steen's deposition states "He felt [Dr Sands] that the differential diagnosis should include non-fitting status epilepticus, encephalitis and encephalopathy".

Dr Steen's oral evidence to the Inquiry on the 17 October 2012 and Coroners Deposition dated 16 March 2005 is inconsistent with her Inquiry witness statement dated 6 March 2012.

WS143-1 page 18 question 21a Dr Steen.

(Q) Identify the author of the note in Claire's medical notes of "encephalitis/encephalopathy" after the note "Imp.Non fitting status".

(A) This is unsigned and I do not recognise the writing.

WS143-1 Page 18 question 21b Dr Steen.

(Q) State when the note "encephalitis/encephalopathy" was made, the reasons for this addition to the medical notes and whether those 2 conditions comprised part of your diagnosis or whether they were part of a diagnosis by another person. If so, state by whom and when was that diagnosis made.

(A) This is unsigned and not dated so I do not know who or when this note was made.

Mr and Mrs Roberts firmly believe at 04:00am 23 October 1996 that Dr Steen, on reading the medical notes, would have recognised the obvious omissions, shortcomings and failures with regard to Claire's fluid management, blood testing and the rapid fall in her sodium level. They believe Dr Steen had a decision to make regarding Claire's diagnosis and the cause of the cerebral oedema. Dr Steen had two options. Inform the parents that there had been mistakes made in Claire's fluid management, mistakes made about when blood tests should have been carried out, mistakes made that resulted in Claire's sodium level falling rapidly from 132mmol/L to 121 mmol/L within 23 hours (acute hyponatraemia), mistakes made with the diagnosis and mistakes made with Claire's care management, or inform the parents that a virus had spread to Claire's brain. Mr and Mrs Roberts firmly believe that Dr Steen was very much aware of her options when she

informed them that the cause of Claire's brain swelling was the result of a virus. Dr Steen should have informed Mr and Mrs Roberts that Claire's sodium levels had fallen rapidly as a consequence of continuous vomiting and nausea over a period of twenty hours, causing an electrolyte imbalance and that the bodies normal release of ADH (anti-diuretic hormone) when combined with the infusion of hypotonic IV fluids had led to an osmotic fluid shift and dilution of Claire's sodium level to 121mmol/L leading to cerebral oedema, and brain swelling.

The Inquiry will note that the blood test result recorded by Dr Steen at 04:00am on Wednesday 23 October in the left hand margin of the medical notes (090-022-057) defines a blood osmolality of 249mmol/L (normal range 275 to 290mmol/L) and would have identified dilutional hypotonic hyponatremia to Dr Steen.

No one should be influenced, distracted or misled by Dr Steen's unscrupulous attempts to attribute the cause of Claire's brain swelling to a virus or infection and cover up of the clinical errors made by Dr Sands, Dr Stevenson and the other junior doctors for whom she was responsible.

Dr McFaul T14-11-12

T14-11-12P156L6-L19

(Q) So what is the significance of that figure (249mmol/L) so far as you understand it?

(A) Well, one of the simplest ways to estimate the osmolality is roughly to double the blood sodium level. So it was 121, double that, it's 240. It's not far off. And so you always have to add the glucose on as well and a bit of potassium, but they're small figures. As a rough estimate of osmolality at any stage you simply double the sodium for a quick answer, unless you have a blood osmolality, which they have here. It is low. It's significantly low.

(Q) And what does that mean in relation to her condition?

(A) Water overload or syndrome of inappropriate ADH secretion.

T14-11-12P123L6-L21

(Q) What I was asking you is: given that he's (Dr Webb) actually, in cryptic terms, set that out in the previous page, which she's had to look at to get the results, is that something she should have thought about to at least have a discussion of that sort with Dr Webb ahead of speaking to the parents?

(A) Yes, I believe so, and whether she recorded it or not is the issue that we were discussing before. But yes, she should have considered how hyponatraemia could arise and, as we've been discussing the mechanisms were well-known at the time to be combination of inappropriate ADH and volume overload, water overload. Yes, she should have done and I think so should Dr Webb. We know from subsequent events that there doesn't appear to have been any consideration of the two factors which were combining to produce the hyponatraemia.

Prof Neville 232-002-019 (xxii) The appearance of papilloedema indicates severe raised intracranial pressure and the pupil signs and lack of responsiveness suggest widespread severe brain damage as would be anticipated from uncontrolled cerebral oedema, preventing sufficient blood to reach the brain. The sodium levels of 121 mmol/L is sufficient cause of this problem. Mannitol, an osmotic diuretic was given and this was

appropriate to attempt to reduce the water content of the brain but was in my opinion given much too late and sadly was not effective.

b). Dr Steen failed to provide continuity of care between paediatrics and neurology.

2.16 Allen Ward Wednesday 23 October 1996 - Dr Webb medical note 04:40am (090-022-057)

Dr Webb (Consultant) WS138

It is noted that the medical note by Dr Webb at 04:40am records coning following prolonged epileptic seizures as a result of SIADH, hyponatraemia, hypo-osmolality, cerebral oedema. This was Dr Webb's immediate thought pattern which does not refer to or make any reference to encephalitis.

3. Dr Steen and Dr Webb failed to provide truthful, accurate or complete information to Claire's parents in PICU on Wednesday 23 October 1996

Dr Steen (Consultant) WS 143

Dr Webb (Consultant) WS138

a). Dr Steen and Dr Webb informed Mr and Mrs Roberts in PICU that a virus had caused Claire's brain to swell.

They reassured the parents that everything possible had been done for Claire and nothing more could have been done. At that time the parents believed and trusted in Dr Steen and Dr Webb and accepted the explanations and information given to them. They never questioned the accuracy of Claire's diagnosis or the quality of the treatment she received and accepted the information given by both doctors. Mr and Mrs Roberts now firmly believe that their trust was misplaced and both Dr Steen and Dr Webb failed to be open and truthful about the cause of Claire's cerebral oedema, dilutional hyponatraemia and the dangers associated with hypotonic low sodium fluids. They believe Dr Steen and Dr Webb failed to inform them that there had been errors and mistakes made in Claire's care management.

There must also be concern expressed about the adequacy of discussions between consultants in PICU on 23 October regarding No 18 IV fluids, fluid management, hyponatraemia and the rapid fall in Claire's sodium levels. At that time (October 1996) Dr Webb and Dr Taylor had been involved in the case of Adam Strain in November 1995, the Coroners Inquest into Adams death in June 1996 and an ongoing litigation case between the RBHSC and Adam Strain's family. The Coroners Inquest into Adams death 4 months before Claire's admission to the RBHSC defined dilutional hyponatraemia and fluid mismanagement as one of the causes of Adam's death.

T12-12-12 Dr McKaigue

T12-12-12P8L17-L25

(A) Yes. I personally was not -- not being a paediatrician, I wasn't aware that encephalitis or status epilepticus could cause SIADH, so I wanted to clarify with -- I believe, Dr

Webb was present at that stage -- with the paediatricians. I recall it was Dr Steen who said ... I can't remember exactly, but it was either she had seen a case like this before or she was aware that this could happen in cases of encephalitis, meningoenephalitis, that SIADH and hyponatraemia could occur.

T12-12-12P9L8-L14

(The Chairman) When you said earlier that you had knowledge that Claire had encephalitis and status epilepticus, that's from the notes and records over the previous 24 hours, which showed that that's what she was being treated for?

(A) That's what the paediatricians were saying.

(The Chairman) Right.

T12-12-12P16L8-L25

(The Chairman) Whichever it was, the fact that such a case had been seen before or Dr Steen was aware of such a case, that means that it can happen, but the question surely in Claire's case was: is that what happened? So how do you move from saying, "This can happen in a case", to saying confidently, "This is what has happened in Claire's case. I therefore know why she died. I can issue a death certificate"?

(A) What I ... I wasn't actually making any of the diagnoses--

(The Chairman) Yes

(A) -- in Claire's case. Therefore, I was accepting the diagnoses which had been made. And I was satisfying myself that the diagnoses were in keeping with the history I had received and also the fact that the hyponatraemia was not caused by maladministration of No.18 solution because that's what happened in Adam Strain's case.

WS143-1 Page 77 (47e) Dr Steen.

(Q) State if you discussed the cause of death with Dr Webb and/or Dr Taylor. If you did, state their view on the cause of death and when each expressed that view.

(A) I have no recollection of the events but would expect that Dr Webb and I discussed Claire's cause of illness and subsequent death with Dr Taylor.

b) Dr Steen's failure to discuss a metabolic cause for the hyponatraemia, recognise the rapid fall in Claire's sodium level of 11mmol/L in 23 hours as acute hyponatraemia and identify fluid mismanagement as a cause of the cerebral oedema.

As a paediatric consultant Dr Steen's evidence to the Inquiry is that in 1996 she and other doctors were not aware that the administration of a maintenance infusion of No18 IV fluids could lead to hyponatraemia. However, Dr Stewart as a first term paediatric SHO defined his understanding as "Well, I certainly tried to think along the lines of first principles, so when a patient's sodium drops, with the risk of oversimplification, you're either thinking: are they losing sodium or do they have too much water causing a relative dilution of the sodium concentration in their blood". It is extremely difficult to understand how a very junior doctor in 1996 had a better understanding than that of his consultant about the association between No18 hypotonic IV fluids, hyponatraemia and sodium dilution.

The Royal Hospitals Letter dated 12 January 2005 (096-018-113) question 9 states "The practice at that time would have been firstly, to restrict fluid intake and secondly, to consider administration of fluid with a higher content of sodium, if symptoms attributable to hyponatraemia were present.

The Inquiry are aware that on 21 October 1996 one of Dr Webb's patients (Patient W2) had two blood tests results that indicated a sodium level of 135mmol/L and 130mmol/L. On the basis of the 130mmol/L result medical staff changed this patients fluid management from 0.18% NaCl to 0.45% NaCl. Within a few hours an improvement was noted in patient W2 clinical condition. This was a very significant alteration to this patients fluid management and highlights the awareness of medical staff in October 1996 with regard to the monitoring, reviewing and changing a patients fluid management in line with their blood test results and sodium level.

T17-10-12 Dr Steen

T17-10-12P114L3-L6

(A) But I certainly do not feel that myself or others were aware that unless you gave more than maintenance of fifth-normal saline, you would induce hyponatraemia per se on it's own.

Dr McFaul T14-11-12

T14-11-12P124L5-L14

(Q) And although it's not a very comfortable discussion to have with the parents at whichever stage you do it, but is not the potential significance of it that if it's caused -- and if I can call it Dr Stewart's first line -- like that, then that's a fluid management issue, and that does bring with it the possibility that her fluid management was inadequate?

(A) Absolutely. The iatrogenic causation of hyponatraemia is documented in text books as a significant causation of hyponatraemia in acute encephalopathy.

T14-11-12P125L21 to P126L6

(The Chairman) Sorry, when you say, "I suppose one would have to say", that's ---

(A) It's difficult -- one is always hesitant to lay blame on oneself, I think, and on the regime. It would have to be stated because if you're explaining the hyponatraemia and you've properly conceived its mechanism, then you are considering the two main causes. One is fluid overload and the other is inappropriate ADH. There's only one way that the fluid overload could have occurred and that is by the fluid that had been administered.

T14-11-12P127L13-L20

(A) But in terms of saying "everything possible had been done" is evading the issue because, actually, her management was not up to the standard of the time. The standard of the time, which we've gone over a number of times, is fluid restriction and adjustment of the sodium content of the intravenous fluid, and that should have happened, in my view, from, at the latest, around mid-afternoon. So in that sense, this was misleading.

Prof Neville 232-002-009 (v)(e)

(Q) Whether Dr Webb should have been aware that sodium metabolism may have been affected by an acute neurological illness of the type experienced by Claire, and if so, how this should have affected his management of Claire.

(A) Dr Webb should be aware of inappropriate ADH secretion in acute brain illness and the need to monitor sodium levels, conscious level and fluid balance.

Dr Scott-Jupp 234-002-006 (v)(e)

(Q) Should Dr Webb have been aware that sodium metabolism have been affected by an illness of this type?

(A) Yes, any General Paediatrician or Paediatric Neurologist should have been aware that acute cerebral illness can result in the syndrome of inappropriate antidiuretic hormone secretion leading to hyponatraemia, and also that hyponatraemia in itself can cause Cerebral Oedema with its resulting neurological symptoms, However, in the context of a child admitted under an acute General Paediatric Team who was acutely unwell, I do not believe that, either then or now, it would have fallen to the Consultant Paediatric Neurologist to take the lead in IV fluid management. This is very much within the remit of the General Paediatrician. The Neurologist should have been aware of any abnormalities, but responsibility for checking the electrolytes and actually prescribing the fluids should have fallen with the General Paediatric Registrar or Consultant. Obviously if Dr Webb had been aware of a falling sodium level before it was eventually checked then this would have prompted a change in Claire's management.

c) Adequacy of discussions regarding No18 IV fluids, fluid management, hyponatraemia and the rapid fall in sodium levels with consultants in PICU on 23 October.

Mr and Mrs Roberts believe it is remarkable and a major concern that two of the doctors, Dr Taylor and Dr Webb, directly involved in the care and treatment of Adam Strain in November 1995, the subsequent reviews, discussions and Inquest into Adam's death within a few months of Claire's admission did not question or query Claire's fluid management and acute hyponatraemia. PICU consultant Dr McKaigue was also involved in Claire's care and it was Dr Taylor and Dr McKaigue who were involved in compiling and "circulating" the Royal Hospitals new recommendations on the prevention and management of hyponatraemia in June 1996.

It is a major concern that the Royal Hospitals did not openly disseminate any learning from Adam Strain's death and dilutional hyponatraemia. It would appear that the hospital attempted to internally suppress the issues around Adam's death and protect Dr Taylor at the time of Claire admission to PICU on 23 October 1996 when she should have been identified as another case of dilutional hyponatraemia.

Dr Taylor WS157/1 page 8 Q15

(Q) State what communication you had with Dr Heather Steen in relation to Claire between 21 October 1996 and her death on 23 October 1996 including.

(A) I cannot recall if I had any communication with Dr Steen during this time. My clinical duties to Claire was as the PICU consultant from 08:30-17:00 on 23 October 1996. As in answer 4 (ii) According to my note (Ref: 090-022-061) there did not

appear to be a need to consult another clinician during this time period.

Dr Taylor WS157/2 page 14 Q52(c.viii)

(Q) During the course of your presentation whether you referred to the fact that there were two other deaths associated with hyponatraemia in 1995 and 1996, namely Adam Strain and Claire Roberts. If not, please state why not.

(A) As in answer 4(a) and 52(a) this was a draft presentation emailed to Dr Paul Darragh. To my recollection it was never tabled at subsequent meetings and never used. It does not appear that Adam or Claire's deaths were part of that data collection. **I was not aware that Claire Roberts' death involved hyponatraemia until 2012.**

Dr Taylor treated Claire in PICU and was on duty and from 08:30 to 17:00 on Wednesday 23 October 1996 (WS157/1 P3Q3c).

Dr Taylor was aware, after reading the medical notes and following a handover from Dr McKaigue, that Claire was receiving No18 IV fluids. (Dr McKaigue WS156/1 P9).

Dr Taylor was aware, after reading the medical notes, of Claire's hyponatraemia and was also aware that her sodium level had fallen from 132mmol/L to 121mmol/L within 23 hours. (WS157/1 P4Q5b).

Dr Taylor read Claire's medical notes which identify hyponatraemia from admission to PICU :

On admission Na 132mmol/L.

11:30pm Dr Stewart's note states - hyponatraemic - ?fluid overload & low Na fluids.

04:00am Dr Steen's note states - Na 121.

04:40am Dr Webb's note states - SIADH - hyponatraemia, hypo-osmolality, cerebral oedema.

07:10 Dr McKaigue's note states - sodium Na also noted to be low 121.

Dr McKaigue's evidence to the Inquiry on 30 May 2013 (T30-05-13P25 to P38) is that in 1996 and 2001 he recognised that hyponatraemia and No18 IV Fluid was **implicated in Claire's death.**

Dr Stewart (SHO) recorded hyponatraemia in the medical notes and was aware that Claire was hyponatraemic and queried fluid overload (090-022-056).

Dr Bartholome was aware of Claire's hyponatraemia (121mmol/L) and advised that fluids be restricted to 2/3rds (090-022-056).

Dr Mannam (PICU SHO) recorded other diagnosis as hyponatraemia on the PICU Discharge Summary (090-009-011).

It is incomprehensible how Dr Taylor and Dr Steen failed to discuss or identify Claire's hyponatraemia and fluid mismanagement in 1996. In 1996 Dr Taylor was refusing to accept and acknowledge his failures in Adam's death and the mechanism for Adam's death as dilutional hyponatraemia. If Dr Taylor had highlighted and attributed Claire's death to dilutional hyponatraemia and fluid mismanagement in 1996 he would have exposed himself, Dr Steen's failures and the RBHSC to another case of dilutional hyponatraemia and fluid mismanagement within 11 months of Adam's death and within 3 months of concluding a high profile Coroners Inquest into Adam's death.

It is a major concern that Dr Taylor together with Dr Steen gave a presentation at the Sick Child Liaison Group at Antrim area hospital in June 2001 (093-035-110o) on hyponatraemia and the dangers of hypotonic fluids only 4 years after Dr Taylor and Dr Steen had allegedly failed to make the link between Claire's hyponatraemia and No18 hypotonic fluids.

It is also noted that in 2001 Dr Taylor believed there had been 5-6 deaths due to dilutional hyponatraemia over a ten year period (021-056-135).

It is a major concern that Dr Taylor made no reference to Adam in 1995 or Claire in 1996 in the bar chart information (007-051-103) for the hyponatraemia working group in September 2001 and that Dr Taylor did not inform the working group in September 2001 about his knowledge of Adam's hyponatraemia in 1995.

4. Dr Steen failed to provide truthful, accurate or complete information to Claire's parents on Wednesday 23 October 1996

Prof Neville 232-002-013 (xiii)(a) The information given to the family was in line with the medical view of the illness which had not included a major consideration of cerebral oedema/hyponatraemia until after the CT scan when the information should have been included. Thus although a virus may have been the initiating cause, cerebral oedema caused or aggravated by hyponatraemia was the ultimate cause of death and should in my opinion have been stated.

Dr McFaul 238-002-065 (309) The parents were not informed or alerted to the role of blood sodium in contributing to the brain oedema. Given the fact the hyponatraemia had been identified in Adam Strain in the same hospital and publicity given to this a few months before admission, and the subsequent action taken by the Trust in producing a public statement which included reference to publications which cover more than the surgical condition from which Adam suffered, it is a matter of remark that more attention had not been paid to the role of low sodium in causation of other deaths or in alerting clinical staff to its importance.

5. Dr Steen failed to comply with her consultant responsibility and GMC obligations

Mr and Mrs Roberts have read and heard evidence from Dr Steen, Dr Webb and Dr Sands with regard to who was responsible for Claire's care. The major concern their evidence highlights is the shambolic care management Claire received throughout Tuesday 22 October 1996 and the doctors shameful attempts in 1996, 1997, 2004 and 2006 to justify their actions and responsibilities. The consultant paediatrician Dr Steen believed that the consultant paediatric neurologist Dr Webb was responsible for Claire's care and management. Dr Webb believed Dr Steen was responsible and the paediatric registrar Dr Sands believed that Claire was under the joint management of Dr Steen and Dr Webb.

The Inquest deposition of Dr Steen (091-011-067) dated May 2006 states "My recollection is that when I contacted the ward I was told Dr Webb had seen her and had taken over her management".

WS143-1 page 46 (29ff) Dr Steen.

(A) I have no recollection of these events and therefore I cannot comment on my understanding of Dr Webb's role at that time. I note in my statement to the Coroner that I recollected contacting the ward and being told Dr Webb had seen her and had taken over her management. Ref 091-011-067. I no longer recollect this.

WS138-1 page 41(24e) Dr Webb

(A) Claire was still under the care of Dr Steen and her team.

WS138-1 page 41(24f)(i) Dr Webb

(A) I understood that Claire's ongoing acute care and management would remain with the paediatric medical team and that I was available to provide further specialist advice as was needed.

WS138-1 page 41(24f)(ii) Dr Webb

(A) I did not believe that I had taken over Claire's care.

WS137/2 page 21(30d) Dr Sands

(A) I would have expected Dr Webb and Dr Steen to discuss Claire's case together. I would have expected both consultants to offer advice on Claire's management. Dr Steen's ongoing interest may have manifest by visiting Claire, talking to her parents and discussing matters further with Dr Webb.

Prof Neville report 232-002-007 (iv)(e) In my view the cause of Claire's brain illness was unexplained and the consultant should have been involved. Whether this would usually happen in this unit I cannot say so that the onus of making it happen could be with the registrar/consultant or both.

T14-11-12 Dr McFaul

T14-11-12P75L8-L15

(Q) During the afternoon, is it the responsibility of her (Dr Steen) registrar to keep up-to-date with what has happened to Claire or is it her responsibility to phone in and to see how matters lie?

(A) Well, if she was aware that Dr Webb was seeing Claire and she was aware that Claire was significantly unwell, it was her responsibility at least to ensure that she spoke to Dr Webb.

Dr McFaul 238-002-019 (89) Claire was admitted under the clinical care of the on-call acute general paediatric consultant Dr Steen. In my view she was the responsible consultant throughout Claire's stay.

6. Dr Steen failed to compile an accurate formulation for cause of death or provide accurate information on the MCCD.

Dr Steen failed to include hyponatraemia on the MCCD.

There is no evidence to suggest that Dr Steen consulted with any other doctor before formulating the cause of death as 1a) Cerebral oedema b) Status epilepticus

WS138-1 Page 54 (35d) Dr Webb.

I was not consulted on the completion of Claire's death certificate.

T19-12-12 Dr McFaul

T19-12-12P32L12-L14

(A) But in the immediate aftermath I don't know to what extent Dr Webb had signed up to Status epilepticus.

Professor Lucas 239-002-001 (6) The cause of death is most probably/almost certainly hyponatraemic cerebral oedema.

Dr McFaul 238-002-059 (280) However following death it is not clear on what grounds Doctors Steen and Webb came to the conclusion that the death was secondary to status epilepticus. Dr Steen and Dr Webb were both aware of the low sodium. Dr Steen noted this on the autopsy request form. On what grounds did they not consider that it had a greater contribution to Claire's death and given the inquest information relating to Adam Strain did they not consider that intravenous fluids may have contributed to the hyponatraemia?

Prof Neville report 232-002-013 (xii) I think it was appropriate to include hyponatraemia on the death certificate as it was the main cause of cerebral oedema which was the main cause of death.

Prof Neville report 232-002-015 (xvi)(d) There is no clear evidence of status epilepticus and I cannot understand why an early EEG was not performed, I do not agree that it was a contributory cause of death.

7. Dr Steen failed to report Claire's death to the Coroner on 23 October 1996

Dr Steen did not refer Claire's death to the Coroner on 23 October 1996. The causes and the reasons for Claire's death did not receive external scrutiny and were restricted to a limited RBHSC internal post mortem investigation only. This action by Dr Steen raises serious questions regarding how such a decision was made by the clinician responsible for Claire's care in relation to that clinician's GMC professional self regulation procedures, who Dr Steen discussed and agreed the cause of death with and how an accurate and independent cause of death was established.

There is no evidence that Dr Steen carried out any investigations, discussions, reviews or audits immediately after Claire's death. The importance of those failures and omissions is highlighted by the fact that the RBHSC and Dr Steen in particular had been participating in a team responsible for preparing for and obtaining accreditation from the Kings Fund Organisational Audit in the months preceding Claire's admission. However, it is clearly evident on review of the medical notes which highlight an incorrect diagnosis, the failure to do a simple blood test, the medication overdoses, the fluid mismanagement, the failures in Claire's care management and the failure to recognise Claire's clinical condition that it is difficult to find any area within Claire's clinical management and care that was acceptable.

The decision not to report Claire's death to the Coroner on 23 October 1996 appears to have been made solely by Dr Steen.

WS143-1 page 72 (45d) Dr Steen.

(Q) Identify the person/s who determined that Claire should have a "*limited post mortem only of her brain*", rather than a full post mortem".

(A) I have no recollection of the events and can only comment that this most likely was agreed following discussion with Dr Webb and myself and the PICU consultant.

WS143-1 page 73 (45m) Dr Steen.

(Q) Explain precisely the basis upon which Claire's case was not "*a Coroner's case*".

(A) At the time of Claire's death, it was felt the sequence of events leading to her death was known and there were **no areas of concern around her care**.

WS143-1 page 73 (45n) Dr Steen.

(Q) Identify the person(s) who made the decision not to refer Claire's case to the Coroner at that time, and describe your involvement or input into the decision not to refer Claire's case to the Coroner at the time of her death.

(A) I have no recollection of these events but would presume that this decision was made by myself, Dr Webb and the PICU consultants.

WS138-1 page 91 (78a) Dr Webb.

I don't believe I was involved in the discussions about the extent of post mortem on Claire or whether it should be referred to the Coroner.

WS138-2 page 16 (22a) Dr Webb.

Dr Steen dealt with the issue of whether the Coroner should be involved and I don't believe we discussed it.

WS138-2 page 16 (24a) Dr Webb.

Dr Steen dealt with Claire's death certificate completion. My opinion on Claire's death was clearly indicated in my clinical note.

WS157-2 page 4 (10) Dr Taylor.

I did not discuss Claire's death with the Coroner's Office as I was not present at the time of her death and I do not know if any advice was sought.

WS157-2 page 4 (11) Dr Taylor.

I do not think any advice was sought from me or that I had any input into Claire's cause of death included on her death certificate.

WS156-2 page 3 (10) Dr McKaigue.

I was not asked for my opinion as to whether or not Claire Roberts' death should have been referred to the Coroner.

WS156-2 page 4 (13) Dr McKaigue.

No advice was sought from me and I did not have any input into the causes of death included on the death certificate of Claire Roberts.

WS156-2 page 4 (18) Dr McKaigue.

~~My opinion was not sought as to whether or not a full or restricted post-mortem examination of Claire Roberts should be requested.~~

Mr and Mrs Roberts are also very concerned about the reasons why Dr Steen did not

report Claire's death to the paediatric Clinical Director Dr Hicks.

T11-12-12 Dr Hicks.

T11-12-12-P40L21 to P41L3

(The Chairman) What we're going to come to in a few minutes is that Dr Hicks was not aware of Claire's death. Sorry, let me take you to that now. Were you aware of Claire's death?

(A) No.

(The Chairman) Do you understand how that seems absolutely extraordinary?

(A) I do.

T11-12-12-P41L22 to P42L11

(The Chairman) In Claire's case, absolutely nothing was done. If you were Mr and Mrs Roberts sitting here today and you know that they're only finding out about this because they picked up from a documentary some concerns, which then translated into them going to the hospital, things being opened up sufficiently for an inquest to be held and then sufficiently for Claire's case to be added to the inquiry, what confidence would you have in the Health Service if you were Mr and Mrs Roberts?

(A) I understand. Not much.

(The Chairman) And you had just come into the position of paediatric lead. If the news of Claire's death doesn't reach you, it's not going to get very far at all, is it?

(A) Yes.

T11-12-12-P47L7 to P49L7

(The Chairman) Sorry, before you move on. An untoward event. Dr Webb has told the inquiry that he went home after he saw Claire or soon after he saw Claire at about 5 or 5:30 on Tuesday 22 October. He knew that she was unwell, but he expected her to recover, ok? Dr Steen has said that she was out in Cupar Street that afternoon. There was some level of contact between her and the hospital, however that was triggered, as a result of which she understood that it was not necessary for her to return to the hospital to see Claire, or any other child for that matter. So both the consultant who was formally responsible for Claire, Dr Steen and the consultant who had been intervening to help identify what was wrong with Claire and treat her, Dr Webb, they left work at 5, 5:30, 6, something like that, on Tuesday evening, expecting nothing untoward would happen; ok? They come back into the hospital in the early hours of Wednesday morning at 3am -- maybe 4am on Dr Webb's case -- to find that, to all intents and purposes, Claire is dead. Entirely unexpected on their parts for a girl who had arrived in on Monday evening with her parents and was dead less than 36 hours later. Does that strike you as something untoward?

(A) Yes.

(The Chairman) Do you understand or can you help me understand why that would not be regarded as an untoward event?

(A) I can't understand that.

(The Chairman) Do you understand how either one or both of them, depending on which version I take, took the view that they were sufficiently confident about identifying the cause of Claire's death that it need not be referred to the coroner?

(A) I don't.

(The Chairman) Or that they advised Mr and Mrs Roberts that it would be sufficient to have a brain-only autopsy?

(A) I don't.

(The Chairman) Do you understand my problem?

(A) I do.

(The Chairman) And more particularly, do you understand Mr and Mrs Roberts' problem?

(A) I do. I appreciate it.

(The Chairman) If their understanding, as they've told the inquiry, was correct, they should have come back into the hospital on Wednesday morning and Claire would still have been there, recovering or not recovering to some level, and the treatment would have continued. But what happened just doesn't stand up to any scrutiny at all, does it?

(A) No.

T17-10-12 Dr Steen

T17-10-12P142L19 to P143L12

(A) If we think she died because of something we did do, then there's no death certificate that can be issued; it is a coroner's case. So the fact that a death certificate was issued means that myself and, I would suggest, Dr Webb felt that her death was from explained natural causes rather than a contributory factor from mismanagement of IV fluids.

(Q) If I may say so, that is exactly the point.

(A) Of course that is the point.

(Q) The point is precisely the extent to which the treating clinicians could have understood that there was culpability in Claire's death, and therefore it was completely and utterly inappropriate not to have a coroner's inquest. That is exactly one of the points.

(A) I accept that's exactly one of the points and what I'm saying is: as we did not move to that step and looking at what was done, the significance of the hyponatraemic solutions, the fifth-normal, was not appreciated at that time.

Dr Steen's evidence is contrary to Dr McKaigue's evidence on 30 May 2013 regarding the contribution of No18 IV fluids and the awareness of the treating clinicians at the time about how No18 IV fluids had been implicated in Claire's death.

T30-05-13 Dr McKaigue

T30-05-13P25L15 to P26L5

(Q) No, but what I'm asking you is : when you mentioned Adam and Claire, were you saying that because it was recognised in the Children's Hospital in 2001 that solution 18 had been implicated in Claire's death?

(A) I recognised that it was implicated. I'm not sure, you know, what the um, the hospital itself, the corporate hospital, had recognised.

(Q) Did you make that known to the hospital that you thought the use of a low-sodium fluid, solution 18, was implicated in her death?

(A) No, I didn't

(Q) Can I ask you why?

(A) I remember that in Claire's case it was it was a contributory cause to her death.

(Q) Yes, I said "implicated".

(A) Implicated, yes.

It will be for the Inquiry to determine Dr Steen's motive and reason for not reporting Claire's death to the Coroner and whether her evidence is fact or fabrication.

Prof Neville 232-002-013 (xiv) I do not understand how the hospital could be sufficiently clear about the cause of Claire's death so as not to require it to be reported to the Coroner.

Prof Neville 232-002-013 (xiv) I would have expected a full post mortem as the death was unexplained. I would have expected the death to be reported to the Coroner.

Dr Scott-Jupp 234-002-011 (xiv)

(Q) Would I have expected Claire's death to have been reported to the Coroner?

(A) Yes, undoubtedly. Although the threshold for reporting to the Coroner is lower now than it was in 1996, even then a sudden acute death in a child who had no life-threatening illness before, and where there was some diagnostic doubt, the Coroner should have been informed. This could have been explained to the parents as a routine procedure and should not have been unduly traumatic for them. The only circumstances in which a child's death should not be reported to a Coroner is if there is already a firm diagnosis made that is known to be fatal. The General Paediatric Consultant, i.e.: Dr Steen should have made the report.

T19-12-12 Dr McFaul

T19-12-12P16L13-L24

(Q) Is what you are saying that the clinical lead should have been able, after Claire's death, to have in some way or other identified those failings?

(A) Well, I think it was -- and I have referred to it in my report -- the extent to which the clinicians recognised that this was a unexplained and unexpected death. This is were -- if it was unexplained, then clearly there would have been an incident raised. The profile of the event would have been higher and it would have been investigated, but it seems to me that the clinicians had come to the conclusion that this was a natural death.

T19-12-12P20L14-L19

Dr McFaul explains that a death from status epilepticus is not common.

(A) So it was an unusual event in and of its own, but I would have expected the forum, where, if you like, there's a cross-check quality control of the clinicians' conclusion to have been through the audit meetings at that time if they hadn't seen it as a major adverse event.

T19-12-12P30L23 to P31L16

(The Chairman) Doctor, can we look at Claire's case from a slightly different perspective? Let's suppose what you are talking about in the mid-1990 there is an audit process, but it should be more developed and perhaps a bit more sophisticated than it actually is, but even by the standards of the time, is there not a terrible lack of curiosity among the doctors about why Claire died?

(A) Yes. I mean, I think one would have to say that what is outstanding there is, in Claire's case, a lack of reflection upon -- for example, the death certificate showed "status epilepticus" and then they had later the information from the pathologist that it was meningoencephalitis, but I would --

(The Chairman) You don't need any developed or sophisticated governance structures to think -- surely that must have made people pause and think and really reconsider what went wrong in Claire's case.

8. Dr Steen failed to compile an accurate Autopsy Request Form (090-054-183).

Dr Steen gave misleading and incorrect information to the pathologist.

The autopsy request form completed by Dr Steen on 23 October 1996 failed to provide an accurate clinical summary to the pathologist for post mortem. The content of the autopsy request form is inaccurate and the format is biased and steered towards infection and a viral cause of death. It does not question or query a fluid management problem.

When Mr and Mrs Roberts had first sight of and read the autopsy request form (090-054-183) at the Coroners Inquest in 2006 they were deeply distressed by the content and format but recognised immediately that Dr Steen had outlined a guide and direction that she required the pathologist to take. Mr and Mrs Roberts believe the autopsy request form is another example of Dr Steen's manipulative attempts to cover up and conceal a fluid mismanagement problem.

The history of present illness states that Claire was well until 72 hours prior to admission which is **incorrect**. The first indication that Claire was unwell was the day of admission, Monday 21 October, on returning home from school.

The history of present illness states that Claire started to vomit 24 hours prior to admission which is **incorrect**. Claire did not vomit on Sunday the day before admission.

The history of present illness states that Claire had a contact with a cousin who had vomiting and diarrhoea and that Claire had a few loose stools which is **incorrect**. As stated on the hospital admission note (090-012-014) Claire had no diarrhoea.

The history of present illness states Claire's sodium level dropped to 121 and there was a query of inappropriate ADH secretion. The pathologist was not informed of the rapid fall in Claire's sodium level from 132mmol/L to 121mmol/L within 23 hours while receiving No18 hypotonic IV fluids.

The history of present illness states Claire's fluid's were restricted which is **incorrect**.

The history of present illness omits any reference to the administration of midazolam or the overdose of midazolam.

The past medical history states that Claire had seizures from 6 months to 4 years which is **incorrect**.

WS247/1-page 8-(11b) Dr Mirakhur

(Q) Explain what, if anything, you did, or if you cannot recall, what you likely/normally would have done, in 1996 and 1997 to ensure that any information or guidance from the clinicians relating to Claire's or any other case was accurate and impartial, particularly

where there may have been an issue over the conduct of the clinicians and their involvement in the child's death.

(A) Pathologists are entirely reliant on the information supplied by the clinicians as it is the clinicians who have looked after Claire. The pathologist is not involved in the patient care. The pathologist would not carry out an investigation to check if the information supplied by the clinicians is correct.

T05-12-12 Dr Squire

T05-12-12P107L10-L17

(The Chairman) And one of the themes of their evidence, both Dr Mirakhur and Dr Herron, was that in an ideal world they would be able to spend more time looking through medical notes and records, not just relying on the autopsy request form, but there weren't many days when they lived in the ideal world. Would that be consistent with your experience?

(A) I think so.

T05-12-12P108L2-L22

(The Chairman) Dr Herron said that the autopsy request form, which he received, was rather more detailed than the type of form that he very often receives, and certainly more detailed than one you'd receive for a coroner's post-mortem. Having seen the autopsy request form in Claire's case, would that be fuller than you would expect in your setting?

(A) Yes. I think he's absolutely right there. I very often get brains sent to me with perhaps a name, an age and "history of epilepsy" or something and I have to fight very hard to get clinicians -- these are often from hospitals outside, but I have to make quite an effort to get more information.

(The Chairman) Is it a paradoxical result of that possibly that when you get a fuller request form that normal, then that might lead you to focus more on what's in the request form, particularly if you're under pressure, than going back through the medical notes and records because someone has taken the trouble, whether perfectly or otherwise, to give you more information than you normally get?

T05-12-12P109L4-L10

(The Chairman) Right. But in this case it was within the same hospital and it was from a consultant paediatrician of some standing.

(A) I think he would very understandably rely on that form to do the autopsy. I would expect him to have the notes at a later stage to look at in more detail when he comes to formulating the final diagnosis.

9. Nursing Notes (090-040-138 to 141) and Nursing Care Plan (090-043-145/146)

A major omission within the nursing notes and the nursing care plan is any note or reference to encephalitis. This would be in line with Dr Webb's view that by 05:00pm on Tuesday 22 October he did not think that meningoencephalitis was likely but would not be in agreement with Dr Sands evidence that encephalitis was discussed during the ward round or that Dr Sands thought it likely that Claire was admitted with meningo-encephalitis (WS137/1 page 43 question 24a) or Dr Steen's evidence to the Coroner on 4

May 2006 that "our view was meningoencephalitis going to status epilepticus and then to cerebral oedema and this has not changed significantly since then" (096-014-102). The omission of encephalitis within the nursing notes and the nursing care plan on Tuesday 22 October again highlights the question regarding when Dr Sands added encephalitis/encephalopathy to the medical notes or if he discussed it with the nurses on the ward. It may therefore be unfair to criticise any nurse for not including encephalitis within the nursing notes or nursing care plan.

However, nurses have a duty of care to inform the doctor of a patient's condition and alert the doctor to any concerns they have. The nurses responsible for Claire's care failed to recognise the dangers of ongoing vomiting, nausea, electrolyte imbalance and the administration of No18 hypotonic IV fluids which continued for a duration of over twenty-eight hours. The nurses failed to adequately record or test Claire's urine output or its composition and were therefore unable to establish an accurate fluid balance. They failed to recognise and did not highlight that Claire had not passed any urine for around eight hours from the Tuesday morning through to Tuesday evening, an indication that Claire was retaining fluid. The nurses also failed to recognise the deterioration in Claire's clinical condition throughout Tuesday 22 October or raise any concerns with a doctor. Mr and Mrs Roberts understand that there were failures in Claire's nursing care but they are also aware and wish to emphasise that the nurses were directed and instructed by the doctors examining and treating Claire, specifically Dr Sands, Dr Webb and Dr Stevenson. Dr Sands' evidence is that there may have been a gap in understanding between himself and the nursing staff regarding Claire's clinical condition and as a result this may have led to a breakdown in communication between the nurses and Mr and Mrs Roberts. Mr and Mrs Roberts are particularly aggrieved at Dr Sands' evidence, explanations and attempts to justify and conceal his errors and failures.

10. Parenteral drugs prescription Sheet (090-026-075) (090-026-073)

Prescription sheet (090-026-075) states a drug's once only dose of midazolam 120mg and the entry is unsigned. This very distressing error was first identified on review of the medical notes by Mr Roberts in 2010 and is one of numerous errors the parents identified when reading Claire's medical notes. The failure by the RBHSC and the doctors responsible for Claire's care management to identify and investigate such errors will be a major concern for the Inquiry.

Dr McFaul 238-002-069 (330) The dose written up on prescription was a significant overdose with significant risk of respiratory depression. The failure to note this and the failure to identify this later in the clinical audit death review and later in 2004 is striking. Furthermore the consultants who were asked to review the case of Claire by the Coroner did not comment on it.

11. Meeting at RBHSC to discuss post-mortem report 3 March 1997

At a meeting on 3 March 1997 Dr Steen discussed the results of the post-mortem report with Mr and Mrs Roberts, advising them that a virus, known as an enterovirus, had caused

a build up of fluid around Claire's brain and that this virus was responsible for the brain swelling. The parents were not advised and no discussion took place about Claire's sodium levels, hyponatraemia or fluid management. Dr Steen advised and reassured the parents that Claire had received appropriate medical care and that everything possible had been done for Claire. The accuracy of the information given at this meeting by Dr Steen to Mr and Mrs Roberts raises serious issues regarding how the clinicians responsible for establishing an accurate cause of death combined their interpretation of the post mortem report with their clinical treatment to ensure a correct cause of death had been agreed.

Dr McFaul 238-002-059 para 279 In the circumstances given the clinical and autopsy conclusion, the sodium problem should have been highlighted as an issue with the parents at the time. And the clinicians should have appreciated that the low sodium could have been an iatrogenic complication given the existing knowledge in 1996 about SIADH in acute neurological conditions.

12. Dr Steen failed to provide accurate information to Dr McMillin (GP) Ref Letter from Dr Steen 6 March 1997 (090-002-002)

Dr Steen failed to identify hyponatraemia or a metabolic cause and the role it played in the cause of death to Claire's GP Dr McMillin .

Mr and Mrs Roberts were not aware of this letter from Dr Steen to Claire's GP Dr McMillin until after the PSNI investigation concluded and reports were made available in May 2009. Within the content of this letter Dr Steen described the post mortem results in a very definitive way as "Other changes were in keeping with a viral encephalomyelitis meningitis" and without any other reference to hyponatraemia or fluid management. This is another example of Dr Steen's manipulation, distortion of facts and attempt to conceal the truth.

T29-11-12 Dr Herron

T29-11-12P210L17 to P211L9

(Q) "Dr Steen informed my wife and I that the post-mortem had identified a viral infection in Claire's brain responsible for the brain swelling, but that the virus itself could not be identified. Dr Steen explained to my wife and I how an enterovirus starts in the stomach and can then spread to other parts of the body, as in Claire's case. She did not discuss Claire's sodium levels, hyponatraemia or fluid management". If that is what Dr Steen did in fact explain and discuss with the parents, how accurate a version of events is that, bearing in mind your own investigations on the pathology?

(A) I think the situation is more complex than a viral infection of the brain. As I said in my -- what I maybe understood what was going on with Claire was that, at the most, there was a very little infection of the brain, which wouldn't have explained her bad trajectory. So there must be other issues involved as well.

In comparison the autopsy report (090-003-003) states:

In summary the features here are those of cerebral oedema with neuronal migrational defect and a low grade subacute meningoencephalitis. No other discrete lesion has been

identified to explain epileptic seizures. The reaction in the meninges and cortex is suggestive of a viral aetiology, though some viral studies were negative during life and on post mortem CSF. With the clinical history of diarrhoea and vomiting, this is a possibility though a metabolic cause cannot be entirely excluded.

In a letter to the Coroner dated 3 February 2005 (097-003-004) Dr Herron stated the cerebral oedema (brain swelling) that was present may have many causes, one of which is hyponatraemia. The autopsy did not exclude this as a cause of the brain swelling nor did it show any specific findings (structural changes) to make the diagnosis of hyponatraemia.

T29-11-12P207L9-L17

(The Chairman) He wasn't being asked it, but he was being asked to comment, since he had some involvement in Claire's investigations after Claire died. He was being asked to express a view on how the letter, which your client wrote to the family GP, sits with the autopsy report.

(Mr Fortune) Well, I --

(The Chairman) And frankly, he has said it doesn't sit all that comfortably.

Professor Lucas 239-002-013 (11w) Drs Steen & Webb have over-interpreted the infection pathogenesis, compared with the original autopsy report comment, which was more cautious; so in that sense I do not agree with it.

13. Dr Steen failed to comply with the Royal Hospitals Clinical Audit processes

- a). Dr Steen failed to inform the paediatric clinical director Dr Hicks of Claire's death.
- b). Dr Steen failed to report Claire's death as a serious adverse incident (SAI).
- c). Dr Steen failed to carry out an adequate, independent or transparent mortality meeting with involvement and input from the doctors and nurses involved in Claire's care.
- d). Dr Steen failed to ensure that there was an adequate, independent and accurate outcome of the Clinical Audit review process.
- e). Dr Steen failed to learn any lessons following her review of Claire's death.

f) Adequacy, independence and outcome of mortality meetings.

T19-12-12 Dr McFaul

T19-12-12P34L16 to P35L5

(A) So a properly constituted mortality meeting should have been set up on Claire and in that meeting should have been Dr Steen, Dr Webb and Dr Sands and Dr Bartholome and, if they were available, the SHOs together with the pathologist. And it is in that debate that that issue about whether this mortality was consistent with the severity of the

histology. Without that debate, a clinician, knowing that a child has died from a brain illness, who gets a pathology report which gives them a natural cause, they wouldn't necessarily understand the fact that the pathologist didn't grade it as sufficiently bad unless there had been an active debate. Therefore, the omission of the properly constituted mortality meeting is a major flaw and a a major shortcoming.

T19-12-12P38L19 to P39L8

(A) There could have been two outcomes from that. One would have been: we have seriously mismanaged that child and we must report this upwards. The other would be to say: we have not managed her properly, let's do a guideline. You know, there are various outcomes, but it should then have appeared in the aggregated -- at the end of a period of time, if, in fact, it wasn't regarded as sufficient to say, "We must do something now", like report it to the clinical director or medical director as a serious adverse event which was justifiable -- I mean that's an argument -- or to the coroner, then there is a minimum one. This is the purpose of audit: we must try to improve in the future, how can we do that to avoid it happening again? That's a minimum. None of those things seem to have happened.

g). Adequacy, independence and outcome of Clinical Audit review.

Dr Taylor has advised the Inquiry that the death of every child was selected for presentation at the mortality meeting. However, there is very little evidence that Claire's case was ever presented at a mortality meeting or a clinical audit meeting. The only doctor with any recollection that Claire's case was presented for audit is Dr McKaigue. The Chairman has expressed his concern and questioned if such a review or audit ever took place because none of the other doctors involved in Claire's care have any recollection of being invited to or being present at a mortality meeting or review.

WS156-2 page 5 Q(22) Dr McKaigue.

(Q) Please specify all meeting, discussions, reviews and audits which took place touching on the death of Claire Roberts: identifying those who attended the meetings where such meetings took place and whether a note was taken of the same.

(A) Dr Steen presented Claire's death at the audit meeting in RBHSC (#3) at which I was present. I do not recall who else was present at that meeting, or the date of the meeting. I did not make a note of this meeting.

It is possible that Dr McKaigue may be mistaken. It is also possible that Dr Steen did present Claire's case at an audit meeting to comply with procedure but in keeping with Dr Steen's policy of decision making, transparency and review the other clinicians involved in Claire's care may not have received an invite.

It may have been Dr Steen's view that no discussion was required at the clinical audit meeting as her opinion is defined in WS143-1 page73 (45m) - At the time of Claire's death, it was felt the sequence of events leading to her death was known and there were **no areas of concern around her care.**

Dr Steen may have preferred to spend a short time presenting Claire's case without any input from the doctors directly involved in Claire's treatment, regard Claire's death as a clear cut case with just a tick in the box required for compliance.

WS138-1 page 100 (97a) Dr Webb.

(Q) Please specify all meeting, discussions, reviews and audits which took place touching on the death of Claire Roberts: identifying those who attended the meetings where such meetings took place and whether a note was taken of the same.

(A) I don't believe there was any medical or clinical audit of Claire's case in the time that I was at RBHSC.

WS137-3 page 5 (10) Dr Sands.

(Q) Please specify all meeting, discussions, reviews and audits which took place touching on the death of Claire Roberts: identifying those who attended the meetings where such meetings took place and whether a note was taken of the same.

(A) I am not aware of any such meetings in relation to Claire, until 2004.

WS157-2 page 6 (20) Dr Taylor.

(Q) Please specify all meeting, discussions, reviews and audits which took place touching on the death of Claire Roberts: identifying those who attended the meetings where such meetings took place and whether a note was taken of the same.

(A) I do not have any recollection of any meeting regarding Claire Roberts.

Dr McFaul 238-002-061 para 286 Comment. The extent to which the clinical team were aware that the death might be related to the treatment seems to be very limited. There is no real evidence of reflection upon the management of the case by the clinicians. Claire's death was listed amongst 4 deaths considered at the audit meeting in November 1996. The record of that meeting is blank in respect of the deaths in contrast with moderate detail about discussions of case note review and administrative matters which would have taken up a substantial portion of the allocated time for that meeting. A detailed scrutiny of Claire's notes should have generated discussion about the lack of referral to a consultant at 23:00 hours on 22 October, consideration given to the low sodium and its potential linkage to the fluids which were used and identified the potential overdose of midazolam.

Dr McFaul 238-002-066 (314) There is no evidence that the junior medical staff together with the nursing and senior staff involved had a meeting to talk through issues arising from the illness and death for their professional and personal development.

h). Adequacy, independence and outcome of Grand Round review.

There is evidence that Claire's case was presented at a Grand Round discussion by Dr Mirakhur. However, there is no evidence of any additional questioning of the post mortem findings or any concern by the clinicians present about the accuracy for the cause of death.

T29-11-12 Dr Herron

T29-11-12P198L20

(The Chairman) Do you see anything in Claire's case which makes you think that anything came out of the grand round to contribute to Claire's report?

(A) I haven't seen anything that has added -- it's 16 years ago and it was Dr Mirakhur

who, I think, took it to the grand round. It doesn't seem like anything has been added as a result of that. From a pathology point of view, I'm not sure.

(The Chairman) Assuming it went to the grand round, none of the 30 or 40 people who were there discussing Claire's case seem to have picked up from the discussion at the grand round any point which then led to the report being altered or added to before it was issued?

(A) It doesn't seem to have changed things.

Professor Lucas 239-002-009 (11f) This is the major issue in this case - the lack of clinical-pathological correlation after the autopsy and histopathology had been completed.

Professor Lucas 239-002-012 (11g) The pathologists - Dr Mirakhur at the time of initial reporting, and Dr Herron in retrospect - believe this to be present. I suspect they are wrong. But it can be difficult, and it did fit with some of the clinical concepts of Claire's disease at the time. So no one was going to contradict that. Perhaps had there been a mortality conference after the autopsy, a bright clinician might have asked "But is that enough inflammation/encephalitis to account for what happened?" - then the initial story would have unravelled and a focus on other causes such as hyponatraemia might have emerged.

It is noted that Dr Bartholome was aware of the Adam Strain Inquest in 1996 prior to Claire being admitted to the RBHSC [WS142/2 page 9 (Q13)] and that she has no recollection of an audit or mortality meeting into Claire's death.

Mr and Mrs Roberts would also highlight the failure by Dr Herron, Dr Steen, Dr Sands, Dr Webb and Mr Walby at the Coroners Inquest into Claire's death in 2006 to ask the same question as Professor Lucas "is that enough inflammation/encephalitis to account for what happened?".

14. Dr Mirakhur and Dr Herron failed to provide factual and accurate pathological evidence within the autopsy report.

a). Dr Mirakhur and Dr Herron failed to ensure that there was an adequate, independence and accurate outcome of the neuropathology Grand Round review.

It is a major concern that two pathologists from the Royal Hospital identified pathological findings to support the inaccurate autopsy request form compiled by Dr Steen. The Inquiry pathology experts Dr Harding, Dr Squire and Professor Lucas exclude and do not see any evidence from histological slides of meningoencephalitis or neuronal migration disorder.

b). Accuracy of the content of autopsy report - low grade sub acute meningoencephalitis and neuronal migration disorder or metabolic cause.

T05-12-12 Dr Squire

T05-12-12P60L16-L24

(A) Yes, indeed. So there could be infection in the meninges, which are the membranes surrounding the brain, or there can be infection in the brain tissue itself. One is

meningitis, one is encephalitis, and commonly one sees meningoencephalitis, a combination of the two.

(Q) And when you looked at the slides that Professor Harding saw, which were the ones prepared by the pathologists in Claire's case, did you see evidence of that?

(A) No, I didn't.

T05-12-12P52L7-L18

(Q) This is the point I wanted to bring you to: "...though a metabolic cause cannot be entirely excluded." Is that the pathologist trying to signal this might in some way be related to your problem of SIADH or inappropriate ADH, but we can't assist further, we're just putting it there for you to try and see the extent to which that is something that you yourselves should explore further?

(A) Yes, indeed. They're saying there's brain swelling, essentially, it could be infectious or it could be because of a metabolic disruption.

T05-12-12P53L2-L16

(The Chairman) Right. So that phrase, "though a metabolic cause cannot be entirely excluded", could that be inserted into every comment?

(A) I'm sorry

(The Chairman) Could that be inserted into nearly all brain-only autopsy reports?

(A) It could be, wherever you have brain swelling. We simply can't say--

(The Chairman) This may be just the nature of the beast, but I'm wondering, is it something which actually can give anybody a steer when they read the report?

(A) I think the sort of steer it's giving is that if there is a problem with serum sodium and abnormal ADH secretion, that this may have been a cause of the brain swelling, but we can't tell from the pathology.

T05-12-12P85L11-L19 (neuronal migration disorder).

(Q) This was thought to be quite subtle as well. Why does this not come down to a matter of judgement? Dr Mirakhur looks at it, she thinks she sees the cells in a position that she wouldn't expect to see them for a child of Claire's age. You look at it and say I think that's all perfectly normal. Does that not all amount to a matter of judgement?

(A) I think that this doesn't come anywhere near the basic criterion for diagnosing a neuronal migration disorder.

Dr Squire 236-004-002 52(a) I saw no evidence of encephalitis, meningo-encephalitis or meningitis

Dr Squire 236-004-009 58(i) There were cellular collections around one or two vessels which are illustrated in the submitted photographs. In my understanding, Dr Herron is referring here to what he considers to be a meningoencephalitis. I do not agree with this interpretation.

T05-12-12 Professor Harding

T05-12-12P141L3-L15

(The Chairman): Professor, can I put it to you this way: Dr Squier gave evidence earlier this afternoon, our time -- this morning, your time-- and she said looking at this particular

slide, that she did not interpret that slide to show neuronal migration disorder. She said it looked perfectly normal to her and, in fact, that there was nowhere near sufficient of a cluster for her to regard it as abnormal.

(A) Exactly.

(The Chairman) Do you agree with that?

(A) That's what I've been saying in terms, yes. And they are not mature enough. It's just no way a migration disorder.

T05-12-12P142L3-L25

(Q) This is one of the slides that Dr Herron and Dr Mirakhur relied upon as indicating evidence of some inflammatory response and therefore some evidence for encephalitis albeit that they considered it a low-grade sub-acute meningoencephalitis. But nonetheless, Dr Mirakhur was sure that they had seen something, it was just low grade. Dr Squier's evidence was that she didn't think that amounted to evidence of meningoencephalitis. Can you explain what you think is happening in that slide.

(A) There are a few excess cells in the perivascular space, which you do sometimes see. But there is not an infiltration of the tissue around it to suggest that there's an encephalitis. There are no clusters of inflammatory cells in the grey matter of the brain around it. There was not evidence of nerve cells being attacked by inflammatory cells, which you see in encephalitis and I like Dr Squier, did not consider that the number of cells that I saw in the meninges were sufficient to call it a meningitis either.

T05-12-12P144L7-L13

(Q) Although you say you would expect to see a much more florid reaction, is it nonetheless possible that this is actually evidence of just how the pathologists have described it: a low grade sub-acute meningoencephalitis?

(A) On the evidence of what I saw at the time I looked at it, I wouldn't agree that it's a low-grade meningoencephalitis. That's all I can say.

Professor Lucas 239-002-001 (4) The autopsy produced pathological positive and negative information, some almost certainly incorrect (encephalitis), that could be used in further clinico-pathological review of the case.

c). Dr Mirakhur and Dr Herron failed to accurately define the neuropathological findings in the autopsy report regarding the degree of low grade sub acute meningoencephalitis identified and the evidence for neuronal migration disorder.

d). Dr Steen, Dr Mirakhur and Dr Herron failed to ensure that a clinical and pathology consultation and review provided an accurate cause of death.

e). Dr Steen failed to establish an accurate and independent cause of death.

Dr Steen's "interpretation" of the post mortem report cannot be justified and raises serious issues about how an accurate and independent cause of death was established in 1996 and 1997 and how one doctor can control the process for identifying a cause of death. Dr Steen misused the post mortem report which was inconclusive and did not support a viral cause of death to conceal failures, errors and mistakes in Claire's clinical care

management. Dr Steen attempted to use the post mortem report in 1997 and at the Inquest in 2006 as supportive evidence for the untruthful explanations she gave to Mr and Mrs Roberts on 23 October 1996 regarding a viral cause of death and deflect from a fluid mismanagement issue. Dr Steen did not question or discuss the level of infection identified within the post mortem report, in fact she expanded and enhanced on the level of infection found by explaining to Mr and Mrs Roberts in March 1997 that a virus was responsible for Claire's brain swelling and also by informing the family GP in March 1997 of a viral encephalomyelitis meningitis. Mr and Mrs Roberts believe they have been misled, deceived and betrayed by Dr Steen.

WS143-3 page 11 (49j) Dr Steen.

(Q) What did you learn from the Autopsy Report that you did not already know? Did it assist you in identifying a cause of death?

(A) The Autopsy Report provided me with confirmation of the cause of death.

T18-12-12 Dr Steen

T18-12-12P36L23 to P37L19

(A) My reconstruction of the post mortem or understanding of the post-mortem results was there was inflammatory change and that there was a viral encephalitis. I know the experts have now discussed this and looked at it. I know there may be slightly different views, but my understanding going back and looking at what we did and how we acted was that we had felt there was inflammatory change in keeping with a viral encephalitis and, as such, I should have notified the register of death of a change in death certification.

(Q) Yes, it is one of the other, isn't it?

(A) Yes.

(Q) If you think that how you interpreted that report was that that virus -- that change, sub-acute inflammation, that that was sufficient to tell you that there was a presence of encephalitis, then the death certificate isn't quite right, is it?

(A) No

(Q) So then why didn't you change it?

(A) I don't remember. I don't think there was any specific reason why not. It just got missed in what needed to be done.

T18-12-12P70L11 to P71L9

(The Chairman) The only point I am trying to get to with Dr Steen is that the -- we are trying to get through this point as quickly as we can to move on to 2004 -- had there been a discussion along the lines you have talked about, Dr McKaigue has talked about, Professor Lucas has talked about, it is most likely it would have emerged at this conference or discussion that, in fact, encephalitis is not part of Claire's cause of death. Therefore we have to -- we have to discuss between ourselves what did actually cause her death. We have to reconsider referral to the coroner. We have to reconsider perhaps the death certificate. All of that can only be done if there's a discussion.

(A) Yes, and we've no evidence of the discussion.

(The Chairman) Yes.

(A) And, as you suggested yesterday, if there was a discussion, then it was totally ineffectual. So either the discussion didn't happen, or if it happened, it didn't actually go

into enough depth or interrogate the case to such an extent.

(The Chairman) So either it didn't happen, or if it did happen, it wasn't worth it because it did nothing -- nothing was learned despite the fact that there are clearly some things that could have emerged from it.

T05-12-12 Professor Harding

T05-12-12P160L17-L22

(Q) Yes. Then if you were commenting on the cause of death, is it your view, that on the evidence you saw, you can support neither the verdict on Inquest nor the death certificate?

(A) Well, from what I've said it sounds that that is true, yes.

T19-12-12 Dr McFaul

T19-12-12P16L7 to P17L12

(Q) If I can just pause you there at that stage: when you say you would have expected that to happen, given the sorts of things that you ever read about in terms of what people have conceded or accepted was deficient in Claire's treatment and care during her admission and the sort of categories of things that I just read out to you then, summarised to you there, is what you are saying that the clinical lead should have been able, after Claire's death, to have in some way or other identified those failings?

(A) Well, I think it was -- and I have referred to it in my report -- the extent to which the clinicians recognised that this was an unexplained and unexpected death. This is where - - if it was unexplained, then clearly there would have been an incident raised. The profile of the event would have been higher and it would have been investigated, but it seems to me that the clinicians had come to the conclusion that this was a natural death. The certification was flawed because it seemed to me that with Dr Steen sending a letter to the parents in November giving a leaflet about meningitis, that she had in her own mind come to the conclusion that this was a death from encephalitis; in other words, an infection.

(Q) Then if she forms that view, Dr MacFaul, are you saying because she is -- both she and Dr Webb, who are senior consultants dealing with Claire, if I can put it that way, if they form that view, does that stifle any overall review of Claire's case to enable the clinical lead to identify these sorts of deficiencies or failings?

(A) Well, I think it does.

Prof Neville 232-002-014 (xv) I am not sure how reliable post-mortem CSF cell counts are. There was not a gross excess of white cells and the post mortem did not show evidence of meningo-encephalitis. Thus I do not regard this as a well-supported conclusion.

Professor Lucas 239-002-014 Additional material, wrt the CSF analysis and Prof Keith Cartwright evidence.

I find it impossible to analyse coherently -- as has been indicated throughout the transcript - since it does not relate well to the actual brain morphology, which either shows no encephalitis or minimal encephalitis, and it does not show meningitis. Therefore I suspect the CSF results are artefactual and should be disregarded, since the

tissue pathology has to carry more weight in this scenario than CSF content numbers.

15. Dr Steen failed to provide honest and truthful information to Mr and Mrs Roberts at their meeting on 7 December 2004 at RBHSC (089-002-002)

a). **The minute for this meeting (089-002-002) contains several errors.**

The last paragraph states "Dr Steen stated that Claire's muscles were stiff and she was fitting". This is an incorrect statement and contrary to the ward round medical note (090-022-053) which states "no seizure activity observed" and contrary to Dr Sands impression of non-fitting status.

Other incorrect information given to the parents at this meeting is detailed within the report of Dr McFaul 238-002-074/075.

Mr and Mrs Roberts main area of concern at this meeting was to ask questions with regard to Claire's fluid management, fluid type and the amount of fluid given. They also discussed Claire's diagnosis, care management, fluid management, what Claire's sodium levels were and when blood tests were carried out on 21 to 23 October 1996. Doctor Steen outlined Claire's treatment and management and repeated the explanation she gave to the parents for Claire's death in 1996 and 1997, that an entrovirus caused the fluid build up and swelling of Claire's brain. Dr Steen did not deviate from the 1996 diagnosis and at no time indicated to the parents that there had been a fluid mismanagement or care management problem. Dr Steen stated at the meeting that it is very difficult to evaluate how much the IV fluids contributed to the situation. Mr and Mrs Roberts were not informed that blood tests should have been repeated sooner than they were or informed about an EEG or when a CT scan should have been done.

This is contrary to Dr Steen's written and oral evidence to the Coroner and this Inquiry.

T17-10-12 Dr Steen

T17-10-12P125L8-L17

(Q) But what did you see when you looked at the case in 2004?

(A) I can't tell what I saw other than what I have documented in 2004. But my understanding is that when we went back through, when I look at the documentation, we appreciated without a doubt the U&E should have been done sooner, and if the U&E had been done sooner, plus or minus an EEG, plus or minus a CT scan, her management would have been very different and the outcome would have been very different.

WS143-3 page 13 (Q63) Dr Steen

(Q) Did you learn any lessons from the death of Claire Roberts and with hindsight were lessons to be learned from it? If so, what were those lessons?

(A) I have no specific recollection of learning any lessons from the death of Claire Roberts at the time. However since November 2004 it has become obvious to me that there was/is a need for a comprehensive review of all aspects of care relating to Claire's management.

Dr Steen's evidence at the Inquest in 2006, two years later, stated the cerebral oedema was due to a viral infection and status epilepticus and that these neurological reasons gave rise to excess ADH production which led to fluid retention. Dr Steen did not inform

the Coroner that there had been a fluid mismanagement problem, that blood U&E should have been done sooner or that a comprehensive review was required.

The information about fluid mismanagement and blood tests Dr Steen gave to Mr and Mrs Roberts at their meeting on 7 December 2004 and her evidence to the Coroner in 2006 is also contrary to the evidence she gave to the Inquiry on 18 December 2012.

T18-12-12 Dr Steen

T18-12-12P91L18 to P92L9

(Q) Effectively they (Mr & Mrs Roberts) got the impression that you were wedded to your original view

(A) No. Once Professor Young reviewed the situation --I think you used the term "fluid mismanagement", which I think is a very good term to use for Claire's case, because we had been very sure we had given her maintenance fluids, what would be given normally to a child in this way, but, in fact, a lot of what this inquiry and the coroner's case have been about is how her fluids should have been managed because of her condition, how her U&E should have been repeated earlier. So the fifth-normal saline per se as the key issue. I don't think I put that top of the issue. What I put top of the issue was we didn't check her U&E. We didn't monitor her condition. We didn't repeat the levels and we didn't take actions early enough to make a difference.

T18-12-12P92L19 to P93L7

(Q) Did you understand that as being -- as the implication from what he was saying?

(A) I can't remember exactly where we got it from, but I know we clearly felt -- we looked and we saw here the U&E had been done. It had been done 27 hours I think after she had been admitted. Routine would have been 24 hours, but, in fact, because of her condition, it should have been done earlier. I don't think there was ever, once Professor Young had reviewed her notes from a fluid management perspective, there was any query that her **fluids had been mismanaged**. The proportion of how the fluid mismanagement had contributed to her overall condition, the slice of the pie, were where I think the discussion lay.

T18-12-12P93L18 to P94L4

(Q) Did you feel that, what you have just said now, that her fluids had been mismanaged, was something that could have been disclosed -- communicated to the family?

(A) I thought it had been communicated. I think Professor Young very clearly -- I mean, I took -- when it came to the fluid bit, the decision had been made Professor Young would do that bit, so that was his clear opinion as agreed with the Medical Director, and I thought Professor Young had indicated that.

(Q) **That the Fluid had been mismanaged?**

(A) Yes. You would have to show me the documents.

T18-12-12P99L4 to P99L14

~~(A) I think we did try to raise with the parents the issue that the fluids had changed. We were doing things differently, that things had been done wrongly at the time. If it was not conveyed by that, I apologise.~~

(The Chairman) Doctor, you certainly conveyed the fact that things had changed.

(A) Yes

(The Chairman) What was not stated was that things been done wrongly at the time.

(A) Yes.

Mr and Mrs Roberts are very concerned, angry and frustrated at the obvious inconsistencies and deception between what Dr Steen stated at their meeting on 7 December 2004 together with her response in a letter dated 12 January 2005 and the evidence Dr Steen gave at the Inquest in 2006 in comparison to Dr Steen's Inquiry evidence in 2012. In 2004, 2005 and 2006 Dr Steen, even with the advantage of hindsight and greater acquired knowledge, maintained a very defensive attitude to Claire's diagnosis, treatment and care management and did not highlight any clinical failures or care management issues.

b). Professor Young failed to provide an independent review of Claire's clinical treatment in 2004.

c). Professor Young failed to limit the extent of his review to Claire's fluid management and expressed an opinion and supported Dr Steen's viral encephalitis diagnosis.

At a meeting on 7 December 2004 Professor Young stated that he had been asked by the RBHSC to provide an independent review of Claire's fluid management. The level of independence Professor Young provided to Mr and Mrs Roberts is very questionable. The parents understanding in 2004 was that Professor Young was a professor from Queens University who would review and provide an independent report on the fluid management Claire received. Mr and Mrs Roberts were shocked when they received the Inquiry files No139 and No140 and reviewed the contents with regard to Professor Young's internal communications with the doctors involved in Claire's care and the Royal Hospitals litigation manager Mr Walby. The paperwork of the solicitors representing the Trust is headed Claire Roberts (deceased) V Royal Group of Hospitals. Professor Young is included in numerous correspondence, involved in meetings with the Trust solicitor and involved in offering advise to Mr Walby of the Royal Hospitals Litigation Management Office from December 2004 through to the preparation for the Inquest in May 2006.

The pre Inquest consultation between the Trust solicitors Brangam Bagnall & Co and Professor Young (140-061-001/006) dated 07/04/2006 states:

"Bld (blood) test every 24 hrs - in this case bld test 25 hours. Does not think this 1 hr delay caused any probs - had any significance".

This was the approach taken by the hospital before and during the Inquest in May 2006 and is contrary to Dr Steen's and Mr Walby's Inquiry evidence that the failure to repeat the blood test sooner was identified at the Inquest.

"Hyponatraemia caused by enc-----".

~~Professor Young's Inquest evidence in May 2006 on the formulation for cause of death was meningoencephalitis. Professor Young stated that this was clearly present at autopsy (140-043-003).~~

"If recognised the Na low on admission - possible to alter fluid management and avoid

hyponatraemia - impossible to say what would have been the outcome - would have been different".

"Speak to Dr Webb - why did he write Na norm when 132!"

"132-121 w/i 24hrs - leads to swelling of the brain !!"

"Could have an experts who say hypo primary cause of death and encephalopathy".

"Dr Webb letter "low grade infection" to family 28/2/97. Why".

"This is not the same as the other cases as this child did not start with a normal brain".

"Hyponatraemia not mentioned on death cert but expressly mentioned in the referral to the pathologist".

"What/why bld test delay to 25hrs - Was it an after thought".

Mr and Mrs Roberts believe that on the evidence of file No139 and file No140 Professor Young did not provide an independent opinion or carry out an independent review of Claire's fluid management and that he was simply an additional member of the Royal Hospitals "team", set up to defend and attempt to justify the shocking, inadequate and inappropriate care management Claire received. Had an independent report been made available the parents and the Coroner would then have been appropriately informed.

Professor Young's latest witness statement to the Inquiry WS178-6 is an attempt by Professor Young to provide some form of justification for his failure in 2004 to identify the primary role of IV fluid management and how it was responsible for Claire's clinical condition. In this statement Professor Young also attempts to justify his belief in 2004 that the failure to do a blood test on the Tuesday morning or early afternoon did not constitute mismanagement. Professor Young also attempts to defend his position in relation to Dr Steen's Inquiry evidence of the 18 December 2012 regarding their acceptance of fluid mismanagement in 2004.

Dr McFaul 238-002-074 (351)(352) This was appropriate for a quick review to determine whether the low sodium level was significant in Claire's illness but in my view, a written report should have been obtained given both the publicity and the circumstances of Claire's death in respect of hyponatraemia, from an independent consultant paediatric neurologist or a consultant paediatrician with expertise in management of acute encephalopathy.

The report should have been available to the meeting held with parents and ideally the independent expert should have been present at the meeting. Instead as well as being attended by Dr Steen and Dr Sands, Prof Young attended and stated that he was offering an independent view.

Mr and Mrs Roberts were not aware of Claire's hyponatraemia or low sodium until the meeting on 7 December 2004. It was during this meeting that they learned for the first time that Claire's sodium level on 21 October 1996 was 132mmol/L which then dropped to 121mmol/L on the 22 October 1996 and that the fluid type administered to Claire was hypotonic-IV-0.18%-NaCl.

At the meeting on 7 December 2004 (089-002-005) Dr Sands stated "that it would have helped if medical staff had spoken to Mr and Mrs Roberts before they left at 9:30pm". However, Dr Sands failed to speak to Mrs Roberts at 05:30pm before he left the hospital.

The only doctors to see Claire between 05:30pm and 03:00am on the Wednesday morning were two SHO's Dr Hughes and Dr Stewart and neither doctor examined Claire. Dr Hughes simply administered anti-biotics at 05:30pm and antiviral medication at 09:30pm. Dr Stewart erected IV phenytoin at 11:00pm and recorded the blood test result at 11:30pm.

Mr and Mrs Roberts raised concerns in December 2004 about the number and type of drugs administered to Claire on Tuesday 22 October 1996, what the compound effect of the drugs would be and how they would interact. The reply from Dr Steen and the RBHSC was that Claire's medication was very important and was aimed at controlling her seizures. Without this medication, her condition could have deteriorated more rapidly. There was a failure by Dr Steen, Dr Sands and Professor Young to carry out an appropriate, independent and transparent review and analysis of Claire's medical notes in December 2004 and they therefore failed to identify and highlight the medication overdoses and errors within the medical records and prescription sheets.

At the meeting on 7 December 2004 Dr Steen informed Mr and Mrs Roberts that medicine had moved on in the previous ten years. Dr Steen advised that new procedures were in place at the RBHSC and they should consider what would be gained by taking Claire's case further. Professor Young explained that lessons had been learned at the RBHSC. Following the meeting Mr and Mrs Roberts perception of the discussions and the responses given by Dr Steen was an attempt to dissuade them from taking Claire's case any further. Mr and Mrs Roberts now have a clearer understanding of why Dr Steen, Dr Sands, Professor Young and the RBHSC adopted that approach. It is clearly evident from the documentation, investigations and reports circulating the Royal Hospitals Litigation Office in 2003 and 2004 into the deaths of Adam Strain, Lucy Crawford, Raychel Ferguson and Conor Mitchell that the RBHSC did not want another damaging case of fluid mismanagement and dilutional hyponatraemia. The meeting identified obvious areas of concern and shortcomings in Claire's treatment and fluid management. Mr and Mrs Roberts compiled a series of questions on the 8 December 2004 and emailed that document to Dr N Rooney (089-003).

T19-12-12 Dr McFaul

T19-12-12P40L21 to P41L1

(A) If they had done as I have suggested, get an external expert, then I think a number of things would have come out from that: one, the midazolam dose; two, the fluid mismanagement by the standards of 1996 and 2004, which didn't differ. They could have done a root cause analysis, but a root cause analysis -- and this is my personal view -- is basically structured common sense. That's all it is. Structured common sense would have come up with what had happened, how it happened, and why?

T19-12-12P44L1-L10

(A) It is not entirely evident to me from reading the correspondence between Dr Rooney and the parents that Professor Young had fully grasped the lack of -- let's put it this way -- the gap between what should have been done in the management of an acute encephalopathy in a child specifically and what was done. I took the view that it would

have -- that gap would have become more clear if they had got a paediatric neurologist to do what Professor Young had been asked to do.

Dr McFaul's suggestion that the RBHSC should have obtained an external expert in 2004 is supported by the fact that Dr Steen, Dr Sands and Dr Webb defended their diagnosis and care management plan at the Coroner's Inquest in 2006. Mr Walby noted that this Inquest ended on 4 May 2006 with **no criticism** of the Trust's care of this patient.

16. Dr Steen failed to provide honest and truthful answers to Mr and Mrs Roberts Ref Letter from RBHSC Dr Rooney to Mr & Mrs Roberts 12 January 2005 (089-006-012)

a). Response by Dr Steen and Professor Young to the questions raised by Mr and Mrs Roberts on the 8 December 2004.

This letter is another example of Dr Steen's unyielding stance on Claire's diagnosis and care management in 1996 and her continued defence of that management in 2005. The answers to Mr and Mrs Roberts questions by Dr Steen in 2005 are inconsistent with and contrary to Dr Steen's Inquiry evidence of 18 December 2012.

The letter states:

- i) Claire's symptoms were attributed to encephalitis, which was confirmed at post mortem.
- ii) Claire's condition was not under-estimated as she was considered to be very unwell, with a diagnosis of non-convulsive status epilepticus and encephalitis-encephalopathy. Claire consequently received intensive medical intervention.
- iii) However in 1996, before there was such extensive knowledge about hyponatraemia, it would have been normal practice to monitor sodium level every twenty-four hours.
- iv) Claire's medication was very important and was aimed at controlling her seizures. Without this medication, her condition could have deteriorated more rapidly.
- v) It is not possible to say whether a change in the amount and type of fluids would have made any difference in Claire's case as she was very ill for other reasons.
- vi) The paediatric registrar co-ordinated the subsequent treatment. The correct action was taken.
- vii) Hyponatraemia was not thought at the time to be a major contributor to Claire's condition.
- viii) The full post mortem report states in relation to cerebral oedema that a metabolic cause can not be entirely excluded.
- ix) The Coroner had not been informed at the time as it was believed that the cause of Claire's death was viral encephalitis.

T19-12-12 Dr McFaul

T19-12-12P40L9-L17

(A) Set aside the coroner's inquest, there was evidence here of -- well, I am not sure it was fully grasped from what I have seen of what was given in the written communications which were done by Dr Rooney on behalf of the Trust. It is not her responsibility. She was conveying, she was a conduit. But from what was in that

correspondence, it wasn't absolutely clear to me that they had fully understood that Claire had not been managed properly.

b). Dr Steen and the RBHSC medical director Dr McBride failed to carry out an investigation into Claire's care management in 2004/2005.

Dr Steen and the RBHSC medical director Dr McBride adopted a wait and see policy rather than a pro-active internal review and external investigation into Claire's death in 2004/2005. Openness and transparency was then replaced with a defensive approach with preparations made by Mr Walby and the Royal Hospitals litigation office for the defence and justification of the actions of Dr Steen, Dr Sands and Dr Webb at a Coroners Inquest. It is a major concern that an email dated 15 December 2004 from the medical director Dr McBride to the litigation manager Mr Walby states "At the meeting on my recommendation we clearly indicated that following our case note review and the expert opinion of Prof Young and others that we were significantly confident that their daughters **fluid management was a contributory factor to her death** amongst the many others involved".(WS177-1 page 45).

T19-12-12P42L6-L17

(Q) Dr McFaul, what Dr McBride, who was the medical director in 2004, when the case came back to the Trust, would say, "Yes, we could have done that, but what, in fact, we had done was we had referred that to the coroner and the coroner was going to conduct an investigation and appoint his own experts. And, not only that, if it hadn't already happened, there was a very great possibility that the PSNI would have been involved and if we had started doing that sort of thing and carrying out that kind of internal investigation, then there was a risk that we might compromise those investigations. So since they are already looking at it, we thought it better to await the outcome of those investigations.

17. Dr Steen, Dr Sands, Dr Webb, Professor Young and the RBHSC failed to provide honest, truthful and complete depositions to the Coroner and provide honest, truthful and complete oral evidence at the Inquest on 4 May 2006

a). Dr Steen, Dr Sands, Dr Webb, Professor Young and the RBHSC Inquest evidence.

Before the Coroners Inquest the RBHSC (Professor Young, Dr Steen, Dr Sands and Mr Walby) were made aware of Dr Webb's erroneous understanding that Claire's urea and electrolytes had been checked on the morning of Tuesday 22 October 1996 and recognised this as a substantial issue which could become significant at the Inquest (139-042-001). This email dated 07 April 2004 states "Dr Webb also draws attention to the **failure** to take an electrolyte sample on the morning following Claire's admission, which he states was routine practice. In addition he states that he believed at the time that such a sample had been taken, and that if he had been aware that the sodium of 132 had been taken the previous evening that he would have requested an urgent repeat". This email was preparation for the forthcoming Inquest.

Dr Webb's erroneous understanding regarding Claire's sodium reading was also identified as a major issue by the Trust solicitor and counsel prior to the Inquest in a note dated 24 April 2004. (140-046-001).

However, this fundamental error was not highlighted to the Coroner during oral evidence or emphasised as a critical failure by any witness.

Dr Webb's evidence to the Coroner was "true to say - did not consider Na (sodium). Did consider it but low Na132 would not cause her symptoms".

Dr Webb was asked at the Inquest "Is it likely that next am [her] Na [would] fall?"

Dr Webb stated "Do not know".

Dr Webb was asked at the Inquest "Would she have been treated differently?"

Dr Webb stated "Yes by the medical team. But do not know rate of Na fall. But we do encephalitis". (140-045-009)

Professor Young was asked at the Inquest "According to Dr Webb had a blood sample been taken on the morning (22-10-96) it might have shown a low sodium".

Professor Young stated "it's not possible to say. The fall from 132 to 121 might have been gradual in time" (096-014-092).

Professor Young was asked at the Inquest about "Good clinical practice to take blood 1st thing in the morning"

Professor Young stated "At least once a day, usually taken in childrens hospital in afternoon" (140-043-007).

Dr Sands stated at the Inquest "an urgent sample (U&E) was not requested (urgently) but it is likely that it was requested for sometime that day". (096-014-095)

Dr Steen was not questioned or asked about Dr Webb's erroneous understanding during her oral evidence to the Coroner.

The Coroners verdict states "I accept the evidence of Dr Heather Steen, Consultant Paediatrician, that the first blood test showing a serum sodium level of 121mmol/L [11:30pm Tuesday 22 October] should have led to a clinical re-assessment of Claire". (091-002-003)

The defensive, evasive and restrictive approach taken by Dr Webb, Professor Young, Dr Sands and Dr Steen at the Inquest in 2006 regarding the most critical and fundamental failure in Claire's clinical care management, not to do a blood test first thing on the Tuesday morning 22 October, highlights their collective attempts to retain crucial knowledge and withhold important information from the Coroner. This serious failure by Dr Webb, Professor Young, Dr Sands, Dr Steen, Mr Walby and the RBHSC to provide open, transparent and truthful information to the Coroner is contrary to Mr Walby's view that after the Inquest the failure to do a blood test on the Tuesday morning was accepted and acknowledged by the Trust.

Doctor Steen also attempted to suggest during Dr Webb's Inquest evidence and before giving her own evidence to the Coroner that the blood test sodium result of 121mmol/L at

11:30pm on 22 October 1996 could have been contaminated in an attempt to dismiss the severe fall in Claire's sodium levels.

It was during Dr Webb's oral evidence on 28 April 2006 that a second sodium result of 121mmol/L at 03:00am on 23 October was identified as being recorded by Dr Steen within the medical notes (090-022-057) and to which Dr Webb stated he had no knowledge of. (139-034-001).

This major issue was brought to the attention of Professor Young, Dr Steen and Dr Sands before their oral evidence on 4 May 2006 by Mr Walby following a letter dated 03 May 2006 from Mr Daly for Brangam and Bagnall to Mr Walby (139-164-001). It is noted that Professor Young, Dr Steen and Dr Sands failed to identify the second sodium result of 121mmol/L at 03:00am on 23 October within their depositions to the Coroner.

The letter from Mr Daly to Mr Walby (139-164-002) also states "It remains possible that the death of Claire Roberts will be referred to Mr O'Hara's Public Inquiry. This death does not appear to fit within the terms of reference of that Inquiry and Counsel Mr Michael Lavery BL, will make this point to the Coroner in due course".

Dr Herron at the Coroner's Inquest in May 2006 stated that he would have expected a higher level of infection in a death attributed to meningoencephalitis.

Dr Steen was asked by the Coroner : Why Dr Steen do you think she died?

Dr Steen stated "I assumed cerebral oedema due to viral infection and status epilepticus and that those neurological reasons gave rise to excess ADH production which led to fluid retention" (096-014-099).

Dr Steen was also asked at the Inquest about a letter from Dr McBride to Mr and Mrs Roberts which stated "Our medical case notes (review) may have shown a care problem relating to hyponatraemia in Claire's case". Do you accept that view?

Dr Steen stated "Our view was meningo-encephalitis going to status epilepticus and then cerebral oedema and **this has not changed significantly since then** (096-014-102).

In 2006 Dr Steen was still defending and defining viral meningo-encephalitis as the primary cause of death. This was another example of Dr Steen's determination to defend and not deviate from her position in 1996 and was a missed opportunity to establish the truth.

WS178-6 page 8 Professor Young

In 2004, I was unsure whether removing the contribution of the hyponatraemia would have made any difference to Claire's outcome. This would have depended on the severity and significance of the status epilepticus and viral encephalitis, which I was **not in a position to judge**. This explains the wording which I provided, and my recommendation that the case go to the Coroner where I anticipated that independent experts in these conditions would give an opinion.

Unfortunately Professor Young did not limit his evidence to the Coroner in 2006 to hyponatraemia and fluid management. The Coroner decided to base his verdict on Professor Young's evidence and draft MCCD formulation of meningoencephalitis (according to Professor Young this was clearly present at autopsy 140-043-003), hyponatraemia due to excess ADH production and status epilepticus.

Professor Young also stated at the Inquest that Claire's clinical manifestations were more in keeping with encephalitis and various other causes and the focus in Claire's case was meningoencephalitis and status epilepticus (140-043-006).

T05-12-12 Dr Squire

T05-12-12P97L24 to P98L2

(Q) But when it comes to the verdict on Inquest, because there is a specific reference to something that you are able to see and address in the pathology, you don't accept the meningoencephalitis?

(A) That's correct.

T25-06-13 HMC Mr Leckey

T25-06-13P106L15 to P107L3

(Q) And then finally, that the histological evidence of meningoencephalitis, which formed an important part of the conclusion as to her cause of death, that that actual histological evidence was so minimal as to be capable of being discounted. The concern that the family have is that this is something that the clinicians should have known and appreciated in 2004 and yet, when it comes to 2006, they're concerned that you are not being provided either with that information then or certainly not being provided as soon as the clinicians formed that view, which on the way that we have been discussing their duty to report to you, one would have thought would have generated a requirement to notify you much sooner of their own volition.

(A) I agree.

The Coroners Inquest concluded on 4 May 2006 with Mr Walby advising that there was **no adverse criticism** of the RBHSC (139-027-001). As a result of the inaccurate and untruthful evidence given during the Inquest by Dr Steen, Dr Sands, Dr Webb, Professor Young and the stance taken by the RBHSC litigation manager Mr Walby another statutory body had failed Claire, failed her parents and failed to identify the errors and mistakes in Claire's care management, diagnosis and treatment. Mr Leckey, HM Coroner, at the time, did state that he can only base his verdict on the accuracy of the information available to him at the time. The accuracy of the information and evidence given by Dr Steen, Dr Webb, Dr Sands and Professor Young at the Inquest into Claire's death raises serious concerns about how a truthful, accurate and independent cause of death was established.

Following the Coroners Inquest a letter from Mr Walby to Mr Daly the Trust solicitor dated 16 June 2006 (139-159-001) states "Evidence given at the Inquest was **not critical of the fluid management**".

The Trust solicitor wrote to the Coroner on the 4 July 2006 (140-012-001) stating "Our clients are of the view that evidence given at the Inquest was not critical of the fluid management".

It is also noted that Dr Steen's evidence to the Coroner stated that Claire's fluid management was "normal" and that there was "no issue of fluid management at that time" (140-043-001).

Contrary to the above is the evidence given by Dr Steen to the Inquiry.

T17-10-12 Dr Steen

T17-10-12P143L15-18

(A) I think the minute we looked back at the case in 2004, in light of what we knew by 2004, it became very obvious that **fluid mismanagement** was a contributory factor to her underlying condition.

Fluid mismanagement was not defined during the RBHSC meeting with Mr and Mrs Roberts on the 7 December 2004, within the RBHSC letter dated 12 January 2005, at the Inquest in 2006, within the Coroners verdict or communicated to Mr and Mrs Roberts at any time and is contrary to Dr Steen's Inquiry evidence of the 17 and 18 December 2012.

The Inquiry has asked Dr Steen several questions with regard to when a blood test should have been done on Tuesday 22 October. This was obviously one of the major failings in Claire's clinical care management. However, it is a failure that Dr Steen must have been aware of in 1996 but one she has attempted to cover up, defend and justify for 16 years and now states that on reflection she has a different view.

WS143-1 page 22 Q23(f) Dr Steen.

(Q) State whether a further blood sample ought to have been taken from Claire on 22 October 1996 to carry out another electrolyte test. If so, explain why and when and also identify who should have taken that sample. If not explain why not.

WS143-1 page 39 Q29(g) Dr Steen.

(Q) State whether the clinicians ought to have considered checking Claire's electrolytes by 17.00 on 22 October 1996.

Dr Steen's reply to both questions:

(A) As a witness of fact at this Inquiry and not an expert witness, I am prepared to give a factual evidence about my involvement in the treatment of the Deceased and, where appropriate, to interpret and explain entries in the Notes and Records. As a witness of fact, I do not consider it appropriate for me to comment on, to explain, to justify or to criticise the acts or omissions of other clinicians or members of the nursing staff involved in the care of the Deceased.

Ref WS143-1 page 68 Q40(e) Dr Steen.

(Q) State whether a "close check on serum Na and serum osmolality and urine output" ought to have been carried out on Claire's admission to Allen Ward and thereafter. If so, state when. Explain why/not.

(A) As stated previously in 1996 it would have been normal practice to monitor the serum U&E of a patient on IV fluids every 24 hours. However in light of Claire's deterioration on the afternoon of 22 October 1996, it would have been better to repeat the U&E earlier.

This answer by Dr Steen is contrary to the information given to Mr and Mrs Roberts in December 2004 (096-018-112 Q3b) which states "as already explained, common practice in 1996 would have been to monitor sodium level approximately every twenty four hours. It is also inconsistent with Dr Steen's evidence to the Coroner in 2006.

WS143-1 page 108 (88e) Dr Steen.

(Q) If "[Claire's serum sodium concentration of 132mmol/L on 21 October 1996]" was "an early indicator" of hyponatraemia, state at what time intervention including "a change

in the amount and type of fluids" would likely have made any difference and explain the reasons for your answer.

(A) I feel on reflection, Claire's U&E should have been repeated before 5pm on Tuesday the 22 October 1996.

Dr Steen states on reflection a blood test should have been repeated before 5pm.

Dr Steen's Inquiry evidence on T18-10-12P91L25 to P92L4 stated:

In fact, a lot of what this Inquiry and the coroner's case have been about is how her fluids should have been managed because of her condition, how her **U&E should have been repeated earlier**.

However, Dr Steen's evidence at the Inquest in 2006 was that at 23:30 the bloods U&E should have been repeated. Not before 5pm, as she has stated in evidence to the Inquiry.

T12-12-12 Mr Walby

T12-12-12P108L21 to P109L12

(The Chairman) And your evidence yesterday, Mr Walby, was simply on the failure to repeat the blood test, that that would be enough for the Trust to be advised to settle a medical negligence claim.

(A) Yes.

(The Chairman) You see, the contrast here is between the information given to the Roberts in 2005, I think this letter is, and what you said yesterday.

(A) But what I said yesterday was with the benefit of all my knowledge at the **end of an Inquest**. I mean, I fully accept that the doctors, the paediatricians, would have been monitoring electrolytes once a day in children where there wasn't any specific reason to do it more often. I think we've heard evidence that indeed there was reason to be doing it more often. And that will have been the basis of -- was the basis of my answer yesterday, that a claim would have been settled.

T12-12-12P109L23 to P110L5

(The Chairman) In terms of internal audit or lessons learned? I know we're jumping around a bit on this, but do you see that point?

(A) Yes, and I did say that the normal sequence of events, which would occur following an Inquest, didn't happen in her case because there was knowledge by most parts of the Trust about this issue. The medical director knew about it and therefore it wasn't taken any further.

T12-12-12P176L14 to P177L3

(Mr Quinn) That's not the point, Mr Walby, about whether or not the coroner criticises the trust. It's what you do in relation to what's on your mind. You're writing in one e-mail that there was no criticism by the coroner of the Trust, yet you know the Trust are at fault. So how does that sit together?

(A) They're different things.

(Mr Quinn) In your mind.

(The Chairman) Are you suggesting that: well, thankfully there was no criticism of the Trust, even though any medical negligence case is open and shut?

(A) That indeed was the case, but on the other hand that's... That's just a factual statement of what occurred.

(Mr Quinn) I take it no further, sir.

This evidence is contrary to Mr Walby's email dated 5 May 2006 (139-161-001) to Pauline Webb which states "This Inquest ended on 4 May 2006 with **no criticism of the Trust's care of this patient**". "I spoke to Mr Roberts at the end of the Inquest and advised him that **if he still had concerns** he should write to the Chief Executive".

A letter from Mr Walby to Brangam Bagnall dated 16 June 2006 (139-159-001) states "The issue is that if the Verdict were allowed to stand and disseminated as it is, it will encourage Mr O'Hara to include the case in his Public Inquiry, and probably encourage the Roberts family to embark on a clinical negligence claim. I believe we should **do all we can to avoid these outcomes**".

The letter from Mr Walby to Brangam Bagnall dated 16 June 2006 (139-159-001) also states "**Evidence given at the Inquest was not critical of the fluid management**".

Mr and Mrs Roberts have found this section of evidence by the Royal Group of Hospitals Associate Medical Director and Litigation Manager Mr Walby to be quite pathetic and insulting but it once again highlights Mr Walby's defensive and damage limitation approach rather than providing Claire's parents with open and honest answers. It is very difficult to correlate the evidence Mr Walby has given to the Inquiry in comparison to his approach and written responses before, during and after the Coroners Inquest.

The Inquiry will note that Mr Walby's evidence is also contrary to Dr Steen's evidence of 18 December 2012 (T18-10-12P91L20 to P92L9), that in 2004 she believed fluid mismanagement had been identified and communicated to the parents.

Notification of Claire's Inquest was reported to the Department on a Serious Adverse Incident report, SAI 1-3-06 dated 28 March 2006 (302-164-003). It is a major concern that five years after the Department published a consultation paper Best Practice Best Care in April 2001 to promote a culture of openness and four years after the publication of the hyponatraemia guidelines in 2002, fluid mismanagement and hyponatraemia in Claire's case was not recognised or openly accepted or made transparent by the Royal Belfast Hospital and the DHSSPS.

Mr and Mrs Roberts also listened with frustration to the Inquiry oral evidence of Mr Walby and noted his incorrect and confused but not surprising attempt to continue to deflect from a situation where fluid mismanagement and an excess volume of No18 hypotonic IV fluid was responsible for Claire's cerebral oedema. It would appear even at this late stage that the Royal Group of Hospitals Associate Medical Director and Litigation Manager is referring to Professor Young's evidence on the 10 December 2012 regarding euvolemic hyponatraemia and attempting to defend the serious impact that No18 hypotonic IV fluid had on Claire's cerebral oedema, brain swelling and death. ~~Claire's case is one of hypovolemic hypotonic-hyponatraemia and does not fall into a case of euvolemic hyponatraemia.~~ Once again Mr Walby has failed to accurately represent the key learning point about dilutional hyponatraemia. It is the **type** of fluid administered, the duration of that administration and the rate in which the sodium level falls secondary to

the volume of fluid given. How are lessons to be learned when in 2012 Mr Walby is still trying to defend the indefensible.

T12-12-12P168L2-L17 Mr Walby.

(A) I felt that if all Mr O'Hara got was the verdict on Claire Roberts, that he might add it to the Inquiry on the basis of it being a -- as we heard Professor Young refer to it as, and I hadn't heard this -- this hypernatraemic as opposed to euvolemic. Euvolemic hyponatraemia. I hadn't really taken on board that there were three types of hyponatraemia -- hypervolemic, euvolemic and hypovolemic -- and that this case was falling into the case of euvolemic hyponatraemia. And I suspect, Mr Chairman, at that stage that you weren't aware your inquiry would be moving into an area to deal with other than the situation where far too much fifth-normal saline had been given to a child. And that is the basis of me wanting to make sure that the verdict properly reflected that, that there had been a reduction of the ...

It would appear that Mr Walby has failed to accept or understand a fundamental definition in the 1992 Arieff report 'It is important to recognise that in children when there is substantial extrarenal loss of electrolytes a minimal positive balance of hypotonic fluid can lead to fatal hyponatraemia'.

Mr Walby was also aware of Dr Webb's concerns about admitting Claire to PICU (139-096-001) (139-098-021). This information was withheld at the Inquest and only became available to Mr and Mrs Roberts through the disclosure of Inquiry file 139 and the various "amendments" Mr Walby suggested Dr Webb should make to his deposition. If the consultant neurologist responsible for providing an input into Claire's care management believed he made a mistake regarding admission to PICU that information should not have been withheld from Mr and Mrs Roberts or the Coroner.

Mr and Mrs Roberts view Mr Walby's alterations and amendments to the deposition of Dr Webb as another example of manipulative tampering that highlights a defensive and protective action by the Trust and Royal Belfast Hospital for Sick Children and a wilful attempt to mislead and conceal information from the Coroner. This unwillingness by Mr Walby to be open and transparent is an issue of great concern, considering that Dr Webb has not changed his view regarding his mistake not to consider admitting Claire to PICU at 17:00 on Tuesday 22 October.

T12-12-12 Mr Walby

T12-12-12P132L7-L17

(Q) There, Dr Webb had written: "I made the mistake of not seeking an intensive care placement for Claire before I left the hospital." And you have put a line through that and written in: "Although I did not seek ..." It seems as though Dr Webb was making an acceptance or an admission of error there and you thought that was inappropriate and decided to excise it. Can you explain why that was?

(A) Well, "decided to excise it" it not the way I would put it.

T12-12-12P137L22 to P138L5

(Q) Dr Webb has told this Inquiry that he still believes that he made a mistake in not seeking a placement for Claire that afternoon in PICU. In other words, he was trying in his statement to be transparent and honest, and you were trying to stop that information

getting through and to shield the Trust from any criticism, even self-criticism..

(A) Well, I wouldn't accept that.

WS138-1 page 73 (53d) Dr Webb.

(Q) State whether after 17:00 on 22 October 1996 you considered and/or took any steps to discuss Claire with a PICU Consultant who could have assessed Claire on Allen Ward and given advice, whilst also being pre-warned about a possible later admission. If so, state when you considered this and what steps you took to do so. If you neither considered this nor took any steps, explain why not.

(A) I do not believe I took any steps to discuss Claire with a PICU Consultant after 17:00 on 22 Oct 1996 and in hindsight I believe this was a mistake.

WS138-2 page 23 (42) Dr Webb.

(A) I have acknowledged in my previous statement that I think, with hindsight, it was a mistake not to have taken any steps to discuss Claire's case with a PICU Consultant after 17:00 on 22 October 1996 and this is a mistake I will always regret.

T25-06-13 HMC Mr Leckey

T25-06-13P98L15 to P99L8

(The Chairman) It's okay, you don't need to go through what the experts said. The evidence was that by the time Dr Webb left the Children's Hospital at around 5 or 6 o'clock on that evening, Claire was very seriously ill. That's why he put in his statement he says: "I made the mistake of not seeking a transfer to intensive care before I left." He put that into his statement and then the handwritten changes that you see there were proposed by others and he adopted them. So the statement as it reached you was not as he had drafted it. On the basis of what you were saying this morning, you would want a factual statement, but you would also want people to be candid and open with you?

(A) Absolutely, yes.

(The Chairman) So if Dr Webb thought he had made a mistake, that's exactly the sort of thing that you would want to see in a statement?

(A) That is correct.

T25-06-13P101L4-L9

(The Chairman) Just to complete that : this isn't the only example in this inquiry of a statement being changed at the instigation of managers within the hospitals in order to control the information which reached you. I presume you find that disappointing.

(A) I do.

T25-06-13P104L13-L16

(The Chairman) The concern I have, sir, is that we have had doctors who eventually have expressed very clear views here about what went wrong and those are views which were not expressed to you at the inquest.

Mr Walby also recommended "alterations" to Dr Sands statement for the Coroner regarding the use of No18 IV fluids and the information Dr Sands should include in his statement (139-106-001). This email dated 07 June 2005 states "The issue of what was and is fluid practice remains under debate and 0.18 N saline remains "standard fluid

therapy" when monitored adequately".

The content of this email is inconsistent with and contrary to the information given to Mr and Mrs Roberts at their meeting with Dr Steen, Professor Young and Dr Sands on 7 December 2004. The meeting note 089-002-002/003 states "At the Royal Hospitals, lessons have been learnt regarding management of sodium levels in children - which is still not the case in many UK hospitals. Dr Steen added that text books still recommend previous thinking on fluids. Professor Young continued that the use of 5th normal fluid saline is in fact now banned in the Royal Hospital for Sick Children, with a different type of fluid used today to avoid fall in sodium levels".

A letter from the Royal Hospitals to Mr and Mrs Roberts dated 12 January 2005 (096-018-112) states "Claire was given 5th normal saline fluid, which was the most common type of fluid to be administered in 1996. Treatment has now changed. Nowadays, Claire would be given smaller amounts of a different type of fluid following admission".

It is therefore a major concern that the RBHSC litigation manager Mr Walby tampered with Dr Sands Coroners statement, provided misleading and incorrect information to Dr Sands and that Dr Sands accepted that guidance and information based on his knowledge of the information given to Mr and Mrs Roberts in December 2004 and January 2005.

Mr and Mrs Roberts would again highlight and question the level of independence Professor Young provided to the Coroner's Inquest in 2006 and the consistency of his evidence to the Inquiry. As already stated Mr and Mrs Roberts were shocked when they received the Inquiry file No139 and reviewed its contents with regard to Professor Young's internal communications with the doctors involved in Claire's care and the Royal Hospitals Associate Medical Director Mr Walby. There are numerous emails between Professor Young and Mr Walby from the Royal Hospitals Litigation Management Office.

At the Inquest in 2006 the Coroner asked Professor Young "Should this case have been reported in 1996?"

Professor Young stated "Perhaps not back in 1996" (140-043-004).

The Coroner asked Professor Young if Claire's case should be referred to the hyponatraemia Inquiry?

Professor Young replied "I agree that it should be left to the Inquiry. The causes of cerebral oedema are less straightforward. **I don't think any new lessons can be learned from the inclusion of Claire Roberts death in the Inquiry**" (096-014-090).

Professor Young stated at the Inquest in 2006 in relation to the fluid management that on net Claire did have some degree of fluid overload and between 08:00pm and 12 midnight the volume was somewhat great (096-014-092).

This is contrary to Professor Young's Inquiry evidence
WS178-6 page 4 Professor Young

When I reviewed Claire's clinical notes in 2004, as I have explained in detail in my written submissions and in oral evidence, I came to the view that Claire's fluid management had been in-keeping with prevailing standards of 1996. I did not believe that there had been "fluid mismanagement" by these standards. The important relevant aspects of Claire's fluid management were the initial choice of maintenance fluids and the actions taken at 11:30pm in relation to fluid restriction. My views on these two issues

have been outlined in detail in my written statements and oral evidence, where I have indicated why I believe that management was in line with 1996 standards.

Mr and Mrs Roberts believe that one of the critical periods for Claire and her fluid management was between 08:00pm and 12 midnight. All the Inquiry experts agree that by 11:30pm Claire was at the point of no return, therefore any action taken after 11:30pm to reduce the fluids was too little too late.

The fluid management maintenance plan was 64ml/hr.

Fluids administered between 21:00 and 22:00 $(943-868)+30+(10.9-8.7)=107.2\text{ml/hr}$

Fluids administered between 22:00 and 23:00 $(1014-943)+30+(13.9-10.9)=104\text{ml/hr}$

Fluids administered between 23:00 and 24:00 $(1037-1014)+110+(16.8-13.9)=135.9\text{ml/hr}$

Fluids administered between 21:00 and 24:00 $(1037-868)+60+110+(16.8-8.7)/3=347.1/3=115.7\text{ml/hr}$

By this stage Claire's sodium level had fallen rapidly and acute dilutional hyponatraemia was causing cerebral oedema. Claire should have had fluid restriction or fluids with a higher sodium content, not an increase in fluids or the continuation of maintenance fluids. Dr Sands, Dr Webb and Dr Bartholome failed to review Claire's fluid management throughout Tuesday 22 October to ensure that the **type** of IV fluid administered was **replacement** IV fluid rather than standard **maintenance** IV fluid.

No tests were carried out in October 1996 to check the composition of Claire's urine for sodium or osmolality.

Mr McCrea raised this issue at the Inquest in 2006 and Professor Young was asked a specific question regarding tests on Claire's urine.

Professor Young's Inquest evidence stated that "a urine test would not have been a useful indicator" (096-014-092), that a urine sample "wouldn't have given any useful additional information" (140-043-009) and that much has been said about a urine test but in his opinion this would only have indicated that Claire was not dehydrated.

Professor Young's Inquest deposition (091-010-061) dated May 2006 states "An interpretation of a urine sample would have been complex - I think it would have shown that Claire was adequately hydrated".

Professor Young's Inquest evidence is contrary to his Inquiry evidence where the importance of urine testing is identified.

T10-12-12 Professor Young

T10-12-12P151L9-L14

(The Chairman) Sorry, euvoletic means that ---

(A) It means having a normal volume, not being fluid, overloaded in the sense of being puffy and not appearing dehydrated. That's critical because -- and then you need the urinary sodium and urine osmolality. That's the other key investigations.

T10-12-12P152L15-L17

(A) But the urine osmolality and the urinary sodium are critically important to understanding the cause and they are the key investigations.

Mr and Mrs Roberts are also very concerned about Professor Young's evidence on the 10 December 2012 regarding the euvoletic definition for Claire's dilutional hypotonic

hyponatraemia and would ask that the Inquiry experts and peer reviewers consider and comment on this topic. Mr and Mrs Roberts would emphasize the rapid fall in Claire's sodium level from 132mmol/L to 121mmol/L within twenty three hours, that her nausea started around lunchtime while at school, her vomiting started on an hourly basis around 03:30pm on Monday 21 October, continued through to 06:00am on Tuesday 22 October and that she was still retching some twenty three hours later at 11:00am as recorded in the ward round note. The sodium composition of Claire's urinary losses was not tested and is therefore unknown, but it is likely that Claire did have urinary sodium loss.

T10-12-12 Professor Young

T10-12-12P165 to P167

Professor Young has given evidence about the 3 different categories of hypotonic hyponatraemia. Hypovolemic, euvolemic and hypervolemic. The three children investigated by this Inquiry did have different types of dilutional hypotonic hyponatraemia. Adam obviously had hypervolemic hypotonic hyponatraemia based on the gross and excessive volume of No18 IV fluid he received. Claire, like Raychel, had hypovolemic hypotonic hyponatraemia based on the higher fall ++ in her sodium level due to persistent vomiting and loss of fluids and electrolytes (sodium) relative to the volume of No18 low sodium IV fluids administered +. Therefore the fall in Claire's sodium level was greater than the sodium content of the fluids administered and this resulted in dilutional hypovolemic hypotonic hyponatraemia. This is supported by the fact that Claire's initial sodium level was 132mmol/L as a consequence of continuous vomiting, she was already hyponatraemic before No18 IV fluids were started and she continued to vomit while receiving No18 IV fluid. It was the continuation of this IV fluid regime overnight on Monday 21 October and throughout Tuesday 22 October that accelerated the acute fall and dilution of Claire's sodium level to 121mmol/L which caused the neurological conditions that resulted in severe cerebral oedema. The other compounding factor is the unknown amount of urinary sodium loss Claire had. Claire, like Raychel, did not have fluid overload in the same context as Adam but she did have an excessive volume of an incorrect type of fluid with a low sodium content. The important principle point that has been emphasised by many of the Inquiry experts is, it is the **type** and duration of IV fluids administered secondary to the volume.

It appears that the RBHSC, Mr Walby and Professor Young even at this late stage are still attempting to define Claire's hyponatraemia as euvolemic, attribute the cause to infection related SIADH and defend the fluid regime Claire received as an appropriate maintenance level.

b). Dr Steen failed to provide consistent factual evidence under oath at the Inquest in 2006 and during her oral evidence to the Public Inquiry.

Mr and Mrs Roberts were not informed by Dr Steen or any doctor from the RBHSC in 1996, 1997, 2004 or at the Inquest in 2006 that they believed there had been an IV fluid mismanagement issue. During the Coroners Inquest Professor Young, Dr Sands and Dr Steen prepared a Medical Certificate of Cause of Death draft (MCCD) and gave oral evidence defining viral-meningoencephalitis as the cause of the hyponatraemia. Dr Webb, Professor Young, Dr Sands and Dr Steen did not give any explanation to the Coroner that Claire's hyponatraemia was related to or caused by IV fluid mismanagement. Each doctor related the hyponatraemia to meningoencephalitis and SIADH in an attempt to cover up

their shocking failures, incorrect diagnoses and inappropriate care management and deflect the cause of the hyponatraemia away from a hospital acquired IV fluid mismanagement issue. The Coroner was misled.

Mr Roberts wrote to his solicitor on the 4 August 2006 (096-019-115) to raise his concerns about the inadequacies in the Coroners verdict and how the hyponatraemia had been defined as "due to excess ADH production", without any reference to fluid management.

The Inquest verdict in May 2006 changed the initial 1996 cause of death from 1(a) Cerebral oedema (b) Status epilepticus to 1(a) Cerebral oedema due to (b) Meningo-encephalitis, hyponatraemia due to excess ADH production and status epilepticus, in no ranking order. The Inquiry will therefore be aware of Mr and Mrs Roberts ongoing concerns regarding the accuracy of the current death certificate and that after more than sixteen years they still do not have an accurate cause of death or a correct Medical Certificate of cause of death (MCCD).

T25-06-13 HMC Mr Leckey

T25-06-13P171L21 to P172L15

(Q) I may have asked you this and I apologise if I have already asked you, sir: what can you do now to try and improve that? Apart from you saying the climate may have changed, the pressure from patients' families and so forth, but from yourself to try and ensure you're getting the information in its purest form, if I can put it that way. What can you do now?

(A) Well, I've been here for most of the day and I've heard a lot of information that I didn't know previously. So there's a lot of food for thought. I don't feel, sitting in the witness box now, I could give a measured response. I think it's something I'd want to reflect on, not only with my legal advisers who are with me, but also my colleagues and the office staff.

(Q) Yes. I take it you found it troubling, these matters that did not emerge in the course of some fairly thorough investigations that you conducted as Inquests?

(A) Yes, I agree entirely. **I have heard matters that are troubling.**

T25-06-13P83L22 to P84L9

(The Chairman) When that then leads on to you seeking witness statements from the doctors and nurses who were involved, do you expect that those will only be factual statements or do you also expect that, if they have concerns, that they will be flagged up in those statements?

(A) Both, and this does happen.

(The Chairman) I have to tell you, Mr Leckey, it hasn't happened in this inquiry, and on a number of occasions -- and Ms Anyadike-Danes will come on to it -- what you might call the underplaying of information or the withholding of information is a recurring theme in this inquiry.

18. PSNI investigation 2007 to 2008

Up to and following the Coroners Inquest in May 2006 Dr Steen, Dr Webb, Dr Sands and

the RBHSC maintained a diagnosis of meningoencephalitis. Mr and Mrs Roberts continued to question that diagnosis and when they agreed to an investigation by the PSNI in 2007 one of the key areas for further investigation was a neuropathology report to review and identify any level, if any, of infection found in Claire's brain.

The PSNI obtained a statement dated 22 August 2007 from Dr Harding Consultant Neuropathologist at Great Ormond Street Hospital. (096-027-357)

Dr Harding's statement defines "There is no evidence of acquired infection (meningitis or encephalitis)".

"The cause of death as given on the death certificate and in the Inquest verdict remains in my opinion non concordant with my observations".

"I consider meningo-encephalitis excluded, both by microbiology and the post mortem neuropathology".

"Hyponatraemia has been identified from the chemical-pathology data. There is a history of vomiting which when severe may result in electrolyte disturbance. Hyponatraemia is known to cause brain swelling. But there is no other specific neuropathological indicator for hyponatraemia that I am aware of".

"The child was said to suffer from seizures. None were witnessed prior to hospital admission, and certainly not status epilepticus. Moreover the neuropathological sequelae of status were not present. Nor was there damage to the hippocampus which may be seen in children with chronic epilepsy".

"Conclusion: Although the data are incomplete, in my opinion the evidence suggests that brain swelling was the immediate cause of death and hyponatraemia is the only causative factor that has been positively identified".

Dr Harding's report states that there is no evidence of acquired infection (meningitis or encephalitis) and he states that the death certificate and Inquest verdict is non concordant with his observations. He also excludes status epilepticus and defines hyponatraemia as the only causative factor positively identified.

The PSNI also obtained statements from Dr Evans dated 1 March 2008 (096-022) and Dr Gupta dated 9 September 2008 (097-011). Both reports support Dr Hardings opinion and Dr Evans report details the unsatisfactory level of care Claire received and the significant breach of duty of care.

The report by Dr Harding reaffirmed Mr and Mrs Roberts belief that Claire did not have any type of brain infection or status epilepticus and the cause of her cerebral oedema was hospital acquired dilutional hyponatraemia as a result of IV fluid mismanagement caused by the inappropriate administration of hypotonic low sodium No18 IV fluids.

The neuropathology report by Dr Harding exposed the unscrupulous, devious and shameful actions of Dr Steen, Dr Sands, Dr Webb and the Royal Hospitals attempts to cover up Claire's death and attribute the cause of death to an unknown, unidentified brain virus for which there is and there never was any clinical, pathological or histopathological evidence.

Dr Steen's misleading and incorrect evidence to the Coroner in 2006 was "**Therefore it was important for the post mortem to determine the viral illness which triggered the S-E (status epilepticus) which caused the ADH excess to produce C-O (cerebral oedema)**" (096-014-100).

19. Public Inquiry evidence of the Royal Hospitals Medical Director and Chief Executive 1996

Dr Carson Medical Director, Royal Group of Hospitals & Dental Hospital HSS Trust (1996)

T15-01-13 Dr Carson

T15-01-13P151L7-L15

(A) I would have thought there was sufficient happening in Claire's case that that should have been brought to the attention initially of the clinical director and then subsequently... There were issues there that should have been explored that would have been my responsibility.

(Q) Fair enough. Would you classify that as a failing in the system?

(A) I think the system did not do justice to Claire.

T16-01-13 Dr Carson

T16-01-13P34-L15 to P35L7

(A) In relation to Claire's case, I said I was more surprised that that hadn't come to me because -- and again, I was not aware of Claire's death at the time, it wasn't brought to my attention and I had left the Trust by the time that the Roberts family drew the hospital's attention to their concerns. And learning from the transcripts and so on of the inquiry, there were incidents that took place during Claire's management that I think merited further investigation. Who was in charge of the patient? Who looked after-- who was responsible? The issue about drugs, administration of drugs, overdose of drugs. I mean, those should have been triggers that should have precipitated further investigation and a deeper investigation at the time. The debate around whether a death certificate could or could not be signed, you know there was sufficient, I think, grounds there for a discussion to be held, even with the coroner's office.

Mr William McKee Chief Executive, Royal Hospitals (1996)

T17-01-13 Mr McKee

T17-01-13P110L3-L13

(A) It's clear that we failed Claire Roberts in the treatment she received. And we failed in communication, both before Claire's death and afterwards, because, for example, we led Mr and Mrs Roberts to believe that they could safely go home, that there was not going to be a crisis that evening, et cetera. And then subsequently, I think we failed the Roberts family when they drew to our attention the question: is there a link between the two deaths? So we could have handled -- we should have handled our communication with Mr and Mrs Roberts much better.

T17-01-13P106L20 to P107-L13

(The Chairman) Because even if you weren't aware in 1995 or 1996 of what has gone wrong in Claire's case and even if that wasn't more generally recognised by those who were involved in her care -- let's make that assumption -- it was recognised between 2004 and 2006 how badly things had gone wrong in Claire's case. But I think the Robert's concern is they never got that acknowledgment from the Trust. But your annual report is saying, "This is what we do". So how can you say in your annual report, "This is what we do", when, in this case, it wasn't done? That's the problem.

(A) I accept that, chairman. But in mitigation, if you like, I'm saying that this was a general statement of what we believed we were doing, notwithstanding that we clearly failed Mr and Mrs Roberts on a number of engagements throughout the time from the death of Claire to their raising it with us after the program to subsequent discussions with Mr and Mrs Roberts. I accept that.

The evidence given to this Inquiry by Mr McKee the Chief Executive of the Royal Group of Hospitals Trust in 1996 raises major concerns with regard to the Trust's responsibilities and accountability for patient care. Mr McKee's evidence is that in 1996 the Trust was not responsible for patient clinical safety or care until new legislation was introduced in 2003 and that the onus for patient care in 1996 was the responsibility of self regulating doctors within their professional responsibilities to the GMC. The fact that neither the Royal Hospitals Trust or Board of Directors were aware of the death Adam Strain or Claire Roberts until 2004 raises major concerns with regard to corporate governance in Northern Ireland's main teaching hospital prior to 2004. Mr McKee was aware of and therefore responsible and accountable for the actions taken by Dr Steen, Dr Sands, Dr Webb, Dr McBride, Professor Young and Mr Walby when Mr and Mrs Roberts contacted the RBHSC in 2004. The Royal Belfast Hospitals Trust and Chief Executive must therefore be accountable for the inadequate and improper actions of Dr Steen, Dr Sands, Dr Webb, Professor Young and Mr Walby during and following the Coroners Inquest into Claire's death in May 2006.

Professor Scally's view is that the Trust was accountable and responsible for the duty of care provided to a patient in 1996.

T01-07-13 Professor Scally

T01-07-13P20L7-L19

(A) If I could go back perhaps to the 1993 circular that we touched on a minute ago. In the paragraph from which you read an excerpt in relation to the accountability of trusts, it clearly states: "The contracting mechanism will provide the means for these to be specified and monitored." So I think there already existed, as a result of that circular, a requirement for the specification of quality and for the monitoring of quality. So to go back to your 2003 circular, I think what that does is put on to a statutory basis and a much firmer expectation of how that would be reported and particularly reported through the board mechanisms.

Conclusion

Having heard the oral evidence of the Inquiry expert witnesses and read their reports it is reassuring for Mr and Mrs Roberts that the inclusion of Claire's death within the Inquiry's terms of reference has been justified and their efforts to establish the truth recognised despite the numerous obstacles placed in their way over the years by the Belfast Trust, the Royal Belfast Hospital for Sick Children and the doctors responsible for Claire's care. Doctors do and will continue to make mistakes; however those mistakes must never be concealed and must be made open and transparent at the time. Dr Steen, Dr Sands, Dr Webb and the Royal Belfast Hospital for Sick Children have attempted to willfully cover-

up and conceal the true reasons for Claire's death. These doctors have attempted to disguise the cause of death and attribute Claire's death to a viral meningoencephalitis, conceal fluid management issues, conceal drug overdoses and protect themselves, the hospital and the Belfast Trust from open investigation, judgment and criticism. They have failed Claire, failed Mr and Mrs Roberts, failed their profession and failed the public who they serve. It is highly probable that other children have died as a direct consequence of their actions, lack of honesty and failure to be transparent when mistakes were made. Dr Steen, Dr Sands, Dr Webb, the Royal Belfast Hospital for Sick Children and the Belfast Trust cannot and must not be allowed to hide under the protective umbrella of hindsight or systemic failure. The cover-up of Claire's death in 1996, the explanations given to Mr and Mrs Roberts in 2004, the defence of their actions at the Coroners Inquest nine years after Claire's death in 2006 and their continuing defensive approach during this Public Inquiry in 2012 must be exposed. There must be accountability for their failures, deception and shameful actions.

The oral and written evidence of the main doctors responsible for Claire's care, Dr Steen, Dr Sands and Dr Webb highlights a continuing difficulty for the Inquiry in its attempt to obtain openness, transparency and honest facts. Mr and Mrs Roberts are totally exasperated, very angry and frustrated by the statements and oral evidence of the these doctors and they believe that the full truth is still proving very elusive. This is not surprising given the severity of this situation and the doctors attempts to defend and justify their actions, care management, diagnosis and treatment plan for Claire and their attempts to cover up their errors and failures over a 16 year period. Were there has been wilful covering up of someone else's actions, errors and mistakes or there has been wilful intent to cover up malpractice those actions should be a criminal matter.

Mr and Mrs Roberts pose the question, where would they be today but for the broadcast of a television programme, or if the PSNI and this Public Inquiry had not investigated Claire's death?

However, they remain confident that this Public Inquiry and the Chairman, Mr Justice O'Hara, following his consideration of all the facts, evidence and submissions will identify the important and crucial issues and consider recommendations to the following authorities.

- i) The Attorney General for a review of the current Inquest verdict.
- ii) The Coroner for establishment of a new Inquest and revision of the current incorrect medical cause of death certificate (MCCD). Mr and Mrs Roberts currently have two incorrect death certificates.
- iii) The Public Prosecution Service (PPS) for a review of the initial decision regarding prosecution.
- iv) The PSNI for a review of the initial investigations into Claire's death with regard to new evidence.
- v) The Health and Safety Executive (HSE) for an investigation into the failures in Claire's clinical care.
- vi) The General Medical Council (GMC) for an investigation into the actions of Dr Steen, Dr Sands, Dr Webb and Mr Walby and their fitness to practice.

Mr & Mrs Roberts would also like to express how Claire's unexpected death in 1996, the subsequent enquiries and investigations into Claire's death, culminating in this Public

Inquiry in 2013, has impacted on their own lives, personal wellbeing and health. Claire's sudden, unexpected death had a devastating impact and caused untold emotional distress for them as parents, their two sons, grandparents and entire family circle. Their grief never diminished. Claire's death caused unbearable emotional turmoil for both parents and is something they will never fully recover from. Their attempts to live with this loss have been compounded and heightened over the last nine years by the defensive approach of the Belfast Trust and individual doctors' denials and attempts to conceal the truth. During the last nine years Mr & Mrs Roberts have had to live with the realisation that if some very basic medical decisions had been made and if Claire had received appropriate treatment and care management, her death was totally preventable and avoidable. This realisation has reopened their grief, triggered additional trauma and resulted in extreme ongoing emotional, mental and physical distress and anguish, all of which has caused further suffering and increased anxiety. They believe it is despicable that Dr Steen, in 1996, attributed the cause of Claire's death to a brain virus. The way in which the last two days of Claire's life was cast aside and the way in which her death has been concealed is unforgivable. The doctors who made fundamental but crucial errors and mistakes are responsible for Claire's death and they have robbed and deprived Mr & Mrs Roberts and their two sons of the opportunity to have Claire as part of their lives, to share in their family love and be part of their life experiences. Mr & Mrs Roberts believe they were denied the truth in 1996 and that they have had to fight for almost 17 years to breakdown defensive deception and cover up to obtain justice for their daughter. This process which has included an Inquest into Claire's death in 2006 and a PSNI investigation in 2007 has dominated their lives for 17 years and has had a profound impact on their personal life and their health. Mr and Mrs Roberts have to attempt to live with the loss of their daughter, Claire. Dr Steen, Dr Sands and Dr Webb have to live with their conscience.