Witness Statement Ref. No. 143/2

NAME OF CHILD: Claire Roberts

Name: Heather Steen

Title: Dr

Present position and institution:

Consultant Paediatrician, Belfast Health and Social Care Trust

Previous position and institution:
[As at the time of the child's death]

Consultant Paediatrician, North and West Belfast Health and Social Services Trust

Membership of Advisory Panels and Committees:
[Identify by date and title all of those since your Witness Statement dated 6th March 2012]

Previous Statements, Depositions and Reports:
[Identify by date and title all those since your Witness Statement dated 6th March 2012]

OFFICIAL USE:
List of previous statements, depositions and reports:

Ref:	Date:	
090-050-154	16.03.05	Statement to the Coroner
091-011-067	25.04.06	Deposition to the Coroner
WS-143-1	06.03.12	Inquiry Witness Statement

IMPORTANT INSTRUCTIONS FOR ANSWERING:

Please attach additional sheets if more space is required. Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number.

If the document does not have an Inquiry reference number, then please provide a copy of the document attached to your statement.

QUERIES ARISING OUT OF YOUR INITIAL WITNESS STATEMENT

With reference to your Witness Statement dated 6th March 2012, please provide clarification and/or further information in respect of the following:

(1) Answer to Question 11 at p. 7:

"I had been aware that Claire was in the ward at 9am on the 22-10-1996"

(a) 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.

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

(2) Answer to Question 18(k) at p. 13:

"It would have been normal process for the junior doctors or at times the senior nurse to initially contact the named consultant or out of hours, the consultant on call and following discussion with that consultant seek further opinions if required. Practice in RBHSC was that telephone contact could be made with the named paediatrician from 0900 on Mondays to 1700 on Fridays if it was felt that that consultant could deal with the issue more appropriately. The admitting consultant was not however required to respond when he/ she was not on call."

(a) Explain why you, and not "*the consultant on call*"

(i) were contacted

(ii) responded and attended PICU

in the early hours of 23rd October 1996.

Custom and practice in RBHSC was that if a consultant's patient became unwell out of hours on Mondays to Friday evenings, – even if that consultant was not on call, staff could contact the named consultant first although the consultant was not required to attend. Often the issue could be dealt with by telephone and if it was something serious the consultant would wish if possible to attend. I have no recollection of events but assume this is why I was contacted and I attended because I was in the position to do so.

(3) Answer to Question 23(k) (i) & (ii) at p.23:

"The IV fluid prescribing should have been the responsibility of both groups of professionals especially as additional fluids were given to administer IV Drugs."

(a) Explain why "*the IV fluid prescribing should have been the responsibility of both groups of professionals*", including with whom (paediatrics or neurology) primary responsibility lay for the:

(i) nature of the initial prescription for IV fluids

(ii) management of IV fluids

(iii) checking of electrolytes.

The junior medical staff would primarily be responsible for the management of IV fluids and checking of electrolytes. This would be a routine part of their role. However when there were areas of concern, consultants would expect to be informed as it may affect the management of the case including drug administration. I have always found that in complex cases, all consultants would expect to be informed.

(4) Answer to Question 25(k) at p.25:

"The trainees would have been trained in the calculation of drug dosages and expected to be competent. The BNF prescriber would have been available in the ward to guide them."

(a) Please provide a copy of the entries from October 1996 from *"the BNF prescriber"* for the drugs prescribed for Claire including:

(i) rectal diazepam

(ii) IV phenytoin

(iii) IV midazolam

(iv) sodium valproate.

If you are unable to provide the October 1996 entries, please clarify so far as you are able if the entries have changed since October 1996.

I do not have a copy of the 1996 BNF and so cannot provide copies.

Without this publication, I have no way of being able to decide if the information provided has changed in the interim.

(5) Answer to Question 25(l) at p.25:

"I do not think I was aware of this miscalculation [of IV phenytoin] at the time and so did not discuss it with the family."

(a) If you had known of this miscalculation of IV phenytoin, describe what you would have done or said.

I was not aware of the miscalculation but the normal process would have been I would have sought advice from Dr Webb and the pharmacy department to determine if any further action was required. I would ask Dr Webb if he wished to lead the process as he had instructed that the drug be given. Once I had this information, I would seek to meet with Claire's parents to inform them of what had happened and reassure them that there were no long term complications as a result of the error. The junior doctor would have been interviewed, any additional training required delivered and the doctor's performance closely monitored to ensure further performance issues were not occurring. I am unsure if we had an incident reporting mechanism in 1996.

(6)Answer to Question 26(b) at p.26:

"From the medical and nursing notes it would appear that Claire's condition was reasonably stable until late morning on Tuesday 22nd October 1996 and so 4 hourly observations were deemed appropriate."

(b) Explain what you mean by and the basis of your statement that Claire's observations were *"reasonably stable"*.

The nursing notes Ref 090-040-140 state that at 0700 she was apyrexic and observations were satisfactory. The entry for 8am to 2pm states ***"slept for periods during early morning-bright when awake, no vocalisation but ???? active. Late morning Claire became lethargic and vacant."***

I have no recollection of events but, on reviewing the notes, the observation chart Ref 090-044-147 shows that between 9 45pm on the 21st October until 12 MD on the 22nd October 1996, her temperature had returned to normal, her respiratory rate was normal, and her heart rate which was initially elevated had returned to normal.

(c) Explain how Claire's observations changed after "*late morning on Tuesday 22nd October 1996*" so that they were no longer "*reasonably stable.*"

I have no recollection of events but on reviewing the notes, her parents were concerned that she had become more vacant and after 12 MD her observations had changed to CNS observations. At 1pm her pulse temperature and respiratory rate remained satisfactory but her Glasgow Coma scale is reduced at 9.

This would indicate a change in Claire's level of consciousness.

(7) Answer to Question 28(e) at p.32:

"The named paediatrician for this case remained myself with Dr. Webb now managing her neurological condition. The medication regime being used was beyond that normally prescribed by a general paediatrician in RBHSC in October 1996.

(d) Explain what you mean by your statement that Dr Webb at approximately 15.10 was now "*managing her neurological condition*".

Dr Webb would oversee the investigation, monitoring and treatment of Claire's condition as related to her altering level of conciousness and non convulsing status epilepticus.

(e) Identify who had primary responsibility for the "*medication regime being used*" in Claire's case at this stage.

Dr Webb was responsible for Claire's anticonvulsant medication regime at this point in time.

(8) Answer to Question 29(c) at p.38:

"Claire's unresponsiveness was probably due to several reasons

1. *Her underlying illness*
2. *Her encephalopathy/encephalitis*
3. *Her seizures*
4. *Her medication*
5. *Developing cerebral oedema"*

(a) Explain the basis for your answer.

All of the above will individually make a patient unwell. How much each contributed to Claire's overall condition, I am unable to determine.

(b) Identify "*her underlying illness*", and explain the reasons for your answer.

It appears from her notes the underlying illness was a viral infection as she had a history of a loose stool, vomiting, low grade temperature and her white cells were slightly elevated

(9) Answer to Question 29(x) at p.43:

"There was no HDU in RBHSC in October 1996"

(a) Please state whether the location of the HDU in October 1996 was as shown on the attached drawing of RBHSC (Ref: 300-005-005). If not, please describe the location of HDU in October 1996.

The 2 beds indicated in the attached diagram are 2 of the 6 bedded intensive care unit with the other 4 beds in the area indicated as ICU. My understanding is they were commissioned and managed as PICU beds. As far as I am aware there was no HDU unit in RBHSC in 1996.

(10) Answer to Question 29(ee)(ii) at p.45:

"I would have expected that the registrar on call for the night would have had a discussion at approximately 17.00 with ward staff to identify patients about whom there were concerns."

(a) Identify by job title the *"ward staff"* with whom you would have expected the registrar on call for the night to have had a discussion.

This would have been the most senior doctor on the ward-the registrar or if that person not available, the second term senior house officer as well as the nurse in charge.

(b) Explain whether you would have expected Claire to have been one of the *"patients about whom there were concerns"* identified *"at approximately 17.00"* by ward staff in any discussion with the registrar on call for the night. In particular, state what concerns you would have expected to have been raised about Claire at that time.

I would have expected that Claire would have been discussed as her condition had given concern throughout the afternoon. I would have expected that her management plan would have been discussed as advised by Dr Webb.

(c) Explain your role as the named consultant paediatrician in ensuring that the *"ward staff"* provided details of Claire's case to *"the registrar on call for the night"*.

Consultants have very little time allocated to ward duties and may often be off site. Therefore having agreed a management plan with medical and nursing staff, the consultant is dependent on staff feeding back if there are any problems.

The handover of unstable or complex patients at the beginning and end of the working day between registrars was routine but not documented and should not have required consultant input unless, the doctors had fresh concerns.

(11) Answer to Question 31(g) at p.51:

"My view of Claire's condition was that she had most likely an encephalopathy secondary to viral encephalitis resulting in status epilepticus. The description of the episode at 19.15 and 21.00 are suggestive of seizures. A short self-limiting seizure on its own would not normally have required medical reassessment but if associated with other signs of deterioration eg. changes in the GCS then there should be discussion with medical staff. See 31(b)"

(a) Explain the basis for your *"view of Claire's condition was that she had most likely an encephalopathy secondary to viral encephalitis resulting in status epilepticus"*.

I have no recollection of events but on reviewing the notes, I believe that Claire had an underlying viral illness as she had a history of a loose stool, vomiting, low grade temperature, her white cells were slightly elevated. Her level of consciousness then deteriorated with increasing "vacantness". Viral encephalitis causes encephalopathy and seizures.

(b) Please clarify whether you are stating or suggesting that Claire's *"episode[s] at 19.15 and 21.00"* were *"short self-limiting seizure[s]"* or were *"associated with other signs of deterioration"* and explain why.

I have no recollection of events so can only answer this by trying to interpret the records. The nurses have recorded these 2 episodes on the Record of Attacks Ref 090-042-144 and I feel it is reasonable to suppose that these were short self-limiting seizures. The nursing staff who recorded the events would perhaps be able to clarify further.

(12) Answer to Question 33(h)(iii) at p.55 & p.56:

"Her fluids should have been reviewed looking at her losses from vomit/urine along with complications of her underlying condition... If no other factors arose – U & E would have been checked every 24 hours... Her fluids should have been reviewed looking at her losses from vomit/urine along with complications of her underlying condition and intravenous therapy."

(a) Explain what you mean by the "*complications of her underlying condition*".

Complications would include development of new symptoms eg increased vomiting, diarrhoea, neurological signs, changes in observations.

(b) Explain whether any "*other factors arose*" in Claire's case which required "*U & E [to]... have been checked*" more frequently than "*every 24 hours*". If so, identify those factors and, as the consultant paediatrician with care of Claire, explain when you would have expected U&E to have been first checked on 22nd October 1996.

I believe that the deterioration in Claire's condition on the afternoon of the 22nd October and her continuing need for IV fluids should have resulted in consideration of repeating a U&E that afternoon.

(13) Answer to Question 33(n) at p.57:

"My belief at the time was that Claire had aviral encephalitis resulting in status epilepticus and inappropriate ADH secretion. The role of N/5 saline would not have been implicated at that time."

(a) Explain what you mean by "*aviral encephalitis*".

This should have read a viral encephalitis-inflammation of the brain caused by a virus.

(b) State the basis for your belief that Claire's viral encephalitis resulted in:

(i) "*Status epilepticus*" and

(ii) "*Inappropriate ADH secretion*".

These are both known complications of viral encephalitis. In addition, inappropriate ADH secretion is also a complication of status epilepticus.

(c) Explain what you mean by "*[t]he role of N/5 saline would not have been implicated at that time*" and state the basis for your belief.

In 1996 in RBHSC, N/5 saline was used as the replacement fluid of choice in children greater than 6 weeks of age admitted to medical wards. Claire received a normal maintenance volume of fluid with no additional replacement for her vomiting. She had additional fluid with her anticonvulsant medication but these were probably made up in N Saline although I do not know. Therefore, at the time, Claire would not have been thought to have hyponatreamia secondary to over prescription of N/5 saline but rather to inappropriate ADH secretion and water retention.

(14) Answer to Question 36(a) at p.62:

"This would have been written following discussion with medical and nursing staff, review of medical notes and clinical assessment of Claire in PICU."

(a) Identify the "*medical and nursing staff*" you discussed your note with, and state when you spoke to them, and what you discussed.

I have no recollection of events and as this is not documented I cannot comment further.

(b) Identify the "*medical notes*" you reviewed in the production of your note.

I have no recollection of events but assume these are the RBHSC medical records Ref 090

(15) Answer to Question 45(a) at p.71:

"I have no recollection of the events. A limited PM is usually indicated if it is felt only certain organs were involved in the disease process and additional information as to the cause of death or any underlying disorders may be gleaned by examining those organs."

(a) Explain why it was *"felt only certain organs were involved in the disease process"* in Claire's case and what input you had to that 'feeling'.

I have no recollection of events so cannot comment on my input to the decision. On reviewing the notes, there would appear to be no indication of other organs significantly contributing to Claire's condition

(b) Explain why it was felt that no *"additional information as to the cause of death or any underlying disorders may be gleaned by examining"* organs other the brain and what input you had to that 'feeling'.

As per 13 (a)

(16) Answer to Question 45(m) at p.73:

"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."

(a) Explain who felt that *"the sequence of events leading to her death was known and there were no areas of concern around her care."*

I have no recollection of events but would think that it had been agreed by all staff but in particular the consultants involved in her care.

(17) Answer to Question 54(i) at p. 83 & 84:

"If I had seen Claire as part of the ward round, I would not have made a note as this would have been part of the role of the junior doctors. If Dr Sands had discussed Claire with me and I was content with his findings which he had ensured were recorded, I would not have made a note."

(a) You have not adequately answered the question. If you had attended Claire at any time other than during the ward round, state whether a note would have been made of your attendance. State whether you would have made the note or whether this would also *"have been part of the role of the junior doctors."*

I do not usually make notes in charts, if I have attended a patient with other doctors, to confirm the ongoing treatment plan which has already been noted in the chart. If there was a new finding or new instructions, I would have expected that to have been recorded by myself or a junior doctor.

(18) Answer to Question 54(j) at p. 84:

"My usual practice would have been to complete the post take ward round prior to joining the Cystic Fibrosis Ward Round. The Grand Teaching Round commenced at 1 pm and then I would have gone to my community clinic in Cupar Street which commenced at 2pm. This clinic finished at around 5 30pm and I would then have gone home unless I had been contacted to return to RBHSC."

(a) Explain at what time and where *"the Cystic Fibrosis Ward Round"* took place in October 1996.

I have no recollection of events but, normally, the cystic fibrosis ward round took place at 11 a.m. in Allen Ward.

(b) Explain what the *"Grand Teaching Round"* is, and explain its purpose, who would normally attend it and where it is held.

This is a meeting held each Tuesday lunchtime for all doctors and other interested professionals in RBHSC. The usual format is that junior doctors present interesting clinical cases and that a consultant then leads an overview of the case/condition and co-ordinates a question and answer session.

(19) Answer to Question 54(k) at p. 84:

"I have no recollection of events but have no reason to think I did not take the ward round. The general paediatric round should have been completed before 11am and yet Dr Sands was asked to see Claire late morning, she not having been seen by that time. Claire was in Ward 7 and the round should have been there by 10am. I can only postulate that there were other problems on the ward that morning delaying the round."

(a) If you did take the ward round in Allen Ward on 22nd October 1996, identify the notes made of your ward round, particularly those made by you or on your direction.

I have no recollection of events and have no way of checking this now. It was not routine at that time to note in the medical records the most senior doctor on the ward round but that has now changed.

(b) Identify by whom *"Dr Sands was asked to see Claire late morning"*, and how you became aware of this information.

I do not know by whom Dr. Sands was asked. I have simply referenced the notes and records for this information *(090-040-140)*

(20) Answer to Question 54(m) at p. 84:

"I have no recollection of events so cannot comment other than in my deposition to the Coroner I commented that I had contacted the ward- presumably at the end of my afternoon clinic- and was told that Dr Webb had seen Claire and taken over her care."

(a) Explain the basis for your presumption that the time you contacted the ward was *"at the end of my afternoon clinic"*.

I have no recollection of events but it has always been my routine practice to contact the ward at the end of my working day, if a patient was giving concern.

(21) Answer to Question 55(f) at p. 86:

"My understanding of this would have been that Dr. Webb was the consultant lead."

(a) Explain what you mean by *"the consultant lead"* and explain what your role was if *"Dr. Webb was the consultant lead."*

As Claire's clinical condition was in keeping with an acute neurological disorder, I would have expected Dr. Webb to lead on investigations and management. I would have remained in support for any general paediatric issues on which Dr. Webb wished to consult.

(b) Explain what role and input you would have expected to have had in any change in the lead consultant with care of Claire in October 1996 prior to Dr Webb taking over Claire's management.

I would have expected to be informed of Dr. Webb's input and agreement as it was more appropriate for neurology to manage Claire's care.

(c) Describe what discussions you would have expected to have had in October 1996 prior to Dr Webb taking over Claire's management about whether and when Dr Webb should take over Claire's management.

I would have expected a discussion, if need be by telephone, indicating Dr. Webb's findings, ongoing management and requirement for further input from general paediatrics.

(d) Identify with whom you would have expected to have had these discussions and when you would have expected the discussions to have taken place.

This discussions may have been directly with Dr. Webb or via the Registrar or 2nd term SHO..

(e) Identify who you would have expected to have requested the transfer of care and management of Claire to Dr. Webb.

I would have expected that there would have been mutual agreement that Dr. Webb would lead on Claire's care as she had acute neurological condition.

(f) State whether you would have expected that transfer of care to have been:

(i) recorded in Claire's medical notes, and if so, when and by whom.

(ii) I would have expected Dr. Webb's input to have been noted in the chart but we did not formally note transfer of care at that time.discussed in the handovers to the medical and nursing staff in the late afternoon and evening of 22nd October 1996.

I would generally have expected that Claire's ongoing management should have been discussed at handover along with Dr. Webb's instructions for ongoing care including when to contact the relevant consultants should difficulties arise.

(g) If you had been told that Dr. Webb, as Consultant Paediatric Neurologist, had taken over as the lead consultant in Claire's management, state whether it would have been your (and your medical team's) responsibility or the responsibility of Dr. Webb:

(i) to take the lead in IV fluid management in October 1996

The junior doctors would still have been the ones involved in monitoring IV fluids and electrolytes and contacting consultants if there were concerns. I would have expected the Junior Doctors to keep both myself and Dr. Webb informed if there were any concerns.

(ii) to check electrolytes and prescribe the fluids

As per 21 (g) (i)

(22) Answer to Question 55(h) at p. 86:

"Dr. Webb would as part of the neurology service have had a registrar and SHO allocated to the department. I do not know who these were."

(a) Explain whether the *"registrar and SHO allocated to the [neurology] department"* would be available 'out of hours' or whether the paediatric registrar and SHO would cover for them during this time.

The paediatric registrars and SHOs on call covered all medical wards out of hours.

(23) Answer to Question 55(i)(i) at p. 86:

"I would have expected Dr. Webb or the ward staff to come back to me if there were concerns"

(a) Explain what responsibility you personally had to monitor Claire and identify any concerns.

As I was not on site, I was dependent on staff contacting me if there were any concerns as was the usual practice. Junior doctors and senior nurses would be aware that it was their responsibility to contact consultants if there were any concerns just as consultants would be aware of the need to be contactable.

(24) Answer to Question 55(n) at p. 88:

"Custom and practice in RBHSC was that if a consultant's patient became seriously unwell – even if that consultant was not on call, staff could contact the named consultant first although the consultant was not required to attend."

(a) Identify any documents / guidelines / protocols that recorded this *"custom and practice in RBHSC"* in October 1996 that *"staff could contact the named consultant first although the consultant was not required to attend"*.

I am not aware of any guidelines or protocols, however, I attach a copy of a rota from 1999, which includes a statement of how to contact consultants on-call. I have no access to rotas from 1996 so I do not know if this statement was included in them at that time.

(b) Explain the purpose of contacting the *"named consultant first"* if *"the consultant was not required to attend."*

As the named consultant had an ongoing knowledge of the patient, he/she could quite often deal with queries by telephone. If, however, the patient had become seriously ill, the consultant would, if possible, wish to attend to ensure continuity of care.

(25) Answer to Question 55(r) at p. 88:

"There was a consultant paediatrician on call who normally would have been the first person to contact."

(a) Explain why you were contacted at approximately 3am on 23rd October 1996 and not the *"consultant paediatrician on call"*.

I have no recollection of events so do not know why I was contacted first; others may be better placed to answer this.

(b) Explain who, in October 1996, should have been contacted first at approximately 3am on 23rd October 1996 according to *"custom and practice in RBHSC"*:

(i) *"The named consultant"*

(ii) The *"consultant paediatrician on call"*

The named consultant.

(26) Answer to Question 56(d) at p. 89:

"The reporting process would have been the nurse caring for Claire to the nurse in charge to the junior doctor on call who in turn would have communicated with the registrar. It would be normal for the registrar to contact the consultant but at times nurses and other junior doctors will do so."

(a) Explain in what circumstances and at what times "*nurses and other junior doctors*" will contact the consultant directly rather than through the registrar.

The registrar had to cover the entire hospital including the Emergency Department and if busy with another sick patient would delegate contacting consultants to other staff.

(27) Answer to Question 57(a) at p. 90:

"It is difficult to postulate when during the evening of the 22nd October, Claire's condition deteriorated to such an extent that more active treatment would not have helped. There is no documentation of a clinical assessment to help determine this. As a general paediatrician I would be concerned that by 2330, the cerebral oedema may have been so advanced that even with ventilation and mannitol induced diuresis, she would still have sustained coning of the brain. However this does not mean that these treatments should not have been considered even at that stage of her illness."

(a) Explain the basis of your concern that "*by 2330, the cerebral oedema may have been so advanced that even with ventilation and mannitol induced dieresis, [Claire] would still have sustained coning of the brain.*"

My postulation is based on the discussions which took place at the Coroner's Inquest between expert witnesses.

(28) Answer to Question 59(f) at p. 92:

"[These changes were prompted by] changes in practice nationally with new guidance on fluid management."

(a) Identify the "*new guidance on fluid management*" to which you refer.

I do not recall at this stage.

(29) Answer to Question 64(d) at p. 94:

"I indicated that Dr Webb and I had met with the Roberts to discuss the post mortem result. The meeting facilitated by Dr Rooney is summarised in minutes Ref(089-002)"

(a) In relation to the meeting with the Roberts "*to discuss the post mortem result*", please state, to the best of your recollection:

(i) Who was present at the meeting.

I have no recollection of the meeting but the letter of the 6th March 1997 ref 090-002 would suggest that Dr Webb and I were present. I donot know if anyone else was there.

(ii) Whether any record was made of the discussions at the meeting. If so, state where and by whom the record was kept. If not, explain why.

I have no recollection of events and so do not know if records were kept and if not, why not.

(30) Answer to Question 71 at p. 96:

"Please note Dr. Sands note indicates that he had spoken to Mr and Mrs. Roberts before 15.35 on 11-11-96. I do not believe I was made aware of this meeting prior to it taking place."

(a) Explain when and how you were first made aware of this meeting between Dr Sands and Mr and Mrs Roberts and what action you took as a result of it.

I have no recollection of events and so cannot comment. My letter of the 18th November 1997 Ref 090-004 was after the meeting but I do not know if it is in response to the meeting. I believe that the Roberts were a "walk in" that is, had no appointment.

(31) Answer to Question 72(a) at p. 97 & 73(g) at p. 98:

"This was a neuropathy case and requires at least 3 months tofix the brain before microscopic examination can commence."

(a) Explain the basis of your statement that it *"requires at least 3 months to fix the brain"*.

Neuropathology would be better placed to respond.

(32) Answer to Question 77(c) at p. 101:

"5th Normal saline had been removed from RBHSC except for the renal unit and PICU by this time."

(a) State when and why *"5th Normal saline had been removed from RBHSC"* (except for the renal unit and PICU).

I cannot recollect the exact date but believe pharmacy department will be able to provide this information.

(b) Explain why *"5th Normal saline"* was not removed from *"the renal unit and PICU"* by 7th December 2004.

My understanding is that this is required for some complex renal patients and was to be retained in the two areas, its use to be prescribed only by consultants. The NPSA alert of 2007 confirms this.

(33) Answer to Question 79(a) at p. 102:

"By December 2004 N Saline and N/2 saline with potassium and dextrose additions were being used in wards. U &E would be carried out at least once in 24 hours and more frequently if abnormal. If a low serum sodium did not respond to fluid restriction, discussion on further management took place with PICU. Children with acute intracranial illness had IV fluids restricted to 2/3rd maintenance from time of admission. These were the result of changes in practice which had been taking place for some time but also following clear guidance from the Department of Health."

(a) State when and why *"N Saline and N/2 saline with potassium and dextrose additions"* were introduced into RBHSC wards.

These two solutions were always available within RBHSC wards and used according to the needs of the child. I cannot provide exact dates of when they became the replacement fluid of choice.

(b) State when the *"changes in practice which had been taking place for some time"* began and explain the reasons for those changes.

I have no clear recollection of dates or guidelines which have affected changes in practice. By 2000, we certainly were restricting fluids to two-thirds maintenance for all acute neurology patients. I do recollect guidance from the Department in 2002 and in 2004 on the management of hyponatraemia.

(c) Specify to which *"clear guidance from the Department of Health"* you are referring and when it was introduced.

I am referring to the publications from the Department of Health in 2002 and 2004.

(34) Answer to Question 79(b) at p. 102:

"In general paediatrics in RBHSC in 1996, a serum sodium above 130 in a general medical patient would not have been considered unusual and requiring closer monitoring than a repeat U&E in 24 hours unless the child's condition deteriorated. Adam Strains death was seen as an extremely rare case of a child with high output renal failure undergoing transplant."

(a) Explain why *"in general paediatrics in RBHSC in 1996, a serum sodium above 130 in a general medical patient would not have been considered unusual and requiring closer monitoring than a repeat U&E in 24 hours unless the child's condition deteriorated."*

Often children presenting with acute medical illness such as bronchiolitis will have a reduced serum sodium and if the child did not require intravenous fluids, it would not have been routine to repeat the urea and electrolytes in less than twenty-four hours. If the child required intravenous fluids, then the U&E would normally be repeated in twenty-four hours.

(b) Explain your view of Adam Strain's case in October 1996 and now and whether you believed it was *"an extremely rare case of a child with high output renal failure undergoing transplant."*

I do not now have a clear recollection of my understanding of Adam Strain's case in October 1996. Explain who saw it as *"an extremely rare case"* and how and when you became aware of this.

I have no clear recollection of events but believe that this information came to me via colleagues.

(35) Answer to Question 79(c) at p. 103:

"[By 7th December 2004, low sodium levels were acknowledged as important] through medical research-guidelines-training e.g. APLS-CMO guidance and regional work."

(a) Identify the:

(i) *"medical research-guidelines-training"*

(ii) *"APLS-CMO guidance"* and

(iii) *"regional work"*

to which you refer.

I have no clear recollections of dates and time lines of how new guidance and additional research resulted in changes in practice. The Department of Health issued guidance in 2002 and 2004 on the management of hyponatraemia and BMA had introduced an e-learning module on hyponatraemia. APLS guidance had been updated.

(36) Answer to Question 87(e) at p. 107:

"I think that the initial seizures are unlikely to be related to the hyponatraemia as if the sodium had dropped so quickly to such a low level by late morning as to cause seizures her cerebral oedema and subsequent coning would have occurred earlier than it did"

(a) Specify to which seizures you refer as *"the initial seizures"*, with particular reference to the Record of Attacks (Ref: 090-042-144).

On reviewing the notes, Dr. Sands and Dr. Webb's assessment would indicate non-convulsive status epilepticus during the later morning of Tuesday 22nd October. The record of attacks was kept by nursing staff after this.

(b) Specify to which level of sodium in mmol/L you refer as *"a low level ... as to cause seizures"*

Textbooks would indicate a level of 122 as critical, however, generally I would be more concerned about the speed of any drop in sodium rather than the absolute level. I have seen patients with sodiums as low as 116 mmols/L who have not had seizures.

(c) Explain to what time or time period you are referring as *"by late morning"*

This reference is from nursing notes.

(d) Explain the basis of your statement that you think *"that the initial seizures are unlikely to be related to the hyponatraemia as if the sodium had dropped so quickly to such a low level by late morning as to cause seizures her cerebral oedema and subsequent coning would have occurred earlier than it did"*.

Ref. 36B.

(37) Answer to Question 87(g) at p. 107:

"Dr Webb will be able to answer this more fully but I believe that if Claire had remained in status epilepticus, cerebral oedema would have developed more quickly."

(a) Explain the basis for your belief that Claire was *"in status epilepticus"*.

I deferred to Dr. Webb's judgment on this as it was because of concerns of non-convulsive status that he was asked to see and advise upon Claire's management.

(b) Explain the basis for your belief that *"if Claire had remained in status epilepticus, cerebral oedema would have developed more quickly"*.

Cerebral oedema is a recognised complication of status epilepticus and my understanding is that the longer seizures continue the risk of cerebral oedema increases.

(38) Answer to Question 90(d) at p. 109:

"I do not recollect events but on reviewing documents I believe that I thought the hyponatraemia was as a complication of viral encephalitis, status epilepticus, cerebral oedema and SIADH."

(a) Explain what you mean by *"the hyponatraemia was as a complication"*

Please see 38B.

(b) Explain how *"hyponatraemia was as a complication of"*:

(i) *"Viral encephalitis"*

(ii) *"Status epilepticus"*

(iii) *"Cerebral oedema"*

(iv) *"SIADH.*

All these conditions induce inappropriate ADH secretion which leads to water retention, hyponatraemia and an increased risk of cerebral oedema. The cerebral oedema in its turn causes further SIADH and a vicious cycle is established.

(39) Answer to Question 91(a) at p. 110:

"Hyponatraemia is low serum sodium. I believe that it was felt that this was secondary to SIADH and not fluid dilution due to IV fluid administration."

(a) Explain why and by whom it was felt that hyponatraemia was *"secondary to SIADH and not fluid dilution due to IV fluid administration"*.

I have no recollection of events but have no reason to think, from reviewing the notes, that any staff felt the hyponatraemia was related to IV fluid administration.

(40) Answer to Question 92(b) at p. 110:

"The entry was not complete as a viral encephalitis was a differential diagnosis albeit one we felt at the time most likely, which the post mortem report would help clarify."

(a) Identify to whom you refer to when you state *"... one we felt at the time most likely"*.

I have no recollection of events but presume it was all the medical staff involved in Claire's care, as there is no record of any concerns in medical or nursing notes

(b) Explain the reasons why the *"most likely" "differential diagnosis"* was not referred to in your note that the death certificate was issued at Ref: 090-022-161

Refer to 91B of WS143/1.

(c) Explain your level of input into the information on Claire's death certificate. If you were not involved, explain why.

I have no recollection at this stage but I did complete it, presumably with the available information at that time.

(41) Answer to Question 92(c) at p. 111:

"Cerebral oedema was present and it was presumed that the underlying causes were viral encephalitis and status epilepticus but the post mortem would clarify if encephalitis was present."

(a) If *"viral encephalitis" "was presumed [to be] an ...underlying cause..."* explain why the entry on Claire's diagnosis of brain stem death form failed to record it as a diagnosis or condition leading to brain stem death. (Ref: 090-045-148).

It was still a presumptive diagnosis, the limited PM of brain would have helped confirm it. Ref to 91B of WS143/1.

(42) Answer to Question 97 at p.113:

"The deaths of all children were reported to the Audit Co-ordinator and the charts once available were given to the audit co-ordinators secretary. The Co-ordinator then scheduled in a date for the case to be discussed at the Mortality Meeting at a time that ensured all relevant specialities could attend and any outstanding results eg post mortem results were available. There were no records kept on the discussion but any learning points would have been disseminated to the relevant professionals within RBHSC."

(a) Describe any *"learning points"* arising in Claire's case that were *"disseminated to the relevant professionals within RBHSC"*.

I have no recollection of these events and, as there seems to have been no documentation kept at the time, I cannot comment further

(b) State whether any *"learning points"* arising in Claire's case were *"disseminated to the relevant professionals within RBHSC"* orally or in writing. If in writing, please identify the document and furnish a copy thereof.

As above (42) a

(c) Identify by name and job title *"the relevant professionals within RBHSC"* in Claire's case.

It would have been all medical staff and senior nurses in PICU and medical wards.

(43) Answer to Question 99(g) at p.115:

"Practice [of if / when care would be formally taken over by another Paediatric Consultant and by the neurology team] would have been following discussion between the two specialities."

(a) State which grade of clinician in each speciality would have the discussion regarding the formal takeover of a patient.

Discussion would have taken place at least at Registrar level with Consultants being made aware of any decisions.

(44) Answer to Question 100(a) at p. 117

"I have no recollection of any discussions other than those already documented. By the time Claire's Inquest had taken place the there had been significant changes in practice not only for the prevention and management of hyponatraemia but also the management of children with acute neurological disease with improved investigation facilities and PICU access."

(a) Specify the *"significant changes in practice"* that had taken place by the time of Claire's inquest in:

(i) *"the prevention and management of hyponatraemia"*

(ii) *"the management of children with acute neurological disease"*

and when these changes occurred.

I no longer have any clear recollection of when guidance and changes in practice occurred. These will have happened over the passage of time. With regards to hyponatraemia I am aware there was clear advice given by the Department of Health in 2002, 2004 and following the NPSA alert in 2007.

(b) Specify the *"improved investigation facilities and PICU access"* available by the time of Claire's inquest and when they were introduced.

The new PICU unit opened in 1999 with additional medical and nursing staff support.

I am unsure when the CT scanner became available in RBHSC

QUERIES ARISING FROM THE AUTOPSY REQUEST FORM

With reference to the Autopsy Request form (Ref: 094-054-183 to Ref: 094-054-185)(attached), please answer the following queries:

(45) Please confirm you have signed the autopsy request form as the requesting doctor. If so, explain why it was you who filled in this form, and not Dr Webb or any other clinician. If you did not sign this form, state who did and why.

I have no recollection of events but assume as I had been one of the doctors involved it was appropriate for me to complete the form.

(46) *"CONSULTANT:*

Dr Webb / Dr Steen"

(a) Explain why both you and *"Dr Webb"* are both noted as the *"Consultant"*.

Because we were both involved in her care.

(b) Explain why *"Dr Webb"* is noted first.

I have no recollection of events but have no reason to suppose there was any relevance into which consultant's name was mentioned first.

(c) Describe any practice / protocols / guidelines concerning:

(i) the noting of consultants

(ii) the noting of advising specialist consultants

on an autopsy request form.

I am not aware of any documents relating to this in 1996.

(47) *"DATE OF ADMISSION:*

"22.10.96"

(a) Explain why Claire's admission date is recorded as *"22.10.96"*.

I can only assume this was an error.

(48) *"CLINICAL PRESENTATION:*

9 ½ year old girl ĉ a history of mental handicap admitted with increasing drowsiness and vomiting."

(a) Explain the basis of your statement that Claire had *"a history of mental handicap"*.

Mental handicap was the unfortunate term used at that time to describe children and adults with learning difficulties. Claire's learning disability had been recognised through her developmental delay and subsequent placement at a special needs school.

(49) *"HISTORY OF PRESENT ILLNESS:*

Well until 72hours before admission. Cousin had vomiting and diarrhoea. She had a few loose stools and then 24 hours prior to admission started to vomit. Speech became slurred and she became increasingly drowsy. Felt to have sub clinical seizures. Treated ĉ rectal diazepam / IV phenytoin / IV valproate. Acyclovir & cefotaxime cover given. Serum Na^+ dropped to 121 @ 23-30hrs on 22-10-96. ?Inappropriate ADH secretion. ...Intubated + transferred ICU – CT scan – cerebral oedema. Brain stem death criteria fulfilled @ 0600 + 18.15 hrs. Ventilation discontinued 18.45hrs."

(a) Explain the basis of your statement that Claire *"had a <u>few</u> loose stools"* (emphasis added).

I have no recollection of events but think this was taken from Dr. Webb's note

(b) Identify who *"felt"* Claire had *"sub clinical seizures"* and the basis for this belief.

I believe from my review of the notes that Dr Sands had been concerned about this when he had first asked Dr Webb to see Claire and, Dr Webb's medication plan would support his belief that Claire was having seizures, but this is speculation on my part.

(c) Explain why you omitted to include the administration of IV midazolam in the list of the anti-convulsant drugs that Claire received during her treatment.

I have no recollection of events but can think of no particular reason for omitting this. The medical records should have been available to the Pathologist. This document was only a clinical summary.

(d) Explain why you omitted the other serum sodium concentration results from a sample taken on 21st October 1996 and from samples taken on 23rd October 1996.

I have no recollection of events but this was intended as a summary document only. The Neuropathology Team would have had full access to Claire's medical records so not all blood results were included in this document. Please see 49C.

(e) Explain your note *"?Inappropriate ADH secretion."*

I had no recollection of events but presume that I had felt the most probable explanation of her low serum sodium was inappropriate ADH secretion. This was not confirmed at the time as there are no results available for urinary U&E and osmolality.

(50) *"PAST MEDICAL HISTORY (incl drug therapy):*

Mental handicap

Seizures from 6 months – 4 years"

(a) Explain the basis of your statement that Claire had *"mental handicap"*.

Please see reference 49A.

(51) *"INVESTIGATIONS (include laboratory, ECG, X-ray etc) See chart."*

(a) Identify the *"chart"* to which you refer and the information it contained

I have no recollection of events but presume this is the medical and nursing records which normally are available for the pathologist to review.

(52) *"CLINICAL DIAGNOSIS*

Cerebral oedema 2° to status epilepticus

? underlying encephalitis"

(a) Explain why you did not note the possibility of hyponatraemia as part of Claire's clinical diagnosis.

I have no recollection of events but I appear to have viewed hyponatraemia as a complication of underlying disease.

(53) *"LIST CLINICAL PROBLEMS IN ORDER OF IMPORTANCE*

(This list will enable the pathologist to produce a more relevant report.)

(1) Cerebral Oedema

(2) Status Epilepticus

(3) Inappropriate ADH secretion

(4) ?viral encephalitis"

(a) Explain why you omitted "hyponatraemia" from the list of clinical problems on p.3 of the autopsy request form.

I have no recollection but presume it was because I considered hyponatraemia was a complication not a direct cause of her condition.

(b) Explain the basis upon which you listed the clinical problems in the order of importance set out in the autopsy request form.

I have no recollection of events but presume that the cerebral oedema was the defining condition which led to Claire's death and so I put it first. The other three conditions contributed so they came next. I cannot remember why I put them in this order. These were presumptive findings and we were awaiting the Post Mortem results to confirm our list of clinical problems.

(54) *"DEATH CERTIFICATE: If a death certificate has already been prepared please copy it below for our records"*

(a) State whether a death certificate had already been prepared at the time you completed the autopsy request form.

I have no recollection of events and so do not know the order that the tasks were completed.

(55) *"Antecedent causes, morbid conditions, if any, giving rise to the above cause, stating the underlying condition last.*

(b) Status epilepticus"

(a) Explain the basis upon which you completed the section titled *"antecedent causes, morbid conditions"*

I have no recollection of events and so am unsure why I placed the conditions in the order I did. See 53B.

(b) Explain why you omitted to state "hyponatraemia" in this portion of the form.

I have no recollection of events but it may have been that I felt hyponatraemia was a complication.

(56) *"Will you or a colleague be attending the review session at 1.45pm on the day of the autopsy? YES NO"*

(a) Explain why you did not wish to attend *"the review session at 1.45pm on the day of the autopsy."*

I have no recollection of events but suspect I had other commitments, which may have been at a clinic off site. Also, as this was a limited PM of brain, detailed findings would only be available once slides had been prepared and viewed. As the brain needed fixed, this would take up to three months.

(57) *"THE FINDINGS OF THE AUTOPSY WILL BE TELEPHONED TO THIS NUMBER"*

(a) State whether you were telephoned in relation to the findings of Claire's autopsy. If so, state by whom, when and what was discussed. In addition, identify any notes of this conversation. If no note exists, explain why.

I have no recollection of events and have found no documentation concerning this so I cannot comment further.

QUERIES ARISING FROM THE POST-MORTEM CONSENT FORM

With reference to the Post Mortem Consent form (Ref: 094-054-185) (attached), please answer the following queries:

(58) State whether you completed this form, other than the signature of Mr Alan Roberts. If so, explain why it was you who filled in this form, and not Dr Webb or any other clinician. If not, identify who did complete the form.

It is my writing on the Post Mortem Form.

(59) *"Physician or Surgeon*

Dr Heather Steen"

(a) Explain why you alone are recorded as the *"Physician"* on this form

I have no recollection of events and so cannot comment.

ADDITIONAL QUERIES

(60) Provide any further points and comments that you wish to make, together with any documents.

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: Heather J Shaw Dated: 10/7/02

My Copy 25.10.99 —

19.12.99

ON-CALL ROTA FOR MEDICAL PAEDIATRICS

One Consultant Paediatrician will be responsible for all medical patients admitted from A&E starting from 9.00 am on the date given to 9.00 am the following morning.

Patients whose admission has been arranged with a specific ward by the family, general practitioner or A&E will be placed under the care of the appropriate consultant and not the consultant on-call. Medical patients admitted to ICU from A&E or other hospitals will be placed under the care of the consultant anaesthetist.

Junior medical Staff are asked to use the above rota as a guide and should not hesitate to contact other Consultants if more appropriate for the patient's care.

In the event of an acute problem in a patient previously admitted to the ward, junior staff should seek advice from the consultant looking after that patient. If that consultant is not available advice can be obtained from the consultant on-call.

Mon 25 Oct	Dr Steen
Tues 26 Oct	[redacted]
Wed 27 Oct	
Thurs 28 Oct	
Fri 29 Oct	
Sat 30 Oct	
Sun 31 Oct	

Mon 22 Nov	Dr Steen
Tues 23 Nov	[redacted]
Wed 24 Nov	
Thurs 25 Nov	
Fri 26 Nov	
Sat 27 Nov	
Sun 28 Nov	

Mon 1 Nov	Dr Steen
Tues 2 Nov	[redacted]
Wed 3 Nov	
Thurs 4 Nov	
Fri 5 Nov	
Sat 6 Nov	
Sun 7 Nov	

Mon 29 Nov	Dr Steen
Tues 30 Nov	[redacted]
Wed 1 Dec	
Thurs 2 Dec	Dr Shields
Fri 3 Dec	[redacted]
Sat 4 Dec	Dr Steen
Sun 5 Dec	[redacted]

Mon 8 Nov	[redacted]
Tues 9 Nov	
Wed 10 Nov	
Thurs 11 Nov	Dr Shields
Fri 12 Nov	Dr Shields
Sat 13 Nov	Dr Steen
Sun 14 Nov	Dr Shields

Mon 6 Dec	Dr Steen
Tues 7 Dec	[redacted]
Wed 8 Dec	
Thurs 9 Dec	
Fri 10 Dec	
Sat 11 Dec	
Sun 12 Dec	

Mon 15 Nov	Dr Steen
Tues 16 Nov	[redacted]
Wed 17 Nov	
Thurs 18 Nov	
Fri 19 Nov	
Sat 20 Nov	
Sun 21 Nov	

Mon 13 Dec	[redacted]
Tues 14 Dec	
Wed 15 Dec	
Thurs 16 Dec	Dr Shields
Fri 17 Dec	Dr Shields
Sat 18 Dec	[redacted]
Sun 19 Dec	Dr Shields

PAEDIATRIC NEUROLOGY CONSULTANT ROTA

FEBRUARY 1997

FEBRUARY

Sat	1st	Dr Hicks
Sun	2nd	Dr Hicks
Mon	3rd	Dr Webb
Tues	4th	Dr Webb
Wed	5th	Dr Hicks
Thurs	6th	Dr Hicks
Fri	7th	Dr Webb
Sat	8th	Dr Webb
Sun	9th	Dr Webb
Mon	10th	Dr Hicks
Tues	11th	Dr Hicks
Wed	12th	Dr Hicks
Thurs	13th	Dr Hicks
Fri	14th	Dr Hicks
Sat	15th	Dr Hicks
Sun	16th	Dr Hicks
Mon	17th	Dr Webb
Tues	18th	Dr Webb
Wed	19th	Dr Webb
Thurs	20th	Dr Webb
Fri	21st	Dr Webb
Sat	22nd	Dr Webb
Sun	23rd	Dr Webb
Mon	24th	Dr Hicks
Tues	25th	Dr Hicks
Wed	26th	Dr Hicks
Thurs	27th	Dr Hicks
Fri	28th	Dr Hicks

MARCH

Sat	1st	Dr Hicks
Sun	2nd	Dr Hicks

Please contact Senior Registrar Dr A Thompson (Bleep [redacted]) in the first instance to discuss Neurological problems, or if not contact Paul Ward extn 2252.

Dr Hicks Home Tel. No: [redacted] Vodapage
Dr Webb Home Tel. No: Vodapage [redacted]

ccs Dr Hicks, Dr Webb, Secretaries Office, Paul Ward, A&E, Admissions, Directorate Office, Paediatric Intensive Care Unit, Neurosurgery