

**BRIEF FOR PAEDIATRIC NEUROLOGIST EXPERT  
CLAIRE ROBERTS**

**Introduction**

1. Claire Roberts is one of four children who are the subject of a public inquiry being conducted by John O'Hara QC.
2. Claire was born on 10<sup>th</sup> January 1987. She was admitted to the Royal Belfast Hospital for Sick Children ("the Royal") on 21<sup>st</sup> October 1996 with a history of malaise, vomiting and drowsiness and she died on 23<sup>rd</sup> October 1996. Her medical certificate recorded the cause of her death as Cerebral Oedema and Status Epilepticus. That certification was subsequently challenged after a television documentary into the deaths of Adam and two other children (Lucy Crawford and Raychel Ferguson).
3. The Inquest into Claire's death was carried out nearly 10 years after her death by John Leckey on 4<sup>th</sup> May 2006. He engaged Dr. Robert Bingham (Consultant Paediatric Anaesthetist at Great Ormond Street) and Dr. Ian Maconochie (Consultant in Paediatric A&E Medicine at St Mary's, London) as experts. The Inquest Verdict found the cause of Claire's death to be Cerebral Oedema with Hyponatraemia as a contributory factor.
4. The other 3 children are :
  - (1) Adam Strain was born on 4<sup>th</sup> August 1991. He died on 28<sup>th</sup> November 1995 in the Royal following kidney transplant surgery. The Inquest into his death was conducted on 18<sup>th</sup> and 21<sup>st</sup> June 1996 by John Leckey, the Coroner for Greater Belfast, who engaged as experts: (i) Dr. Edward Sumner, Consultant Paediatric Anaesthetist at Great Ormond Street Hospital for Sick Children ("Great Ormond Street"); (ii) Dr. John Alexander, Consultant Anaesthetist at Belfast City Hospital; and (iii) Professor Peter Berry of the Department of Paediatric Pathology in St. Michael's Hospital, Bristol. The Inquest Verdict identified Cerebral Oedema as the cause of his death with Dilutional Hyponatraemia as a contributory factor.
  - (2) Raychel Ferguson was born on 4<sup>th</sup> February 1992. She was admitted to the Altnagelvin Area Hospital on 7<sup>th</sup> June 2001 with suspected appendicitis. An appendectomy was performed on 8<sup>th</sup> June 2001. She was transferred to the Royal on 9<sup>th</sup> June 2001 where brain stem tests were shown to be negative and she was pronounced dead on 10<sup>th</sup> June 2001. The Autopsy Report dated 11<sup>th</sup> June 2001 concluded that the cause of her death was Cerebral Oedema caused by Hyponatraemia.

The Inquest into Raychel's death was conducted on 5<sup>th</sup> February 2003 by John Leckey who once more engaged Dr. Edward Sumner as an expert. The Inquest Verdict found the cause of Raychel's death to be Cerebral Oedema with Acute Dilutional Hyponatraemia as a contributory factor. It also made findings that the Hyponatraemia was caused by a combination of inadequate electrolyte replacement following severe post-operative vomiting and water retention resulting from the secretion of anti-diuretic hormone (ADH).

- (3) Conor Mitchell was born on 12<sup>th</sup> October 1987 with cerebral palsy. He was admitted to A&E Craigavon Hospital on 8<sup>th</sup> May 2003 with signs of dehydration and for observation. He was transferred to the Royal on 9<sup>th</sup> May 2003 where brain stem tests were shown to be negative and he was pronounced dead on 12<sup>th</sup> May 2003.

The Inquest into Conor's death was conducted on 9<sup>th</sup> June 2004 by John Leckey who again engaged Dr. Edward Sumner as an expert. Despite the Inquest, the precise cause of Conor's death remains unclear.

The clinical diagnosis of Dr. Janice Bothwell (Paediatric Consultant) at the Royal was brainstem dysfunction with Cerebral Oedema related to viral illness, over-rehydration/inappropriate fluid management and status epilepticus causing hypoxia. Dr. Brian Herron from the Department of Neuropathy, Institute of Pathology, Belfast performed the autopsy. He was unsure what 'sparked off' the seizure activity and the extent to which it contributed to the swelling of Conor's brain but he considered that the major hypernatraemia occurred after brainstem death and therefore probably played no part in the cause of the brain swelling. He concluded that the ultimate cause of death was Cerebral Oedema. Dr. Edward Sumner commented in his Report of November 2003 that Conor died of the acute effects of cerebral swelling which caused coning and brainstem death but he remained uncertain why. He noted that the volume of intravenous fluids was not excessive and the type appropriate but queried the initial rate of administration. That query was raised in his correspondence shortly after the Inquest Verdict. In that correspondence, Dr. Sumner described the fluid management regime as 'sub-optimal'.

The Inquest Verdict stated the cause of death to be Brainstem Failure with Cerebral Oedema, Hypoxia, Ischemia, Seizures and Infarction and Cerebral Palsy as contributing factors.

5. The impetus for this Inquiry was a UTV Live Insight documentary 'When Hospitals Kill' shown on 21<sup>st</sup> October 2004.<sup>1</sup> The documentary primarily focused on the death of a toddler called Lucy Crawford (who was subsequently

<sup>1</sup> See DVD of the programme with the accompanying Core Files

also found to have died in hospital in 2000 as a result of hyponatraemia) and what was presented as significant shortcomings of personnel at the Erne Hospital. In effect, the programme alleged a cover-up and it criticised the hospital, the Trust and the Chief Medical Officer. The programme also referred to the deaths of Adam and Raychel in which hyponatraemia had similarly played a part. At that time, no connection had been made with the deaths of Claire and Conor.

### **Original Terms of Reference**

6. The Inquiry was established under the Health and Personal Social Services (Northern Ireland) Order 1972, by virtue of the powers conferred on the Department by Article 54 and Schedule 8 and it continues pursuant to the Inquiries Act 2005.
7. The original Terms of Reference for the Inquiry as published on 1<sup>st</sup> November 2004 by Angela Smith (then Minister with responsibility for the Department of Health, Social Services and Public Safety) were to:

To hold an Inquiry into the events surrounding and following the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson, with particular reference to:

- i. The care and treatment of Adam Strain, Lucy Crawford and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
- ii. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson.
- iii. The communications with, and explanations given to, the respective families and others by the relevant authorities.

In addition, Mr O'Hara will:

- (a) Report by 1 June 2005 or such other date as may be agreed with the Department, on the areas specifically identified above and, at his discretion, examine and report on any other relevant matters which arise in connection with the Inquiry.
- (b) Make such recommendations to the Department of Health, Social Services and Public Safety as he considers necessary and appropriate.

(Emphasis added)

### **Changes**

8. There have been a number of significant changes in the Inquiry since 2005. Firstly, the Crawford family wished to have Lucy excluded from the Inquiry's work and the Inquiry therefore received the following Revised Terms of Reference from the Minister:

1. The care and treatment of Adam Strain and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
2. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain and Raychel Ferguson.
3. The communications with and explanations given to the respective families and others by the relevant authorities.

In addition, Mr O'Hara will:

- (a) Report by 1 June 2005 or such date as may be agreed with the Department, on the areas specifically identified above and, at his discretion, examine and report on any other matters which arise in connection with the Inquiry.
- (b) Make such recommendations to the Department of Health, Social services and Public Safety as he considers necessary and appropriate.

9. Secondly, Claire Roberts and Conor Mitchell were included into the Inquiry's work by the Chairman. That decision arose out of the Royal's belated acknowledgement that hyponatraemia played a part in Claire's death as well as the apparent fluid mismanagement in Conor's case so soon after the implementation of Guidelines on Hyponatraemia that stressed the importance of fluid management.
10. The effect of the Revised Terms of Reference was to exclude all explicit references to Lucy Crawford. The Chairman has interpreted them in the following way:

... the terms still permit and indeed require an investigation into the events which followed Lucy's death such as the failure to identify the correct cause of death and the alleged Sperrin Lakeland cover-up because they contributed, arguably, to the death of Raychel in Altnagelvin. This reflects the contention that had the circumstances of Lucy's death been identified correctly and had lessons been learned from the way in which fluids were administered to her, defective fluid management would not have occurred so soon afterwards (only 14 months later) in Altnagelvin, a hospital within the same Western Health and Social Services Board area.

11. Claire Roberts' case is being investigated in accordance with precisely the same terms as those of Adam Strain and Raychel Ferguson. The investigation of Conor will address more limited issues in view of the fact that hyponatraemia was not thought to be a cause of his death (if anything he developed hypernatraemia). Similarly, the fluid mismanagement referred to by Dr. Sumner was not considered to have been a cause of his death. The Chairman has stated:

It is obviously a matter of concern if guidelines which have been introduced as a result of a previous death or deaths and which are aimed at avoiding similar events in the future, are not properly communicated to hospital staff and followed. It is relevant to the investigation to be conducted by the Inquiry whether and to what extent the guidelines had been disseminated and followed in the period since they were published. Another matter of interest is whether the fact that Conor was being treated on an adult ward rather than a

children's ward made any difference to the way in which it appears that the guidelines may not have been followed.

Accordingly, the Inquiry will investigate the way in which the guidelines had been circulated by the Department, the way in which they had been made known to hospital staff and the steps, if any, which had been taken to ensure that they were being followed. While this is an issue of general importance, it will be informed by an examination of the way in which the guidelines had been introduced and followed in Craigavon Area Hospital by May 2003.

### **Role of the Experts**

12. The Role of the Experts to the Inquiry is set out in 'Protocol No.4: Experts', a copy of which is attached.<sup>2</sup> There are 4 categories of expert assistance:
  - (i) Expert Advisors to assist the Inquiry in identifying, obtaining, interpreting the evaluating the evidence within their particular area of expertise, currently: (a) Paediatrician; (b) Paediatric Anaesthetist; (c) Nurse in Paediatric Intensive Care; and (d) National Health Service Hospital Management
  - (ii) Experts appointed to 'peer review' the work of the Expert Advisers, currently: (a) Internal Medicine/Nephrology; (b) Paediatric Anaesthetist; and (c) Paediatric Intensive and Critical Care Nursing
  - (iii) Experts on a case by case basis as Expert Witnesses
  - (iv) Experts to provide commissioned 'Background Papers'

### **Background to Claire**

#### ***Initial admission to the Ulster Hospital (1987)***

13. Claire Roberts was born on 10<sup>th</sup> January 1987. Claire was first admitted to hospital on 23<sup>rd</sup> July 1987 when she was admitted to The Ulster Hospital in Dundonald ("the Ulster Hospital"), aged 6 ½ months, because of seizures. Further episodes occurred during August 1987 resulting in treatment with the anticonvulsant, carbamazepine (Tegretol ®). Further convulsions occurred in September 1987, together with findings on examination of being floppy with possible abnormal posture and tone on the left side.

#### ***First referral to the Royal Belfast Hospital for Sick Children (1987)***

14. Claire's presentation in September 1987 resulted in her being referred to the Royal on 3<sup>rd</sup> September 1987 under the care of Dr. Hicks<sup>3</sup>. A summary sent to her GP following discharge on 21<sup>st</sup> September 1987, described her as having

<sup>2</sup> See Tab 1 of the accompanying Core File

<sup>3</sup> Ref: 090-018-033, 034

'poor trunk control and poor ability to lift her head when prone' and described certain behaviours which were more typical of a much younger infant (e.g. 'no stabilising reflexes; could only roll from semi-prone; makes no effort to reach and take objects.'). Seizures were witnessed that were described as 'salaam attacks' (myoclonic epilepsy) although the contemporaneous handwritten notes also referred to tonic-clonic seizures and absences. Investigations, including brain CT scanning and electroencephalography, did not define any causative diagnosis for her epilepsy. She was prescribed the anticonvulsant sodium valproate (Epilim®) before discharge, while weaning her from her previously prescribed Tegretol<sup>4</sup>.

### *Ulster (1988 and 1996)*

15. Dr. Gleadhill saw her at the Ulster Hospital on 9<sup>th</sup> February 1988, when he 'felt there was definitely some concern about her developmental delay.'
16. In May 1996, she was seen by Dr. Gaston, Consultant Community Paediatrician, in relation to behavioural problems. He concluded that she could be categorised as having 'attentional difficulties' and he noted in his letter to Claire's GP, the option of treating Claire with a stimulant medication, such as Ritalin®, Pemoline® or amphetamine<sup>5</sup>. Dr. Gaston saw Claire again on 1<sup>st</sup> August 1996 and a trial of Ritalin was discussed. He noted 'a very small risk of inducing seizures with Ritalin.' Claire was treated with Ritalin 10 mg daily until 2<sup>nd</sup> October 1996 when her parents reported 'dry mouth, viscous, pacing, ?agitated/unsettled 30 minutes after Ritalin.' Dr. Gaston noted his advice to 'hold meds' and 'restart on a weekend with just 5 mg. Mother to call 5 days later...'<sup>6</sup> It is not known whether the Ritalin was restarted. There is no mention of it in her A&E admission notes<sup>7</sup> or in the ward assessment<sup>8</sup>.

### *Second referral to the Royal (1996)*

17. On 21<sup>st</sup> October 1996 Claire's GP referred her for admission to the Royal Belfast Hospital for Sick Children ("Royal"). He described Claire as a 9-year-old girl with severe learning disability and past history of epilepsy who had been seizure-free for 3 years and had been weaned off anticonvulsant drugs 18 months previously. The referral also stated 'No speech since coming home. Very lethargic at school today. Vomited x 3 - speech slurred. Speech slurred earlier'<sup>9</sup>. Claire was described as pale, not liking the light and with no neck stiffness. The GP considered her tone increased on the right side and suggested that Claire was post-seizure and had an underlying infection<sup>10</sup>.

<sup>4</sup> Ref: 090-015-026, 027

<sup>5</sup> Ref: 090-013-017, 018

<sup>6</sup> Ref: 090-013-016, 017

<sup>7</sup> Ref: 090-011-013

<sup>8</sup> Ref: 090-022-050

<sup>9</sup> Ref: 090-011-013

<sup>10</sup> Ref: 090-011-013

18. Claire was admitted to the Royal later on 21<sup>st</sup> October 1996 exactly 4 months after the conclusion of the Inquest into Adam Strain's death of hyponatraemia at the Royal. The A&E note repeated parts of that history and noted non-bilious vomiting 'since this evening'. She was 'drowsy, tired, afebrile' with no other abnormal signs except for increased left sided muscle tone and reflexes. At 2045, a decision was made to admit Claire to hospital under the care of Dr. Heather Steen<sup>11</sup>.
19. The admission note (dated at 2000) refers to Claire as 'vomiting at 3 pm and every hour since' and to her having experienced a loose bowel motion 3 days previously. The admitting doctor, Dr. O'Hare, noted that Claire had severe learning difficulties but normally had meaningful speech and referred to the recent trial of Ritalin and its apparent side effects<sup>12</sup>. Dr O'Hare also noted that Claire 'sits-up and stares vacantly' and was ataxic. She was not responding to her parents' voice and only intermittently responding to a deep pain stimulus. She had cogwheel rigidity of her right arm and increased tone in all other limbs. Tendon reflexes were brisker on the right than the left and there was bilateral ankle clonus<sup>13</sup>.
20. The admission diagnoses were noted as: (1) Viral illness; (2) Encephalitis (but this was subsequently ruled out)<sup>14</sup>.
21. Blood was taken for a full blood count, urea and electrolytes, bacteriological culture and viral studies. Treatment to be given was noted as 'IV fluids, IV diazepam if seizure activity'. She was to be reassessed after fluids<sup>15</sup>. An IV prescription chart was prepared, ordering 500 ml of 0.18% sodium chloride in 4% dextrose to be given at 64 ml/h (equivalent to 65 ml/kg/24 h)<sup>16</sup>. The nursing care plan referred to administering 'IV fluids as prescribed by doctor, according to hospital policy'<sup>17</sup>.
22. The nursing record includes a fluid balance chart, which shows that treatment was started at 2130 with 64 ml hourly of 5/N saline. By 0700, Claire had received 536 ml [just under 57 ml hourly]. During those 9½ hours, she was noted by Nurse McRandal to have had one 'medium' and five 'small' vomits<sup>18</sup>. The nursing notes of the night of 21<sup>st</sup> October and early morning on 22<sup>nd</sup> October 1996 describe those vomits as bile-stained; this was a change from the A&E note, where the vomits were described as 'non-bilious'<sup>19</sup>.

<sup>11</sup> Ref: 090-012-014

<sup>12</sup> Ref: 090-022-050

<sup>13</sup> Ref: 090-022-051

<sup>14</sup> Ref: 090-022-052

<sup>15</sup> Ref: 090-022-052

<sup>16</sup> Ref: 090-038-134

<sup>17</sup> Ref: 090-043-146

<sup>18</sup> Ref: 090-038-133

<sup>19</sup> Ref: 090-040-140, 090-012-014

23. A medical note at midnight stated that she was 'slightly more responsive' and had no meningism. It was noted that she would be 'observed and reassessed a.m.' Directly beneath this note is a manuscript entry for the blood biochemical and haematological results. These were:

Sodium 132; Potassium 3.8; Urea 4.5; Glucose 6.6; Creatinine 36; Chloride 96;  
Haemoglobin 10.4; Packed cell volume 31; White cell count 16.5; platelets 422,000

24. The laboratory reference range for sodium ('normal range') is given as 135-145<sup>20</sup>. Next to the sodium result is the symbol ↓ and next to the white cell count is the symbol ↑<sup>21</sup>.
25. The nursing record at 0700 by Nurse McRandal states: 'Slept well. Much more alert and brighter this morning. One further bile stained vomit ... no oral fluids taken...'<sup>22</sup> A nursing note timed at 0800 - 1400 states: 'Slept for periods during early morning - bright when awake; no vocalisation but arm [?] active. Late morning Claire became lethargic and "vacant". Parents concerned as usually Claire is very active. Seen by Dr. Sands - status epilepticus - non-fitting. Rectal diazepam given ...'<sup>23</sup>
26. The first medical note on 22<sup>nd</sup> October 1996.10.96 referred to a ward round by Dr Sands (at the time, a registrar in paediatric cardiology) and stated 'Admitted ? viral illness. Usually very active, has not spoken to parents as per normal. Wretching [sic]. No vomiting. Vagueness/Vacant appearance (apparent to parents). No seizure activity observed ...' The sodium of 132 and raised white count were restated. She was described as apyrexial, pale and showing little response compared to normal. Her pupils were 'sluggish to light.' The impression was of 'non-fitting status.' A different hand has added 'encephalitis/ encephalopathy.'<sup>24</sup>
27. A plan was noted to give rectal diazepam (actually administered at 1230), to discuss her past medical history with Dr. Gaston and to consult Dr. Webb<sup>25</sup>. Dr. Webb also attended Adam Strain when he was admitted to PICU after he failed to regain consciousness following his renal transplant surgery.<sup>26</sup>
28. The fluid chart for 22<sup>nd</sup> October 1996<sup>27</sup> does not note the solution given. However, an undated prescription chart<sup>28</sup> also referred to 500 ml of 'No 18

<sup>20</sup> Ref: 090-031-100

<sup>21</sup> Ref: 090-022-052

<sup>22</sup> Ref: 090-040-140

<sup>23</sup> Ref: 090-040-141

<sup>24</sup> Ref: 090-022-052, 053

<sup>25</sup> Ref: 090-022-052, 053

<sup>26</sup> Ref: 058-035-139 - see his note in Adam's medical notes and records at 1930 on 27<sup>th</sup> November 1995 when he refers to "severe acute cerebral oedema" and the possibility of "unexplained fluid shifts". See also Ref: 058-035-142 and his note at 09.10 on 28<sup>th</sup> November 1995 recording that the criteria for brain stem death had been met - just below the entry for 0745: "electrolyte/fluid problem overnight" Tab 2 of core file

<sup>27</sup> Ref: 090-038-135

<sup>28</sup> Ref: 090-038-136



solution at 64 ml/hr'. A total of 562 ml was given over eight hours from 0800, i.e. 70 ml/h.

29. At 1530 Claire was reported as having a 5-minute 'strong seizer [sic]' at 1525. At 1630, her teeth tightened slightly<sup>29</sup>. At 1600, Dr. Webb made a note. He saw Claire with her grandmother, noting a history of 'Vomiting and listless yesterday p.m. - followed by prolonged period of poor responsiveness.' He added that she had appeared to improve after rectal diazepam, given at 1230. She was afebrile and pale with no meningism. She opened her eyes to voice, was non-verbal, withdrew [limb] from painful stimulus and had (questionably) reduced movements on the right side. He found mildly increased tone in her arms and symmetrical brisk reflexes, sustained ankle clonus and upgoing plantar responses. Claire was sitting up with eyes open and looking vacant, not obeying commands. She did not have papilloedema<sup>30</sup>. Dr Webb's impression was 'I don't have a clear picture of prodrome + yesterday's episodes. Her motor findings today are probably long-standing but this needs to be checked with notes. The picture is of acute encephalopathy, most probably postictal in nature. I note (N) [normal] biochemistry profile'<sup>31</sup>.
30. Dr Webb suggested starting Claire on the anticonvulsant phenytoin intravenously: 18 mg/kg as a first dose, followed by 2.5 mg/kg 12 hourly. He asked for hourly neurological observations and a CT scan the following day 'if she doesn't wake up'<sup>32</sup>.
31. Although Dr. Webb's note is timed at 4pm, he states in his Deposition at the Inquest that he believed he saw Claire at about 1400. The SHO noted calculations of phenytoin dose at 1430 and ordered a dose of 18[mg] x 24 [h] which he or she wrongly calculated as 632 mg rather than 432 mg. The calculation of the continuing dose of 2.5 mg/kg 12 hourly is then stated as 60 mg 12 hourly<sup>33</sup>.
32. Those doses were ordered on a prescription chart<sup>34</sup>. The nursing notes record a stat dose of phenytoin given at 2.45pm<sup>35</sup>, with a second dose at 11pm following blood sampling for phenytoin levels<sup>36</sup>.
33. The next medical note (untimed) referred to Claire being seen by Dr. Webb and being 'still in status.' It went on to calculate a dose of the anticonvulsant/sedative midazolam to be given as a first dose of 0.5 mg/kg (12 mg) followed by 2 mcg/kg/minute, calculated as 2.88 mg/h. The nursing notes record 'stat IV

<sup>29</sup> Ref: 090-042-144

<sup>30</sup> Ref: 090-022-053, 054

<sup>31</sup> Ref: 090-022-054

<sup>32</sup> Ref: 090-022-054

<sup>33</sup> Ref: ibid

<sup>34</sup> Ref: 090-026-075

<sup>35</sup> Ref: 090-026-075, 090-040-141

<sup>36</sup> Ref: 090-040-138, 090-038-135, 090-026-077

hypnovel (midazolam) at 3.25pm<sup>37</sup>. No dosage was recorded against this entry. The continuing infusion of midazolam was ordered as 69 mg in 50 ml normal saline to be given at 2 ml/h, which is confirmed by the fluid charts as having been given from 1630<sup>38</sup>. Also from 1600, No 18 solution was continued with 452 ml given over 7 h to 2300 [64 ml/h]<sup>39</sup>.

34. At 1700, Dr Webb, having received information from Claire's mother about the onset of the illness, described Claire as 'largely unresponsive' with intermittent vomiting and chewing. He prescribed the antibiotic cefotaxime and the antiviral drug acyclovir for 48 hours, although he noted that he did not think meningoencephalitis very likely. He noted that stool, urine, blood and a throat swab should be checked for evidence of enterovirus infection. He also suggested an additional anticonvulsant intravenous infusion: sodium valproate 20 mg/kg as an initial dose, followed by 10 mg/kg over 12 h<sup>40</sup>. A nursing note at 1715 referred to Claire being given a stat dose of Epilim and added 'Very unresponsive - only to pain. Remains pale. Occasional episode of teeth clenching ...'<sup>41</sup>
35. At 2100, a nurse reported that Claire had a 30-second episode of screaming and drawing up of her arms with her pulse rising to 165. A doctor was informed<sup>42</sup>.
36. At 2330, an SHO (possibly Dr Stewart) noted that a blood sample likely to have been taken when the doctor attended at 2100 - 2130, showed a sodium concentration of 121 mmol/L, potassium 3.3 mmol/L, urea 2.9 mmol/L and creatinine 33 µmol/L. The phenytoin level was 23.4 mg/L (reference range 10-20 mg/L). It was noted: 'Hyponatraemic - ? Fluid overdose with low sodium fluids. ? SIADH' and 'Imp[ression]. ? need for ↑ sodium content in fluids. Discussed with registrar - ↓ fluids to 2/3 of present value - 41 ml/h. Send urine for osmolality'<sup>43</sup>.
37. In fact, between 2300 and 0200 Claire received 56 ml of No 18 solution (18.5 ml/h) and 7.6 ml of normal saline. Also between 2200 and 0100 Claire received 170 ml of other fluids, recorded as IV Acyclovir 60 (presumably 'ml') and Phenytoin 110 (? 'ml') recorded in the oral fluids columns. The exact nature of the fluids in which the Acyclovir and Phenytoin were dissolved is not stated<sup>44</sup>.
38. A nursing note at 2130 referred to Claire receiving midazolam at 3 ml/h, completed by 2240. At 2300, she was given IV phenytoin over 1 hour. In addition, the fluid chart refers to two 'small mouthfuls' of vomit/aspirate

<sup>37</sup> Ref: 090-040-141

<sup>38</sup> Ref: 090-038-135, 136

<sup>39</sup> Ref: 090-038-135

<sup>40</sup> Ref: 090-022-055

<sup>41</sup> Ref: 090-040-141, 090-142-144

<sup>42</sup> Ref: 090-042-144

<sup>43</sup> Ref: 090-022-056

<sup>44</sup> Ref: 090-038-135

recorded at 2400 and 0100<sup>45</sup>. It is unclear whether these were discussed with the doctors, as they are not referred to in the medical or nursing notes. As a result of instructions from 'a registrar', 20 mmol of potassium chloride was added to the No 18 solution and the rate reduced to 41 ml/h. At 0230, a nurse noted 'Slight tremor of right hand noted lasting few seconds. Breathing became laboured and grunting. Respiratory rate 20 per minute. Oxygen saturations 97%. Claire stopped breathing. Dr contacted immediately. Oxygen and suction given. Registrar attempted to pass ET tube but unsuccessful - anaesthetist called and ET tube inserted. Transferred to intensive care at 3.25 am'<sup>46</sup>.

39. The medical note states that Claire 'had been stable when suddenly she had a respiratory arrest and developed fixed dilated pupils.' The doctor who attended noted she was 'Cheyne-Stoking'. Oxygen was being administered by a facemask and 'bagging' with oxygen saturation in the 'high 90s' and a 'good volume pulse.' The doctor unsuccessfully attempted intubation. It was subsequently carried out by the on-call anaesthetist and Claire was then transferred to the ICU<sup>47</sup>.
40. The neurological observation chart, started at 1300 on 22<sup>nd</sup> October 1996, shows that at 1300 she was noted as *opening her eyes to speech* and at 1430 as *opening eyes to pain*. Thereafter, hourly recordings until 0200 on 23.10.96 all stated there was *no eye opening*. 'Best verbal response' was noted as *none* from 1300 to 1800 and thereafter as *incomprehensible sounds*. Her 'best motor response' was noted as *obey commands* at 1300 and at 2000, *localise pain* between those times and *flexion to pain* thereafter<sup>48</sup>.
41. Her Glasgow Coma Scale (GCS) score was given as 9 on first checking and thereafter was 6 - 7, except recorded as 8 at 2000. There was a rise in temperature from normal to between 37.5 C and 38 C from 1900 and of pulse rate from <90 at 1300 to 115 at 1800, thereafter remaining at 100-105. There was no significant change recorded in blood pressure<sup>49</sup>.
42. Claire was admitted to ICU at 0315 on 23<sup>rd</sup> October 1996 and the first ICU note was made at 0400. It reiterated the history as given above and noted that 'Claire was 'now intubated and ventilated. Pupils fixed and dilated. Bilateral papilloedema [swelling of the optic discs visible using an ophthalmoscope and implying raised intracranial pressure] L>R. No response to painful stimuli ...' She was given mannitol to reduce the cerebral oedema and dopamine and a brain CT scan was requested. At that time, the serum sodium concentration was recorded at 121mmol/L, which was equivalent to the result recorded at 2330 on 22<sup>nd</sup> October 1996<sup>50</sup>. It is not clear precisely when those bloods were taken or the

<sup>45</sup> Ref: 090-038-135

<sup>46</sup> Ref: 090-040-138, 139

<sup>47</sup> Ref: 090-022-056

<sup>48</sup> Ref: 090-039-137

<sup>49</sup> Ref: 090-039-137

<sup>50</sup> Ref: 090-022-057

laboratory results communicated but the phenytoin result states that it was received at 0420 and vetted at 0438<sup>51</sup>. The blood could therefore have been taken between 0315 and 0400.

43. Dr. Webb noted, at 0440, 'SIADH (syndrome of inappropriate antidiuretic hormone secretion] – hyponatraemia, hyposmolarity, cerebral oedema + coning following prolonged epileptic seizures. Pupils fixed and dilated following mannitol diuresis. No eye movements ...<sup>52</sup>'
44. A first test for brain stem death was conducted by Drs. Webb and Steen at 0600<sup>53</sup>. The CT scan was reported as showing 'severe diffuse hemispheric swelling with complete effacement of the basal cisterns. No focal abnormality identified'<sup>54</sup>.
45. Dr. McKaigue, ICU Consultant, reiterated the history of her hospital admission in a note at 0710. This included the serum sodium, checked by Drs. Webb and Steen at the same time as brain stem tests [0600], and found on the ICU blood gas analyser, was 133 mmol/L (and pH 7.13, PO<sub>2</sub> 124.5 mm Hg and PCO<sub>2</sub> 79.2 mm Hg). A laboratory sample sent at the same time was reported as: sodium 129 mmol/L and osmolality 274 mOsmol/kg. Dr. McKaigue noted a plan to 'maintain circulatory support as Claire is a potential organ donor' and ordered a dopamine infusion to maintain blood pressure and a 'close check on serum sodium and osmolality and urine output. If serum sodium >150 mmol/L and osmolality >300 mOsmol/kg then commence desmopressin ...' He changed the IV infusion fluid to 0.9% saline and at 0810 or 0850 requested 2 hourly measurements of urea and electrolytes<sup>55</sup>.
46. An untimed note, placed between that of Dr. McKaigue at 0810 or 0850 and that of Dr. Steen at 1825 referred to Claire becoming hypotensive (BP 70/?) 'with DI [diabetes insipidus], given HPPF 500 ml. Needs DDAVP to limit polyuria. Appears brain stem death informally. Sodium 129 (from 121).' In her witness statement to the Police Service of Northern Ireland ("PSNI"), Dr. Steen identifies the writer as Dr. Robert Taylor, Consultant Paediatric Anaesthetist in charge of the PICU on 23<sup>rd</sup> October 1996. Dr. Taylor was the Paediatric Anaesthetist in charge of Adam's anaesthesia and fluids for his kidney transplant at the Royal 26<sup>th</sup> November 1996.
47. Two untimed laboratory reports on 23<sup>rd</sup> October 1996 showed serum sodium concentrations as 139 mmol/L and 152 mmol/L respectively, with osmolality 274 and 313 mOsmol/kg. The latter blood sample was identified by Dr. Steen as having been taken in the afternoon<sup>56</sup>.

<sup>51</sup> Ref: 090-031-101

<sup>52</sup> Ref: 090-022-057

<sup>53</sup> Ref: 090-045-148

<sup>54</sup> Ref: 090-022-058

<sup>55</sup> Ref: 090-022-059, 060

<sup>56</sup> Ref: 090-050-156

48. At 18.25 on 23<sup>rd</sup> October 1996 the brain stem death test protocol was repeated<sup>57</sup>, and it was noted there was no spontaneous respiration while the PaCO<sub>2</sub> was 70 mm Hg. These findings were discussed with the parents who agreed that ventilation should be withdrawn; consent for limited post-mortem examination was given. Ventilation was discontinued at 1845. The Death Certificate issued for Claire gave the cause of death as cerebral oedema secondary to status epilepticus<sup>58</sup>.
49. An untimed 'Relative Counselling Record' for 22<sup>nd</sup> October 1996 (query whether it should be 23<sup>rd</sup> October 1996) stated that parents were seen by Drs. Steen and Webb. Dr Steen [?] explained that Claire had trouble with her breathing and needed to have ventilatory support now. Following the CT scan, she explained that 'Claire had swelling of the brain and could be (possible) brain dead.' Dr Webb [?] explained that Claire's brain had swollen and that the CT scan and brain stem tests showed Claire's brain had died. Only the ventilator was keeping her heart beating.' When they asked why her brain had swollen, they were told it was probably caused by a virus<sup>59</sup>.
50. Dr Sands made a note on 11<sup>th</sup> November 1996 that he had spoken at length with Claire's parents, talking through the events before her death 'and also talked generally with them.' He noted that they were anxious to know the post mortem findings and he would 'pass this on to Dr. Steen ASAP'<sup>60</sup>.

#### *Post-mortem findings*

51. Certain pathological investigations requested during her life were reported after Claire's death. These included a blood culture that was sterile, an unremarkable urine specimen, absence of blood antibody to mumps, measles, herpes simplex, herpes zoster, cytomegalovirus, adenovirus, Q Fever, PLG virus, Mycoplasma pneumoniae, and Influenza A & B. A cerebrospinal fluid sample [taken post-mortem] was bloodstained with protein 95 gm/L (normal 0.15 -0.45 gm/L), globulin present +++, red cells 300,000/ $\mu$ L and white cells 4000/ $\mu$ L - mostly lymphocytes. No organisms were cultured<sup>61</sup>.
52. An autopsy of the brain only was carried out on 24<sup>th</sup> October 1996 by Dr. Herron. The clinical summary referred to Claire's admission with vomiting after contact with a relative with diarrhoea and vomiting. It went on to refer to her increasing drowsiness, that 'she was felt to have subclinical seizures' and mentioned her anticonvulsant treatment and that her serum sodium concentration had decreased to 121mmol/L. There was a query of inappropriate

<sup>57</sup> Ref: 090-045-148

<sup>58</sup> Ref: 090-022-061, 091-012-077

<sup>59</sup> Ref: 090-028-088

<sup>60</sup> Ref: 090-022-061

<sup>61</sup> Ref: 090-030-092 to 098

ADH secretion. There is a statement that Claire had 'iatrogenic epilepsy since 10 months'<sup>62</sup>.

53. Dr. Herron noted Claire's brain weighed 1606 g. His evidence to the Coroner's Inquest was that he would have expected it to be 1300 g. There was no cortical venous thrombosis or meningeal exudate. There was symmetrical brain swelling with effacement of gyri, confirmed on sectioning. He reported observing focal meningeal thickening over the cortex and a cellular reaction in the meninges and perivascular space. In the deep white matter, there were focal collections of neurones arranged in a 'rather haphazard manner.' Dr. Herron also described focal collections of neuroblasts in the subependymal grey matter suggestive of a migration problem. There was focal haemorrhagic necrosis in the brain stem.
54. Dr. Herron's diagnosis was cerebral oedema with neuronal migrational defect and a low-grade sub acute meningoencephalitis. He concluded that the reaction in meninges and cortex was suggestive of a viral aetiology although viral studies were 'negative during life and on a post-mortem cerebrospinal fluid'. Dr. Herron could not rule out a metabolic cause.<sup>63</sup>
55. On 5<sup>th</sup> March 1997, Dr. Steen wrote to Claire's GP stating that the abnormal neuronal migration [as described by Dr Herron] would have accounted for her learning difficulties and that other changes 'were in keeping with a viral encephalomyelitis meningitis.' She added that she and Dr. Webb had discussed the findings with Claire's parents and 'we will be happy to see them if they want to discuss things further with ourselves.'<sup>64</sup>
56. Dr. Webb wrote to Claire's parents on 28<sup>th</sup> February 1997 (letter typed on 21<sup>st</sup> March 1997), offering condolences and summarising the post-mortem findings similarly. He added that the reaction in the meninges and cortex suggested a viral cause with which the history of diarrhoea and vomiting was in keeping.<sup>65</sup>
57. A brief handwritten summary and a typed précis written by Dr. Mannam, an ICU SHO, dated 29<sup>th</sup> October 1996 records the principal diagnosis is recorded as Cerebral Oedema, other diagnoses are listed as Status Epilepticus and finally hyponatraemia. This summary dealt only with the events in ICU, not those preceding it.<sup>66</sup>

<sup>62</sup> Ref: 090-003-003

<sup>63</sup> Ref: 090-003-004, 005

<sup>64</sup> Ref: 090-002-002

<sup>65</sup> Ref: 090-001-001

<sup>66</sup> Ref: 090-006-008, 011

### *Coroner's Inquest (2005)*

58. That certification was subsequently challenged after her parents had seen the UTV Live Insight documentary 'When Hospitals Kill', which was shown on 21<sup>st</sup> October 2004. The documentary dealt with the death primarily of Lucy Crawford but also the deaths of Adam Strain and Raychel Ferguson.
59. On 7<sup>th</sup> December 2004, Dr Nicola Rooney, Consultant Clinical Psychologist, arranged a meeting with Claire's parents, herself, Dr Andrew Sands, Dr Heather Steen and Professor Ian Young, Professor of Medicine at Queen's University Belfast ('independent adviser').<sup>67</sup>
60. Their initial questions were whether Claire's condition was misdiagnosed, what role did sodium and fluid management play in her case and what led to her sudden deterioration.<sup>68</sup>
61. In the minute of the meeting, Mrs Roberts stated that, just before leaving the hospital at 9pm on 21<sup>st</sup> October 1996, she had a discussion with a nurse and was not unduly concerned, hoping Claire would be well enough to be discharged on Wednesday. Neither she nor her husband got the impression from staff that the situation was critical (or they would not have left). Dr Steen responded that medical staff would have been concerned, as evidence by Claire's hourly observations and that 'three different medicines had already been administered.' Dr Steen added that it would have helped if medical staff had spoken to Mr & Mrs Roberts before they left the hospital at 2130h.<sup>69</sup>
62. Professor Young stated that on arrival Claire's serum sodium concentration was 'slightly low at 132,' that she was given standard fluid intravenously which was 'the text book recommendation' and that approximately 24 hours later the sodium concentration was rechecked and that the result, 27 hours after arrival, was 121 mmol/L, which was very low. In response, the amount of fluid given was reduced. Professor Young considered that the fall in sodium concentration had contributed to Claire's death but could not say to what extent. He stated that lessons had been learned at the Royal and that the use of 5<sup>th</sup> normal saline was now banned. The Trust would now approach the Coroner for advice on the best course of action.
63. By letter, dated 16<sup>th</sup> December 2004, Mr AP Walby, associate medical director at the Royal, reported Claire's death to Mr. John Leckey, HM Coroner. He summarised Claire's admission in 1996 and the subsequent events, consequent upon the screening of the UTV programme. He noted that Professor Young 'has

<sup>67</sup> Ref: 089-003-006 & 002-002

<sup>68</sup> Ref: 089-002-002

<sup>69</sup> Ref: 089-002-002 to 005

examined the notes and in his opinion there was an indication that hyponatraemia had played a part in Claire's death ...'<sup>70</sup>

64. On the following day, Dr. Michael McBride, Medical Director, wrote to Claire's parents stating that the Trust's medical case review suggested that 'there may have been a care management problem in relation to hyponatraemia and that this may have significantly contributed to Claire's deterioration and death.'<sup>71</sup>
65. The Inquest into Claire's death was carried out on 4<sup>th</sup> May 2006 by the Coroner who had engaged as experts Dr. Robert Bingham, Consultant Paediatric Anaesthetist at Great Ormond Street Hospital ("Great Ormond Street") and Dr. Ian Maconochie, Consultant in Paediatric A&E Medicine at St Mary's, London ("St Mary's"). The Inquest Verdict found the cause of Claire's death to be Cerebral Oedema with Hyponatraemia as a contributory factor.
66. Dr Bingham considered the admission diagnosis was reasonable and acute encephalopathy (viral or ictal) a likely cause of the presenting illness. He did not consider the serum sodium concentration of 132 mmol/L a likely cause. He also considered it reasonable to give Claire intravenous fluids, as she could not hydrate herself, and noted that she was given the fluid used as standard in 1996 within the recommended volume for full maintenance fluid therapy. He believed there were, however, reasons why Claire might have required fluid restriction – namely low level of metabolism related to impaired consciousness (which is the evidence that you produce significantly less urine just because your conscious level is impaired, as long as a 'normal' fluid intake is maintained) and possible reduced urinary output due to secretion of ADH which often accompanies both encephalopathy and nausea and vomiting. He concluded that if the reported sodium concentration of 121 mmol/L was accurate, then it was the likely cause of her deterioration and death. He could not exclude the possibility of an inaccurate reading given the subsequent ICU measurements, in which case acute encephalopathy was involved or even central. He considered it possible that 'aggressive treatment at 2100 when her coma score reduced from 8 to 6, may have been effective'.
67. In his evidence at the Inquest, Dr. Bingham stated he agreed with Dr. Maconochie's formulation of cause of death and that he considered her neurological illness caused ADH secretion. Hyponatraemia was not her presenting problem.<sup>72</sup>
68. Dr. Maconochie considered the diagnosis of encephalitis/encephalopathy was made at an early stage and that of non-convulsive status epilepticus had a high probability given her past history of seizures. He regarded management of these diagnoses was appropriate and did not comment on hyponatraemia as it

<sup>70</sup> Ref: 089-004-009

<sup>71</sup> Ref: 089-005-010

<sup>72</sup> Ref: 091-006-021



was addressed by Dr. Bingham. He considered Dr. Webb and other members of the team looking after Claire gave careful and informed advice. At the Inquest, he gave his opinion as to cause of death as I(a) cerebral oedema; (b) encephalitis/encephalopathy and hyponatraemia and II status epilepticus.<sup>73</sup>

69. He considered that the finding of a sodium concentration of 121 mmol/L should have led to an immediate repeat sample and clinical reassessment. In addition, a blood sample should have been taken the morning after her admission, which may have shown a decrease in serum sodium concentration. Consideration would have had to be given to the cause. He considered her symptoms on 22<sup>nd</sup> October 1996 were consistent with a number of conditions including hyponatraemia but there was no hyponatraemia issue on presentation.<sup>74</sup>
70. Dr. Sands informed the Inquest that he had seen Claire first on the morning of 22<sup>nd</sup> October 1996, requested notes to be faxed from the Ulster Hospital and went to speak to Dr. Webb to seek his opinion. He emphasised that he was very concerned regarding Claire's level of consciousness, and this concern prompted the urgent neurology referral. He recalled spending some time with Claire and her mother to get a clear history and idea of her normal behaviour and also believed he explained his concerns without causing alarm.<sup>75</sup>
71. Dr Webb's statement to the Coroner listed the Glasgow Coma Score findings and gave as his interpretation that there had been a period of change between 1300 and 1500 on 22.10.96, which may have been related to administration of anticonvulsants, especially midazolam, or to the observed seizure at 1525. After 2000, there was a definite and sustained change.<sup>76</sup>
72. He stated that when he first saw Claire he was uncertain whether there had been seizure activity on the day before admission but concluded, after speaking to Mrs Roberts, that there had been a definite right-sided seizure the previous day. His conclusion was that Claire was having subtle non-convulsive seizure activity provoked by a viral infection, so appeared 'encephalopathic.' He also raised other differential diagnostic possibilities. He commented that his note about her blood results as normal (when her serum sodium concentration was <135 mmol/L) was likely to be because he believed her sodium concentration was a product of her recent vomiting and diarrhoea and could not on its own have explained her current encephalopathy or seizures. He also believed he erroneously understood the result to have been from a sample taken that morning (rather than the night before) and his entry in the note was a memo to himself that it could not have explained her clinical state. He stated that he

<sup>73</sup> Ref: 091-007-028

<sup>74</sup> Ref: ibid

<sup>75</sup> Ref: 091-009-055 to 057

<sup>76</sup> Ref: 091-008-049,050

believed if he had understood the result to be from the previous evening he would have asked for an urgent repeat sample.<sup>77</sup>

73. Dr Webb also stated that he was not sure Claire would have met the criteria for admission to ICU when he left the hospital on 22<sup>nd</sup> October 1996, as there was no problem with her airway or breathing and no supportive signs of raised intracranial pressure such as papilloedema, hypertension or bradycardia.<sup>78</sup>
74. In his deposition, Professor Young noted that losses were not accurately recorded on Claire's fluid chart so that fluid balances could not be judged. He judged the possibility of an inaccurate laboratory result for sodium as negligibly small, provided an appropriate sample was taken.<sup>79</sup>
75. Dr. Steen, the consultant paediatrician under whose care Claire had been admitted, stated to the Inquest that the blood test result at 2330 on 22<sup>nd</sup> October 1996 should have led to a repeat test, reduction in fluid intake and a clinical reassessment. She recalled being told that Dr. Webb had taken over her management, that she was not contacted again until 0300 on 23.10.96 and that the Glasgow coma score at 2100 should have led to a discussion with a consultant.<sup>80</sup>
76. The Coroner accepted Dr Steen's evidence that the sodium concentration of 121 mmol/L should have been repeated and have led to fluids being reduced and a clinical reassessment. However, by then it was unlikely that her condition was survivable even if prompt action had been taken.<sup>81</sup>
77. The Inquest verdict gave as the cause of death 1(a) Cerebral Oedema due to (b) meningoencephalitis, hyponatraemia due to excess ADH production and Status Epilepticus.

#### *PSNI Investigation (2008)*

78. Following investigations into the deaths of initially Lucy Crawford and then Adam and Raychel, the PSNI decided to investigate Claire's death. The PSNI engaged a number of experts to assist with its investigations.
79. Dr Dewi Evans, consultant paediatrician at Singleton Hospital, Swansea provided a report at the request of the PSNI on 1<sup>st</sup> March 2008, having read the report of Dr. Harding (see below). Dr Evans stated that there was nothing in the medical notes to suggest Claire had suffered a seizure prior to admission. He

<sup>77</sup> Ref: 091-008-050 to 052

<sup>78</sup> Ref: 091-008-053

<sup>79</sup> Ref: 091-010-063,064

<sup>80</sup> Ref: 091-011-067, 8

<sup>81</sup> Ref: 096-013-087

further stated that I suspect my primary diagnosis [on admission] would have been an encephalopathy secondary to an unknown viral infection.

80. He drew attention to the post-mortem cerebrospinal fluid examination and compared the findings with the three peripheral blood samples reported during her admission. In Claire's blood the ratio of white to red cells varied between 1:228 and 1:696. In the CSF, it was 1:75. He pointed out that conventional teaching was that a CSF sample [contaminated accidentally by blood when inserting the needle] should contain a ratio of 1:500. Thus, there was an excess of white cells over what was to be expected (predominantly lymphocytes) which would be compatible with a diagnosis of viral meningoencephalitis.
81. Dr Evans referred to the admission serum sodium concentration of 132 mmol/L with no clinical or biochemical evidence of dehydration. It is his opinion that in the context of her having an encephalopathy, 'one needs to consider seriously the possibility of her already experiencing the syndrome of inappropriate ADH secretion.' He did not disagree with the calculated volume of fluid prescribed. He attached to his report a copy of the 1997 *Advanced Paediatric Life Support Manual* that recommended the routine use of 1/5<sup>th</sup> normal saline but that his own practice had been to use 0.45% saline because of the risk of 'waterlogging.' Nonetheless, despite the recommendation for such routine use, he considers Claire's case merited a more concentrated solution because of the reasons expressed above.
82. He is also critical of the failure to measure urinary volume or its analysis for sodium concentration and osmolality and the failure to re-measure blood electrolytes the following morning. He considers the combination of urine and blood investigation would have allowed the medical staff to adjust her fluids carefully and accurately.
83. Dr Evans notes the first record of an observed seizure was at 1525 on 22<sup>nd</sup> October 1996. Given the disturbing GCS scores, he considers this event to have reflected raised intracranial pressure due to relatively early cerebral oedema, rather than primary epilepsy or non-convulsive status. This, he states, mandated CT scanning, the result of which would have led to treatment to control any such oedema.
84. Dr. Brian Harding, Consultant Neuropathologist at Great Ormond Street provided a report to PSNI on 22<sup>nd</sup> August 2007. He reported on numerous stained sections taken from Claire's cerebral hemispheres. He found no evidence of meningitis, encephalitis, haemorrhage or stroke. He found no evidence of malformation. He summarised his findings as:

Brain swelling (macroscopic description)  
Acute hypoxic damage to nerve cells (probably terminal)  
No evidence of acquired or inherited disease

85. Dr. Harding noted the Inquest verdict on cause of death and stated that he considers meningoencephalitis excluded both by microbiology and post-mortem neuropathology. He found no neuropathological sequelae of status epilepticus, so concludes that hyponatraemia was the only causative factor positively identified as the reason for brain swelling.
86. Dr Rajat Gupta, paediatric neurologist provided a report to the PSNI in October 2008, having read the report of Dr Harding. He concluded that the cause of death was cerebral oedema, itself most likely caused by hyponatraemia.<sup>82</sup>
87. Dr Gupta considers there was no clear evidence for the diagnosis of non-convulsive status epilepticus, although it was reasonable that it was considered as a possible diagnosis during Claire's admission. 'While possible it was unlikely and would have required EEG analysis for confirmation.' He commented that there was no definite improvement in Claire's condition following the use of anticonvulsants and that the (possible?) seizures seen during her admission may 'very well have been precipitated by hyponatraemia'. In support for his opinion, he states that (i) Dr Harding saw no pathological evidence of status epilepticus; (ii) Claire had not before had any episodes of non-convulsive status and (iii) Dr Harding saw no damage to the hippocampus as might be seen in children with chronic epilepsy.
88. Dr Gupta considered it reasonable that a diagnosis of meningoencephalitis was entertained although unlikely in the absence of fever and meningism.
89. He pointed out that Claire's GCS scores were between 6 and 7 from 1400 to 2000 on 22<sup>nd</sup> October 1996 (or 6-8 by Dr Webb's calculations). Dr. Gupta stated that as a GCS <8 is generally regarded as evidence of severe brain injury, serious consideration should have been given at that time to transferring her to ICU.
90. Susan Chapman, Nurse Consultant for acute and high dependency care at Great Ormond Street, provided a report to the PSNI on 11<sup>th</sup> April 2008. She considered Nurse McRandal's initial assessment and care plan acceptable as was the overnight nursing assessment and the observation chart. Claire was placed on four hourly observations of temperature, pulse, respirations and blood pressure, which were described by Nurse McRandal as 'within normal limits'. However, Ms Chapman states that the pulse rate and blood pressure were elevated,<sup>83</sup> and later suggests that 'there was an overall lack of recognition of the seriousness of Claire's clinical condition'.<sup>84</sup>
91. Ms Chapman also considers the neurological observation chart, the intravenous therapy and fluid charts, drug chart and record of observed attacks to be completed to an acceptable standard. In particular, she notes that it was

<sup>82</sup> Ref: 097-011-026

<sup>83</sup> Ref: 097-014-185

<sup>84</sup> Ref: 097-014-190

acceptable practice in 1996 not to calculate an accurate fluid balance by recording actual output, rather than an estimate of amount and frequency. We note that the nursing care plan requires nurses to 'record accurate fluid balance chart'.<sup>85</sup> As Claire wore a nappy at night <sup>86</sup> and possibly during the day as well whilst she was drowsy and lethargic, it may have been possible to weigh the nappies to provide a more accurate assessment of urine output. On 22<sup>nd</sup> October 1996, it would appear that the nurses had collected a urine specimen; this was sent to the lab at 1100, <sup>87</sup> but the urine volume was not recorded on the fluid chart.

92. Ms Chapman notes the absence of neurological observations from admission and considers this was related to the medical staff initially regarding the problem as 'viral' and subsequently not making it explicit that Claire's condition required regular neurological observation, until requested by Dr Webb.

### **Requirements**

93. The Inquiry team requires your assistance with the following:
- (i) Analysing the documents including the Reports and Statements
  - (ii) Understanding the medical processes involved in Claire's care and subsequent death
  - (iii) Identifying areas where other Expert views should be sought
  - (iv) Determining the further matters to be addressed in Witness Statements
94. The most pressing matter is to receive your advice on the following, which have been specifically identified by the Inquiry's Expert Advisors:
- (i) The appropriateness of the decision to admit Claire under the care of a consultant paediatrician rather than a consultant paediatric neurologist
  - (ii) The quality of the diagnostic assessment and management by the paediatric registrar, Dr. Bernie O'Hare, on admission on 21<sup>st</sup> October 1996, including:
    - (a) The differential diagnosis that a reasonably competent Paediatric Registrar would have made, given the information available to him/her at the time of Claire's admission to the ward

<sup>85</sup> Ref: 090-043-146

<sup>86</sup> Ref: 090-041-143

<sup>87</sup> Ref: 090-038-135

- (b) Whether the investigations proposed were appropriate and sufficiently comprehensive in the circumstances, and if not, why they were not
  - (c) The appropriateness, in the circumstances, of the prescription at admission for IV fluid therapy, including:
    - Whether both the nature and the volume of the IV fluid prescribed was within the usually accepted practice at the time.
    - Whether both the nature and the volume of the IV fluid prescribed would be appropriate now, and if not, what the appropriate fluid regime would be
    - Whether, in light of Claire's condition, additional consideration should have been given to a more restricted fluid regime than that prescribed
- (iii) The frequency of blood and electrolyte results, including:
- (a) Whether the blood results (from the sample obtained on 21<sup>st</sup> October 1996) received after midnight on 22<sup>nd</sup> October 1996 were abnormal in any way and whether they mandated a reassessment and/or any change in management
  - (b) The appropriate time(s), with your reasons, that Claire's electrolyte should have been checked, given the IV therapy and that her serum sodium was 132mmol/L after midnight on 22<sup>nd</sup> October 1996
- (iv) The quality of Dr Sands' diagnostic assessment and management of Claire, including:
- (a) The reasonableness or otherwise of Dr Sands' diagnosis of non-convulsive status epilepticus the following morning (on 22<sup>nd</sup> October 1996) and of the other recorded differentials of encephalitis and encephalopathy, including
    - The evidence on which your opinion is based
    - Whether any other conditions should have been considered in Dr Sands' differential diagnosis at that time and if so why
  - (b) The appropriateness or otherwise of Dr Sands' treatment using rectal Diazepam
  - (c) The reasonableness of the referral by Dr Sands to Dr Webb, consultant paediatric neurologist, who saw Claire at either 1400h or 1600h (depending on whether his recall, or the time appended to the case notes, is correct), including:

- Whether Dr Steen, the consultant paediatrician under whom Claire had been admitted should have been informed, or been asked to attend, prior to Dr Webb's arrival
- (d) The appropriateness of the continuing IV fluid therapy, including:
  - Whether both the nature and the volume of the IV fluid prescribed was within the usually accepted practice at the time
  - Whether both the nature and the volume of the IV fluid prescribed would be appropriate now, and if not, what the appropriate fluid regime would be
- (v) The quality of the diagnostic assessment and management by Dr Webb when he saw Claire on the afternoon of 22<sup>nd</sup> October 1996, including:
  - (a) The accuracy or otherwise of his note that Claire had a "(N) biochemistry profile ..." (Ref: 090-022-054), given that she had a sodium result of 132mmol/L, which was from a sample obtained the previous night
  - (b) Whether any action should have been taken in regard to Claire's biochemical status at the time
  - (c) Whether the apparent error in the calculation of the prescription for phenytoin given by the SHO on Dr Webb's instructions would have had any ill effect
  - (d) The continuing anticonvulsant therapy arranged by Dr Webb and in particular:-
    - At 14.00/16.00
    - Between 14.30 and 15.25
    - At 17.00
    - On 22<sup>nd</sup> October 1996 and thereafter
  - (e) 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
  - (f) The appropriateness or otherwise of Dr Webb's request for the administration of an intravenous dose of sodium valproate
  - (g) At the time of Dr Webb's last assessment on the ward (1715h), a nursing note referred to Claire being given a stat dose of Epilim and describes Claire as: "Very unresponsive - only to pain. Remains pale. Occasional episode of teeth clenching ..." If that was an accurate

description of Claire's state at that time, whether Dr Webb should have taken any other action and if so what

- (vi) The appropriateness of the procedure for the alleged transfer (according to Dr. Steen Ref: 091-011-067) of Claire's care from Dr Steen to Dr Webb, including:
- (a) The circumstances in which a transfer of care takes place, how it should have been done and whether the transfer should be recorded in the case notes
  - (b) How the transfer of care between consultants is normally communicated to the medical and nursing team
  - (c) Whom you would have reasonably expected to have been responsible for Claire's care after 1700 on 22<sup>nd</sup> October (when Dr Webb makes his last note)<sup>88</sup>
  - (d) To whom you would have reasonably expected that individual to be accountable
  - (e) When a child is referred from the admitting paediatrician to a neurologist, how both of their teams know who has continuing responsibility and whether this was clear in this case
  - (f) Whether the omission of any evidence in the medical notes that on 22<sup>nd</sup> October 1996 Dr Webb communicated his opinions and/or advice to Dr Steen is of any concern
- (vii) The quality of the diagnostic assessment and management by the on-call paediatric SHO (possibly Dr Neil Stewart) and the registrar Dr. Brigitte Bartholome, including:
- (a) The SHO's reaction when he was informed that Claire was showing further seizure activity at 2100h on 22<sup>nd</sup> October 1996, and what action should have been taken at the time, given Claire's overall condition
  - (b) Your comments on Dr Stewart's note following the blood sample taken about 21.30, noted at 2330h as having a serum sodium of 121mmol/L, in which he noted his conclusions about this, the action he considered taking and the advice he received from his registrar, Dr. Brigitte Bartholome

<sup>88</sup> Please see para. 62 above in which Dr Steen states she had been told care of Claire had been taken over by Dr Webb.



- (c) 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
- (d) Whether you consider that any actions could or should have been undertaken at 2100h or at 2330h that would have prevented Claire's sudden collapse at 0230h. If not, please comment on whether the paediatric team on duty from 1700h should have been able to predict the possibility of a potentially brain-damaging condition and, if so, what action was available for prevention
- (viii) The quality of the neurological observation chart recordings, in particular the estimates, initiation and frequency of GCS observations, including whether any particular recorded measurement or measurements should have provoked medical review and, if so, what action was required
- (ix) Whether, at any stage, a CT scan should have been sought, and if so, when, by whom, why, and what effect this might have had on Claire's diagnosis and treatment
- (x) The appropriateness of the decision to admit Claire to PICU at 0315h on 23<sup>rd</sup> October 1996, including whether this would have been appropriate at an earlier stage than 0315h on 23<sup>rd</sup> October 1996, and if so:
  - (a) At what stage she should have been transferred
  - (b) What factors should have led to the conclusion to transfer to PICU
  - (c) On whom should the responsibility lie of deciding whether admission to PICU was appropriate
  - (d) The effect that admitting Claire to PICU at an earlier stage would have had on her diagnosis and treatment
- (xi) When Claire was admitted to PICU at about 0315h on 23<sup>rd</sup> October 1996 when she came under the care of Dr McKaigue (anaesthetist) but it is clear that Dr. Steen attended the ward and made a note at 04.00 on 23<sup>rd</sup> October 1996. Dr Steen also contacted Dr Webb who attended and made a note at 0440h. What do you consider to have been Dr Steen's clinical role from the time of admission to ICU and that of the first brain stem death tests?
- (xii) Whether, given the information that was available to Dr Steen before the post-mortem examination, the stated cause of death on the death certificate was reasonable and/or appropriate. In particular, whether hyponatraemia should have been entered on the death certificate.

- (xiii) The communication by medical staff with colleagues and with Claire's family, including:
- (a) The accuracy and appropriateness of the explanation given by Drs Steen & Webb to Claire's parents for why Claire's brain had swollen, as per the 'Relatives Counselling Record' (ie that it was probably caused by a virus), including other possibilities that should have been raised.
  - (b) The accuracy of Dr Steen stating that Claire's parents should have been spoken with before they left the hospital at about 2130h on 21<sup>st</sup> October 1996, including who should have spoken to them and what information should have been conveyed
- (xiv) Whether you would have expected Claire's death to have been reported to the Coroner at the time, and if so, why and by whom
- (xv) Please see paragraph 80 above and the comments of Dr Dewi Evans, consultant paediatrician at Singleton Hospital. Please confirm if this topic is within your expertise, and, if so, please comment on Dr Evans' hypothesis with regard to the blood/CSF white cell ratio.
- (xvi) The treating doctors at the time, the pathologist who conducted the post-mortem, the Experts called by the Coroner and the Experts who made statements to the PSNI have all given different interpretations of the likely nature and course of Claire's illness. From your perspective as a paediatric neurologist, can you equate these opinions such that you can offer a rational explanation for the course of events and the cause of the cerebral oedema? Please describe any remaining uncertainties.

95. You will need to consider all the Claire documents so as to carry out a thorough review of the evidence and form an opinion on the issues. However, to assist you we have attached an index of 'key documents' together with a 'core bundle' identifying and providing the documents that would appear to be of especial significance.

### **Conclusion**

96. It is of fundamental importance that the Inquiry receives a clear and fully reasoned opinion on these neurological issues.
97. Your assistance on the Inquiry's requirements should be provided in the form of a fully referenced Expert's Report.

## APPENDIX

The main events surrounding Claire's admission to the Royal on 21<sup>st</sup> October 1996 and the care she received there until her death on 23<sup>rd</sup> October 1996 are summarised in the following table:

DATE	TIME	EVENT
20.10.1996		Claire had a loose motion following contact with her cousin on Saturday 19 <sup>th</sup> October 1996 who had a stomach upset <sup>89</sup>
21.10.1996		Claire attended school (Torbank Special School, Dundonald) during which time her teacher reported that she had vomited at school <sup>90</sup>
	15.00	Claire returns from school and continues to be unwell, vomiting on 2 or 3 occasions. She also has one loose bowel movement but no symptoms of diarrhoea <sup>91</sup>
	18.00	Claire's GP, Dr. Savage, who had been called for advice made a home visit to examine her <sup>92</sup>
	19.00	Claire referred to the Royal by her GP at Castlereagh Medical Centre, Belfast:  <i>Very lethargic at school today. Vomited x3. speech slurred. On examination – pale. Pupils reacting, does not like light. No neck stiffness. Tone increased. Right side plantar reflex up-going, left side plantar reflex down-going. Ear nose and throat – nothing abnormal detected. Chest clear. Further fit? Or underlying infection?<sup>93</sup></i>
	19.15	Claire was seen in the Accident & Emergency Department of the Royal and assessed by Nurse EA Jackson:  <i>History of being off form and lethargy. Seizure? Apyrexia. Pale and drowsy. Temperature 36.9, Respiratory rate 24, Heart rate 96. Seen by medical registrar admit to Allen Ward<sup>94</sup></i>
	20.00	The history taken by the Medical Registrar (?):  <i>On examination – drowsy, tired, no fever, no enlarged lymph nodes. Pupils equal and reactive to light. No neck stiffness. Ears normal. Heart sounds normal with no murmurs. Pharynx – unable to examine. Abdomen soft and non-tender, no masses and bowel sounds present. Lungs – air entry good, no added sounds. Plantar reflexes down-going right and left. No apparent limb weakness. Limb tone increased. Reflexes brisker on left than right. Plan – admit. Primary diagnosis – encephalitis?</i>

<sup>89</sup> Ref: 090-022-050

<sup>90</sup> Ref: 089-012-035

<sup>91</sup> Ref: 089-012-035

<sup>92</sup> Ref: 089-012-035

<sup>93</sup> Ref: 091-008-039

<sup>94</sup> Ref: 091-008-039

DATE	TIME	EVENT
	20.45	Claire is assessed by Dr. O'Hare the Paediatric SHO on call and admitted on to Allen Ward: <sup>95</sup> The note made includes:  <i>Pres, sit-up + stares vacantly ... Tone upper limb cogwheel rigidity ... Clonus ... not responding to parents voice/intermittently responding to deep pain ... Viral illness ... afebrile ... IV fluids<sup>96</sup> IV diazepam ? seizure. Activity Re-assess after fluids</i>
	21.45	Claire's weight on admission to Allen Ward is recorded as 24.1kg <sup>97</sup>
	12.00 Mid- night	Claire is re-assessed by Dr. O'Hare the Paediatric SHO:  <i>Slightly more responsive - No meningism Observe and reassess am<sup>98</sup></i>  Further entry from Dr. O'Hare showing: <i>Sodium 132 [falling]...</i>
22.10.1996		Dr. Sands' ward round. The note made includes: <sup>99</sup>  <i>Wretching. No vomiting Vagueness/vacant (apparent to parents) No seizure activity observed ... U&amp;E - Na+ 132 Apresic on IV fluids Pale colour. Little response compared to normal Pupils sluggish to light ... Diag. Non fitting status ["encephalitis/ encephalopathy"]<sup>100</sup> Plan. Rectal Diazepam</i>
	13.07	Result of CAT scan of Claire's brain: "There is generalised cerebral swelling with effacement of the cortical sulci as well as basal cisterns and the third ventricle. No focal lesion has been identified" <sup>101</sup>
	14.30	Dr. Stein noted that Claire's levels should be checked <sup>102</sup>
		Claire was seen by Dr. Webb and it is noted that she is "Still in status" <sup>103</sup>
	16.00	Examination by Dr. Webb and history taken. The note made includes: <sup>104</sup>  <i>O/E Afebrile, no meningism. Pale Rousable - eye opening to voice. Non verbal, withdraws from painful</i>

<sup>95</sup> Ref: 090-022-050 and Ref: 090-022-051

<sup>96</sup> Ref: 090-022-052

<sup>97</sup> See Ref: 090-041-142. See also Ref: 090-021-049 and Ref: 091-008-040

<sup>98</sup> Ref: 090-022-052 and Ref: 091-008-042

<sup>99</sup> Ref: 090-022-052

<sup>100</sup> The quoted comment is written in a different hand.

<sup>101</sup> Ref: 090-033-114

<sup>102</sup> Ref: 090-022-054

<sup>103</sup> Ref: 090-022-055

<sup>104</sup> Ref: 090-022-053 and Ref: 090-022-054

DATE	TIME	EVENT
		<p><i>stimulus. Reduced movements Rt. Side?</i>  <i>... Mildly increased tone both arms</i>  <i>Reflexes symmetrically brisk</i>  <i>Clonus – sustained both ankles ...</i>  <i>Sits up eyes open and looks vacantly</i>  <i>Not obeying commands</i>  <i>Imp. I don't have a clear picture of episode+ yesterdays episodes. Her motor findings today are probably long standing but this needs to be checked with notes. The picture is of acute encephalopathy most probably restricted in nature... Suggest ...</i>  <i>(ii) Hrly obs</i>  <i>(iii) CT tomorrow if she doesn't wake up</i></p>
	17.00	<p>Dr. Webb noted the results of his examination of Claire:<sup>105</sup></p> <p><i>... She continues to be largely unresponsive. She responds by flexing her ... arm to deep sup... pain + does have facial grimace</i></p>
	23.30	<p>Dr. Stewart examined Claire and noted the results of her blood sodium as 121.<sup>106</sup> He also queried and noted: "hyponatraemia", "fluid overload &amp; low Na fluids" and "SAIDH":</p> <p><i>Imp -?Need for ↑ Na content in fluids</i>  <i>-O/ [?] Reg - ↓ to 2/3 of present value - 41mls/hr</i>  <i>-send urine for osmolality</i></p>
23.10.1996	03.00	<p>Registrar called to see Claire and recorded that she had been stable but had suddenly developed respiratory arrest and fixed and dilated pupils.<sup>107</sup> The note records that she was 'cheyne stoking' and required oxygen via a face mask. It also records that an attempt at intubation was unsuccessful and an "anaesthetic colleague [Dr. Clarke?<sup>108</sup>] came and intubated her orally with a 6.5 tube"</p> <p>Claire transferred to PICU</p>
	04.00	<p>Dr. Steen recorded Claire's recent history as:<sup>109</sup></p> <p><i>↓ level of consciousness</i>  <i>[seen by] Dr. Webb ... acute encephalopathy ...</i>  <i>... Na +121 ... Fluids restricted to 2/3<sup>rd</sup> maintenance</i>  <i>Obs otherwise stable</i></p>
	04.40	<p>Dr. Webb examined Claire and recorded the following in her medical notes and records:<sup>110</sup></p> <ul style="list-style-type: none"> <li>▪ <i>S.I.A.DH - hyponatraemia, hypoosmolality, cerebral oedema + coning following prolonged epileptic seizures</i></li> </ul>

<sup>105</sup> Ref: 090-022-055

<sup>106</sup> Ref: 090-022-056

<sup>107</sup> Ref: 090-022-056

<sup>108</sup> See Ref: 090-022-058. See also Ref: 090-022-057 referring to: "Reg asked to see because of resp difficulties. Cheyne-Stoke breathing – intubated + transferred to ICU. At present intubated + ventilated ... pupils fixed + dilated. Bilateral papilloedema L > R. Plan – mannitol stat – dopamine infusion – urgent CT scan". Her blood sodium level was also recorded as "Na 121".

<sup>109</sup> Ref: 090-022-057

<sup>110</sup> Ref: 090-022-057

DATE	TIME	EVENT
		<ul style="list-style-type: none"> <li>▪ Pupils fixed and dilated following normal diuresis</li> <li>▪ No eye movements</li> </ul> → For CT scan
	05.30	Claire had her CT brain scan, the results of which were recorded by Dr. Kennedy (radiology) <sup>111</sup> as:  <i>There is severe diffuse hemispheric swelling, with complete effacement of the basal cisterns. No focal abnormality is identified</i>
	06.00	Claire's brain stem death evaluation no.1. The results were recorded by Dr. Webb <sup>112</sup> and included:  <i>CT Cerebral herniation ...            Claire fulfils criteria for Brain stem death            The evaluation should be repeated in 4-6 hrs</i>
	07.10	Dr. McKaigue examined Claire and recorded a full history in her notes, <sup>113</sup> including:  <i>Initially admitted to hospital with decreased level of consciousness with the clinical picture of acute encephalopathy. Status epilepticus subsequently developed ... Serum Na also noted to be low ↓ 121 presumably on basis of SIADH</i>  <i>In PICU hyper ventilated and given manitol 0.5g/kg pupils fixed and dilated ... CT scan shows severe cerebral oedema. I set of brain stem tests performed by Dr. Webb/Dr. Steen. Serum Na also checked at same time (133 – blood gas analyser PICU) ... Plan: maintain circulatory support as Claire is a potential organ donor ... Dr. Webb/Dr. Steen have discussed Claire's clinical condition with her parents. They initially appear to be giving consent for organ ... I would be concerned that ... this picture [mottling] could be explained by pulmonary aspiration or early neurogenic pulmonary oedema. Any potential transplant centre should be alerted to the possibility of pulmonary aspiration. Lab. Sample at time of brain stem tests: Na 129</i>
		Dr. Taylor noted in Claire's medical notes and records that: "Needs DDAVP to limit polyuria. Appears B.S. Dead informally ... Na+ 129 (from 121)" <sup>114</sup>
	18.25	Diagnosis of Brain death protocol completed. <sup>115</sup>  Dr. Steen records in Claire's medical notes and records that: "Discussed ... parents – agree that ventilation should be withdrawn. Consent for limited pm given"
	18.45	Ventilation withdrawn from Claire after discussion with her parents <sup>116</sup>
		Death Certificate issued – "cerebral oedema 2 to status epilepticus"

<sup>111</sup> Ref: 090-022-058

<sup>112</sup> Ref: 090-022-058

<sup>113</sup> Ref: 090-022-058

<sup>114</sup> Ref: 090-022-061

<sup>115</sup> Ref: 090-022-061

<sup>116</sup> Ref: 090-006-008