BRIEF FOR EXPERT ON CLINICAL & HOSPITAL MANAGEMENT GOVERNANCE
CLAIRE ROBERTS

Introduction

1. Claire Roberts is one of four children whose deaths are the subject of the public inquiry being conducted by John O'Hara QC.

2. Claire was born on 10th January 1987. She was admitted to the Royal Belfast Hospital for Sick Children ("RBHSC") on 21st October 1996 with a history of vomiting, drowsiness and slurred speech and she died on 23rd October 1996. Her death certificate recorded the cause of her death as Cerebral Oedema and Status 'epilephicus' (sic). There was no Inquest held at the time. The certification as to cause of death was challenged eight years later by her parents who had seen a television documentary into the deaths of three other children in which hyponatraemia was implicated.

3. Thereafter an Inquest into Claire's death was carried out nearly 10 years post death by Mr. John Leckey (Coroner for Greater Belfast) between 25th April and 4th May 2006. He engaged as experts: (i) Dr. Robert Bingham (Consultant Paediatric Anaesthetist at Great Ormond Street Hospital, London); and (ii) Dr. Ian Maconochie (Consultant in Paediatric A&E Medicine at St Mary's, London). The Inquest Verdict found the cause of Claire's death to be Cerebral Oedema with meningo-encephilitis, hyponatraemia due to excess ADH production and status epilepticus as contributory factors.

4. The other three children who are the subject of the Inquiry's work are:

   (i) Adam Strain was born on 4th August 1991. He died on 28th November 1995 in the Royal Belfast Hospital for Sick Children ("RBHSC") following kidney transplant surgery. The Inquest into his death was conducted on 18th and 21st June 1996 by Mr. John Leckey (Coroner for Greater Belfast) who engaged as experts: (i) Dr. Edward Sumner (then Consultant Paediatric Anaesthetist at Great Ormond Street Hospital); (ii) Dr. John Alexander (Consultant Anaesthetist at Belfast City Hospital); and (iii) Professor Peter Berry (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 and was delivered four months before Claire's death.

   (ii) Raychel Ferguson was born on 4th February 1992. She was admitted to the Altnagelvin Area Hospital on 7th June 2001 with suspected appendicitis. An appendectomy was performed on 8th June 2001. She was transferred to the RBHSC on 9th June 2001 where brain stem tests were shown to be negative and she was pronounced dead on 10th June 2001. The Autopsy

Report dated 11th June 2001 concluded that the cause of her death was Cerebral Oedema caused by Hyponatraemia.

The Inquest into Raychel's death was conducted on 5th February 2003 by Mr. John Leckey. He 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).

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

The Inquest into Conor's death was conducted on 9th June 2004 by Mr. John Leckey. He 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 RBHSC was brainstem dysfunction with Cerebral Oedema related to viral illness, over-rehydration/inappropriate fluid management and status epilepticus causing hypoxia. Dr. Brian Herron (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 hyponatraemia 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 as to the cause. 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 the UTV Live Insight documentary 'When Hospitals Kill' shown on 21st October 2004. The documentary primarily focused on the death of a toddler called Lucy Crawford (who died in hospital in 2000 and whose death was subsequently also found to have been as a result of hyponatraemia). The programme makers identified what they considered to have been significant shortcomings of personnel at the Erne Hospital where Lucy had been initially treated before being transferred to the RBHSC. 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 was 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 1st 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. First, 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 RBHSC's 2004 acknowledgement that hyponatraemia played a part in Claire's death as well as the apparent failure to follow guidelines on fluid management in Conor's case.

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. 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.

12. As is apparent this Inquiry is not confined to 'clinical matters', as is evident from the requirement of the Revised Terms of Reference which require that the following matters are also investigated:

> ii The **actions of** the statutory authorities, other organisations and responsible individuals concerned in the **procedures, investigations and events which followed the death of Adam Strain** and Rachel Ferguson [**and Claire Roberts**]
>
> iii The **communications** with, and **explanations** given to their families and others **by the relevant authorities**.
>
> (Emphasis added)

13. The reference in the Revised Terms of Reference to investigating the *"procedures, investigations and events which followed the death"* and the *"communications"* and *"explanations"* given by the relevant authorities to the children's *"families and others"* raises important 'management and governance' issues as well as the ability of the relevant bodies to learn lessons and act upon them.

14. In terms of Claire's case, such an investigation requires consideration of the significance of Adam's death and its aftermath, including his Inquest, for the care and treatment of Claire who died 11 months after Adam's death and within 4 months of his Inquest. Both children died in PICU at the RBHSC and both of them were treated by Dr. Robert Taylor (Consultant Paediatric Anaesthetist) and Dr. David Webb (Consultant Neurologist).

15. The investigation into Claire's case also requires some consideration of the 'aftermath' of her death because this raises the question of what impact a different handling of Claire's death and its 'aftermath' might have had on the diagnosis of Lucy's condition at the Erne Hospital 3½ years later and, more especially, at the RBHSC where she was transferred, treated and declared dead.

Role of the Experts

16. There are 4 categories of expert assistance:

(i) Advisers[1] appointed to assist the Inquiry in identifying, obtaining, interpreting and evaluating the evidence within their particular area of expertise, which currently comprises the following:

(a) Consultant Paediatrician
(b) Consultant Paediatric Anaesthetist
(c) Paediatric Nurse, previously Consultant Nurse in Paediatric Intensive Care
(d) National Health Service Hospital Management

(ii) Experts engaged on a case-by-case basis as Expert Witnesses.

The Experts are required to provide their Expert opinion in the form of a Report incorporating an 'expert declaration' and attached to a Witness Statement. The Report will be made public. The Expert Witnesses may be required to attend the oral hearings and present their views.

(iii) Experts to provide commissioned 'Background Papers'[2]

(iv) Experts appointed as Peer Reviewers of the work of the Advisors[3]

17. You are briefed as an expert whose role falls within category (ii) above. This briefing paper contains some clinical issues on which we do not expect you to comment, but they are included to provide context and show the depth of the work of the Inquiry.

Background to Claire

Initial admission to the Ulster (1987)

18. Claire Roberts was born on 10th January 1987. Claire was first admitted to hospital on 23rd 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

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1 Dr. Harvey Marcovitch (Paediatrics); Dr. Peter Booker (Paediatric Anaesthesia); Carol Williams (Paediatric Nursing); Grenville Kershaw (Health Service Management and Patient Safety)

2 To date the Inquiry has sought 'Background papers' on: (i) Education & Training of Doctors (Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust and Professor Sir Alan Craft, Emeritus Professor of Child Health, Newcastle University); (ii) Education & Training of Nurses (Professor Mary Hanratty, former Vice-President of the Nursing and Midwifery Council and Professor Alan Glasper, Professor of Children and Young Person's Nursing, University of Southampton); (iii) Coroners (Dr. Bridget Dolan, Barrister-at-Law and Assistant Deputy Coroner); (iv) Dissemination of Information following Adverse Incidents (Dr. Jean Keeling, retired Consultant Paediatric Pathologist, New Royal Infirmary); (v) Adverse incidents and coding of deaths (Joy Trouton, retired Regional Coder for Northern Ireland); (vi) Statistics (Dr. David Marshall, Northern Ireland Statistics & Research Agency)

3 Professor Allen Arieff at the University of California Medical School in San Francisco (Internal Medicine & Nephrology), Dr. Desmond Bohn of the Critical Care Unit at the Hospital for Sick Children in Toronto (Paediatric Anaesthesia), Ms. Sharon Kinney at the Intensive Care Unit and Clinical Quality and Safety Unit at the Royal Children's Hospital in Melbourne (Paediatric and Intensive Care Nursing)

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 RBHSC (1987)

19. Claire's presentation in September 1987 resulted in her being referred to the RBHSC on 3rd September 1987 under the care of Dr. Hicks[4]. A summary sent to her GP following discharge on 21st September 1987, described her as having '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[5].

Ulster (1988 and 1996)

20. Dr. Gleadhill saw her at the Ulster Hospital on 9th February 1988, when he 'felt there was definitely some concern about her developmental delay.'

21. 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[6]. Dr. Gaston saw Claire again on 1st 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 2nd October 1996 when her parents reported 'dry mouth, vicious, 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…'[7] It is not known whether the Ritalin was restarted. There is no mention of it in her A&E admission notes[8] or in the ward assessment[9].

Second referral to the RBHSC (1996))

[4] Ref: 090-018-033, 034
[5] Ref: 090-015-026, 027
[6] Ref: 090-013-017, 018
[7] Ref: 090-013-016, 017
[8] Ref: 090-011-013
[9] Ref: 090-022-050

22. On 21st October 1996 Claire's GP referred her for admission to the RBHSC. She 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'[10]. 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/queried that Claire had suffered a further fit and/or had an underlying infection[11].

23. Claire was admitted to the RHBSC later on 21st October 1996 exactly 4 months after the conclusion of the Inquest into Adam Strain's death of hyponatraemia at the RBHSC. The A&E note repeated parts of that history and noted non-bilious vomiting 'since this evening'. She was 'drowsy, tired, apyrexial' with no other abnormal signs except for increased left sided muscle tone and reflexes. At 20:45, a decision was made to admit Claire to hospital under the care of Dr. Heather Steen[12].

24. The notes and records indicate that the Admitting Consultant with responsibility for Claire's care was Dr. Steen. An issue has arisen as to whether or not that responsibility might have been referred/ transferred to Dr. Webb or shared with him. It is suggested by the notes and records that Dr. Steen did not attend hospital nor meet Claire until 04:00 on the 23rd October 1996. Dr. Steen cannot now recall having seen Claire earlier. The notes are not specific as to who the Consultant on call on the evening of the 22nd October 1996 was.

25. The admission note (timed at 20:00) 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[13]. 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[14].

26. The admission diagnoses were noted as: (1) Viral illness; (2) Encephalitis (but this was subsequently scored through)[15].

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[10] Ref: 090-011-013
[11] Ref: 090-011-013
[12] Ref: 090-012-014
[13] Ref: 090-022-050
[14] Ref: 090-022-051
[15] Ref: 090-022-052

27. 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[16]. 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)[17]. The nursing care plan referred to administering 'IV fluids as prescribed by doctor, according to hospital policy'[18].

28. The nursing record includes a fluid balance chart, which shows that treatment was started at 21:30 with 64 ml hourly of 5/N saline. By 07:00, 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[19]. The nursing notes of the night of 21st October and early morning on 22nd 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'[20].

29. 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 an untimed entry recording the blood biochemistry 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

30. The laboratory reference range for sodium ('normal range') is given as 135-145[21]. Next to the sodium result is the symbol ↓ and next to the white cell count is the symbol ↑[22].

31. The nursing record at 07:00 by Nurse McRandal states: 'Slept well. Much more alert and brighter this morning. One further bile stained vomit … no oral fluids taken…'[23] A nursing note timed at 08:00 – 14:00 states: 'Slept for periods during early morning – bright when awake; no vocalisation but arms [?] 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 …'[24]

32. The first medical note on 22nd October 1996 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.

[16] Ref: 090-022-052
[17] Ref: 090-038-134
[18] Ref: 090-043-146
[19] Ref: 090-038-133
[20] Ref: 090-040-140, 090-012-014
[21] Ref: 090-031-100
[22] Ref: 090-022-052
[23] Ref: 090-040-140
[24] Ref: 090-040-141

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.'[25]

33. A plan was noted to give rectal diazepam (actually administered at 12:30), to discuss her past medical history with Dr. Gaston and to consult Dr. Webb[26]. Dr. Webb also attended Adam Strain when he was admitted to the Paediatric Intensive Care Unit ('PICU') after he failed to regain consciousness following his renal transplant surgery.[27]

34. The fluid chart for 22nd October 1996[28] does not note the solution given. However, an undated prescription chart[29] also referred to 500 ml of 'No 18 solution at 64 ml/hr'. A total of 562 ml was given over eight hours from 08:00, i.e. 70 ml/h.

35. Dr. Webb examined (and made an entry timed at 4pm but which was more probably entered at 14:00). Dr. Webb 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 12:30. 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[30]. 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'[31]. At 15:30 Claire was reported by her mother as having suffered a 5-minute 'strong seizer [sic]' at 15:25. At 16:30, her teeth tightened slightly[32].

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[25] Ref: 090-022-052, 053

[26] Ref: 090-022-052, 053

[27] Ref: 058-035-139 – see his note in Adam's medical notes and records at 1930 on 27th 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 28th November 1995 recording that the criteria for brain stem death had been met – just below the entry for 0745: *"electrolyte/fluid problem overnight"*

[28] Ref: 090-038-135

[29] Ref: 090-038-136

[30] Ref: 090-022-053, 054

[31] Ref: 090-022-054

[32] Ref: 090-042-144

36. 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'[33].

37. 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 14:00. The SHO noted calculations of phenytoin dose at 14:30 and ordered a dose of 18[mg] x 24 [h] which he 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[34].

38. Those doses were ordered on a prescription chart[35]. The nursing notes record a stat dose of phenytoin given at 2.45pm[36], with a second dose at 11pm following blood sampling for phenytoin levels[37].

39. 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 drugs – once only prescription chart misstates the dose to be "120mg", records that this drug was administered intravenously at 15.25 but the person administering the dose has not signed that chart [38]. The nursing notes record 'stat IV hypnovel (midazolam) at 3.25pm'[39]. No dosage was recorded against this nursing 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 16:30[40]. Also from 16:00, No 18 solution was continued with 452 ml given over 7 h to 23:00 [64 ml/h][41].

40. At 17:00, Dr Webb, spoke to Claire's mother and recorded further background information detailing 'contact with cousin on Sat who had a G.I.T upset. Claire had loose motions on Sunday and vomiting Monday. She had some focal szs on Monday with right sided stiffening'. He described Claire as 'largely unresponsive' with intermittent vomiting and chewing. He prescribed the antibiotic cefotaxime and the anti-viral 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

[33] Ref: 090-022-054
[34] Ref: ibid
[35] Ref: 090-026-075
[36] Ref: 090-026-075, 090-040-141
[37] Ref: 090-040-138, 090-038-135, 090-026-077
[38] Ref: 090-026-075.
[39] Ref: 090-040-141
[40] Ref: 090-038-135, 136
[41] Ref: 090-038-135

h[42]. A nursing note at 17:15 referred to Claire being given a stat dose of Epilim and added 'Very unresponsive – only to pain. Remains pale. Occasional episode of teeth clenching …'.[43] There does not appear to be an obvious care plan from 17:00 onwards.

41. The Record of Attacks states that at 19.15 Claire clenched her teeth and groaned for 1 minute. At 21:00, 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[44].

42. At 23:30, an SHO (Dr Stewart) noted that a blood sample likely to have been taken when the doctor attended at 21:00 – 21:30, 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 ⅔ of present value – 41 ml/h. Send urine for osmolality'[45].

43. In fact, between 23:00 and 02:00 Claire received 56 ml of No 18 solution (18.5 ml/h) and 7.6 ml of normal saline. Also between 22:00 and 01:00 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[46].

44. A nursing note at 21:30 referred to Claire receiving midazolam at 3 ml/h, completed by 22:40. At 23:00, she was given IV phenytoin over 1 hour. In addition, the fluid chart refers to two 'small mouthfuls' of vomit/aspirate recorded at 24:00 and 01:00[47]. 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 02:30, 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'[48].

[42] Ref: 090-022-055
[43] Ref: 090-040-141, 090-142-144
[44] Ref: 090-042-144
[45] Ref: 090-022-056
[46] Ref: 090-038-135
[47] Ref: 090-038-135
[48] Ref: 090-040-138, 139

45. 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 (Dr. Bartholome) 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 PICU[49].

46. The neurological observation chart, started at 13:00 on 22nd October 1996, shows that at 13:00 she was noted as '*opening her eyes to speech'* and at 14:30 as '*opening eyes to pain'*. Thereafter, hourly recordings until 02:00 on 23.10.96 all stated there was '*no eye opening'*. 'Best verbal response' was noted as '*none'* from 13:00 to 18:00 and thereafter as '*incomprehensible sounds'*. Her 'best motor response' was noted as '*obey commands'* at 13:00 and at 20:00, '*localise pain'* between those times and '*flexion to pain'* thereafter[50].

47. Her Glasgow Coma Scale (GCS) score was given as 9 on first checking (and after correction of initial observations) and thereafter was 6 - 7, except recorded as 8 at 20:00. There was a rise in temperature from normal to between 37.5 C and 38 C from 19:00 and of pulse rate from <90 at 13:00 to 115 at 18:00, thereafter remaining at 100-105. There was no significant change recorded in blood pressure[51].

48. Claire was admitted to PICU at 03:15 on 23rd October 1996 and the first PICU note was made at 04:00. 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 23:30 on 22nd October 1996[52]. It is not clear precisely when those bloods were taken or the laboratory results communicated but the phenytoin result states that it was received at 04:20 and vetted at 04:38[53]. The blood could therefore have been taken between 03:15 and 04:00.

49. Dr. Webb noted, at 04:40, 'SIADH (syndrome of inappropriate antidiuretic hormone) – hyponatraemia, hypo-osmolarity, cerebral oedema + coning following prolonged epileptic seizures. Pupils fixed and dilated following mannitol diuresis. No eye movements …[54]'

[49] Ref: 090-022-056
[50] Ref: 090-039-137
[51] Ref: 090-039-137
[52] Ref: 090-022-057
[53] Ref: 090-031-101
[54] Ref: 090-022-057

50. A first test for brain stem death was conducted by Drs. Webb and Steen at 06:00[55]. The CT scan was noted by Dr. Peter Kennedy as showing 'severe diffuse hemispheric swelling with complete effacement of the basal cisterns. No focal abnormality identified'[56].

51. Dr. McKaigue, ICU Consultant, reiterated the history of her hospital admission in a note at 07:10. This included the serum sodium, checked by Drs. Webb and Steen at the same time as brain stem tests [06:00], and found on the PICU blood gas analyser, was 133 mmol/L(and pH 7.13, PO_2 124.5 mm Hg and PCO_2 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 08:10 or 08:50 requested 2 hourly measurements of urea and electrolytes[57].

52. An untimed note, placed between that of Dr. McKaigue at 08:10 or 08:50 and that of Dr. Steen at 18:25 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).' The note implies that it was made 'only 7 ½ hours post arrest'- giving time of entry as approximately 10:00. 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 23rd October 1996. Dr. Taylor was the Paediatric Anaesthetist in charge of Adam's anaesthesia and fluids for his kidney transplant at the RBHSC 26th November 1996.

53. Two untimed laboratory reports on 23rd 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[58].

54. At 18:25 on 23rd October 1996 the brain stem death test protocol was repeated[59], and it was noted there was no spontaneous respiration while the $PaCO_2$ was 70 mm Hg. These findings were discussed with the parents who agreed that ventilation should be withdrawn; consent from Mr. Roberts for a limited brain-only post-mortem examination was obtained by Dr. Steen and ventilation was discontinued at 18:45.It also recorded 'Is this a Coroner's case? No.' The Death

[55] Ref: 090-045-148
[56] Ref: 090-022-058
[57] Ref: 090-022-059, 060
[58] Ref: 090-050-156
[59] Ref: 090-045-148

Certificate issued for Claire gave the cause of death as cerebral oedema secondary to status epilepticus[60].

55. An untimed 'Relative Counselling Record' dated 22nd October 1996 (surely 23rd 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'[61].

56. The PICU Case Note Discharge Summary[62] records a principal diagnosis of cerebral oedema, noting status epilepticus and hyponatraemia as other diagnoses. It is dated 29th October 1996 and signed by Dr. Mannam (SHO PICU).

57. Dr Sands made a note on 11th 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'[63].

Post-mortem findings

58. 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/μL and white cells 4000/μL – mostly lymphocytes. No organisms were cultured[64]. An x-ray of the lungs[65] showed some pulmonary abnormality.

59. The Autopsy Request form[66] was compiled by Dr. Steen citing a clinical diagnosis of 'cerebral oedema 2° to status epilepticus ? underlying encephalitus'. She listed clinical problems in order of importance as '1. Cerebral oedema 2. Status epilepticus 3. Inappropriate ADH secretion 4. ?Viral encephalitis', and confirmed the entry in the death certificate as cerebral

[60] Ref: 090-022-061, 091-012-077
[61] Ref: 090-028-088
[62] Ref: 090-009-011
[63] Ref: 090-022-061
[64] Ref: 090-030-092 to 098
[65] Ref: 090-033-115
[66] Ref:090-054-177

oedema due to status epilepticus with no other significant conditions noted as having contributed to the death. She indicated that neither she nor a colleague would be attending the review session on the day of the autopsy.

60. A Provisional Anatomical Summary[67] was prepared under Dr. Herron, Senior Registrar Neuropathology. It noted the date of admission as 22nd October 1996 (sic) and the time of death 6:25 hrs (sic). It further noted as an anatomical summary 'history of acute encephalopathy, brain to be examined after fixation'. A Neuropathology Department document which may be a laboratory day book[68] records the diagnosis as 'viral encephalitis. Epilepsia'.

61. The initial stages of the autopsy of the brain only was carried out on 24th October 1996 by Dr. Herron. It has now emerged for the first time from Dr. Herron's witness statements to the Inquiry that the unsigned Autopsy Report[69] was the work of a Dr. Mirakhur, Consultant Neuropathologist, notwithstanding that the named pathologist is Dr. Herron. It contains an Anatomical Summary which differs from the Provisional Anatomical Summary. The clinical summary refers to Claire's admission with vomiting after contact with a relative with diarrhoea and vomiting. It refers 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 121. There was a query of inappropriate ADH secretion. There is a statement that Claire had 'iatrogenic epilepsy since 10 months'.

62. Dr. Herron noted Claire's brain weighed 1606g. His evidence to the Coroner's Inquest was that he would have expected it to be 1300g[70]. 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.

63. The Autopsy Report comments by way of summary that 'the features here are those of cerebral oedema with neuronal migrational defect and a low-grade sub acute meningoencephalitis'.It 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'. The report did not rule out a metabolic cause.[71]

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[67] Ref: 090-005-007
[68] Ref:090-054-177
[69] Ref: 090-003-003
[70] Ref:096-006-035
[71] Ref: 090-003-004, 005

64. On 6th March 1997, Dr. Steen wrote to Claire's GP to report the post mortem results as described, by stating that the abnormal neuronal migration (as described by [?] Dr Herron's Autopsy Report) 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.'[72] It is believed that a Paediatric Mortality meeting was held at which Claire's case was discussed. There is no record of this meeting[73].

65. Dr. Webb wrote to Claire's parents on 28th February 1997 (letter typed on 21st March 1997), offering condolences and summarising the post-mortem findings to be a swelling of the brain with evidence of a developmental brain abnormality (neuronal migration defect) and a low grade infection (menigo-encephalitis). 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. Dr. Webb omitted to inform the Roberts that no other discrete lesion was identified to explain epileptic seizures, that some viral studies were negative during life and on post mortem CSF and that a metabolic cause could not be excluded.[74]

Coroner's Inquest (2005)

66. Prompted by the UTV Live Insight documentary 'When Hospitals Kill', which was shown on 21st October 2004, Claire's parents sought further clarification and explanation as to the cause of their daughter's death. In consequence and on 7th 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').[75] Mr and Mrs. Roberts' 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.[76]

67. In the minute of the meeting, Mrs. Roberts stated that, just before leaving the hospital at 9pm on 21st 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 evidenced by Claire's eye

[72] Ref: 090-002-002
[73] Letters from DLS 24.11.10 and 10.01.11
[74] Ref: 090-001-001
[75] Ref: 089-003-006 & 002-002
[76] Ref: 089-002-002

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 and Mrs. Roberts before they left the hospital at 21:30 hours[77]

68. 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 RBHSC and that the use of 5th normal saline was now banned. The Trust would now approach the Coroner for advice on the best course of action.

69. By letter, dated 16th December 2004, Mr AP Walby, Associate Medical Director at the RBHSC, 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 examined the notes and in his opinion there was an indication that hyponatraemia had played a part in Claire's death …'[78]

70. 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.'[79]

71. The Inquest into Claire's death was carried out between 25th April and 4th May 2006 by the Coroner who had engaged as experts Dr. Robert Bingham (Consultant Paediatric Anaesthetist at Great Ormond Street Hospital) and Dr. Ian Maconochie, (Consultant in Paediatric A&E Medicine at St Mary's Hospital). The Inquest Verdict found the cause of Claire's death to be Cerebral Oedema with Hyponatraemia as a contributory factor.

72. 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

[77] Ref: 089-002-002
[78] Ref: 089-004-009
[79] Ref: 089-005-010

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 21:00 when her coma score reduced from 8 to 6, may have been effective'.

73. 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.[80]

74. 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 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'.[81]

75. 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 22nd October 1996 were consistent with a number of conditions including hyponatraemia but there was no hyponatraemia issue on presentation.[82]

76. Dr. Sands informed the Inquest that he had seen Claire first on the morning of 22nd 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.[83]

[80] Ref: 091-006-021
[81] Ref: 091-007-028
[82] Ref: ibid
[83] Ref: 091-009-055 to 057

77. Dr Webb's statement to the Coroner listed the GCS findings and gave as his interpretation that there had been a period of change between 13:00 and 15:00 on 22nd October 1996, which may have been related to administration of anticonvulsants, especially midazolam, or to the observed seizure at 15:25. After 20:00, there was a definite and sustained change. [84]

78. 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 believed that had he understood the result to be from the previous evening he would have asked for an urgent repeat sample.[85]

79. Dr Webb also stated that he was not sure Claire would have met the criteria for admission to PICU when he left the hospital on 22nd 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.[86]

80. 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.[87]

81. Dr. Steen, the consultant paediatrician under whose care Claire had been admitted but who did not attend Claire until approximately 04.00 on 23rd October 1996 after the respiratory arrest, stated to the Inquest that the blood test result at 23:30 on 22nd 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 03:00 on 23.10.96 and that the GCS at 21:00 should have led to a discussion with a consultant.[88]

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[84] Ref: 091-008-049,050
[85] Ref: 091-008-050 to 052
[86] Ref: 091-008-053
[87] Ref: 091-010-063,064
[88] Ref: 091-011-067, 8

82. 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.[89]

83. Dr. Herron has now admitted in his witness statements to the Inquiry that he made an oral deposition at the Inquest on the mistaken assumption that he had conducted all of Claire's autopsy and had written the autopsy report. When preparing his witness statement to the Inquiry it was discovered that Dr. Herron was only involved in the initial stages of the autopsy and the brain cut and that Dr. Mirakhur was involved in Claire's autopsy and wrote the autopsy report.

84. 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)

85. 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.

86. Dr Dewi Evans (Consultant Paediatrician at Singleton Hospital, Swansea) provided a Report[90] at the request of the PSNI on 1st 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 further stated that 'I suspect my primary diagnosis [on admission] would have been an encephalopathy secondary to an unknown viral infection'.

87. 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.

88. 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.

[89] Ref: 096-013-087
[90] Ref: 096-022-122

He attached to his report a copy of the 1997 *Advanced Paediatric Life Support Manual* that recommended the routine use of 1/5th 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.

89. 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.

90. Dr Evans notes the first record of an observed seizure was at 15:25 on 22nd 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.

91. Dr. Brian Harding (Consultant Neuropathologist at Great Ormond Street Hospital) provided a statement to PSNI on 22nd August 2007[91]. 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'.

92. 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.

93. 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.[92]

94. 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

[91] Ref: 096-027-357
[92] Ref: 097-011-026

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.

95. Dr Gupta considered it reasonable that a diagnosis of meningoencephalitis was entertained although unlikely in the absence of fever and meningism.

96. He pointed out that Claire's GCS scores were between 6 and 7 from 14:00 to 20:00 on 22nd 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 PICU.

97. Susan Chapman (Nurse Consultant) for acute and high dependency care at Great Ormond Street Hospital, provided a report to the PSNI on 11th 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,[93] and later suggests that 'there was an overall lack of recognition of the seriousness of Claire's clinical condition'.[94]

98. 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 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'.[95] As Claire wore a nappy at night [96] 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 22nd October 1996, it would appear that the nurses had collected a urine specimen; this was sent to the lab at 11:00, [97] but the urine volume was not recorded on the fluid chart.

[93] Ref: 097-014-185
[94] Ref: 097-014-190
[95] Ref: 090-043-146
[96] Ref: 090-041-143
[97] Ref: 090-038-135

99. 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.

100. Adam's Inquest took place on 18th and 21st June 1996. Dr. Robert Taylor stated in his Inquiry Witness Statement that on 19th June 1996 (i.e. during the course of the Inquest and just before his evidence on 21st June 1996) he worked with Dr. George Murnaghan (at the time Director of Medical Administration, The Royal Hospitals Trust), Dr. Maurice Savage (Consultant Paediatric Nephrologist) and Dr. Joe Gaston (Consultant Anaesthetist and Clinical Director of Anaesthesia, Theatres and Intensive Care) to develop Draft Recommendations for Paediatric Surgery. That statement was a revised version of the original. The revised statement amended *"major surgery"* to *"major paediatric surgery"* and focused on those with *"a potential for electrolyte imbalance"*, which was portrayed as a rare circumstance. The original simply stated *"the Royal Group of Hospitals wishes to make it known that the future management of patients undergoing paediatric surgery will be carefully monitored and re-appraised having regard to this information which is now available"*. Dr. Murnaghan stated in his Inquiry Witness Statement that *"all elective major surgery on children and infants in Northern Ireland is conducted in the RBHSC"*. No definition of 'major surgery' was given (although it would seem not to include the appendectomy undergone by Raychel Ferguson in the Altnagelvin Area Hospital). The significance of that statement would seem to be that it rendered unnecessary consultation with non-RBHSC medical personnel and with other hospitals. Dr. Murnaghan also made a note in relation to the Inquest proceedings that: *"Other issues identified which relate to structure and process of paed. renal transplant services – agreed with IWC that should deal with this as RM [risk management?] issue & arrange a seminar"*. It would seem the suggested invitees were to be restricted to RBHSC personnel. The suggestion that the 'lessons learned' from Adam's death may have been confined to RBHSC personnel would seem to be reinforced by the e-mail on 20th September 2004 from Christine Stewart (Press and Public Relations Officer, the RBHSC) to the Department: *"I've just spoken with Dr. Bob Taylor, consultant anaesthetist in PICU, who was involved in the management of Adam Strain and gave evidence at the inquest. Following a detailed examination of the issues surrounding patient AS [Adam Strain] there were no new learning points, and therefore no need to disseminate any information"*. The Coroner stated in his Witness Statement to the Inquiry dated 15th July 2005 that: *"I had assumed that the Royal Belfast Hospital for Sick Children would have circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some 'best practice' guidelines. Children are not always treated in a paediatric unit and, in the event of surgery, the anaesthetist may not always be a paediatric anaesthetist"*.

<u>Defining the Scope of Clinical Governance</u>

101. The 'governance' issues arising out of the Inquiry's revised terms of reference are being considered at three 'levels': (i) hospital management and clinical governance; (ii) corporate or trust level; and (iii) government or departmental level within the Health and Social Care Services (HSC).

102. So far as 'clinical governance' is concerned, the Inquiry team has interpreted this as the system through which the HSC organisations are accountable for continuously monitoring and improving the quality of their care and services and safeguarding high standards of care and services. This system largely operates at the clinical level, with reporting lines to Directorate and Trust managers.

103. The Inquiry team has adopted the term clinical governance is an 'umbrella' term which encompasses a range of activities in which clinicians should become involved in order to maintain and improve the quality of the care they provide to patients and to ensure full accountability of the systems to patients. On the management side, we understand that term embraces the leadership, procedures and systems that the organisation requires in order to maintain high quality services to patients and for which they are accountable.

104. In addition, the Inquiry team understands that clinical governance can be separated into the following main areas for the purposes of the Inquiry:

Clinical

(i) Clinical effectiveness and research:
- Adopting an evidence-based approach in the management of patients;
- Changing practice, developing new protocols or guidelines based on experience and evidence if current practice is shown to be inadequate;
- Implementing NICE and professional College guidelines and adhering to HSC Service Frameworks and other national standards to ensure optimal care;
- Conducting or reviewing research to develop the body of evidence available and therefore enhancing the level of care provided to patients in future.

(ii) Audit:
- Continuous monitoring of clinical practice, (mostly about groups of patients or services);
- Identifying deficiencies in relation to set standards of care and remedying them;
- Identifying improvements required and instituting them.

(iii) Risk management:
- Instituting robust systems to identify, understand, monitor and minimise the risks to patients;

- Complying with protocols;
- Reporting and investigating adverse incidents, looking closely at complaints or legal cases etc;
- Learning from mistakes and near-misses (informally for minor issues, formally for the more serious events);
- Assessing the risks identified for their probability of occurrence and the impact they could have if an incident did occur;
- Assessing equipment and staffing requirements to ensure optimal care;
- Promoting a blame-free culture to encourage everyone to report problems and mistakes.

(iv) Education and training:
- Instituting appropriate support to enable staff to be competent in doing their jobs and to develop their skills so that they are up to date;
- Promoting continuous professional development (CPD), regular assessment and appraisals.

(v) Patient and public involvement:
- Ensuring that the services provided suit patients, that patient and public feedback is used to improve services into day-to-day practice to ensure an increased level of quality and suitability, and that patients and the public are involved in their care, the development of services and the monitoring of treatment outcomes.

(vi) Using information and IT:
- Patient data is accurate and up-to-date, both in case notes and electronically;
- Confidentiality of patient data is respected;
- Full and appropriate use of the data is made to measure quality of outcomes (e.g. through audits) and to develop services tailored to local needs.

(vii) Staffing and staff management:
- Appropriate recruitment and management of staff;
- Ensuring that underperformance is identified and addressed;
- Encouraging staff retention by motivating and developing staff and providing good working conditions.

Management

(1) Strategic management – The development of aims and specific objectives, the planning of services, facilities and equipment;
(2) General management – the day-to-day operational issues, including meeting objectives;
(3) Finance – the effective use of resources;
(4) Human Resources – all aspects of staff management;

(5) Public Relations – communications on a wide range;
(6) Information Technology – which normally embraces case notes recording;
(7) Governance – ensuring the Board complies with statutory regulation and is accountable;
(8) Clinical Governance – the quality of care (see above).

Requirements

105. The Inquiry team requires your assistance with the following:

(a) The provision of a detailed analysis and overview of the clinical governance issues arising from Claire's case, with particular regard to issues at a clinical level. Should your interpretation of the term 'clinical governance' and your view of its scope differ significantly from that of the Inquiry, as set out above, then please advise the Inquiry as to the basis upon which you consider the material might be more appropriately considered.

(b) An analysis of the documents, including the Reports and Statements, in terms of the main areas of 'management and clinical governance' identified above.

(c) The identification of any protocols, guidance, standards or practices (hereafter referred to throughout collectively as "guidance" save where the context indicates to the contrary) that were applicable to the issues raised in Claire's case in 1996 and which the RBHSC may have been expected to take cognisance of and/or comply with. They should include any available guidance in the UK generally on the provision of services to children in hospital and how they were applied at that time, together with an indication of how that guidance and its application has developed since then. Identification of the literature, if any, that was available in 1996 that discusses such issues.

(d) Consideration of the Inquiry's particular queries identified below. You are not asked to determine any of the matters that are still in dispute or in respect of which there remain differences of view as that is ultimately a matter for the Chairman, but simply advise in the light of them.

(e) In addition, you are asked to identify and (only after approval by the Chairman) pursue any additional issues that arise from the papers provided but which are not raised in this Brief.

106. The particular areas of Inquiry which have been identified and should be considered in the light of the contents of the Appendix, are:

a) Medical Care and Services insofar as they bear upon 'risk management', 'lessons learned' and/or 'governance' in respect of:

(i) Attendance of the Consultant with patient admitted under his/her care
(ii) Organisation of and co-ordination between the Consultant and medical team with responsibility for care of Claire and any specialist advice/input
(iii)
(iv) Transfer of responsibility and care from one Consultant to another; or Joint care for patient
(v) Transfer of responsibility and care from an unavailable/absent consultant;
(vi) Management of handover arrangements, if any, between clinicians and also medical teams;
(vii) Accountability and responsibility of junior medical staff and Consultants;
(viii) Testing serum electrolytes, ensuring any request for this testing is recorded, carried out and the test results checked.
(ix) Checking the prescription, calculation of dose and administration of drugs
(x) Nurses ensuring amendment of Nursing Care Plan when appropriate Transfer and handover to PICU;
(xi) Systems/ Policies for junior medical staff to inform Consultant of changes or concerns, especially in 'after hours' period;
(xii) Systems/ Policies for nursing staff to contact Registrar/ Consultant if unhappy with responses of JHO/ SHO;
(xiii) Systems for the supervision of junior staff;
(xiv) Systems for keeping Consultants informed and arrangements for reporting to more senior team members when Consultant unavailable;
(xv) Role of Ward Sister;
(xvi) Arrangements and criteria for use of CT/ EEG facilities;
(xvii) Provision/ availability of guidance in respect of a) measuring and recording of fluid balance b) frequency of electrolyte testing c) CNS observations;
(xviii) Guidance as to the provision for incoming doctor of patient history, differential diagnoses, relevant physical findings, results of investigations/ those needed and awaited and current clinical management plan.

b) The accuracy and adequacy of Claire's notes and records insofar as they bear upon 'risk management', 'lessons learned' and /or 'governance' in respect of:

(i) Accurate, signed and timed clinical and nursing notes.

(ii) Recording of request for testing serum electrolytes, blood sample being taken for that test and results recorded.
(iii) Fluid balance sheets;
(iv) Observations including GCS, including the threshold for concern;
(v) Test results;
(vi) Drug prescription, calculation of dose and administration;
(vii) Nursing care plans, their review and update;
(viii) Identification of medical teams i.e. a) Lead Consultant with responsibility for Claire and her attendance on the ward b) Ward Sister with responsibility for ward and her attendance thereon c) those present on ward rounds and tasked with undertaking directions;
(ix) The maintenance and preservation of ward round diary;
(x) Information given to the Roberts family and discussions held with them;
(xi) Responsibility for the monitoring and correction of notes and records;
(xii) The co-relation of medical and nursing notes;
(xiii) The monthly paediatric directorate audit;
(xiv) Whether the severity of Claire's condition should have been reflected in the clinical and nursing notes.

c) Communications with the Roberts family, including the accuracy and sufficiency of the information/ advice given to them during or in relation to:

(i) The working diagnoses, care plans, treatment and prognosis at time of admission and throughout the course of 22nd October and to time of death;
(ii) Upon the seriousness of her condition between her admission and 23rd October 1996, particularly on 22nd October 1996, especially during the ward round, the afternoon and evening and also just prior to when the Roberts family left the ward at 21:30 on 22nd October 1996;
(iii) When the critical nature of her condition became apparent;
(iv) Upon admission to PICU;
(v) Upon her unexpected death- being both before and after the performance of brain stem tests;
(vi) As to the causes of death;
(vii) As to the identity of the medical team responsible for her care;
(viii) As to the reasons for non-referral to the Coroner;
(ix) As to obtaining the consent for a limited brain-only post mortem;
(x) As to the post mortem findings;
(xi) Following the UTV documentary on 21st October 2004;

(xii) Following the meetings at the Royal Hospitals on 7th December 2004;
(xiii) Together with that information, sought from the Roberts family as to history, concerns and perceptions relevant to Claire's illness;
(xiv) Together with comment as to how parental concerns where managed in the context of established practices for handling complaints and concerns and how these practices related to departmental and professional guidance.

d) The procedures adopted after Claire's death with particular reference to the post mortem investigations and the establishment an accurate and independent view as to the causes of death, including:

(i) The accuracy, impartiality and quality of information given to the Pathologist in light of the content of the medical records;
(ii) The process of certification of cause of death for death certificate;
(iii) The decision not to refer the death to the Coroner nor seek his advice nor have the reasons for that decision documented;
(iv) The decision to seek a post mortem limited to brain autopsy only and how it was documented;
(v) The consent obtained in respect of the restricted post mortem;
(vi) The policies regarding the reporting of 'an unexplained death' to the clinical or medical Directors;
(vii) The extent to which treating Clinicians were trained in the production of information for the Pathologist;
(viii) The presentation of Claire's case to the monthly paediatric Directorate Audit;
(ix) The Autopsy Report with particular regard to a) prolonged period of preparation b) being the unsigned work of an unnamed author c) whether it identified causes of death;
(x) Whether the Autopsy or Autopsy Report be reviewed by the Clinician concerned;
(xi) The promptness and quality of the information given to the Roberts family in respect of post mortem findings;
(xii) Whether the post mortem process was subject to audit, review or monitoring;
(xiii) The review carried out for the RBHSC by Professor Young;
(xiv) The timing of the final decision to refer the death to the Coroner in 2004 and whether there was delay and whether further investigation was warranted;
(xv) The procedures consequent to Claire' Inquest and the verdict of 'cerebral oedema due to meningo-encephalitis,

hyponatraemia due to excess ADH production and status epilepticus'.

e) Dissemination of information and Institutional links, including steps taken to:

(i) Investigate Claire's treatment and death by way of audit, review, learning, formal conference or informal discussion ;
(ii) Assess (and develop) the competence of staff involved in her treatment;
(iii) Assess (and develop) the competence of staff involved in the determination of her cause of death;
(iv) Disseminate outcomes and lessons learned internally and externally in respect of both Adam Strain and Claire and whether this prompted any change;
(v) Provide information to RBHSC, Trust Management, DHSSPS and/ or medical community for the purposes of dissemination in 1995/96 and 2006 6. Identify those post holders who might have been expected to undertake such tasks.

f) And additional comment as to:

(vi) The extent to which any deficiencies in the dissemination of information in respect of Adam's death in 1995 and lessons learned from his Inquest in 1996 could have played a role in the death of Claire (i.e. changes in patient care; especially fluid management and record keeping with particular regard to hyponatraemia);
(vii) The extent to which any such deficiencies in respect of dissemination of information in respect of Claire's death and lessons learned could have played a part in the death of Raychel on 10th June 2001;
(viii) The policies and practices within the RBHSC, other parts of the NIHSS and the coronial system for the dissemination of information on deaths in hospital to ensure lessons learned and shared and responses implemented. Were such procedures followed and if not was this a failure of system or individual?
(ix) The obligations on RBHSC in 2006 to revise its database in the light of the information deriving from Claire's Inquest;
(x) How Northern Ireland compared with the rest of the UK in respect of the above.

Conclusion

107. It is of fundamental importance to the Inquiry that it receives a clear and reasoned opinion on these issues. Furthermore, if there are any other issues which have not been raised with you but which you regard as relevant and of importance in Claire's case, please inform us of these issues as soon as possible to enable to consider if they should be addressed in your report.

108. We have now received witness statements in Claire's case and may refer further issues arising from those witness statements to you for your consideration.

109. Your assistance in compliance with the Inquiry's requirements should be provided in the form of a fully referenced Expert's Report appended to the attached Witness Statement form. Your Report, and any supplemental or addendum Reports will be made public and will be peer-reviewed in accordance with the Protocol No.4 on Experts.

110. We have attached an Appendix of relevant documents for your convenience. Please inform us as soon as possible if you require any further documentation.

APPENDIX

Documents

We attach the following documents that are referred to in the Brief to provide a context and information for the preparation of your Report:

(i) DVD of 'When Hospitals Kill' – UTV documentary that was shown in 2004;

(ii) Hospital Papers (File 90);

(iii) General Practitioner Notes (File 112);

(iv) Family Papers (File 89);

(v) Coroner's papers (File 91);

(vi) PSNI papers (Files 96 & 97);

(vii) Clinical Chronology(308-001)

(viii) Governance Chronology(308-002)

(ix) List of Persons Involved: Claire Roberts (308-003)

(x) Witness Statements:

- Dr. Andrew Sands, Registrar in Paediatrics, RBHSC (137/1
- Dr. David Webb, Consultant Paediatric Neurologist, RBHSC (138/1),
- Dr. Brigitte Bartholome, Senior Registrar in Paediatrics, RBHSC (142/1),
- Dr. Heather Steen, Consultant Paediatrician, North & West Belfast Health and Social Services Trust (143/1),
- Ms. Geraldine McRandal, Staff Nurse, Allen Ward, RBHSC (145/1),
- Ms. Sara Field (now Jordan), Staff Nurse, Allen Ward, RBHSC (148/1),
- Dr. Robert Taylor, Consultant Anaesthetist, Belfast HSC Trust (157/1),
- Dr. Peter Crean, Consultant Paediatric Anaesthetist, Royal Group of Hospitals (168/1);

- Dr. Brain Herron, Senior Registrar, Neuropathology, Royal Victoria Hospital (224/1),
- Mrs. Angela Pollock, Ward Sister, Allen Ward, RBHSC (225/1)

(xi) Reports of Mr. Stephen Ramsden;

(xii) Report of Professor Aidan Mullan;

(xii) Letter from DLS to Inquiry dated 15th Feb 2012 with notes and records of regional neuropathology service in relation to the autopsy (with enclosures).(090-054)