CLINICAL OPENING: CLAIRE DOB 10th January 1987

THE ORAL HEARINGS IN THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Chairman: John O'Hara QC

Banbridge Court House, September 2012

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I. Introduction

Claire

1. Claire Roberts was born on 10th January 1987. She was the youngest of three children, and the only daughter. She is described by her father as a 'little girl who had overcome her early setback and was happy, energetic and much loved'.

2. Although what her father describes as her 'early setback' left her with learning difficulties, she attended school, loved adventure playgrounds and had an active, and otherwise normal, child's life.

The Opening

3. Claire's case involves clinical and hospital management and governance issues. As with Adam's case, the clinical issues are to be addressed first. There will then be another hearing concerning management and governance issues that I will open separately.

4. This Opening will:

   (i) Set out the principal clinical issues in Claire's case in the context of the evidence gathered to date and the revised Terms of Reference and List of Issues and

   (ii) Identify the main areas that the Legal Team considers requires further investigation through questioning in the oral hearing.

II. The addition of Claire's case to the Inquiry

5. The basis upon which Claire's case was included in the work of the Inquiry was explained by you Mr. Chairman during the Public Hearing on 30th May 2008:[1]

   "*In broad terms, however, my concern is about the apparent conflict between the initial explanation given to the Roberts' family and the subsequent explanation given to them after, but only after, they contacted the Royal following the television broadcast. I am also concerned whether more should have been learned from Adam's death and inquest and whether there should therefore have been better fluid management in the Royal for Claire a relatively short time later.*"

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[1] Transcript of Progress Hearing on 30th May 2008, p.4 – Ref: 303-008-176

6. As you are aware, and as I commented in the General Opening, the then Minister of Health Michael McGimpsey, revised the original Terms of Reference on 17th November 2008 to exclude entirely Lucy Crawford's name.[2] However, he did not add the case of Claire (or that of Conor) as he acknowledged that Mr. Chairman you had the discretion to examine and report on any other matter that you saw fit and that you had already exercised that discretion in relation to the investigation of those cases.

7. Despite the fact that Claire's death is not included in the Terms of Reference,[3] her case is being investigated according to precisely the same terms as those for Adam and Raychel. Therefore, the Inquiry is concerned to investigate:

   (i) Claire's care and treatment from her admission to the Royal Belfast Hospital for Sick Children ("Children's Hospital") on 21st October 1996 until her death in the Paediatric Intensive Care Unit ("PICU") on 23rd October 1996.

   As with the cases of Adam and Raychel, special attention is being paid to the management of Claire's fluid balance, for example, how often her serum sodium level was checked and whether she should have received the particular type of fluid that she did at the rate that it was administered. However, her treatment also includes other elements, including for example the monitoring of her neurological symptoms, medication and her admission to PICU.

   It also involves investigation into whether the way in which the aftermath of Adam's death and his Inquest were handled had any impact on Claire's care and treatment at the Children's Hospital. It will be appreciated Mr. Chairman that Adam died at the Children's Hospital in November 1995 and the verdict in his Inquest was given in June 1996 which was, in the case of his death, almost one year before Claire was admitted to the Children's Hospital and, in the case of his Inquest, almost exactly four months before she was admitted there.

   (ii) The second part of the Terms of Reference requires an investigation into the actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events that followed her death.

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2 Ref: 303-033-460

3 Inquiry's Terms of Reference published on 18th November 2004 - Ref: 021-010-024

At an immediate level, it involves an investigation into what happened immediately after her death including therefore the 'brain-only' post-mortem that was carried out by the hospital. However, it also extends to an investigation into why it was that there was no Inquest into Claire's death until 2006, following the action of her parents to raise the matter with the Children's Hospital in 2004 after the chance viewing of the UTV documentary.

(iii) The third part of the Terms of Reference concerns the communications with and explanations given to Claire's family and others by the relevant authorities.

(iv) This area of investigation therefore includes an investigation into the information provided to Claire's family about her condition and the conduct of a 'brain only' post-mortem, as well as the information given to them during the meeting at the Royal in December 2004 following the airing of the UTV documentary.

III. Evidence Received

8. The Inquiry's search and requests for relevant documents began in or about the beginning of 2005[4] and are ongoing. Such requests are guided by the Inquiry's Advisors and its Experts as well as arising out of documents received and responses to the Inquiry's requests for Witness Statements.

9. For convenience, the sources of the documents and other material received are set out in Appendix 1 to this Opening.

10. As with Adam's case, I am conscious that you, Mr. Chairman will be making findings and recommendations on the basis of the totality of the evidence received and not just what is heard during the Oral Hearings, important as that aspect of the investigation is. You of course have a complete set of the papers and so I do not propose to recite or summarise them. Rather, I will try to indicate key elements of the evidence that has been received in Claire's case.

Expert Reports

11. The Inquiry has, with the guidance of its Advisors, engaged Experts to address the role of the clinicians and nurses involved in Claire's case, particularly the roles of her Consultant Paediatrician, her Consultant

[4] Ref: 089-007-016

Paediatric Neurologist and the nurses on duty in Allen Ward during her admission there:

(i) Dr. Robert Scott-Jupp (Consultant Paediatrician, of Salisbury District Hospital, England) whose reports concern the role and responsibilities of the Consultant Paediatrician and the paediatric medical issues in Claire's case.[5]

(ii) Professor Brian Neville (Consultant Paediatric Neurologist, and Professor of Childhood Epilepsy, Institute of Child Health, University College London and Great Ormond Street Hospital, National Centre for Young People with Epilepsy, Lingfield), whose reports address the role and responsibilities of the Consultant Paediatric Neurologist and the neurological aspects of Claire's case.[6]

(iii) Ms. Sally Ramsay (Independent Children's Nursing Advisor) who has provided a report on the nursing aspects of Claire's care.[7]

12. The Inquiry has also engaged Experts to address certain specific issues, including:

(i) Professor Keith Cartwright (Consultant Clinical Microbiologist) who has provided reports on the cerebral spinal fluid ("CSF") sample, the CSF report and changes in Claire's white blood cell count.[8]

(ii) Professor Brian Harding (Consultant Paediatric Neuropathologist and Professor of Pathology & Laboratory Medicine, University of Pennsylvania, USA) has provided a follow-up report to the one that he provided to the PSNI on 22nd August 2007[9] dealing with the question of whether encephalitis could occur in the absence of clear neuropathological changes.[10]

(iii) Dr. Waney Squier (Consultant Neuropathologist and clinical Lecturer, John Radcliffe Hospital, Oxford) who has provided a neuropathological opinion from histological slides that she made from tissue blocks of Claire's brain.[11]

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5 Ref: File 234
6 Ref: File 232
7 Ref: File 231
8 Ref: File 233
9 Ref: 096-027-357
10 Ref: File 235
11 Ref: File 236

(iv) Dr. Philip Anslow (Consultant Neuroradiologist, John Radcliffe Hospital, Oxford) has provided, at the request of Dr. Squier, a report on the interpretation of the CT scans taken of Claire's brain on 23rd October 1996[12] to assist in the provision of her own report.

(v) Dr. Caren Landes (Consultant Paediatric Radiologist, Alder Hey Children's NHS Foundation Trust), who has examined and reported on 2 chest x-rays taken of Claire at 03:50 and 07:15 on 23rd October 1996 and a CT scan taken on the same day.[13]

(vi) Dr. Jeffrey Aronson (Consultant Pharmacologist, Oxford University Hospitals NHS Trust) who has provided a report on pharmacological issues in Claire's case, in particular the likely effects of the medication recorded as having been prescribed and administered to her.[14]

(vii) Dr. Roderick MacFaul (Consultant Paediatrician, now retired) who has provided a report on the governance matters in Claire's case. However, he has also addressed some clinical issues in the course of providing his governance report.[15]

(viii) Professor Sebastian Lucas, (Professor of Clinical Histopathology and Consultant Histopathologist,[16] to Guys and St Thomas' Hospitals Trust, London) has been asked to provide expert assistance in this case. He previously provided a report dealing with the competency of the autopsy in Adam's case.[17]

13. The Legal Team, together with the Inquiry's Advisors and its Experts, have also reviewed the reports of the experts that were engaged by the Police Service of Northern Ireland ("PSNI") to assist with its investigations:

(i) Dr. Dewi Evans, consultant paediatrician at Singleton Hospital, Swansea, provided a report at the request of the PSNI on 1st March 2008.[18]

(ii) Dr. Brian Harding, consultant neuropathologist at Great Ormond Street, provided a report to PSNI on 22nd August 2007.[19]

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12 Ref: File 236-006
13 Ref: File 230
14 Ref: File 237
15 Ref: File 238
16 See List of Persons - Ref: 310-003-001
17 Ref: 209-001-001
18 Ref: 096-022-122
19 Ref: 096-027-357

(iii) Dr. Rajat Gupta, consultant paediatric neurologist at Birmingham Children's Hospital, provided a report to the PSNI in October 2008.[20]

(iv) Susan Chapman, Nurse Consultant for acute and high dependency care at Great Ormond Street, provided a report to the PSNI on 11th April 2008.[21]

Background Papers

14. I have previously referred to the commissioning of Background Papers by Experts in both the General Opening and Adam's Clinical Opening. The background papers which may be of particular relevance to the clinical issues in Claire's case are:

(i) Dr. Michael Ledwith[22], Clinical Director of Paediatrics, Northern Trust and Professor Sir Alan Craft[23], Emeritus Professor of Child Health, Newcastle University Education on the training and continuing professional development of doctors in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2009.

(ii) Professor Mary Hanratty[24], former Vice-President of the Nursing and Midwifery Council and Professor Alan Glasper,[25] Professor of Children and Young Person's Nursing, University of Southampton on the training and continuing professional development of nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2011.

(iii) Dr. Bridget Dolan[26], Barrister at Law and Assistant Deputy Coroner, on the systems of procedures and practices in the United Kingdom for reporting and disseminating information on the outcomes or lessons to be learned from Coroner's Inquests on deaths in hospital (involving Hospitals, Trusts, Area Boards, Department of Health and Chief Medical Officer).

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20 Ref: 097-011-015

21 Ref: 096-024-183

22 "A Review of the Teaching of Fluid Balance and sodium management in Northern Ireland and the Republic of Ireland 1975 to 2009" Ref: 303-046-514

23 "A Review of the teaching of fluid balance and sodium management in Northern Ireland and the Republic of Ireland 1975 to 2009" Ref: 303-047-561

24 "Chronology of Nurse Education in Northern Ireland – Comparisons with UK mainland and Republic of Ireland 1975 to date" Ref: 303-048-571

25 "A Selective Triangulation of a Range of Evidence Sources Submitted to Explain the Chronology of Nurse Education in Northern and England with Reference to the Teaching of Record Keeping and the Care of Children Receiving Intravenous Infusions 1975 to date" Ref: 303-049-674

26 "Report to the Inquiry into Hyponatraemia-Related Deaths" Ref: 303-052-715

(iv) Dr. Jean Keeling[27], Paediatric Pathologist, on the system of procedures for the dissemination of information gained by post-mortem examination following unexpected death of children in hospital.

15. All of those reports have been made available to you Mr. Chairman and to the Interested Parties. The reports of the Inquiry's Experts will be published on the Inquiry's website in due course in accordance with the Inquiry Protocols and procedures. The other expert reports are already available on the Inquiry's website.

IV. Schedules compiled by the Inquiry

16. In an attempt to summarise succinctly the vast amount of information received by the Inquiry, the Legal Team has compiled a number of schedules and charts to provide this information to you Mr. Chairman and the Interested Parties in a more accessible way.

List of Persons involved in Claire's case

17. The Legal Team has compiled a list of all those involved in the Clinical aspects of Claire's case from all of the information received by the Inquiry.[28] It explains their position then and briefly summarises their role in Claire's case. As you know from Adam's case, the Legal Team has already provided two schedules to explain the terminology in use over the period 1995 top date in respect of the grading of medical and nursing staff: 'Nomenclature & Grading of Doctors 1948 to 2012'[29] and 'Nomenclature & Grading of Nurses 1989 to 2012'.[30] Accordingly, unless it is of particular relevance to the issues, I shall not therefore deal with the grade or training of any particular clinician. The List of Persons also identifies those who have made statements and for whom they were provided. Importantly it also indicates the witnesses that it is proposed to call to give evidence during the Oral Hearing.

18. As with Adam's case, there will be a number of witnesses who will not be required to give evidence at the Oral Hearings and will have their Witness Statement tendered in lieu of oral evidence from that Witness. In due course Mr. Chairman the Legal Team will compile a Schedule of all those whose evidence it is tendering to you in that way. It will then be a matter for you Mr. Chairman whether you nonetheless wish the Witness to be called.

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27 "Paper to the Inquiry into Hyponatraemia-Related Deaths: Dissemination of information gained by post-mortem examination following unexpected death of children in hospital" Ref: 303-053-754

28 Ref: 310-003-001

29 Ref: 303-003-048

30 Ref: 303-004-051

19. Unfortunately, there are a number of Witnesses in respect of whom it has not been possible for the Legal Team to obtain an Inquiry Witness Statement or who are not available to give evidence at the Oral Hearing. For example, Staff Nurse Patricia Ellison, who cared for Claire during the afternoon of 22nd October 1996, died before she was able to provide a Witness Statement for the Inquiry. In addition, Dr. David Webb, Claire's Consultant Paediatric Neurologist, is unavailable during the course of the scheduled time for Claire's clinical and governance case due to ill health, but it is hoped that he will be fit enough to provide his oral evidence in both Claire and Adam's case at a later date.

Chronology of Events (Clinical)

20. The Legal Team has prepared a Chronology of Events (Clinical) which, as with Adam's case, details the clinical events that occurred over the period of Claire's admission.[31] This document is compiled almost exclusively from Claire's medical notes and records. It does include some matters from other sources, such as Depositions or PSNI Statements and this is generally where there is no other source and the matter has not been queried or challenged.

21. The structure of the Chronology is straightforward. The date and time are on the left-hand side, the event is in the middle and the reference for the source of the information is on the right-hand side. The far right columns identify the doctors and nurses that were on duty at the relevant time. The footnotes contain any comments or clarifications.

Timeline of Claire's treatment (21st October to 23rd October 1996)

22. A companion document to the Chronology is the Timeline of Claire's treatment, which visually charts Claire's condition over time during her admission.[32] It contains details such as:

    (i) The cumulative total of Solution 18 she received

    (ii) Her Glasgow Coma Scale (normal and modified)

    (iii) Her seizures and attacks

    (iv) Admissions and examinations by clinicians

    (v) Her sodium results

    (vi) Administration of medication

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31 Ref: 310-004-001

32 Ref: 310-001-001

(vii) The doctors and nurses on duty or on call during each period.

23. As can be seen, the Timeline is colour-coded. Items in blue relate to Claire's fluid and sodium balance. Items in red concern any attacks or seizures suffered by Claire. Items in purple relate to medications administered to Claire.[33] Items in black relate to admission and attendances by doctors.

Other documents

24. The Legal Team has also compiled other documents to address certain discrete issues:

(i) Schedule of Consultant Responsibility (22nd October 1996 to 23rd October 1996)[34]

(ii) Schedule of Medications[35]

(iii) Chart of Over-lapping Medication Timeline[36]

(iv) Schedule of Experts' Views on Cause of Death[37]

(v) Glossary - Ref 310-007 of Medical Terms (building on the Glossary - Ref 310-007 provided for Adam's case)[38]

25. These other documents will be further explained and discussed under the relevant sections.

V. List of Issues in relation to Claire

26. The issues raised by the Terms of Reference are reflected in the Inquiry's List of Issues.[39] The List of Issues is a working document that is updated and revised as appropriate. The current List of Issues was published by the Inquiry on 14th February 2012. In relation to the clinical area of Claire's case, they particularly fall into five areas:

(i) Investigation into the relevance of the medical notes and records from the Ulster Hospital and the Children's Hospital on Claire Roberts prior to her presentation to the Children's Hospital on 21st October 1996:

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33 For the purposes of the timeline, all medications are assumed to have been administered. As shall be seen when discussing Claire's medication, some administrations are in dispute.
34 Ref: 310-005-001
35 Ref: 310-006-001
36 Ref: 310-008-001
37 Ref: 310-009-001
38 Ref: 310-007-001
39 Ref: 303-038-478

(ii) Investigation into the care and treatment that Claire received upon her presentation to the Children's Hospital on 21st October 1996 until her death on 23rd October 1996 and in particular in relation to the management and monitoring of fluid and sodium intake and output

(iii) Investigation into the continuity, co-ordination and communication of care provided to Claire during her admission

(iv) Investigation into the quality of the information provided to and received from Claire's next of kin from when she was in hospital in 1996 until the period of her Inquest in 2006

(v) The accuracy and quality of information provided by the treating clinicians to the hospital pathologist for post-mortem

27. As with the treatment of clinical issues in Adam's case, the issues to be addressed during the Oral Hearing will essentially concern four categories of as yet unresolved differences between:

(i) The documents and the evidence of a witness

(ii) The evidence of witnesses, whether between the accounts given by a witness or between the accounts of different witnesses

(iii) The evidence of a witness and the views of an expert

(iv) The views of the Experts on a particular issue

VI. Claire's Clinical History prior to October 1996

28. Claire Roberts was born at full term on 10th January 1987 in the Ulster Hospital Dundonald ("the Ulster Hospital").[40] She was the youngest of three children, and the only daughter. Her parents have described her as a normally happy and very active child.

29. Claire was first admitted to the Ulster Hospital on 23rd July 1987 aged 6½ months with queried febrile convulsions.[41] Further episodes occurred during August 1987[42] and September 1987[43] for which she received treatment.

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40 Ref: 099-032-045
41 Ref: 099-059-075
42 Ref: 099-059-077
43 Ref: 099-059-085

30. Dr. Valerie Gleadhill, Consultant Paediatrician in the Ulster Hospital,[44] referred Claire to Dr. Elaine Hicks, Consultant Paediatric Neurologist in the Children's Hospital,[45] on 3rd September 1987.[46] Investigations, including brain CT scanning and electroencephalography (EEG),[47] did not define any causative diagnosis. The EEG was not diagnostic of hypsarrhythmia (an abnormal and characteristically random electroencephalogram often found in babies with infantile spasms) but did show an abnormality. A summary sent to her GP following discharge on 18th September 1987, described her as having "*poor trunk control for her age … no stabilising reflexes and could only roll from a semi-prone position and poor ability to lift her head when prone*".[48] She was also described in the same summary as having apparently normal tone "*apart from poor trunk control and poor ability to lift her head when prone*".[49] Seizures were witnessed which "*clinically appeared like Salaam attacks*"[50] (infantile spasms) although the contemporaneous handwritten notes also referred to tonic-clonic seizures and absences.[51] She was prescribed the anticonvulsant sodium valproate (Epilim®) before discharge, while weaning her from her previously prescribed Tegretol.[52] However, and after her discharge, Claire continued to have 'seizures' and her dosage of Epilim was increased. She was reviewed on 30th September 1987 and Dr. Gleadhill saw her at the Ulster Hospital on 9th February 1988 when she "*felt there was definitely some concern about her developmental delay*".[53]

31. Claire's convulsions ceased at the age of 4 years[54] and Claire was weaned off Epilim from February 1995.[55]

32. On 30th May 1996, she was seen by Dr. Colin Gaston, Consultant Community Paediatrician,[56] in relation to behavioural problems including inattention, being easily distracted, having obsessions and constant activity.[57] He refers in his letter to Claire's GP[58] to Claire having attentional difficulties, moderate learning difficulties and a history of seizures from 6 months to 4 years of age. He also notes in the same letter to having discussed with Mrs. Roberts the option of a brief

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44 See List of Persons - Ref: 310-003-001
45 See List of Persons - Ref: 310-003-001
46 Ref: 090-018-033, 034
47 Ref: 090-035-120 to 090-035-123
48 Ref: 090-015-027
49 Ref: 090-015-027
50 Ref: 090-015-027
51 Ref: 099-059-086
52 Ref: 090-015-026, 027
53 Ref: 090-015-024
54 Ref: 090-013-018
55 Ref: 099-006-008, Ref: 099-007-009
56 See List of Persons - Ref: 310-003-001
57 Ref: 090-013-017
58 Ref: 090-013-018

trial for Claire with a stimulant medication, such as Ritalin, Pemoline or amphetamine.[59]

33. Dr. Gaston saw the family again on 1st August 1996 and suggested a trial of one week's placebo vs. one week's Ritalin, such that one parent administered medication to which the other was blind.[60] He noted *'a very small risk of inducing seizures with Ritalin.'*[61] A series of manuscript notes referred to telephone conversations. It was noted that the blind trial was not attempted but instead she had been treated with Ritalin 10mg daily until 2nd October 1996. It is recorded that on that date the parents reported "*dry mouth, viscous, pacing,?agitated/unsettled 30 minutes after Ritalin.*"[62] Claire was also recorded as having "*??greater social awareness.*"[63]

34. Dr. Gaston noted his advice to "*hold meds*" and "*restart on a w/e [weekend] with just 5 mg. M[other] to call 5 days later*".[64] It seems that Claire may not have been re-started on the Ritalin. Mr. and Mrs. Roberts state that Claire was not on any Ritalin, or any other medication, by the time of her admission to the Children's Hospital on 21st October 1996.[65] There is no mention of it in her A&E admission notes,[66] which records no medication, nor any mention of it in the ward assessment.[67]

VII. Claire's Admission to Children's Hospital on 21st October 1996

35. Claire had a loose bowel motion on Friday 18th October 1996 but no diarrhoea. Subsequently, on Saturday 19th October 1996 Claire visited her paternal grandparents for about 3-4 hours.[68] During the course of that visit, she came into contact with her 12-year-old cousin who had a tummy upset during the week. She then spent Sunday 20th October 1996 with her maternal grandparents. Her state of health over the weekend was regarded as normal by her parents.[69]

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59 Ref: 090-013-018
60 Ref: 090-013-016
61 Ref: 090-013-017
62 Ref: 090-013-017
63 Ref: 090-013-017
64 Ref: 090-013-017
65 Ref: WS-253-1, p.2 and WS-254-1, p.2
66 Ref: 090-011-013
67 Ref: 090-022-050
68 Ref: WS-253-1, p.2
69 Ref: WS-253-1, p.2

36. However, on Monday 21st October 1996, when Claire was at school, her teacher considered that she was unwell and wrote a note in Claire's homework diary describing her as pale and lethargic.[70]

37. Claire returned home at approximately 15:15[71] and thereafter vomited on 2-3 occasions. Her parents state that she had no convulsions or episodes prior to her admission to the Children's Hospital on 21st October 1996.[72] Claire's GP, Dr. Deirdre Savage,[73] was called for advice and she examined Claire at the house at approximately 18:00.

Examination by G.P.

38. Dr. Savage referred Claire for admission to the Children's Hospital.[74] 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*".[75] Claire was described as pale, not liking the light but with no neck stiffness. However, the GP considered that Claire's tone increased on the right side and suggested that Claire was post-seizure and/or had an underlying infection.[76]

Examination at Accident & Emergency

39. Claire attended the Children's Hospital A&E Department at approximately 19:00 on 21st October 1996.[77] The A&E initial nursing assessment refers to Claire as "*Epileptic. H/O Off form and lethargy. GP referral with H/O ?seizure. Apyrexic O/A. Pale and drowsy O/A. H/O Mental Handicap*".[78] Claire is recorded as being on no medication.

40. Dr. Janil Puthucheary, the A&E Department SHO whose posting to the Children's Hospital in August 1996 was his first posting as an SHO,[79] assessed Claire at 19:15.[80] He took a history and recorded that Claire had a severe learning difficulties, had a past history of epilepsy, no fits for 3 years and off anti-epileptic medication; that she was vomiting (non-bilious) since that evening. He also records in his history that Claire had no diarrhoea, cough or pyrexia, that her speech was very

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70 Ref: WS-253-1, p.19
71 Ref: WS-253-1, p.3
72 Ref: WS-253-1, p.2
73 See List of Persons - Ref: 310-003-001
74 Ref: 090-011-013
75 Ref: 090-011-013
76 Ref: 090-011-013
77 Ref: 090-010-012
78 Ref: 090-010-012
79 See List of Persons - Ref: 310-003-001
80 Ref: 090-012-014

slurred and that she was hardly speaking. On examination, he noted that Claire was drowsy and tired, had no neck stiffness, was apyrexic with no other abnormal signs except for increased left sided muscle tone and reflexes. Her pupils were equal and reacting to light and accommodation. Claire's tone was generally increased and her tendon reflexes were increased on the left as compared to the right. Claire's plantar reflexes were down-going bilaterally, which was different from the GP's observations of some asymmetry.

41. Dr. Puthucheary entered a presumptive diagnosis of encephalitis on the basis of Claire's acute presentation of altered mental state, a concern of raised intracranial pressure (vomiting as well as asymmetric and changing neurological signs) and also the GP's concerns about a possible fit or underlying infection, and photophobia.[81] He acknowledges *"in the setting of encephalitis, one is concerned about the complication of cerebral oedema"*.[82]

VIII. Claire's Admission to Allen Ward on 21st October 1996

Examination by Dr. O'Hare

42. Dr. Bernadette O'Hare, the on-call Medical Paediatric Registrar,[83] was asked to review Claire.[84] Dr. O'Hare had been a paediatric registrar in Children's Hospital for just under 10 months at the time.[85] She examined Claire at 20:00 in A&E[86] and Mrs. Roberts provided a history.[87]

43. The admission note refers to Claire vomiting at 15:00 and every hour since, having slurred speech and being drowsy, being off form the previous day and to her having a loose bowel motion 3 days previously. Mr. Roberts stated at the Inquest that Claire did not have diarrhoea but only one loose bowel movement, and that she had been well when she went to school on 21st October 1996.[88] 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.[89] Claire's central neurological examination revealed her to have normal fundii, normal response to light, normal

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81 Ref: WS-134-1, p.7
82 Ref: WS-134-1, p.7
83 See List of Persons - Ref: 310-003-001
84 Ref: 090-012-014, WS-134-1 p.4 -5 Q7-9; p.7 Q15
85 Ref: WS-135-1, p.2 Q1
86 Ref: 090-022-050
87 Ref: WS-253-1, p.4
88 Ref: 091-003-004
89 Ref: 090-022-050

7th, 9th and 10th cranial nerves.[90] Dr. O'Hare recorded that Claire sat up and stared vacantly and she queried if Claire was ataxic (unable to coordinate muscle movement[91]).

44. At that stage, Claire 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.[92]

Diagnosis by Dr. O'Hare

45. Dr. O'Hare recorded her working diagnoses in A&E following her examination as:

(i) Viral illness;

(ii) Encephalitis (though this was subsequently scored through).[93]

46. Dr. O'Hare presumes that the reason she deleted this differential diagnosis was that she thought it to be unlikely due to the absence of a fever, as she believed that infective encephalitis is usually associated with a fever.[94] Dr. O'Hare believes that she also considered a subclinical seizure as she had recorded treatment with diazepam if there were any seizures.[95] She notes in her first witness statement that neither she, the GP nor Dr. Puthucheary, appear to have elicited the history of focal signs with right sided stiffening on 21st October 1996.[96] That was first recorded by Dr. Webb at 17:00 on 22nd October 1996.[97]

47. Dr. O'Hare also states that Claire's pulse in A&E was normal (initially 96 beats per minute, and then later 80 beats per minute), and that with a child who had cerebral oedema and raised intracranial pressure, one would have expected it to be bradycardic i.e. have a slow pulse rate.[98]

48. Dr. O'Hare recorded on admission the investigations to be carried out as tests for full blood count, urea and electrolytes, bacterial culture and viral titres.[99] A blood sample was taken on Allen Ward for these tests. It is likely that this was done when the cannula was inserted and the fluids were erected, which was approximately 22:30. The nursing

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90 Ref: 090-022-051
91 See Glossary - Ref 310-007
92 Ref: 090-022-051
93 Ref: 090-022-052
94 Ref: WS-135-1 p.3 Q4a
95 Ref: WS-135-1 p.6 Q11d
96 Ref: WS-135-1 p.6 Q11d
97 Ref: WS-135-1 p.8 Q12d & e
98 Ref: WS-135-1 p.7 Q11e &g
99 Ref: 090-022-052

evaluation note timed at 22:00 records that a blood specimen was taken for the various tests.[100] If that is correct, it means that the U&E result of 132mmol/L[101] reflected Claire's serum electrolytes before any IV fluid was administered.[102]

49. On the evening of 21st October, Claire's parents were advised by the doctors that Claire had a viral infection, and it was not thought that Claire was in danger of meningitis[103].

50. Dr. Robert Scott-Jupp, Consultant Paediatrician and the Inquiry's Expert on Paediatrics,[104] commends Dr. O'Hare for "*clear and competently set out*" admission notes.[105] The important points in the history are "*clear*" and "*a competent clinical examination recorded.*" However, he considers her initial investigation to be "*somewhat limited*", and would have expected more extensive biochemical tests.

51. Professor Brian Neville, Consultant Paediatric Neurologist and the Inquiry's Expert on Paediatric Neurology,[106] states that Dr. O'Hare performed a '*competent examination*',[107] but that her differential diagnosis and investigations were not adequate:

    (i) Dr. O'Hare should have discussed the patient with the Consultant Paediatrician.[108]

    (ii) Hyponatraemia / cerebral oedema should have been considered as part of the differential diagnosis and tested for in a child with vomiting and reduced consciousness.[109]

    (iii) A CT on the evening of 21st October 1996 should have been an 'urgent requirement' on the basis of a child having unexplained reduced consciousness to exclude or confirm a number of causes of raised intercranial pressure.[110]

    (iv) As with Dr. Scott-Jupp above, more extensive biochemical tests should have been performed.[111]

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100 Ref: 090-040-140
101 Ref: 090-022-053
102 Ref: WS-135-1 p.11 Q15d, p.13 Q16a
103 Ref: 096-001-004
104 See List of Persons - Ref: 310-003-001
105 Ref: 234-002-002
106 See List of Persons - Ref: 310-003-001
107 Ref: 232-002-003
108 Ref: 232-002-004
109 Ref: 232-002-003
110 Ref: 232-002-004
111 Ref: 232-002-003

52. Dr. Dewi Evans, Consultation Paediatrician engaged as an expert by the PSNI,[112] considers that Claire should have been on a CNS observation chart from admission as "*not responding to parents' voice*" and "*intermittently responding to deep pain*" are both indicators of a serious neurological disorder. He adds that failure to do so is indicative of unsatisfactory care.[113]

53. The appropriateness of Dr. O'Hare's diagnosis, the adequacy of the investigations done on admission, and whether she should have contacted her consultant Dr. Steen are all issues that will be considered during the Oral Hearings.

Decision to admit to Allen Ward

54. At 20:45, Dr. O'Hare is recorded as having decided to admit Claire to the Children's Hospital,[114] and she was admitted under the care of Dr. Heather Steen,[115] the on-call Consultant Paediatrician.[116] The Admission Sheet records the actual time of admission to Allen Ward as 21:14.[117]

55. A Nursing Admission sheet was completed by Staff Nurse Geraldine McRandal[118] at approximately 21:45 on that evening and she signed it as the "*accountable nurse*".[119] The reason recorded on that sheet for Claire's admission was "*? Seizure, vomiting*".[120] Claire's weight was recorded as 24.1kg[121] and she is recorded as being nursed in Cubicle 7, Bed C on Allen Ward, which is a cubicle that held 4 beds.[122]

56. Claire's admission occurred exactly 4 months after the conclusion of the Inquest into Adam Strain's death at the Children's Hospital of cerebral oedema with dilutional hyponatraemia and impaired cerebral perfusion as contributory factors.

Review at midnight

57. Dr. O'Hare reviewed Claire at midnight in Allen Ward, and recorded that she was slightly more responsive and had no clinical signs of meningitis.[123] She recorded that Claire could be observed and

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112 See List of Persons - Ref: 310-003-001
113 Ref: 096-022-136
114 Ref: 090-012-014
115 See List of Persons - Ref: 310-003-001
116 Ref: 090-014-020014-020
117 Ref: 090-014-020
118 See List of Persons - Ref: 310-003-001
119 Ref: 090-041-142
120 Ref: 090-041-142, 090-141-143
121 Ref: 090-041-142 and Ref: 090-021-049
122 Ref: WS-148-1 p.7 Q16
123 Ref: 090-022-052, WS-135-1 p.3 Q4b

reassessed in the morning. Dr. O'Hare states that she likely wrote the U&E results after her review of Claire at midnight.[124] The serum sodium result at 132mmol/L[125] is slightly below the normal range of 135-145mmol/L. The haematology results are in another hand, and appear to have been recorded and signed by Dr. Andrea Volprecht,[126] Paediatric Senior House Officer. The white cell count result was higher than the normal range (4-11). The results recorded were:[127]

"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"

58. The U&E results were confirmed in a printed biochemistry laboratory report.[128] Dr. Andrew Sands, the paediatric registrar on duty for the day shift on 22nd October 1996,[129] suggests that serum sodium concentration levels "*may ... be spuriously low, due to sampling technique*".[130]

59. The white cell count result of 16.52 on admission was from a sample taken at approximately 22:00/22:30 on 21st October 1996.[131] Claire's white cell count results then dropped to a normal range on 23rd and 24th October 1996[132] – the first normal result being 9.4 recorded in the medical notes at 04:00 on 23rd October 1996[133] and for which there appears to be a printed lab report result of 09.35.[134]

60. Dr. Evans expressed himself in his report for the PSNI as being "*rather surprised*" that a major Children's Hospital did not carry out a differential white count as a matter of course in order to distinguish the cause of any possible infection.[135] He also states that the 132mmol/L result is evidence that Claire was already showing signs of retaining fluid,[136] as was her 'lowish' creatinine value of 36 (normal range 40-110).[137] Dr. Evans believes that, within the context of her clinical

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124 Ref: WS-135-1 p.14 Q17b, 18a
125 Ref: 090-022-052
126 See List of Persons - Ref: 310-003-001
127 Ref: 090-022-052
128 Ref: 090-031-099
129 See List of Persons - Ref: 310-003-001
130 Ref: WS-137-2 p.29 Q52
131 Ref: 090-022-052, 090-032-108
132 There are also printed lab reports for normal white cell count results from a specimen on 23rd October 1996 (Ref: 090-032-112) and a specimen on 24th October 1996 (Ref: 090-032-110)
133 Ref: 090-022-057
134 Ref: 090-032-111
135 Ref: 096-022-133
136 Ref: 096-022-134
137 Ref: 096-022-133

condition, the possibility of her already experiencing the symptoms of SIADH should have been seriously considered.[138]

61. Dr. Scott-Jupp states in his Report for the Inquiry that, although the sodium level is technically abnormal, it was "*acceptable*" as this level would not in itself have resulted in any seizure activity or decrease in conscious level.[139] In 1996, it was appropriate not to have acted on a sodium level of 132mmol/L.[140] Dr. Scott-Jupp states that standard practice in 1996 was to check serum electrolytes in children receiving IV fluid only once every 24 hours, and that even now the advice is to check electrolytes four to six hourly only if the serum sodium level is below 130mmol/L, thus a sodium level of 132 would not have warranted a repeat within six hours. However, because of Claire's lack of improvement, Dr. Scott-Jupp believes that electrolytes should have been repeated about twelve hours later.

62. Professor Neville disagrees stating in his Report for the Inquiry that, although the 132mmol/L result at midnight was just below the lower limit of the reference range and not "*grossly abnormal*",[141] it still should have been "*urgently repeated.*"[142] In addition, he states that the electrolytes should also have been urgently repeated six hours after admission because of Claire's reduced conscious level and the marginally reduced initial sodium level. Contrary to Dr. Scott-Jupp, he did not think it was reasonable to wait longer in this clinical situation, "*whatever the arrangements for biochemistry at night.*"

63. The adequacy of the electrolyte testing is therefore an issue to be considered during the Oral Hearings.

Fluid management on 21st October 1996

64. Dr. O'Hare determined on admission that Claire should be given IV fluids, and recorded that, should there be any seizure activity, it should be treated with intravenous diazepam and to review after fluids were administered.[143]

65. Dr. O'Hare states that she did not prescribe the fluids nor specify the type of fluid but says that the prescription was correct for maintenance fluids for Claire's weight and the standard type of fluid used in paediatrics in 1996.[144] She further states[145] that at that time:

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138 Ref: 096-022-134
139 Ref: 234-002-005
140 Ref: 234-002-003
141 Ref: 232-002-008
142 Ref: 232-002-005
143 Ref: 090-022-052
144 Ref: WS-135-1 p.4 Q6

"*the prescribing SHO would have prescribed these fluids unless there was a clear indication to do otherwise such as an abnormal urea and electrolyte result or on instructions from a senior member of staff*"

In addition, she states that it would not have been usual to restrict fluids in a child who was vomiting "*unless the electrolytes indicated that they were significantly hyponatraemic*".

66. Dr. Volprecht appears to have completed the IV fluid prescription chart, prescribing 500ml of 0.18% sodium chloride in 4% dextrose ("Solution No. 18") to be given at 64ml/h (equivalent to 65ml/kg/24 h).[146] The nursing care plan referred to administering *'IV fluids as prescribed by doctor, according to hospital policy.'*[147] Claire, like Adam, was administered Solution No. 18 whilst she was on the Ward. In Claire's case, the administration of Solution No. 18 continued throughout her admission on Allen Ward until her transfer to PICU. Dr. Seamus McKaigue, Consultant Paediatric Anaesthetist,[148] changed her maintenance fluids in PICU to 0.9% saline at approximately 08:00 on 23rd October 1996.[149]

67. The nursing record includes a fluid balance chart. Nurse McRandal was the admitting nurse and apparently the principal nurse who cared for Claire overnight. She made her first entry on the fluid balance sheet at 22:30, suggesting that IV fluids commenced at that time,[150] with 64mls hourly of 5/N saline. By 07:00, Claire had received 536mls, which equates to approximately 63mls hourly, i.e. just under the prescribed rate of 64mls hourly.

68. During those 8½ hours, she was noted by the nurses to have had one 'medium' and five 'small' vomits.[151] The nursing notes describe these vomits as bile-stained; this was a change from the A&E note, where vomits were described as 'non-bilious'.[152]

69. Dr. Evans considers in his report for the PSNI that while the rate of administration of fluid was correct,[153] the receipt of the serum sodium result of 132mmol/L should have prompted an immediate change to Claire's fluid regime to 0.45% saline.

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145 Ref: WS-135-1 p.11 Q15(c)
146 Ref: 090-038-134
147 Ref: 090-043-146
148 See List of Persons - Ref: 310-003-001
149 Ref: 090-022-060
150 Ref: WS-145-1 p.9 Q18c
151 Ref: 090-038-133
152 Ref: 090-040-140, 090-012-014
153 Ref: 096-022-134

70. In his Report for the Inquiry, Dr. Scott-Jupp states that Solution No. 18 was "*absolutely the standard IV fluid given to most children needing fluids for any reason in 1996*."[154] He believes that even when the low sodium level of 132mmol/L was noted at midnight, most practitioners at the time would still have continued on with Solution No. 18.[155] He also considers the rate prescribed to have been appropriate. Indeed, Dr. Scott-Jupp states that severe fluid restriction at that stage could potentially have been harmful due to Claire's history of vomiting and risk of dehydration.

71. Whilst Professor Neville accepts in his Report for the Inquiry that Solution No. 18 was in common use,[156] he claims its use in a drowsy child should have been with at least a warning for urgent review.[157] He states it would have been appropriate to use restricted fluids. On the initial low sodium level coming back at midnight, he believes that a higher concentration of salt containing fluid regime such as 0.45% or 0.9% saline should have been administered as a precautionary measure, although he notes that "*not everyone would have done so*".[158]

72. Dr. Roderick MacFaul, the Inquiry's expert in clinical governance,[159] has commented on some of the medical aspects states in his Report for the Inquiry. He agrees with Professor Neville that Solution 18 was the conventional fluid used throughout the NHS at the time,[160] but that in the context of a possible encephalopathy, the ideal/high-quality practice was to use IV fluid with a higher sodium concentration[161].

73. The appropriateness of the type, rate and volume of fluid administered to Claire are issues to be considered during the Oral Hearings.

IX. Claire's care and treatment overnight until the morning of 22nd October 1996

Evening handovers between medical staff

74. Dr. O'Hare has stated that in October 1996 there "*was no evening handover when the consultant and the resident on call staff would have made contact*",[162] and that in 1996:

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154 Ref: 234-002-002
155 Ref: 234-002-003
156 Ref: 232-002-007
157 Ref: 232-002-004
158 Ref: 232-002-004
159 See List of Persons - Ref: 310-003-001
160 Ref: 238-002-035
161 Ref: 238-002-018
162 Ref: WS-135-1 p.5 Q9e&f

(i) there was no system of handing over patients between shifts,

(ii) that clinicians went to the wards and started ward rounds first thing in the morning, and

(iii) that nurses on the ward would have identified to the clinicians critically unwell patients who required immediate review.[163]

75. These are issues that will be addressed during the Oral Hearings.

Nursing Care Plan

76. Nurse McRandal completed the Nursing Care Plan on Claire's admission.[164] The plan notes problems with potential further seizures and vomiting. Nurse McRandal records that the plan is to be reviewed daily.[165] One of the goals was to "*ensure safe administration of IV fluids*".[166] The Nursing actions required are noted as:

(i) informing doctor of length and type of seizure;

(ii) administer medicine as prescribed observing for desired effects/side effects;

(iii) to record an accurate fluid balance chart and

(iv) to report abnormalities to doctor/nurse in charge.

77. The Ward Sister with overall responsibility of Allen Ward between 21st and 23rd October 1996 was Angela Pollock,[167] although the times at which she was on duty are not known.[168] Sister Pollock was responsible for monitoring the quality of Claire's nursing care plan.[169]

78. Observations were made 4 hourly of temperature, pulse and respirations by nurses following Claire's admission.[170]

79. Nurse McRandal states this was in keeping with a child admitted with a suspected viral illness, and accepts that it would also be appropriate to observe for any seizure activity and claims that during her shift Claire was observed for seizures.[171]

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163 Ref: WS-135-1 p.19 Q34
164 Ref: 090-043-145 & 090-043-146
165 Ref: 090-043-145 & 090-043-146
166 Ref: 090-043-145 & 090-043-146
167 See List of Persons - Ref: 310-003-001
168 Ref: WS-145-1 p.21 Q35
169 Ref: WS-148-1 p.21 Q33
170 Ref: 090-044-147
171 Ref: WS-145-1 p.3 Q5a, p.6 Q14, p.25 Q51

80. Nurse McRandal states that hourly neurological observations would not routinely be commenced on admission unless specifically directed by medical staff, and there was nothing to suggest that Claire's condition required more than the standard observations for a child admitted with a suspected viral illness.[172]

81. Ms. Sally Ramsay, Independent Children's Nursing Advisor,[173] states in her Report for the Inquiry that the nursing actions listed in the care plan were "*comprehensive*",[174] prepared "*in a timely manner*" and reflected the identified problems associated with a diagnosis of seizures and vomiting. However, she also states that "*more frequent observation of some vital signs should have been made*", specifically hourly recordings of heart rate, respiratory rates and level of consciousness to ensure that Claire was checked regularly and not experiencing further seizures.[175] However, she adds that these observations were within normal limits by 06:00 on 22nd October 1996[176].

82. Whether Claire's vital signs, particularly her level of consciousness, should have been more frequently observed is an issue to be considered during the Oral Hearings.

Urine testing

83. Nurse McRandal records that a direct urine specimen was taken at the time of Claire's admission[177] and that this sample was to be tested in the laboratory for direct microscopy and organisms and sensitivity. [178] However, the results of the laboratory tests are not recorded in the notes.

84. Similarly, the fluid balance chart records that Claire passed a large amount of urine at approximately 11:05 which was sent to the laboratory for analysis.[179] The type of test/analysis is not recorded on that sheet or the nursing notes.

85. There are also two printed laboratory reports relating to urine microscopy and a test for urine culture.[180] It is unclear if these reports related to urine samples taken overnight and as recorded in the

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172 Ref: WS-145-1 p.8 Q15h, p.12 Q20d., p.17 Q28c & d
173 See List of Persons - Ref: 310-003-001
174 Ref: 231-002-019
175 Ref: 231-002-003
176 Ref: 231-002-023
177 Ref: 090-040-140
178 Ref: WS-145-1 p.14, Q25a
179 Ref: 090-038-135, WS-148-1 p.8 Q17a
180 Ref: 090-030-094, 090-030-097

nursing notes on 21st October[181] or whether they were from the sample passed at approximately 11:05 on 22nd October 1996.

86. Dr. O'Hare adds that, in 1996 at Children's Hospital, urinary sodium and osmolality would not have been available after hours and that in hours a result would not have been available for one to two days.[182]

87. Ms. Ramsay states in her Report for the Inquiry that it would have been usual for all children being admitted to have their urine tested on the ward by a nurse, and for the nurse to record those results and inform the doctor of any abnormalities.[183] The usual ward based urine test would have measured specific gravity which can indicate dehydration or over-hydration, although Ms. Ramsay indicated that it was not used routinely to assess hydration. Staff Nurse Sara Field (now Jordan)[184] states that measuring the specific gravity would have been at the request of medical staff.[185]

88. Ms. Ramsay states in her Report for the Inquiry that the failure to note the results of the ward-based test was an omission in nursing care, but that, as a specimen had also been sent to the laboratory for assessment of osmolality, it was not an omission of "*major significance*".[186]

89. Dr. Scott-Jupp states that urine electrolyte and osmolality measurements were not routine tests in October 1996 in cases of vomiting, possible dehydration and/or seizures, and would not be indicated by the sodium result of 132mmol/L.[187] It was appropriate to do so at 23:30 on 22nd October 1996, and it was done at this time.

90. In contrast, Dr. Evans states in his report for the PSNI that assessing urine electrolyte and osmolality should be a routine procedure and he considered the failure to conduct these measurements and measure urine is considered to be "*indicative of unsatisfactory clinical practice.*"[188]

Fluid balance measurement

91. As regards the fluid balance charts,[189] Ms. Ramsay indicates in her Report for the Inquiry that they appear to show accurate recordings of fluid intake.[190] She adds that the volume of vomiting is appropriately

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181 Ref: 090-040-140
182 Ref: WS-135-1, p.13 Q16(c)
183 Ref: 231-002-027
184 See List of Persons - Ref: 310-003-001
185 Ref: WS-148-1 p.9(j)
186 Ref: 231-002-028
187 Ref: 234-003-003
188 Ref: 096-022-135
189 Ref: 097-012-102, 096-025-340
190 Ref: 231-002-028

recorded, although it is good practice to record the colour of vomit, which is not described on the fluid charts.

92. Urine output is only shown as "*PU*" (i.e. 'passed urine'), indicating that it was not measured. In Ms. Ramsay's opinion:

(i) this is not an accurate measurement of output[191]

(ii) urine output could easily have been measured by weighing nappies before and after use[192]

(iii) the nurses should have been aware of the possibility of either dehydration of fluid overload in a child with altered consciousness

(iv) accurate recording of output in children receiving IV fluids is a nursing responsibility

(v) Claire's urine output should have been measured.

However, Ms. Ramsay concedes that it was "*custom and practice in many situations to only record the frequency of passing urine and not the volume.*"[193]

93. Nurse McRandal states that it was not normal practice in paediatrics to measure urinary output particularly for a child wearing a nappy, that it would normally be acceptable to record the number of episodes of urination, but that medical staff would direct nursing staff to weigh nappies if they required an accurate measurement of urine.[194] It is not clear whether Nurse McRandal's reference to 'normal practice in paediatrics' is intended to refer to the Children's Hospital at that time or more generally.

94. Whether further action should have been taken to test and measure Claire's urine output is a matter that will be considered during the Oral Hearings.

X. Claire's care and treatment during the morning of 22nd October 1996

95. At approximately 07:00 on 22nd October 1996, Claire is recorded as having slept well and being much more alert and brighter.[195] She had had one further bile-stained vomit. Her IV fluids were continued. From

191 Ref: 231-002-028
192 Ref: 231-002-029
193 Ref: 231-002-028
194 Ref: WS-145-1 p.10 Q18(i)
195 Ref: 090-040-140

08:00 onwards she slept during some of the early morning, was bright when awake, her arms were active but there was no vocalisation. Nurse Field recalls Claire moving actively around her bed that morning, and on 2 occasions the bandage covering her cannula became loose and she was alert and unravelled it.[196] However, in the late morning of 22nd October 1996, Claire, who was described as usually very active, became lethargic and vacant.

96. The fluid chart for 22nd October 1996[197] does not note the solution given but an undated prescription chart[198] referred to 500mls of No.18 solution at 64ml/hr. A total of 562mls was given over eight hours from 08:00, i.e. a rate of 70ml hourly.

Medical handover

97. Dr. O'Hare has already stated in relation to the 'handover' between the evening and morning shift that in October 1996 there "*was no evening handover when the consultant and the resident on call staff would have made contact*".[199] She also states that, in 1996, there was no system of handing over patients between shifts and that each clinician would simply go to their wards and start their ward rounds first thing in the morning.[200] However, although there was no formal handover, registrars may have informally handed over between themselves[201] if there was a particular concern about a given patient or if they wished the day staff to complete a task for a given patient, although she claims the latter was not the usual practice at the time.[202] Critically unwell patients who required immediate review would have been identified by the nurses on the ward.[203]

98. Her fellow paediatric registrars Dr. Sands and Dr. Brigitte Bartholome[204] agree that informal handovers were carried out. Dr. Sands notes that brief personal notes may have been made by the person or persons receiving the handover.[205]

99. Dr. Bartholome states that notes were made by the individual doctors as they felt appropriate.[206] She adds that the senior doctor working in the general paediatric ward would inform the doctor working the night shift regarding the patients on the ward, their conditions,

196 Ref: WS-148-1 p.10 Q18a
197 Ref: 090-038-135
198 Ref: 090-038-136
199 Ref: WS-135-1, p.5
200 Ref: WS-135-1, p.19
201 Ref: WS-135-2, p.2
202 Ref: WS-135-2, p.5
203 Ref: WS-135-1, p.19
204 See List of Persons - Ref: 310-003-001
205 Ref: WS-137-1, p.33-34
206 Ref: WS-142-1, p.14

investigations and management plan. Handovers occurred at 09:00 and 17:00 daily, but were not a formalised process.[207]

Nursing handover

100. Nurse Field was on duty between 08:00 and 14:00 on 22nd October 1996 on Allen Ward, and had been allocated to care for a group of patients that included Claire.[208] Nurse McRandal had informed Nurse Field during the handover at approximately 07:45 that Claire had learning difficulties, had been admitted for management of vomiting and possible seizure activity, and that Claire had a previous history of seizure activity.[209] Nurse Field does not recall being informed of the primary diagnosis of viral illness or encephalitis.[210]

101. Before the ward round, Nurse Field had been informed by Claire's parents of concerns that Claire was lethargic, vacant and did not appear her usual self, as she was normally an active child.[211] Nurse Field states that she immediately told Enrolled Nurse[212] Kate Linsky[213] of those concerns and the change in Claire's condition to report during the ward round. At that time, Dr. Sands was conducting the ward round in Cubicle 6. [214]

Ward round on morning of 22nd October 1996

102. The ward round on the morning of 22nd October 1996 was held at approximately 11:00 to 12:00.[215] Dr. Sands, who was then in his first substantive post as a paediatric registrar and who is now a Consultant Paediatric Cardiologist at the Children's Hospital, led the ward round that morning as the most senior clinician on the ward round team.[216] It was also attended by paediatric SHOs Dr. Neil Stewart[217] and Dr. Roger Stevenson[218] (who recorded the ward round note)[219] together with Nurse Linsky. It is not known whether a more senior nurse attended.

103. Dr. Sands examined Claire with Nurse Linsky in attendance.[220] He believes that the recorded admission notes suggested a short history of

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207 Ref: WS-142-2, p.4
208 Ref: WS-148-1 p.20 Q27a
209 Ref: WS-148-1 p.6 Q14a
210 Ref: WS-148-1 p.6 Q14, 15
211 Ref: WS-148-1 p.10 Q18b
212 'Nomenclature & Grading Nurses 1989-2012', Ref: 303-004-051
213 See List of Persons - Ref: 310-003-001
214 Ref: WS-148-1 p.4 Q7, p.10 Q18b
215 Ref: WS-137-1 p.38 Q18
216 Ref: WS-137-2 p.10 Q8; WS-137-1 p.15 Q7
217 See List of Persons - Ref: 310-003-001
218 See List of Persons - Ref: 310-003-001
219 Ref: WS-139-1, p.5 Q7
220 Ref: WS-148-1 p.11 Q18e, p.24 Q44b

vomiting small quantities, increasing lethargy and impaired level of consciousness.[221] The note records[222] that no seizure activity had been observed, Claire's serum sodium was 132mmol/L and that she was apyrexial, pale and showing little response compared to normal. It also records that her pupils were sluggish to light, it was difficult to see the fundi and that there were bilateral long tract signs.

104. Dr. Sands concluded "*non-fitting status*"[223] (i.e. continuous epileptic activity in the brain without clinical effects[224]). The nursing note relating to the ward round records only "*Status epilepticus – non-fitting*" (i.e. not having a seizure).[225] He believes that status epilepticus may cause cerebral oedema, and that cerebral oedema may cause status epilepticus.[226]

105. Dr. Sands states that he added the handwritten note of "*encephalitis/encephalopathy*"[227] following the words "*impression non fitting status*"[228] entered by Dr. Stewart after he had sight of the ward round entry and immediately after his first conversation with Dr. David Webb, Consultant Paediatric Neurologist,[229] whom he recalls mentioning the term encephalopathy.[230] Dr. Sands believes that the possibility of Claire having an infection in the brain or encephalitis was discussed on the ward round and was likely to have been discussed with her parents.

106. Dr. Sands claims to have "*been very concerned that Claire had a major neurological problem*" (i.e. her impaired level of consciousness and abnormal neurological signs) and felt that Claire *"was really very unwell"*.[231] At the Inquest, he stated he was very concerned regarding Claire's level of consciousness on the morning of 22nd October and that this prompted the urgent neurology referral.

107. Dr. Scott-Jupp concludes in his Report for the Inquiry that it would have been normal practice at the time of Claire's admission for Dr. Sands to have led the ward round.[232] In addition, he considers that Dr. Sands' diagnosis was "*not unreasonable*"[233] but that other differentials, including encephalitis and encephalopathy, should have been

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221 Ref: 091-009-055
222 Ref: 090-051-157
223 Ref: 090-022-053
224 See Glossary - Ref 310-007
225 Ref: 090-040-141
226 Ref: WS-137-2 p.29 Q51
227 Ref: WS-137-1 p.6 Q3c
228 Ref: 090-022-053
229 See List of Persons - Ref: 310-003-001
230 Ref: WS-137-1 p.6 Q3c
231 Ref: 091-009-056
232 Ref: 234-003-004
233 Ref: 234-002-004

considered. He was also surprised at the lack of any consideration of an EEG to make a firm diagnosis of non-convulsive status. He notes in his Report that urgent EEGs may not always be available and if so that he would expect such a lack of availability to have been recorded. However, he states that he would have expected a large tertiary Children's Hospital with a paediatric neurology service to have had an EEG service.[234]

108. Dr. Scott-Jupp considers Dr. Stevenson's note of the ward round to be adequate, but he would have expected a request from Dr. Sands to repeat any tests (if a request was made) to have been recorded in the ward round note,[235] and it would have been Dr. Stevenson's responsibility to take the blood test.

109. Professor Neville criticises Dr. Sands' differential diagnosis in his Report for the Inquiry:[236]

(i) Non-convulsive status epilepticus was not the likely diagnosis as it is not common and epilepsy was not prominent in Claire's recent history.

(ii) Non-convulsive status epilepticus needed to be proved by an urgent EEG.

(iii) An incorrect diagnosis of non-convulsive status leads to inappropriate treatment with anti-epilepsy drugs which could further reduce her conscious level and respiratory drive.

(iv) Cerebral oedema related to hyponatraemia was a more likely cause of the reduced conscious level and poorly reacting pupils and should have been considered as a matter of urgency as it is reversible by treatment in its early stages

110. Professor Neville is concerned that in Claire's case, it was assumed that she had sub-clinical seizure activity[237] and that the team were firmly sticking to non-convulsive status as the diagnosis which seems to have stopped other avenues being pursued until it was too late.[238]

111. Dr. MacFaul states that there is an increased incidence of hyponatraemia in cases of acute encephalopathy,[239] and that in cases of acute encephalopathy, the following should be done:[240]

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234 Ref: 234-002-004
235 Ref: 234-003-005
236 Ref: 232-002-005 to 232-002-006
237 Ref: 232-002-001
238 Ref: 232-002-012
239 Ref: 238-002-016

(i) Identify the cause by investigation

(ii) Treat the treatable e.g. infection

(iii) Take steps to prevent, identify and treat emerging signs of raised intracranial pressure by clinical monitoring

(iv) Carefully monitor and restrict fluid to the minimum necessary, and to ensure that low-sodium IV fluid is not used

(v) In the presence of advancing and clear raised intracranial pressure, mannitol or steroids may be used.

112. He notes that there is no clear record that Claire had a fit before admission[241] and that the proposed diagnosis of non-convulsive status epilepticus was not of high or even moderate likelihood.[242]

113. Ms. Ramsay states in her Report for the Inquiry that a diagnosis of status epilepticus should have prompted greater concern.[243] Dr. Sands' Statement for the Coroner and Witness Statement note his concerns regarding Claire's condition, however, the other Witness Statements received by the Inquiry to date do not indicate that Claire's level of consciousness was of particular concern to the medical and nursing staff involved at the time.

114. The appropriateness of Dr. Sands' diagnosis and whether the diagnosis should have prompted more concern in the medical team as a whole is a matter to be considered during the Oral Hearings.

Discussions between Dr. Sands and Claire's parents

115. Mr. Roberts recalls that Claire's condition had not improved from the previous evening of 21st October.[244] Both he and Mrs. Roberts were present during the morning ward round, which Mr. Roberts recalls as being *"casual"* and lasting some *"5 to 10 minutes"*.[245]

116. Mr. and Mrs. Roberts state that during the morning of 22nd October they expressed their concerns to Dr. Sands about Claire's unresponsiveness and that she did not appear to be 'herself'.[246]

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240 Ref: 238-002-017
241 Ref: 238-002-026
242 Ref: 238-002-020
243 Ref: 231-002-029
244 Ref: WS-253-1, p.6
245 Ref: WS-253-1, p.6
246 Ref: 091-004-006

117. Dr. Sands claims to have had a lengthy discussion with Mrs. Roberts at the time of the morning ward round on 22nd October during which he explained his concerns whilst endeavouring to avoid alarming her.[247] In his second witness statement, Dr. Sands claims to recall discussing with the Roberts family that Claire may well have had a significant neurological problem, and he believes he would have explained concerns about possible ongoing seizure activity and the need for specialist advice from a neurologist. He stated he would only have given limited detail pending consultant assessment. He has no recollection of talking later on 22nd October with Claire's parents. [248]

118. Mr. Roberts recalls a discussion regarding a viral illness and that Claire may have been experiencing some form of 'internal fitting'.[249] He does not recall any discussion of blood samples being taken. He believes he spoke to Dr. Sands for about five to ten minutes. Her past history of epileptic seizures and her being seizure free for over three years and off anticonvulsants were discussed with Dr. Sands, as was her vomiting. However, he does not recall encephalitis, encephalopathy or diarrhoea being mentioned.[250]

119. Claire's parents did not appreciate that Claire may have had a *"significant neurological problem"*[251] or that Dr. Sands thought that was a possibility. Rather, they believed at the time that Claire had a 24/48-hour stomach bug.[252]

120. Dr. Scott-Jupp states that parents should be told of:[253]

    (i) Any change in diagnosis

    (ii) Possible reasons for any deterioration

    (iii) The management plan

    (iv) Any significant neurological deterioration

    He would not expect them to be told that periodic neurological assessments and/or GCS recordings were being done.

121. The appropriateness or otherwise of the communications with Claire's parents, including how clinicians and nurses kept them aware of her

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247 Ref: 091-009-057, WS-137-1 p.51 Q43
248 Ref: WS-137-2 p.7 Q4, WS-137-1 p.51-2 Q43
249 Ref: WS-253-1, p.7
250 Ref: WS-253-1, p.7-8
251 Ref: WS-137-2, p.7
252 Ref: WS-253-1, p.8
253 Ref: 234-003-007

diagnosis, her treatment and the severity of her condition are matters that will be considered during the Oral Hearings.

Urine and electrolyte testing

122. An issue being investigated by the Inquiry is whether a request or decision was made to carry out the serum electrolytes test at the ward round or at any time prior to 21:30 on 22nd October 1996.

123. There is no documentary evidence in the clinical or nursing notes of this request/decision.

124. Dr. Sands could not recall at the Inquest whether he was aware of the serum sodium concentration of 132mmol/L at the time of his morning ward round on 22nd October, or how blood test results were relayed to him. He states that it seems likely he was unaware of "*the exact timing of the first serum sodium test*" and of the exact timing of the blood sample but he believes that he and the ward round team would have considered it a blood test which should be repeated.[254]

125. In his second statement to the Inquiry, Dr. Sands does not recall whether he was aware that the serum sodium result related to a sample from the evening of 21st October or on the morning of 22nd October, nor whether he had read Claire's admission notes and medical records prior to his examination of Claire and the ward round discussion.[255] Dr. Sands stated at the inquest "*We did not know at what time the 2nd test of electrolyte test was requested or taken... With hindsight, further investigations may well have drawn attention to sodium loss or fluid retention*".[256] He thinks it likely these results were mentioned as part of the presentation of Claire's case on the ward round.[257]

126. Dr. Sands cannot recall if at any time during his day shift on 22nd October he considered having a blood test carried out or if the serum sodium result was considered immediately relevant to Claire's clinical condition.[258] He does not remember if a blood test was specified by himself on 22nd October and does not know why such a test was not carried out until the evening, particularly if it was requested or planned at the ward round. Sampling was usually done between 09:00 and 17:00. He believes that the electrolyte result is one that would have prompted a request for a repeat electrolyte sample probably not as a matter of urgency.[259] He claims that it is likely that a decision was made to repeat a test of electrolytes because electrolytes were repeated

254 Ref: 091-009-059, WS-137-1 p.42 Q23
255 Ref: WS-137-2 p.10 Q7
256 Ref: 091-009-057
257 Ref: WS-137-1 p.42 Q23
258 Ref: WS-137-2 p.9 Q7
259 Ref: 091-009-057, 091-009-059, WS-137-1 p.12 Q6, p.41 Q21, p.42 Q23

later that evening, although he does not recall a discussion relating to further checking of electrolytes on the ward round.[260] However, he cannot be sure that the test was repeated because of the ward round discussion/decision or as a result of the policy at the Children's Hospital of carrying out such tests at least once every 24 hours. He suggests that blood tests out of hours had to be telephoned through as an emergency to the on-call laboratory staff.[261]

127. Dr. Sands cannot explain why neither the ward round note nor the clinical notes contain any record, plan or decision for a further check of Claire's urea and electrolytes. He claims that such an instruction may be passed on verbally or recorded on a separate sheet of paper or book (the Inquiry has been informed about a ward round diary which seems to have been destroyed) as *"an aide memoire"*,[262] and that such a decision may not always end up being recorded in the clinical or nursing notes.[263] Angela Pollock, who was the ward sister in charge of Allen Ward during Claire's admission, states that any particular tests required following a ward round would have been noted in the 'ward round diary' but that such a document would have been destroyed by now under the Trust's disposal of records policy.[264]

128. Whatever the position with recording requests for urea and electrolyte tests, Dr. Sands states that he, Dr. Stevenson and Dr. Stewart (the 'ward team') would have considered that Claire's fluid input was roughly balanced by fluid output and that her electrolytes were not markedly deranged or considered to be a significant problem on the 22nd October up to at least the middle of the afternoon.[265] Dr. Sands states that "*there may have been no definite evidence to suggest that fluids needed to be altered*" prior to 23:30 on 22nd October, and that *"a major change in clinical condition or key investigation result may have prompted an urgent repeat of serum sodium earlier in the day*".[266]

129. Dr. Webb, as Claire's consultant paediatric neurologist, states he would have expected a further blood test on the morning of 22nd October 1996 because the result was below normal and Claire was receiving IV fluids:[267] *"It would be routine for children on IV fluids to have their urea & electrolytes measured on a daily basis or more frequently if necessary to facilitate adjustments to the fluids. Blood testing in hospital is routinely undertaken first thing in the morning."*[268] He accepts that a repeat serum

260 Ref: WS-137-2 p.16 Q19
261 Ref: WS-137-2 p.10 Q7
262 Ref: WS-137-2 p.9 Q7
263 Ref: WS-137-2 p.9-10 Q7, WS-137-1 p.37 Q17
264 Ref: WS-225-1 p.5 Q12
265 Ref: WS-137-2 p.11 Q9, WS-137-1 p.10 Q5,
266 Ref: WS-137-2 p.12 Q12, WS-137-1 p.9 Q5
267 Ref: WS-138-1 p.79 Q60
268 Ref: 090-053-174

sodium test should have been repeated on Claire at some point during the day on 22nd October 1996.[269] Dr. Sands states that routine electrolyte tests would usually have been carried out during normal laboratory hours, and blood is very often drawn at the time of siting a new cannula to avoid any further puncturing of Claire's veins.[270]

130. Dr. Sands accepts that as part of the medical team he would have had some responsibility for checking that serum electrolyte testing had not been overlooked.[271]

131. Dr. Evans in his report for the PSNI[272] and Dr. Scott-Jupp[273], Dr. MacFaul[274] and Professor Neville[275] in their Reports for the Inquiry, all consider that Claire's electrolytes should have been tested by the time of the morning ward round on 22nd October.

132. Whether Claire's electrolytes should have been tested, and whether the record keeping of any such request was adequate, are matters that will be considered during the course of the Oral Hearings.

XI. Consultant with responsibility for Claire's care and treatment

133. An issue that has yet to be resolved and therefore which will need to be addressed during the Oral Hearings, is the Consultant who had the responsibility for Claire's care and treatment from approximately 14:00 on 22nd October 1996 until her admission to PICU on 23rd October 1996. In particular, whether it was Dr. Steen, the Consultant Paediatrician or Dr. Webb the Consultant Paediatric Neurologist and also how any change in Consultant responsibility was brought about.

Dr. Steen's involvement in Claire's case

134. There is no evidence that between Claire's admission to the Children's Hospital and Claire's transfer to PICU on 23rd October:

(i) Dr. Steen attended and/or examined Claire at any time

(ii) Dr. Steen had any verbal communication with Dr. Webb about Claire at any time. There is no record of any communication

269 Ref: 090-053-174, WS-138-1 p.36 Q23
270 Ref: WS-137-2 p.12 Q10
271 Ref: WS-137-2 p.16 Q19
272 Ref: 096-022-135
273 Ref: 234-002-003
274 Ref: 238-002-020
275 Ref: 232-002-005

between these consultants either directly or through the respective registrars on the paediatric and neurology teams.[276]

135. Dr. Steen cannot recall where she was in the morning of 22nd October and says that she would usually have been on Allen Ward. She states she would usually have been conducting an off-site clinic on a Tuesday afternoon which would be over at about 17:00.[277]

136. Dr. Sands does not recall where Dr. Steen was – he states that she was not present in the hospital, that it is likely that he would have known her location and that she was contactable by telephone, although he cannot recall if she was immediately contactable by telephone.[278] He claims that she was "*unavailable*" although he believes that "*she was kept informed by telephone*"[279] at some time after Dr. Sands subsequently spoke to Dr. Webb. Dr. Sands states that he recalls telephoning Dr. Steen in the afternoon of 22nd October to inform her that Dr. Webb had been consulted about Claire.[280]

137. There is no record in Claire's medical or nursing notes of any contact/discussion between Dr. Steen and any other member of the clinical or nursing team members prior to Claire's respiratory arrest on 23rd October. Dr. Webb states that it was the normal practice for a Consultant to see the patient admitted on the morning after admission.[281] However, Dr. Sands states that he would have expected both Dr. Steen and Dr. Webb to discuss Claire's case together and both to offer advice on Claire's management.[282]

138. Nurse Field does not recall having any contact with Dr. Steen during her shift. However, she does recall speaking to Dr. Webb when he saw Claire at approximately 14:00 on 22nd October and telling him about Claire's condition in the morning.[283]

139. Professor Neville in his Report for the Inquiry states that "*the consultant [paediatrician [i.e. Dr. Steen] should have been involved*"[284] as the cause of Claire's brain illness was unexplained, although he says that this could have been the responsibility of Dr. Sands, Dr. Webb or both depending on the local practice.[285]

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276 Ref: WS-138-1 p.13 Q4
277 Ref: WS-143-1 p.3 Q2
278 Ref: WS-137-1 p.17 Q8, WS-137-1 p.20 Q10, p.42 Q22
279 Ref: 090-051-158
280 Ref: WS-137-2 p.17 Q20, p.10 Q24, WS-137-1 p.16 Q7,17 Q8
281 Ref: WS-138-1 p.96 Q91
282 Ref: WS-137-2 p.21 Q30
283 Ref: WS-148-1 p.22 Q38, 39
284 Ref: 232-002-007
285 Ref: 232-002-007

140. Dr. MacFaul agrees that Claire should have been seen by a consultant morning following her admission, or, at a minimum, Claire should have been discussed with Dr. Steen.[286] He also considers that if a consultant was not able to carry out a scheduled ward round, then they should have telephoned either the Ward or the registrar to determine whether any significant cases had been admitted overnight.[287]

141. The extent to which Dr. Steen as the consultant paediatrician on duty, should have been, and was, involved in Claire's care is a matter that will be considered during the Oral Hearings.

Decision to seek neurological opinion

142. The plan recorded at the ward round was to administer rectal diazepam, consult Dr. Webb and discuss Claire's previous medical history with Dr. Colin Gaston. Dr. Sands states "*[w]hat I saw was outside my experience and [I] then contacted Dr. Webb*" as a Consultant Paediatric Neurologist.[288] He states that he asked Dr. Webb about having a CT scan performed and believes that he checked that Dr. Webb was in agreement with his plan for a trial dose of rectal diazepam[289] and that Dr. Webb mentioned encephalopathy to him. Dr. Sands believes that the timing of his discussion with Dr. Webb may have been around 12:00.[290] On his return, Dr. Sands states that he added the note "*encephalitis / encephalopathy*" to the differential diagnosis. He believes that he recorded this additional note at approximately 12:00 as part of the ward round note. He states that he would have expected Dr. Webb to provide further information to Claire's parents and to direct further investigations.[291] Dr Sands adds that, although he sought guidance from Dr. Webb, he did not seek to specify what role Dr. Webb was to have in Claire's care, as that something more usually discussed between consultants.[292]

143. For his part, Dr. Webb believes that Dr. Sands contacted and consulted him between 13:00 and 14:00 on 22nd October to provide neurological advice on the management of Claire. He states that Dr. Sands did not request him or his team to take over Claire's care, management and treatment. In particular, Dr. Webb states that Dr. Sands asked for advice about a child whom he felt had non-fitting status, what medication to prescribe for further seizures and whether he should request a CT scan. Dr. Sands also wanted Dr. Webb to assess Claire. Dr.

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286 Ref: 238-002-039
287 Ref: 238-002-043
288 Ref: 091-009-059
289 Ref: WS-137-2 p.13 Q15, WS-137-1 p.11 Q6
290 Ref: WS-137-2 p.28 Q39; WS-137-1 p.23 Q11
291 Ref: WS-137-2 p.7-8 Q5
292 Ref: WS-137-1 p.17 Q8

Webb agreed to see Claire first thing that afternoon and within the hour. Dr. Webb regarded his role as to assess Claire with history and clinical examination, provide a probable diagnosis and offer a management strategy to the paediatric medical team.[293]

144. Both Dr. Scott-Jupp and Professor Neville consider in their Reports for the Inquiry that Dr. Sands' referral to Dr. Webb for neurology advice was appropriate,[294] although both consider that it should have been the designated Consultant Paediatrician, Dr. Steen, who agreed that a neurological opinion was required. Dr. Scott-Jupp believes that, at a minimum, a telephone call should have been made to Dr. Steen under the circumstances, and it would have been reasonable for Dr. Steen to have seen a child who was "*clearly unwell and causing diagnostic difficulties*."[295] Dr. Scott-Jupp finds it "*concerning*"[296] that there is no record that Dr. Sands discussed the case with Dr. Steen, and if, as Dr. Sands says, she was unavailable, then that was "*certainly unacceptable*."[297]

145. Professor Neville comments that it appears that specialist advice had been sought by the paediatric team from Dr. Webb. He states that in that case, a junior member of staff would commonly see the patient and also show the patient to the consultant neurologist. Dr. Sands does not recall being present when Dr. Webb first attended Claire or at any other time during the afternoon when Dr. Webb saw Claire, nor does he recall any further discussions with Dr. Webb after his first initial discussion relating to the CT scan.[298] He states that Dr. Webb's assessments of Claire may have lessened some of his concern.[299]

146. How the referral to Dr. Webb for neurological opinion occurred is a matter that will be considered during the Oral Hearings.

Consultant Responsibility

147. As an aid to the analysis of the evidence received on this issue, the Legal Team has compiled a schedule from the Inquiry Witness Statements received which details the views of each of the clinicians and the nurses as to whom they believed to be the responsible Consultant at the relevant times.[300]

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293 Ref: WS-138-1 p.4 Q1, p.5-5 & 9 Q2
294 Ref: 234-002-004 and 232-002-007
295 Ref: 234-002-005
296 Ref: 234-002-004
297 Ref: 234-002-005
298 Ref: WS-137-1 p.38-9 Q18
299 Ref: WS-137-1 p.51 Q42
300 Ref: 310-005-001

148. Dr. Webb is clear that he considers Dr. Steen to have been the Consultant responsible for Claire's care and treatment between her admission and her death. He states that the Paediatric Neurology Team did not at any time formally takeover Claire's care. He did not consider himself to have taken over Claire's care from Dr. Steen and he was not asked to take over her care. He said the normal practice was that a request for transfer would be made to the specialist Consultant prior to transfer, and that he would not expect a transfer of care to be made to him without him being asked. In addition, Dr. Webb states that a note is usually made in the medical and nursing notes to document a transfer of care between teams. No note was made in Claire's case and Dr. Webb states that he did not discuss a transfer of Claire's care with anyone. Parents would also be told informally of the plan to transfer care. Dr. Webb also states that if Claire's care had been taken over by his team then he would probably have moved Claire to the Paediatric Neurology Ward. Dr. Webb states to his knowledge no other member of the paediatric neurology team examined Claire during her admission to the Children's Hospital.[301]

149. Dr. Webb has stated that where a child is admitted to hospital under a General Paediatrician, routine biochemical investigations would usually be managed and fluids are prescribed by the paediatric medical team and supervised by Paediatric Medical Registrar on that team, and that since his appointment as a Consultant Paediatric Neurologist ten years before Claire's admission, he *"cannot recall writing a prescription for intravenous fluids and during this period have never written a fluid prescription for another Consultant's patient. [He] would therefore not have had any input into the choice of fluids in Claire's case"*.[302]

150. Dr. Steen accepted at the Inquest that she was the Consultant on call at that time and that Claire fell within her remit. She claimed to have been aware that Claire was in the ward at 09:00 on 22nd October but could not recall if she examined Claire before that time. She recalled that when she contacted the ward, she was told that Dr. Webb had seen Claire *"and had taken over her management"*. However, Dr. Steen has since noted in her Inquiry Witness Statement that she can *"no longer recall this"*.[303] Dr. Steen was not contacted again until 03:00 on 23rd October.[304]

151. Dr. Sands states that he does not recall and is not aware of whether Claire's care had been formally taken over by Dr. Webb/the neurology team but he considers that any agreement for such a transfer of care

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301 Ref: WS-138-1 p.7-9 Q2, Q4, p.96-97 Q91
302 Ref: 090-053-174
303 Ref: WS-143-1 p.46 Q29(ff)
304 Ref: 091-011-067

would usually have been between consultants.[305] He considered himself under the supervision of Dr. Steen, and when Dr. Webb saw and examined Claire, he regarded himself as partly under the supervision of Dr. Webb also. Following Dr. Webb's first attendance, he understood that Claire was being jointly cared for by the medical and neurology team.[306] He refers to the fact that Claire remained on Allen Ward and so he was of the view that with both the medical and neurology team contributing to Claire's care – responsibility for Claire's management was shared.[307]

152. Dr. Sands accepts that he did not record the change in management and does not recall the reason why.[308] He states that transfer of care arrangements "*grew informally, depending on the nature of the patient's clinical problem*",[309] but a change from sole care of a medical team to joint care of a medical team and a team from another speciality may have involved verbal agreement between consultants. There is no record of any such verbal agreement or discussion. He claims that actual transfer of care may or may not have been recorded in the medical or nursing notes, and that it was not uncommon to have no specific statement in the medical notes of a transfer of care.[310] However, Dr. Sands believed that, by 17:15 on 22nd October, Dr. Webb's team was primarily responsible for Claire's care as all of Claire's direct consultant care had been given by the paediatric neurologist on duty, although he acknowledges that the medical team on Allen Ward were also assisting with that care.[311]

153. Ms. Ramsay states in her Report for the Inquiry that she believes "*the nurses could have concluded that Dr. Webb had taken over her care*"[312] as Claire had neurological problems, Dr. Webb was a Consultant Neurologist and "*spent a length of time examining Claire and interviewing her mother, whereas Dr. Steen did not visit Claire.*"[313]

154. Professor Neville takes the contrary view in his Report for the Inquiry in that it "*appears from the documents that Dr. Steen and the medical team retained primary care of Claire whilst seeking specialist advice from Dr. Webb*"[314] and that Dr. Webb was "*making suggestions and not taking over care*".[315] In addition, he considers that the hospital notes should make it

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305 Ref: WS-137-1 p.17 Q8
306 Ref: WS-137-2 p.3 Q2, p.4 Q3, p.5-6 Q3, p.18 Q22
307 Ref: WS-137-2 p.4 Q3
308 Ref: WS-137-2 p.5 Q3
309 Ref: WS-137-2 p.5 Q3
310 Ref: WS-137-2 p.21 Q30, p.25 Q38
311 Ref: WS-137-1 p.29 Q12
312 Ref: 231-002-018
313 Ref: 231-002-018
314 Ref: 232-002-007
315 Ref: 232-002-010

clear if there has been a transfer of care, and the nursing staff would be informed by a Consultant or Registrar.[316]

155. Dr. MacFaul agrees in his Report for the Inquiry that Dr. Steen was the responsible Consultant throughout Claire's stay, and there is no indication in any documentation that consultant responsibility was transferred.[317]

156. Dr. Scott-Jupp adds in his Report for the Inquiry that he does not believe that it would have fallen to the Consultant Paediatric Neurologist to take the lead in IV fluid management where an acutely unwell child is admitted under an acute General Paediatric Team. He is of the view that was the position in 1996 and is the position now. He is also of the view that Claire's care was "*very much*" within the remit of the General Paediatrician.[318] Likewise, he considers that responsibility for checking the electrolytes and actually prescribing the fluids should have fallen with the General Paediatric Registrar or Consultant.[319] He also believes that any transfer of care should have been recorded in the notes by the team requesting the transfer of care and all medical and nursing teams should have been made aware of this at their respective handover meetings.[320]

157. The Consultant responsible for Claire's care, the methods by which a transfer of care would be noted and staff made aware of any transfer are matters that will be considered during the Oral Hearings.

XII. Claire's care and treatment during the afternoon of 22nd October 1996

Neurological observations during 22nd October 1996

158. During the ward round, the medical staff requested that hourly central nervous system (CNS) observations be recorded hourly.[321] Dr. Sands notes that this was most likely *"a collective decision"* and may also have been suggested during his initial discussion with Dr. Webb.[322] The nursing staff started recording them from 13:00 and Claire's respiratory rate at that time is recorded as 28 per minute, with 19 to 20 being normal.[323]

316 Ref: 232-002-010
317 Ref: 238-002-019
318 Ref: 234-002-006
319 Ref: 234-002-006
320 Ref: 234-002-007
321 Ref: WS-148-1 p.3 Q4b
322 Ref: WS-137-1 p.18
323 Ref: 090-040-141, WS-148-1 p.12 Q18(i), 231-002-022

159. Throughout 22nd October 1996, the observations of Claire's neurological state were recorded using the Glasgow Coma Scale (GCS), which is a tool widely used to assess a patient's level of consciousness.[324] In a patient with reduced conscious level, a painful stimulus is applied to assess their response. Three specific responses are examined – the patient's best visual response, verbal response and motor response giving a total score out of 15.[325] Dr. Webb states that the scale was modified for use in very young children with the omission of one of the motor scores (flexion withdrawal), giving a total score out of 14.[326]

160. A score of 8 or less is considered by most to reflect the onset of coma.[327] Professor Neville states that scores of 9 - 12 require investigation and explanation and less than 9 require urgent investigation and management.[328]

161. Nurse Field recorded the first observations on the CNS chart with Nurse Linsky being present at that time.[329] The recordings for 'eyes open' and 'best motor response' are changed on the 'Central Nervous System Observation Chart'. Nurse Field accepts that if the original readings were correct then it would have resulted in Claire having a GCS of 6, as opposed to the recorded GCS of 9.[330] She cannot recall why they were changed.[331] No CNS observations are recorded at 14:00. Dr. Webb requested hourly observations in his note and he is uncertain who directed them from 13:00.[332]

162. 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*. The '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.[333]

163. Claire's GCS score was given as 9 on first checking and thereafter was 6 or 7, except at 20:00 when it was recorded as 8. It may be noteworthy that the nursing shift changed at 20:00 and a different nurse may have

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324 See Glossary - Ref 310-007
325 Ref: 090-053-170 *et seq*
326 Ref: 090-053-172
327 Ref: 090-053-171
328 Ref: 232-002-016
329 Ref: WS-148-1, p.4 Q7
330 Ref: 090-039-137, WS-148-1 p.15 Q21c
331 Ref: WS-148-1 p.15 Q21c
332 Ref: WS-138-1 p.24
333 Ref: 090-039-137

recorded that higher GCS scale.[334] 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.[335]

164. Dr. Webb identifies two periods of change[336]:

(i) Between 13:00 and 15:00, due to the administration of rectal diazepam at 12:30 and phenytoin at 14:45 which could have had effects on Claire's level of awareness during this period.[337] The observed seizure at 15:25 may have contributed to her persistent low scores between 16:00 and 17:00.[338] The post-ictal effects of convulsive seizures last usually between one to three hours.[339] He regards the improved GCS score of 8 at 20:00 as supporting this view;[340] and

(ii) From 20:00 when there was a definite, sustained change in Claire's GCS.[341]

165. Dr. Scott-Jupp considers that the neurological observations were appropriately recorded.[342] He states that the fall in GCS from 8 to 6 occurred around 21:00, but this was when she deteriorated anyway, so the chart in itself would not necessarily have provoked earlier medical review,[343] although her seizure at 21:00 should have prompted reassessment.[344]

166. Professor Neville states that any drop in the GCS score (for example at 21:00) should have prompted contact with the Registrar or Consultant by an SHO.[345]

167. Ms. Sally Ramsay says a GCS score of 8 and the need for complex IV therapy should have prompted discussions between nursing and medical staff about admission to PICU.[346] She notes that the failure to record when information concerning changes in observations had been passed to a doctor suggests that such information may not have been shared. However, she adds that charts would have been readily

334 Ref: WS-146-1,p.2 Q3a; WS-152-1, p.2 Q2a
335 Ref: 090-039-137
336 Ref: 090-053-172
337 Ref: WS-138-1, p.63b
338 Ref: WS-138-1, p.63d
339 Ref: WS-138-1, p.63f
340 Ref: 090-053-172
341 Ref: 090-053-172
342 Ref: 234-002-009
343 Ref: 234-002-009
344 Ref: 234-002-008
345 Ref: 232-002-011
346 Ref: 231-002-031

available for the medical staff to check,[347] and Claire was seen by doctors on at least seven occasions and that therefore they may have been aware of the changes to her neurological status and vital signs.[348]

168. The response of clinicians and nursing staff to Claire's neurological signs, and particularly her GCS scores, is a matter that will be considered further during the Oral Hearings.

Review of the nursing care plan

169. The Nursing Plan was not altered or reviewed following the ward round on the morning of 22nd October 1996 or seemingly at any other time after this. The reasons for this are unknown.

170. Ms. Sally Ramsay states that it is usual to evaluate care regularly, at least at the end of each shift, prior to handing over to another nurse.[349] On Ms. Ramsay's analysis, Claire's nursing care plan should have at least been reviewed at 08:00, 14:00 and 20:00 on 22nd October 1996. Ms. Ramsay also states that the plan ought to have been revised in response to changes in care needs e.g. need for a coma score.[350]

171. Ms. Ramsay states that:

(i) The diagnosis noted at the ward round of non-fitting status epilepticus/encephalitis/encephalopathy warranted a care plan entry related to on-going monitoring of level of consciousness as there was the possible of deterioration.[351]

(ii) The fact the care plan was not changed meant that it did not reflect the potential severity of Claire's condition.

(iii) The implementation of the Coma Score ought to have been separately identified.[352]

(iv) The eating and drinking sections of the care plan ought to have been changed as they were no longer applicable when Claire was unconscious.[353]

(v) As an unconscious patient, Claire's needs concerning mouth, skin and eye care and positioning ought to have been recorded.[354]

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347 Ref: 231-002-033
348 Ref: 231-002-033
349 Ref: 231-002-012
350 Ref: 231-002-012
351 Ref: 231-002-019
352 Ref: 231-002-019 to 231-002-020
353 Ref: 231-002-021
354 Ref: 231-002-021

(vi) A naso-gastric tube should have considered and passed when the Coma Score was introduced at 13:00.[355]

(vii) Observations and recordings of heart rate and breathing every 30 minutes were needed and should have started at or around 14:00.[356] Although the omission of respiratory observations "*is not uncommon*",[357] they should at least have been recorded at least every 30 minutes during the infusions of midazolam.[358]

172. Nurse Field accepts that:

(i) She was responsible for reviewing the care plan during her shift from 08:00 to 14:00 on 22nd October 1996.[359]

(ii) The nursing care plan should have been reviewed at the change of diagnosis to address Claire's current care needs and at 13:00 to include CNS observation.[360]

173. Between 14:00 and 20:00, Claire was cared for by Staff Nurses Patricia Ellison[361] and Karen Taylor[362]. The latter states that she had no involvement in the development of Claire's Nursing Plan.[363] The former is deceased.

174. After 20:00, Staff Nurse Lorraine McCann[364] was responsible for reviewing the nursing care plan.[365] She states that since there was no change in Claire's condition at the time, it would not have been necessary to review the care plan.

175. Whether the nursing care plan ought to have reviewed or revised during 22nd October 1996 is a matter to be considered during the Oral Hearings.

Nursing requirements

176. Ms. Ramsay considers that by 15:00, when the GCS was 7 and a midazolam infusion was planned to start shortly afterwards, Claire needed 1:1 nursing to facilitate continuous observation and monitoring.[366] She adds that it is "*often difficult*" to provide 1:1 nursing

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355 Ref: 231-002-028
356 Ref: 231-002-026
357 Ref: 231-002-025
358 Ref: 231-002-017
359 Ref: WS-148-1, p.18
360 Ref: WS-148-1, p.18
361 See List of Persons - Ref: 310-003-001
362 See List of Persons - Ref: 310-003-001
363 Ref: WS-150-1, p.14
364 See List of Persons - Ref: 310-003-001
365 Ref: WS-151-1, p.21
366 Ref: 231-002-021

on a general ward as there are usually insufficient nurses available. She therefore considers that Claire should been admitted to PICU at that time. This is because Claire's nursing needs were above those that could reasonably be provided on a busy general ward, given Claire's level of consciousness, diagnosis, anti-epileptic treatment and level of nursing dependency.[367]

177. Dr. Webb did not seek a PICU placement for Claire on 22nd October 1996. He states he is not sure whether Claire would have met the criteria for admission as there was no problem with her airway or breathing and no supportive signs of raised intracranial pressure (ICP) – for example papilloedema, hypertension or bradycardia.[368]

178. The Inquiry has not been provided with the criteria for PICU admission in operation at the time. It is not known who devised them or when. Nor is it known whether the criteria has since been revised in the light of Claire's case. Those issues are to be considered further in relation to Governance at a later stage.

179. Professor Neville agrees that Claire should have been admitted to PICU earlier. If cerebral oedema had been identified, elective ventilation should have been used to reduce raised intracranial pressure, and this would have required admission to PICU. He believes that this would have been considered early on 22nd October if repeat electrolytes and CT had been performed.

180. Dr. Scott-Jupp agrees that by today's standards, Claire should certainly have been admitted to PICU with a GCS as low as 6,[369] but that in 1996 PICU beds were less readily available. He accepts that the need for artificial ventilation would probably have been a pre-requisite for admission to PICU.[370]

181. Whether Claire warranted increased nursing care including 1:1 nursing and/or admission to PICU at an earlier stage are issues that will be addressed during the Oral Hearings and during the Governance Oral Hearings.

Dr. Webb's attendance with Claire at 14:00

182. At approximately 13:00, Mr. and Mrs. Roberts left Claire with her grandparents over lunchtime when they went into Belfast to buy some personal items for Claire, in the hope that the viral infection would pass and she would be well enough to go home the following day.

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367 Ref: 231-002-031
368 Ref: 090-053-175
369 Ref: 234-002-009
370 Ref: 234-002-010

They returned to the hospital at around 14:00 and were informed that a doctor had examined Claire.[371]

183. Dr. Webb attended Claire in Allen Ward at approximately 14:00 on 22nd October 1996 and spoke to her grandmother who was present with the nurse looking after Claire.[372] The note he made in Claire's medical notes is timed at "*4pm*" but he claims this was an error. The nursing note timed at 14:00 records his attendance with Claire.[373] Dr. Webb states that he believes he discussed the consultation with a member from Dr. Steen's team before and after seeing Claire and that during consultations he would have been accompanied by members of the ward nursing staff.[374]

184. Dr. Webb noted a history of vomiting and listlessness followed by a prolonged period of poor responsiveness.[375] He added that she had appeared to improve after rectal diazepam, given at 12:30. He also noted that Claire was afebrile and pale with no meningism, that she opened her eyes to voice, was non-verbal, withdrew from painful stimulus and he queried reduced movements on the right side[376]. He found mildly increased tone in her arms and symmetrical brisk reflexes, sustained ankle clonus and upgoing plantar responses. He recorded Claire as sitting up with eyes open and looking vacant, not obeying commands. She did not consider that she had papilloedema, which is a swelling of the optic discs seen in the retinae of the eyes suggestive of severe raised ICP.[377] However, the Inquiry's Expert Professor Neville considers in his Report that: "*The lack of papilloedema would not exclude this [raised or fluctuating intracranial pressure] since it can take 1-2 days for this change*".[378]

185. Dr. Webb's impression was that Claire's motor findings were probably long-standing and that whilst that should be checked with her notes, the "*picture is of acute encephalopathy, most probably post-ictal in nature*".[379] He explained that in his Inquiry Witness Statement as: "*I felt Claire was having predominantly sub clinical[380] non convulsive seizure activity associated with altered awareness and referred to her presentation as post ictal[381] in this context*".[382]

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371 Ref: 089-012-035
372 Ref: WS-138-1 p.10 Q3
373 Ref: 090-040-141, WS-138-1 p.5 Q1
374 Ref: 090-053-161, WS-138-1 p.11 Q4
375 Ref: 090-022-055
376 Ref: 090-022-053
377 Ref: 090-022-053, 054 ; Ref: 232-002-019
378 Ref: 232-002-019
379 Ref: 090-022-054
380 i.e. 'without clinical presentation' – See Glossary - Ref 310-007
381 i.e. 'following a seizure' – See Glossary - Ref 310-007
382 Ref: WS-138-1 p.20 Q14

186. Dr. Webb noted the biochemistry profile as normal, but while accepting that the result was slightly lower than the normal range, he attributed this to Claire's vomiting/loose motion(s) as it could not alone have explained her encephalopathy or seizures.[383] However, Claire's parents consider the reference to and any reliance on 'loose motions' to be an error as Claire's mother in her Inquiry Witness Statement refers only to: "*Claire had a smelly poo (as I described) on Friday*".[384] It also does not accord with the recollection of Claire's father, which was that Claire had a single loose bowel motion on the Friday.[385]

187. In his witness statement, Dr. Webb states that he felt the most likely explanation for her presentation was a recurrence of seizures in the context of an inter-current viral illness. He agreed with Dr. Sands that Claire was probably having semi-continuous non-convulsive seizures that were contributing to her altered level of consciousness and which he tried to treat.[386]

188. Dr. Webb admits that he erroneously understood Claire's serum sodium to be 132mmol/L on the day he saw her as he thought that the U&E results were from a sample taken that morning rather than from the previous day. He states that he must have obtained this impression from Dr. Sands report to him and as it was routine for blood samples to be taken early in the morning. He also states he may have misinterpreted the note "*12MN*"[387] as reading 12 noon.

189. The basis for Dr. Webb's misunderstanding is unclear and remains a matter that will be investigated during the Oral Hearings.

190. Dr. Webb states that his note was a memo to himself that the results could not have explained her clinical state of encephalopathy and seizures. If he had understood the results to have been from the previous evening, he says he "*would have requested an urgent repeat sample*" as Claire was on IV fluids and he may not have been confident that the sodium was not relevant to her presentation.[388]

191. Dr. Webb asked for hourly neurological observations and a CT scan the following day if she did not wake up.[389] Dr. Steen stated at the Inquest

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383 Ref: 090-022-054 , 090-053-174

384 Ref: WS-257-1, p.10 Q10. The reference to "as I described" is to be found at Ref: WS-257-1, p.3 where she states that: "*She visited her Grandparents … Auntie and three cousins … We learned during the visit that her cousin ... had a tummy upset that week (midweek)*"

385 Ref: WS-253-1, p.3 Q1 and WS-253-1, p.21: "*Claire only had one small loose bowel motion on the Friday, with normal bowel motions on Saturday, Sunday and Monday*"

386 Ref: WS-138-1 p.10-11 Q3, p.18 Q11

387 Ref: 090-022-052

388 Ref: 090-053-174, WS-138-1 p.21 Q14, p.22 Q15, p.69-70 Q50, p.88 Q66

389 Ref: 090-022-054

that if a CT scan had been performed and had shown cerebral oedema, she thinks "*it would have been attributed to encephalitis and her seizure*".[390]

192. In his statement to the Inquest, Dr. Webb claims for the first time that he had planned to organise an EEG (electroencephalography) the following morning (23rd October). He accepts he did not record the plan for an EEG in Claire's notes.[391]

193. Professor Neville believes that Dr. Webb performed a "*competent examination*" on the afternoon of 22nd October 1996,[392] but makes the following criticisms:[393]

(i) He failed to include the possibility of rising intracranial pressure to explain Claire's reduced conscious level and motor signs.

(ii) He failed to require an urgent sodium level as part of his assessment.

(iii) He should have been aware that because there is a possibility of inappropriate secretion of anti-diuretic hormone (SIADH) in acute brain illness Claire's sodium levels/conscious level and fluid balance should be monitored and should have directed that to be done.[394]

194. Dr. MacFaul agrees with Professor Neville that Dr. Webb should have been aware of the significance of the slightly reduced blood sodium and should have advised fluid restriction.[395] He adds that a neurologist should be aware of the risk of the development of raised intracranial pressure even if there are no signs of it at the time.[396]

195. The quality of Dr. Webb's diagnostic assessment of Claire and whether his management of her care was competent are matters to be considered during the Oral Hearings.

EEG

196. Forfar and Arneil's Textbook of Paediatrics, 4th edition, 1992,[397] which is referenced by Dr. Webb in his Statement for the Coroner,[398] states

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390 Ref: 091-011-067
391 Ref: 090-053-174, WS-138-1 p.67 Q48a
392 Ref: 232-002-008
393 Ref: 232-002-008
394 Ref: 232-002-009
395 Ref: 238-002-026
396 Ref: 238-002-046
397 Campbell AGM, McIntosh N (eds) Forfar & Arneil's Textbook of Paediatrics 4th edition. Edinburgh: Churchill Livingstone, 1992
398 Ref: 090-053-176

that: "*it is usual to carry out an EEG both in patients known to have had an epileptic seizure and in those in whom the diagnosis is suspected.*"[399]

197. According to Professor Neville, an EEG was the only means by which the diagnosis of non-convulsive status epilepticus could have been definitively confirmed or denied.[400] Accordingly, he is of the view that Claire should not have been treated on the basis of such a diagnosis without an EEG having confirmed it, as it leads to inappropriate treatment with anti-epilepsy drugs which could have further reduced her conscious level and her respiratory drive.[401]

198. No request was made for an EEG at any time prior to Claire's death and Dr. Sands does not recall discussing an EEG with the ward round team.[402]

199. Dr. Webb states that at the time of Claire's admission, the EEG service at the Children's Hospital was based on 1.5 EEG technician staff that provided an outpatient based service only, which was the only EEG service for children in Northern Ireland. Dr. Webb states that: *"he did not have access to an emergency EEG service"*.[403] It is not clear whether that would have precluded an urgent request at any time during business hours. However, Dr. Webb has stated that it would not have been routine to request an urgent EEG in a child with known epilepsy who has had a recurrence of seizures with an intercurrent infection. Dr. Webb then states that he may have considered an EEG the following day,[404] which suggests that he was at least able to access the service during the day.

200. In a letter to the Inquiry dated 24th November 2010, the Trust confirmed EEG services were available at the Children's Hospital in 1996 between the hours of 09:00 and 17:00 Monday – Friday. An ad-hoc, out-of-hours service, was also available at the request of Consultant Neurologists through an informal arrangement.[405] Dr. Sands is unsure if an EEG was possible on Claire at that time, though a consultant neurologist would have had to arrange it.[406]

201. Professor Neville characterises the lack of an urgent EEG as a '*major omission*'[407] which should have been arranged at the latest by the

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399 Forfar and Arneil's Textbook of Paediatrics, 4th edition, 1992, p.748-749
400 Ref: 232-002-002
401 Ref: 232-002-006
402 Ref: WS-137-1 p.48 Q33
403 Ref: WS-138-1 p.23 Q16
404 Ref: WS-138-1 p.23 Q16, p.25-27 Q18, p.67 Q48
405 Ref: 302-005-001
406 Ref: WS-137-2 p.12 Q11
407 Ref: 232-002-006

morning of 22nd October 1996,[408] and which should have been carried out before the administration of any further anti-convulsant medication, following the rectal diazepam.[409]

202. The extent to which the lack of an EEG constituted a major failing in the clinical care of Claire is a matter to be considered during the Oral Hearings.

CT and MRI scans

203. Dr. Sands believes CT scans were carried out in the A-block or main X-ray Department in the Royal Victoria Hospital.[410] Dr. Sands estimates that an urgent CT scan could have been arranged within 3 hours, depending upon the availability of the scanner and personnel and ambulance availability. Dr. Webb estimates 1-6 hours and states the scanner was 500 yards from the Children's Hospital.[411]

204. Dr. Webb recalls that CT scans were available at the Children's Hospital *"on a 24/7 basis"* but required sedation or a general anaesthetic.[412] He states he did not request a CT scan on 22nd October 1996 as he felt this investigation was unlikely to help him as the principal indication to undertake CT urgently would have been to exclude a neurosurgical emergency and Claire was unlikely to have a problem that required neurosurgery in the absence of trauma or focal weakness.[413]

205. In a letter from DLS dated 24th November 2010, the Trust confirmed that CT scans in 1996 were carried out at the Royal Victoria Hospital as the Children's Hospital did not get its own CT scanner until 2002.[414]

206. There were no MRI scanners in the Children's Hospital in October 1996 and this remains the case to date. A MRI scanner was located in Carrickmannon House, Royal Victoria Hospital.[415] Dr. Sands does not recall discussing an MRI scan with Dr. Webb.[416] Dr. Webb states that MRI was not available on an urgent basis.[417]

207. Dr. Scott-Jupp states that, given the uncertainty of her diagnosis, a CT scan would certainly have helped rule out a number of possible

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408 Ref: 232-002-007
409 Ref: 232-002-006
410 Ref: 300-003-003
411 Ref: WS-137-1 p.36 Q16, p.46 Q30; WS-138-1 p.27 Q18, p.48 Q31
412 Ref: WS-138-1 p.25 Q18
413 Ref: WS-138-1 p.26-27 Q18
414 Ref: 302-005-001
415 Ref: 302-026-002
416 Ref: WS-137-1 p.48 Q33
417 Ref: WS-138-1 p.25-27 Q18

diagnoses, but recognises that the threshold for requesting a CT scan was considerably higher in 1996 than now.[418]

208. Dr. Evans goes further and considers that Claire should have had an urgent CT scan at some time on 22nd October 1996, even possibly first thing in the morning,[419] given that she had an altered level of consciousness for nearly 12 hours by 9am, was showing no signs of improvement, there was no obvious evidence of infection, and there were minor but significant biochemical abnormalities (the sodium result of 132mmol/L).[420]

209. Professor Neville notes that a CT scan, rather than a more detailed MRI scan, was adequate in Claire's case to exclude or confirm a number of causes of raised intracranial pressure as the cause of reduced consciousness,[421] but it was performed "*very late*".[422] Again, he characterises the lack of a CT scan as a '*major omission*'.[423] He believes that a CT scan should have been carried out on the evening of 21st October 1996,[424] and by the latest the morning of 22nd October 1996,[425] notwithstanding the fact that the emergency scanner was in the adult hospital.[426] Again, he believed this should have been carried out before the administration of any further anti-convulsant medication, other than the rectal diazepam.[427]

210. Dr. MacFaul is of the view that a CT scan should have been carried out when Dr. Webb assessed her.[428]

211. Whether a CT scan should have been performed during the evening of the 21st or throughout the course of 22nd October 1996 is a matter to be considered during the Oral Hearings.

Seizures on 22nd October 1996

212. The attacks or seizures that Claire experiences during 22nd October 1996 are noted on the Timeline generated by the Legal Team in red.[429]

213. Mr. Roberts left the Children's Hospital at 15:00 to collect Claire's brothers from school and Mrs. Roberts remained with Claire.

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418 Ref: 234-002-009
419 Ref: 096-022-136
420 Ref: 096-022-137
421 Ref: 232-002-003
422 Ref: 232-002-002
423 Ref: 232-002-006
424 Ref: 232-002-004
425 Ref: 232-002-007
426 Ref: 232-002-004
427 Ref: 232-002-006
428 Ref: 238-002-026
429 Ref: 310-001-001

214. At 15:10, Claire was reported as having a five-minute strong seizure. Dr. Sands does not think that he was present in Allen Ward when that seizure occurred and does not recall being informed of it.[430]

215. Claire was seen by Dr. Webb between 14:45 and 15:25, and at 17:00, whilst she was seen by Dr. Sands at about 17:15.

216. Dr. Webb suggests that the record of attacks shows there were two attacks – one at 15:10 which was incompletely recorded and a second seizure recorded at 15:25 described as a 'strong seizure', suggesting that it was convulsive. Dr. Webb states that the recorded seizures may have contributed to Claire's low GCS scores at 16:00 and 17:00 as the post-ictal effects of convulsive seizures usually last between one and three hours.[431]

217. Subsequently it is recorded at 16:30 that Claire's teeth tightened slightly for a few seconds.

218. Dr. Sands does not recall being informed of that observation.[432] Indeed, he does not recall being present on Allen Ward during the mid-afternoon (from approximately 14:00 to 16:30) as he considers that he may have had teaching or other duties. He states that he would have been carrying a pager and present in the hospital at that time so that he would have been contactable by medical or nursing staff and responded if necessary. Dr. Sands believes that he perhaps returned to Allen Ward between 16:00 and 17:00.[433] However, he "*did not feel that Claire's condition had changed*". At that time he did not recall if Claire's care had been formally taken over by the Neurology team, and he was not clear when any request for a further serum electrolyte test was made or sample taken.[434]

219. Professor Neville says that a drop in sodium level and cerebral oedema may themselves provoke seizures and that this possibility should have been taken into consideration. [435]

220. The record of Clare's condition from in and around the time that Dr. Sands believes that he might have returned to the ward include two respiratory recordings of around 30 that were made at 16:00 and 20:00.[436] They were above the level recorded earlier that day although Dr. Webb states that he would consider this respiratory rate as normal

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430 Ref: 090-042-144, WS-137-1 p.49 Q36
431 Ref: WS-138-1 p. 63 Q41
432 Ref: 090-042-144, WS-137-1 p.49 Q37
433 Ref: WS-137-2 p.4 Q3, WS-137-1 p.25 Q12
434 Ref: 090-051-158
435 Ref: 232-002-009
436 Ref: 090-039-137

for a girl of Claire's age.[437] Claire's GCS scores for 16:00 and 17:00 were 6. This information on Claire's charts would have been available to be seen by any doctor examining Claire and the nurses could have advised about the detail of their own observations.

221. The reaction of medical and nursing staff to Claire's seizures during the afternoon of 22nd October 1996, and whether it was appropriate, are issues that will be considered during the Oral Hearings.

Dr. Webb's second attendance with Claire

222. The two letters from Dr. Colin Gaston, Consultant Community Paediatrician, dated 30th May 1996 and 1st August 1996[438] were faxed to Dr. Stewart at approximately 15:15 on 22nd October 1996 following the plan recorded at the morning ward round to discuss with Dr. Gaston Claire's previous[439] medical history.[440] Dr. Sands does not recall speaking to Dr. Gaston about Claire's past medical history and Dr. Webb did not make contact with Dr. Gaston.[441] There is no record of any discussion between Dr. Sands, Dr. Webb or Dr. Steen and Dr. Colin Gaston at any time prior to Claire's respiratory arrest.

223. An entry in Claire's medical notes, which Dr. Stevenson acknowledges is his,[442] records Claire as having been seen by Dr. Webb and being "*still in status*".[443] Although untimed, it is entered between an earlier entry by Dr. Stevenson that is timed at 15:30 and an entry by Dr. Webb that is timed at 17:00.

224. The note prescribes the administration of the anticonvulsant/sedative midazolam to be given as both a "*stat dose*" or bolus[444] first dose[445] and as an infusion. The 'bolus' was prescribed as 0.5mg/kg, which Dr. Stevenson calculated as 12mg. It was to be followed by an infusion of 2 mcg/kg per minute, which he calculated as 2.88 mg per hour.[446]

225. Dr. Webb believes that he attended Claire for a short period and that this note, which refers to him seeing her, was recorded at about 15:25.[447] He accepts that he did not write his own clinical note at the time.[448] He states in his Inquiry Witness Statement that whilst he does

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437 Ref: WS-138-1 p.64 Q41
438 Ref: 090-013-016 to 090-013-019
439 Ref: 090-038-136
440 Ref: 090-022-053
441 Ref: WS-137-1 p.44 Q25, WS-138-1 p.18 Q11
442 Ref: WS-139-1, p.5
443 Ref: 090-022-055
444 A dose given over a period of a few seconds, Ref: 237-002-007
445 Ref: 090-053-165
446 Ref: 090-022-055
447 Ref: WS-138-1, p.31 Q21
448 Ref: WS-138-1, p.31 Q21

not believe that he undertook a *"formal examination"*,[449] he would have reviewed Claire's GCS score and nursing observations. Dr. Webb also states that he believes that he may have also spoken to Dr. Sands by telephone before Claire was started on midazolam at 15:25.[450]

226. Dr. Webb explains in his Inquiry Witness Statement that he *"was of the ongoing impression that Claire was in non-convulsive status"*.[451] It seems that he did not consider SIADH as he had mistakenly understood Claire's serum sodium level to have been 132mmol/L earlier that morning. Although he was concerned about Claire, Dr. Webb did not feel her condition had changed significantly. He believed Claire could be managed on the ward, that she did not have any problems with breathing, heart rate or blood pressure and that the most likely explanation of her presentation was *"a recurrence of seizures in the context of an intercurrent viral infection"*.[452]

227. For those reasons, Dr. Webb states that he did not discuss Claire with a PICU consultant or staff.[453]

Dr. Webb's examination at 17:00

228. At 17:00, Dr. Webb recorded Claire as continuing to be largely unresponsive responding *"by flexing her left arm to deep supra-orbital pain"*[454] and having facial grimace but no vocalisation. He also records her has having intermittent mouthing and chewing movements.[455] Dr. Webb explains in his Inquiry Witness Statement his use of *"largely unresponsive"* as not responding to voice but only to *"tactile stimulus"*.[456]

229. Dr. Webb obtained background from Claire's mother, which he records as Claire having had contact with a cousin on 19th October 1996 who had a gastrointestinal upset and her having loose motions on the Sunday (20th) and vomiting on the Monday (21st). The reference to 'loose motions on the Sunday' does not accord with the account provided by Claire's mother in her Inquiry Witness Statement who refers only to: *"Claire had a smelly poo (as I described) on Friday"*.[457] It also

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449 Ref: WS-138-1, p.31 Q21
450 Ref: WS-138-1 p.11 Q4
451 Ref: WS-138-1, p.31 Q21
452 Ref: WS-138-1 p.31 Q21, p.37 Q23
453 Ref: WS-138-1 p.31 Q21, p.37 Q23
454 'Supra-orbital pain' is applied by placing the thumb parallel to the indentation found on the eyebrow ridge nearest the nose. The supra-orbital nerve plexus is stimulated by strong pressure. See Glossary - Ref 310-007
455 Ref: 090-022-055, Ref: 091-008-044
456 Ref: WS-138-1, p.38 Q23. 'Tactile stimulus' includes activating nerve signals beneath the skin's surface. See Glossary - Ref 310-007
457 Ref: WS-257-1, p.10 Q10. The reference to "as I described" is to be found at Ref: WS-257-1, p.3 where she states that: *"She visited her Grandparents … Auntie and three cousins … We learned during the visit that her cousin ... had a tummy upset that week (midweek)"*

does not accord with the recollection of Claire's father, which was that Claire had a single loose bowel motion on the Friday.[458]

230. Dr. Webb also records that Claire had some 'focal signs'[459] on the Monday and right sided stiffening. Dr. Webb states that the description of stiffening in a seizure is what he would consider a convulsive episode.[460] When he attended Claire at about 15:25 and 17:00, he was aware of the observed attacks recorded before 17:00 and he states that "*this would have influenced [his] decision[s] to continue trying further anti-convulsant medication to try and stop the occasional break through 'convulsive' seizures that Claire was experiencing*".[461]

231. Dr. Webb later states he obtained a history from Claire's mother of a definite seizure affecting her right side, and that he was in no doubt that she had had a convulsive seizure on 21st October 1996. He states that his diagnosis was predominantly of an "*epileptic encephalopathy*"[462] and that his impression was that Claire was having subtle non-convulsive seizure activity triggered by a recent inter current viral infection.[463] Dr. Webb defines status epilepticus as any seizure activity persisting beyond 30 minutes duration.[464]

232. Dr Webb states that he also considered that Claire's bowel infection may have spread to involve her brain so as to cause meningo-encephalitis[465] or encephalomyelitis.[466] He adds that enteroviral infection[467] is a common cause of childhood meningitis and encephalitis.[468] He therefore prescribed the antibiotic cefotaxime and the anti-viral drug acyclovir for 48 hours[469] and noted that stool, urine, blood and a throat swab should be checked for viral cultures, especially enterovirus.[470] However, he considered this diagnosis less likely in the absence of fever, stiff neck or disliking bright lights.[471] Dr. Webb did not record in Claire's notes that serum U&E should be checked and Dr. Sands states in his Inquiry Witness Statement that he

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458 Ref: WS-253-1, p.3 Q1 and WS-253-1, p.21: "*Claire only had one small loose bowel motion on the Friday, with normal bowel motions on Saturday, Sunday and Monday*"

459 'Focal signs' - impairments of nerve, spinal cord or brain function affecting a specific region of the body such a weakness in a limb. See Glossary - Ref 310-007

460 Ref: WS-138-1 p.66 Q45

461 Ref: WS-138-1 p.42-3 Q25

462 Ref: WS-138-1, p.17 Q11d

463 Ref: 090-053-173

464 Ref: 090-053-173, WS-138-1 p.39 Q23

465 'Meningo-encephalitis' - inflammation of the lining of the brain and the brain itself. See Glossary - Ref 310-007

466 Ref: 090-053-173; WS-138-1, p.17 Q11d

467 'Enteroviral infection' – a common cause of gastroenteritis. See Glossary - Ref 310-007

468 Ref: 090-053-173

469 Ref: WS-138-1, p.17 Q11 and Ref: 090-022-055

470 Ref: 090-022-055; 090-053-166

471 Ref: 090-053-173

was not aware of Dr. Webb requesting any blood tests other than the viral cultures.[472]

233. However, Claire's continued altered awareness, intermittent evidence of chewing and mouthing movements at 17:00 and normal vital signs suggested to Dr. Webb that she had ongoing sub-clinical seizure activity. He interpreted Claire's GCS and Central Nervous Observations between 14:00 and 17:00 to reflect a combination of ongoing non-convulsive seizure activity, post-ictal effects and the possible effect of anti-convulsant therapy (midazolam).[473] He was also aware of Claire's blood pressure and respiratory rate at that time and did not consider them a cause for concern. He states his evaluation included assessment of features that one would expect to have been abnormal in the presence of intracranial pressure – for example, her vital signs did not show any significant change in blood pressure or heart rate, she had no vomiting since his last examination and her reactive pupils were not large.[474] He believes that he did not think at the time that Claire's condition was due to raised intracranial pressure, and that cerebral oedema is not usually a feature of non-convulsive status epilepticus.[475]

234. His assessment was that Claire's overall condition at 17:00 was very similar to that at 14:00, and her GCS had reduced from 8 to 7 which could have been accounted for by the IV midazolam.[476] Dr. Webb states that he would have planned to arrange an EEG on the morning of 23rd October. However, he accepts he did not record that plan.[477]

235. Dr. Webb believes he did not recommend undertaking further measurement of U/E because he felt the paediatric team were managing that aspect of Claire's care.[478]

236. Dr. Sands states that he did not require a further serum sodium and full blood count test at 17:15 because he believes "*there would have been an expectation that this had been carried out already and the result awaited*".[479] Dr. Sands goes on to explain that, if repeat electrolytes had been requested, then someone would usually have checked for the result when the routine reports returned at about 18:00. However, he states that, if a routine sample was requested, then it was less likely that someone would check that it had actually been taken, and the

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472 Ref: WS-137-1 p.38 Q17
473 Ref: WS-138-1 p.17 Q11, p.74-75 Q53
474 Ref: WS-138-1, p.35 Q23a
475 Ref: WS-138-1, p.35 Q23a
476 Ref: WS-138-1 p.35-6 Q23, p.74 Q53, p.90 Q71, 72
477 Ref: WS-138-1 p.66-7 Q45 & Q48
478 Ref: WS-138-1 p 80 Q60
479 Ref: WS-137-1 p.29 Q12

result may only have been recorded on the official laboratory printed report and not otherwise included in the patient's notes.[480]

237. Dr. Webb states that the usual next line therapy for convulsive status epilepticus would be IV phenobarbitone, but as Claire had received IV midazolam it would not have been safe to administer this on the ward and Claire would have required admission to PICU.[481] Non-convulsive status epilepticus does not usually require admission to PICU because the risk from the seizures is less of a concern. Dr. Webb states that he had initiated the treatment he thought Claire required overnight and expected that if there was any change in her neurological status he would have been contacted.[482]

238. Professor Neville considers that Claire's state at 17:00, when she was examined by Dr. Webb, required a diagnostic assessment of the cause of her deterioration including electrolyte testing, EEG and CT scan.[483] He also considers that any differential diagnosis should have specifically included the causes of raised intercranial pressure, particularly as they are quite common and potentially treatable.[484] Furthermore, any review of Claire's condition should also have included a review of the prescribed drugs. [485]

239. Dr. Scott-Jupp also believes that Dr. Webb should have taken further action at 17:00. In particular and because there may have been some uncertainty as to who was taking ongoing responsibility for Claire, he thinks that Dr. Webb should have:[486]

    (i) Made it clear at the time whether he had taken over Claire's care completely and was prepared to be consulted about all aspects of her treatment or whether he expected her ongoing acute management to be in the hands of the General Paediatric team, with him being available for specialist advice only

    (ii) Spoken directly to the overnight Paediatric Registrar (Dr. Bartholome) or the on-call Consultant Paediatrician (whose identity is unknown)[487], or possibly the Consultant on-call for PICU at the time (Dr. McKaigue)

240. Dr. Scott-Jupp does not believe that the on-call team at 17:00 had any idea as to the seriousness of Claire's underlying problem or her

480 Ref: WS-137-2 p.29 Q50
481 Ref: WS-137-1 p.41 Q24d
482 Ref: WS-137-1 p.41 Q24e
483 Ref: 232-002-010
484 Ref: 232-002-010
485 Ref: 232-002-010
486 Ref: 234-002-007
487 Ref: 302-068a-001

potential for collapse, particularly as he regards cerebral oedema from hyponatraemia as being a rare condition both then and now and that it was likely that none of the doctors involved in Claire's case had ever seen it before.[488]

241. The extent to which those doctors could and should have known about 'cerebral oedema from hyponatraemia' is a matter that will be considered later in the context of governance. The proximity of Adam's death and Inquest to Claire's admission, the latter being only four months earlier, will be appreciated Mr. Chairman. Furthermore and as you have heard during the Oral Hearings in Adam's case, Dr. Webb was directly involved in that case and Dr. McKaigue was involved with the drawing up of the draft recommendations that were provided to the Coroner on 21st June 1996.[489]

242. Dr. Webb did not believe that Claire met the criteria for admission to PICU, the main criteria for which was a need to provide support to airway, breathing and circulation for children who required it. He believes he had communicated his plan to those involved in Dr. Steen's team verbally and through his medical notes. He states that he understood that Claire's ongoing care would remain with the paediatric medical team and that he was available to provide further specialist advice as required. He had not planned to re-attend that evening but was available to do so. He was not consulted again about Claire until 04:00 on 23rd October 1996. He did not take any steps to discuss Claire with a PICU Consultant after 17:00 on 22nd October and he states "*in hindsight I believe this was a mistake*".[490]

243. Dr. Sands, however, states there was an expectation that any further tests and investigations would be guided by the on-call neurologist,[491] who was Dr. Webb.[492] He also states that it was his usual practice to conduct a handover with on-call junior medical staff. He believes that the on—call Registrar would have covered for general medicine and the paediatric specialities. The paediatric on-call SHO may also have been supported by a "*specialities*" SHO. He recalls that he, Dr. Stevenson, Dr. Stewart, Dr. Hughes and Dr. Bartholome may have carried out medical and neurology roles, irrespective of whether the lead consultant was medical or neurology. During on-call periods, Dr. Sands states that both he and Dr. Bartholome were likely to have had a role in general paediatric and speciality cover including neurology, while Dr. Stevenson and Dr. Stewart worked primarily as general

488 Ref: 234-002-009
489 Ref: 303-045-512
490 Ref: WS-138-1 p.41-42 Q24, p.74 Q53
491 Ref: WS-137-2 p.14, Q16
492 Ref: WS-138-1 p.5 Q1

paediatric SHOs at that stage, although they may have assisted with speciality patients including neurology.[493]

244. The adequacy of the ongoing diagnosis and treatment of Claire by Dr. Webb, and the provision for her treatment overnight, are matters to be considered during the Oral Hearings.

XIII. Fluid management during 22nd October 1996

245. The IV fluid started after Claire's admission was dextrose 4%/0.18% saline ("Solution No.18"). On 22nd October, those fluids were continued at maintenance dose. Dr. Sands stated that "[*t]his was standard fluid therapy at that time*"[494] and Dr. Steen referred to Claire's fluid regime in 1996 as "*normal*".[495]

246. Dr. Sands states that the IV fluids initially prescribed by Dr. Volprecht were continued by Dr. Stevenson and the decision to continue with the current fluid management was most likely part of the ward round discussions.[496] He believes it likely that adjusting fluid management was not immediately necessary or considered a central part in Claire's case, and the main focus was to control seizure activity and treating possible infective causes of this.[497]

247. Dr. Webb states that he was not aware of Claire's fluid regime nor does he believe at that time that he had any reason for any concerns about Claire's fluid regime.[498]

248. The cumulative total of Solution No. 18 received by Claire over the course of her admission to Allen Ward is noted on the Timeline generated by the Legal Team as a blue line.[499] The nurses noting each individual entry on the fluid balance sheet are indicated by their initials.

249. Dr. Scott-Jupp believes that at this stage there was no particular reason for suspecting cerebral oedema which would have mandated fluid restriction. However, the electrolytes should have been checked earlier in which case the Solution No.18 may have been changed to a more concentrated solution.[500]

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493 Ref: WS-137-2 p.24-25 Q37
494 Ref: 091-009-055, WS-137-1 p.7 Q5
495 Ref: 091-011-067
496 Ref: WS-137-1 p.7 Q5
497 Ref: WS-137-2 p.10 Q9, p.11 Q10
498 Ref: WS-138-1 p.68 Q49
499 Ref: 310-001-001
500 Ref: 234-002-005

250. Dr. Scott-Jupp has calculated that between the start of Claire's IV therapy and 23:00 on 22nd October 1996, she received 1479mls of Solution No.18 and 71mls of 0.9% saline, as the latter was the normal dilutant at the time for the midazolam and acyclovir infusions, although the exact nature of the fluids in which they were dissolved is not stated.[501] Claire therefore received approximately 61mls/hr which was close to the 64mls/hr that had been intended and was in Dr. Scott-Jupp's view "*an appropriate quantity*".[502]

251. In contrast, Professor Neville is again critical of the fluid management, stating that although Solution No.18 was in common use and what was given was "*routine*",[503] in the context of a low sodium level and reduced consciousness, it would have been more appropriate to give a reduced volume of a higher strength of sodium chloride and to carefully monitor her sodium and conscious levels.[504]

252. Professor Neville considers that Claire's fluid management ought to have been reviewed throughout 22nd October for the following reasons:[505]

(i) Her deteriorating level of consciousness

(ii) The attacks that occurred

(iii) The lack of response to four types of anti-epileptic medication

(iv) The lack of urine output.

253. Whether Dr. Webb should have known Claire's fluid regime and the priority that the medical team should have given to fluid management throughout 22nd October 1996 are matters to be addressed during the Oral Hearings.

XIV. Medication during 22nd October 1996

Schedule of drugs administered

254. There is an issue that will be addressed during the Oral Hearings in regard to the appropriateness of the various medications that Claire received during her treatment at Children's Hospital, including the quality of recordkeeping by clinicians and nurses in regard to the medications. In certain cases, there is some disagreement as to whether

501 Ref: 090-038-135
502 Ref: 234-003-001
503 Ref: 232-002-008
504 Ref: 232-002-007
505 Ref: 232-002-008

a certain dosage was given or, indeed, whether or not a particular administration took place.

255. To simplify matters, the Legal Team has compiled a schedule,[506] 'Schedule of Medications', showing each possible prescription and administration raised by the medical notes and records, including:

(i) Time of prescription

(ii) Dosage prescribed

(iii) Prescribing clinician

(iv) Time(s) of administration

(v) Dosage(s) of administration

(vi) Administering clinician/nurse

(vii) Comments from Inquiry Witness Statements regarding each medication

(viii) Comments from Inquiry Expert Reports regarding each medication

256. The various medications administered to Claire are noted on the Timeline generated by the Legal Team in purple. [507]

Rectal diazepam

257. Nurse Linsky administered rectal diazepam at 12:15 which had been prescribed by Dr. Stewart.[508] This arose from Dr. Sands suggesting a *"trial dose of rectal diazepam"* to Dr. Webb during a discussion after the ward round at about 11:00,[509] who it seems agreed with it.[510]

258. Dr. Webb states in his Inquiry Witness Statement that it is common for a child who has non-convulsive status to improve following a dose of diazepam.[511] However, he accepts that diazepam may cause sedation in a child who is not having seizure activity and, rarely, can cause respiratory depression. Dr. Webb also accepts that the diazepam administered at 12:30 and the phenytoin that was administered at 14:45

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506 Ref: 310-006-001

507 Ref: 310-001-001. For the purposes of the timeline, all medications are assumed to have been administered. As shall be seen when discussing Claire's medication, some administrations are in dispute.

508 Ref: WS-148-1 p.11 Q18h, Ref: 090-026-075, Ref: 090-040-141, WS-137-1 p.16 Q8, WS-141-1 p.9 Q20(d)

509 Ref: WS-137-2, p.13 Q15

510 Ref: WS-138-1, p.18 Q11

511 Ref: WS-138-1 p.18 Q11

could have affected Claire's level of awareness[512] and therefore contributed to the change recorded between 13:00 and 15:00 in her GCS score. Nevertheless, he characterises diazepam (and midazolam) as short-acting benzodiazepines and did not regard Claire as being in any danger from what was administered to her.[513]

259. Dr. Jeffrey Aronson, Consultant Clinical Pharmacologist, the Inquiry Expert on Clinical Pharmacology,[514] states in his Report that he would expect the onset of action of the rectal diazepam to occur within about 10 to 30 minutes.[515] As diazepam is a sedative, it would tend to reduce GCS score and impair other neurological functions for the duration of its action. Apparently, contrary to the view expressed by Dr. Webb, Dr. Aronson states that diazepam has a long duration of action and is metabolised in the body to a compound that has an even longer duration of action. The effect of a single dose could last as long as one to two days, therefore the dose administered to Claire could have reduced her GCS score during her last hours of life, and this drug would have made it more difficult to have assessed the extent to which Claire's neurological impairment was due to the primary illness.

260. Dr. Scott-Jupp states that the diazepam was "*standard*" anti-epileptic treatment at the time.[516]

261. Professor Neville believes that "*giving one dose of diazepam was reasonable in this situation*".[517] However, he considers that more should not have been given or any further anti-epilepsy medication, without an EEG to confirm or refute the working diagnosis of non-convulsive status, a CT scan and the checking of her electrolytes. [518]

Phenytoin

262. At 14:00, Dr. Webb suggested starting Claire on the anticonvulsant phenytoin intravenously: 18mg/kg as a bolus dose[519] followed by 2.5 mg/kg 12 hourly with levels to be read 6 hours after the loading dose. He states that IV phenytoin was the first choice drug for all prolonged seizures in childhood who had failed to respond to diazepam.[520] Dr. Webb states he was not present when Claire received her IV phenytoin infusion.[521]

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512 Ref: WS-138-1 p.18 Q11, p.63 Q41
513 Ref: Ws-138-1, p.25 Q17
514 See List of Persons - Ref: 310-003-001
515 Ref: 237-002-008 2(c)
516 Ref: 234-002-004
517 Ref: 232-002-006
518 Ref: 232-002-006
519 Ref: 090-053-165
520 Ref: WS-138-1 p.23 Q16(e)
521 Ref: WS-138-1 p.28 Q19(a)

263. Dr. Stevenson noted at 14:30 his calculations of the phenytoin dose to be administered to Claire. He also ordered a loading dose of 18 mg x 24 hours and that the levels of phenytoin in Claire's blood should be checked at 21:00.

264. Dr. Stevenson's calculations for the 'continuing dose' of phenytoin of 2.5mg/kg 12 hourly are correctly recorded as 60mg 12 hourly. However, his recorded calculation of the 'loading dose' is incorrect. He calculated it as 632mg rather than 432mg.[522]

265. The 'continuing dose' of 60mg is ordered on a prescription chart signed by Dr. Stevenson.[523] He also orders the 'loading dose' although he records and that as 635mg rather than his calculated 632mg. Dr. Stevenson signed for the administration of that 635mg of IV phenytoin at 14:45 in a column titled *"Given by"*.[524] The nursing notes also record a stat dose of IV phenytoin at 14:45,[525] with a second dose at 23:00 which was administered over the course of an hour following blood sampling for phenytoin levels.[526]

266. In addition to those doses of phenytoin, there is also a possibility that Claire received a dosage of phenytoin at 21:30 as the Drug Recording Sheet records 'A' (phenytoin) at 21:30[527] and the Prescription Sheet is ticked at 21:30. [528]

267. Dr. Webb states that a loading dose of 432mg of IV phenytoin should have no effect on Claire's respiratory drive and he would not have expected an additional dose of 8mg/kg to have any ill effects on Claire. He notes that the subsequent phenytoin level was just above the recommended treatment range, and states that phenytoin would normally be given in normal saline as a solution.[529] He also states that phenytoin has no effect on respiratory function.[530]

268. Dr. Webb states that drug calculations are usually checked with two people (usually with the attending nurse) at the time of the drug administration, and that it was not his normal practice to check every drug dosage that was written up. He claims to have been unaware of the miscalculation of the loading dose or that Claire had received the wrong dose until asked for an Inquiry Witness Statement,[531] despite

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522 Ref: 090-022-054, 090-040-141
523 Ref: 090-026-075
524 Ref: 090-026-075
525 Ref: 090-040-141
526 Ref: 090-040-138, 090-038-135
527 Ref: 090-026-077
528 Ref: 090-026-073
529 Ref: WS-138-1 p.24 Q16
530 Ref: WS-138-1 p.25 Q17
531 Ref: WS-138-1 p.29 Q19, p.97-98 Q91

the fact that he reviewed Claire's medical notes and records in detail in his Statement for the Coroner and specifically refers to the phenytoin calculations:

"The next medical note written October 22nd at 2.30pm documents the calculations made to prescribe intravenous phenytoin (an anti-convulsant) initially as a bolus dose and then a 12 hourly dose".[532]

269. Professor Neville considers that Dr. Webb's 17:00 review of Claire should have included a review of the prescribed drugs.[533]

270. Dr. Aronson has stated that if phenytoin was clinically indicated, then the loading dose of 18mg/kg i.e. 432mg would have been appropriate.[534] He stated that for a dose of 635mg of phenytoin, one would use 12.7mls of such a solution (obtained from three vials) and give it intravenously at a rate no greater than 72mg/kg/minute or over no less than nine minutes.[535]

271. Dr. Aronson states that the onset of action of IV phenytoin is 30 minutes to an hour, and the effect lasts for up to 24 hours. He would have expected some adverse reactions to the overdose of 635mg phenytoin since the dose was about 50 percent more than was indicated. The most common adverse reactions of this drug affect the central nervous system including decreased coordination, slurred speech, mental confusion, somnolence, drowsiness but, since Claire was unconscious when she was given the phenytoin, most of these effects, if they occurred, would not have been detectable. The drug would also have reduced Claire's GCS score and would have made it more difficult to assess Claire's progress and the extent to which Claire's neurological impairment was due to the primary illness. However, Dr. Aronson considers that would not be a reason to withhold effective treatment, and the clinician who administered such treatment would make allowance for its effects on neurological markers of progress.[536]

272. Dr. Aronson states that toxic concentrations of phenytoin can be associated with seizures, and considers that it is possible that Claire's seizure at 15:25 may have been due to, or contributed to by, her phenytoin toxicity.[537]

273. Dr. Aronson adds that this overdose of phenytoin would have been expected to put Claire in the toxic range (>20mg/L) for the drug, and

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532 Ref: 091-008-043
533 Ref: 232-002-010
534 Ref: 237-002-009(g)
535 Ref: 237-002-009(e)
536 Ref: 237-002-009(f) to (h), 237-002-010 (i)
537 Ref: 237-002-011

that the more phenytoin is in the body, the more slowly it is removed. He estimates that Claire would have been in the 'toxic range' for about 9½ hours. Dr. Aronson believes this is consistent with the measured phenytoin concentration of 23.4mg/L seven hours after the initial loading dose.

274. Dr. Aronson states that, during the intravenous administration of phenytoin, continuous monitoring of the electrocardiogram (ECG) is essential. He adds that there is no need to monitor continuously after the end of an infusion for about 30 minutes, although it is wise to do so.[538] There is no note of any ECG monitoring having been done in Claire's case during the afternoon administration of IV phenytoin. Dr. Webb accepts it would have been routine practice to have a cardiac monitor in situ during this IV infusion for Claire and thinks that the nursing note[539] would suggest that this was done.[540]

275. It is important to note that Professor Neville is of the opinion that it was not appropriate to give IV phenytoin at this stage without proof that non-convulsive status epilepticus was present.[541]

276. As regards the possible overdose of phenytoin, Professor Neville does not think it was a "*huge overdose*" or that it was likely to have materially altered the outcome, or have had "*a major effect*" on diagnosis or management. However, he notes that it would have reduced her conscious level temporarily.[542]

277. Dr. Scott-Jupp considers the position in relation to the administration of phenytoin to be confusing, largely due to the record-keeping.[543]

278. He notes that Claire should have received a 'loading dose' of 632mg[544] of phenytoin at 14:45[545] but it is not recorded on the fluid balance sheets[546] even though it was to have been given as an IV infusion.

279. The first record of phenytoin on the fluid balance sheet is 110mls at 23:00, which Dr. Scott-Jupp considers to be a more dilute solution than necessary for a 'loading dose'. However, it is not possible to identify from the fluid balance sheet whether that phenytoin dose recorded at 23:00 dose was the 'loading dose' or the first 'maintenance dose'. If it

538 Ref: 237-002-012(r)
539 Ref: 090-040-138
540 Ref: WS-138-1 p.23 Q16
541 Ref: 232-002-009
542 Ref: 232-002-009
543 Ref: 234-003-002
544 Medical notes and records – Ref: 090-022-054. Alternatively, 635mg according to the Prescription Sheet – Ref: 090-026-075
545 Ref: 090-026-075
546 Ref: 090-038-135

was the 'loading dose', then Dr. Scott-Jupp points to the fact that there is no record on the prescription sheet of the 'maintenance dose' being given. If it was the first 'maintenance dose', then Dr. Scott-Jupp considers that it was being given too early and with far too much fluid. The phenytoin 'maintenance dose' was not due until 02:24 and he is of the view would only have required a solution of 6-12mls to dilute it not the 110mls that is recorded.

280. He also points out that the prescription sheet for 'regular prescriptions' (i.e. repeat prescriptions) specifies by ticks that the 'maintenance doses' are to be given at 08:30 and 21:30,[547] which he considers to be routine medicine round times.

281. On the basis that it was the 'loading dose' that was given at 23:00 and therefore nearly nine hours late, Dr. Scott-Jupp calculates that the total IV fluids given between 23:00 and 02:00 was 173.5mls, which equates to 58mls/hr and therefore considerably more than the 41mls/hr that was intended when her fluids were reduced at 23:00.[548] Indeed he points out that it is only slightly less than the original rate of infusion.

282. Dr. Scott-Jupp concludes that the 110mls of phenytoin recorded at 23:00[549] was the 'loading dose'.[550] Leaving aside some of the notes and records to which he refers, such a conclusion does not accord with Dr. Webb's entry in Claire's medical notes at 17:00 on 22nd October: *"Claire has had a loading dose of phenytoin and a bolus of midazolam"*.[551]

283. The amount and rate of phenytoin administered to Claire, together with its likely effect on her, are matters that will be investigated during the Oral Hearings.

Serum phenytoin concentration test

284. The nursing notes at 23:00 record that IV phenytoin was erected by the doctor and run over one hour. The directed dose was 2.5mg/kg once every 12 hours, which Dr. Aronson considers would be expected to be infused at the usual rate of 1-3mg/kg/minute i.e. over a few minutes.

285. Dr. Aronson states that after a 'loading dose the serum phenytoin concentration should be checked before the administration of a maintenance dose. He considers that measurement of Claire's phenytoin concentration levels would have been expected at 21:00 so as to allow enough time for the result to be reported before 23:00 when

547 Ref: 090-026-075
548 Ref: 090-038-136 and Ref: 090-038-135
549 090-038-135
550 Ref: 234-003-002
551 Ref: 090-022-055. The midazolam is recorded on the prescription sheet as having been administered at 16:30

the next dose was due to be administered. Dr. Aronson is of the view that the phenytoin recorded at 23:00 should not have been administered until the result of the serum measurement was known.[552]

286. In Claire's case, the phenytoin result was not recorded until 23:30[553] but it is not clear whether this result of 23.4mg/L was known before the administration of the phenytoin at 23:00, as there is no printed laboratory report for that result. All that is known is that a phenytoin serum concentration of 23.4mg/L, which was outside the usual target range of 10-20mg/L, is recorded at 23:30.

287. Nevertheless, Dr. Aronson states that the maintenance dose given at 23:00 was likely to have been appropriate as by 04:20 Claire's serum phenytoin levels were 19.2mg/L and had therefore been brought from 23.4mg/L into the normal 10-20mg/L range.[554] Furthermore, Dr. Aronson has calculated Claire's expected phenytoin concentration at 04:20 using a standard pharmacokinetic calculation and states that it is likely to have been 20mg/L, which is consistent with the measured concentration of 19.2mg/L.[555]

Midazolam

288. Dr. Stevenson records in Claire's medical notes that she was seen by Dr. Webb and he includes a calculation for the anticonvulsant/sedative midazolam to be administered to her immediately after the observation *"still in status"*.[556] Dr. Webb acknowledges in his Statement for the Coroner that he *"reviewed Claire during the afternoon and because of concerns about ongoing seizure activity recommended the use of midazolam"*.[557] He also states that he may have spoken to Dr. Sands by telephone before Claire was started on midazolam at 15:25.[558]

289. There would appear to be no record of that discussion or its purpose and Dr. Sands does not refer to it in his evidence. Furthermore, there seems to be no note of what Dr. Webb recommended as to the 'use of midazolam'.

290. There are four main issues in relation to the administration of midazolam to Claire:

(i) General effect of midazolam;

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552 Ref: 237-002-011
553 Ref: 090-022-056
554 Ref: 237-002-011
555 Ref: 237-002-010
556 Ref: 090-022-055
557 Ref: 090-053-165
558 Ref: WS-138-1 p.11 Q4 and Ref: 090-040-141

(ii) Calculation of the loading dose;

(iii) Prescription and administration of the loading dose;

(iv) Continuous infusion.

General effect of midazolam

291. Professor Neville states that the giving of midazolam was inappropriate because there was no confirmation by EEG of the diagnosis.[559] He believes that midazolam has a sedative effect and could have caused or contributed to a fall in Claire's GCS, with the effect of the drug lasting at least one to two hours.

292. Dr. Webb accepts that midazolam has a sedating effect, but states that it is short acting and is an effective anti-convulsant in resistant seizure activity.[560]

293. Dr. Aronson explains that midazolam has its onset of action at about two minutes after an injection.[561] He also states that midazolam is a sedative which would tend to reduce the GCS score and impair other neurological functions for the duration of its action – this would have made it more difficult to assess the extent to which Claire's neurological impairment was due to her primary illness.[562]

294. Dr. Aronson also states that according to the 1996 edition of the Summary of Product Characteristics (SPC) for midazolam (Hypnovel), the indications do not specifically include the management of status epilepticus. The SPC also notes that "*Hypnovel has not been evaluated for use as an intravenous sedative in children*." He was therefore not able to comment on the appropriateness of using intravenous midazolam in a 9-year-old child with suspected status epilepticus.[563]

295. Whether midazolam should have been directed at all for use in Claire's case is an issue that will be considered during the Oral Hearings.

Calculation of the loading dose

296. Whatever Dr. Webb's recommendation, Dr. Stevenson prescribed 0.5 mg/kg of midazolam to be given as a bolus[564] first dose,[565] which he calculated and recorded as 12mg. That bolus was then to be followed

559 Ref: 232-002-009
560 Ref: 090-053-174
561 Ref: 237-002-012 to 237-002-014
562 Ref: 237-002-012 to 237-002-014
563 Ref: 237-002-013(x)
564 Given over a period of a few seconds, Ref: 237-002-007
565 Ref: 090-053-165

by an infusion of 2 mcg/kg/minute, which he calculated and recorded as 2.88 mg/hour.[566]

297. Dr. Webb states that the loading dose of midazolam should have been calculated at 0.15mg/kg stat and he is not aware of how a dose of 0.5mg/kg was charted.[567] At 0.15mg/kg, the loading dose should have been a 3.6mg IV stat dose. Dr. Webb states that 12mg of IV midazolam would have put Claire to sleep. He states that drug calculations are usually checked with two people at the time of drug administration, and he did not check or read the calculation.[568]

298. Professor Neville states that the Roche sheet for that time recommends a maximum of 0.3mg/kg as a loading dose (7.2mg).[569] He adds that that 12mg was a *"big dose"* and there was *"no evidence"* that Claire required this dose of medicine.[570] He believes it was likely to have:

(i) Reduced her conscious level

(ii) Reduced her breathing

(iii) Increased her partial pressure of carbon dioxide.

299. Professor Neville therefore believes it was possible that this medicine tipped her over to a higher PCO_2 (partial pressure of carbon dioxide) level which caused greater cerebral oedema. He also states that Dr. Webb's 17:00 review of Claire should have included a review of the prescribed drugs.[571]

300. Dr. MacFaul agrees with Professor Neville as to the possible effects of the midazolam on cerebral oedema and that Dr. Webb should have noted the dose errors.[572] He cites 'Medicines for Children 2003'[573] which indicates a maximum bolus dosage of 0.2mg/kg (4.8mg in Claire's case) in the treatment of status epilepticus.[574]

Prescription and administration of the loading dose

301. There is an issue to be considered during the Oral Hearings as to what dosage of midazolam was administered at 15:25, if any. Dr. Stevenson

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566 Ref: 090-022-055
567 Ref: WS-138-1 p 32 Q22(b)
568 Ref: WS-138-1 p.32-3 Q22
569 Ref: 232-002-016
570 Ref: 232-002-016
571 Ref: 232-002-016
572 Ref: 238-002-021
573 Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group (2003) Medicines for Children, RCPCH Publications Limited on behalf of the RCPCH and the Neonatal and Paediatric Pharmacists Group: London
574 Ref: 238-002-010

recorded in the prescription chart the once only dose as 120mg (rather than 12mg) with the time of administration 15:25,[575] which amounted to twenty-five times the advised dose for status epilepticus. Dr Stevenson accepts that he "*cannot be certain the exact dose I gave, other than give the opinion that if 120mg of Midazolam had been given as a single dose that would have had a profound effect on a child, which would have been obvious at the time of administration.*"[576]

302. Dr Stevenson did not sign the drug chart to confirm that the prescribed stat dose was given.[577] He states that "*it is possible that I forgot to sign that I had given it.*"[578] However, the nursing notes record *'stat IV Hypnoval [midazolam] at 3.25pm,'*[579] although the entry does not include the dosage that was administered. Dr Webb was not present and is unable to confirm if the drug was administered as noted but states *"the chart seems to suggest that no stat dose was administered".*

303. In a letter to the Inquiry dated 11th July 2012,[580] it was confirmed that the ampoule size available on the wards and departments of Children's Hospital at the time was 2mg/ml in 5ml ampoules. Each box of midazolam contained ten ampoules and, in October 1996, Allen Ward held a stock of one box (containing ten ampoules). Thus, the maximum available on Allen Ward at any one time was 100mg of midazolam.

304. Dr. Aronson states that midazolam for IV administration was available in ampoules containing a solution of 2 or 5mls of midazolam in a concentration of 2mg/ml (i.e. 4 or 10mg per ampoule).[581] Dr. Aronson adds that 120mg of midazolam, even if given over 24 hours, is a very large dose and would have caused major anaesthesia, coma, severe respiratory depression and possibly death.[582]

305. Professor Neville is "*doubtful*" that 120mg was actually administered, particularly as it would have seemed an "*excessive amount*" to draw up from ampoules and, if it had been given, it would have been a "*gross overdose*" likely to stop Claire's breathing and reducing her conscious level.[583]

306. The actual dosage that was administered to Claire, and, indeed, whether any midazolam was administered at all at 15:25, are issues that will be investigated during the Oral Hearings.

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575 Ref: 090-026-075
576 Ref: WS-139-2, p. 9 Q15
577 Ref: 090-026-075
578 Ref: WS-139-1, p.21
579 Ref: 090-040-141
580 Ref: 302-085-001
581 Ref: 237-002-012(t)
582 Ref: 237-002-014(dd)
583 Ref: 232-002-017

Continuous infusion

307. A cannula was resited during the afternoon.[584] The continuing infusion of midazolam was ordered as 69mg in 50ml normal saline (0.9% saline, containing 150mmol/L sodium) to be given at 2mls per hour over 24 hours. This was prescribed by Dr. Stevenson[585] and erected by Nurse Taylor.[586] The Fluid Balance and IV Prescription Sheet signed by Nurse Taylor records midazolam as having been given from 16:30.[587] A total of 13.9mls appears to have been given over the nine and a half hour period from 16:30 until 23:00.

308. The rate of infusion of the midazolam was increased at 21:30 by 0.1ml every 5 minutes until running at 3mls/h. The change was complete by 22:40.[588] This increase was not noted in Claire's clinical notes, but was in the nursing notes[589]. It is not known who directed that the infusion be increased. Dr. Joanne Hughes, who was the SHO in Allen Ward at the time, re-wrote the prescription sheet at 21:30[590], and included the increase in the rate of infusion. She states that she does not recall rewriting the prescription but "*on reviewing the notes the original midazolam dose needed to be changed. The original prescription was full and therefore the whole thing was rewritten.*"[591]

Sodium valproate

309. Dr. Webb also directed that sodium valproate, an anti-epileptic drug, be administered: 20mg/kg by IV bolus as an initial dose, followed by 10 mg/kg intravenously over 12 hours.[592] In his witness statement, Dr. Webb states that he tried unsuccessfully to stop Claire's clinical and sub-clinical seizure activity, and that after sodium valproate other measures were unlikely to be successful.[593]

310. Dr. Sands wrote the prescription for the sodium valporate and signed the prescription sheet as having administered it at 17:15.[594] He acknowledges that as he was aware that Dr. Webb had just reviewed Claire and her observations at 17:00,[595] his own reading and checking

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584 Ref: 090-040-138

585 Dr. Aronson states that as it was intended to be given by continuous IV infusion he would have expected the prescription to have been written on another part of the chart intended for continuous infusions. It was written in a section intended for regular prescriptions of intravenous drugs where frequency of administration is indicated Ref: 237-002-013(y) to 237-002-014

586 Ref: 090-038-136

587 Ref: 090-038-135, 136

588 Ref: 090-040-138

589 Ref: 090-040-141

590 Ref: 090-026-073

591 Ref: WS-140-1, p.21 Q30a

592 Ref: 090-022-055

593 Ref: WS-138-1 p.39 Q23

594 Ref: 090-026-075

595 Ref: 090-022-055

of Claire's CNS observations and observation chart at around 17:00 "*may have been limited*".[596] A nursing note at 17:15 referred to Claire being given a stat dose of Epilim (sodium valporate) and being responsive only to pain, remaining pale and having the occasional episode of teeth clenching.[597]

311. Dr. Aronson thinks it unlikely that this drug contributed to Claire's hyponatraemia. He expects that the onset of action of IV sodium valproate, which is not a sedative, would have been 30-60 minutes and that it would not have affected Claire's neurological assessment.[598]

312. Professor Neville thinks the administration of sodium valproate was inappropriate due to the lack of EEG to confirm the diagnosis.[599]

313. Dr. Scott-Jupp states that in 1996 an intravenous preparation of sodium valproate had been recently introduced and that it was "*in vogue … as a second, third or fourth line anti-convulsant where other drugs appeared to have failed*".[600] He therefore concludes that it "*was an appropriate intervention*".[601] However, he does not address the issue raised by Professor Neville as to whether it should have been administered in the absence of an EEG to conform the diagnosis. In addition, he defers to the views of a paediatric neurologist on the entire question of whether the anti-convulsant therapy ordered by Dr. Webb was appropriate.[602]

Cefotaxime

314. Dr Webb noted at 17:00 that Claire was to be covered with cefotaxime[603] for the next 48 hours.[604] Dr. Webb states that cefotaxime is a broad spectrum antibiotic widely used in cases of potential intracranial infection to cover the common causes of bacterial meningitis.[605] The prescription was written up by Dr Stevenson noting that a dose of 600mg was to be administered 4-times daily, including doses at 17:30 and 21:30.

315. Cefotaxime is administered by IV but it is not noted on the Fluid Balance & IV Prescription Sheet[606] and the volume /nature of dilutants is unknown.

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596 Ref: 090-026-075, WS-137-2 p.22 Q32
597 Ref: 090-040-141, 090-042-144
598 Ref: 237-002-015 5(b) & (d)
599 Ref: 232-002-009
600 Ref: 234-002-006
601 Ref: 234-002-006
602 Ref: 234-002-006
603 See Glossary - Ref 310-007
604 Ref: 090-022-055
605 Ref: WS-138-1, p. 40 Q24
606 Ref: 090-038-135

316. Administrations are noted on the 'Regular Prescriptions – Drug Recording Sheet'[607] at 17:30 by Dr. Hughes[608] and at 23:20 Nurse McCann[609] respectively. It is not clear why cefotaxime came to be administered at 23:20 rather than the intended time of 21:30.[610]

317. The nursing notes are not in accord with either the evidence of Dr. Hughes nor the other records since they record at 20:00 that Claire was "*commenced on IV Claforan [cefotaxime]*",[611] rather than 17:30.[612] Confusingly, the nursing notes also record that the first dose of cefotaxime is "*due at 9.30pm*"[613] despite the fact they have just recorded that as having happened at 20:00 and in any event it is recorded elsewhere as having happened at 17:30. [614]

Acyclovir

318. Dr Webb also noted at 17:00 that Claire was to be covered with acyclovir,[615] an antiviral, for the next 48 hours.[616] Dr. Webb did not know the fluid used to dissolve the acyclovir but understands this would normally have been normal saline. The prescription was written up by Dr Stevenson noting that a dose of 240mg was to be administered 3-times daily, including a dose at 21:30.

319. An administration is noted on the 'Regular Prescriptions – Drug Recording Sheet'[617] at 21:30 by Dr. Hughes[618].

320. Dr Webb has stated that he would have expected the acyclovir to have been started within an hour or two and that he does not know why there was a delay until 21:30 in administering the acyclovir.[619]

321. Again, the nursing notes are not in accord with either the evidence of Dr. Hughes or the other records since they record at 20:00 that Claire was "*commenced on [..] IV acyclovir*" rather than 21:30.[620] However, at 21:30, the nursing notes do record the "*first dose*" of IV acyclovir being erected by the doctor and running over 1 hour.[621]

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607 As indicated by 'C' Ref: 090-026-077
608 Ref: WS-140-1 p.24 Q33
609 Ref: 090-026-077, WS-151-1 p.5 Q9(a)
610 Ref: 090-026-073
611 See Glossary - Ref 310-007
612 Ref: 090-040-141
613 Ref: 090-040-141
614 Ref: 090-026-077 and Ref: 090-026-075
615 See Glossary - Ref 310-007
616 Ref: 090-022-055
617 As indicated by 'D' Ref: 090-026-077
618 Ref: WS-140-1 p.25 Q33
619 Ref: WS-138/1 p.41, Q24
620 Ref: 090-040-141
621 Ref: 090-040-138

322. The IV acyclovir is also noted on the Fluid Balance & IV Prescription Sheet.[622] This is entered at 21:00, with a total administration of 60mls at 22:00.

Paracetamol

323. Paracetamol was prescribed on 21st October 1996, with a dosage of 240mg to be administered every four to six hours.[623] It is not known who prescribed the paracetamol. The only note of its administration is on the regular prescriptions sheet at 20:25 on 22nd October 1996 by Nurse Ellison.[624]

324. When Dr. Hughes re-wrote the drugs prescription sheet at 21:30 on 22nd October 1996, the entry for paracetamol is also re-written.[625] However, the re-written version has a 'Date Commenced' entry of 22nd October 1996, and Dr. Hughes noted herself as the prescribing clinician.

Cumulative effect of medication

325. The Legal Team has produced a Chart of Over-lapping Medication Timeline[626] which shows the cumulative effect of the medications that Claire received over the course of 22nd and 23rd October 1996. [627]

326. Dr. Aronson states that the effect of each of the anti-convulsant drugs administered to Claire - diazepam, phenytoin and midazolam - would have tended to worsen her GCS score by sedative effects on her brain. The effect of 120mg of midazolam (if administered) would have been much greater on its own than the effects of each of the other drugs, possibly even in combination. He observes that Claire's score fell from 9 to between 6 and 8, which (if those scores are consistent and accurate) would suggest that the sedative effects were not as great as might have been expected from such a dose. He states that the drugs would have been unlikely to have had any effect on cerebral oedema, serum sodium or the risk of SIADH. However, he also suggests that the sodium valproate, without having any effect on the brain itself, may have increased the amount of free phenytoin available to enter the tissues for a short time and therefore potentiated the action of phenytoin on the brain.[628]

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622 Ref: 090-038-135
623 Ref: 090-026-076
624 Ref: 090-026-077
625 Ref: 090-026-074
626 Ref: 310-008-001
627 For the purposes of the timeline, all medications are assumed to have been administered. As shall be seen when discussing Claire's medication, some administrations are in dispute.
628 Ref: 237-002-016

327. Dr. Webb accepts that Claire's GCS "*went up and down and some of this would have been medication related*."[629]

328. Ms. Ramsay states that it would have been preferable to administer midazolam and phenytoin intravenously in an appropriately equipped high dependency unit or Intensive Care setting.[630]

329. Although antiepileptic drugs, for example phenytoin and sodium valproate, can occasionally cause seizures as *"paradoxical adverse reactions"* he regards them as *"rare reactions"*.[631]

330. Whether the drugs that Claire received could have in part contributed to her respiratory arrest at 02:30 on 23rd October 1996 is a matter that the Inquiry is investigating.

XV. Claire's care and treatment during the evening of 22ndOctober 1996

Nursing observations

331. Mr. Roberts returned with Claire's two brothers at 18:30. Mrs. Roberts informed him that Dr. Webb had examined Claire at about 16:00 and 17:00 with a different type of medication being administered. Mr. Roberts assumed that this medicine was counteracting any viral infection Claire had and was having a sedating effect. Between 18:30 and 21:15, Claire was reviewed by the ward nurse but no concerns were communicated to the Roberts.[632]

332. At 19:00, Claire's blood pressure was recorded as 130/70 and her pulse fell to 100. Another attack is recorded at 19:15. Dr. Webb states he was not aware of this attack but would have expected to have been informed.[633]

333. Dr. Webb believes it probable with hindsight that Claire's awareness level after 20:00 was affected by her serum sodium concentration

334. At 21:00, Nurse McCann reported that Claire had a 30-second episode of screaming and drawing up of her arms with her pulse rising to 165 bpm. It is noted that a doctor was informed.[634] Dr. Hughes was the SHO in Allen Ward at the time, but she cannot recall being contacted,[635] and there is no document that specifically identifies her as

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629 Ref: WS-138-1 p.24 Q17
630 Ref: 231-002-031
631 Ref: 237-002-016(c)
632 Ref: 089-012-035
633 Ref: 090-042-144, WS-138-1 p.43 Q25
634 Ref: 090-042-144
635 Ref: WS-140-1, p.28 Q37b

the "*doctor informed*". Dr. Webb states he was not aware of this attack but would have expected to have been informed.[636]

335. Dr. Scott-Jupp states that the further seizure at 21:00, in spite of having received a considerable amount of anti-convulsant medication, should have prompted reassessment, including electrolyte testing (which was done) and a repeat neurological examination (which was not). He believes that Dr. Hughes as the SHO should have contacted Dr. Bartholome, the on call Registrar, who should have seen and re-examined the child at this time as it would not be appropriate for a SHO to manage this child without a more senior doctor seeing her.

336. Professor Neville does not think that the seizure at 21:00 need have prompted any further action by the SHO,[637] although the fall in GCS should have.[638]

337. Nurse McCann's nursing note timed at 21:30 records that a line was inserted in Claire's right hand and blood samples were taken to test U&E and the phenytoin level.[639] Acyclovir was administered by Dr. Hughes at 21:30,[640] so there was an opportunity for medical review at that time. [641]

338. Claire's Glasgow Coma Score peaked at 8 at 20:00 and remained at 6 from 21:00 onwards. The midazolam infusion was in place at that time. Dr. Steen,[642] Dr. Webb,[643] and Professor Neville[644] all agree that Claire's management should have been discussed with a consultant when Claire's GCS deteriorated at 21:00.

339. Claire's temperature is recorded as approximately 38°C at about 20:30 and 22:30. Ms. Ramsay regards the failure to record blood pressure readings at 22:00, 23:00 and midnight as "*serious omissions*" in recordkeeping.[645]

340. Respiratory observations are not recorded for 17:00, 18:00, 19:00, 20:00, 22:00 and 23:00 – Ms. Ramsay states that these should have been recorded at least every 30 minutes during the infusions. The

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636 Ref: 090-042-144, WS-138-1 p.43 Q25
637 Ref: 232-002-011
638 Ref: 232-002-011
639 Ref: 090-040-138
640 Ref: 090-026-077
641 Ref: 231-002-025
642 Ref: 091-011-068
643 Ref: 091-011-068, WS-138-1 p.86 Q65
644 Ref: 232-002-011
645 Ref: 231-002-025

respiratory rate was elevated to 30 breaths per minute and this would have been seen during Dr. Webb's examination.[646]

341. Ms. Ramsay considers that the nurses had a duty to ensure a doctor was aware of any changes in Claire's condition, particularly the following:

(i) Seizure lasting 5 minutes at 15.10.[647]

(ii) Failure to pass urine for six hours at 17:00.[648]

(iii) Blood pressure of 130/70 at 19:00.[649]

(iv) Episode of groaning and teeth clenching at 19:15.[650]

(v) The episode of screaming, the coma score of 6 and the raised pulse rate at 21:00.[651] The nursing record shows "doctor informed" of the episode at 21:00,[652] but this is not confirmed by an entry in the medical record.

342. Ms. Ramsay also states that the episode of screaming at 21:00 should have been recorded in the main nursing evaluation, including any further action needed.[653]

343. Whether nursing staff should have reacted to these events identified by Ms. Ramsay including informing a doctor is a matter that will be considered during the Oral Hearings.

Claire's parents leave for the night

344. At approximately 21:15/21:30, when Claire's parents thought that she was asleep, the nursing staff reassured them that Claire was comfortable, and they left the hospital. Mr. and Mrs. Roberts told the nurses that they would return the following morning. No doctor, nurse or any other member of the medical staff informed the Roberts that Claire was in a serious condition or in any danger.[654]

345. In his witness statement to the Inquiry, Mr. Roberts explains that they were unaware that Claire had a neurological illness, and they were not

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646 Ref: 090-039-137, 231-002-025 to 231-002-026
647 Ref: 231-002-024
648 Ref: 231-002-030
649 Ref: 231-002-030
650 Ref: 231-002-025
651 Ref: 231-002-025
652 Ref: 090-042-144
653 Ref: 231-002-025
654 Ref: 091-004-006; WS-253-1 p.11-12

aware of any concerns about Claire from the nursing staff.[655] Mr. Roberts refers of being so unaware of Claire's condition and the concerns that it was generating, that he was able to watch 'A Question of Sport' on the television with his son.[656]

346. Most of the entries in the nursing evaluations concerning Claire's parents show they were either in attendance or not. There are no records giving details of information shared with them and any discussions they had with a doctor prior to 03:00 on 23rd October 1996.

347. Dr. Scott-Jupp is critical of the fact that Claire's parents were not appropriately informed by either medical or nursing staff of the severity of her condition.[657] He says that a senior doctor, i.e. registrar or consultant, or senior nurse, should have spoken to them and they should have explained that:

(i) Claire was quite unwell.

(ii) Her diagnosis was still not entirely certain.

(iii) Further investigations might have been necessary.

(iv) There was a possibility that, if she did not improve, a transfer into Intensive Care might be necessary.

348. Ms. Ramsay states that "*as a minimum*"[658] there should have been a record of the information given to Claire's parents with their understanding and concerns. The nurses ought to have ensured Claire's parents understood the diagnosis, its implications and the treatment needed; the medicines, what they were used for and any potential side effects, why observations were being made and an explanation of the ongoing process. It is likely that had Claire's parents been aware of the severity of Claire's condition, they would not have left the hospital.[659]

349. Whether clinicians and/or nursing staff should have made Claire's parents aware of the seriousness of her condition before they left the Children's Hospital at around 21:15/21:30 on 22nd October 1996 is a matter to be considered during the Oral Hearings.

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655 Ref: WS-253-1, p.11
656 Ref: WS-253-1, p.11
657 Ref: 234-002-011
658 Ref: 231-002-032
659 Ref: 231-002-033

Serum sodium result at 23:30

350. At 23:30, Dr. Neil Stewart, SHO, recorded a serum sodium concentration result of 121 mmol/L. The phenytoin level was 23.4 mg/L (reference range 10-20 mg/L). The Inquiry has not received any printed laboratory reports for any of those results.

351. He contacted his registrar, Dr. Brigitte Bartholome who instructed that he reduce the IV fluids to two-thirds of the maintenance rate. On Dr. Stewart's instruction, Nurse Rachel Murphy reduced the fluid infusion rate to 41ml/hr at 23:40,[660] and Claire's urine was sent for osmolality. He noted in the medical notes:

'*Hyponatraemic - ? Fluid overdose with low sodium fluids. ? SIADH*' and '*Imp[ression]. ? need for ↑ sodium content in fluids.*'[661]

352. Dr. Stewart's note querying hyponatraemia, and effectively dilutional hyponatraemia, as a possibility appears to be the first time that the condition was associated with Claire.

353. Between 23:00 and 02:00, Claire received a further 56mls of No.18 solution, which equated to 18.5mls per hour, together with 7.6mls of 0.9% saline as part of the midazolam infusion. In addition, Claire received 110mls of an unknown dilutant as part of her phenytoin infusion.[662] Dr. Scott-Jupp considers that the dilutant was probably 0.9% saline[663] although there is no evidence about it from any of those treating Claire.

354. Those fluids amounted to a total of 173.5mls administered over three hours or approximately 58ml/hr. As was mentioned earlier, Dr. Scott-Jupp comments that this was considerably more than the 41ml/hr intended, and indeed only slightly less than the 61ml/hr she was receiving initially.[664] He adds that Claire also received more than intended from 20:00 to 23:00, an excess of about 133mls. He states that although it is difficult to be certain, he considers it unlikely that such a relatively small excess would have contributed significantly to Claire's cerebral oedema.[665]

355. Dr. Steen accepts that the blood test results should have led to a clinical reassessment of Claire and a repeat test being conducted; she believed

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660 Ref: 090-038-136
661 Ref: 090-022-056
662 Ref: 090-038-135
663 Ref: 234-003-002
664 Ref: 234-003-002
665 Ref: 234-003-003

that Claire may not have been retrievable at 23:30 and later agrees that intervention at 23:30 would have been too late.[666]

356. Dr. Webb states that Dr. Bartholome's response to the serum sodium result was appropriate but inadequate as this blood result in a child with altered consciousness indicated a clear risk of cerebral oedema requiring urgent attention and PICU admission for ventilation, dieresis and very careful fluid management.[667] Dr. Webb also believes that the Paediatric Registrar on call could have sought advice from a PICU Consultant and then advised their Consultant after the event.[668]

357. Dr. Webb,[669] Dr. Scott-Jupp[670], Dr. MacFaul[671] and Professor Neville[672] all agree that a Consultant should have been involved at this stage.

358. Dr. Scott-Jupp believes that Dr. Bartholome should have re-examined Claire and that a more severe fluid restriction should have been imposed at this point.[673] He considers that it may even have been appropriate to stop IV fluids completely.[674] It would have been advisable to check blood osmolality as well as the urine osmolality test that was done.

359. Professor Neville states that Dr. Stewart's assessment of the significance was "*appropriate at SHO level*."[675] However, he would have expected Dr. Bartholome to take further action including inducing diuresis by mannitol and ventilating Claire to reduce intracranial pressure.

360. Whether the clinicians' response to the low sodium result at 23:30 was sufficient and/or appropriate in the circumstances is a matter that will be addressed during the Oral Hearings.

Respiratory arrest on 23rd October 1996

361. 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.*"[676] Dr. Brigitte Bartholome, the on-call Paediatric Registrar, attended and noted at 03:00 that she had been called to see Claire who had suddenly had a

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666 Ref: 091-011-067 & 091-011-068
667 Ref: WS-138-1 p.61 Q39, p.75 Q 53
668 Ref: WS-138-1 p.61 Q39, p.75 Q 53
669 Ref: WS-138-1 p.61 Q39, p.75 Q 53
670 Ref: 234-002-008
671 Ref: 238-002-053, Ref: 234-002-008
672 Ref: 232-002-011
673 Ref: 234-002-008
674 Ref: 234-002-008
675 Ref: 232-002-011
676 Ref: 090-040-138

respiratory arrest and developed fixed dilated pupils. Claire was 'Cheyne-Stoking'[677] when she arrived. Oxygen was administered by a facemask and 'bagging' with oxygen saturation in the 'high 90s' and a 'good volume pulse.' Dr. Bartholome could not intubate Claire and Dr. Chris Clarke, the on-call anaesthetic registrar,[678] was called and he intubated Claire orally.[679] Dr. Steen states that Claire's condition was not retrievable after 03:00.[680]

XVI. Transfer to PICU

362. Claire was transferred to PICU at 03:25[681] on 23rd October 1996 following her respiratory arrest. Dr. Steen was the first Consultant called to attend Claire there. The DLS state Dr Steen was not on call overnight, but they are unable to identify who was the on-call consultant paediatrician that evening.[682] Dr. Steen states that although after 17.00 hours the on-call consultant would have been first point of contact for paediatric medical problems, practice was that the registrar could also contact the named consultant for that patient even though that consultant was not on call and the named consultant not have to respond if unable to do so.[683]

Dr. Steen's examination of Claire

363. Dr. Steen examined Claire and made a note timed at 04:00. She described Claire as a 9½-year-old girl with learning difficulties who had been admitted 32 hours previously with a reduced level of consciousness. She records the history as having been seen by Dr. Webb, "Δ *acute encephalopathy ? aetiology*", covered with acyclovir and cefotaxime, loaded with phenytoin, and valproate added in at 17:00. She also records that Claire had had some midazolam but it was no longer running. Dr. Steen recorded the low serum sodium concentration result, that fluids were restricted to two-thirds maintenance and that her observations were otherwise stable.

364. Dr. Steen examined Claire 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 severe raised*

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677 Cheyne-Stokes respiration is an abnormal pattern of breathing, which in such a case, suggests a serious abnormality, typically involving the brain stem and is often terminal (Aronson para. 25) See Glossary - Ref 310-007

678 See List of Persons - Ref: 310-003-001

679 Ref: 090-022-056, 090-040-138 to 090-040-139

680 Ref: 091-011-067

681 Ref: 090-040-138, 139

682 Ref: 302-068a-001

683 Ref: WS-143-1, p.45

intracranial pressure] L>R. No response to painful stimuli".[684] She was given mannitol to reduce the cerebral oedema and dopamine and an urgent CT scan was requested.

365. At that time, a second serum sodium concentration was recorded at 121mmol/L, which was equivalent to the result recorded at 23:30 on 22nd October 1996.[685] The Inquiry has not received a printed laboratory report for those results. It is not clear precisely when those bloods were taken or the laboratory results communicated but the printed laboratory report for the phenytoin result states that it was received at 04:20 and vetted at 04:38.[686] The blood could therefore have been taken between 03:15 and 04:00. Claire's white cell count had returned to normal by that time, and this is confirmed in the printed haematology laboratory report.[687]

Chest x-rays

366. Two chest x-rays were performed in the Children's Hospital on 23rd October 1996. The first at 03:50,[688] in respect of which no radiologist's report has been furnished to the Inquiry, and the second was carried out at 07:15.[689] Dr. McKaigue records in Claire's medical notes that there is some mottling of both hilar regions more so on her right side. He expresses concern that there could be pulmonary aspiration or early neurogenic pulmonary oedema.[690] The Radiologist's Report for the 2nd X-rays states that there is patchy consolidation in the mid and upper zones on both sides, slight more extensive in examination 2.[691]

367. Dr. Caren Landes, the Inquiry's Expert on Radiology, [692] has stated that both chest x-rays show "*bilateral perihilar air space shadowing*" which is typical of pulmonary oedema, but can also be seen in widespread infection. It is not possible to differentiate between infections, changes related to inhalation or aspiration, and pulmonary oedema from other causes on the basis of the imaging alone.[693]

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684 Ref: WS-138-1 p.46 Q29
685 Ref: 090-022-057
686 Ref: 090-031-101
687 Ref: 090-022-057, 090-032-111. Later haematology laboratory reports from samples on 23rd and 24th October 1996 confirm that the white cell count remained normal Ref: 090-032-112 & 090-032-110.
688 Ref: 308-008-001
689 Ref: 308-009-001
690 Ref: 090-022-060
691 Ref: 090-033-115
692 See List of Persons - Ref: 310-003-001
693 Ref: 230-002-006

Dr. Steen contacts Dr. Webb

368. At 04:00, Dr. Steen also contacted Dr. Webb,[694] who was the on-call Consultant Paediatric Neurologist. He attended PICU and is recorded as having noted at 04:40, "*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*".

369. Dr. Webb states that, on 23rd October 1996, he believed that hyponatraemia was the cause of Claire's cerebral oedema and that the cerebral oedema had caused brain herniation resulting in her brain stem compression and death. He believed that SIADH was the most likely cause of the hyponatraemia leading to Claire's cerebral oedema and death. He did not know the cause of SIADH: he believes it was meningoencephalitis, of which evidence was found in the autopsy report. Meningitis is a well-recognised cause of SIADH, and is also reported after convulsive status epilepticus but would be very unusual in non-convulsive status epilepticus.

370. Dr. Webb does not believe that Claire's fluid regime caused Claire's SIADH but that it will have exacerbated the problem by further diluting her serum. Dr. Webb believes it is possible that Claire's fluid regime did contribute to her hyponatraemia and was not an appropriate fluid regime for a child with low sodium.[695] Mr. Roberts has raised the question of why Dr. Webb's diagnosis of SIADH leading to hyponatraemia, cerebral oedema and coning, was not included in Claire's death certificate.[696]

Care in PICU

371. The Inquiry has recently been provided with copies of the PICU fluid balance chart and IV fluid prescription sheet. The DLS had previously stated that "*there is no fluid balance and IV fluid prescription sheet for 23rd October 1996 present in the records... The Medical Records Department have checked the archive and offsite storage and no separate PICU records have been found.*"[697]

372. Staff Nurse Sandra Ross[698] was the admitting nurse in PICU and she completed the PICU Patient Assessment Sheet at approximately 07:00. She records that on admission Claire's GCS was 3, Claire was unconscious and hypotensive, her weight was 25kgs, Claire had a

694 Ref: 090-050-156, WS-138-1 p.13 Q4
695 Ref: 090-022-057, WS-138-1 p.47 Q30 , p.72 Q51, 52, p.81 Q61
696 Ref: 091-004-012
697 Ref: 302-025-001
698 See List of Persons - Ref: 310-003-001

peripheral line in the right subclavian and an arterial line in her right dorsum (the nursing note records a cannula sited in her right hand,[699] although an arterial line is sited in her right foot in PICU), a midazolam infusion was in situ.[700] Nurse Ross also completed a brief PICU nursing note recording that Claire was admitted from Allen Ward to PICU at 03:00 following respiratory arrest and that the CT scan showed diffuse swelling.[701]

373. Staff Nurse Margaret Wilkin[702] completed the PICU admission sheet in respect of Claire on 23rd October 1996, although it is not signed or timed. She records the reason for Claire's admission as respiratory arrest, the medical diagnosis as "*? Viral"* the responsible consultant as Dr. Steen.[703]

374. Ms. Ramsay is not critical of the nursing care in PICU stating[704] that the nursing care plan is of an "*appropriate standard*" and that the records of discussions between the doctors and Claire's parents is "*satisfactory*".

CT scan and first brain stem death test

375. The CT scan, performed by Dr. Peter Kennedy, Radiology Registrar,[705] in the Royal Victoria Hospital at approximately 05:30[706] was reported at that time as showing "*severe diffuse hemispheric swelling with complete effacement of the basal cisterns. No focal abnormality is identified*".[707] Dr. Webb has stated that at this point *"it was clear that Claire had sustained severe brain injury and was not going to survive"*.[708] Dr. McKaigue recorded that the CT scan showed severe cerebral oedema.[709] Dr. Mark Love, Radiologist,[710] furnished a Radiologist's report on the CT scan marked with Dr. Steen's name on it. It identified "*generalised cerebral swelling with effacement of the cortical sulci as well as the basal cisterns and the third ventricle. No focal lesion has been identified."*[711]

376. The first Brain Stem Death Criteria Evaluation was conducted by Dr. David Webb and Dr. Heather Steen at 06:00. At that time, Claire's serum sodium results were 129mmol/L, which is outside the normal range of 135 to 145mmol/L. In addition, Dr. Aronson notes that several

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699 Ref: 090-040-138
700 Ref: 090-027-080 & 090-027-081
701 Ref: 090-027-086
702 See List of Persons - Ref: 310-003-001
703 Ref: 090-027-078 & 090-027-079
704 Ref: 231-002-033
705 See List of Persons - Ref: 310-003-001
706 Ref: 308-010-001
707 Ref: 090-022-058
708 Ref: 090-053-168
709 Ref: 090-022-059
710 See List of Persons - Ref: 310-003-001
711 Ref: 090-033-114

of the anti-convulsant drugs that Claire received may have affected Claire up to, and over, 24 hours after their administration.[712]

377. Dr. Simon Haynes, Consultant Paediatric Anaesthetist, who was retained by the Inquiry as an expert in Adam's case, gave evidence on 3rd May 2012 in relation to brainstem testing.[713] He also produced the 1998 Code of Practice for the Diagnosis of Brain Stem Death,[714] which he said applied also to practice in 1995 and explained the procedure for the diagnosis and management of brain stem death that is included in the Code as a 'flow chart'.[715] The third step in the flow chart states: "*Exclusion of hypothermia, intoxication, sedative drugs, neuromuscular blocking agents, severe electrolyte, acid base or endocrine abnormalities as causative*".[716] Dr. Haynes referred to Adam being hyponatraemic at the time that his brain stem tests were carried out and he felt that, in accordance with the Code of Practice, "*active steps should have been taken to normalise over a period of hours the concentration of sodium in his blood*".[717]

378. Dr. Webb and Dr. Steen both considered that Claire fulfilled the criteria for brain stem death and signed the Diagnosis of Brain Death form.[718] In particular, the reference at 1(c) to "*Could other drugs affecting ventilation or level of consciousness be responsible for her condition?*" is answered in the negative.[719] There is no reference to her hyponatraemia and the question at 1(f), "*Could patient's condition be due to a metabolic/endocrine disorder?*" is also answered in the negative. [720]

379. Dr. Webb recorded that the evaluation should be repeated in four to six hours.[721]

380. In the meantime, Dr. McKaigue, ICU Consultant Anaesthetist who was on-call in the early morning of 23rd October 1996, examined Claire and reviewed her history. He noted at 07:10 that Claire was initially admitted with a decreased level of consciousness with the clinical picture of acute encephalopathy, status epilepticus subsequently developed requiring phenytoin, valproate and midazolam, that serum sodium was 121mmol/L "*presumably on basis of SIADH*". He records that in PICU Claire was hyperventilated and that her pupils were fixed and dilated. He also noted that Claire's serum sodium concentration

712 Ref: 237-002-008; 237-002-009
713 Ref: Transcript of 3rd May 2012, p.106 to 112
714 Ref: 306-035-001
715 Ref: 306-035-021
716 Ref: 306-035-021
717 Ref: Transcript of 3rd May 2012, p.112, L.12
718 Ref: 090-045-148
719 Ref: 090-045-148
720 Ref: 090-045-148
721 Ref: 090-022-058, 090-045-148

was measured at approximately 06:00: the laboratory result was 129mmol/L,[722] and the PICU blood gas analyser result was 133mmol/L.[723] He noted that Drs. Steen and Webb had spoken to Claire's parents and that Dr. Webb was going to speak to them again at about 10:00.[724]

381. Dr. McKaigue ordered a dopamine infusion to maintain blood pressure and a close check on serum sodium and osmolality and urine output. Dr. McKaigue records the maintenance fluids as dextrose 4%/Saline 0.18% and states to ventilate to PCo2 35. He expressed concern about deterioration in Claire's blood gases, which might have been in keeping with pulmonary aspiration or early neurogenic pulmonary oedema. [725]

382. At 08:00, he recorded a change in Claire's IV infusion fluid to 0.9% saline and requested two hourly measurements of urea and electrolytes.[726]

383. Dr. Robert Taylor, the Consultant Paediatric Anaesthetist in Adam's case, [727] was on duty in PICU on 23rd October from approximately 08:30 to 17:00. Dr. Taylor believes that his untimed note was made at around 10:00 during the PICU ward round on 23rd October 1996. It refers to Claire becoming hypotensive (BP 70/?) "*with DI [diabetes insipidus]*"and states that Claire was "*given HPPF 500ml, [and] needs DDAVP to limit polyuria.*" He notes a serum sodium level of "*129 (from 121)*".

Contact with Claire's parents

384. Mr. Roberts received a call from Dr. Bartholome at 03:45 on 23rd October 1996 to say that Claire was having breathing difficulties and requesting that he and Mrs. Roberts attend as soon as possible. On their arrival, they met with Dr. Steen and Dr. Webb. Dr. Steen informed them that there was a build up of fluid around Claire's brain and pressure was being applied to her brain stem, and that a CT scan would confirm this.[728]

385. After the CT scan at approximately 05:30, Claire's parents met again with Drs. Steen and Webb. Mr Roberts states that Dr. Steen explained to him that "*the virus from Claire's stomach has spread and travelled into*

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722 Ref: 090-057-207
723 Ref: 090-022-059 and 090-022-060 (the Inquiry has received no printed laboratory report for this result).
724 Ref: 090-020-060
725 Ref: 090-020-060
726 Ref: 090-022-059, 060
727 See List of Persons - Ref: 310-003-001
728 Ref: WS-253-1, p.13 Q13(g)

Claire's brain and caused a build up of fluid"[729], which had been confirmed by the CT scan.

386. Mr Roberts states that he asked Dr. Steen if it was possible "*for any type of surgery or to drill into Claire's skull to drain the fluid, or relieve the pressure build up*".[730] He states that Dr. Steen informed him that that was not possible. He also asked if everything possible had been done for Claire and if anything else could have been done. He states that Dr. Steen informed him that "*everything possible had been done for Claire and nothing more could have been done*".[731]

387. After the brain stem tests, it was explained that Claire's brain had died.[732] The Relative Counselling Record states that the parents understood the explanation and that, in answer to the Roberts' question why Claire's brain had swollen, they were informed "*it was probably caused by a virus*".[733]

388. Dr. Webb does not believe the nursing note accurately records the conversation: he states that "*[i]f a "virus" was discussed it was probably on the basis of a theory that a virus may have triggered Claire's seizures and her brain oedema*", and although he cannot recall the details of what was said about hyponatraemia and brain oedema, he believes that he "*would have indicated that the brain swelling was due to hyponatraemia*" and that he communicated his view about the cause of death as set out in his medical note at Ref: 090-022-057.[734]

389. While Dr. Scott-Jupp considers that the discussions with Claire's parents were appropriate given the information available and the clinicians' views at the time,[735] Professor Neville believed that cerebral oedema caused or aggravated by hyponatraemia should have been explained to the parents.[736]

Second brain stem death test

390. In the intervening period between the two brain stem tests, Claire's serum sodium results were: 139mmol/L at 09:00, 152mmol/L at 12:00, 154mmol/L at 14:00, 154mmol/L at 16:00 and 152mmol/L at 18:00.[737] As previously stated, Dr. Aronson notes that several of the anti-

729 Ref: WS-253-1, p.14 Q14(c)
730 Ref: WS-253-1, p.14 Q14(c)
731 Ref: WS-253-1, p.14 Q14(c)
732 Ref: 090-028-088
733 Ref: 090-028-088
734 Ref: 090-028-088, WS-138-1 p.50-51 Q33, p.55 Q35
735 Ref: 234-002-010
736 Ref: 232-002-013
737 Ref: 090-057-207

convulsant drugs that Claire received may have affected Claire up to, 48 hours after their administration.[738]

391. The second brainstem death test was carried out by Dr. Webb and Dr. Steen at 18:25 and they certified that Claire fulfilled the criteria. The diagnosis was identified as "*Cerebral Oedema*".[739]

392. Claire did not recover, ventilation was discontinued at 18:45 on 23rd October 1996 with the agreement of Claire's parents[740] and she died in PICU.

393. Dr. Webb states that he did not believe that Claire's brain stem herniation was due to a reversible metabolic or endocrine disorder, that the purpose of that part of the form is to prompt consideration of any reversible metabolic or endocrine disorders that cause coma when assessing brain stem death – the form is to establish the fact of death, not the cause of brain stem death.[741]

394. None of the clinicians or experts has suggested that Claire was anything other than irretrievable from her admission to PICU and some consider that she was irretrievable before then. However, the expert evidence provided to the Inquiry in Adam's case was that meticulous compliance with the procedure for the certification of brainstem death is important.

395. Accordingly, whether the answers on the Diagnosis of Brain Death form were strictly correct at either 06:00 or 18:25 on 23rd October 2012 and whether the procedure for certifying brainstem death was appropriately followed, are issues that are being investigated.

XVII. Brain only autopsy

Decision to conduct a brain-only autopsy

396. Dr. Steen obtained consent from Mr. and Mrs. Roberts to a limited brain only autopsy being carried out.[742] She states that a limited PM is usually indicated if it is felt only certain organs were involved in the disease process and additional information as to the cause of death or any underlying disorders may be gleaned by examining those organs.[743]

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738 Ref: 237-002-008
739 Ref: 090-045-148
740 Ref: 090-022-061
741 Ref: WS-138-1 p.53, Q34
742 Ref: 090-022-061
743 Ref: WS-143-1, p.71 Q45b

397. Dr. Steen adds that she has no recollection of events but on review she still feels that a limited post mortem of the brain was appropriate and that the only additional benefit of a full post mortem may have been isolation of an enterovirus from gut contents.[744]

398. Mr. Roberts states that Dr. Steen advised them that the post mortem may or may not be able to identify the virus responsible for Claire's brain swelling but that it was important that doctors learned from Claire's death as the reasons for her death might help prevent similar tragedies in the future.[745] They state that the brain-only nature was recommended by Dr. Steen.[746]

399. The autopsy consent form was signed by Mr. Roberts on 23rd October 1996.[747]

400. Dr. Steen completed the autopsy request form, in which she records the clinical diagnosis as "*Cerebral oedema 2° status epilepticus ?underlying encephalitis*", and the clinical problems in order of importance as "*(1) Cerebral Oedema; (2) Status Epilepticus; (3) Inappropriate ADH secretion; (4) ?viral encephalitis*".[748]

401. Dr. Webb states that he believes he was not aware that Claire's post mortem was limited to brain only, that he had no input into the decision to have a limited post mortem nor any discussion with the Roberts family on the nature of the post mortem and he does not know why the post mortem was limited in this way. He would have expected there to have been a full post-mortem pending the parents' consent. At the time of referral for limited post mortem, he states he thought Claire had died from cerebral oedema due to SIADH following a viral meningitis.[749]

402. Professor Neville would have expected a full post mortem as the death was unexplained,[750] but in the absence of reporting the death to the Coroner, he thinks it was reasonable to obtain information from a brain only post mortem.[751]

403. The basis upon which the decision to carry out a limited brain only autopsy was made and the reason for it are matters that will be considered during the Oral Hearings and will be dealt with in the Governance section.

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744 Ref: WS-143-1, p.72 Q45f
745 Ref: WS-253-1 p.15 Q16a
746 Ref: WS-253-1 p.16 Q16f
747 Ref: 090-054-185
748 Ref: 090-054-183 & 090-054-184
749 Ref: WS-138-1 p.52 Q34, p.91 Q79
750 Ref: 232-002-014
751 Ref: 232-002-014

Autopsy request form

404. The autopsy request form is signed by Dr. Steen.[752] The date the form was filled in is unknown. Dr. Steen noted as follows:

> "*9 ½ year old girl [with] a history of mental handicap admitted with increasing drowsiness and vomiting. Well until 72 hours before admission. Cousin had vomiting and diarrhoea. She had a few loose stools and then 24 hours prior to admission started to vomit. Speech became slurred and she became increasingly drowsy. Felt to have sub clinical seizures. Treated [with] rectal diazepam / IV phenytoin / IV valproate. Acyclovir + cefotaxime cover given. Serum Na^+ dropped to 121 @ 23-30 hrs on 22-10-96. ?Inappropriate ADH secretion. Fluids restriced. Respiratory arrest 0300 23-10-96. Intubated + transferred. ICU – CT scan – cerebral oedema. Brain stem death criteria fulfilled @ 0600 + 1815 hrs. Ventilation discontinued 18-45 hrs.*"

405. Dr Steen noted the clinical diagnosis as cerebral oedema secondary to status epilepticus with a query of underlying encephalitis.[753] She listed the clinical problems in order of importance as follows:

(i) Cerebral oedema

(ii) Status epilepticus

(iii) Inappropriate ADH secretion

(iv) ?Viral encephalitis

406. The death certificate's cause of death was noted as cerebral oedema due to status epilepticus.[754]

407. The consultant noted on the autopsy request form in Claire's case is listed as "*Dr Webb / Dr Steen*". Dr Steen states that she entered this as they were both involved in her care.[755]

408. Dr Squier does not think it was unreasonable that the details of the serum sodium and the nature of the fluids administered were omitted from the form, as fluids and sodium levels are not normally in the remit of a Neuropathologist, but should have been part of the investigation of the clinicians following receipt of the autopsy report.

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752 Ref: 090-054-183 to 184
753 Ref: 090-054-184
754 Ref: 090-054-184
755 Ref: WS-143-2 p.16, Q46(b)

Autopsy

409. An autopsy of the brain only was carried out on 24th October 1996, the brain cut was carried out on 28th November 1996 and slides were examined in or about January 1997. Dr. Brian Herron, a Senior Registrar in Neuropathology at the time,[756] is named as the sole pathologist in the undated, signed provisional anatomical autopsy report.[757] He accepts he was likely involved in its preparation and the brain cut and the author of that provisional report.[758]

410. The final autopsy report dated 11th February 1997[759] also names Dr. Herron as the sole pathologist. The clinical summary referred to Claire's vomiting, 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 ADH secretion. There is a statement that Claire had '*iatrogenic epilepsy since 10 months'*.[760]

411. Mr. Roberts has stated that the clinical summary in Claire's autopsy report is inaccurate and wrong including:

(i) Claire was well when she went to school on 21st October and returned home from school with a note that she was unwell

(ii) Claire's cousin had a tummy upset, not vomiting and diarrhoea

(iii) Claire did not have diarrhoea. She did have one loose bowel on the Friday.

(iv) Claire did not start to vomit until 21st October

(v) Claire did not have any seizures on 20th October.[761]

412. Dr. Squier comments that Dr. Herron's clinical summary appears, in almost all respects, to be "*reasonably accurate*"[762] and compares with the clinical summary provided to him in the autopsy request form. However, she is concerned with his comment that Claire had "*iatrogenic epilepsy since 10 months*" as there was no evidence that the she suffered any convulsions after the age of four, and and convulsions began at six months, not ten.

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756 See List of Persons - Ref: 310-003-001
757 Ref: 090-005-007
758 Ref: WS-224-3 p.5 Q4c, p 14 Q25, p.9 Q7b
759 Ref: 090-003-003
760 Ref: 090-003-003
761 Ref: 091-003-004, 091-005-016
762 Ref: 236-004-006

Autopsy findings

413. 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. The final autopsy report stated that there was no cortical venous thrombosis or meningeal exudates, and that there was symmetrical brain swelling with effacement of gyri, which was confirmed on sectioning. The report stated that focal meningeal thickening over the cortex and a cellular reaction in the meninges and perivascular space were observed. In the deep white matter, there were focal collections of neurones arranged in a '*rather haphazard manner*.' The report also describes focal collections of neuroblasts in the subependymal grey matter suggestive of a migration problem, and states that there was focal haemorrhagic necrosis in the brain stem.

414. The final autopsy report was not conclusive. The report's diagnosis was 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*'. It could not rule out a metabolic cause.[763] There was no other discrete lesion identified to explain epileptic seizures.

415. The accuracy of the interpretations provided by the pathologists are issues to be considered during the course of the Oral Hearings. Likewise, there are issues as to why the following appeared to have not been included in the autopsy report:

    (i) The possibility of an iatrogenic component

    (ii) The low blood sodium or its link to the administration of IV fluids, although presented to Dr Herron, and thus presumably to Dr Mirakhur, as clinical information

    (iii) Any evidence of a clinico-pathological correlation with the clinicians who requested the autopsy

    (iv) Any evidence that the death was reviewed at a multi-disciplinary meeting, so that all parties could arrive at a consensus on why the death occurred.

416. In addition, the autopsy report did not follow the Royal College of Pathologists Guidelines on Autopsy Reports 1993 in several respects:[764]

    (i) Timeliness

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763 Ref: 090-003-004, 005

764 To be provided

(ii) Lack of commentary that reconciled the major clinical problems

(iii) No mention of a clinico-pathological or audit meeting in a complex case

417. Professor Sebastian Lucas, Professor of Clinical Histopathology and Consultant Histopathologist,[765] has been asked to provide expert assistance in this case. He previously provided a report dealing with the competency of the autopsy in Adam's case.[766]

Authorship of the autopsy report

418. Dr. Herron has recently stated in his witness statements that he was not the author of that final autopsy report.[767] Dr. Herron believes that the author was in fact Dr. Meenakshi Mirakhur,[768] his supervising Consultant Neuropathologist, who was Head of the Regional Neuropathology Service/Link Laboratories between February 1988 to December 2010.[769] Dr. Mirakhur's supervision of the neuropathology trainees, including Dr. Herron, usually involved day-to-day supervision in the mortuary and discussion of the case with trainees and some of the clinical colleagues involved, and also a weekly organ review which took place after fixation.[770] Dr. Mirakhur was the same consultant whose involvement in the production of Dr. Armour's autopsy report on Adam is in issue.

419. Dr. Herron admits that until 2011 he had assumed that he was the author of that final autopsy report.[771] He gave oral evidence at Claire's inquest on 25th April 2006 in relation to the examination and appearance of the brain after fixation and in his Inquest deposition, he produces a copy of "*my report*" which is exhibited.[772] He states that it was only when documents were retrieved from off-site storage in 2011 to answer his Inquiry Witness Statement request that he saw the draft autopsy reports edited by Dr. Mirakhur and he realised he was not the actual author of the final autopsy report.[773]

420. Dr. Herron states that he does "*remember specifically what was done before the Inquest in 2006, but [he] do[es] recall reviewing the case in detail.... I also read the final autopsy report and reviewed the slides... Also, following review of the case [he] agreed with the commentary and the conclusion in the case (as*

765 See List of Persons - Ref: 310-003-001
766 Ref: 209-001-001
767 Ref: WS-224-1 p.3 Q.7
768 Ref: WS-224-3 p.21 Q19f
769 See List of Persons - Ref: 310-003-001
770 Ref: 306-066-002
771 Ref: WS-224-3 p.15 Q13b-f
772 Ref: 091-005-015
773 Ref: WS-224-1 p.7 & 14 Q25; WS-224-3 p.14 Q13a.

written in the final autopsy report)". [774] Dr. Herron claims that he was able to make certain comments in his oral evidence to the Coroner based on his review.[775]

421. Dr. Herron has stated that in the 1990s the policy was to record the junior doctor's (and not the consultant's) name on the autopsy reports and provisional anatomical reports, but that since then the consultant pathologist is named on any report.[776] He has also stated that the final report would not have been sent out had it not been signed, that the signed report is the copy that goes to the clinician and that to his knowledge a final report has never left neuropathology unsigned.[777] The DLS have informed the Inquiry in a letter dated 20th June 2012[778] paragraph 3: that "*there is no copy of the signed final report in the Neuropathology Department file. Dr Herron has advised that he does not know whom it was sent*".

422. Dr. Mirakhur states the final report was produced jointly with Dr. Herron.[779] She claims that it was "*not usual to put in the Consultant's name if the autopsy was carried out by a person of the status of a Senior Registrar who also drafted the report*" and that she supervised Dr. Herron as part of the team. She also accepts that it is the usual practice for the author to sign such reports.[780] Dr. Herron states that he "*may have been involved in preparing further documents or in discussions, but [he] does not remember this specifically.*"[781] Dr. Mirakhur was not asked to attend or notified by the Coroner regarding the inquest.[782] She states that Dr. Herron delivered the pathological findings of Claire's autopsy at the Inquest because his name was on the report and he was a consultant by the time of the Inquest.

423. Dr. Squier has commented on this issue in her reports to the Inquiry. She states that the named author is the pathologist who is responsible for the case and has made the various examinations.[783] If a junior pathologist or trainee is responsible for part of the case, he or she may sign the report but it would usually be signed also by a senior and accredited consultant who assumes ultimate responsibility for the case. However, she notes that in 1996, systems were less robust than they are today, there was no clear guidance on this matter, and non-consultants (trainees) may have taken responsibility for completing reports.

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774 Ref: WS-224-3 p.15-16 Q13(h)(i)-(iv); p.23 Q20h
775 Ref: WS-224-3 p.16 Q13h(ix), p.17 Q13h(vi-x)
776 Ref: WS-224-3 p.4 Q2 & p.7 Q5b
777 Ref: WS-224-3 p.7-8 Q5h
778 Ref: 302-075b-001
779 Ref: WS-247-1 p.6 Q8
780 Ref: WS-247-1 p.6 Q8a & c
781 Ref: WS-224-3 p.22 Q20e
782 Ref: WS-247-1 p.7 Q8g; p.17 Q35
783 Ref: 236-004-006

424. The identity of the author/s of the final autopsy report and findings of that report are all issues which the Inquiry is investigating. The Inquiry is also investigating how Dr. Herron came to give evidence about "his report" when in fact Dr. Mirakhur was the final author thereof.

425. There are number of issues concerning the way in which the autopsy was carried out including whether the autopsy should have been carried out as part of a Coroner's Inquest, and the accuracy of the death certificate. Those matters are being addressed as part of the Governance investigation and hearing.

XVIII. Experts' views on the cause of death

426. Under the Terms of Reference of the Inquiry, it is not necessary to address the exact cause of Claire's death. However, the Experts engaged by the PSNI and the Inquiry have expressed views on the cause of Claire's death, which, for convenience, are summarised below and in a schedule compiled by the Legal Team.[784]

Dr. Brian Harding (PSNI expert in Neuropathology)

427. Dr. Brian Harding, Consultant Neuropathologist at Great Ormond Street, Hospital,[785] provided a report on behalf of the PSNI dated 22nd August 2007.[786] Unlike the other experts, he does not believe there is evidence of an infection[787] as there was no evidence of either meningitis or encephalitis on microscopic examination of the brain.[788] Nor was there any evidence of status epilepticus.

428. He therefore concludes that the cerebral oedema was the immediate cause of death and hyponatraemia is the only causative factor that has been positively identified.[789]

429. The Inquiry asked Dr. Harding on 18th March 2011[790] whether encephalitis causing cerebral oedema, coning and death in the space of three days could occur in the absence of clear neuropathological changes, but he rejected this contention,[791] stating that he had seen it occurring in as little as 36 hours, and that it would be "*extremely unlikely*" that microscopic evidence would not be evident by 3 days.

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784 Ref: 301-009-001
785 See List of Persons - Ref: 310-003-001
786 Ref: 096-027-357
787 Ref: 096-027-360
788 Ref: 096-027-359
789 Ref: 096-027-361
790 Ref: 235-001-001
791 Ref: 235-002-001

Dr. Rajat Gupta (PSNI expert in Paediatric Neurology)

430. Dr. Rajat Gupta, Paediatric Neurologist,[792] provided a report to the PSNI in October 2008, having read the report of Dr. Harding.[793] He agreed with Dr. Harding that the cause of death was cerebral oedema, itself most likely caused by hyponatraemia.[794]

431. Dr. Gupta considers there was no clear evidence for the diagnosis of non-convulsive status epilepticus,[795] although it was reasonable that it was considered as a possible diagnosis during Claire's admission.[796] Dr. Gupta considered it reasonable that a diagnosis of meningoencephalitis was entertained although unlikely in the absence of fever and meningism.

Dr. Dewi Evans (PSNI expert in Paediatrics)

432. Dr. Dewi Evans, Consultant Paediatrician, provided a report on behalf of the PSNI dated 1st March 2008.[797] He concluded that Claire's death was caused by cerebral oedema in which hyponatraemia was a factor. The hyponatraemia was due initially to SIADH and progressed due to the failure to prescribe the appropriate fluids and the failure to adequate measures to monitor sodium balance.

433. Dr. Evans considers that the post-mortem CSF is consistent with a diagnosis of viral meningo-encephalitis because of the ratio of white to red blood cells and the fact that the white cells were "mostly lymphocytes". He does note that this is "*far from being an exact science*".[798]

434. He does not believe there is any evidence of Claire having had a seizure or that her condition was due to status epilepticus.[799] He states that the episode at 15:15 was an indication of Claire's worsening neurological condition, not the cause of it.

Dr. Waney Squier (Inquiry expert in Neuropathology)

435. Dr. Waney Squier, Consultant Neuropathologist and the Inquiry's expert in Neuropathology,[800] believes that the most likely cause of

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792 See List of Persons - Ref: 310-003-001
793 Ref: 097-011-026
794 Ref: 097-011-026
795 Ref: 097-011-026
796 Ref: 097-011-027
797 Ref: 096-022-122
798 Ref: 096-022-132
799 Ref: 096-022-139
800 See List of Persons - Ref: 310-003-001

Claire's terminal illness was epileptic activity precipitated by a concurrent infection and complicated by hyponatraemia.[801]

436. On examination of blocks and stained sections of Claire's brain tissue, she concludes that Claire suffered severe brain oedema (swelling),[802] and this may have been due to hyponatraemia,[803] though she could not determine the latter from microscopic examination of the brain.[804] The cause of the swelling was not apparent in the brain, and there was no evidence of meningitis or encephalitis.[805] She did discover marked gliosis in the hippocampus, the pattern of which was that of old mild hippocampal sclerosis (scarring), which is associated with epilepsy.[806]

437. She added that the febrile seizures that Claire suffered when she was 6 months old may be associated clinically with a "mesial temporal lobe syndrome" in which a history of convulsions in infancy is followed by a phase of latency and a third phase of focal epilepsy.[807]

438. Dr. Squier agrees[808] with the diagnosis on the death certificate "I*(a) Cerebral oedema (b) Status epilephicus (sic)*"[809], but not the Verdict on Inquest: "*cerebral oedema due to meningo-encephalitis, hyponatraemia due to excess ADH production and status epilepticus*".[810]

Dr. Robert Scott-Jupp (Inquiry expert in Paediatrics)

439. Dr. Scott-Jupp believes that Claire was suffering from a progressive viral encephalitis (inflammation of the brain) or encephalopathy (disorder or disease of the brain).[811] He agrees with Dr. Evans' finding that the abnormal ratio of white cells in the CSF compared to the blood was significant, with the caveat that it was a post-mortem CSF.[812]

440. He states that on the facts of the case as presented, Dr. Harding's hypothesis, that acute deterioration and the Cerebral Oedema with coning were caused by hyponatraemia, is entirely plausible.[813] However, he notes that it is also plausible that the initial presenting illness was caused by a viral encephalitis or an encephalopathy.

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801 Ref: 236-004-017
802 Ref: 236-003-004
803 Ref: 236-003-006
804 Ref: 236-004-002
805 Ref: 236-003-007
806 Ref: 236-003-006
807 Ref: 236-003-006
808 Ref: 236-004-002
809 Ref: 091-012-077
810 Ref: 091-002-002
811 Ref: 234-002-011
812 Ref: 234-002-011
813 Ref: 234-002-012

441. He adds that is entirely plausible that a pre-existing encephalitic illness may have made the brain cells more susceptible to the damaging effects of hyponatraemia and thus more likely to swell up and become oedematous, than had this pre-existing condition not been present.[814]

442. Dr. Scott-Jupp believed that cerebral oedema was already beginning to develop by 21:30. He considers that it is very difficult to be certain whether any action at that stage would have made any difference to the outcome and that even severe fluid restriction may not have been enough to prevent the collapse that happened only three to four hours later.

Professor Brian Neville (Inquiry expert in Paediatric Neurology)

443. Professor Neville believes that Claire had an unexplained acute encephalopathy (disorder or disease of the brain) with terminal cerebral oedema with hyponatraemia related to inappropriate ADH secretion.[815] He believes the most likely antecedent cause of the SIADH was a virus infection involving the brain, and pneumonia could have been part of the intercurrent viral illness given the abnormality on the chest x-ray.

444. Although Claire had a long standing, unexplained cognitive impairment and any child with a neurology problem is more likely to develop significant SIADH, Professor Neville does not know of any evidence that her long-term brain impairment would predispose her to SIADH.[816]

445. He disagrees with Dr. Evans' hypothesis with regard to the blood / CSF white cell ratio, questioning the reliability of post-mortem CSF cell counts. In any event, he believes there was not a gross excess of white cells and the post mortem did not show evidence of meningo-encephalitis.

446. He agrees with the Coroner's finding of SIADH and hyponatraemia causing Claire's cerebral oedema, but not status epilepticus, stating that subclinical epilepsy was "*unlikely*".[817]

447. He believes that Claire was "*certainly retrievable*" by early-mid 22nd October 1996, but that it was "*quite possible*" that she could have been retrievable by taking measures at 21:00 or 23:30, although "*it is difficult to know*".[818] The possibility of Claire developing SIADH should have

814 Ref: 234-002-012
815 Ref: 232-002-014
816 Ref: 232-002-014
817 Ref: 232-002-015
818 Ref: 232-002-013

been considered on the initial sodium result of 132mmol/L, but should have been seriously considered on 22nd October 1996 when she became more drowsy, vacant and unresponsive. He believes the medical team "*firmly stuck*" to a diagnosis of non-convulsive status which seemed to stop other avenues being pursued "*until it was too late*".[819]

Professor Keith Cartwright (Inquiry Expert in Microbiology)

448. Professor Keith Cartwright, Consultant Clinical Microbiologist and the Inquiry's Expert in Microbiology,[820] believes that Claire had an acute and fulminant encephalitis,[821] with the most likely cause being a viral infection.[822] He notes that SIADH is a well-recognised complication of encephalitis.[823]

449. He considers that the white blood cell count taken on Claire's admission is strongly suggestive, though not diagnostic of, an acute infective process.[824]

450. He agrees "*completely*" with Dr. Evans' interpretation of the post-mortem CSF sample,[825] though he notes that it is a "*crude tool*" when bloodstained[826] and that the longer the interval between death and the collection of a CSF sample the greater the uncertainty attaching to the CSF ratio. He further agrees with Dr. Evans that the predominant lymphocyte nature of the white cell count makes a viral infection a "*real possibility*".[827]

451. Professor Cartwright notes Dr. Harding's view that there was no neuropathological evidence of encephalitis and queries that Claire's death was due solely to hyponatraemia stating that it does not explain:

(i) The fact that she became unwell prior to her admission to hospital with what appeared to be an acute infection

(ii) Her markedly high peripheral white blood cell count on admission

(iii) The relative leucocytosis and lymphocytosis in Claire's cerebrospinal fluid.

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819 Ref: 232-002-012
820 See List of Persons - Ref: 310-003-001
821 Ref: 233-002-006
822 Ref: 233-002-016
823 Ref: 233-002-015
824 Ref: 232-002-010
825 Ref: 233-002-015
826 Ref: 233-002-008
827 Ref: 233-002-015

452. Professor Cartwright believes that Claire did not have meningitis, as there was no real clinical evidence of meningitis (fever, headache, stiff neck) and it would have been obvious on autopsy.[828]

[828] Ref: 233-002-016

Appendix I – Evidence Received By the Inquiry

453. Following the announcement by the Chairman on or about 30th May 2008 of his decision to examine and report on Claire's case, requests for information and evidence were made to a number of bodies including:

(i) Department of Health, Social Services and Public Safety

(ii) Royal Group of Hospitals HSST

(iii) Ulster Hospital, Dundonald, Belfast ("Ulster Hospital").

(iv) South Eastern Health and Social Services Board

(v) State Pathology

(vi) Coroner for Greater Belfast

(vii) Police Service of Northern Ireland ("PSNI")

(viii) Claire's family

Documents and Other Material

454. The Inquiry's search and requests for relevant documents began in or about May 2008 when Claire' case was included within the Inquiry's investigation and are ongoing. They are guided by its Advisors and its Experts and also arise from responses to requests for Witness Statements.

455. The material received to date in relation to Claire's case includes:

(i) Claire's hospital medical notes and records[829]

(ii) Claire's GP's notes and records[830]

(iii) X-rays and scans from the Royal Belfast Hospital for Sick Children ("Children's Hospital") between 21st and 23rd October 1996

(iv) Claire's undated provisional anatomical summary autopsy report,[831] brain only autopsy report dated 11th February 1997[832]

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829 Ref: 090-001-001 to 090-054-202, and from Ref: 099-001-001 to 099-124-184
830 Ref: 112-001-001 to 112-058-081
831 Ref: 090-005-007
832 Ref: 090-003-003 to 090-003005

and Neuropathology Department's documents relating to the autopsy[833]

(v) Statements to and depositions[834] from the Inquest into Claire's death and Reports commissioned by the Coroner, including those from:

- Alan Roberts[835]
- Dr. Brian Herron (Senior Registrar, Neuropathology Department, Royal Victoria Hospital in Claire's case, and Consultant Neuropathologist at the time of Inquest)[836]
- Dr. Andrew Sands (Paediatric Registrar in Claire's case and Consultant Paediatric Cardiologist at the time of the Inquest)[837]
- Dr. David Webb (Consultant Paediatric Neurologist in Claire's case)[838]
- Dr. Heather Steen (Consultant Paediatrician in Claire's case)[839]
- Dr. R.M. Bingham (Consultant Paediatric Anaesthetist at the Hospital for Sick Children, Great Ormond Street, London) who was asked to provide an expert report on the circumstances surrounding Claire's death[840]
- Dr. Ian Maconochie (Consultant in Paediatric A&E Medicine at St. Mary's Hospital, London) who was asked to provide an expert report to the Coroner on the circumstances surrounding Claire's death[841]
- Professor Ian Young (Consultant in Clinical Biochemistry) who was asked by Dr. Michael McBride, Medical Director of the Royal Group of Hospitals to review Claire's medical records and give his opinion on whether hyponatraemia may have contributed to Claire's death)[842]

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833 Ref: 090-054-177 to 090-054-202

834 The positions of those involved is given as it was at the relevant time, unless it is relevant also to identify their position at any other time.

835 Ref: 091-003-004 to 091-003-005 and 091-004-006 to 091-004-014

836 Ref 091-005-015 to 091-005-019 and 096-006-034 to 096-006-035

837 Ref: 091-009-055 to 091-009-059 and 096-003-020,

838 Ref: 091-008-035 to 091-008-054 and 096-010-069

839 Ref: 096-004-021 to 096-004-023, 091-011-067 to 091-011-074

840 Ref: 091-006-020 to 091-006-027

841 Ref: 091-007-028 to 091-007-034

842 Ref: 096-007-039 to 096-007-040 and 091-010-060 to 091-010-066

(vi) Documents held by Claire's family[843]

(vii) Documents from the investigations of the PSNI including:

- Statements from witnesses including Mr. Alan Roberts[844], Dr. Andrew Sands[845], Dr. David Webb[846], Dr. Heather Steen[847] and Dr. Brian Herron[848]

- Reports PSNI commissioned from Dr. Brian Norman Harding[849] (Consultant Paediatric Neuropathologist at Great Ormond Street Hospital, London), Dr. Dewi Evans[850] (Consultant Paediatrician at the Singleton Hospital, Swansea), Ms Sue Chapman[851] (Nurse Consultant for Acute and High Dependency Care at Great Ormond Street Hospital, London) and Dr. Rajat Gupta[852] (Consultant Paediatric Neurologist at Birmingham Children's Hospital)

- Correspondence and other documents including documents from the Roberts' family.[853]

(viii) Correspondence from Directorate of Legal Service ("DLS") providing responses to the Inquiry's requests for information[854]

456. The Inquiry also obtained tissue blocks and histological slides held by the Neuropathology Department, to be examined and reported on by its Expert Neuropathologist, Dr. Waney Squier.

Publications

457. The Legal Team has added to its bibliography any publications referred to by its Advisors, Experts, Witnesses and legal representatives of Claire's family or any interested party. It is available on the Inquiry website and is updated as further authorities are cited.

Expert Reports & Background Papers

458. These are referred to in detail in Section III of the Opening.

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843 Ref: 089-001-001 to 089-012-043
844 Ref: 096-001-001 to 096-001-012, 096-026-356
845 Ref: 096-002-013 to 096-002-014
846 Ref: 096-009-049 to 096-009-064
847 Ref: 096-004-021 to 096-004-023
848 Ref: 096-006-032 to 096-006-038
849 Ref: 096-027-357
850 Medical Report Ref:096-022-122
851 Medical Report Ref:096-024-183
852 Medical Report Ref: 097-011-015
853 Ref: 096-019-115 to 096-019-116, 096-025-196
854 Ref: Contained at Ref 302 (see all)

Witness Statements

459. The Legal Team requested and received a large number of Witness Statements and Supplemental Witness Statements from persons involved in Claire's case. These requests were made with the guidance of the Advisors and arose from a number of materials including Claire's medical notes and records, Statements/Depositions to the Coroner, PSNI Statements or Inquiry Witness Statements, Reports from the Inquiry's Experts and documents received from DLS and other sources.

460. The Legal Team has compiled a list of all those involved in the Clinical aspects of Claire's case from all of the information received by the Inquiry.[855] It explains their position then and now, briefly summarises their role in Claire's case, and whether they have provided a statement and if so for whom. Importantly it also indicates the witnesses that it is proposed to call to give evidence during the Oral Hearing.

[855] Ref: 310-003-001