GOVERNANCE OPENING: CLAIRE ROBERTS

THE ORAL HEARINGS IN THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Chairman: John O'Hara QC

Banbridge Court House, 6th December 2012

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PREAMBLE

I. Evidence Received

1. This Opening will seek to set out the information that has been received by the Inquiry in relation to governance issues. To assist in appreciating the key events in Claire's case, the Legal Team has compiled a 'Chronology of Hospital Management and Governance',[1] which is divided into four Schedules:

   (i) Schedule 1: Position as at Claire's admission on 21st October 1996 – which shows the Protocols, Guidance, Circulars and Practices in force together with particularly relevant papers and publications

   (ii) Schedule 2: From Claire's death on 23rd October 1996 until the notification of the results of the Limited Autopsy on 21st March 1997 – showing the events that particularly relate to Claire's case as well as other developments that relate to governance

   (iii) Schedule 3: Main events in the period between the notification of the results of the Limited Autopsy on 21st March 1997 and the UTV broadcast on 21st October 2004 – which shows events in relation to Claire together with other governance developments

   (iv) Schedule 4: From the UTV broadcast on 21st October 2004 to the inclusion of Claire's case in the work of the Inquiry on 30th May 2008- showing the events that particularly related to Claire's case as well as other developments that relate to governance.

2. During the Clinical Opening on 24th September 2012[2], it was explained that following the setting up of the Inquiry on 1st November 2004[3], requests for information and evidence were sent out.

Documents

3. The call for documents has been ongoing since the resumption of the Inquiry's work in 2008 and is continuing. While much of this documentation will have been considered at the Oral Hearing into

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1 Ref: 310-021-001 *et seq*

2 Ref: 'Opening Statement- Claire Roberts, Clinical by Senior Counsel to the Inquiry' on the Inquiry website, under heading of 'Oral Hearings'

3 Ref: 008-032-093

clinical issues, it is relevant to set out those documents that have significance for governance issues.

4. To date the Inquiry has received a significant amount of material in relation to the governance issues arising in Claire's case, including:

(i) Documents held by the Coroner (Depositions from the Inquest into Claire's death and Reports commissioned by the Coroner) including those from[4]:

- Mr. Alan Roberts[5]
- Dr. Brian Herron (Senior Registrar, Neuropathology)[6]
- Dr. David Webb (Consultant Paediatric Neurologist)[7]
- Dr. Andrew Sands (Consultant Paediatric Cardiologist, the Royal Belfast Hospital for Sick, "the Children's Hospital")[8]
- Professor Ian Young (Consultant in Clinical Biochemistry)[9]
- Dr. Heather Steen (Consultant Paediatrician)[10]
- Dr. R.M. Bingham (Consultant Paediatric Anaesthetist)[11]

(ii) Documents held by Claire's family[12]

(iii) Medical Notes and Records in respect of the care and treatment of Claire Roberts[13]

(iv) Documents from the investigations of the Police Service of Northern Ireland ("PSNI")[14], including correspondence and reports[15] and email communication[16]

(v) Correspondence from the Directorate of Legal Service ("DLS") providing responses to the Inquiry's requests for information[17]

(vi) Case notes from the Ulster Hospital[18]

(vii) Royal Group of Hospitals ("RGH") Litigation Management Office Coroner's File[19]

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4 Throughout this Opening, the positions of those involved is given as it was at the relevant time, unless it is relevant to also identify their position at any other time
5 Ref: 091-003; Deposition
6 Ref: 091-005; Deposition
7 Ref: 091-008; Deposition
8 Ref: 091-009; Deposition
9 Ref: 091-010; Deposition
10 Ref: 091-011; Deposition
11 Ref: 091-006; Deposition
12 Ref: 089-001-001 to 089-012-043
13 Ref: 090-001-001 to 090-059-211
14 Ref: 096-001-001 to 096-254-215
15 Ref: 097-001-001 to 097-025-231
16 Ref: 097-029-273 to 097-084-384
17 Ref: 302-001-001 to 302-129-001
18 Ref: 099-001-001 to 099-124-184

(viii) Solicitors Inquest File[20]

(ix) RGH Media Interest File[21]

(x) Solicitor's UTV file[22]

5. The Inquiry has been referred to numerous publications and papers by its Advisors, Experts and Witnesses. The Legal Team has carried out its own research and has added publications and papers to the bibliography for Claire's case that to date has largely comprised clinical material. The bibliography is available on the Inquiry website[23] and is up dated as further material is cited.

Background Papers

6. In the Clinical Opening, I referred to the commissioning of Background Papers by Experts to provide a context for consideration of the evidence. Of particular relevance to the investigation into the governance issues involved in Claire's case are the Background Papers of:

(i) Dr. Jean Keeling (Paediatric Pathologist) on the system of procedures for the dissemination of information gained by post-mortem examination following unexpected death of children in hospital[24]

(ii) Ms. Bridget Dolan (Barrister at Law and Assistant Deputy Coroner)[25] 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 ("DoH") and Chief Medical Officer)

(iii) Professor Mary Hanratty (former Vice-President of the Nursing and Midwifery Council)[26] and Professor Alan Glasper (Professor of Children and Young Person's Nursing, University of

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19 Ref: 139-140-001 to 139-158-003
20 Ref: 140-001-001 to 140-090-001
21 Ref: 141-001-001 *et seq*
22 Ref: 137-001-001 *et seq*
23 Ref: 'Articles Index' under heading 'Key Inquiry Documents'.
24 Paper to the Inquiry into Hyponatraemia-Related Deaths: 'Dissemination of information gained by post-mortem examination following unexpected death of children in hospital' (Dr Jean Keeling)- Ref: 308-020-295
25 '*Report to the Inquiry into Hyponatraemia-Related Deaths'* (Dr. Bridget Dolan) – Ref: 303-052-715
26 '*Chronology of Nurse Education in Northern Ireland - Comparisons with UK mainland and Republic of Ireland - 1975 to date'* (Professor Mary Bridget Hanratty) – Ref: 303-048-571

Southampton)[27] 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

(iv) Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust[28] and Professor Sir Alan Craft, Emeritus Professor of Child Health, Newcastle University Education[29] 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.

Expert Reports

7. The Inquiry has also engaged Experts to provide Reports on a number of specific issues, including:

(i) Dr. Roderick MacFaul (FRCP, FRCPCH, DHC, Consultant Paediatrician) who has provided a report on the governance aspects of Claire's case[30]

(ii) Dr. Jeffrey Aronson (Consultant Pharmacologist, Oxford University Hospitals NHS Trust) who has provided a report on pharmacology issues arising out of the medication prescribed and administered to Claire over Tuesday 22nd October and the early morning of Wednesday 23rd October 1996[31]

(iii) Professor Keith Cartwright (Consultant Clinical Microbiologist, member of the scientific panel providing a steering function for the University of Liverpool DH-funded Biomedical Research Centre) who has provided a report on 'viral issues' in Claire's case including the CSF result[32]

(iv) Ms. Sally G. Ramsay (Children's Nursing Advisor) who has provided a report on Claire's nursing care at the Children's Hospital in October 1996[33]

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27 '*A Selective Triangulation of a Range of Evidence Sources Submitted to Explain the Chronology Of Nurse Education in Northern Ireland and England with Reference to the Teaching of Record Keeping and the Care Of Children Receiving Intravenous Infusions - 1975 to date'* (Dr Edward Alan Glasper) – Ref: 303-049-674

28 '*A Review of the Teaching of Fluid Balance and Sodium Management in Northern Ireland and the Republic of Ireland 1975 to 2009'* (Dr. Michael Ledwith) – Ref: 303-046-514

29 '*A Review of the teaching of fluid balance and sodium management in Northern Ireland and the Republic of Ireland 1975 to 2009'* (Professor Sir Alan Craft) – Ref: 303-047-561

30 Ref: 238-002-001 to 238-002-348

31 Ref: 237-002-001 *et seq*

32 Ref: 233-2, 233-3 and 233-4

33 Ref: 231-002-001 *et seq*

(v) Dr. Waney Squier (Consultant Neuropathologist and clinical Lecturer, John Radcliffe Hospital, Oxford) who has provided reports on the post-mortem findings and the conduct of the 'brain-only' Autopsy carried out on Claire[34]

(vi) Professor Brian Harding (Professor of Pathology & Laboratory Medicine, University of Pennsylvania) who has provided a report addressing the issue of the CSF results and the evidence of whether encephalitis can cause cerebral oedema[35]

(vii) Professor Sebastian Lucas (Department of Histopathology, St. Thomas' Hospital, London) who has provided a report on Claire's Autopsy[36]

(viii) Professor Aidan Mullan RGN, DMS, MBA who has provided a detailed analysis and overview of the clinical governance issues arising from Adam's case[37] and the period immediately preceding Claire's case.

Witness statements

8. The Legal Team has requested and received a large number of Witness Statements and Supplemental Witness Statements from others involved in Claire's case. The Legal Team has been informed in that task by:

(i) The Inquiry's Advisors

(ii) Medical notes, records and other contemporaneous material

(iii) Previous statements made, whether through Depositions to the Coroner, Statements taken by the PSNI or Witness Statements to the Inquiry

(iv) Statements from others and in some cases the evidence of others during the Oral Hearings

(v) Subsequent documents and information received from the DLS and a variety of other sources

(vi) Reports from the Inquiry's Experts

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34 Ref: 236-007-001 *et seq*
35 Ref: 235-002-001
36 Ref: 239-002-001 *et seq*
37 Ref: 210-003-003; Report to the Inquiry into Hyponatraemia-Related Deaths (Professor Aidan Mullan)

9. The Legal Team has compiled a list of all those involved in the governance aspect of Claire's case from the information received by the Inquiry.[38] It identifies positions held, briefly summarises roles, and notes whether they have provided a statement and if so for whom. Additionally it also indicates those Witnesses who may be called to give evidence during the Oral Hearings.

10. As with the evidence of the Witnesses on clinical issues, it is entirely possible for the evidence provided in a Witness Statement to be sufficient on any given issue, particularly where it is not contradicted or where it is clear from an Expert Report that further questioning of the Witness would not be useful. Should the evidence in a Witness Statement be regarded as sufficient, then it will stand in lieu of oral evidence from that Witness. The Inquiry Witness Statement, PSNI Statement or Deposition, as the case may be, of those who are not being called will be tendered as an unchallenged account.

11. In due course the Legal Team will compile a Schedule of all those whose evidence is tendered to you in that way. It will be a matter for you Mr. Chairman whether you nonetheless wish the Witness to be called.

Oral Testimony

12. Finally, there are the accumulated Transcripts of the Inquiry's Oral Hearings.[39] For the most part it will not be necessary for that oral evidence to be set out in any detail since Mr. Chairman you have had the benefit of hearing it first hand and in many cases of questioning the Witnesses yourself.

13. Some of that oral evidence bears upon governance. Of particular relevance to the governance issues arising in Claire's case is the evidence that was given by:

    (i) Dr. Heather Steen[40]

    (ii) Dr. Andrew Sands[41]

    (iii) Ms. Angela Pollock[42]

    (iv) Professor Brian Neville[43]

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38 Ref: 310-023-001 *et seq*
39 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable'
40 Ref: Transcript of Oral Hearings on 15th, 16th and 17th October 2012
41 Ref: Transcript of Oral Hearings on 19th October 2012
42 Ref: Transcript of Oral Hearings on 30th October 2012
43 Ref: Transcript of Oral Hearings on 1st November 2012

(v) Professor Keith Cartwright[44]

(vi) Ms. Sally Ramsay[45]

(vii) Dr. Roderick MacFaul[46]

(viii) Mr. and Mrs. Roberts[47]

14. In addition the evidence of some of the other witnesses touched on governance issues, such as that of Drs. Bernie O'Hare and Brigitte Bartholome in relation to staffing levels[48] and the Inquiry's expert on pharmacology Dr. Jeffery Aronson on the 'brainstem death test' that was carried out at 06:00 on Wednesday 23rd October 1996.[49]

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

15. 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:[50]

> "*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.*"

16. Despite the fact that Claire's death is not included in the Terms of Reference, 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 Children's Hospital on 21st October 1996 until her death in PICU on 23rd October 1996

(ii) 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.

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44 Ref: Transcript of Oral Hearings on 7th November 2012
45 Ref: Transcript of Oral Hearings on 8th November 2012
46 Ref: Transcript of Oral Hearings on 13th and 14th November 2012
47 Ref: Transcript of Oral Hearings on 31st October and 1st November 2012
48 Ref: Transcript of Oral Hearings on 18th October 2012
49 Ref: Transcript of Oral Hearings on 8th November 2012 p.10
50 Ref: Transcript of Progress Hearing on 30th May 2008, p.4 – Ref: 303-008-176

Chairman that Adam died at the Children's Hospital in November 1995 and the Verdict at Inquest was given in June 1996 which was almost exactly four months before Claire was admitted into the hospital

(iii) 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, including what happened immediately after her death including the 'brain-only' post-mortem carried out by the hospital. It extends to an investigation into why there was no inquest into Claire's death until 2006

(iv) The communications with and explanations given to Claire's family and others by the relevant authorities.

III. List of Governance Issues

17. The issues raised by the Terms of Reference are reflected in the Inquiry's List of Issues. The List of Issues is a working document which is updated and revised as appropriate. The current List of Issues was published by the Inquiry on 14th February 2012.[51] The governance issues surrounding Claire's case may be broadly described as:

(i) Investigation into the relevant governance issues which arise out of the care and treatment that Claire received at the Children's Hospital upon her admission until her death on 23rd October 1996

(ii) The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the death of Claire Roberts

(iii) Investigation into teaching and training in Northern Ireland on fluid management (in particular regard to hyponatraemia), record keeping and drug administration to medical students and student nurses as part of their qualification and to doctors and nurses as part of their induction, training and continuous professional development

(iv) Investigation into the changes made in patient care, particularly in regard to fluid management, between the death of Adam Strain and Claire's admission

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[51] Ref: Revised List of Issues - Inquiry into Hyponatraemia-related Deaths website, under 'Key Inquiry Documents'.

(v) Investigation into the extent of any procedures to examine adverse incidents/unexpected deaths at the time of Claire's death and following her parent's concerns expressed in 2004 and how those lessons were communicated

(vi) Investigation into the accuracy and quality of information provided by the treating clinicians to the hospital pathologist for post-mortem

(vii) Investigation into whether it was necessary to have a full post-mortem examination and to report the death of Claire to the Coroner

(viii) Investigation into the extent to which, at the time of Claire's Inquest in 2006, the Children's Hospital revised its statistical database in the light of new information about the cause of her death

(ix) Investigation into the extent to which procedures and practices in the Children's Hospital for the reporting and dissemination of information to the Department of Health, Social Services and Public Safety, Northern Ireland ("DHSSPSNI") and the medical and nursing community in general of unexpected deaths in hospital and the outcome of Coroner's Inquests, had changed following the death of Adam, but prior to the death of Claire in October 1996

(x) Investigation into the information that was actually provided to the DHSSPSNI and the medical and nursing community in general on the death of Claire in 1996 and following her Inquest in 2006

IV. Context

18. Mr. Chairman, the Inquiry now intends to examine the governance issues surrounding Claire's case. These are issues which share, to some extent, a time and a place and a context with Adam Strain's case, and issues which foreshadow the future work of the Inquiry in relation to the deaths of Raychel Ferguson and Conor Mitchell.

19. Both Claire and Adam died in the same ward of the same hospital within 11 months of each other. When Claire died some of the doctors working in Intensive Care had been there for Adam. Drs. Webb and Taylor were involved with both.[52] The names of Drs. McKaigue and

[52] Ref: 303-045; See schedule entitled 'Clinicians and Pathologists involved in more than one case'

Crean appear in both. The clinical governance structures applicable to both were the same and most of the senior personnel in the clinical management structure were still in post.

20. Hyponatraemia was an issue which had been considered by Drs. Taylor, McKaigue and Crean in their preparation for Adam's Inquest four months before. They had referenced the Arieff et al paper[53] on hyponatraemia in their formalised recommendations for H.M. Coroner. The content of the Arieff et al paper was relevant to Claire's condition. Its full title was 'Hyponatraemia and Death or Permanent Brain Damage in Healthy Children'. Dr. Taylor considered that this paper had *"wider significance in terms of alerting the profession to the potential risks of dilutional hyponatraemia"*[54] and Dr. Bartholome has recalled how the *"events surrounding this Inquest had been known to me and to most of the doctors in the Children's Hospital."*[55]

21. Dr. Michael McBride, the then Medical Director, has emphasised to the Inquiry how *"Claire's death did however reinforce for me the critical importance of ensuring that clinical practice continually evolved in line with the emerging evidence."*[56] The poignancy about this part of the Inquiry's work is that exactly the same thing might have been said about Adam's death.

22. No new governance initiatives of significance appear to have occurred in the period between November 1995 and October 1996. The Children's Hospital continued as the Regional Paediatric teaching hospital.

23. However and as is evident from the Inquiry witness statements of Dr. Michael Shields and Ms. Helen Chambers[57] at the very time of Claire's admission the Children's Hospital, as part of the RGH, was actively pursuing accreditation from the Kings Fund Organisational Audit ("KFOA"). Nevertheless, the work of the Audit Committee, the Medical Record Committee and the Clinical Risk Management Committee seemingly continued as before. The Trust Board deliberated its business but seems to have been more concerned with corporate matters than patient matters. A review of the Board Minutes for 'The Royal Hospitals NHS Trust' for the period December 1995- December 1996 reveals only three references to specific clinical incidents. There is no reference to the death of Adam Strain.

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53 Ref: 011-011-074 (British Medical Journal, May 1992)
54 Ref: Transcript of Oral Hearings on 20th April 2012 p.139 line
55 Ref: Transcript of Oral Hearing on 18th October 2012, p.4 line 11
56 Ref: WS-269-1 p.13
57 Ref: WS-301-1 (Dr. Shields) and Ref: WS-300-1 (Ms. Chambers)

24. Notwithstanding such elements of clinical governance as may have been in place in 1995-1996, it is now clear that in Claire's case, just as in Adam's, there was no formal report of the death at the time of death to the Clinical Lead of the Paediatric Directorate nor to the Director of Nursing or the Medical Director. There was no reporting of Claire's death to the Chief Executive or to the Board. It will be a matter for you Mr. Chairman, to determine the extent to which her death was noted within the structures of governance.

25. In Claire's case, just as in Adam's, there was no internal hospital investigation into the death. In neither case is there conclusive evidence of the death being reviewed at audit or mortality meetings.[58] In neither case is there any documentation to suggest that any learning was extracted from what was known, whether to be shared by way of continuous professional development or otherwise incorporated into teaching.

26. By reason of the failure to report the deaths to the Directorate Clinical Lead in the Children's Hospital there was no opportunity for an overview to be taken and the relevance of the Arieff et al paper[59] to general paediatric practice to have been appreciated. Dr. Connor Mulholland was Clinical Lead at the time of Adam's death. He was told nothing and did not seek to find out.[60] Dr. Elaine Hicks, who succeeded him, was denied the opportunity of learning about hyponatraemia in Adam's case because Dr. Murnaghan's plans for a seminar were not communicated to her[61], and in any event were subsequently abandoned.

27. The medical negligence case concerning Adam's treatment and death was still live and ongoing at the time Claire was admitted. It had become clear after Adam's Inquest that there was no real likelihood of successfully defending the legal action. Yet, there is no evidence to suggest that the Director of Risk and Litigation Management took any steps to draw clinical lessons from the litigation. Nor were any steps taken to ensure that performance failings or 'care management problems' or adverse clinical incidents were reported. The convention seems to have been that clinicians were left to themselves to determine

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58 Dr. James McKaigue states in his Inquiry witness statement that: *"Dr Steen presented Claire's death at the Audit meeting in RBHSC … at which I was present. I do not recall who else was present at that meeting. I did not make a note of this meeting"* (Ref: WS-156-2, p.6, Q.22). However, correspondence from DLS suggests that such a meeting did not take place (Ref: 302-075b-001). In any event no other evidence has been adduced to the Inquiry to confirm that the presentation actually took place. Nor has any evidence been adduced as to what happened as a result of the presentation referred to by Dr. McKaigue.

59 Ref: 011-011-074 *et seq* (British Medical Journal, 1992)

60 Ref: Transcript of Oral Hearings (Dr. Mulholland) on 21st June 2012, p.146 lines 21-22

61 Ref: WS-244-1 p.7

whether a medical error had arisen or an adverse clinical incident had occurred.

28. It will be a question for you Mr. Chairman to determine whether such self-regulation was consonant with clinical governance, best practice and the interests of healthcare standards.

29. By the time the role of hyponatraemia in Claire's death was being questioned in 2004-2006 clinical governance had developed. Clear protocol on adverse incident reporting and root cause analysis investigation was available. Mechanisms had seemingly been put in place in order that lessons learnt from clinical audit, from adverse event monitoring, 'near miss' reporting, patient complaints and clinical negligence claims were routinely translated into better practice.

30. Yet, even then, there was still no investigation into Claire's case. Ultimately it will be a matter for you Mr. Chairman to determine whether misinformation was given to both Claire's parents and H.M. Coroner, and whether a culture of defensiveness to criticism existed and, if so, its likely significance.

31. Such similarities as existed between Adam's case and that of Claire's are relevant, not for the purposes of clinical comparison, but by reason of those patterns of clinical governance management that may emerge.

32. Some areas of governance enquiry are common to both cases. In other respects, Claire's case presents its own problems. The first of these relates to the practices and directives that governed the very responsibility of a doctor for a patient, namely:

V. Consultant Responsibility

33. Dr. Heather Steen was the consultant paediatrician *"on call"* when Claire was admitted to the Children's Hospital in the evening of Monday 21st October 1996. The hospital admission documentation records *"Dr. H.J. Steen"* as *"the Consultant."*[62] Dr. Steen has accepted that Claire's case fell within her remit.[63]

34. Dr. MacFaul describes that *"a consultant takes responsibility for all patients admitted under their care either by planned or acute admission and then responsibility for continuing care."*[64]

35. Claire's case records do not, however, contain any reference to:

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62 Ref: 090-014-020
63 Ref: 091-011-067
64 Ref: 238-002-106

(i) Dr. Steen seeing Claire at any time in the 33 hours between the time of her admission and her collapse

(ii) Any information that Dr. Steen may have had as to Claire's presence or her illness

(iii) Any request for Dr. Steen to examine Claire

(iv) Any communication between Dr. Steen and Dr. Webb or between Dr. Steen and any other member of her medical or nursing team, whether direct or indirect, in relation to Claire

(v) The whereabouts of Dr. Steen during this period

(vi) Any referral by Dr. Steen whether for an opinion or transfer of care

(vii) What the nursing staff were told in relation to the consultant with responsibility for Claire's care

(viii) What Claire's parents were told about the identity of the consultant responsible for Claire's care.

36. In her email of 8th February 2005 to Mr. Walby, Dr. Steen writes *"prior to her coning, although I was her admitting consultant and would have been aware of her and the fact that Andrew Sands had asked David Webb to see her, I did not actually see or examine her."*[65] Dr. Steen gave evidence at the Inquest that she remembered contacting Allen Ward and being *"told Dr. Webb had seen her and had taken over her management."*[66] She explained: *"I was not contacted until 3am on Tuesday morning. I would have expected Dr. Webb to be contacted first if the concern was neurological."*[67] She has further informed the Inquiry that "*I note in my statement to the Coroner that I recollected contacting the ward and being told Dr. Webb had seen her and had taken over her management. I no longer recollect this. When I was called to PICU at 03:00 on 23rd October I contacted Dr. Webb and undertook joint care with him and the paediatric intensive care consultants."*[68] Giving her evidence at the Oral Hearings Dr. Steen added: *"I am not saying Claire was no longer my patient, but that Dr. Webb was doing her management and that everything was moving forward, and I was not required back in the hospital"*[69] and *"until its formally taken over and there's a formal transfer, and Dr. Webb and I discuss it, I remain the named consultant."*[70]

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65 Ref: 139-132-005
66 Ref: 091-011-067
67 Ref: 091-011-067
68 Ref: WS-143-1p.46
69 Ref: Transcript of Oral Hearings on 15th October 2012 p.93 line 23
70 Ref: Transcript of Oral Hearings on 15th October 2012 p.94 lines 4-6

37. Dr. Webb is however clear in his view that Dr. Steen was the consultant responsible for Claire's care and treatment from the time of her admission to the time of her death and that *"I was not asked to take over her care and would not expect a transfer of care to be made without being asked. When care is transferred between teams a note is made routinely to document this."*[71]

38. Dr. Sands 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. Steen also. He thought the responsibility for Claire's management was shared.[72] There would not appear to have been a clear and universally understood policy or procedure in respect of inter-consultant referrals, or transfer of overall responsibility. Dr. Sands observed *"whilst it can work very well where two consultants share the care of a patient, it can also lead to an ambiguity."*[73] He is noted as having told the Coroner at Inquest that *"there is seldom anything written down when a case is transferred from one consultant to another."*[74]

39. The lead responsibility for Claire was highly important and should have been made clear.[75] Dr. MacFaul recounts how *"consultant allocation of patients on a ward which caters for a number of consultants is made clear in a variety of ways. The name of a consultant may be entered on a board or a card attached to the patient's bed, also in many wards, then and now, this is entered on to a white board at the nurses' station. It will also appear on the nursing Kardex and should appear on the hospital information system."*[76] Dr. MacFaul goes on to highlight the significance of 'lead consultant responsibility': *"The consultant would be responsible overall both for the care of the child and the supervision of the junior medical staff in the team and [would] at the same time be responsible for the quality of service provided for that patient by the medical and nursing staff."*[77] A consultant would also be expected to bear responsibility for the training of junior medical staff and for correcting the failings of trainees in respect of drugs and dosage calculations.

40. The Inquiry's experts Dr. Scott-Jupp on general paediatrics and Professor Neville on paediatric neurology are in agreement with the importance to be accorded the lead responsibility for Claire's case from the perspective of her effective care and treatment.

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71 Ref: WS-138-1p.8
72 Ref: WS 137-2p.5
73 Ref: Transcript of Oral Hearings on 19th October 2012 p.218 line 15
74 Ref: 097-012-118
75 Ref: 310-005 'Schedule of Consultant Responsibility'
76 Ref: 238-002-038
77 Ref: 238-002-248

41. Professor Neville having reviewed the documentation concludes that Dr. Steen and her medical team retained primary care of Claire whilst seeking specialist advices from Dr. Webb.[78] Dr. Scott-Jupp expresses the view that Claire's care was *"very much"* within the remit of the general paediatrician[79] and that any transfer of care should have been recorded in the notes by the team requesting the transfer and that all nurse medical and nursing teams should have been made aware of any transfer at their respective handover meetings.[80]

42. Ms. Ramsey highlights the uncertainty that could arise in the situation in which Dr. Webb, as a consultant neurologist, having spent time *"examining Claire and interviewing her mother, whereas Dr. Steen did not visit Claire"*[81] may have allowed *"nurses [to] have concluded that Dr. Webb had taken over her care."*[82] Notwithstanding that, it is clear that the nursing information sheet compiled by Nurse McRandal expressly identifies Dr. Steen as the consultant responsible.[83]

43. Dr. MacFaul notes in relation to the evening of 22nd October 1996 that: *"it is not evident which consultant general paediatrician was on-call and thus taking responsibility in delegated form for Claire after 17:00, nor whether that consultant was informed of Claire's illness in terms of nature or severity, nor of the deterioration which occurred over the evening. It is not evident why that consultant was not involved in Claire's care when the very low sodium of 121mmol was detected."*[84] In addition Dr. Steen states that *"there was a paediatric consultant on-call 09:00 22nd October 1996 until 09:00 on 23rd October 1996. I was not that consultant and do not know who was on-call. After 17:00 hours that consultant would have been first point of contact for paediatric medical problems. There would have been a paediatric neurologist on-call but I do not know who that was. Practice was that the Registrar or senior nurses, Monday to Friday, could also contact the named consultant for that patient even though that consultant was not on-call and did not have to respond if unable to do so."*[85]

44. It is to be noted that it was Dr. Steen who was contacted when Claire collapsed. It is unclear why she was called rather than the Acute Paediatric Consultant who was on-call at the time. Dr. Steen provided a possibly contradictory explanation for this: *"on the on-call rota there is a paragraph, very clearly written, that if there is a deterioration in a patient, that you contact the named consultant first, because quite often we can deal with it as we know the patient. And then, if that consultant for some reason*

78 Ref: 232-002-007
79 Ref: 234-002-006
80 Ref: 234-002-007
81 Ref: 231-002-018
82 Ref: 231-002-018
83 Ref: 090-041-142
84 Ref: 238-002-051
85 Ref: WS-143-1p.45

isn't contactable, because they don't have to be, they're no longer on call, you go to the on-call paediatrician."[86] The DLS have advised that *"unfortunately my client has no records confirming who had been the official on-call paediatrician at that time."*[87] The on-call rota[88] for the time did not provide a column for the identified Paediatric Consultant. This omission is seen by Dr. MacFaul as representing a *"significant clinical risk for the management of emergencies in Accident & Emergency, Children's Ward, Intensive Care and for the Switchboard. The design of this on-call rota constitutes a significant shortcoming in clinical governance."*[89]

45. The General Medical Council ("GMC") 'Principles of Good Practice' enjoin all doctors that they *"must be satisfied that when ... off duty, suitable arrangements are made for [their] patient's medical care. These arrangements should include effective handover procedures and clear communication between doctors."*[90] By implication this may be taken to impose a collective responsibility upon all consultants to liaise with colleagues and co-ordinate individual activities so as to ensure appropriate levels of patient care.

46. None of the issues of 'lead responsibility' that arise from Claire's case appear to have been addressed at any clinical audit meeting.

47. It will be a matter for you Mr. Chairman to determine the extent to which the lead responsibility for Claire's care and treatment for the afternoon and evening of Tuesday 22nd October 1996 was clear to the clinical and nursing staff and, if not, the likely effect that had on her care and the communications with her parents. It will also be a matter for you to assess the extent to which communications about the lead responsibility for Claire's care and treatment were adequately recorded.

48. The issue of 'lead responsibility' also gives rise to the related issue of the availability of Dr. Steen over the course of Tuesday 22nd October 1996. Whilst that is primarily a clinical issue it also concerns the governance issues of 'staffing levels and cover' and 'communication between clinicians'. Both of those are matters that are dealt with in more detail later on but as regards Dr. Steen, they raise some discrete issues.

49. Dr. Steen's evidence is that the Children's Hospital had a 'consultant-led service'. She personally seems to have had only two days when she was rostered to be in the Children's Hospital, one of which was

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86 Ref: Transcript of Oral Hearings on 16th October 2012, p.25 lines 5-12
87 Ref: 302-068a-001
88 Ref: 302-031-003
89 Ref: 238-002-051
90 Ref: 314-001-011; 'Good Medical Practice' October 1995

Tuesday mornings from about 09:00 to about 13:00. On all other occasions she was working in the community and, in particular, on Tuesday afternoons she had a clinic at Cupar Street from about 14:00 to 17:00. In her case a 'consultant-led service' raises particular issues about 'cover' and 'continuity'. For example the appropriate arrangements to be made if she is unable to carry out her ward duties on a Tuesday, as appears to have been the case during Claire's admission, and yet may be unavailable in the afternoon particularly if that is the Tuesday when her registrar is himself carrying out a clinic, as again appears to have been the case during Claire's admission.

50. Dr. MacFaul is of the view that:

"Dr. Steen should have made sure that her junior staff knew when to call her and how to call her. If Dr. Steen knew when she was not available or likely [not] to be contactable, she should have made arrangements with a colleague to provide care for her. It is not clear whether another consultant paediatrician was covering the ward during the daytime hours on 22nd October nor who was responsible for the evening of 22nd October for covering the general paediatric service ... While on-call out of hours a consultant general paediatrician would expect to be called by a member of their junior staff at any time for telephone advice or to permit face-to-face consultation with the child and thus expect a return to the hospital to see the child at any time. Such a recall consultation would take place when a child was significantly ill or where a diagnosis or procedure lay outside the competence expected of the junior medical staff in the team[91] *… The consultant would need to be satisfied from experience or knowledge of the junior doctors that those doctors were competent to undertake … his or her responsibility. This would be custom and practice rather than in written documentation, and, would be regarded as a means of discharging a consultant's professional responsibilities"*[92] *... "I would have expected a telephone notification from the junior doctor to the consultant given the degree of reduced level of consciousness and the diagnosis made of encephalitis. It is this sort of issue which comes up in clinical meetings during presentations of cases or at clinical audit meetings."*[93]

51. Dr Steen's evidence is that the clinicians did know how to contact her and that she had a mobile telephone that could be used. However, Dr. Sands' evidence does not make it clear that he was aware of how to reach her in the morning, although the Inquiry witness statements of both Dr. Steen and Dr. Sands suggest that she was contacted at least in the afternoon.[94] However, none of that is documented so it is not possible now to comment on the adequacy of the information communicated and the appropriateness of the response.

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91 Ref: 238-002-041
92 Ref: 238-002-107
93 Ref: 238-002-137
94 Ref: WS-143-1 p.7 (Dr. Steen) and WS-137-1 p.20 (Dr. Sands)

52. Dr. MacFaul takes the view that "*given the presentation of significantly altered level of consciousness, which had persisted overnight, and her illness severity [that he] would have expected Claire to have been seen at the latest, by the morning following her admission, by the consultant responsible for her care. Or, if the consultant was not able to attend ward round, then at a minimum, Claire should have been discussed with her.*"[95] Further and if unable to attend a scheduled ward round, then Dr. Steen should have made other arrangements to have the children under her care reviewed. The apparent failure of Dr. Steen to attend upon Claire at the morning consultant ward round meant that early consultant opinion and focused treatment plan were absent from her care. This was, in the view of Dr. MacFaul "*a shortcoming in the arrangements for the provision of care for Claire.*"[96]

53. None of the issues arising out of the arrangements for effective communications between Dr. Steen and the ward in relation to the care and treatment of children causing concern, which arise out of Claire's case, appear to have been addressed in any clinical audit meeting.

54. It is for you Mr. Chairman to determine, not only the identity of the consultant with overall responsibility for Claire's care, but also whether there was a failure in discharging consultant responsibility. Further whether any such failure was indicative of a broader systemic failing in communication, delegation and contingency planning.

Staffing Levels

55. Broader responsibility for the provision of 24-hour cover to patients rests with the Paediatric Clinical Directorate. Dr. MacFaul expresses some reservations about levels of staffing and workload in that the resident medical staffing out-of-hours in the Children's Hospital was thought by him to be low given the range of responsibilities undertaken. He referred in his oral evidence to the workload on Dr. Bartholome who was the registrar in the 'night-team' on 22nd October and into the morning of 23rd October 1996 as being: "*clearly an unreasonable workload.*"[97] Thus early consultant involvement in complex or unusual cases was rendered all the more relevant given the limited level of medical staffing otherwise available.[98] Dr. Steen advises that "*consultants only have a small amount of time allocated to ward work and have fixed commitments at other times often off site e.g. clinics.*"[99]

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95 Ref: 238-002-038
96 Ref: 238-002-042
97 Ref: Transcript of Oral Hearings on 14th November 2012, p.113 line 18
98 Ref: 238-002-052
99 Ref: WS-143-1 p.19

56. Some discussion of workload pressures appears in the RGH Strategy for Children's Services- 'Getting it Together' (1996).[100] This policy document received broad input from Drs. Mulholland, Hicks and Crean in conjunction with Mr. Gordon Clarke, Paediatric Directorate Manager. It recognised that workload pressures were becoming evident and *"it was acknowledged that nursing and medical staff are under considerable pressure of work and there were cases where mothers felt that standards of care were inadequate or insensitive. The first phase of the redevelopment of the Royal Belfast Hospital for Sick Children will alleviate some of these problems, but the Trust is concerned that the pressure on staff has continued to intensify."*[101] It was noted that *"the Royal Hospitals have reviewed staffing levels and cost pressures within the Royal Belfast Hospital for Sick Children, on the basis of current activity levels."*[102] It concluded that there was a shortfall in staffing across the range of clinical professions which: *"continues to inhibit the provision of comprehensive assessment, treatment and rehabilitation services in a number of specialties."*[103] Dr. Bartholome has confirmed in her evidence that this was an issue that had been raised with management.[104]

57. In relation to staffing levels it will be recalled that:

    (i) Dr. O'Hare states that "*there was one registrar covering, I think, about 120 patients, which included four ICU beds*"[105] and that she worked a 36 hour shift between the 21st to 22nd October[106]

    (ii) Dr. Bartholome was the sole Registrar on duty in the Children's Hospital between 17:00 on 22nd October 1996 and 04:00 on 23rd October 1996 and was responsible for 114 inpatients in 12 wards in addition to covering the A&E department[107] which dealt with about 100 patients per day, half of whom were seen after 17:00[108]

    (iii) Dr. Sands agrees, in relation to there being a single registrar in charge of the Children's Hospital overnight, that "*that was an onerous job, a big responsibility.*"[109] Furthermore, one Tuesday afternoon in four he was engaged with Dr. Nan Hill's clinic, the 'cover' arrangements for which are not yet clear.

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100 Ref: WS-266-1 p.28
101 Ref: 266-1 p.51
102 Ref: 266-1 p.54
103 Ref: 266-1 p.54
104 Ref: Transcript of Oral Hearings on 18th October 2012 p.58 line 17
105 Ref: Transcript of Oral Hearings on 18th October 2012, p.124 lines 6-7
106 Ref: Transcript of Oral Hearings on 18th October 2012, p.173 lines 11-13
107 Ref: 302-139-001
108 Ref: Transcript of Oral Hearings (Dr.Bartholome) on 18th October 2012 p.10 line 18
109 Ref: Transcript of Oral Hearings on 19th October 2012, p.47 line 15

(iv) Dr. Bartholome gives her view that the relative inexperience of the SHOs on duty was "*a worry because you had to depend on junior staff who were very inexperienced... as a safety issue it was always a big concern [because] children can become sick very quickly.*"[110] "*I would have had to keep an eye on every junior doctor. That is part of the role of a registrar*"[111]

(v) Whilst Ward Sister Angela Pollock had no difficulty deploying two trained children's nurses, there was no Night Sister on Allen Ward.[112] Rather, the "*Night Sister would have covered the entire hospital*"[113]

(vi) Ward Sister Pollock has stated that when she could not cover Allen Ward, an F-grade Sister would act as back up. However, because there would not seem to have been any F-grade Sisters in post until November 1996- she conceded that it would have been a fairly common event to have an E-grade Sister take charge.[114] Accordingly, in October 1996 it would appear that Allen Ward could fall under the responsibility of an E-grade Sister during the day and under a Ward Sister at night who was also charged with covering the rest of the Children's Hospital

(vii) Further and in addition: "*There was no permanent Nurse Manager in post in the Paediatric Directorate in 1996. Three of the Sisters in RBHSC were acting into this position and had responsibility for different wards/departments of RBHSC.*"[115] Unfortunately neither the Trust nor the Nurses themselves can assist the Inquiry in ascertaining who was responsible for Allen ward.[116]

58. The consideration that should have been given to 'staffing levels' in relation to the types of issues that arose in Claire's case is a matter to be further explored during the Oral Hearings.

VI. Communication with Parents

59. The NIHPSS 'Charter for Patients and Clients' (March 1992)[117] accords a "*right to… be kept informed about your progress. Your relatives and friends are also entitled to be informed.*"[118] Accordingly, and "*if it is accepted that*

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110 Ref: Transcript of Oral Hearings on 18th October 2012, p.13 lines 1-15
111 Ref: Transcript of Oral Hearings (Dr. Bartholome) on 18th October 2012 p.17 line 20
112 Ref: WS-225-2 p.9
113 Ref: Transcript of Oral Hearings (S/N McRandal) on 29th October 2012 p.11 line 16
114 Ref: Transcript of Oral Hearings on 30th October 2012 p.154 line 5
115 Ref: WS-225-1 p.9; Ward Sister Pollock
116 Ref: 302-160
117 Ref: 306-085-004
118 Ref: 306-085-004

the patient has a right to information about his condition it follows that the professional practitioners involved in his care have a duty to provide such information."[119]

60. During the course of the Oral Hearings on clinical matters you heard evidence, Mr Chairman, from the clinicians in respect of their impressions of the seriousness of Claire's condition. Dr. Steen has stated that *"this child's condition was extremely serious... the picture during the night is getting more and more complex: a sicker and sicker child with more complications."*[120] Dr. Sands confirms that he considered Claire to be *"very neurologically unwell"*[121] and Dr. Bartholome too accepts that *"there's no doubt she [Claire] was the sickest patient on the ward at that time."*[122] The Inquiry's experts have also expressed the view that Claire was very unwell. The issue is therefore the extent to which any of that was adequately communicated to Claire's parents.

61. The edition of the Paediatric Prescriber that is specifically produced by the Children's Hospital which was in operation at the time states in relation to 'status epilepticus': *"Once seizure controlled, institute maintenance therapy, keep patients informed and supported."*[123]

62. Dr Stevenson acknowledged in his evidence that as he was 'ward-based' he would have been a point of contact for the nurses and parents.[124] Nurse Sarah Jordan has described the channels of communication between nurse and parent in general terms *"you communicate with families all the time when you are working with their children, so you have an ongoing conversation, and parents are quite good at asking questions and doctors will speak to parents and then you'll come along behind and check that they understand what they have been told and there are no other questions arising from the conversation they've had with the doctor."*[125]

63. However, Mr. and Mrs. Roberts have expressed upset that they were not informed by clinicians as to the severity of their daughter's illness. They recall:

    (i) "*My understanding of Claire's condition when I left the hospital that evening (21st October) was that she had nothing more than a tummy bug with no concerns raised about Claire's condition*"[126]

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119 Ref: 314-002-001 *et seq*; UKCC: '*Exercising Accountability*' March 1989.
120 Ref: Transcript of Oral Hearings on 16th October 2012, p.26 lines 11-18
121 Ref: Transcript of Oral Hearings on 19th October 2012, p.238 line 23
122 Ref: Transcript of Oral Hearings on 18th October 2012, p.44 lines 8-9
123 Paediatric Prescriber, Royal Belfast Hospital for Sick Children, 3rd edition July 1994 - Ref: 311-023-010
124 Ref: Transcript of Oral Hearings (Dr. Stevenson) on 15th October 1996, pgs.107-108
125 Ref: Transcript of Oral Hearings (Nurse Jordan) on 29th October 2012 p.105 line 16
126 Ref: WS-253-1 p.5

(ii) At the ward round on morning of 22nd October: "*Dr. Sands did not express any view on the seriousness or otherwise of Claire's condition*"[127]

(iii) On evening of 22nd October: "*My understanding of Claire's condition when I left hospital at 21:15 was that she was comfortable and in her night sleep*"[128]

(iv) "*No one expressed any concerns regarding Claire's condition*"[129]

(v) "*The response of the nursing staff appeared casual, relaxed and without concern*"[130]

(vi) "*The staff replied 'okay' and 'see you in the morning'*"[131]

(vii) "*To highlight the low level of concern I had at that time I do recall watching television (A Question of Sport) with my son.*"[132]

64. Dr. Steen told you Mr. Chairman on 15th October 2012 that: *"I think we failed the parents completely around communication. I failed to… and the team failed… to get through to the Roberts just how sick Claire was."*[133]

65. Dr. Sands recounts a discussion with Mrs. Roberts in which he *"expressed concerns regarding Claire. I would only have given limited detail, pending consultant assessment."*[134] *"This discussion has not been recorded in the notes."*[135] When further pressed for detail Dr. Sands recalls*:* *"Discussing with her family that Claire may well have a significant neurological problem. I believe that I would have explained concerns regarding possible ongoing seizure activity and the need for specialist advice from a neurologist"*[136] and *"I did not record Claire's parents understanding of information given."*[137] Mr. Roberts recalls that on the evening of 22nd October: *"A viral illness was discussed and I also recall a doctor saying that Claire may be experiencing some form of internal fitting."*[138]

66. A review of statements made by Mr. and Mrs. Roberts to the Inquiry reveals that they do not believe that they were informed of the:

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127 Ref: WS-253-1 p.8
128 Ref: WS-253-1 p.11
129 Ref: WS-253-1 p.12
130 Ref: WS-253-1 p.12
131 Ref: WS-257-1 p.13
132 Ref: WS-253-1 p.11
133 Ref: Transcript of Oral Hearings on 15th October 2012 p.56 line 21
134 Ref: WS-137-1 p.51
135 Ref: WS-137-1 p.52
136 Ref: WS-137-2 p.7
137 Ref: WS-137-1 p.52
138 Ref: WS-253-1 p.7

(i) Name of the consultant in charge of Claire's care[139]

(ii) Further differential diagnoses of encephalitis,[140] encephalopathy[141] and or some kind of *"neurological illness"*[142]

(iii) Nature of treatment to be given[143]

(iv) Prognosis[144]

(v) Number (and nature) of the different medications prescribed for Claire[145]

(vi) GCS scores[146] and their likely significance

67. In addition, it would seem from the evidence that you have heard Mr. Chairman that they were not informed about Claire's low serum sodium result and whether it was of any significance, nor about what tests and examinations could be carried out to confirm the differential diagnoses and check on the efficacy of the treatment being administered.

68. Part of the explanation for that might be that the evidence during the Oral Hearings on the clinical issues indicated that the clinicians did not appreciate the possible significance of Claire's serum sodium level of 132mmol/L before intravenous fluids were administered and because in large part testing such as CT scans and EEGs were postponed until the next day when she suffered her respiratory arrest and it was not until the evening of Tuesday 22nd October 1996 that a further blood test was carried out which revealed that she was seriously hyponatraemic.

69. It will be for you Mr. Chairman to determine the adequacy of the communications with Claire's parents about her condition and treatment.

70. Dr. Sands' evidence is that during his examination of Claire during the ward round he did try to explain to Claire's parents his thoughts on her condition and its seriousness to her parents in terms that he believed they could understand and without unduly frightening them. Dr. Webb cannot his conversation with Claire's mother during his

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139 Ref: WS-253-1 p.6
140 Ref: WS-253-1 p.8
141 Ref: WS-253-1 p.8
142 Ref: WS-253-1 p.11
143 Ref: WS-253-1 p.6
144 Ref: WS-253-1 p.7
145 Ref: WS-253-1 p.11
146 Ref: WS-257-1 p.12

examination of Claire at about 17:00 but *"imagines he would have relayed the position to them as set out in the notes."*[147]

71. Notwithstanding the evidence of the clinicians about their recollection of events, it is unclear why no record was made of the information given to Claire's parents over 22nd October 1996.[148] The GMC 'Good Medical Practice' Guidelines direct at paragraph 3 that doctors: *"in providing care must keep clear accurate and contemporaneous patient records which report… information given to parents."*[149]

72. Commenting on this glaring lack of record Ms. Sally Ramsey gives as her opinion: *"that as a minimum there should have been a record of the information given to Claire's parents, their understanding and concerns."*[150] Dr. Robert Scott-Jupp is of the view that: *"the parents should be told of any change of diagnosis, possible reasons for any deterioration and the management plan."*[151] However, he would have: *"expected them to be informed in general terms of the significant neurological condition."*[152] Dr. MacFaul observes that: *"There is no documentation in the notes of communication with parents but from my knowledge of case notes and audit results in a significant number of units I am aware that this is frequent (although undesirable), so this cannot be seen as an unusual shortcoming for the time. It is now getting better partly as a result of audit scrutiny."*[153]

73. Seemingly, the only internal review touching upon the communication with Claire's family was conducted by Professor Young in 2004. He formed the conclusion that: *"communication with the family at the time of Claire's death seemed to have been reasonably good. However, some aspects of Claire's condition may not have been discussed at the time (such as hyponatraemia)."*[154]

74. There is no evidence that the records of Claire's case were ever subjected to audit scrutiny. There is little evidence of the impact, if any, that the *"Multidisciplinary Medical Records Committee"*, which the Chief Executive William McKee states was in place by 1995/96,[155] had upon the quality of the records in this significant respect. There is no evidence that the system for medical records scrutiny was functioning efficiently. This may have prompted the plea voiced at the Paediatric Directorate Clinical Audit meeting on 10th December 1996 that *"it is*

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147 Ref: WS-138-1 p.40

148 There is a 'counselling record' of what was said to Claire's parents but that was made of communications with them after Claire's respiratory collapse and she was beyond any hope of saving – Ref: 090-028-088

149 Ref: 314-001-004

150 Ref: 231-002-032

151 Ref: 234-003-007

152 Ref: 234-003-007

153 Ref 238-002-040

154 Ref: WS-178-1 p.6

155 Ref: WS-061-2 p.10

important that each unit continues to do the case note review audit and the completed forms should be returned to the Clinical Audit Department on a monthly basis."[156]

75. It may have been a long-standing problem, which had not been adequately addressed given that: *"in 1995, a 'Junior Monitor' exercise was undertaken in wards throughout the Royal Belfast Hospital for Sick Children. Junior Monitor is a recognised tool for assessing the quality of care given to children and their families in hospital. The survey identified areas of strength, and areas (such as documentation) where there was scope to improve standards."*[157] The Medical Director, Dr. Carson, had addressed the RGH Hospital Council on 29th April 1996 *"on some progress which [had] been made on risk management issues [and] drew attention to a workshop which [had] been scheduled for September on medical negligence issues which would address matters such as communication of information to parents."*[158]

76. There is also a flow of information from parents to clinicians and nursing staff about their children, which is regarded as important since they are usually the best source of information on their child's normal presentation. This was particularly important in Claire's case given that she had experienced some 'seizure' activity when she was very young and had been successfully treated but the information from the Ulster Hospital about it was not received until the Tuesday afternoon and was scanty.[159] In addition, Claire's parents were best able to describe her usual capabilities, whilst Claire was unable to articulate her own symptoms.

77. During the course of his oral evidence Dr. Scott-Jupp emphasised the general importance of obtaining information from parents: *"In a child, particularly in a child known to have learning difficulties or a long-term neurological handicap, one has to always ask the parents what their normal functioning level is and judge it. So taking a Glasgow Coma Scale in isolation can be quite unhelpful."*[160]

78. The entry made by Dr. O'Hare in Claire's clinical notes on Monday 21st October 1996 indicates that she sought to obtain some of that type of information.[161] So too does the entry made by Dr. Stevenson recording Dr. Sands' examination of Claire during the ward round on Tuesday 22nd October 1996.[162]

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156 Ref: 302-083a-002
157 Ref: WS-266-1 p.52
158 Ref: 305-117-037
159 Ref: 090-013-015
160 Ref: Transcript of Oral Hearings on 12th November 2012 p.156 line 14 *et seq.*
161 Ref: 090-022-050
162 Ref: 090-022-052

79. Dr. Webb records in Claire's clinical notes at about 14:00 on Tuesday 22nd October 1996 that he does not have: *"a clear picture of the prodrome + yesterdays episodes. Her motor findings today are probably long standing but this needs to be checked with her notes."*[163] In addition, Dr. Webb has recalled how *"on examining her arms and her legs I noted that she had some stiffness and that her reflexes were abnormal. It would appear that I did not have access to her previous hospital chart as I made the comment that these findings 'needed to be checked with her clinical notes'. It was certainly possible in a child with known learning difficulties and epilepsy that the findings in her limbs could have been long standing."*[164] However, there is no evidence from his note at his subsequent examination of Claire at about 17:00 that he had taken the opportunity to inform himself of such matters in any discussion with Claire's mother.[165] Nor is there any evidence that he factored any information that he received from Claire's mother, who was present with her daughter throughout most of the day, into any assessment that he might have made about Claire including from her 'Central Nervous System Observation Chart'[166] or the 'Record of Attacks Observed'.[167]

80. It will be a matter for you Mr. Chairman to determine the adequacy of the queries made about Claire and or the records made of them.

81. The GMC 'Good Medical Practice' Code provides a reminder that to establish a successful relationship between doctor and patient that the doctor *"must listen to patients."*[168] It is axiomatic that listening is essential to oral communication.

82. The evidence of Claire's parents is that, in a number of respects, the information they provided was incorrectly recorded. Exception is taken to Dr. Webb's record entered into the chart at 17:00 on the 22nd October 1996 in that it states: *"Background from mum… She had some focal seizures on Monday with right-sided stiffening."*[169] This allowed Dr. Webb to entertain no doubt that she had a convulsive seizure on 21st October 1996 leading to his diagnosis principally of an *"epileptic encephalopathy."*[170] Dr. Webb *"Cannot recall the details of the episodes reported to me but my interpretation of the information provided was that these episodes represented focal seizure activity."*[171]

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163 Ref: 090-022-054
164 Ref: 139-098-018
165 Ref: 090-022-055
166 Ref: 090-039-137
167 Ref: 090-042-144
168 Ref: 314-001-006
169 Ref: 090-022-055
170 Ref: WS-138-1 p.17
171 Ref: WS-138-1 p.38

83. As far as Claire's parents are concerned, that failing to record the information which they had provided accurately is most particularly noted in the post death processes of Autopsy Request and Autopsy Report where information detailing presenting illness and epilepsy do not accord with Mr. and Mrs. Robert's recollection.

84. Mrs. Roberts denies telling Dr. Webb that Claire had suffered a seizure on 21st October or on any other previous day or that she had seen right sided stiffening.[172] When asked about this during her evidence, Mrs. Roberts reiterated: *"On Monday, definitely not."*[173] The content of the medical notes and records, GP referral and record of history and presenting symptoms would appear consistent with her recollection. Furthermore, Mrs. Roberts was adamant that she had not stated that Claire was: *"Well until 72 hours before admission"* as is stated in Autopsy Request Form[174] provided by Dr. Steen. She stated in her oral evidence: *"Could I also say that this is our daughter we're talking about and if she had been unwell 72 hours before admission, she would have been brought to the hospital. The GP would have been contacted."*[175] She went on to say that in such circumstances she would not have taken her to church on the Sunday 20th October nor allowed her to go to school on the Monday 21st October 1996.

85. Without a note of the history given, internal review, audit or investigation of Claire's care the differences between the clinicians and Claire's parents may prove difficult to resolve.

86. It will be a matter for you Mr. Chairman, to determine whether such elements of internal control might have been expected in 1996, and whether they were in place in 1996. Equally, it will be a matter for you to determine the extent to which such systems would have assisted in monitoring standards and achieving the quality assurance that is the key to demonstrating clinical governance standards.

87. Mrs. Roberts has told the Inquiry: *"Serum sodium and hyponatraemia was never mentioned to me during Claire's admission to RBHSC in October 1996. I was not told of serum sodium and hyponatraemia prior to 2004"*[176] She also states that *"Dr. Steen explained that the virus from Claire's stomach had spread and travelled into Claire's brain and caused a build up of fluid"*[177] and *"Dr. Steen informed me that everything possible had been done for Claire and nothing more could have been done."*[178] *"We accepted the explanation given*

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172 Ref: WS-257-1 p.11
173 Ref: Transcript of Oral Hearings on 31st October 2012, p.101 line 16
174 Ref: 090-054-183
175 Ref: Transcript of Oral Hearings on 1st November 2012 p.206 line 12 et seq
176 Ref: WS-257-1 p.15
177 Ref: WS-257-1 p.15
178 Ref: WS-253-1 p.14

by both doctors."[179] Dr. Steen states however, that *"I think the low sodium was mentioned to Claire's family. We didn't use the word 'hyponatraemia' and we don't particularly now."*[180]

88. The important issues as to what Claire's parents were told or not told and the extent to which the information given was adequate or misleading will be addressed in greater detail during the Oral Hearings in connection with the events and procedures that followed Claire's death.

89. The oral evidence of both Dr. Scott-Jupp and Dr. MacFaul is that the parents should have been given information before their departure on the evening of Tuesday 22nd October 1996 that would have enabled them to have exercised the choice of staying with their daughter if that was possible. The oral evidence of Mr. and Mrs. Roberts is that they could and would have made such arrangements if they had been told how seriously ill Claire was and they refer to the arrangements that they made when they brought her to the Children's Hospital on the evening of Monday 21st October and when they came to Children's Hospital in the early hours of Wednesday 23rd October 1996 after being informed of her collapse.

90. It is a matter for you Mr. Chairman to consider whether Mr. and Mrs. Roberts should have been advised as to the seriousness of Claire's condition and whether they should have been allowed to leave the hospital unaware that Claire was really very sick and, as we now know, quite possibly dying.

91. You might consider it ironic Mr. Chairman that at the time of Claire's care and treatment at the Children's Hospital on 22nd October 1996, which has been the subject of criticism by the Inquiry's experts, the Children's Hospital together with the rest of the RGH was in the process of applying for accreditation with KFOA. Indeed an explanation for the absence of Dr. Steen from the ward round that Tuesday morning is that she may have been involved in a mock KFOA survey.[181]

92. As a further irony, when Dr. Connor Mulholland was asked to identify any changes in practice which occurred as a result of this process he answered: *"The main ones I recall related to precision in drug prescription and clinical note taking in particular documenting what was said to parents of children."*[182] Dr. Connor Mulholland had as a member of a *"Shadow*

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179 Ref: WS-257-2 p.4
180 Ref: Transcript of Oral Hearings on 17th October 2012 p.122 line 22
181 See the Inquiry witness statement of Dr. Shields – Ref: WS-301-1, p.8
182 Ref: WS-243-1 p.5

assessing team"[183] within the Children's Hospital. He was clinical lead within the Paediatric Directorate until shortly before Claire's admission to the Children's Hospital and engaged with the KFOA in the clinical governance accreditation process undertaken in 1995-1997.

93. It will be a matter for you to determine Mr. Chairman, the extent to which the changes in practice, which Dr. Mulholland identified, involved Dr. Sands or Dr. Webb.

94. Dr. Mulholland described his particular interest in communication with parents as having: *"Developed from my time in the Sick Children's Hospital in Toronto where I had my basic paediatric cardiology training and the example there of the time taken by staff to ensure that parents knew what was happening to their children and what the risks and so on were was something that I brought back with me and developed further... I brought it to the paediatric cardiology part. I didn't disseminate it deliberately around the hospital."*[184]

95. Again, it is a matter for you Mr. Chairman to determine whether it was a clinical governance failure that such good practice does not seem to have been shared by teaching or the guidance of senior clinicians.

96. Nonetheless, the UKCC 'Guidelines for Professional Practice'[185] of Nurses (1996) were available to advise that in order: *"to ensure that you gain the trust of your patients and clients, you should recognise them as equal partners, use language that is familiar to them and make sure that they understand the information you are giving."*[186]

97. Notwithstanding that clear guidance and the clinical governance procedures that were available in 1996 in respect of record keeping, audit, accreditation, communication and sharing of best practices, the information made available to the Inquiry would suggest that they may not have been implemented and monitored to ensure the high quality of health care services that the code of accountability envisages.[187]

98. The preamble to the GMC 'Good Medical Practice' Guidance for Doctors, proceeds from the central premise that: *"Patients must be able to trust doctors with their lives and wellbeing. To justify that trust, we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life. In particular as a doctor you must*

- *Listen to patients and respect their view;*

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183 Ref: Transcript of Oral Hearings on 21st June 2012 p.170 line 10
184 Ref: Transcript of Oral Hearings on 21 June 2012 p.171-2
185 Ref: 314-003-001 *et seq*
186 Ref: 314-003-016
187 Ref: 210-003-150

- *Give patients information in a way they can understand."*[188]

99. In emphasis of this concept of trust, paragraph 11 continues, that the: *"successful relationship between doctors and patients depends on Trust. To establish and maintain that Trust you must … Give patients information they ask for or need about their condition, its treatment and prognosis."*[189] It may, therefore, be inferred that the GMC regarded withholding information as potentially damaging to public trust and confidence in the medical profession.[190]

100. You may wish to consider Mr. Chairman the extent to which the damage to the public trust done by failures in communication with parents (which in part was a reason for the establishment of this Inquiry)[191] is something that should have been of concern to the clinicians and administrators involved with the Children's Hospital and evident in its procedures.

VII. Children with Learning Disabilities

101. When Claire's GP referred her to the Children's Hospital on 21st October 1996 she described her as a *"nine year old girl with severe learning disability."*[192] This was an aspect of her presentation that prompted Dr. MacFaul to observe: *"Claire was known to have severe learning disability which can be associated with reduced social responsiveness and with speech disorder, at this point Claire presented with both and it may be that the Junior Doctors were not sufficiently familiar with the degree of change from the normal state. They would rely on the parents' account."*[193]

102. The Children's Hospital's admitting doctor, Dr. O'Hare, appears to have been alert to the relevance of documenting the extent of her difficulties, noting: *"Can speak in sentences, meaningful… cannot dress herself… Torbank Special School. Dundonald."*[194]

103. Stephen Quinn QC, counsel for Claire's parents, in addressing the Inquiry on behalf of the Roberts Family made reference to how: *"Mr. and Mrs. Roberts arrived back at hospital at 9.30am on Tuesday, 22nd October*

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188 Ref: 314-001-006
189 Ref: 314-001-006
190 Ref: 314-002-007
191 See*: "I believe it is of the highest importance that the general public has confidence in the quality and standards of care provided by our health and social services. This is why I recently announced that I had appointed John O'Hara, QC, to conduct an independent Inquiry"* (Ministerial Statement released on 18th November 2004). See too the terms of reference released at the same time, which included*: "(iii) The communications with, and explanations given to, the respective families and others by the relevant authorities."*
192 Ref: 090-011-013
193 Ref: 238-002-038
194 Ref: 090-022-050

1996. They recall that they were advised by the nursing staff that Claire was much more alert and had a comfortable night but when they saw Claire they both expressed concern to the nursing staff that Claire did not appear to be herself. She was pale and lethargic and not as responsive as usual… The parents now express some concerns about the information they got at the Royal Victoria Hospital in relation to how comfortable Claire was…"[195]

104. Whilst the nursing staff may have experienced some difficulties in appreciating the extent of Claire's uncharacteristic unresponsiveness it is clear that Mr. and Mrs. Roberts were very careful to bring this to the attention of Dr. Sands on his morning ward round. He had it noted in the record by Dr. Stevenson: *"Usually very active… has not spoken to parents as per usual … vagueness/vacant (apparent to parents)… pale colour… little response compared to normal."*[196]

105. There is no evidence that an appreciation of Claire's illness was affected by any lack of understanding about her learning difficulties and the extent to which she favoured one side. There is also no evidence that the description of Claire as a child with a *"severe learning disability"*[197] affected the treatment that she received or the clinicians' response to her.

106. Apprehension that children with disabilities are sometimes subject to less concern by medical staff than children of normal ability has led to guidance and recommendations, most notably 'Welfare of Children and Young People in Hospital' (DoH 1991)[198] which emphasises that children with disabilities are *"doubly disadvantaged"*[199] when admitted to hospital. It recommends that hospitals ensure that staff are able to cope with the children's special needs.

107. The Chief Executive, Mr. William McKee, has advised the Inquiry in respect of those recommendations that: *"I do not recollect this guidance being adopted by the Department of Health in Northern Ireland"*[200] and the Medical Director Dr. Carson has observed that: *"It is unlikely that guidance issued by the Department of Health in England would have been acted on by the RBHSC without prior consideration by the DHSSPS. However, the Paediatric Directorate RBHSC may be able to comment."*[201] The Clinical Director of the Paediatric Directorate in 1996 Dr. Connor Mulholland could *"not recall"* if the Children's Hospital had taken any steps to implement this guidance.[202]

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195 Ref: Transcript of Oral Hearings, Opening of Stephen Quinn Q.C.24th September 2012, p.57 line 15
196 Ref: 090-022-052
197 Ref: 090-011-013
198 Ref: 314-004-001 *et seq*
199 Ref: 314-004-027
200 Ref: WS-061-2 p.7
201 Ref: WS-077-2 p.5
202 Ref: WS-243-1 p.4

108. It is to be noted that the Royal College of Nursing specifically cite these guidelines as being *"Endorsed by the DHSS Northern Ireland."*[203]

109. The extent to which, or if at all, the RGH had implemented that guidance or provided staff in the Children's Hospital with training in respect of working with children with disabilities will be pursued during the Oral Hearings.

110. Dr. MacFaul also comments on the: *"(often misguided) impression that children with severe learning disability have a life limiting condition with an increased risk of death. Certainly there is an increased incidence of complications with illness both in detection and severity in children with severe learning disabilities and, to that extent, deaths are more common amongst children with disabilities. These factors may have impacted upon the thinking process in respect of reporting to the Coroner at that time."*[204]

111. There is no evidence that these considerations played any part in Dr. Steen's decision that Claire's death need not be referred to the Coroner. It is however to be noted that when entering her written synopsis of Claire's history and treatment into the medical record at 04:00 on 23rd October 1996, Dr. Steen described Claire as having *"learning difficulties."*[205] However when citing Claire's clinical presentation for the purpose of the Autopsy Request Form she gave a *"major symptom"* as being *"a history of mental handicap"*, which she repeated under the section on *"past medical history."*[206] The Roberts family stress that: *"She was <u>not mentally handicapped.</u>"*[207]

112. When asked during the Oral Hearings about the reasons for the use of this term in the medical notes and records, Dr. Steen stated: *"'mental handicap' by definition, which has now changed to 'learning difficulties' encompassed, at that time, the whole gambit [sic] from a child with significant delay... to a child with poor progress within a school. It is an emotive term, it has obviously upset the parents, and I'm sorry about that."*[208] However, it was not made clear on the Autopsy Request Form itself why that had been included as a *"major symptom"* to be drawn to the attention of the pathologists, since the clinical diagnoses that are recorded for their investigation were: *"Cerebral oedema 2º to status epilepticus ? underlying encephalitis."*[209] The explanation in Dr. Steen's evidence would appear to go to a matter that is disputed by Claire's parents and is yet to be determined, namely the extent to which the pathologists were being

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203 Ref: 314-012-003; 'Patient Information and the Role of the Carer'
204 Ref: 238-002-062
205 Ref: 090-022-057
206 Ref: 302-070b-009-10
207 Ref: Transcript of Oral Hearings, Opening of Stephen Quinn Q.C. 24th September 2012, p.54 line 19
208 Ref: Transcript of Oral Hearings on 17th October 2012 p.198 lines 3-12
209 Ref: 090-054-183

asked to look for a possible explanation for Claire's developmental problems.[210]

113. The reason for Claire's developmental problems is not included in the Autopsy Request Form as an issue to be investigated by the pathologists. The explanation for that is a matter to be pursued during the Oral Hearing. So too, from a governance perspective, is the general appropriateness and adequacy of the Autopsy Request Form.

VIII. Communication between Clinicians

114. Patient safety relies upon effective communication as and between clinicians. Systems must therefore be in place to facilitate and record communication to ensure important medical information is passed between clinicians. Central to such systems are the entries made by clinicians into medical notes and records.

115. It is a matter for you Mr. Chairman to determine whether those systems were effectively used in Claire's treatment of Claire Roberts and, specifically, whether as Claire failed to improve over Tuesday 22nd October 1996 there were any shortcomings in the record keeping, the communication of her serum sodium and other results and in the channels of communication with her named consultant Dr. Steen.

116. The Paediatric Medical Guidelines published in 1997: *"help junior medical staff of the Royal Belfast Hospital for Sick Children with the management of common paediatric medical conditions."*[211] The introduction gives an indication of the degree of importance attached to effective communication, stating: *"consultation with an experienced colleague remains a cardinal rule when managing a sick child."*[212] It might therefore be supposed that a high standard of verbal communication might have been expected as and between clinicians at all times.

117. Dr. Webb recalls that in relation to Claire's treatment: *"I had been in regular contact with Dr. Steen's team all afternoon and I believe I communicated my plan to those involved verbally and through my medical notes."*[213] He accepts that: *"the responsibility for communication and record keeping in relation to clinical handover between daytime and on-call Registrar is with the individual doctors involved"* but that he was: *"not aware of any protocols in place at the time to guide communication or record keeping."*[214]

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210 Ref: Transcript of Oral Hearings on 17th October 2012 pgs.198-199
211 Ref: 238-002-072
212 Ref: 238-002-072
213 Ref: WS-138-1p.42
214 Ref: WS-138-2p.21

118. Dr. Webb clearly recognised the importance of communication and record keeping in that he states that had there been any deficiency in these areas he would *"have raised those issues with the individual staff member."*[215] There is no evidence that any such concerns were raised whether by Dr. Webb or by other clinicians or nurses in respect of his own communication and record keeping.

119. Dr. Sands does: "*not recall specific instruction re the procedures for junior medical staff to inform consultants of changes or concerns."*[216]

120. Dr. Steen explains that the normal practice for contacting consultants in the Children's Hospital was: "*for the junior doctors, or at times the senior nurse to initially contact the named consultant or, out of hours, the consultant on-call and following discussion with that consultant seek further opinions if required."*[217] Moreover she states that the: *"Practice in RBHSC was that telephone contact could be made with the named paediatrician from 09:00 on Mondays to 17:00 on Friday if it was felt that that consultant could deal with the issue more appropriately."*[218] Furthermore, she explains that if a speciality opinion was required urgently: "*referrals were usually verbally from Registrar/Consultant to Registrar/Consultant with a note written in the chart."*[219]

121. Notwithstanding, Dr. Steen's evidence is that she had the impression that matters were 'under control' over the afternoon of Tuesday 26th October 1996 and there was no need for her to return to the Children's Hospital to either see Claire or speak to her mother as she would otherwise have been minded to do. Whereas, Dr. Webb's evidence is that he was providing specialist guidance on her neurological presentation but was not taking over her overall care. Furthermore, there seems to have been no direct communication between Dr. Steen as Claire's named consultant and Dr. Webb who was brought in to give a specialist opinion and who had been directing Claire's drug therapy that afternoon. Accordingly, Dr. Steen may have had little knowledge of the treatment plan should Claire's neurological presentation fail to respond to the further anti-convulsant therapy (as it had failed to do all afternoon) prescribed by Dr. Webb. In addition, there is no evidence of any communication between Dr. Steen and the on-call paediatric consultant given that she was going off duty. Nor, is there any evidence of any communication between Dr. Webb and that consultant to brief them of Claire's diagnoses and treatment plan.

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215 Ref: WS-138-2p.21
216 Ref: WS-137-3 p.9
217 Ref: WS-143-1p.13
218 Ref: WS-143-1p.13
219 Ref: WS-143-1p.13

122. It will be a matter for you to determine Mr. Chairman the extent to which there were deficiencies in the extent of communications between the clinicians.

123. In the opinion of Dr. MacFaul matters of effective communication between clinicians assume real significance in Claire's case given that the diagnosis of encephalitis was *"unusual"* and that she was a child presenting with persistent reduction in consciousness level.[220] He states with particular reference to the assessment and management of Claire on 21st October 1996 that: *"many junior doctors would choose to discuss with the consultant on-call"* however *"this step does not seem to have been taken."*[221] Dr. MacFaul would have: *"expected a telephone notification from the junior doctor to the consultant given the degree of reduced level of consciousness and the diagnosis ... it is this sort of issue which comes up in clinical meetings ... or at clinical audit meetings."*[222]

124. Dr. Steen accepted that the failure to make clear to clinicians who they should look to and for what purpose, amounted to a failing.[223]

125. There is no evidence that telephone communication with absent consultants was considered at clinical audit meetings or that any clear guidelines were available for junior doctors in this regard. It will be a matter for you to determine Mr. Chairman the extent to which such matters warranted being discussed at any review of Claire's case.

126. The standard of communications between the clinicians involved in Claire's care is also criticised by Dr. MacFaul in the following respects:

    (i) Dr. Sands referred the care of Claire to Dr. Webb: *"without Claire having been seen by Dr. Steen or without any telephone contact being made with Dr. Steen"*[224]

    (ii) *"Dr. Steen should have made sure that her junior staff knew when to call her and how to call her. If Dr. Steen knew that she was not available or [un]likely to be contactable she should have made arrangements with a colleague to provide cover for her"*[225] It should however, be noted that Dr. Steen stated during the Oral Hearings that: *"in the evenings or overnight if there were any concerns, the junior doctors would have had the option of actually going to those consultants or they would have contacted me. I had to be contactable."*[226]

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220 Ref: 238-002-037
221 Ref: 238-002-037
222 Ref: 238-002-037
223 Ref: Transcript of Oral Hearings on 17th October 2012 p.66 line 20
224 Ref: 238-002-041
225 Ref: 238-002-041
226 Ref: Transcript of Oral Hearings on 15th October 2012 p.10 lines 20-24

(iii) There is no evidence of the handover or any communication between the daytime and the on-call registrar in relation to Claire.[227] Dr. Bartholome accepted during her oral evidence that: *"it wouldn't have been routine in any of the hospitals that I worked in to have handover"*[228] and that this practice only emerged in and around 2002.

(iv) If a consultant was unable to attend a scheduled ward round that consultant should have made arrangements for the children under their care to be reviewed: *"This was a shortcoming in the arrangements for the provision of care for Claire."*[229]

(v) An on-call rota for junior medical staff and consultant paediatricians should have been available to the hospital ward staff so as to make it very clear who should be contacted. In order to permit communication, nursing staff and parents should be made aware of the name of the consultant under whose care a child is admitted.[230]

(vi) At each stage of the care and treatment the doctor involved should make clinical handwritten notes: "*There was no formal grading of the level of reduced consciousness."*[231] The clinicians did not communicate any assessment of Claire's Glasgow Coma Scores, whether or not in combination with the other observations on her 'Central Nervous System Observation Chart'[232] and Record of 'Attacks Observed'.[233]

(vii) At the time of Claire's collapse at 03:00 on the morning of Wednesday 23rd October 1996, Dr. Bartholome contacted Dr. Steen who was no longer the on-call consultant with responsibility for the care of Claire.[234] She did not contact the consultant paediatrician on-call at that time. Indeed neither she nor anyone else has been able to provide the Inquiry with the identity of that consultant.

127. The Inquiry has already investigated the circumstances in which Dr. Webb came to mistake the Monday 21st October 1996 serum sodium result as being from the morning of Tuesday 22nd October 1996. In addition, Mr. Chairman, you heard evidence on the matter during the Oral Hearings in respect of clinical issues.

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227 Ref: 238-002-012
228 Ref: Transcript of Oral Hearings on 18th October 2012 p.173 lines 4-12
229 Ref: 238-002-045
230 Ref: 238-002-032
231 Ref: 238-002-032
232 Ref: 090-039-137
233 Ref: 090-042-144
234 Ref: 238-002-041

128. That mistake is cited by Dr. MacFaul to emphasise the serious errors that can arise from deficiencies in communication. He notes that the laboratory printout confirming Claire's serum sodium result of 132mmol/L[235] contained: *"no timing of sample receipt or process."*[236] Neither does the medical record note the time at which the result was received on the Ward. It is not disputed that such printed result forms can play a vital role in communicating critical information. However, Dr. MacFaul notes that *"the design of the pathology form is [thus] substandard"* and that an error, such as Dr. Webb's, might have led to audit and useful dialogue to correct such problems, however:. *"There is no evidence from the post event discussions that this was a recognised issue."*[237]

129. The extent to which the design of such forms was or has been considered will be a matter to be pursued in the Oral Hearings.

IX. Nursing

130. The role of the nursing staff in Claire's care and treatment has already been considered at the Oral Hearings into clinical issues. However, the matter has further relevance from a governance perspective, in order to understand the appropriateness of the systems and procedures in place for the provision of nursing care.

131. In considering such matters the following key issues arise in respect of nursing care and will be addressed at the Oral Hearings:

(i) The degree of autonomy given the nursing staff in the initiation of observations and other aspects of care

(ii) The adequacy of nursing assessment, care planning and written evaluation of care

(iii) Procedures for ward rounds and the delivery of care when the lead consultant is unavailable

(iv) Identification and management of errors by junior staff in treatment and prescribing

(v) Communication with doctors

(vi) Communication with Mr. and Mrs. Roberts

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235 Ref: 090-031-099
236 Ref: 238-002-045
237 Ref: 238-002-045

(vii) The failure to report the death of Claire Roberts as an adverse incident

132. Records show that on admission to Allen Ward, Claire's *"accountable nurse"*[238] was Staff Nurse McRandal. It was she who signed and completed the Nursing Care Plan which required daily review.[239] The scope of nursing care to be provided was noted on the Care Plan to include:

(i) The administration of prescribed medicine

(ii) The recording of an accurate fluid balance chart

(iii) The reporting of abnormalities to the doctor/nurse in charge[240]

133. It is relevant to note that the UKCC Code of Professional Conduct:[241] *"recognises that, in a growing number of settings, patients and clients will be in the care of an 'identified' practitioner"*[242] who should: *"assume responsibility for co-ordinating and supervising the delivery of care, drawing on the general and specific resources of colleagues where appropriate. Professional practice naturally involves recognising and accepting accountability for these matters."*[243]

134. The Ward Sister with overall responsibility for Allen Ward between Monday 21st and Wednesday 23rd October 1996 was Sister Angela Pollock who had: *"continuing responsibility for the assessment of care needs, the development, implementation and evaluation of programmes of care … [and was] responsible for the ongoing management of Allen Ward including the deployment, supervision and teaching of students and other staff."*[244] She was also responsible for supervising Claire's Nursing Care Plan and the nursing care provided to her. It was accepted practice in 1996 that all children admitted to hospital received an individualised Care Plan.[245]

135. The Inquiry's expert on paediatric nursing, Ms. Ramsay, has described a Care Plan in her Report to the Inquiry[246] as: *"an assessment of nursing care needs... reflect[ing] the care needs arising from the medical diagnosis."*[247] She states that: *"the care plan would normally be prepared within 24 hours of*

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238 Ref: 090-041-142
239 Ref: 090-043-145-146
240 Ref: 090-043-145-6
241 Ref: 202-002-058-64 (June 1992)
242 Ref: 202-002-063
243 Ref: 202-002-063
244 Ref: WS-225-2 p.3
245 Ref: 231-002-012
246 Ref: 231-002-001 *et seq*, 'Nursing Care given at the Royal Belfast Hospital for Sick Children in October 1996' dated 14th June 2012
247 Ref: 231-002-012

admission to hospital and reviewed and revised on a regular basis in response to changes in care needs, if an aspect of care was no longer needed or additional interventions required."[248] She goes on to explain that it: *"was usual to evaluate care regularly, at least at the end of each shift, prior to handing over to another nurse. Depending on local work patterns this was usually after a 7.5 or 12-hour period. Good practice was to record important events or changes in the child's condition as soon as possible."*[249] She is therefore critical of the apparent lack of review in the case of Claire Roberts in that: *"the care plan was not revised when the diagnosis changed and did not fully indicate the care needs of a child with altered consciousness."*[250]

136. Dr. MacFaul is of the opinion that: *"by the morning following her admission at latest Claire should have been seen by Dr. Steen."* and that: *"Dr. Steen should have been involved in the decision making."*[251]

137. However, there is no record of either Dr. Steen or Ward Sister Pollock being involved in Claire's care, whether directly or indirectly. Furthermore, no changes were made to the Nursing Care Plan for Claire following the ward round on Tuesday 22nd October 1996 or thereafter.

138. Ms. Ramsay states that there were no guidelines in 1996 setting out the frequency for observations.[252] She concludes that: *"it is my opinion, that both doctors and nurses shared responsibility for ensuring vital signs were assessed and monitored as frequently as the child's condition required. The nurses' responsibility was to take appropriate action in response to any changes and, where necessary, to inform the nurse in charge or the doctor."*[253]

139. Of further relevance to the standard of nursing care provided is the UKCC publication 'The Scope of Professional Practice',[254] which enjoins nurses to: *"be sensitive, relevant and responsive to the needs of individual patients and clients and have the capacity to adjust, where and when appropriate, to changing circumstances."*[255] It would seem that Claire's changing circumstances failed to cause any adjustment to her Nursing Care Plan. Whether the Care Plan maintained by nursing staff in the Children's Hospital during the period of Claire's treatment was used and developed to the standards expected at the time, will be a matter to be considered during the Oral Hearings.

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248 Ref: 231-002-012
249 Ref: 231-002-012
250 Ref: 231-002-004
251 Ref: 238-002-020
252 Ref: 231-002-013
253 Ref: 231-002-014
254 Ref: 202-002-060
255 Ref: 202-002-060

140. It will be a matter for you to determine, Mr. Chairman, the extent to which there were deficiencies in Claire's Nursing Care Plan and, if so, whether as a consequence it failed to reflect the potential severity of Claire's condition.

141. The UKCC published its 'Standards for Records and Record Keeping'[256] in April 1993 which described the purpose and relevance of medical records to nursing staff as being to:

(i) *"Provide accurate, current, comprehensive and concise information concerning the condition and care of the patient or client and associated observations*

(ii) *Provide a record of any problems that arise and the action taken in response to them*

(iii) *Provide evidence of care required, intervention by professional practitioners and patient or client responses*

(iv) *Include a record of any factors (physical, psychological or social) that appear to affect the patient or client*

(v) *Record the chronology of events and the reasons for any decisions made*

(vi) *Support standard setting, quality assessment and audit*

(vii) *Provide a baseline record against which improvement or deterioration could be judged."*[257]

142. Nurses would have been expected to comply with the 'Guidelines for Professional Practice'[258] and to recognise that: *"communication is an essential part of good practice"*[259] and that for effective communication nurses: *"may need to consult other colleagues with specialist knowledge ..."*[260] In the exercise of professional accountability nurses must: *"report to an appropriate person or authority ... any circumstances in the environment of care which could jeopardise standards of practice."*[261]

143. Nursing care should be provided in accordance with the UKCC Code of Professional Conduct[262] which requires a registered nurse to be accountable for his or her practice and conduct. The Code: *"provides a statement of the values of the professions and establishes the framework within*

256 Ref: 202-002-052 *et seq*
257 Ref: 202-002-053
258 Ref: 314-003-001 *et seq*
259 Ref: 314-003-016
260 Ref: 314-003-016
261 Ref: 314-003-022
262 Ref: 202-002-058-64 (June 1992)

which practitioners practice and conduct themselves."[263] Once registered each nurse remains subject to the Code and ultimately responsible to the UKCC for his or her acts and omissions. This reflects the central role which the registration process plays in maintaining standards in the public interest. The Code provides that nurses: *"in the exercise of [your] professional accountability, must:*

(i) *Act always in such a manner as to promote and safeguard the interests and well being of patients and clients*

(ii) *Ensure that no action or omission on your part, or within your sphere of responsibility, is detrimental to the interests, condition or safety of patients or clients*

(iii) *Maintain and improve your professional knowledge and competence;*

(iv) *Acknowledge any limitations in your knowledge and competence and decline any duties and responsibilities unless able to perform them in a safe and skilled manner."*[264]

144. Mr. and Mrs. Roberts have expressed their concern at the quality of information communicated to them by the nursing staff. In the Opening Statement made on their behalf on 24th September 2012, reference was made by Stephen Quinn QC to the morning of the 22nd October when Mr. and Mrs. Roberts: *"were advised by the nursing staff that Claire was much more alert and had a comfortable night"* but when they saw Claire *"they both expressed concern to the nursing staff that Claire did not appear to be herself."*[265] It is not clear whether they were also informed that during that night Claire was recorded as having vomited six times between the hours of 22:00 on Monday 21st October and 06:00 on Tuesday 22nd October 1996 (i.e. very nearly every hour) or how that was compatible with her having had *"a comfortable night."*

145. Mr. and Mrs. Roberts also maintain that at no time on Tuesday 22nd October, during the ward round or any other time, did any nurse in attendance tell them that Claire was being treated for a possible virus of the brain or encephalitis.[266] It was their further recollection that: *"the nursing care from 6:30 to around 9:30 was general and without any alarm or concern, the nursing staff did not discuss or mention any sort of condition that would give the parents any concern and there was no mention of any of those other condition that now appear in the medical records."*[267] They further state that: *"staff did not raise any concerns whatsoever"* and that

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263 Ref: 202-002-061
264 Ref: 202-002-061
265 Ref: Transcript of Oral Hearings, Opening of Stephen Quinn Q.C. 24th September 2012, p.57 lines 15
266 Ref: Transcript of Oral Hearings, Opening of Stephen Quinn Q.C.24th September 2012, p.60 line 22
267 Ref: Transcript of Oral Hearings, Opening of Stephen Quinn Q.C.24th September 2012, p.71 lines 2-9

they went home thinking that Claire would be: *"released from hospital within a day or two."*[268]

146. Nursing practice also plays a very important role in the administration of drugs. This aspect of nursing is governed by the 'Standards for the Administration of Medicines.'[269] Those standards direct that professional nursing judgement be focussed on:

(i) *"Confirming the correctness of the prescription*

(ii) *Judging the suitability of administration at the scheduled time of administration*

(iii) *Reinforcing the positive effect of the treatment ...*

(iv) *Assisting in assessing the efficacy of medicines and the identification of side effects and interactions."*[270]

147. Dr. Steen stated in her Inquiry witness statement that: *"For oral administration - nurses as part of their responsibility would need to ensure that the dose prescribed was correct before administration."*[271]

148. There is no evidence that the nursing staff providing Claire's care took the view that her deterioration and death amounted to an adverse clinical incident. Otherwise, as Ward Sister Pollock explained: *"we would have completed documentation in relation to adverse clinical incidents."*[272]

149. The extent to which the nursing staff should have considered Claire's deterioration and resulting death in that way is a matter that will be pursued during the Oral Hearings and as will the nursing lessons that might have been learned had they done so and completed the appropriate documentation in relation to adverse clinical incidents.

X. Medical Records & Record-Keeping

150. High quality healthcare records are the foundation which allows high quality evidenced based healthcare to be provided. Information has most value when it is accurate, comprehensive, up to date, accessible and targeted at clinical need. It is necessary for clinical and other types of audit, review and research.

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268 Ref: Transcript of Oral Hearings, Opening of Stephen Quinn Q.C.24th September 2012, p.72 line 1
269 Ref: 314-005-001 *et seq*; UKCC (October 1992)
270 Ref: 314-005-003
271 Ref: WS-143-1 p.37
272 Ref: WS-225-2 p.6

151. Guidelines for record keeping were available in 1996 from a number of sources including the DoH, Royal Colleges and professional regulatory bodies including The GMC. The DoH 'Risk Management in the NHS' Manual[273] addressed the importance of medical records and records generally, including their role in risk management through: "*tracking, trending, monitoring and projection.*"[274]

152. The GMC at paragraph 3 of 'Good Medical Practice' (1995) directed doctors in providing care to: "*keep clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, information given to patients and any drugs or other treatment prescribed.*"[275]

153. In 1996 nurses were subject to the UKCC 'Standards for Records and Record Keeping' (1993).[276] Miss Elizabeth Duffin, Director of Nursing Services RGH, has stated: "*the Trust Medical Records Committee had produced a policy/procedure which used the UKCC guidelines as its base.*"[277] She described how the medical staff within the RGH: "*decided to adopt our guidelines and use them for the policy for the Trust and procedure for the Trust.*"[278] Whilst Miss Duffin could not remember the date of adoption she said it was: "*certainly around 1994/1995.*"[279]

154. The Guidelines to which she referred - the UKCC 'Standards for Records and Record Keeping' - describe at paragraph 5 the importance of records as a means of: [280]

    (i) Communicating with others and describing what has been observed or done

    (ii) Organising communication and the dissemination of information among the members of the team providing care for a patient

    (iii) Demonstrating the chronology of events, the factors observed and the response to care and treatment

    (iv) Demonstrating the properly considered clinical decisions relating to patient care

155. In making the medical record, importance is attached to the organisation of the information so that a: "*measurable up to date*

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273 Ref: 314-013-001
274 Ref: 314-013-001
275 Ref: 314-001-004
276 Ref: 202-002-052 *et seq*
277 Ref WS-245-1 p.6
278 Ref: Transcript of Oral Hearings on 20th June 2012 p.57 line 4
279 Ref: Transcript of Oral Hearings on 20th June 2012 p.57 lines 6-7
280 Ref: 202-002-053

description of the condition of the patient and the care delivered can be easily communicated to others and the plan and other records complement each other."[281] The record would therefore: *"demonstrate the chronology of events and all significant consultations, assessment, observations, decisions, interventions and outcomes."*[282]

156. These observations and advices were clearly felt necessary given the: *"substantial evidence to indicate that inadequate and inappropriate recordkeeping concerning the care of patients neglects their interests through:*

(i) *Impairing continuity of care*

(ii) *Introducing discontinuity of communication between staff*

(iii) *Creating the risk of medication or other treatment being duplicated or omitted*

(iv) *Failing to focus attention on early signs of deviation from the norm*

(v) *Failing to place on record significant observations and conclusions"*[283]

157. Further guidance was available from a range of sources including 'Guidelines for Clinicians on Medical Records and Notes' (Royal College of Surgeons in England 1994)[284] which make the point that: *"notes should be supplemented and updated regularly to include details and reports of all investigations, treatments and verbal advice given to the patient and his or her relatives."*[285]

158. Notwithstanding, the Inquiry has received no evidence that the RGH formally adopted any particular guidance or policy to inform clinicians on the standard of note or record keeping that should be being achieved. Nor has it received any evidence of organised audit or review of patient records. Miss Duffin gave evidence of random audit scrutiny of nursing records. She described how this partly arose from the KFOA Accreditation Standards.[286] She described the issues most commonly arising from such review as being legibility of handwriting, lack of signature and failure in timing an entry.[287] It is not known whether such audit activity led to any demonstrable improvement in record keeping.

159. It seems that those audits were not extended to all notes and records, were not interdisciplinary and the results do not appear to have been

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281 Ref: 202-002-054
282 Ref: 202-002-054
283 Ref: 202-002-053
284 Ref: 314-007-001 *et seq*
285 Ref: 314-007-002
286 Ref: Transcript of Oral Hearings on 26th June 2012 p.58 lines 1-7
287 Ref: Transcript of Oral Hearings on 26th June 2012 p.31 line 22

measured against identifiable standards or guidelines. Furthermore, although a Children's Hospital Medical Records Committee existed at that time which liaised with the RGH Medical Records Committee, its focus seems to have been confined to issues concerning storage, retrieval and accessibility rather than quality, utility and accuracy.

160. The reasoning behind the target of those random audits of nursing records and the focus of the Children's Hospital Medical Records Committee is a matter to be explored during the Oral Hearings.

161. A number of issues have arisen in respect of the records relating to Claire's case. Amongst others, the following are worthy of note from a governance perspective:

(i) The nursing evaluation for Monday 21st October omits to record the results of the urine test, although both *"urine direct"* and *"O+S"* are 'ticked'.[288]

(ii) The serum sodium result of 132mmol/L is entered into Claire's clinical notes under midnight but without reference to the time the sample was taken or the time the result was actually received.[289]

There is also no indication as to who actually entered it as both Dr. O'Hare, the registrar who made the immediately preceding entry, and Dr. Volprecht, the SHO who entered some of the other test results, deny having done so. This may be implicated in Dr. Webb's misunderstanding of the timing of this test.

(iii) Dr. Webb made an entry in the record timed at *"4pm"* on 22nd October.[290] It seems by reference to other internal evidence within the record that this should have been timed at 14:00 and indeed Dr. Webb has subsequently acknowledged that as likely to be the correct time.[291]

(iv) Dr. Stevenson made an entry in the record at 14:30 on 22nd October in which the phenytoin dosage is miscalculated.[292] The dose indicated by Dr. Webb as 18mg per kilo. The result should have been 432mg, i.e. the product of 18mg x 24kg, but it was recorded by him as 632mg. It was also prescribed by him as 635mg, which amount he signed as having administered.[293]

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288 Ref: 090-040-140
289 Ref: 090-022-052
290 Ref: 090-022-053
291 Ref: 091-008-042
292 Ref: 090-022-054
293 Ref: 090-026-075

That error went uncorrected and, apparently, unnoticed by clinicians in 1996 and when they reviewed Claire's medical notes and records for the family in 2004 and for her Inquest in 2006 and for the PSNI.

(v) Dr. Stevenson interprets the successive doses of *"2.5mg/kg 12 hrly"* (i.e. 60mg) indicated by Dr. Webb[294] as to be administered at 21:30 on Tuesday 22nd October and 08:30 on Wednesday 23rd October 1996, which he prescribes[295] and which is also recorded in the 'Drug Recording Sheet'.[296] It would seem though from Claire's 'Fluid Balance and IV Prescription Sheet' that it was not administered then but that the 60mg of phenytoin was administered in a solution of 110mg over an hour at 23:00 on Tuesday 22nd October[297] as is also recorded in Claire's nursing notes.[298]

However, there is no reference to it on the 'Intravenous Fluid Prescription Chart'[299] and there is no record of the reason for the change.[300]

(vi) The drug prescription sheet[301] contains a mis-recording of the midazolam dosage, which also may indicate a misunderstanding. The dosage entered by Dr. Stevenson in Claire's clinical notes is 0.5mg per kilo, producing 12mg[302] but it is prescribed by him as 120mg.[303]

There is also an issue as to whether the dose of 0.5mg which Dr. Stevenson recorded and used was correct. Although not noted at the time, Dr. Webb has subsequently provided the Inquiry with a witness statement indicating that he believed the dose he recommended, and the correct dose, was a loading dose of 0.15mg/kg[304] which would produce a bolus of 3.6mg. Dr. Stevenson has no recollection of this.

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294 Ref: 090-022-054
295 Ref: 090-026-075
296 Ref: 090-026-077
297 Ref: 090-038-135
298 Ref: 090-040-138
299 Ref: 090-038-136
300 The oral evidence of the SHO Dr. Stewart indicates that the delay in the administration of the phenytoin was caused by the fact that the results of Claire's phenytoin levels were not received until 23:00 and that the dosage was consequently modified following a discussion with the registrar Dr. Bartholome, since her levels were 23.4mg/l as opposed to the therapeutic range of 10-20mg/l. None of that is recorded in Claire's medical notes and records (Transcript of Oral Hearings on 6th November 2012 p.62 line 18)
301 Ref: 090-026-075
302 Ref: 090-022-055
303 Ref: 090-026-075
304 Ref: WS-138-3, p.2

In any event the administration of the midazolam is left unsigned,[305] although it is acknowledged by Dr. Webb in Claire's clinical notes[306] and the nursing notes as having been administered at 15:25.[307]

Again, those errors went uncorrected and, apparently, unnoticed by clinicians until this Inquiry.

(vii) Dr. Webb also indicated a subsequent dose of midazolam which Dr. Stevenson has recorded in Claire's clinical notes as *"69mg/24hrs"*[308] and prescribed by him in the 'Intravenous Fluid Prescription Chart' as *"2mls/hr over 24hrs."*[309] However, he does not record the start time in the 'Regular Prescriptions' sheet (unlike all the other drugs he prescribes there),[310] which appears from Claire's 'Fluid Balance and IV Prescription Sheet' as *"4.30pm."*[311]

That prescription for midazolam is subsequently altered by the SHO Dr. Hughes and is recorded by her on the prescription sheet that she re-wrote at 21:30 on Tuesday 22nd October as being increased from 2mls/hr by: *"0.1ml/hr every 5mins to 3mls/hr."*[312] Whilst that is also recorded in Claire's nursing notes,[313] there is no recorded reason for the increase or who was actually responsible for directing it.[314] The increase is not recorded in the 'Intravenous Fluid Prescription Chart', although it is shown on Claire's 'Fluid Balance and IV Prescription Sheet' as having been administered at 23:00[315]

Those discrepancies do not appear to have been appreciated until this Inquiry.

(viii) Dr. Webb records at 17:00 the addition of sodium valproate to Claire's drug therapy as part of his 'plan': *"20mg/kg iv bolus followed by infusion of 10mg/kg iv over 12 hrs."*[316] The bolus is

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305 Ref: 090-026-075
306 Ref: 090-022-055
307 Ref: 090-040-141
308 Ref: 090-022-055
309 Ref: 090-038-136
310 Ref: 090-026-075
311 Ref: 090-038-135
312 Ref: 090-026-073
313 Ref: 090-040-141
314 Dr. Hughes' oral evidence was that she would not have initiated such a change without a discussion with the registrar. However, she concedes that she made no note of it (Ref: Transcript of Oral Hearings on 5th November 2012, p.137-8)
315 Ref: 090-038-136. See too Claire's nursing notes which record: *"Hypnoval [midazolam] infusion increased by 0.1ml every 5 minutes until running at 3mls/hr as prescribed by doctor – completed at 10.40pm."."*
316 Ref: 090-022-055

prescribed by Dr. Sands as 400mg (slightly less than that directed by Dr. Webb) and he records his administration of it at *"5.15pm."*[317] However, there is no record of it on Claire's 'Fluid Balance and IV Prescription Sheet'.[318]

Furthermore, whilst Dr. Hughes prescribes the IV infusion of Sodium Valproate that was subsequently to be administered, she subsequently strikes that out[319] and does not include it in the prescription sheet that she re-wrote at 21:30.[320]

There is no recorded reason for that change or who was actually responsible for directing it. [321]

(ix) The 'Fluid Balance and IV Prescription Sheet'[322] lacks important information most notably in respect of the output. No entries whatsoever are timed at 14:00. Precise timings are not given for administration of IV fluid and other drugs, save for that of midazolam at *"4.30pm"* and, as already identified, some drugs such as the bolus of midazolam and sodium valproate are not recorded.[323]

(x) The 'Intravenous Fluid Prescription Chart'[324] omits start and finish times of the solution No.18 IV fluid and lacks the signature of the individual erecting the IV equipment. In addition, whilst it prescribes the dilutant for the midazolam, it fails do so for the phenytoin and sodium valproate since it does not record their prescription.[325]

(xi) The GCS scores on the 'Central Nervous System Observation Chart'[326] have not been totalled for 23:00 or midnight and the initial GCS entry made has been crossed out and re-entered with different values. There are no initials or timings entered to validate these corrections.

(xii) The 'Record of Attacks Observed' is not been initialled by the nurses.[327]

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317 Ref: 090-026-075
318 Ref: 090-038-135
319 Ref: 090-026-075
320 Ref: 090-026-073
321 As with the change to the midazolam, Dr. Hughes' oral evidence was that she would not have initiated such a change without a discussion with the registrar. However, once again she concedes that she made no note of it (Ref: Transcript of Oral Hearings on 5th November 2012, p.137-8)
322 Ref: 090-038-135
323 Ref: 090-038-135
324 Ref: 090-038-134
325 Ref: 090-038-136
326 Ref: 090-039-137
327 Ref: 090-042-144

(xiii) The time that Claire's ventilation was discontinued and she died is recorded variously as: 06:25 in the Autopsy Report,[328] 18:15 in the PICU Nursing notes,[329] 18:25 in the Referral letter to H.M. Coroner[330] and 18:45 in Dr. McKaigue's note entered into Claire's clinical notes[331]

(xiv) The medical notes and records fail to record the advices and information given to Mr. and Mrs. Roberts, save for the 'Relative Counselling Record' which records those details in respect of the period when Claire was considered to be beyond hope of recovery.[332] Similarly, they fail to record with particularity the information given by Mr. and Mrs. Roberts

(xv) In addition, the medical notes and records fail to record the communications between the clinicians fully. Of greatest significance, from a governance perspective (because of their clinical implications), are those that it is said were made on Tuesday 22nd October 1996 by Dr. Sands to Dr. Steen and by Dr. Steen to the ward.

162. There are also shortcomings and deficiencies in the Brain Stem Death protocol, the Autopsy Request Form and the Autopsy documentation which will also be addressed.

163. Dr. Steen has conceded that: *"I can in no way defend the quality of my documentation or anyone else's."*[333] – *"Our documentation is poor and we know it is poor."*[334]

164. The extent to which the Trust properly implemented guidance on record keeping and the extent to which the clinicians properly followed the guidance given to them by their professional bodies will be examined at the Oral Hearing.

165. It will be a matter for you Mr. Chairman to consider and determine the extent to which the Children's Hospital allowed the doctors and nurses to regulate the standard of their own record keeping and whether the rudimentary system of audit was sufficient to achieve quality assurance.

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328 Ref: 090-003-003
329 Ref: 090-027-085
330 Ref: 140-061-001
331 Ref: 090-022-061
332 Ref: 090-028-088
333 Ref: Transcript of Oral Hearings on 15th October 2012 p.37 line 24
334 Ref: Transcript of Oral Hearings on 15th October 2012 p.80 line 22

166. The keeping of appropriate and accurate records is one aspect of a records policy. Another is the adequate maintenance and retention of those records.

167. Some documents generated in 1996 by Claire's case and relevant to this Inquiry have not survived. Some have been discarded or destroyed, whilst others have proved untraceable. As a result, the Inquiry has been frustrated in trying to understand the full clinical history of Claire's case by reason of missing laboratory results, nursing rotas, consultant rotas and radiologist report. Attempts to understand the conflicting evidence tendered by Trust witnesses as to the procedures governing the retention and destruction of records has proved futile. Even Mr Noel Williams, Co-Director of Information Services at the Trust was unable to assist, being obliged to give evidence on 22nd June 2012 that: *"looking for records in the Trust is a wee bit like looking for a needle in a haystack... It's absolutely possible that some records exist, it's just that we couldn't locate any."*[335]

168. It is a matter of regret that the healthcare information systems of the RGH should incorporate such healthcare information gaps.

169. The Director of Development, Information Systems and Patient Records at the RGH in 1996 was Mr. Evan Bates. He refers to his own Directorate's 'objective setting documentation' for 1995/96 as setting a requirement for *"the Medical Records Committee [to] seek a Record Storage and Destruction Policy."* He adds *"the documents suggest that the policy was in place by the end of 1994/4; but my handwritten notes for 1995/6 state that implementation was delayed 'hindered by sickness absence'… I have been unable to locate a copy of the policy."*[336] He further relates that as late as 23rd May 2005 *"work was continuing to develop a formal Trust-wide records disposal schedule."*[337]

170. The extent to which the Children's Hospital (as part of the RGH) was allowed to continue on in 1996 and following Claire's death without developing and or implementing a proper 'Record Storage and Destruction Policy' and if so, who was responsible for such a state of affairs, are matters to be further pursued.

XI. Drug administration

171. Drug administration may be described in three parts, namely prescription, formulation and administration.

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335 Ref: Transcript of Oral Hearings on 22nd June 2012 p.151 line 16
336 Ref: WS-266-1 p.8
337 Ref: WS-266-1 p.9

172. During the course of the governance investigation into the death of Adam Strain, Dr. Connor Mulholland identified the main changes in risk management practice which occurred as a result of engaging with KFOA as being: *"related to precision in drug prescription and clinical note taking."*[338] Both of these issues have relevance to Claire's case.

173. The prescription charts,[339] both for the 'Regular Prescriptions' and the 'Drugs-Once Only Prescriptions', that are used to write up the medication prescribed and administered to Claire are cited by Dr. MacFaul as *"open for criticism."*[340] He is of the opinion that the: *"quality of the records system is a design failure"* that indicates the *"need for a quality improvement approach to the review of medication processes within the hospital."*[341] Dr. MacFaul explains that there has been a long-standing recognition of the risk of drug administration errors in respect of children (due to the necessity to adjust dosage for age and weight)[342] as well as a: *"potential for mathematical error to occur in the calculation prior to prescription"* and *"in the dispensing and administration of medication."*[343] It might be supposed therefore, that a greater degree of care was demanded and taken in respect of paediatric medicine.

174. In 1992 the UKCC 'Standards for the Administration of Medicines'[344] described the administration of medicine as: *"not solely a mechanistic task to be performed in strict compliance with the written prescription of a medical practitioner. It requires thought and judgement which is directed to ... confirming the correctness of the prescription."*[345] The 'Strategy for Children's Services' (1996) claimed there was: *"an active clinical audit programme within the Royal Belfast Hospital for Sick Children. In addition to regular medical ward audits (involving all members of the ward teams) … other recent assessments have included: medication prescribing."*[346]

175. The role of a Pharmacist might have been considered central to the process of drugs administration. However, the DLS has informed the Inquiry that *"in 1996 there was no Paediatric Pharmacist and ... no equivalent role existed at the time."*[347]

176. Dr. MacFaul has expressed surprise that there should have been no Paediatric Pharmacist at the Children's Hospital at so late a date. Accordingly drug calculations were left to be checked by two people at

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338 Ref: WS-243-1 p.5
339 Ref: 090-026-075
340 Ref: 238-002-054
341 Ref: 238-002-054
342 Ref: 238-002-054
343 Ref: 238-002-054
344 Ref: 214-005-001 *et seq*
345 Ref: 214-005-003
346 Ref: WS-266-1 p.52
347 Ref: 302-149-001

the time of administration, namely: "*the member of nursing staff responsible for administering the medication and either another nurse or doctor.*"[348] Correspondence from the DLS dated 9th November 2012[349] informs the Inquiry that: "*It is the Trust's understanding that Intravenous medications and controlled drugs have always been checked by two people and this remains the case today. In the case of oral, topical [applied directly to the skin],[350] or PR [per rectum] [351] medications some, but not all, are single checked.*"[352] However, the medications at issue were all administered intravenously and therefore it seems would not have been subject to 'single checking'.

177. Whilst Sister Angela Pollock's detailed job description of January 1994 specifically required her to adhere: "*to the DHSS guidelines for the safe handling, administration, storage and custody of medicinal products*",[353] there is no evidence that any of her nurses carried out such checking of Claire's medication on Tuesday 22nd October 1996. Furthermore they did not enter the midazolam bolus dose in their nursing notes, nor any of the other bolus doses of medication.[354]

178. The evidence of Dr. Webb, who actually directed the medication, is that he did not read or check Dr. Stevenson's prescription for the midazolam,[355] nor it seems did he read or check Dr. Stevenson's prescription for the phenytoin.

179. The errors in the prescription and administration of anti-convulsant medication to Claire over Tuesday 22nd October 1996 simply seemed to go un-noticed by the clinicians and nurses responsible for her care and treatment.

180. It is a matter for you Mr. Chairman to consider whether a Paediatric Pharmacist might have realised, and corrected, the discrepancies in the directions of Dr. Webb and the prescriptions of Dr. Stevenson as a matter of course.

181. Nevertheless, the reasons why the Trust's own practice of 'double checking' appears not to have been followed nor why any such omission picked up and addressed, are matters to be considered further during the Oral Hearings.

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348 Ref: WS-138-2 p.11
349 Ref: 302-158-001
350 See Glossary of Medical Terms Ref: 310-007-001 *et seq*
351 See Glossary of Medical Terms Ref: 310-007-001 *et seq*
352 Ref: 302-158-001
353 Ref: WS-225-2 p.12
354 Ref: 090-040-141
355 Ref: WS-138-1 p.32-3

182. In 1994 the Children's Hospital published the third edition of its 'Paediatric Prescriber'[356] including a series of *"General Guidelines"* in respect of the administration of drugs. These Guidelines cover many of the fundamental aspects of drug administration and advise that: *"cancellation of a prescription should be carried out by drawing a line distinctly through the entry to be cancelled. The date of cancellation and signature should be written in the space provided."*[357] It is noteworthy that the prescription for 120mg of midazolam recorded in the Prescription Chart at 15:25 by Dr. Stevenson has not been scored out in the manner required by the Guidelines, and furthermore, as has already been pointed out, is not signed in the column provided.[358] This may be contrasted with the prescription for sodium valproate in the same Chart which has been appropriately scored through to indicate its discontinuance,[359] albeit that there is no explanation for such a change recorded in Claire's clinical notes.

183. The reasons why the Guidelines appear to have been properly followed in respect of sodium valproate and not midazolam, and the implications of this, will be considered during the Oral Hearing. Insofar as the Prescriber further provides that *"the ward sister or nurse in charge must be informed of any change in drug prescriptions"*[360] it remains to be determined whether such a step was taken.

184. By 1996 procedures for the reporting of adverse drug incidents were well established. The Management Executive's directive PEL (93) 36:[361] defines an adverse incident as *"any adverse or unexpected event, however minor, which could conceivably be attributed to a drug. Reports should be made despite uncertainty about a causal relationship ... and even if other drugs have been given concurrently."*[362] It further provides that: *"adverse drug reactions to medicinal products should be reported to the Medicines Control Agency on specially designed yellow cards"*[363]

185. Dr. MacFaul takes the view that the: *"error with the dosage intended and the dosage written up should have been picked up by Dr. Webb at his review of Claire at 17:00 on the 22nd October"* and could or should also have *"been noted at the review of deaths in the audit meeting and reported as a major medicines error. There is no indication that it was."*[364] Dr. Webb has stated

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356 Ref: 311-023-001 *et seq*
357 Ref: 311-023-007
358 Ref: 090-026-075
359 Ref: 090-026-075
360 Ref: 311-023-007
361 Ref: 210-003-1137
362 Ref: 210-003-1137
363 Ref: 311-028-001 *et seq*; provided as perforated cards attached at the back of the British National Formulary, Number 32 (September 1996); A joint publication of the British Medical Association and the Royal Pharmaceutical Society of Great Britain.
364 Ref: 238-002-180

that he *"was not aware of this miscalculation and became aware of it during my review for the Inquiry"*[365] and that if he had been aware of it he *"would have been concerned by this miscalculation and would have spoken to the doctor involved. I believe I would have stopped Claire's midazolam infusion for an hour and I would have informed her parents and arranged for her to be monitored for ill effects."*[366] Dr. Steen has given evidence that she does not believe that she detected the drug calculation errors at the time and accepted that she should have.[367]

186. There is no evidence that the errors noted on Claire's Prescription charts were ever reported as an adverse incident or near miss, by either a clinician or the nurse in charge, nor is there any evidence that such errors were investigated, assessed or included at review or audit meetings whether as a matter of performance evaluation or patient safety.

187. The UKCC 'Standards for the Administration of Medicines' deal with the management of errors in the administration of medicines, and states: *"In a number of its Annual Reports, the Council has recorded concern that practitioners who have made mistakes under pressure of work, and have been honest and open about those mistakes to their senior staff, appear to have been made the subject of disciplinary action in a way which seems likely to discourage the reporting of incidents and therefore be to the detriment of patients and of standards."*[368] It was therefore a declared aim of the UKCC's Professional Conduct Committee to take: *"great care to distinguish between those cases where the error was the result of reckless practice and was concealed, and those which resulted from serious pressure of work and where there was immediate, honest disclosure in the patient's interest."*[369] It is further the UKCC's: *"position that all errors and incidents require a thorough and careful investigation... and a comprehensive assessment of all the circumstances."*[370]

188. A further matter of general relevance in relation to the prescription of drugs for children is that many drugs need to be used *"off label"* (i.e. outside the terms set out in relation to dosage) or in some instances *"unlicensed"*[371] (i.e. outside the terms of the licence). Such practice is particularly common where variation of dosage calculation is required. The Inquiry's expert on pharmacology, Dr. Jeffrey Aronson, informs the Inquiry in his Report that: *"according to the 1996 edition [of the British National Formulary] the Summary of Product Characteristics for midazolam*

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365 Ref: WS- 138-2 p.12
366 Ref: WS- 138-2 p.12
367 Ref: Transcript of Oral Hearings on 17th October 2012 p.210 line 18
368 Ref: 314-005-014
369 Ref: 314-005-015
370 Ref: 314-005-015
371 Ref: 238-002-054

... the indications do not specifically include the management of status epilepticus."[372] During his evidence he regarded its administration to Claire as: *"a turning point."*[373] Whilst Dr. MacFaul described it in the circumstances as *"avant garde"* but *"not necessarily experimental."*[374] Fundamentally, though the Inquiry's experts regarded its administration as unwarranted and essentially misguided in the absence of an EEG to confirm Dr. Webb's diagnosis. All healthcare professionals prescribing medicine in this manner remain subject to the guidance of their own professional colleges, and the prescribing policies of their employers.

189. The Medical Risk Management Group of the RGH had responsibility for representing the interests of the Drugs and Therapeutics Committee at the Trust Board, Hospital Council and Medical Committee.[375] The Medical Risk Management Group was also specifically charged with responsibility for untoward clinical incident reporting. It would therefore appear that a clear line of communication may have been available for information about drug related risk issues to be brought to the highest level of governance at both Board and Hospital Council levels.

190. The extent to which in those systems were used in practice to address drug administration risk is a matter to be pursued during the Oral Hearings.

191. Whether the Children's Hospital had appropriate systems in place in 1996 to ensure that the medication intended for and provided to Claire Roberts was prescribed, formulated, recorded and administered in safety and with precision will be a matter to be explored at Oral Hearing.

XII. Clinical Services

192. Dr. MacFaul identifies a number of respects in which he considers the delivery of clinical services to be susceptible to criticism. He draws attention to the fact that the CT scanner was not in the Children's Hospital.[376] So, despite the fact that the Children's Hospital provided paediatric intensive care and was the regional Paediatric Neurology service, it nonetheless required the transportation of child patients by ambulance to the Royal Victoria Hospital X-ray Department every time a for CT scan was required. Moving a patient between hospitals when

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372 Ref: 237-002-013
373 Ref: Transcript of Oral Hearings on 8th November 2012 p.195 line 22
374 Ref: Transcript of Oral Hearings on 14th November 2012 p.32 line 12
375 Ref: WS-061-2 p.241
376 Albeit that the CT scanner was on the same overall RGH site as the Children's Hospital.

very ill presents obvious risk potential as well as presenting logistical difficulties which could lead to delay notwithstanding that the child's needs may require speed. Indeed the potential for such delay is specifically noted by Dr. Webb: *"There was a potential for this procedure to be delayed particularly if there was a backlog of Adult cases awaiting brain imaging at the time or there was a delay in arranging anaesthetic supervision for the procedure."*[377]

193. Dr. MacFaul continues: *"The lack of on-site imaging in CT … [at the time] is striking"*[378] and *"For a major regional children's centre this is a late addition to the range of supporting imaging facilities."*[379] Whilst CT facilities were available to the Children's Hospital *"on a 24/7 basis"*[380] it was only for those who were able to arrange the procedure and Dr. Steen was quick to suggest to Mr. Walby that at the Inquest: *"we should point out that we had very limited access to CT scan in 1996."*[381] Dr. Webb states in his third Inquiry witness statement: *"I have no doubt that if a CT scan had been available – down the corridor – in the Children's Hospital in 1996 I would have arranged it for that Tuesday afternoon. However this was not the case."*[382]

194. It is not known whether this state of affairs had caused difficulties or complaint prior to Claire's admission. In any event the inconvenience and risks associated with out-of-hospital CT scanning may be inferred from the subsequent acquisition in 2002 of a CT scanner for the Children's Hospital.

195. The availability of emergency Electro-Encephalography ("EEG") has already been referred to during the Oral Hearings. Professor Neville maintains, and the Inquiry's other experts agree, that an EEG scan was the only means whereby the diagnosis of non-convulsive status epilepticus could have been confirmed.[383] No request was made for an EEG at any time prior to Claire's death. Given that the Inquiry has now been informed that EEG services were available in the Children's Hospital between the hours of 09:00– 17:00, Monday-Friday[384] but were not availed of in Claire's case; consideration of the governance implications of out of hours arrangements is academic. Indeed little difficulty appears to have been experienced in the Children's Hospital in September 1987 in arranging both EEG and CT scans when investigating Claire's epilepsy.[385]

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377 Ref: WS-138-3, p.2
378 Ref: 238-002-058
379 Ref: 238-002-067
380 Ref: WS-138-1 p.25
381 Ref: 139-140-002
382 Ref: WS-138-3, p.2
383 Ref: 232-002-002
384 Ref: 302-005-001
385 Ref: 090-020-044

196. Of greater significance is the extent to which same-day or emergency EEG services were available during Claire's admission on Tuesday 22nd October 1996. The records now released indicate that five children had EEGs on 22nd October 1996, one of them being a patient of Dr. Webb.[386] In his most recent Inquiry witness statement Dr. Webb responds to the criticisms of the failure to have an EEG carried out on Claire: *"I am sure that I gave consideration to requesting an EEG on the Tuesday afternoon but I would have been very conscious of the workload of the EEG department particularly in the absence of the second technician on maternity leave. The single technician … was providing an EEG service to the entire province and dealing with children and families who had often waited weeks and longer for an EEG … EEG technicians were and are a very valuable resource … I had just completed my first year at RBHSC and certainly did not want to jeopardise my relationship with our only technician at the time."*[387]

197. A working party comprised of the British Paediatric Association, the British Paediatric Neurology Association and the Association of British Clinical Neurophysiologists produced a report in January 1989 on 'Neurological Services for Children in the United Kingdom',[388] including the availability of EEG. Northern Ireland was excluded from the survey of neurophysiology services in the UK. However, the ideal requirements for the provision of neurophysiological services for children in Britain states: *"the investigations on children usually take longer than those on adults, and usually two technicians are needed with one child (report of the Association of British Clinical Neurophysiologists – "recommended minimum standards for departments of clinical neurophysiology in the National Health Service – 1986"). Neurophysiological services should be provided by a trained clinical neurophysiologist. It is appreciated that this ideal may not be achieved immediately but it is one towards which we should work."*[389]

198. The extent to which that report was considered and its impact, if any, to the organisation of the EEG services for patients in the Children's Hospital is a matter to be pursued during the Oral Hearings.

199. In any event there would appear to be no review of Claire's case referring to any difficulties associated with the lack of readily available EEG services.

200. Ultimately, it will be a matter for you Mr. Chairman to determine whether in 1996 the availability of EEG services, whether for Claire or for any other acutely ill child in the Children's Hospital, was adequate

386 Ref: 150-001-001 *et seq*
387 Ref: WS-138-3, p.3
388 Ref: 314-015-001 *et seq*
389 Ref: 314-015-003

given that the Children's Hospital provided the Paediatric Neurology service for the entire region.

201. The Inquiry's expert on clinical microbiology, Professor Cartwright, identifies in his Report[390] a deficiency in the laboratory blood Report in that it omitted the differential white blood cell count.[391] That this was not provided on the Report was in his opinion *"irregular"* and something he would not *"expect to see normally."*[392] He was unable to *"understand why a differential white count wasn't available from the machine."*[393]

202. Dr. MacFaul also found: *"a deficiency in the quality of the blood laboratory reports. They are poorly designed. They have no printout of the time of receipt and time of process of sample."*[394] Nor, it may be added, of the time the specimen was taken, which considered: *"leads to difficulties in determining sequences of events and results."*[395] Given that deficiency may be implicated in Dr. Webb's failure to comprehend the timing of the initial serum sodium result of 132mmol/L correctly it is of importance, and could have been identified as a failure (whether of record keeping or record design) at audit. As Dr. MacFaul observes: *"Review of other cases in audit can identify examples such as this and leads to a useful dialogue between laboratory and clinician if the problem is identified and, after such incident reporting or audit [can] lead to changes in practices in the laboratory."*[396] Again this may be categorised as: *"a significant shortcoming and quality management issue."*[397] Significantly, there is no evidence of any such post-death discussions or evidence of any complaints in respect of the laboratory reports.[398]

203. With regards to these important issues of 'service-delivery-response-to-clinical-need' there would not appear to have been any systematic consideration of or internal control over the systems in operation. No audit, review or investigation was pursued into the processes surrounding Claire's care and treatment.

204. The extent to which the Trust had any quality control mechanism whereby it could have been reassured that the systems in operation were appropriate and without risk is a matter to be pursued further.

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390 Ref: 090-032-108
391 Ref: 090-031-099
392 Ref: Transcript of Oral Hearings on 7th November 2012, p.25 line 9
393 Ref: Transcript of Oral Hearings on 7th November 2012, p.26 line 25
394 Ref: 238-002-057
395 Ref: 238-002-057
396 Ref: 238-002-045
397 Ref: 238-002-028
398 Ref: WS-157-2 p.8

XIII. Criteria for Admission to PICU

205. Expert comment has been provided as to when and upon what basis, Claire should have been admitted into PICU. Dr. Nichola Rooney wrote to Mr. and Mrs. Roberts on 12th January 2005 with specific reference to their request for information with: *"regard to why Claire was not moved to PICU - her hourly CNS observations had remained stable for a period of time and no clinical signs of further deterioration were noted. PICU may not have been viewed, therefore, as appropriate/necessary."*[399]

206. You heard evidence Mr. Chairman during the Oral Hearings on clinical issues on the accuracy of that assertion. Both of the Inquiry's expert consultant paediatricians, Dr. Scott-Jupp and Mr. MacFaul, gave evidence that Claire's condition would not be assessed by reference to her GCS scores in isolation.[400] They referred to her apparent failure to respond positively to the considerable amount of anti-convulsant medication prescribed by Dr. Webb and administered to her over the afternoon of Tuesday 22nd October 1996.[401] They also refer to the 'Record of Observed Attacks', which not only recorded a seizure at 15:25 but despite the medication administered also recorded other episodes at 16:30 and 19:15 and one of screaming at 21:00.[402] Viewed in that way, the Inquiry's experts, including Professor Neville and Ms. Ramsay, are of the view that Claire's condition deteriorated and that there could have been a discussion with PICU at 17:00 with consideration being given as to whether she should be transferred there.[403]

207. Ultimately, though whether Claire could properly have been described as having 'deteriorated' will be a matter for you to determine Mr. Chairman as will the accuracy of the statement made by Dr. Rooney in her letter to Claire's parents.

208. Dr. Webb's statement prepared for the Coroner (in liaison with the Litigation Management Office) recounts how he was: *"not sure whether she [Claire] would have met the criteria for admission to Paediatric Intensive Care as there was no problem with her airways or breathing at that point and no supportive signs of raised inter cranial pressure such as papilloedema, hypertension or bradycardia."*[404] Dr. McKaigue, Consultant Anaesthetist in PICU, is of the view that: *"if there was doubt as to whether or not a*

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399 Ref: 089-006-014

400 Ref: Transcript of Oral Hearings on 12th November 2012 p.156 lines 19-20 (Dr. Scott-Jupp) and 14th November 2012 p.60 lines 8-9 (Dr. MacFaul)

401 5mg diazepam at 12:15, bolus of 635mg phenytoin at 14:45, very likely bolus of 12mg midazolam at 15:25, iv midazolam started at 16:30 and increased at 21:30, bolus of 400mg Sodium Valproate at 17:15 and 60mg of iv phenytoin started at 23:00

402 Ref: 090-042-144

403 Ref: 231-002-031 (Ms. Ramsay) and 232-002-012 (Professor Neville)

404 Ref: 090-053-175

patient needed to be admitted to PICU, it was normal practice for a PICU consultant to have been asked for advice on the matter."[405]

209. The issue as to whether the formal criteria existed governing admission to PICU then prompted further explanation from Dr. Webb: *"The system of referral to PICU was usually based on discussion between the medical team involved in a child's care and the paediatric intensive care staff about the individual child. The main criteria for admission to intensive care were to provide support to airway, breathing and circulation for children who required it."*[406] Further: *"I do not believe I took any steps to discuss Claire with a PICU consultant after 17:00 hours on 22nd October 1996 and in hindsight I believe that this was a mistake."*[407]

210. Accordingly, it would seem that Dr. Webb had formed a firm view of Claire's condition which failed to recognise the severity of her illness and it was for that reason that he: *"did not consider transferring Claire to PICU or discuss Claire with the PICU consultant because [he] felt her condition could be managed on the ward."*[408] This was a wasted opportunity in terms of the care and treatment of Claire and a failure highlighted by the GMC 'Good Medical Practice' guideline (October 1995) where at paragraph 3 all doctors are reminded that in providing care: *"you must be willing to consult colleagues."*[409]

211. Nevertheless, it will be a matter for you Mr. Chairman to determine whether Dr. Webb had actually formed such a view and if so the impact on the care and treatment that Claire received.

212. Dr. Webb's colleagues in PICU at that time were Drs. McKaigue and Taylor and possibly also Dr. Crean, all of whom might have been expected to have been aware of the risks of hyponatraemia, having studied the Arieff et al paper only four months earlier at the Inquest into Adam Strain's death. Dr. Webb was himself well aware of those issues having contributed to the RGH preparation for Adam's Inquest.

213. Dr. Scott-Jupp considers the requirement for artificial ventilation to be a prerequisite for admission to PICU.[410] Professor Neville observes that had a CT scan been performed earlier and cerebral oedema identified then artificial ventilation would have been indicated in order to reduce the raised inter cranial pressure,[411] which would of itself have necessitated Claire's transfer to PICU. Ms. Ramsay expressed the view in her oral evidence that if a risk of respiratory arrest can be foreseen,

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405 Ref: WS-156-2 p.7
406 Ref: WS-138-1p.74
407 Ref: WS-138-1p.74
408 Ref: WS-138-1p.37
409 Ref: 314-001-004
410 Ref: 234-002-010
411 Ref: 232-002-012

then that might of itself indicate a transfer to PICU, rather than wait until the arrest occurs.[412]

214. The emergence of recurrent themes in Claire's case - of the failure to recognise the severity of illness, of the failure by clinicians to consult with more senior or other colleagues and of the failure to perform relevant tests in a timely way - all find resonance in the failure to transfer Claire to PICU earlier and on 22nd October. That Dr. Webb should have referred the Coroner to: *"the criteria for admission to paediatric intensive care"*[413] raises the question for the Inquiry as to whether the Children's Hospital should indeed have had, in 1996, a formal clinical guideline setting out the criteria for admission to PICU for the assistance of clinicians.

215. The issue of guidelines for PICU admission is something that is referred to as part of the broader issue of guidelines for the Children's Hospital, and will be explored further during the Oral Hearings.

XIV. Clinical Guidelines at the Children's Hospital

216. Examination of the clinical issues arising from Claire's case has drawn attention to the absence of clinical guidelines or protocols within the Children's Hospital in 1996 to assist in:

(i) Investigating children with impaired consciousness

(ii) Calculating iv fluids in the presence of encephalopathic illness

(iii) Measuring electrolytes in children receiving iv therapy and the frequency with which it should be done

(iv) Summonsing medical help by nurses in response to changes in a child's neurological state

(v) Guiding medical trainees as to when to seek consultant assistance

(vi) Prescribing and administering drugs by junior doctors

(vii) Transferring and admitting children to PICU.[414]

217. Dr. MacFaul considered it relevant to consider those knowledge sources available to and used by junior staff in 1996.[415] By a letter dated

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412 Ref: Transcript of Oral Hearings on 8th November 2012 p.198
413 Ref: 139-098-021
414 Ref: 302-006-002
415 See Dr. MacFaul's Report - Ref: 238-002-067

9th September 2011 the DLS informed the Inquiry that the Children's Hospital: *"did not, in October 1996, and does not now have guidelines, procedures or protocols on the diagnosis and management of a child with reduced level of consciousness."*[416] Indeed it would appear that there were no guidelines on the wards in 1996 even for the management of common medical conditions. Dr. MacFaul comments that: *"in this respect the RBHSC was out of step and timing with the introduction of guidelines in the NHS in England and it is particularly remarkable in that the hospital is a teaching centre for paediatrics, nurses and other specialists in training."*[417] In 1996 the Children's Hospital functioned not only as the *"District General Paediatric Unit, but in addition housed most of the paediatric regional specialities for Northern Ireland."*[418] That permitted close liaison with the Faculty of Medicine, Queens University Belfast, with *"teaching programmes in child health having a large component occurring within RBHSC and contributed to by all medical staff on site"*,[419] which is the kind of connection that it might be thought would have enabled the Children's Hospital to at least 'keep pace' with guidelines being introduced in England.

218. Rather, before the introduction of the 'Paediatric Medical Guidelines'[420] of May 1997, there were no hospital guidelines published in the Children's Hospital. Dr. MacFaul considers that to be an unusually late date for a regional teaching hospital.

219. The use and availability of guidelines had evolved and by the: *"mid 1990s it would be expected that a ward would have a range of protocols/guidelines applicable to common conditions."*[421] However, their development in the Children's Hospital may only have really got underway in response to the 1996 'Strategy for Children's Services', which formally declared it to be a target for the Children's Hospital: *"to prepare and introduce care pathways, multi-disciplinary guidelines and standards for the management of the more common conditions… with a pilot project operational within one year."*[422]

220. Dr. MacFaul regards the absence of such guidelines in 1996 when Claire was admitted to constitute: *"a major shortcoming in standards of clinical governance."*[423]

221. The Guidelines produced in 1997 were based upon a consensus view of the broader detail of clinical management. The first edition ran to 142

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416 Ref: 302-029-001
417 Ref: 238-002-070
418 Ref: 238-002-123
419 Ref: 302-031-016; Dr. Steen's job description
420 Ref: 301-138-002 *et seq*
421 Ref: 238-002-070
422 Ref: WS-266-1 p.59
423 Ref: 238-002-071

pages and described itself as: *"being compiled to help Junior Medical Staff of the RBHSC with the management of common paediatric medical conditions, they reflect the current thinking of many medical consultants. Details of drugs mentioned in the Handbook can be found in the Paediatric Prescriber. It is hoped that the Paediatric Prescriber and the Paediatric Medical Guideline can be used as sister handbooks."*[424] The Guidelines cover a broad range of conditions from general problems to more complex diseases and conditions. Amongst the neurological conditions described are ataxia, hyponatraemia, macrocephalophy and microcephalophy. There are no sections on acute encephalopathy or the management of status epilepticus. These omissions are worthy of note given that Claire's case was a recent memory at the date of publication and Drs. Bartholome and Webb contributed to the Handbook.

222. It is further noted by Dr. MacFaul that one of the leading experts in the UK on the management of Reye's Syndrome (an acute encephalopathy mainly affecting younger children) was Dr. J. Glasgow of the Children's Hospital. Given that conventional management of this encephalopathy at the time included fluid restriction and the monitoring of serum osmolarity,[425] it is a matter of regret that a clinical protocol was not in place for the management of acute encephalopathy in October 1996 and the reasons for this will be pursued further during the Oral Hearings.

223. The Hyponatraemia Guidelines were introduced into the Children's Hospital in 2003. When asked how she became aware of them, Nurse Karen Taylor said: *"it would have been in the ward where I was working. It was something that would have been passed on at a staff meeting and the guidelines would have been put up on notice boards and placed around the ward and we were all advised to undertake hyponatraemia training ... online training."*[426] Staff Nurse McRandal gave evidence that in one important respect these Guidelines are not all uniformly observed: *"the current position in the Children's Hospital is that in some wards urine output is still not measured."*[427]

224. The issue of the implementation and monitoring of guidance continues to be a central concern of clinical governance. Given the particular significance to this Inquiry of the introduction and implementation of the Hyponatraemia Guidelines, Nurse McRandal's evidence of the failure to observe them in full is a matter that the Inquiry will further investigate.

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424 Ref: 301-138-007

425 Ref: 'Recognition and Early Management of Reye's Syndrome' Dezateaux et al, Arch. Dis. Child 1986: 61 at 647-51).

426 Ref: Transcript of Oral Hearings (Nurse Taylor) on 29th October 2012 p.138 line 11

427 Ref: Transcript of Oral Hearings on 29th October 2012 p.27 line 22

225. It is however to be noted, as Dr. MacFaul does at paragraph 317 of his Report to the Inquiry, that acceptance of guidelines by professionals in the 1990s was gradual. The medical profession voiced scepticism about *"Cook Book Medicine"*[428] and expressed apprehension about curtailment of consultant clinical freedom. Dr. MacFaul refers to the view held by some that there was little evidential basis to support the content of guidelines – a reservation *"which had some justification because even now many are based upon the lowest level of evidence, that is: clinical consensus."*[429]

Audit

226. Nevertheless, 'consensus guidelines' at least provide an agreed standard against which practice can be measured. Accordingly in order to audit the processes of care readily, reference to such guidelines or agreed standards is critical. The absence of guidelines may therefore lead to substandard audit. Moreover the sharing of experience and results from audit/review is a powerful mechanism for improving clinical guidelines.

227. The Royal Hospitals Annual Report 1993-94 announced its *"Medical Audit"* programme with the assertion that it had *"developed an effective organisational framework for medical audit which supports and encourages changes in clinical practice as a natural part of organisation-wide quality assurance."*[430] The NIH&PSS Management Executive stressed the need for programmes of audit in its management plan for 1995/6 - 1997/8 with reference to *"better practice."* It required that *"specifically, units should ensure that there is a clear policy on:*

- *Clinical audit as part of a programme to improve all aspects of service quality, not just clinical outcomes*
- *Support and evaluation of quality improvement programmes*
- *Multidisciplinary approaches to the development of Best Practice in Service Delivery."*[431]

228. The introduction of clinical audit implied that practice would be evaluated against some form of agreed standard to establish: *"Better practice."* The presence of agreed clinical guidelines therefore becomes fundamental, in the opinion of Dr. MacFaul, if audit is examining:

(i) quality/extent of clinical records

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428 Ref: 238-002-099
429 Ref: 238-002-099
430 Ref: WS-061-2p.58
431 Ref: 306-083-017

(ii) availability/appropriateness of facilities for diagnosis and treatment

(iii) communications[432]

229. Dr. MacFaul goes on to observe that: *"Given the focus in the 1990s on clinical audit with its implicit requirements for standards against which to judge practice, it is noteworthy and a shortcoming that a range of guidance was not available in print for the staff from the early 1990s"*[433] *and "thus the absence of guidelines leads to less good quality and substandard clinical audit. This again constitutes shortcomings in the quality of clinical governance at that time within RBHSC and indeed within the Trust generally."*[434]

230. Linked to the target set by the 'Children's Services Strategy' for the introduction of guidelines, is the target that it set for the adoption of: *"a clinical audit programme oriented towards the development of clinical guidelines, monitoring variance in the use of guidelines and accessing the clinical effectiveness of services"* with *"an effective clinical information system [which] could facilitate the introduction and implementation of clinical guidelines."*[435]

231. The responsibility for any failings in the introduction of clinical guidelines can be traced through the hierarchies of accountability within the Trust.

232. It will be a matter for you Mr. Chairman to determine the reason for any delay in the introduction of clinical guidelines and whether this may have been linked to shortcomings in the Trust's programme of audit.

233. It is not at all certain that Claire's death was presented at audit, review or mortality meeting. The systems in operation for both audit and review were developing in the mid 1990s and were described in the evidence received by the Inquiry in respect of the governance issues arising in Adam Strain's case. These processes did not however engage the nursing staff. Staff Nurse McRandal gave evidence that no one spoke to her about Claire's case after her death[436] and Nurse Jordon denied any *"recollection of any discussion after Claire's death, about what happened or about lessons that could be learned"* and stated that she was never *"asked to be part of any investigation or audit."* Nor did any *"nursing manager or any senior nurses ever speak to [her] about Claire Roberts' death."*[437]

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432 Ref: 238-002-100
433 Ref: 238-002-070
434 Ref: 238-002-072
435 Ref: WS-266-1 p.59
436 Ref: Transcript of Oral Hearings on 29th October 2012 p.44 line 17
437 Ref: Transcript of Oral Hearings on 29th October 2012 p.112 line 7

234. Notwithstanding, Gordon Clarke, the Directorate Manager, within the Paediatric Directorate in the Children's Hospital confirms that in 1996-97: *"There was a site-wide clinical audit process in operation and the paediatric clinicians would have participated in this process."*[438] This process included mortality meetings discussed within the context of paediatric Clinical Audit meetings together with neurological neuroscience grand rounds. Dr. Herron has found: *"Evidence to suggest that the case was prepared for a neuroscience grand round (NSU) meeting, but there is no record of the meetings from 1997 in the department files."*[439]

235. Dr. Herron states that: *"As far as I can remember all paediatric deaths in the hospital were presented at the paediatric mortality meetings."*[440] It was *"usual to invite the pathologist to attend mortality meetings when there was a post-mortem."*[441] Dr. Taylor confirms: *"The usual practice would have been to wait for the autopsy report."*[442] Neither pathologist has any recollection of attending such a meeting. Dr. Taylor recalls that: *"[I] Would have been responsible for chairing the mortality meetings after I took over the role of Audit Co-ordinator in December 1996. For the mortality section of the audit meeting the PICU secretary would contact the relevant consultants and organise the date of the audit meeting and when they would be available to present the case and ensure that the medical notes were available."*[443] "*The mortality meetings were not minuted so that clinicians could speak openly. This arrangement was in place before I took over the role of Audit Co-ordinator. I would arrange for the clinical audit presentations."*[444]

236. Dr. Steen has no recollection of audit but *"would have expected her (Claire's) case to be presented at a mortality meeting once the post-mortem result was complete."*[445] Audit minutes were taken in such a manner as to preclude any possibility of patient identification. The DLS has informed the Inquiry that: *"the Trust's understanding [is] that Claire's case was not discussed at any Paediatric/ Morbidity meetings"*[446] and *"it is therefore not possible to know whether Claire Roberts' death was discussed at any particular meeting"*[447] and *"the attendance register has not been retained."*[448] Dr. McKaigue states that *"Dr. Steen presented Claire's death at the audit meeting in RBHSC at which I was present. I do not recall who else was present at that meeting, or the date of the meeting. I did not make a note of this meeting."*[449]

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438 Ref: WS-268-1 p.3
439 Ref: WS-224-4 p.5
440 Ref: WS-224-3 p.6
441 Ref: WS-157-2 p.6
442 Ref: WS-157-2 p.7
443 Ref: WS-157-2 p.7
444 Ref: WS-157-2 p.7
445 Ref: WS-143-1 p.113
446 Ref: 302-075b-001
447 Ref: 302-024-001
448 Ref: 302-024-001
449 Ref: WS-156-2 p.6

237. Mr. Chairman you may wish to consider that the likelihood of any learning emerging from a process that was designed to leave no paper trail to be questionable.

238. Dr. MacFaul notes that in 1996-97: *"The clinical management structure was in place and documentation should be available on the audit topics covered and issues which arose from adverse events."*[450] That such documentation is not available, renders it impossible to discover whether Claire's death was presented and discussed at an audit/mortality meeting. It remains unclear whether any scrutiny was brought to bear on the death, the drug prescription errors or the processes surrounding the case.

239. The delay occasioned by the emergence of the Autopsy Report may have served to deny Claire's case the immediacy necessary to prompt the presentation of the death at a mortality meeting. Dr. Taylor as Audit Co-ordinator, would have been aware of deaths from hyponatraemia given the ongoing litigation arising from Adam Strain's case. The PICU Secretary would have been aware of both Claire's death and the diagnosis of hyponatraemia appearing as it did on the PICU Case Note Discharge Summary, and in addition she had a role in entering data onto the *"PICU computer database … that was used for clinical audit."*[451] However, Dr. Taylor states *"I do not think Claire Roberts was identified on the PICU computer database."*[452]

240. It is difficult to understand how Claire's death and the presence of hyponatraemia would not have featured at a mortality meeting or audit discussion. However, there is little evidence that it did.

XV. Brain Stem Death Protocol

241. When Drs. Steen and Webb carried out the first appraisals of Claire's condition for the purposes of formally diagnosing brain death at 06:00 on 23rd October 1996 they were purportedly following clear protocol deriving from established guidelines.[453] The clinical assessments to be made were to be conducted separately by each doctor. The second test performed at 18:25 was a double check against the possibility of error. Dr. MacFaul considers the Diagnosis of Brain Death protocol form[454] used by them to be standard and of good quality. [455]

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450 Ref: 238-002-072
451 Ref: WS-157-2 p.3
452 Ref: WS-157-2 p.3
453 Ref: 090-045-148
454 Ref: 090-045-148
455 Ref: 238-002-048

242. The contemporaneous advices of Forfar and Arneil indicated that *"Following the recommendations of the Royal Colleges of Surgeons and Physicians (1976, 1979) after exclusion of all … sedative or paralysing drugs and in the absence of … metabolic derangements, formal testing for brain death can be carried out by two senior doctors."*[456] The Inquiry's expert paediatric anaesthetist in Adam's case, Dr. Simon Haynes, explained the process in his oral evidence as: *"Brainstem death is a diagnosis made when a patient is comatose, who's on a ventilator, and it is important to exclude any reversible causes of that coma. The first premise is to be that there has to be an underlying demonstrated diagnosis, which in Adam's case there most certainly was. There has to be the knowledge, and the wording is no stronger than that, there has to be a certainty that there is no residual effect of any neuromuscular or sedative drugs or other intoxicating agents, which in Adam's case, none were present. Then there has to be the exclusion of metabolic and biochemical causes of coma. And that exclusion has to be made before doctors making the test can go on and do the test."*[457]

243. The necessity to exclude the possibility that the patient's impaired consciousness might be due to depressant drugs necessarily renders it essential that the patient's medication history be carefully reviewed: *"The benzodiazepines are markedly cumulative and persistent in their actions and are commonly used as anti-convulsants ... It is therefore essential that the drug history should be carefully reviewed and any possibility of intoxication being the cause of or contributing to the patient's comatose state should preclude a diagnosis of brain stem death."*[458] The requirement to consider the patient's drug history is then expressly set out in the first question of the Diagnosis of Brain Death Form at (c): *"Could other drugs affecting ventilation or level of consciousness been responsible for the patient's condition?"* Both Drs. Steen and Webb have answered this question *"No."*[459]

244. During the course of the Oral Hearings on clinical issues, Dr. Aronson was asked about the propriety of starting the Brain Stem death tests on Claire at 06:00 on Wednesday 23rd October 1996 in the light of the medication that might still have been in her system. He expressed the view that as a result of the level of phenytoin likely still to be in Claire's system, question 1(c) in the Diagnosis of Brain Death Form could not properly have been answered *"No."*[460] He went on to state that he

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456 Ref: Forfar and Arneil's Textbook of Paediatrics (4th Edition 1992) p.910

457 Transcript for 3rd May 2012, p.114, line 7 *et seq*

458 Ref: 306-035-008. This preliminary to brain death testing is set out in the 1998 Code of Practice for the diagnosis of brain stem death (Ref: 306-035-001) which repeats and revises the 1983 'Cadaveric organs for transplantation: a code of practice indicating the diagnosis of brain death' London. 1983. HMSO. See too the evidence of Dr. Simon Haynes, the Inquiry's consultant paediatric anaesthetist in Adam Strain's case who gave evidence on brain stem testing on 3rd May 2012 – Transcript of 3rd May 2012, p.106 – p.112

459 Ref: 090-045-148

460 Transcript for 8th November 2012, pgs.270-271, lines 12 *et seq*

agreed with the view expressed by Dr. Haynes about the need to have as: *"a certainty that there is no residual effect of any neuromuscular or sedative drugs or other intoxicating agents."* As a result he concluded: *"could the drugs present in Claire's body have … fallen under that rubric … I think they could."*[461]

245. Dr. Aronson was also asked whether in the circumstances Dr. Webb was correct to enter in Claire's clinical notes at 06:00 on Wednesday 23rd October 1996 that she was: *"Under no sedating/paralysing medication"*,[462] to which he responded *"Well, I think that the presence of phenytoin would contradict that."*[463] In his view, he would have wanted to carry out further blood tests and: *"see the plasma concentration [of phenytoin] below 10 before I felt that the contribution of phenytoin could be disregarded."*[464]

246. Whilst Dr. Aronson was of the view that the midazolam was of less concern at 06:00 when the first Brain Stem death test was carried out, Professor Neville thought that it might have been prudent to do a blood test to check the levels still in Claire's system.

247. Dr. MacFaul is critical of Dr. Webb's entry at 06:00 in Claire's clinical records in the light of the doses of phenytoin, midazolam and sodium valproate recorded as having been administered to her.[465] He is clear in his oral evidence that: *"It was not correct that she was under no sedating medication. The fact is that she was still having some effect of the sedating medication because the phenytoin was likely to be at a significant level, exactly what … I would defer to the pharmacologist."*[466] Dr. MacFaul goes on to state that in his view the Diagnosis of Brain Death Form was incorrectly completed and the answer to question 1(c) should have been 'Yes', which should have led either to the deferral of the first test.[467]

248. Dr. Webb has confirmed that at the time of the brain death tests he was unaware that Claire had been erroneously prescribed 120mg of midazolam, that he does not know what dose was administered and that he believes: *"the effect of 120mg of midazolam would have been to cause*

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461 Transcript for 8th November 2012, p.288, lines 21-23

462 Ref: 090-022-058

463 Transcript for 8th November 2012, p.272, lines 8-9

464 Transcript for 8th November 2012, p.273, lines 6-8. Claire's phenytoin levels had been 19.2 at about 03:00 with the therapeutic range being between 10-20 – Ref: 090-031-101

465 Ref: 238-002-048

466 Transcript for 14th November 2012, pgs.130-131, lines 23 *et seq* See also p.133, line 19 in which in response to the question of whether Dr. Webb could confidence say that Claire had no sedating or paralysing medication: *"Absolutely not because she would definitely have had phenytoin in her system because of its long half-life, as a minimum."."*

467 Transcript for 14th November 2012, p.134, lines 6 *et seq*

Claire to be deeply unconscious but I do not believe that she received that dose."[468]

249. It will be a matter for you to determine Mr. Chairman whether the failure to review Claire's drug history critically and test for levels of phenytoin and midazolam constituted a failure in protocol compliance.

250. In addition to excluding the possible implication of drugs in the condition being examined, the Diagnosis of Brain Death Form asks at question 1(f) *"Could a patient's condition be due to a metabolic/endocrine disorder?"* Notwithstanding that the metabolic disorder of hyponatraemia was already known to both doctors by reason of the low serum sodium values, both doctors answered *"No."*[469] Whilst such a condition (and indeed any of the other deficiencies in the form) would not preclude the diagnosis of brain stem death,[470] Dr. MacFaul nonetheless considered that it would have been preferable to answer the question: 'Yes' and then either defer the first test, or carry on and note the actual level.[471] He explained that by the time a child has reached the stage of brainstem coning the electrolytes are deranged and it can be very difficult to get perfectly in range electrolyte results,[472] i.e. between 135mmol/L and 145mmol/L.

251. Those weakness in the test procedures in relation to Claire, echo those that were discussed in Adam's case.

252. Early and thorough audit and review would have allowed any shortcoming, whether of drug calculation, administration, protocol compliance, procedure or referral to the Coroner to be identified, examined and possibly used for performance improvement and patient safety. That these shortcomings were not appreciated is an issue of clinical governance that will be pursued further during the Oral Hearings.

XVI. Post-Death Events

253. The Diagnosis of Brain Death Form concludes with the final question: *"Is this a Coroner's case?"* It would appear that Dr. Steen alone has answered this and written *"No."*[473] It is worthy of remark that this response is given by one doctor alone and that whilst she was the consultant responsible for Claire's care she had not examined her nor

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468 Ref: WS-138-1p.33-34
469 Ref: 090-045-148
470 Ref: 238-002-028 i.e. such deficiencies were: *"Not likely, in any way, to have affected the results of the assessment of brain death; it is a failure of adequate and proper documentation."*
471 Transcript for 14th November 2012, p.139, lines 9-18
472 Transcript for 14th November 2012, p.139, lines 1-8
473 Ref: 090-045-148

been involved in her treatment since her admission. However, Dr. Webb who had directed Claire's entire medication therapy and developed the differential diagnoses for her presentation, seems to have played no role in responding to that question and states in his Inquiry witness statement that: *"I was not involved in this decision and do not know why Claire's case was not referred to the Coroner."*[474]

254. Dr. Webb has informed the Inquiry that: *"Dr. Steen dealt with the post-mortem arrangements and I don't believe we discussed it."*[475] Dr. Steen maintains that she: *"has no recollection of events but would presume that this decision was made by myself, Dr. Webb and the PICU consultants."*[476] If so, then she would have discussed the question of referral to the Coroner with Drs. Webb, McKaigue, Taylor and possibly Dr. Crean, all of whom had informed knowledge of hyponatraemia by reason of their involvement with Adam Strain's case and Inquest. Dr. McKaigue and Dr. Taylor both deny involvement in the decision not to refer Claire's case to the Coroner.[477]

255. It is worthy of remark that Dr. Steen alone should have decided that the matter need not be referred to H.M. Corner given that Dr. Webb is named as *"Doctor 1"*[478] on the Diagnosis of Brain Death Form, has countersigned with her all other responses to the questions posed and was, unlike Dr. Steen, the consultant who had actually attended, examined and treated Claire and formulated a view as to the likely causes of death. Claire's father recalls Dr. Steen telling him at approximately 19:00 on Wednesday 23rd October 1996 that there would be *"no need"* for an inquest.[479] It is unclear why Dr. Webb should not have played a more active role in this regard.

256. In 1996 the referral of a death in hospital to the Coroner was indicated in three circumstances:

    (i) Under and by virtue of Section 7 of The Coroner's Act (Northern Ireland) 1959: *"Every medical practitioner ... who has reason to believe that the deceased person died, either directly or indirectly, as a result ... of negligence ... or in such circumstances as may require investigation shall immediately notify the Coroner … of the facts and circumstances relating to the death"*

474 Ref: WS-138-1 p.53
475 Ref: WS-138-2p.15
476 Ref: WS-143-1p.73
477 Ref: WS-157-2 p.4 (Dr. Taylor) and WS-156-2 p.3 (Dr. McKaigue)
478 Ref: 090-045-148
479 Ref: 091-004-007

(ii) Where the death is unexplained: on the basis that this is a matter which would have required investigation and thus a Coroner's referral is indicated

(iii) When the death is unexpected, on the basis that this may have required investigation, and further by reason of Directive PEL (93) 36: *"If a patient dies unexpectedly the clinician in charge of the case must report the matter immediately to the Coroner."*[480]

257. With specific reference to that first circumstance Dr. MacFaul stated during his oral evidence that Claire's fluid management was implicated in her death: *"Claire has suffered brain swelling and that that has caused her to stop breathing and has damaged her brain irretrievably, that the brain has swollen from an underlying disease of the brain and the complications of that, which are a reduced sodium level, and that the reduced sodium level was due to the production of a higher amount of hormone, which reacts to acute brain illness, but also to volume overload, fluid overload from retention of water, resulting … possibly in part from the intravenous infusion … one is always hesitant to lay blame on oneself … and on the regime. It would have to be stated because if you're explaining the hyponatraemia and you've properly conceived its mechanism, then you are considering the two main causes. One is fluid overload and the other is inappropriate ADH. There's only one way that the fluid overload could have occurred and that is by the fluid that had been administered."*[481]

258. Dr. MacFaul went on to express the view that it could not be said, as Claire's parents say Dr. Steen informed them, that *"everything possible had been done"*[482] as that was: *"evading the issue because, actually, her management was not up to the standard of the time. The standard of the time … is fluid restriction and adjustment of the sodium content of the intravenous fluid, and that should have happened, in my view, from, at the latest, around mid-afternoon. So in that sense, this was misleading."*[483] In response to the query of whether it was correct for Dr. Steen to say that 'nothing more could be done', Dr. MacFaul said simply: *"Well, I think that is wrong."*[484]

259. It will be a matter for you to determine Mr. Chairman whether on that basis it could not be excluded that Claire died, using the terminology of The Coroner's Act, 'directly or indirectly as a result of negligence or in circumstances requiring investigation'.

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480 Ref: 210-003-1137
481 Transcript of 14th November 2012, pgs.125-126, line 9 *et seq*
482 Ref: WS-253-1, p.14
483 Transcript of 14th November 2012, p.127, line 14 *et seq*
484 Transcript of 14th November 2012, p.127, line 23

260. Similarly, it will also be a matter for you to determine Mr. Chairman whether in all the circumstances Mr. and Mrs. Roberts received an adequate explanation of what had happened to their daughter Claire.

261. Dr. Steen justifies the decision not to refer Claire's death to the Coroner on the basis that: *"At the time of Claire's death, it was felt the sequence of events leading to her death was known and there were no areas of concern around her case."*[485] Dr. Nichola Rooney informed Mr. and Mrs. Roberts by letter of 12th January 2005 that: *"The Coroner had not been informed at the time, as it was believed that the cause of Claire's death was viral encephalitis."*[486] Dr. Steen proofread, suggested amendments to and approved this letter for despatch to Claire's parents.[487] Accordingly, she allied herself to that version of events.

262. It is a matter to be pursued during the Oral Hearings whether Dr. Steen was justified in believing that she sufficiently understood the events leading to Claire's death and was further justified in her belief that there was no cause for concern or reason to refer the matter to the Coroner for further investigation.

263. In that regard it may be relevant to note that:

(i) Dr. Steen did not either treat Claire or attend upon her until about 04:00 on Wednesday 23rd October 1996 which was after her respiratory arrest and transfer to PICU

(ii) Her view of Claire's case must necessarily have been informed by the case record which she first read at approximately 04:00 on Wednesday 23rd October 1996. This included the entries of Dr. Stewart at 23:30 on Tuesday 22nd October and Dr. Webb at 04:40 on Wednesday 23rd October.

Dr. Stewart had raised the possibility that Claire's hyponatraemia of 121mmol/L, which was recorded at 23:30 from a blood sample taken earlier at 21:30, resulted from fluid overload from the administration of low sodium fluids, alternatively from SIADH.[488]

Dr. Webb considered Claire's demise to have resulted from: *"SIADH – Hyponatraemia, hypoosmorality, cerebral oedema + coning following prolonged epileptic seizures*."[489]

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485 Ref: WS-143-1 p.73
486 Ref: WS-143-1 p.73
487 Ref: 089-006-015
488 Ref: 090-022-056
489 Ref: 090-022-057

She had herself noted the hyponatraemic result of 121mmol/L and the response of fluid restriction and any discussion with Dr. Webb might have elicited his opinion that hyponatraemia was causally implicated in Claire's death.

(iii) Any working diagnosis of a non-fitting status epilepticus remained unconfirmed by either EEG or any clear response to the medication administered.

(iv) A review of the medication administered to Claire would have revealed the overdoses of medication that Claire received; about a 40 percent increase of phenytoin and about a 230 percent increase of midazolam (leaving aside the issue of 120mg).

She would also have noted Dr. Bartholome's description of Claire suddenly suffering: *"a respiratory arrest"*[490] Again, a discussion with Dr. Webb, might have raised the possibility of the role of Claire's medication in her condition. For example, the possibility that midazolam was implicated in Claire's respiratory arrest[491] and that phenytoin (or some combination of her medication) may possibly have produced paradoxical seizures.[492]

(v) Any proper review of Claire's medical notes and full discussion with Dr. Webb might have indicated to Dr. Steen that Claire's presentation over the period of her admission and her terminal collapse, warranted detailed consideration and investigation.

264. Having completed the Diagnosis of Brain Death Form but before Claire's ventilation was discontinued at 18:45 Dr. Steen had discussions with Mr. and Mrs. Roberts and obtained a consent for a limited post-mortem.[493] This consent was signed by Mr. Roberts alone and restricted the post-mortem examination to *"brain only."*[494]

265. When Dr. Steen approached Mr. and Mrs. Roberts to obtain their consent to the post-mortem examination (pursuant to the Human Tissue Act 1961)[495], it was at a time of extreme grief. Accordingly, the

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490 Ref: 090-022-056

491 Ref: Transcript of Oral Hearings on 8th November 2012 (Dr. Aronson), p.263, lines 1-3 and the Transcript of Oral Hearings on 5th November 2012 (Professor Neville), p.49 at lines 19-25 (albeit that he later acknowledges at p.50 and lines 2-3 that 'we will never know' whether it in fact did have that effect)

492 Ref: Transcript of Oral Hearings on 8th November 2012 (Dr. Aronson), p.189, lines 1-4 and the Transcript of Oral Hearings on 5th November 2012 (Professor Neville), p.30, lines 12-13 (albeit that he earlier expresses the view at p.26 at lines 21 and 22 that he considers it to have been *"rather unlikely"* that the loading dose of phenytoin at 14:45 contributed to Claire's 'seizure' at 15:25

493 Ref: 090-022-061

494 Ref: 090-054-018

495 Ref: Section 2(2)

discussions relating to the post-mortem examination and its limitation had to be pursued with sensitivity. The discussions had to properly inform as to the reasons for the post-mortem, its limitation and the possible alternatives and all without a sense of pressure being perceived. Notwithstanding that this can have been no easy task, the obligation to provide adequate information in order to permit of a valid consent was clear: *"A practical test for the clinician in considering whether he has given full information is the question whether any significant detail not mentioned could have led to a different decision by the next of kin. If so, then the test for fully informed consent will not have been met."*[496]

266. The extent to which Claire's parents were sufficiently informed as to any lack of clarity surrounding the cause of their daughter's death, the presence of hyponatraemia, the reasoning behind the choice for restriction for post-mortem and the justification not to refer the case to the Coroner; and thus whether they were enabled to reach an informed judgment prior to giving consent are all matters to be further pursued during the Oral Hearings.

267. Dr. Squier refers in her Report for the Inquiry[497] to the absence of guidance to obtaining such consent in the 1993 RCPath Guidelines For Post Mortem Reports[498] but refers to the 1991 Report of the Joint Working Party of the Royal College of Pathologists, the Royal College of Physicians and the Royal College of Surgeons on The Autopsy and Audit as providing guidance on 'Asking for Permission for Autopsy'. It provides that responsibility for obtaining permission for an autopsy should lie with the consultant in charge of the case and that: *"Great care should be taken in obtaining permission for an autopsy … The person obtaining permission should explain to the next of kin the benefits of the autopsy examination in providing information for them, for the medical staff and in the provision of tissue for homografts, for teaching and for research. The consent form must allow relatives to permit a full autopsy examination or to restrict the examination or the use of tissue, in keeping with the Human Tissue Act 1961."*[499]

268. Professor Lucas also refers in his Report for the Inquiry to the Report of the Joint Working Party RCPath 1991 document 'The Autopsy and Audit', chapter 2 for material on obtaining consent and to the: *"'standard historical' practices that applied in each individual hospital."*[500]

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496 Ref: 130-014-001; The Royal Liverpool Children's Inquiry Recommendations, 22nd February 2001
497 Ref: 236-007-001
498 Ref: 236-007-054
499 Ref: 236-007-068
500 Ref: 239-002-005

269. The HPSS 'Guide to Consent for Examination or Treatment'[501] was published on 6th October 1995 but it would seem from the investigation into Adam Strain's case that it may not have been *"cascaded"* down within the Children's Hospital at that time. The reasons for that are matters that are still being investigated by the Inquiry. Nevertheless, the 'guidance' is relevant to the general issues relating to the process of obtaining consent and provides a reminder at paragraph 9: *"that the purpose of obtaining a signature on the consent form is not an end in itself. The most important element of a consent procedure is the duty to ensure that the patient understands the nature and purpose of the proposed treatment. Where a patient has not been given appropriate information the full consent may not always have been obtained despite the signature on the form."*[502] Only Mr. Roberts signed the consent form and his signature was not witnessed by Mrs. Roberts.

270. Mr. Roberts recalls that he did not request any limitation to the post-mortem examination and that this was recommended by Dr. Steen who: *"stated that there would be no need for an inquest but the hospital needed to carry out a brain only post-mortem."*[503] Mr. Roberts has informed the Inquiry that his: *"understanding at that time was that Doctors were aware of the reasons for Claire's death, Dr. Steen had explained that a virus had caused the fluid build up around Claire's brain. If I had been informed that there was any unknown or uncertainty regarding the cause of death then I would have consented to an Inquest."*[504] Dr. Hicks observes that: *"as I was a neurologist it was often the case that the brain was primarily involved in the pathological process and in this circumstance I would explain that a post-mortem limited to the brain was a possible course of action. I would try to assist and support them in making a decision in this matter."*[505] The DLS have advised that in the case of a *"consented hospital autopsy decisions regarding the extent of the post-mortem are made by the clinician and next-of-kin."*[506]

271. Dr. Steen is unable to recall why the post-mortem was restricted or why Mr. and Mrs. Roberts were not advised about the part that hyponatraemia may have played in the cause of death or indeed what she said to them. She has stated: *"I have no recollection of the events and can only comment that this [limited post-mortem] most likely was agreed following discussions with Dr. Webb and myself and the PICU consultants"* and *"I have no recollection of events but would assume I hoped to*

- *Determine if encephalitis was present*

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501 Ref: 305-002-009; (Circular HSS (GHS) 2/95)
502 Ref: 305-002-009
503 Ref: WS-253-1p.16
504 Ref: WS-253-1p.15
505 Ref: WS-264-1 p.7
506 Ref: 302-006-001

- *Determine an underlying cause for seizures and developmental delay for a brain only post-mortem."*

272. Mr. and Mrs. Roberts were absolutely clear in their evidence that nothing was said about the post-mortem possibly providing an explanation for Claire's developmental delay. They stated that whilst they would have wanted to know it was definitely not said.[507]

273. Dr. Steen has given evidence that she was not the lead clinician involved in the decision to restrict the post-mortem: *"this is looking back and thinking… I think the ultimate decision I would put to Dr. Webb which is maybe unfair because I'm putting it to him, but this was a child with an acute neurological condition."*[508]Dr. Webb has informed the Inquiry that: *"I cannot recall my view at the time of Claire's death, but I believe I would have expected her post-mortem to have been a full post-mortem pending the parents' consent. I don't believe I was involved in discussions about the extent of post-mortem in relation to Claire."*[509] Mrs. Roberts remembers that *"the decision was made by Dr. Steen."*[510]

274. The identity of the clinician responsible for deciding that it was appropriate to restrict the post-mortem to brain only (irrespective of who actually discussed it with Claire's parents) and their reasons for such a restriction, are matters to be pursued further in the Oral Hearings.

275. Given the importance of the post-mortem to the medical profession in terms of establishing a precise cause of death, providing feedback on the accuracy of clinical diagnosis and assisting in audit, risk management and medical education – it is surprising that more consideration was not given to recording the justification for the restricted hospital post-mortem. In addition, given the obvious importance to Mr. and Mrs. Roberts of understanding the precise cause of their daughter's death, it is surprising that the discussions with them were not noted.

276. Professor Lucas states in his Report that whilst ideally the reasons for the restriction should be entered in the medical notes but: *"in reality these things do not necessarily happen."*[511] Dr. Squier is also of the view that it would have been helpful but notes that it was not a requirement.[512]

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507 Ref: 239-002-005
508 Ref: Transcript of Oral Hearings on 17th October 2012 p.180 line 10
509 Ref: WS-138-1 p.91
510 Ref: WS-257-1 p.17
511 Ref: 239-002-005
512 Ref: 236-007-003

277. It has been commented that *"a large number of clinicians appear to have never received any formal training or advice in how to approach relatives for permission for a post-mortem."*[513] The training and procedures governing the taking of consent for post-mortems in the Children's Hospital are matters that will be explored further during the Oral Hearings.

278. Consent for a hospital autopsy carries implicit consent not to refer the death to the Coroner. It is a matter of clinical judgment whether a restricted post-mortem is appropriate in all the circumstances. However, the apparent lack of guidance from RGH to direct the process and the absence of any records to explain it are matters of clinical governance. Furthermore, there seems to be no guidance as to the possible merits of a second opinion or when that might be appropriate, or for a review of the exercise of the clinical judgment involved, the appropriateness of the decision reached and the process by which it was made and consent obtained. The issue of 'review' is referred to in the 1991 Report of the Joint Working Party under 'Assessing the Results of Autopsy' and 'Auditing the Autopsy itself'.[514]

279. Those issues of guidance will be considered further during the Oral Hearings as will the question of whether there could or should have been safeguards within the system to protect it from possible abuse.

280. Having decided not to refer Claire's death to the Coroner and to seek a limited hospital post-mortem, Dr. Steen proceeded to issue a death certificate. She has noted in the case record: *"Death Certificate issued – cerebral oedema 2º status epilepticus."*[515] Dr. Webb maintains that he was not consulted by Dr. Steen in relation to the certificate.[516] He describes how *"Dr. Steen dealt with Claire's death certificate completion. My opinion on Claire's death was clearly indicated in my clinical note"*[517] i.e. *"SIADH. Hyponatraemia. Hypoosmolarity, Cerebral Oedema and Coning following prolonged epileptic seizure."*[518] Dr. McKaigue recalls that *"no advice was sought from me and I did not have any input into the causes of death included on the death certificate of Claire Roberts."*[519]

281. It is noteworthy that Dr. Steen felt confident to issue the death certificate without consulting Dr. Webb and to ignore his reference to hyponatraemia appearing in the clinical record. That she also omitted reference to encephalitis or viral infection is striking since - it was one of the differential diagnoses formulated at the very outset of Claire's

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513 Ref: 314-011-001. Post Grad Medical J. 1995.71.269-272; (*"Asking relatives for permission for a post-mortem examination"*)
514 Ref: 236-007-064
515 Ref: 090-022-061
516 Ref: WS-138-1p.54
517 Ref: WS-138-2p.16
518 Ref: 090-022-057
519 Ref: WS-156-1 p.4

admission,[520] she explained to Claire's parents that a virus was the probable cause of their daughter's demise and expressed the view to them that the Autopsy might be able to identify the virus responsible for Claire's brain swelling.[521] Dr. Steen has explained *"why I did not include the viral encephalitis- I don't know"*[522] and *"because it wasn't confirmed."*[523]

282. The basis upon which Dr. Steen chose not to include 'hyponatraemia' on this or any other document in the aftermath of Claire's death is unclear. 'Hyponatraemia' appears as a diagnosis entered into the medical record when Claire was in Allen Ward, in PICU and upon discharge from PICU. If Dr. Steen issued the death certificate without the input of Dr. Webb or others then she can only have done so on the basis of the case record. Dr. Steen now considers that: *"on review of the notes I feel the development of cerebral oedema was due to multi factorial causes – viral encephalitis, status epilepticus – SIADH. Once the serum sodium result of 121 was known, hyponatraemia would have been considered as a contributory factor to the cerebral oedema."*[524] However, why she was not able to do so at the time is a matter to be further pursed during the Oral Hearings.

283. Clear and cautionary guidance is given to all medical practitioners in respect of signing certificates by paragraph 41 of The GMC's 'Good Medical Practice' (October 1995): *"Registered medical practitioners have the authority to sign a variety of documents, such as death certificates, on the assumption that they will only sign statements they believe to be true. This means that you must take reasonable steps to verify any statements before you sign a document. You must not sign documents which you believe to be false or misleading."*[525]

284. Further specific guidance to the certifying medical practitioner on the completion of medical certificates of cause of death is given by the notes accompanying the certificate itself: *"no medical certificate of cause of death may be given on the prescribed form unless the certifying medical practitioner has been in attendance upon the deceased during his or her last illness."*[526]

285. Whether, in all the circumstances, Dr. Steen was justified in issuing the medical certificate of cause of death as she did, in choosing not to refer Claire's death to the Coroner and in limiting the hospital post-mortem

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520 Ref: 090-022-052
521 Ref: WS-231-1, p.15
522 Ref: Transcript of Oral Hearings on 17th October 2012 p.224 line 11
523 Ref: Transcript of Oral Hearings on 17th October 2012 p.225 line 6
524 Ref: WS-143-1p.79
525 Ref: 314-001-014
526 Ref: 139-033-002

to the brain alone, are matters that will be considered further during the Oral Hearings.

XVII. Post-Mortem Request Procedure

286. In accordance with correct procedure, Claire's GP was informed of her death at approximately mid-day on 24th October 1996. The information was relayed by telephone and no standard discharge letter appears to have been sent. A copy of the Discharge Advice Note was sent to Dr. McMillin on 29th October 1996.[527] This was signed by Dr. Mannam, SHO in PICU. It lists the principal diagnosis as 'cerebral oedema' with the diagnoses of 'status epilepticus' and 'hyponatraemia'. There may be doubt as to whether the word 'hyponatraemia' is entered in the same hand as the other entries. It does however appear on the carbon copy of the note known as the Case Note Discharge Summary,[528] which confirms that it was made before it was sent out to Dr. McMillin.

287. The Children's Hospital PICU Coding Form was completed on 23rd October.[529] The principal and subsidiary diagnoses were codified.[530] Mr. Danny McWilliams, who was the Clinical Coding Manager at the Trust at the time of Claire's death states in his Inquiry witness statement: *"it appears that the discharge/transfer pro-forma and case notes were used in conjunction with the PICU Coding Form."*[531] Accordingly Claire's death was clearly coded with reference to the complete hospital record and hyponatraemia was included amongst the coded diagnoses.

288. The Autopsy Request Form was then completed by Dr. Steen.[532] She did not date it. It has been observed that: *"the outcome of an autopsy request is highly dependent on the manner in which it is made."*[533] The information provided by the Autopsy Request Form is inaccurate in certain respects:

    (i) Date of admission to hospital is incorrectly given

    (ii) History of illness is incorrect, in that Claire had not been unwell for 72 hours prior to admission

    (iii) Claire did not start to vomit 24 hours prior to admission

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527 Ref: 112-030-045
528 Ref: 090-009-011
529 Ref: 090-055-203
530 Ref: 090-055-203
531 Ref: WS-294-1 p.8
532 Ref: 090-054-183
533 Ref: McGoogan E. "*The Autopsy and Clinical Diagnosis*" J.R. Coll. Physicians. London. 1984; 18; 240-243).

(iv) History of medication administered is incomplete, in that there is no reference to midazolam being administered

(v) Timing of the second brain stem death test is incorrectly given

(vi) There is no explicit reference to 'hyponatraemia' and whilst the serum sodium level of 121mmol/L is noted, only *"inappropriate ADH secretion"* queried as a possible cause[534] and not the *"fluid overload & low Na fluids"* queried by Dr. Stewart in Claire's clinical notes[535]

(vii) Although the iv administration of solution No.18 was restricted to 41mls/hr being two-thirds the previous rate of 64mls/hr, as directed by the registrar Dr. Bartholome at about 23:30 on Tuesday 22nd October,[536] the total fluids administered to Claire were not restricted because she was receiving 60mgs phenytoin in an iv solution making a total 110mls over the hour commencing on 23:00.[537]

289. Dr. Steen states in her Inquiry witness statement that she hoped the results of the brain-only autopsy would: *"determine if an encephalitis was present"* and *"determine an underlying cause for the seizures and developmental delay."*[538] In addition, during her oral evidence Dr. Steen was of the view that she informed Mr. and Mrs. Roberts that a further benefit of a brain-only autopsy was that it might provide some explanation for Claire's developmental delay.[539] However, that was denied by Mr. and Mrs. Roberts during their evidence. They were adamant that they would have remembered such a statement as they would have wanted to know that but that Dr. Steen did not tell them that.[540]

290. Given Dr. Steen's express objective in requesting a brain-only autopsy, the reasons why she did not provide an accurate history of Claire's pre-admission illness in her Autopsy Request Form will be further explored during the Oral Hearings. So too will the reason why she makes no explicit reference in it to seeking an explanation for Claire's developmental delay.

291. The Department of Neuropathology daybook entry for 24th October 1996 records the receipt of the brain specimen and names the

534 Ref: 090-054-183
535 Ref: 090-022-056
536 Ref: 090-022-056. See too the Intravenous Fluid Prescription Chart – Ref: 090-038-136. See also the Fluid Balance and IV Prescription Sheet – Ref: 090-038-135
537 Ref: 090-026-073. See too the Fluid Balance and IV Prescription Sheet – Ref: 090-038-135
538 Ref: WS-143-1 p.72
539 Ref: Transcript of Oral Hearings on 17th October 2012 p.181-2
540 Ref: Transcript of Oral Hearings on 1st November 2012 p.192

Pathologist as Dr. Herron.[541] It does not record the ward and/or Claire's hospital number, nor use the correct spelling of Claire's name. It also shows the diagnosis *"viral encephalitis. Epilepsia"* which does not quote the Autopsy Request Form.[542] In addition, the time that the Autopsy Request Form was received in the mortuary is not noted in the space provided.

292. It is a matter to be investigated whether those deficiencies in the 'daybook' entry indicate that the post-mortem might have commenced before the receipt of the Autopsy Request Form that provides those details. Professor Lucas has advised that can happen when the pathologist wishes to expedite matters but that a post-mortem should not commence before the consent form has been signed (and presumably the pathologist has satisfied himself that has been done) otherwise the post-mortem would be illegal. [543]

293. Guidance on the request for autopsies is provided in the 1991 Report of the Joint Working Party under 'Posing the Problems for the Pathologist'. It advises that: *"Where cases are difficult or complex it is wise for the requesting consultant to discuss the problem with the pathologist prior to the autopsy and not merely rely on a written request."*[544]

294. It is not known whether there was any discussion between Dr. Steen and Drs. Herron and Mirakhur to offer any guidance as to what in particular she wished to have investigated and why. None is recorded and at this remove, Dr. Steen cannot remember whether or not she had any such discussions.[545]

295. The extent to which the guidance provided in the 1991 Report of the Joint Working Party was considered in the RGH will be explored during the Oral Hearings. The role and benefits of discussions between the clinicians and the pathologists, in terms of the good conduct of hospital autopsies, is also a matter to be explored during the Oral Hearings. So too is the question of whether the quality of the information provided by Dr. Steen on the Autopsy Request Form materially affected the conduct of the Autopsy and or the conclusions in the Autopsy Report.[546]

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541 Ref: 090-054-179
542 Ref: 090-054-180
543 Ref: 239-002-006
544 Ref: 236-008-057
545 Ref: WS-143-2 p.20
546 Ref: 090-003-003

XVIII. Conduct of the Autopsy limited to 'Brain-Only'

296. Dr. Squier has set out in detail in her second Report for the Inquiry, the various stages of a brain-only autopsy.[547] The 1993 RCPath Guidelines for Post Mortem Reports also provide guidance on internal examination and, in particular at appendix 2, 'Neuropathology'.[548]

297. In an echo of Dr. Steen's reasoning for the post-mortem, Dr. Herron has stated: *"The autopsy was done to address the presence or absence of status epilepticus and encephalitis."*[549] He has subsequently stated: *"A Neuropathologist is guided by the autopsy request form."*[550] This notes the clinical diagnosis as *"cerebral oedema 2º to status epilepticus.?underlying encephalitis"*[551] and lists four clinical problems ranked *"in order of importance to enable the pathologist to produce a more relevant report"* as being *"cerebral oedema, status epilepticus, inappropriate ADH secretion and ?viral encephalitis."*[552] These were the specific issues highlighted in the Autopsy Request Form and the Autopsy would therefore have been performed to address these issues.

298. The issue is then whether the way in which the brain-only Autopsy was carried out would be likely to address those problems. This is an area where the clinical and governance issues are to a certain extent inter-linked.

Status epilepticus

299. The Royal College of Pathologist's 'Guidelines on Autopsy Practice' (2002) in respect of autopsies performed in relation to death advises: *"Status epilepticus – this must be clinically documented. Status epilepticus is a specific clinical entity and cannot be assumed from a post-mortem examination in the absence of good clinical documentation."*[553] Although that guidance post-dates the conduct of the autopsy on Claire's brain, it simply re-states what should have been known and appreciated at that time.

300. The Autopsy Report does not make any reference to the clinical documentation of the case record. Indeed, it does not appear to have been written with any knowledge of or reference to the case record. Dr. Herron has no recollection of reading the clinical notes at that time.[554] Dr. Mirakhur advises that she did not normally read the notes, even in

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547 Ref: 236-004-003
548 Ref: 236-007-054
549 Ref: WS-224-1p.7
550 Ref: WS-224-3 p.13
551 Ref: 090-054-183
552 Ref: 090-054-184
553 Ref: 314-008-062
554 Ref: WS-224-3 p.20

relation to drug history.[555] This might be considered particularly significant given that the Report may thus have been prepared on the basis of incorrect information from the Autopsy Request Form and in ignorance of the consideration for the overdoses of phenytoin and midazolam either 'masking symptoms' or producing 'paradoxical effects'.

301. Dr. Mirakhur's approach is not reflected in the guidance. The 1991 Report of the Joint Working Party recommends that Autopsy Requests should be accompanied by the case notes and radiographs[556] (which was apparently done in Claire's case[557]), whilst the 1993 RCPath Guidelines For Post Mortem Reports makes it clear that it is: "*the pathologist's responsibility to be satisfied that a full account has been obtained*"[558] of the history of present illness and the circumstances of death. Also 'Practice guidelines for necropsy: time for action' (1996) specifically refers to: "*Patient notes and consent forms should be studied, carefully, particularly in relation to clinical problems and possible limitations placed on the examination by relatives.*"[559]

302. A consideration of Claire's clinical notes would have made it clear that no EEG been carried out to confirm the differential diagnosis of 'status epilepticus'. Furthermore, Claire had not responded to the intensification of the anti-convulsant drug therapy, in terms of both different drugs and increased dosages.

303. Whilst, Dr. Steen states in her evidence that "*epilepsy won't show on post-mortem*",[560] Dr. Squier is of the view that a CT scan could show evidence of status epilepticus. It is a specialist area of radiology and although she is of the view that: "*Most radiologists would not be willing to attempt to identify features of status epilepticus*", she nonetheless considered that "*the scans should be reviewed to look for causes of status*"[561] and that a referral to a consultant radiologist might therefore have been considered.

304. That latter point goes to the more general issue as to the extent to which it would have been appropriate for the pathologists to seek specialist opinion on some aspects of the case. For example Dr. Squier states in her Report that in: "*the case of a child who has died suddenly with no clear clinical diagnosis*" not only would she expect a full autopsy but

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555 Ref: WS-247-2 p.4

556 Ref: 236-007-065

557 See the reference to "*See chart*" under 'Investigations' on the Autopsy Request Form' – Ref: 090-054-183

558 Ref: 236-008-045

559 Ref: 236-007-077; Roger Start & Simon Cross, 'Practice guidelines for necropsy: time for action', J Clin Pathol 1996; 49:867-868 – Ref: 236-008-066

560 Ref: Transcript of the Oral Hearing on 17th October 2012 p.180 line 24

561 Ref: 236-007-004

also *"I would expect a paediatric pathologist to be consulted or involved."*[562] The extent to which Drs. Herron and Mirakhur sought specialist assistance will be further pursued as will the question of whether they ought to have done so in the interests of carrying out an appropriate investigation in response to Dr. Steen's Autopsy Request Form.

305. Dr. Squier also concedes that an opinion from a paediatric neuropathologist or a neuropathologist specialising in neurogenetics, should have been sought in relation to the evidence of 'neuronal migrational defect' apparently identified by Drs. Herron and Mirakhur: *"In view of the history of mental handicap and epilepsy and the apparent absence of relevant hippocampal pathology it would have been advisable … Review of the brain scans and consultation with someone more experienced in interpretation of paediatric brain pathology would be best practice."*[563] The 'lack of hippocampal pathology' is a reference to the apparent failure of the pathologists to apply: *"special stains … to look for subtle hippocampal pathology to explain the history of epilepsy or to confirm the findings thought to represent neuronal migration disorder."*[564] Dr. Squier regards that as surprising: *"in the context of a consented autopsy, the purpose of which is to make a detailed diagnosis."*[565]

306. Dr. Squier also prepared slides of the hippocampus stained with GFAP so as to demonstrate the presence of any astrocytes[566] that would be consistent with epilepsy. She concluded there was marked gliosis in the hippocampus, the pattern of which was that of old mild hippocampal sclerosis (scarring), which is associated with epilepsy.[567] However, Dr. Squier found no evidence of the 'neuronal migration disorder' that Drs. Herron and Mirakhur claim to have detected. In her view the irregularly clustered cells seen are normal for the site and part of the hypothalamus, whereas the subependymal cells are likely to be residual germinal matrix cells that are also normal for the site.[568] She saw no evidence of Drs. Herron and Mirakhur having particularly stained the slides taken of the areas where they say there is evidence of neuronal migration so as to enhance the imaging and so confirm their opinion.

Encephalitis

307. Dr. Herron informs the Inquiry in his witness statement that: *"Infections that cause diarrhoea are also causes of encephalitis and therefore the history of*

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562 Ref: 236-007-006
563 Ref: 236-007-004
564 Ref: 236-007-005
565 Ref: 236-007-005
566 Ref: 236-007-022
567 Ref: 236-003-006
568 Ref: 236-003-006

diarrhoea was relevant for this reason."[569] It is therefore unfortunate that the pathologists should have predicated the Autopsy Report upon a history of diarrhoea when none was recorded in the case notes.

308. No brain tissue seems to have been taken to be sent off for culture. That might have been appropriate given the fact that differential blood tests were not carried out during Claire's admission to isolate the type of virus involved and that an explanation for the brain-only autopsy that was provided to Mr. and Mrs. Roberts was that: *"the hospital needed to carry out a post mortem on Claire's brain to try to establish and identify the virus responsible for the brain swelling."*[570]

309. Furthermore Professor Lucas expressed his surprise: *"that no one … performed specific immunohistochemical stains on the tissue slides to determine for sure the presence/absence of inflammatory T-cells or reactive astrocytes and microglia; in my book, infiltrating CD8+ve T-cells are necessary to diagnose 'encephalitis' in most cases, and … they are either there in the brain or they are not. If they are not, then it is not encephalitis."*[571]

310. Dr. Squier refers to the fact that: *"There has been no attempt to confirm the observations made with additional studies … No Gram stains were done to look for a bacterial cause."*[572] She prepared her own slides applying the appropriate stains: *"Immunocytochemistry was submitted on blocks Ox15 and 16 with antibodies to L26, CD3 and CD68. All other immunocytochemistry was stained in Oxford. This includes GFAP, βAPP, LBCV and CD68."*[573] Her conclusions are that in respect of Ox15 (midbrain) there *"is no substantial tissue infiltrate"*, whereas in respect of Ox16 (pons) there is *"no excess of macrophages in the meninges and no evidence of meningitis or encephalitis."*[574]

311. There is no description in the Autopsy Report of the stains applied by Drs. Herron and Mirakhur to the slides that they made. Dr. Squier has identified them as H&E and L26, CD68 and CD3.[575] Neither do Drs. Herron and Mirakhur explain in the Autopsy Report how any stains that they did apply were appropriate to identify and 'diagnose' the *"low grade subacute meninoencephalitis"*[576] they claim to have detected.

312. Dr. Squier queries the appropriateness of restricting the autopsy to brain-only: *"when a systemic infection was suspected as the cause of Claire's*

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569 Ref: WS-224-1 p.12
570 Ref: WS-253-1, p.15
571 Ref: 239-002-011-12
572 Ref: 236-007-005
573 Ref: 236-003-008
574 Ref: 236-003-010
575 Ref: 236-003-003
576 Ref: 090-003-005

illness on admission."[577] She considers that Drs. Herron and Mirakhur may also have recognised its disadvantages[578] as the 'Comment' section of the Autopsy Report states: *"as this was a brain only autopsy it is not possible to comment on other systemic pathology."*[579]

Inappropriate ADH

313. The Autopsy Request Form lists *"inappropriate ADH secretion"* as a clinical problem of greater importance than *"? viral encephalitis."*[580] It also provides a history of a low sodium result of 121mmol/L, inappropriate ADH, fluid restriction, respiratory arrest and cerebral oedema. Claire's medical notes apparently accompanied the Autopsy Request Form and they specifically refer to 'hyponatraemia' in the context of SIADH and low sodium fluid overload.[581] However, there is no real evidence of how those potential causes of Claire's fatal cerebral oedema were considered. The comment section merely observes that *"a metabolic cause cannot be entirely excluded."*[582]

314. Dr. Herron lists in his Inquiry witness statement the many diseases that can cause SIADH.[583] Many relate to organs, conditions and drugs that a brain only autopsy could not hope to examine. It seems that the pathologists were not consulted as to the limitations imposed upon the post-mortem.[584]

315. The question that is therefore to be further pursued is the extent to which Drs. Herron and Mirakhur were unable to address issues relating to SIADH as a result of the restriction that Dr. Steen had imposed on the autopsy by limiting it to 'brain only'.

Cerebral Oedema

316. The CT scan that was carried out when Claire was in PICU confirmed the presence of cerebral oedema:[585] *"generalised cerebral swelling with effacement of the cortical sulci as well as the basal cisterns and the third ventricle."*[586] The issue for Drs. Herron and Mirakhur was therefore to seek to shed light on the cause of Claire's fatal cerebral oedema.

317. Professor Lucas observes in his Report that: *"The histological identification of cerebral oedema is a fraught area, with inter-observer*

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577 Ref: 236-007-003
578 Ref: 236-007-003
579 Ref: 090-003-005
580 Ref: 090-054-184
581 Ref: 090-022-056, Ref: 090-022-057 and Ref: 090-022-059
582 Ref: 090-003-005
583 Ref: WS-224-1p.9
584 Ref: WS-224-1 p.7
585 Ref: 090-022-058
586 Ref: 090-033-0-114

variation."[587] Dr. Squier accepts in her Report that it would have been appropriate to have sought a specialist opinion from a consultant chemical pathologist as to the likely cause of Claire's cerebral oedema and or the possible effect of her hyponatraemia.[588]

318. It would seem that there is no real explanation for the cerebral oedema. Accordingly, the manner in which Drs. Herron and Mirakhur investigated the cause of the cerebral oedema is a matter to be further pursued.

Post Autopsy Discussions

319. It is not clear that there were any discussions between Drs. Herron and Mirakhur and Claire's clinicians before they furnished their Autopsy Report.

320. Whilst Dr. Squier acknowledges that it is not always necessary, she states: *"In this case, while two diagnostic conclusions had been reached in the Final Report there remained further uncertainties such as whether the history of diarrhoea and vomiting may have been associated with CNS infection or whether there was metabolic disease. These issues should have been investigated with the relevant clinicians prior to finalising the autopsy report."*[589]

321. Furthermore, Dr. Squier expresses surprise in her Report that given there was no real explanation for the cerebral oedema, that: *"there was no further discussion of the cause of the brain swelling when the clinical deterioration was so fast and the pathology thought to represent inflammation so mild."*[590]

322. The 1991 Report of the Joint Working Party states that: *"Close liaison between physicians, surgeons and pathologists is to be encouraged."*[591] The issue of whether there were in fact any such discussions, together with the practice of the RGH ion 1996 in that regard, is a matter that will be pursued during the Oral Hearings.

XIX. Autopsy Report

323. Dr. Herron prepared[592] and initialled the Provisional Anatomical Summary,[593] which is the initial stage of the reporting process. It

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587 Ref: 239-002-012
588 Ref: 236-007-004
589 Ref: 236-007-004
590 Ref: 236-007-009
591 Ref: 236-007-065
592 Ref: WS-224-3 p.5
593 Ref: 090-005-007

incorrectly gives the time of death as 06:25 on 23rd October 1996 and cites as the *"Anatomical Summary"* a *"history of acute encephalopathy. Brain to be examined after fixation."*[594] It is unclear why the history and diagnosis is not given as stated in the Autopsy Request Form - Dr. Herron explains that *"history of acute encephalopathy"* is an interpretation of the clinical information described under *"history of present illness"* in the Autopsy Request Form.[595] If so, it is unclear why the history of seizures, the low serum sodium result of 121mmol/L, the queried role of inappropriate ADH and the resulting cerebral oedema are all not mentioned in the Provisional Anatomical Summary.

324. Professor Lucas refers to the Provisional Anatomical Summary as being merely *"a holding statement."*[596] Nevertheless, the reasons for those omissions, including the possibility that it was created before the Autopsy Request Form was actually received, are matters that will be addressed at the Oral Hearings in terms of good autopsy practice.

325. The Autopsy Report itself is dated 11th February 1997, which is some three and a half months after Claire's death.[597] It identifies the Pathologist as Dr. Herron[598] who was a registrar at the time of the autopsy and gave evidence in respect of *"[his] report"*[599] to H.M. Coroner at Claire's Inquest. Subsequently, Dr. Herron explained to the Inquiry that whilst he was: *"involved during the initial stages of the autopsy and the brain cut,"*[600] but that *"when the paperwork was retrieved to prepare these depositions, it was discovered that one of my colleagues (Dr. M Mirakhur) was the author of the final report."*[601] However, in her Witness Statement Dr. Mirakhur states that *"I supervised Dr. Herron as part of the team."*[602]

326. Although a number of draft versions of the Autopsy Report have come to light,[603] the Inquiry has yet to be provided with a signed one. Such a copy would confirm the correct final version. Professor Lucas states in his Report that: *"I do not usually sign my reports by hand, but it is made clear that what goes out is the final report."*[604] Dr. Squier has a different view to that of Professor Lucas, stating in her Report: *"This is an official*

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594 Ref: 090-005-007
595 Ref: WS-224-3p.10
596 Ref: 239-002-006
597 Ref: 090-003-005
598 Ref: 090-003-003
599 Ref: 091-005-015
600 Ref: WS-224-2, p.2
601 Ref: WS-224-2 p.2
602 Ref: WS-247-1 p.6
603 Ref: 090-054-186, Ref: 090-054-190 and Ref: 090-054-200
604 Ref: 239-002-009

record of the autopsy and a part of the clinical record. It should be signed by the person responsible for it."[605]

327. In view of Dr. Mirakhur's involvement as the consultant, Dr. Squier goes on in her Report to state that: *"A Consultant should sign the report of a trainee either as a supervisor or as someone who contributed to the report."*[606] Professor Lucas agrees as to the identification of the consultant. He also advises in his Report that joint authorship of autopsy reports by the consultant and junior is frequent but that in his experience: *"it goes out under the consultant's name (hopefully with mention of the junior)."*[607]

328. No proper explanation has been provided to the Inquiry as to why there is no signed version, especially given Dr. Herron's Inquiry witness statement: *"the final report would not have been sent had it not been signed. The signed report is the copy that goes to the clinician and to my knowledge a final report has never left neuropathology unsigned."*[608]

329. Neither Claire's parents nor her GP were sent a copy of the Autopsy Report, so there is no further potential source for the final Report, save for Dr. Steen or Dr. Webb.

330. The Autopsy Report may be criticised in the following factual respects:

(i) Date of admission to hospital at 22nd October 1996 is incorrect

(ii) Time of death at 6.25 hours on 23rd October 1996 is incorrect

(iii) The Anatomical Summary introduces a hitherto unknown history of *"recent diarrhoea"* [609] which does not originate in either the Autopsy Request Form, which refers only to *"a few loose stools"*[610] or the case record, which specifically records *"[no] diarrhoea"*,[611] *"loose motion 3 days ago"*[612] and *"loose motions on Sunday"*[613]

(iv) The Anatomical Summary additionally introduces a previously unrecorded history of *"epileptic seizures since 10 months of age"* [614]

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605 Ref: 236-007-006. See too her second Report for the Inquiry, where she acknowledges that the report can be co-signed by a junior pathologist and the accredited consultant – Ref: 236-004-006

606 Ref: 236-007-007

607 Ref: 239-002-008

608 Ref: WS-224-3 p.7. However, in his more recent Inquiry witness statement Dr. Herron, whilst confirming that as the practice, refers to the possibility that it was sent unsigned but with a signed covering letter that has since been mislaid – Ref: WS-224-4, p.5

609 Ref: 090-003-003

610 Ref: 090-054-183

611 Ref: 090-012-014

612 Ref: 090-022-050

613 Ref: 090-022-055

614 Ref: 090-003-003

which does not originate in either the Autopsy Request Form, which refers to *"seizures from 6 months – 4 years"*[615] or the case record, which refers to *"past history of epilepsy fit free for 3 yrs"*,[616] *"h/o epilepsy – no fits for three years, off antiepileptic medication"*,[617] *"seizures 6mth – 1yr … age 4 – x1 seizure"*[618] and *"6mths old seizures and 1y for this."*[619]

Dr. Squier is also critical of the Anatomical Summary in that she considers that*: "it does not reflect the complete clinical problem or pathological findings. There was no brainstem necrosis and the vessels which have been photographed and submitted to illustrate inflammation are not from the meninges, so the diagnosis of subacute inflammation in the meninges is not supported."*[620]

(v) The Clinical Summary repeats the incorrect statement in the Autopsy Request Form[621] that Claire was unwell for 72 hours prior to admission by stating that: *"She was well until 72 hours before admission."* [622] It also inaccurate in some other respects. It states that Claire: *"had similar symptoms"* to *"her cousin who had vomiting and diarrhoea"* [623] which does not originate in either the Autopsy Request Form[624] or the case record, which states: *"contact with cousin on Sat who had a G.I.T upset. Claire had loose motions on Sunday + vomiting Monday."*[625] It also repeats the incorrect reference in the Anatomical Summary to: *"In her past history she had iatrogenic epilepsy since 10 months."*[626]

331. Drs. Herron and Mirakhur were informed at the outset by the Autopsy Request Form that Claire had suffered a drop in serum sodium levels to 121mmol/L and had developed cerebral oedema. It also suggested, as a result of her clinical history and the reference to 'acyclovir cover' having been given, a viral aetiology. The Autopsy Report appears to add little to that knowledge. It neither confirms nor excludes the involvement of status epilepticus or viral encephalitis stating in the commentary section that: *"with the clinical history of diarrhoea and vomiting"* a viral aetiology *"is a possibility."*[627] Mr. and Mrs. Roberts may wonder as to the purpose, in all the circumstances, of this Report.

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615 Ref: 090-054-183
616 Ref: 090-011-013
617 Ref: 090-012-014
618 Ref: 090-022-050
619 Ref: 090-022-053
620 Ref: 236-007-008
621 Ref: 090-054-183
622 Ref: 090-003-003
623 Ref: 090-003-003
624 Ref: 090-054-183
625 Ref: 090-022-055
626 Ref: 090-003-003
627 Ref: 090-003-005

Dr. Herron admits: *"as a Neuropathologist I can only address neuropathological issues in this case. It is possible that Claire did not have encephalitis in all the circumstances but I cannot comment on the specifics of her cause of death."*[628]

332. Although, Professor Lucas considers that the Autopsy Report broadly follows the 1993 RCPath Guidelines for Post Mortem Reports,[629] however, he regards a major issue with the Autopsy Report as being the: *"lack of clinico-pathological correlation after the autopsy and histopathology had been completed."*[630] The 1993 RCPath Guidelines For Post Mortem Reports requires the commentary section in the report to be written in the light of all the information available, to: *"Reconcile as far as possible the major clinical problems with the pathological findings"* and to: *"Present any inconsistencies in the findings and suggest any steps to be taken, such as further opinions, audit meetings, etc."*[631]

333. Professor Lucas also identifies two other respects in which he does not consider that the Autopsy Report followed those guidelines, namely: *"Timeliness [the three month time it took to produce the report] … No mention of a clinico-pathological or audit meeting in a complex case."*[632]

334. Ultimately, it will be a matter for you Mr. Chairman to determine the adequacy of the autopsy process and the Autopsy Report.

Tissue sampling

335. The post-mortem Report made no reference to any tissue samples being kept and no indications were given as to future intentions in respect of retention or disposal. Mr. and Mrs. Roberts were not advised, at that time, that any remains of their daughter were retained. Still less, were their feelings or wishes sought. Nonetheless, the Inquiry has been informed that tissue samples were retained by Neuropathology services at the RGH but suffered deterioration and were subsequently disposed of. It would appear that although the precise date of disposal was not recorded it was probably in July/August 2009.

336. The Report of the Joint Working Party (1991) emphasises that: "retention of tissue for purposes other than to establish the cause of death is subject to the Human Tissue Act 1961. The constraints provide equally to clinical autopsies and those performed by the Coroner. [633]

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628 Ref: WS-224-4 p.7
629 Ref: 239-002-014
630 Ref: 239-002-009
631 Ref: 236-007-054
632 Ref: 239-002-014
633 Ref: 236-007-070

337. No information has been given as to the place or method of disposal of the tissue. Claire's remains may have been accorded all appropriate respect but there would appear to have been a want of sensitivity towards the feelings of Mr. and Mrs. Roberts in this regard which runs contrary to the guidelines issued by the DoH 'Families and Post-mortems Code of Practice' (2003) which emphasises at paragraph 57: *"Tissue and organs should be handled respectfully at all times, in accordance with any reasonable wishes expressed by family or the deceased person. The method of disposal must be legal."*[634] The Retained Organs Commission issued guidance in July 2001 as to procedure to be followed if Hospital Trusts held previously retained material for which the wishes of families were not obtained or recorded.[635] Mr. and Mrs. Roberts have not been informed as to the procedures adopted.

Post Autopsy Report Discussions

338. Both Dr. Squier and Professor Lucas consider that Claire's case would have benefited from discussions between the pathologists and the clinicians. Professor Lucas takes the view that *"Perhaps had there been a mortality conference after the autopsy, a bright clinican might have asked "But is that enough inflammation/encephalitis to account for what happened?" – then the initial story would have unravelled and a focus on other causes such as hyponatraemia might have emerged."*[636] He further states that the Report *"provided the necessary basis for further discussion with informed clinicians and thus a collective review of critical events."*[637] Dr. Squier states that a meeting between the pathologists and the clinicians either before or after the Autopsy Report was finalised, would have been *"best practice."*[638] It is relevant to note that the Guidelines for Post Mortem Reports (1993) provide the following: *"Regular mortality meetings should be held to discuss and analyse the autopsy findings in individual patients or groups of cases. The major and primary purpose of these meetings should be educational. There should be frank discussion concerning diagnostic procedures, clinical management and outcome as part of normal hospital procedures. They should be used to evaluate both individual cases and the organisation of the hospital as a whole to ensure that in all aspects it is functioning for the benefit of individual patients"*[639]

339. Mr. and Mrs. Roberts received no information as to the progress of this post-mortem examination. They met with Dr. Sands on 11th November 1996. Dr. Sands' *"recollection of the meeting was that Claire's parents needed*

634 Ref: 314-010-024
635 Ref: 314-010-024
636 Ref: 239-002-012
637 Ref: 239-002-014
638 Ref: 236-007-010
639 Ref: 236-007-071

to talk to a senior doctor about outstanding questions they had."[640] He noted in the medical record that *"They are naturally anxious to discuss the post-mortem results with someone. I will pass this on to Dr. Steen ASAP."*[641] Dr. Steen wrote to Mr. and Mrs. Roberts on 18th November 1996 and advised *"Post-mortem results will not be available until after Christmas and even then I may not be able to answer all your questions."*[642]

340. Subsequently Dr. Steen had a meeting with Mr. and Mrs. Roberts on 3rd March 1997. Dr. Webb also attended. It is recalled by Mr. Roberts: *"Dr. Steen informed my wife and I that the post-mortem identified a viral infection in Claire's brain but the virus could not be identified. Dr. Steen advised how an enterovirus starts in the stomach and can spread up to the other parts of the body as in Claire's case. My wife and I asked if everything possible had been done for Claire and if anything else could have been done. Dr. Steen reassured us that everything possible was done."*[643] The post-mortem Report itself was not shared with Mr. and Mrs Roberts and no additional consideration appears to have been given to referring Claire's death to the Coroner.

341. No record of this meeting or of the advice given was kept by Dr. Steen or Dr. Webb, or entered onto the record. The information given may have been intended to assist in the grieving process or to alleviate any possible sense of doubt felt by Mr. and Mrs. Roberts through reassurance that death was inevitable and that all appropriate care had been given. However if Mr. Roberts' recollection is accurate, then a clear misrepresentation of the post-mortem findings was given and information was withheld. The parents would thus have been denied their right, namely knowledge of the precise causes of death.

342. Dr. Steen followed up this meeting with a letter to Dr. McMillin, Claire's family GP, dated 6th March 1997[644] to advise as to post-mortem results. A copy of the Autopsy Report was not enclosed and in respect of the cause of death Dr. McMillin was simply informed that *"Changes w[h]ere in keeping with a viral encephalomyelitis meningitis."*[645] It is difficult to reconcile this information with the broader content of the Autopsy Report or Dr. Steen's statement in her letter to the Roberts of 18th November 1996 that: *"I know meningitis was not Claire's problem."*[646] Dr. Steen advises Dr. McMillin that *"Mr. Roberts wanted a short summary of the post-mortem report which Dr. Webb will send to him shortly."*[647]

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640 Ref: WS-137-3 p.10
641 Ref: 090-022-061
642 Ref: 090-004-006
643 Ref: WS-253-1 p.17
644 Ref: 090-002-002
645 Ref: 090-002-002
646 Ref: 090-004-006
647 Ref: 090-002-002

343. Dr. Webb wrote to Mr. and Mrs. Roberts by letter bearing *"Date of Dictation - 28.2.97; Date of Typing – 21.3. 97."*[648] This letter does provide a short summary of the findings on Autopsy, namely: "*Swelling of the brain with evidence of… a low grade infection (meningoencephalitis). The reaction in the covering of the brain (meninges) and the brain itself is suggestive of a viral cause. The clinical history of diarrhoea and vomiting would be in keeping with that."*[649] This would appear a more faithful summary than Dr. Steen's but is selective in withholding reference to the *"Viral studies [that] were negative during life and on post-mortem CSF."*[650] Dr. Webb makes erroneous reference to *"The clinical history of diarrhoea and vomiting [which] would be in keeping with [a viral cause]."*[651] In respect of the same viral cause the Autopsy Report concludes: *"With the history of diarrhoea and vomiting this is a possibility though a metabolic cause cannot be entirely excluded."*[652] Dr. Webb's summary therefore conveys the sense of a post-mortem result of viral cause. It is a question for the Inquiry as to whether there was any intention on the part of either Dr. Steen or Dr. Webb to withhold information.

344. Dr. Webb did not enclose a copy of the post-mortem Report. Indeed Claire's GP was never provided with a copy of the Autopsy Report. Dr. Ian Carson, Medical Director of RGH in 1996, has advised that *"the purpose of the report is to inform the clinician who may have requested the autopsy… and the family in regard to questions about the person's illness or the cause of death."*[653] The 1991 Report of the Joint Working Party provided that: *"It is important that after the post-mortem the results are communicated and explained to the patient's relatives as soon as possible. It may be done by the hospital consultant (or a delegate) in charge of the case or it may be done by the general practitioner. In either case a copy of the final post-mortem report should be sent to the general practitioner for information"*.[654]

345. It is worthy of remark that neither Dr. Steen nor Dr. Webb made reference to hyponatraemia either at their meeting with Mr. and Mrs. Roberts or in correspondence. It is a matter for the Inquiry to determine why this contributory factor went unmentioned.

346. Professor Lucas has expressed the view that of both: "*Drs. Steen and Webb have over-interpreted the infection pathogenesis, compared with the original Autopsy Report Comment."*[655] Accordingly, in answer to the question as to whether he agreed with the synopsis of the Autopsy

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[648] Ref: 090-001-001
[649] Ref: 090-001-001
[650] Ref: 090-003-005
[651] Ref: 090-001-001
[652] Ref: 090-003-005
[653] Ref: WS-270-1 p.7
[654] Ref: 236-007-070; 'Autopsy and Audit' Report (1991)

Report given by Dr. Steen to Claire's GP and by Dr. Webb to her parents[656] he answered: *"in that sense I do not agreed with it."*[657] Dr. Squier notes in her Report that the correspondence with Claire's GP and with her parents omits any: *"mention of the low serum sodium and how this may have played a part in Claire's death."*[658]

347. This issue was reviewed almost eight years later when Dr. Nichola Rooney wrote to Mr. and Mrs. Roberts on 12th January 2005 to explain *"Hyponatraemia was not thought at the time to be a major contributor to Claire's condition. It is noted from the post-mortem report that the presence of Hyponatraemia was indicated in the clinical summary provided to the Neuropathologist conducting the post-mortem."*[659] This statement is not borne out by a reading of Dr. Webb's entry in the medical chart or the discharge diagnosis from PICU, both of which clearly implicate hyponatraemia. The clinical summary provided does not contain the word 'hyponatraemia'.

348. Mr. and Mrs. Roberts had to wait for over three months before the post-mortem *"results"* were conveyed to them. That they should have waited so long is a matter for disquiet. Professor Lucas is critical of the unnecessary delay and suggests it could have contributed to the possible failure to conduct an audit or review of the findings.[660] Dr. Bartholome has stated in this respect that any prospect of an audit in relation to Claire's death would have been delayed because: *"the problem with Claire was the fact that she had a brain post-mortem and the result of a brain post-mortem can take several months to come back."*[661]

349. The 1993 Guidance advocates auditing the time taken for reports to be issued and delivered.[662] Whether in 1996 the Children's Hospital followed that guidance and if so what was done with the results of such audits, are matters to be further pursued, as is the issue of whether the time taken to produce Claire's Autopsy Report was ever subject to audit.

350. The particular reasons for the delay in producing the Autopsy Report in Claire's case and its likely impact will also be explored at Oral Hearing.

351. In explaining why he did not advance an opinion as to the most likely cause of death on the basis of known information Dr. Herron advised that *"A brain only autopsy is done to assist in coming to overall conclusions*

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656 Ref: 090-002-002 & Ref: 090-001-001
657 Ref: 239-002-013
658 Ref: 236-007-010
659 Ref: 089-006-014
660 Ref: 239-002-013
661 Ref: Transcript of Oral Hearings on 18th October 2012 p.96 line 10
662 Ref: 236-007-058

in a case. It is only with full integration of all the information including clinical, laboratory, radiological and pathological information that a cause of death is obtained…"[663] and the information *"is used by the referring doctor to integrate with all of the other clinical and laboratory findings to come to a diagnosis."*[664] However, Professor Lucas considers that as: *"being economical with the truth. Where, to the pathologist, the clinical features and pathological features all point to one diagnostic process, then he/she states them in the report. The problem with this case is that nothing appeared very clear-cut."*[665]

352. It would not appear that either Dr. Steen or Dr. Webb made any attempt at that time to collate all the information available in order to formulate a likely diagnosis and establish a likely cause of death. That this was entirely feasible is apparent from the medical record, Professor Ian Young's ability to gain a rapid overview of the case, and the statement Dr. Webb submitted to H.M. Coroner: *"Claire's hyponatraemia led to her developing cerebral oedema (swelling) and the brain herniation. The swollen brain will herniate downwards resulting in brain stem compression and cardio-respiratory arrest."*[666]

353. The failure to provide Mr. and Mrs. Roberts with full information surrounding their daughter's death or to reconsider the formulation of cause of death on the death certificate is a matter of clinical governance importance. It may be a cause for concern that the post-mortem process was not subject to audit or review and that no internal control was engaged so as to achieve quality assurance. Notwithstanding that Dr. Hicks is of the belief that *"the Pathology Department audited referrals for post-mortem examinations and reported back via the Hospital Council."*[667]

XX. Adverse Incident Reporting

354. Dr. Steen has informed the Inquiry that she *"would not have expected that [she] would have reported Claire's death to other members of staff as at that time it was felt the sequence of events leading to her death was known and there were no areas of concern around her care."*[668] Dr. Hicks, her Clinical Lead, *"would not have expected the death to have been brought to [her] attention unless it was thought that there had been an untoward event."*[669] Staff Nurse Pollock would *"certainly expect to be [informed] or, you know, hope to be. I can't say I always was."*[670] She made no report herself.

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663 Ref: WS-224-4 p.6
664 Ref: WS-224-7 p.7
665 Ref: 239-002-014
666 Ref: 091-008-053
667 Ref: WS-264-1 p.10
668 Ref WS-143-1 p.113
669 Ref: WS-264-1 p.3
670 Ref: Transcript of Oral Hearings on 30th October 2012 p.205

355. Claire's death was thus 'unreported' in 1996. Furthermore "*there were no investigations into Claire's death prior to December 2004."*[671] No report in respect of the death was furnished to the clinical lead of the Paediatric Directorate who was responsible for the services of the Children's Hospital. *"It would have been the responsibility of the clinicians involved to advise their Clinical Director or Directorate management team in the first instance."*[672] No report was made to the Nurse Manager of the hospital or the Director of Nursing to permit possible nursing issues to be addressed. No report was made to the Director of Medical Administration who, as a representative of the Medical Risk Management Group, bore responsibility for clinical risk management and untoward clinical incident reporting.[673] No report was made to the Chairman of the RGH Drugs and Therapeutics Committee who had professional interest in major prescription errors with the potential to cause serious damage or death of a patient. Nor was a report made to the Medical Director of the Trust who was charged with a duty to advise the Board of the Trust on medical policy or strategy. Nor was the Chief Executive of the Trust enabled to share the information with DHSSPSNI or to consider a proper response to the death; notwithstanding that he: *"would have expected deaths to be reported within the clinical directorate"*[674] and that *"prior to and since that time the Trust has reported on a number of serious adverse events to the DHSSPS where in our view there was information on lessons learnt that were of wider significance."*[675]

356. As Dr. MacFaul observes: *"significant clinical incident and adverse outcomes should be reported within a Trust's structure. The first stage of any such process however is recognition of the event in the first place. In respect of the management of Claire this recognition does not appear to have happened."*[676]

357. Guidance on the 'Reporting of untoward incidents' was available from June 1991 pursuant to Circular ET5/90 (Amended).[677] This covered the onward reporting by hospitals of untoward incidents to the Health & Social Services Board where there was a suggestion of a: *"failure in professional standards of care and treatment"* and the RGH would have had procedures in place to enable this reporting. The system appears to have operated until at least April 1993 when the Royal Hospitals became a Trust[678] but was perhaps thereafter abandoned in line with

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671 Ref: 302-007-003
672 Ref: WS-265-1 p.5; Miss Elizabeth Duffin
673 Ref: WS-061-2 p.241
674 Ref: WS-061-1 p.2
675 Ref: WS-061-1 p.2
676 Ref: 238-002-067
677 Ref: WS-061-2 p.321
678 Ref: WS-061-2 p.169

the intention that the Trust be able to operate with maximum operational freedom and autonomy. The system for gathering reports within the Children's Hospital seems to have lapsed and there is no evidence that any steps were taken to encourage the reporting of untoward incidents involving a failing in standards, other than relying upon clinicians to report their own mistakes or the mistakes of each other.

358. The Medical Risk Management Group, chaired by the Medical Director with high level representation from Dr. Murnaghan and the Director of Nursing had responsibility for clinical risk management and undertook specific responsibility for the reporting of 'untoward incidents (clinical)'. Dr. Murnaghan was also the Director of Risk and Litigation Management and as such had very particular knowledge of hyponatraemia deriving from Adam Strain's case. It is unclear how the Medical Risk Management Group discharged its responsibilities.[679] Indeed it is not at all clear that it did anything in relation to the reporting of untoward clinical incidents. Mr. McKee recalls that: *"prior to 2000 adverse clinical events were reported using a statement book held in the respective clinical area. Details of such incidents as recorded were forwarded to the Director of Nursing and the Director of Medical Administration. These were reviewed and followed up to ensure appropriate actions were taken."*[680]

359. Ward Sister Pollock could not recall any particular process for investigation beyond discussion. However: *"in terms of a formal process, in terms of who I would report it to, or follow it up, I don't recall any particular thing that would have happened."*[681] Had Claire's death been reported then an immediate investigation could have followed in order to provide the Director of Medical Administration and Director of Nursing with a detailed written report. Knowledge of the case and the implication of hyponatraemia would thereby have been circulated at the highest levels of governance. It is a matter for speculation as to what difference this could have made to the growing medical consciousness of hyponatraemia and the risks attaching to Solution 18 and fluid management.

360. Had Claire's death been subjected to scrutiny in 1996 as an adverse incident, it is likely that it would have been referred to the Coroner. That would have provided an additional forum for discussion and learning and could have served as a driver for dissemination. As it was, there does not appear to have been any reporting, hospital investigation, written report, audit, review, learning, performance

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679 Ref: WS-061-2 p.321
680 Ref: WS-061-2 p.68
681 Ref: Transcript of Oral Hearings on 30th October 2012, p.206 line 11

appraisal and internal or external dissemination of lessons learned. In short, there does not appear to have been any engagement of the systems of internal control after the death of Claire. As such the Board cannot have had any means of knowing if proper standards of health care were being achieved and whether it was discharging the responsibilities for which it was accountable.

361. That Adam and Claire should have died within a year of each other in the same intensive care ward of the same children's hospital without prompting medical comment on the broader lessons of fluid management and the prevention of hyponatraemia is striking and an apparent failure of clinical governance which will be more fully explored at Oral Hearing.

XXI. Clinical Coding

362. It has been thought necessary to consider whether or not the Children's Hospital revised the statistical database as to the cause of Claire's death in the light of the Inquest Verdict. This implies an assumption that the cause of Claire's death was entered into the database in 1996, so as to be consistent with the death certificate issued in 1996[682] and would therefore require amendment to reflect the additional finding at Inquest of: *"hyponatraemia due to excess ADH production."*[683] The issue however, is not so straightforward.

363. Consideration of database amendment involves examining the process of 'clinical coding' which is described in the Belfast Health and Social Care Trust's 'Clinical Coding Policy' as being: *"Diagnostic and procedural information for in-patients [is] captured mainly through the examination of patient case notes, diagnoses and procedures are then translated into ICD10 [International Classification of Diseases] and OPCS4 [Office of Population Censuses and Surveys] codes which are entered into the Trust PAS system [Patient Administrative System]. Pro formas and/or discharge notes are used in some specialities as the source documentation."*[684]

364. That Policy observes: *"it is vital that clinical coding is of only the best quality if analysis and comparisons are to be meaningful"* and that *"the bulk of diagnostic and procedural information is provided through the clinical coding function."*[685] The function is therefore an intrinsic patient safety issue and noted as taking place *"on all four hospital sites"* and *"managed centrally within the Trust."*[686] Coding strategy and policy was thus

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682 Ref: 091-012-077
683 Ref: 091-002-002
684 Ref: 302-153-009; (June 2011)
685 Ref: 302-153-007
686 Ref: 302-153-007

implemented by senior teams in line with national guidance and in response to the demands and needs of the Trust.[687]

365. Clinical coding has relevance to the governance matters arising of Claire's case because her death remained seemingly unconnected to hyponatraemia for a period of 8 years until Mr. and Mrs. Roberts contacted the Trust about their daughter's death in 2004 having watched the UTV documentary, 'When Hospitals Kill'. The discovery of this additional, and hitherto unappreciated death, in which hyponatraemia was implicated has focussed attention on the statistics held on deaths relating to hyponatraemia and the importance of the systems to record and categorise deaths. Questions have necessarily arisen as to why the Children's Hospital was apparently unable to implicate hyponatraemia in Claire's death without the intervention of her parents, and whether the system for clinical coding within the Children's Hospital was effective.

366. Clinical coding may be seen as a basis for better analysis, enabling lessons to be learned and disseminated; for the improvement of education and training and the development of guidelines to reduce risk to patients.

367. By a letter of 29th August 2012 the Inquiry received the *"RBHSC-PICU-Coding Form"*[688] completed and signed in relation to Claire on 23rd October 1996 by Dr. James McKaigue who was the Consultant Paediatric Anaesthetist on-call in PICU at the time of her death. This document appears to be a synopsis designed to assist in the task of encoding Claire's death. Significantly it includes the indicator: *"hyponatraemia."*[689] An instruction at the foot of the form provides that it is to *"be retained in the unit for Coding Clerk (Margaret- EXT 3728)."*[690]

368. The Inquiry has now received copies of the clinical codes applied in Claire's case and has been advised by the DLS that: *"that if the coding was entered around the time of death only the addition of 'excess ADH production' would have occurred as a result of the Inquest as the other elements of the cause of death were already coded."*[691] No addition of *"excess ADH production"* has been made to the coding. This is not considered any more than an academic omission because 'hyponatraemia' is clearly included.

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687 Ref: 302-153-008
688 Ref: 090-055-203
689 Ref: 090-055-203
690 Ref: 090-055-203
691 Ref: 302-153-001

369. The 'Clinical Coding Policy'[692] distinguishes between primary and secondary diagnoses in relation to clinical coding, and describes the former as: *"the main condition treated or investigated during a patient's episode. This should be coded to the most specific code available."*[693] The Clinical Coding Manager at the time, Mr. Danny McWilliams, has confirmed that the number of permitted diagnoses and co-morbidities capable of entry into the PAS was seventeen, but that: *"there was only one primary diagnosis inputted."*[694] However in this instance there appears to be two primary diagnoses inputted, namely: *"Primary: G41.8 Other status epilepticus"* and *"Primary: R09.2 Respiratory arrest."*[695] Included beneath these primary diagnoses are a number of co-morbidities (listed as *"subsid[iary]"* and *"diag[nostic]"* or *"second[ary]"*):

(i) *"G04.9 Encephalitis, myelitis and encephalomyelitis, unspecified"*

(ii) *"G41.8 Other status epilepticus"*

(iii) *"E87.1 Hypo-osmolality and* ***hyponatraemia****"*[emphasis added]

(iv) *"E87.0 Hyperosmolality and hypernatraemia"*

(v) *"E87.6 Hypokalaemia"*

(vi) *"G41.8 Other status epilepticus"*

(vii) *"G04.9 Encephalitis, myelitis and encephalomyelitis, unspecified"*

(viii) *"G93.6 Cerebral oedema."*[696]

370. This list of classifications is noteworthy for the following reasons:

(i) The PICU Coding Form,[697] the Discharge Advice Note[698] and the codes inputted onto the PAS all indicate *"hyponatraemia"* which calls into question the omission of *"hyponatraemia"* from the death certificate issued on 24th October 1996[699]

(ii) It contains two primary diagnoses rather than one which would have been considered standard[700] at the time

692 Ref: 302-153-004
693 Ref: 302-153-013
694 Ref: WS-294-1 p.1
695 Ref: 302-153-003
696 Ref: 302-153-003
697 Ref: 090-055-203
698 Ref: 112-030-045
699 Ref: 091-012-077
700 Ref: WS-294-1 p.1

(iii) The coded classifications inputted onto the PAS system differ from the information contained in the PICU Coding Form,[701] in that the coding contains the additional information of status epilepticus, encephalitis, myelitis, encephalomyelitis, hypo-osmolality or cerebral oedema. This appears to demonstrate that the Coding Clerk closely consulted the medical record

371. 'Hyponatraemia' was included as a secondary diagnosis in the clinical coding for Claire Roberts, and seemingly went unnoticed as such until the Roberts contacted the Trust in 2004. The question of what should or could have been done with such inputted information goes to both the function and utility of the clinical coding system: *"Hyponatraemia is a codable condition and can be referenced against deaths"*[702] and the data *"accessed through Trust systems by password only."*[703] The information held implicating hyponatraemia in the cause of Claire's death, and possibly the deaths of others from hyponatraemia, was readily retrievable by the RGH for the purposes of review, research, learning and dissemination. That it was apparently not retrieved, is a matter of clinical governance concern to be pursued further.

372. Dr. Robert Taylor, who was the consultant paediatric anaesthetist in Adam Strain's case and who was also cared for Claire in PICU for a period on 23rd October 1996,[704] describes the Patient Administrative System in his Inquiry witness statement as: *"not very useful for the purposes of clinical audit as it did not contain sufficient or sufficiently accurate information."*[705] Dr. Taylor states that he can *"recall that there were serious inaccuracies with the coding system. One example was that Central Venous line insertions were coded as Varicose Vein surgery, an unlikely procedure in the RBHSC."*[706]

373. Dr. Taylor when undertaking data analysis for presentation to the Hyponatraemia Working Party in 2001[707] and compiling a table entitled 'Incidence of Hyponatraemia at RBHSC',[708] did not use the clinical coding system but rather the PICU-held records as he explained in his Inquiry witness statement: *"the PICU secretary [had] acquired the information for this bar chart from the PICU computer records. These records were distinct from those administered by the Clinical Coding department."*[709] It appears that he used these records in preference to the PAS system and the clinical coding information held on it.

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701 Ref: 090-055-203
702 Ref: WS-294-1 p.7
703 Ref: WS-294-1 p.6
704 Ref: 090-022-061
705 Ref: WS-157-2 p.3
706 Ref: WS-157-2 p.12
707 Ref: 007-051-101 *et seq*; entitled 'Hyponatraemia in Children, Teaching Aid'
708 Ref: 007-051-103
709 Ref: WS-157-2 p.13

Accordingly: "*it does not appear that Adam or Claire's deaths were part of that data collection.*"[710] The end result of this was that Dr. Taylor's incidence analysis undertaken for the Hyponatraemia Working Party entirely omitted the deaths of Adam and Claire. Ultimately his power-point presentation was not given to the Hyponatraemia Working Party. Nevertheless, it is noteworthy that Dr. Taylor should have condemned the PAS in respect of clinical coding for insufficiently accurate diagnostic information when the system he chose denied meaningful analysis or comparison. Mr. Chairman, you may also consider it remarkable that Dr. Taylor, who had been so very closely involved in the Adam Strain case in November 1995 and his Inquest in June 1996 and who had treated Claire, made an entry into her notes and was aware of her death, should nonetheless have considered presenting information on the incidence of Hyponatraemia at the Children's Hospital that excluded any reference to either death.

374. The issue of the audit of clinically coded information was considered in an Article published in 1993, entitled 'Routine Data: A Resource for Clinical Audit.'[711] Amongst its conclusions is the recommendation that: "*clinicians, managers and everyone involved in the health service must not only need to use the data but continue to insist on high quality data. The feedback loop must be closed.*"[712] The effectiveness of the procedures within the Children's Hospital in respect of the use and audit of clinical coding information is therefore a matter that will be considered during the Oral Hearings.

XXII. 2004 - 2006

375. UTV broadcast its documentary 'When Hospitals Kill' on 21st October 2004. The investigative focus was on the role hyponatraemia had played in the deaths of Lucy Crawford, Adam Strain and Raychel Ferguson and whether there was cause to suspect a 'cover-up'. The programme was the product of many months work and had involved contact and correspondence with the RGH. It is to be assumed that the RGH was aware in advance of the date of broadcast and the general content of the programme. Indeed correspondence was directed on 7th October 2004 by the Trust's solicitor Mr. George Brangam to the UTV producer of the programme to express, in the light of the programme maker's: "*unacceptable behaviour*", "*the utmost regret that the Trust cannot participate in the programme or cooperate*"[713] and to suggest legal

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710 Ref: WS-157-2 p.13
711 Ref: 314-006-001 *et seq*; Martin McKee
712 Ref: 314-006-007
713 Ref: 137-005-001

proceedings unless certain allegations be retracted. It is to be supposed that matters were being followed at the highest levels of governance.

376. Mr. and Mrs. Roberts watched the programme. Mr. Roberts described that: *"the circumstances and the unfortunate outcomes of the three children detailed in the programme were so similar to Claire's outcome."*[714] The following day, Friday 22nd October 2004, Mr. Roberts telephoned the RVH press office. He spoke: *"to a lady called Dympna*[715] *who stated that the RVH were expecting calls following the insight programme. She advised me that she would arrange a meeting with Dr. Nichola Rooney. Dr. Rooney contacted me later on Friday 22 October 2004 and I discussed my concerns about Claire's treatment and the insight programme. Dr. Rooney arranged a meeting for Monday 25 October 2004 at RVH."*[716] Mr. Roberts continues: *"My wife and I met with Dr. Rooney on Monday 25th October 2004 at the RVH. We discussed Claire's treatment and our concerns following the insight programme. Dr. Rooney informed my wife and I that she would organise a review of Claire's medical notes with regard to fluid management, fluid type and the amount of fluid given. Dr. Rooney would also arrange for a review of Claire's treatment from Monday 21st October to Tuesday 22nd October 1996. Dr. Rooney contacted me by telephone on Monday 1st November 2004 to say that Claire's notes had been passed on to medical staff for review."*[717]

377. Mr. Roberts further states his Inquiry witness statement that Dr. Rooney:

> *"informed me that Dr. Steen, Dr. Webb, Dr. Hicks and Dr. Sands would carry out the review and a meeting would be arranged in two to three weeks time. I contacted Dr. Rooney by telephone on Monday 22nd November 2004 for an update on the review of Claire's medical notes and a meeting date. Dr. Rooney informed me that Dr. Steen had all Claire's notes and Dr. Steen would be able to chart Claire's treatment. Dr. Rooney also advised me that another senior consultant would be reviewing Claire's fluid management. Dr. Rooney contacted me by telephone on Wednesday 24th November 2004 to inform me that Dr. Steen had prepared a document detailing Claire's treatment. Dr. Rooney advised me that she would like the Medical Director Dr. McBride and a Professor from Queens, Professor Young to look at the document. Dr. Rooney informed me that she would then arrange a meeting on 7th December 2004 with my wife and I together with Dr. Steen, Dr. McBride, Professor Young and Dr. Sands."*[718]

378. The Inquiry has sought, but not received, a copy of the document prepared by Dr. Steen in relation to Claire's treatment (unless it is the undated, and untitled synopsis of the case records provided to the

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714 Ref: WS-253-1 p.17
715 Ref: Dympna Curley, Director of Corporate Affairs, RGH
716 Ref: WS-253-1 p.17
717 Ref: WS-253-1 p.18
718 Ref: WS-253-1p.18

Inquiry by Dr. Rooney).[719] It would seem that contingency planning had resulted in the deployment of Dr. Nichola Rooney, the Psychology Service Manager, to deal with the RGH response to enquiries relating to the UTV programme. She was asked to: *"take the lead in liaising with and supporting Mr. and Mrs. Roberts"*[720] and *"to help Mr. and Mrs. Roberts to gain the information they required regarding their daughter's care. I was asked to do this by the Head of Communications in discussion with the Medical Director."*[721] The extent to which contingency planning also encompassed the review of other cases in which hyponatraemia was implicated is as yet unknown but will be pursued. It is however clear that by October 2004, two and a half years had passed since the DHSSPSNI had published its 'Guidance on the Prevention of Hyponatraemia' and a level of general knowledge of hyponatraemia within the medical profession may be assumed from the general circulation of information by the DHSSPS and The Ulster Medical Society.[722]

379. Such was the public disquiet provoked by the UTV programme that Angela Smyth MP, Minister with responsibility for Health Social Services and Public Safety, was prompted to announce that a public Inquiry would be conducted into the issues raised by the programme. Additionally the Terms of Reference for this Inquiry into the deaths of Adam, Lucy and Raychel were made public on 18th November 2004. In the accompanying press release the Minister said:

"I believe it is of the highest importance that the general public has confidence in the quality and standards of care provided by our Health and Social Services ... the death of any child is tragic and it is essential that the investigation into these deaths is independent, comprehensive and rigorous. The terms of reference I have set for the Inquiry and the powers available to it are wide ranging and should ensure that the Inquiry deals with all the issues of concern."[723]

380. Dr. Michael McBride FRCP, Medical Director of The Royal Hospitals, directed the handling of Mr. and Mrs. Roberts' *"complaint."*[724] To that end he *"personally asked that Claire's medical records be recovered from file. He reviewed the notes and felt it appropriate to request Professor Ian Young, Consultant in Clinical Biochemistry, to review the medical and nursing records to ascertain whether hyponatraemia could possibly have been a contributing factor to Claire's death."*[725] He did not otherwise consider the

719 Ref: WS-177-1 p.34
720 Ref: WS-269-1 p.10
721 Ref: WS-177-1 p.5
722 Ref: 069a-088-358
723 Ref: 021-010-022
724 Ref: WS-062-1 p.351; as defined by HPSS Complaints Procedure Guidance as *"an expression of dissatisfaction requiring a response."*
725 Ref: 302-007-002

'Complaints, Listening, Acting, Improving; Guidance on Implementation of the HPSS Complaints Procedure' (1996) which defines a complaint as *"an expression of dissatisfaction requiring a response"*[726] because whereas *"Mr. and Mrs. Roberts had raised significant concerns in respect of their daughter Claire, and her subsequent death. I am not aware that at this stage, or at any time subsequently, that Mr. and Mrs. Roberts made a formal complaint to the Trust."*[727]

381. The Permanent Secretary of the DHSSPS wrote to the Chair of the RGH on 28th October 2004 to formally require that all documentation relating to the cases of Lucy Crawford, Raychel Ferguson and Adam Strain be secured and kept safe and if necessary, be made available for independent examination. It is to be hoped that the Trust applied the same rigorous approach to all the documentation relating to Claire Roberts.[728]

382. Professor Young did not provide a written opinion but rather his *"advice was given verbally by telephone."*[729]Dr. McBride was to write to Mr. and Mrs. Roberts: *"Our medical case note review has suggested that there may have been a care management problem in relation to hyponatraemia and that this may have significantly contributed to Claire's deterioration and death."*[730] (In this context *"Care management problem"* is defined by 'Procedure for Investigation and Review of Adverse Incidents'[731] (RGHT 2004) as *"actions or omissions by staff in the process of care.")*[732]

383. The intervening years between Claire's death in 1996 and the review of her case in 2004 witnessed a sea change in clinical governance and the approach to adverse clinical incidents. Dr. I.W. Carson, Medical Director, was responsible for a series of governance initiatives (most notably: Clinical Excellence 1997; Clinical Governance 1999; Clinical Governance Report 1999-2000; Clinical Governance Action Plan 2000/2001) which marked the increasing importance of a culture of accountability.

384. The Royal Hospitals Annual Report 2004-05 emphasised at page 5: *"A Framework for Learning: In line with good governance and our commitment to openness and transparency, the Royal Hospitals acknowledges to patients and the public when things go wrong and systematically ascertains what happened, how it happened and why so that we can do all that is possible to ensure lessons are learned to prevent a re-occurrence."*[733] The Report further

726 Ref: 314-016-001 *et seq*
727 Ref: WS-269-1 p.10
728 Ref: 137-002-001
729 Ref: WS-178-1 p.3
730 Ref: 089-005-010
731 Ref: WS-061-1 p.4
732 Ref: WS-061-1 p.4
733 Ref: 302-096-004

states: *"We have introduced root cause analysis which ensures that the learning from adverse events is included in the process and systems of patient care to ensure that we do our reasonable best to prevent further adverse incidents or harm to those in our care. This procedure is the current model recommended by the National Patient Safety Agency (NPSA) in England and is currently being deployed by the Department of Health Social Services and Public Safety in Northern Ireland through the work of the clinical governance support team."*[734]

Investigation into Claire's Death

385. Dr. McBride was alert to the possibility that the acts and omissions of the RGH staff may have contributed to Claire's death. In those circumstances, it is noteworthy that he chose not to initiate an investigation. It is to be noted, as Dr. McBride himself does, that "*the Trust had introduced from 2003, training in Root Cause Analysis*" of serious untoward clinical incidents.[735] Indeed the work of this Inquiry might have been assisted had there been such an investigation.

386. Dr. McBride had noted "*with hindsight and experience, a Trust Root Cause Analysis may have identified additional learning over and above that identified in the case note review and Coroner's Inquest and may also have provided further answers for Mr. and Mrs. Roberts into the circumstances of Claire's death. This may have been the case even though eight years had passed since Claire's tragic death during which time practice had changed and formal guidance on the prevention and management of hyponatraemia had been issued. However, at the time, taking into account the changes in practice in the intervening years, I was concerned that any further Trust investigation could potentially compromise or prejudice statutory investigations.*"[736]

387. However, it is not clear whether any consideration was given to reviewing the conduct of Claire's care and treatment after the Inquest in order to assess the extent to which there might still be scope for the identification of lessons. This is a matter that will be pursued at the Oral Hearings.

388. It is for you Mr. Chairman to determine whether, in the light of the available guidance, Dr. McBride was justified in this decision.

389. The DHSSPSNI interim guidance on 'Reporting and Follow-up on Serious Adverse Incidents' (July 2004)[737] advises that: "*In those situations where a body considers that an independent review is appropriate, it is important that those who will be conducting it are seen to be completely independent. In addition such reviews should normally be conducted by a*

734 Ref: 302-096-004
735 Ref: WS-269-1 p.9
736 Ref: WS-269-1 p.13
737 Ref: WS-061-2 p.422

multi-professional team, rather than by one individual. It is also important that the Department is made aware of the review at the outset."[738] Dr. McBride recalls that *"given the context of Mr. Roberts contacting the Trust, and the level of public concern, it would have been my practice to advise the Chief Executive and Chair particularly as Claire's death was subsequently referred to the Coroner."*[739] Further and *"at my direction a Serious Adverse Incident Report was forwarded to the Department in March 2006 following the notification of the date of the Coroner's Inquest in accordance with Department Circular HSS (PPM) 02/2006- 'Reporting and Follow Up on Serious Adverse Incidents'. It is my understanding that the former Eastern Health and Social Care Board was also informed at this time as was required under guidance."*[740] The Serious Adverse Incident Report forwarded to the Department and dated 28th March 2006 summarised Claire's history and stated that in October 2004 *"and after reviewing notes it was considered in retrospect that the known hyponatraemia which was treated may have had a part to play in the medical condition leading to death."*[741] It is for the Inquiry to assess the accuracy of this Report. Dr. McBride further noted on 31st August 2006 that *"the department has been informed, as per Circular HSS (PPN) 2/2006 and have requested a further background briefing which I will provide."*[742] This briefing document has not yet been seen by the Inquiry.

390. It is unclear why Dr. McBride chose not to make the reports pursuant to the interim guidance of 2004 (Circular HSS (PPM) 06/2004[743] immediately after the matter was brought to his attention. This Guidance is couched in similar terms to the later 2006 Circular and states at paragraph 15: *"the Department will expect urgent local action to be taken to investigate and manage adverse incidents."*[744] In addition it requires that where a serious adverse incident occurs and the senior manager considers that the incident is likely to be *"of public concern"*- *"he should provide the Department with a brief report within 72 hours of the incident being discovered."*[745] Lest the 2004 Guidance had gone unnoted, the Department issued an additional Circular HSS (PPM) 05/05 to reiterate the Guidance previously given and to *"underline the need for HPSS organisations to report serious adverse incidents... in line with Circular PPM 06/04."*[746]

391. It is not apparent that an investigation into Claire's treatment or death was pursued at that time. In a letter to the Inquiry the DLS advises that:

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738 Ref: WS-061-2 p.422
739 Ref: WS-269-1 p.21
740 Ref: WS-269-1 p.21
741 Ref: 302-164-003
742 Ref: 139-046-001
743 Ref: WS-061-2 p.422
744 Ref: WS-061-2 p.425
745 Ref: WS-061-2 p.425
746 Ref: WS-068-1 p.251

"There were no investigations into Claire's death prior to December 2004,"[747] nor is it clear that the RGH conducted any investigation after December 2004. It is to be regretted that this opportunity to assist the work of both H.M. Coroner and this Inquiry was not taken.

Meeting Mr. and Mrs. Roberts

392. The e-mail correspondence passing between Dr. McBride, Professor Young and Mr. Peter Walby FRCS, Associate Medical Director of The Litigation Management Office of the RGHT, on the day before the meeting scheduled with Mr. and Mrs. Roberts for 7th December 2004, reveals some of the preparation for that meeting. Professor Young was then employed as a consultant by the RGH and was based at the Royal Victoria Hospital site. He had discussed the case with Dr. Steen and had exposed areas of disagreement with her in respect of the case: *"Heather has definite views about the significance of the fluid management, which are not quite the same as mine."*[748]

393. Additionally Dr. McBride clearly recalls that he *"met with Professor Young and Dr. Steen in or about the 6th December 2004"*[749] This meeting was *"not formally minuted"*[750] but Dr. McBride recounts that *"the outcome was that I was advised by Professor Young that in his opinion hyponatraemia may have contributed to Claire's death. I asked that Professor Young's opinion was communicated to Mr. and Mrs. Roberts. I indicated that I wished Dr. Nichola Rooney to be present at the meeting to support the family. It was confirmed that Professor Young, Dr. Steen and Dr. Nichola Rooney would attend the meeting with Mr. and Mrs. Roberts and communicate Professor Young's opinion that hyponatraemia may have contributed to Claire's deterioration and death. I determined that in the light of Professor Young's opinion, the Trust would now refer the case to the Coroner. I asked that Mr. and Mrs. Roberts should be informed of this decision at the meeting."*[751] However, Professor Young remembers being *"advised by Dr. McBride during our discussion that he wanted to know the wishes of Mr. and Mrs. Roberts before making a final decision to refer the case to the Coroner."*[752]

394. On the morning of Tuesday 7th December 2004 Mr. and Mrs. Roberts, Dr. Nichola Rooney, Dr. Sands, Dr Steen and Professor Young met at the Clinical Psychology Department of the Children's Hospital to discuss and address unanswered questions and concerns regarding Claire.

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747 Ref: 302-007-003
748 Ref: 139-153-001
749 Ref: WS-269-1 p.20
750 Ref: 302-007-002
751 Ref: WS-269-1 p.20
752 Ref: WS-178-1 p.5

395. Dr. Rooney opened the meeting, outlined the issues and her secretary prepared the detailed four page typewritten minute of the discussions. Dr. Steen charted Claire's progress with reference to the medical notes and allowed Professor Young to field questions relating to the fluid administration. Dr. Rooney summarised the issues discussed and then left it to Mr. and Mrs. Roberts to decide whether they would seek further information or meetings if they wished the case to be referred to the Coroner.

396. The content of Dr. Rooney's minute of this meeting is noteworthy in a number of respects. Despite the fact that reassurance was given to Mr. and Mrs. Roberts that *"questions they feel still remain unanswered regarding Claire's death will be addressed... That the Trust will meet with them at any time to help them in any way possible... And that the Trust wants to be completely open about this case and will be happy to meet with Mr. and Mrs. Roberts again."*[753] Dr. MacFaul believes that the approach to and conduct of the meeting and the minute thereof could be open to criticism:[754]

(i) Consideration could have been given to commissioning an independent written report from a paediatric neurologist and in these circumstances Professor Young may not be regarded as independent, being employed by the Trust at the time. It is to be noted however, that the minute records Professor Young as "*emphasising that he was involved in the case purely as an independent adviser*."[755] In any event his views should have been reduced to writing, especially in the light of his disagreement with Dr. Steen. Furthermore given that his speciality was not in paediatric medicine he was the wrong choice. An external expert should have provided a written report and should have attended the meeting.

(ii) The clinical paediatric lead within the Children's Hospital Dr. Elaine Hicks was not there. She should have been as a part of general governance management. She should have reviewed the death. It is to be regretted that Dr. Hicks was not there as she seems to have been peculiarly qualified to assist in the understanding of Claire's case- she was Clinical Lead, a Consultant Paediatric Neurologist who had previously treated Claire, was seemingly one of the doctors to be tasked with the review of Claire's notes,[756] was qualified in medical legal ethical issues and had been selected by Dr. Murnaghan for inclusion in

753 Ref: 089-002-002
754 Ref: 238-002-015
755 Ref: 089-002-003
756 Ref: WS-253-1 p.18

the seminar group to review the lessons to be learnt from Adam Strain's Inquest only four months before Claire's death.

(iii) There are a number of inaccuracies and omissions contained in the minute in relation to the information given to Mr. and Mrs. Roberts. These seemingly went uncorrected. Dr. MacFaul cites amongst other examples:

- Dr. Steen's assertion that the history given to staff was that she had been vomiting in school that day
- Dr. Steen's conclusion that Claire's muscles were stiff and that she was fitting
- The assertion that fluids were reduced at 23:30 22nd October 1996
- The assurance that at the time of Claire's treatment, and for one in her condition, sodium levels might normally only have been checked every 24 hours.

397. It is to be noted that there is no reference to the Autopsy Report in the discussions that have been minuted. The content of that Report was relevant to all the issues under discussion. It is not clear whether it was available to Professor Young or Dr. Rooney at that time, and if not why not. Dr. Steen remained silent as to the post-mortem conclusions and seemingly did not share the document prepared by her in respect of the care and treatment given to Claire. Claire's medical notes were available and could have been shared with Mr. and Mrs. Roberts. They were not. Dr. Steen is recorded as providing an explanation to Mr. and Mrs. Roberts as to: *"how an illness such as Claire's can arise. Viruses known as Enterovirus can enter the body via the stomach and can then cause swelling of the brain"* and that *"it is not always the case that children with low sodium levels will result in swelling of the brain"* and *"that it is very difficult to evaluate how much the fluids contributed to the situation."*[757]

398. The word 'hyponatraemia' does not appear in Dr. Rooney's minute.

399. Mr. and Mrs. Roberts may not have been clear about Dr. McBride's decision to refer Claire's death to the Coroner because Professor Young: *"reiterated that the Trust would not proceed with any action until they decided how they wish the matter to proceed."*[758] Professor Young explains that was 'independent' by virtue of his *"independence from the team who had been involved in Claire's clinical care and the fact that I had no*

[757] Ref: 089-002-003
[758] Ref: WS-177-1 p.61

prior knowledge of the case."[759] The extent to which Professor Young was appropriately independent whilst also *"authorised to speak on behalf of the Trust"*[760] is a matter to be investigated during the Oral Hearings.

400. No reference was made in the minute to the drug errors relating to midazolam and phenytoin. It will be a matter for you Mr. Chairman to consider and determine whether that constituted a failing in clinical governance review.

401. Mr. and Mrs. Roberts stayed with Dr. Rooney after the meeting and discussed matters further. Dr. Rooney's notes of this conversation record their need for more answers and their continued questioning of the treatment Claire had received. They wanted to know why the: *"Trust did not go back over cases … why did they have to wait for TV programme?"*[761] Their desire to meet further with Professor Young and Dr. McBride was expressed as was their probable intention that Claire's death be referred to you, Mr. Chairman. That afternoon Dr. Rooney sent a message by e-mail to Professor Young and Drs. Steen and Sands: *"Thank you for this morning– the family are v.pleased with all our efforts."*[762] On 8th December 2004, the day after the meeting, Claire's parents wrote to the Trust to raise further questions arising from the information given them at the meeting. At paragraph 10 of their letter the Roberts claim that *"Professor Young stated that the fluid type administered to Claire had a definite input into her death."*[763] This clear and straightforward admission is not recorded in Dr. Rooney's minute. Confirmation that this concession was given is to be found in Dr. McBride's e-mail to Mr. Walby of 15th December 2004: *"At the meeting, on my recommendation, we clearly indicated that following our case note review and the expert opinion of Professor Young and others we were significantly confident that their daughter's fluid management was a contributory factor to her death, amongst the many others involved."*[764]

402. The accuracy of Dr. Rooney's minute is therefore a matter for you Mr. Chairman to assess and determine.

403. The Roberts' letter of 8th December 2004 poses questions of importance, not least and amongst others:

(i) Does the full post-mortem report make any reference to hyponatraemia?

(ii) Will the cause of Claire's death be reviewed by the RGH?

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759 Ref: WS-178-1 p.5
760 Ref: WS-269-1 p.5
761 Ref: WS-177-1 p.19
762 Ref: WS-177-1 p.51
763 Ref: 089-003-006
764 Ref: WS-177-1 p.45

(iii) Given that Claire's death was sudden, unexpected and without a clear diagnosis why was the Coroner not informed or an Inquest held?

404. That letter also stated at paragraph 9 that: *"Professor Young explained that the fluid type administered to Claire would not have been given to a patient at the Royal Hospital today who has sodium levels lower that [sic] 135mmol/L and that such patients would have their sodium levels reviewed every 1-2 hours"* and asked *"What were the guidelines in October 1996 for a patient whose sodium levels were less than 135mmol/L."*[765] That query was answered by Dr. Rooney in her letter of 12th January 2005: *"the management of patients with sodium levels than 135 is dependent on the clinical condition which has led to the low sodium. In Claire's case, it was felt to be due to the syndrome of inappropriate antidiuretic hormone secretion (SIADH). The practice at that time would have been firstly, to restrict fluid intake and secondly, to consider administration of fluid with a higher content of sodium, if symptoms attributable to hyponatraemia were present."*[766]

405. The implications of that answer, given Claire's admission on Monday 21st October 1996 with a serum sodium level of 132mmol/L and the IV fluid therapy administered to her then and up until 23:30 on Tuesday 22nd October 1996 when her serum sodium levels were recorded as being 121mmol/L was raised during Dr. MacFaul's oral evidence on clinical issues. Much depends on when Claire's clinicians did or ought to have considered SIADH.

406. Reference has already been made to Dr. MacFaul's evidence on the adequacy of the explanation given by Dr. Steen to Claire's parents on the cause of her collapse, in that Dr. Steen should have referred to the fluid management as being implicated in the development of her cerebral oedema and therefore her death.[767] It will be a matter for you to determine Mr. Chairman the extent to which, in all the circumstances, the responses and explanations given to Mr. and Mrs. Roberts were misleading in not clearly acknowledging the role of the clinicians' conduct in their daughter's death.

407. The Roberts' letter of 8th December 2004 concludes with the: *"request that Claire's case is referred to the Coroner for further urgent investigation with the desire that the case is made part of the current ongoing enquiry led by Mr John O'Hara QC."*[768]

408. Dr. McBride then directed Mr. Walby to: *"co-ordinate notes of meetings and report to date so that you are in a position to share this information with*

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765 Ref: 089-003-007
766 Ref: 089-006-014
767 Transcript of 14th November 2012, pgs.125-126, line 18 *et seq*
768 Ref: 089-003-007

H.M. Coroner."[769] On 16th December 2004 Mr. Walby wrote to report the matter to the Coroner formally.[770] He described how, having been examined by a paediatric neurologist Dr. David Webb, Claire was considered: "*to have a postictal acute encephalopathy and she was treated as such. She developed hyponatraemia and consideration was given to whether this was from the fluid overload with low sodium fluids or a stress induced anti diuretic hormone effect and her fluid management was altered"*[771] (Mr. Walby largely derived this information from SHO Dr. Stewart's entry in the hospital note[772] but unfortunately misinterprets the acronym "SIADH"). Mr. Walby was able to supply the Coroner with a copy of the post-mortem report. Dr. MacFaul has however observed that some inaccurate information was given the Coroner namely - "*the circumstances are as follows – Claire had a history of epileptic seizure since age 10 months."*[773]

409. Mr. Walby recounts how Dr. Steen also "*considered there were errors in my letter and I requested her to provide corrections for me to forward to the Coroner."*[774] Dr. Steen was thus given the opportunity to edit the information being given to H.M. Coroner. She did so by emphasising that the admitting Registrar had formed a provisional diagnosis of possible encephalitis.[775] She did not correct the other error appearing in Dr. Walby's letter to the Coroner, nor did she point out that the admitting Registrar had actually crossed out the possible diagnosis of encephalitis.[776]

The Coroner

410. Mr. J. L. Leckey met with Mr. and Mrs. Roberts on 7th January 2005 and retained Consultant Anaesthetist Dr. Robert Bingham of Great Ormond Street Hospital ("GOSH") to provide an external opinion.

411. Mr. Walby, having liaised with the Coroner's office, proceeded to "*obtain statements from the staff involved in Claire's case."*[777] It is to be assumed that these statements were intended to form the basis of the Inquest depositions. They appear to have been typed on pro-forma PSNI Witness Statement sheets. This was apparently on the basis that "*this was the historical format preferred by H.M. Coroner."*[778] Dr. Steen's statement is dated March 2005 and predates the PSNI investigation (Dr.

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769 Ref WS-177-1 p.45
770 Ref 089-004-008
771 Ref: 089-004-008
772 Ref: 090-022-056
773 Ref: 238-002-075
774 Ref: WS-176-1 p.4
775 Ref: 090-049-152
776 Ref: 090-022-052
777 Ref: 090-049-153
778 Ref: WS-176-1 p.9

Steen appears to have been reminded several times during the course of the five months it took her to furnish her statement to Mr. Walby). The Inquiry has not been provided with copies of *"statements from all the staff involved in Claire's case"* such as were envisaged by Professor Young when he advised Dr. McBride.[779]

412. The process for taking witness statements to be used in Coroner's inquests and other court proceedings was covered by a DHSSPSNI protocol (2002).[780] A different view of *"best practice"* was however, expressed by H.M. Coroner in his letter dated 30th January 2004 to Medical Director Michael McBride:

"Investigation of Hospital Deaths

Last autumn a senior detective expressed concern to me about the present limited role of the Police in the investigation of hospital deaths. In particular, concern was expressed at the system that has been in operation for a number of years whereby the Medical Director or Clinical Director of the hospital will arrange to obtain statements from staff involved and forward them to me without the statement makers having been interviewed by a Police officer. In many instances the individual concerned had consulted their legal adviser prior to making a statement and the legal advisor had input into how it was drafted. It was put to me that this approach did not constitute "best practice" as the Police should interview those concerned as soon after the event as possible and, where necessary, seize medical notes, any relevant equipment and, if the circumstances of the death warranted it, treat an area of the hospital as a potential crime scene. I agreed that in future I would agree to a Police Officer interviewing those involved. The present system would be discontinued."[781] This letter prompted Mr. Walby to seek advice from Mr. Brangam on the basis that the Coroner's approach *"would seem to me to be a backward step."*[782] No advices were forthcoming from the solicitor and Mr. Walby took no steps to follow the Coroner's advices. He wrote to Mr. Brangam on 21st March 2005 to advise *"as you know we are still operating the old system."*[783]

413. In respect of the preparation for Claire's Inquest the PSNI were not involved. Mr. Walby simply arranged for witness statements to be written on PSNI paper without the involvement of the PSNI. Mr. Walby also:

(i) Arranged for legal advisors to approve the statements prior to release[784]

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779 Ref: 091-010-063
780 Ref: 133-003-002
781 Ref: 129-007-001
782 Ref: 129-006-001
783 Ref: 129-003-001
784 Ref: 139-078-001

(ii) Corrected and redrafted statements[785]

(iii) Permitted professional indemnity insurers to comment on and approve doctor's statements[786]

As to whether this approach would have constituted *"best practice"* is a matter for the Inquiry.

414. Mr. Walby's job description specifies his duty to *"assist H.M. Coroner with enquiries and the preparation of statements prior to inquests."*[787] His job description also requires him to *"give advice and support to staff involved in ... Coroner's cases."*[788]

415. It is a matter for you Mr. Chairman to determine the possible impact on 'good governance' of any tension that there may have between those two obligations and the requirement that Mr. Walby discharge them both.

416. Dr. Rooney had been coordinating the responses to be made in writing to the Roberts' written questions. Her responses are dated 12th January 2005. Empathy and words of reassurance are given. Some criticism may however be levelled at the degree of accuracy and consistency achieved. The responses are nonetheless given by Dr. Rooney with the proviso that *"Dr. Steen and Professor Young could only reply on the documentation available in the medical chart and their knowledge of the practices at the time."*[789] However, both Dr. Steen and Professor Young made amendments and suggestions in respect of this letter which proceeded to a *"final, final, final draft"*[790] before it was approved by Dr. Steen, Dr. Rooney, Professor Young and Mr. Walby for despatch. Dr. Rooney has stressed that all medical information in the *"correspondence with Mr. and Mrs. Roberts was provided by Dr. Steen and Professor Young."*[791]

417. The following advices given in her letter by Dr. Rooney are examples of a failure to properly investigate or inform:

(i) *"1(a). When Claire arrived in A&E at 8.00pm on the evening of Tuesday 21 October, the history given to staff was that she had been vomiting in school that day."*[792] This is not recorded in the notes and it was a Monday.

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785 Ref: 139-096-001; 139-106-001
786 Ref: 139-112-001
787 Ref: WS-176-1 p.14
788 Ref: WS-176-1 p.14
789 Ref: 089-006-012
790 Ref: 139-139-001
791 Ref: WS-177-1 p.7
792 Ref: 089-006-012

(ii) *"1(b). Claire's symptoms were attributed to encephalitis which was confirmed at post-mortem."*[793] The post-mortem report made no such confirmation.

(iii) *"4. Claire's medication was very important and was aimed at controlling her seizures. Without the medicine her condition would have deteriorated more rapidly."*[794] No reference was made to the effect that might have been expected from the midazolam and phenytoin overdose.

(iv) *"5(a). It is not possible to say whether a change in the amount and type of fluid would have made any difference in Claire's case as she was very ill for other reasons."*[795] This appears to attempt to deny Dr. McBride's confidence that Claire's *"fluid management was a contributory factor in her death."*[796]

(v) *"8(a). Hyponatraemia was not thought at the time to be a major contributor to Claire's condition.* This appears to contradict the entries of both Drs. Stewart and Webb in the medical record itself, the PICU Discharge Summary and the information provided by Dr. Walby to H.M. Coroner.

(vi) In answer to the query as to why the Coroner was not informed at the time the letter informed that: *"The Coroner had not been informed at the time as it was believed that the cause of Claire's death was viral encephalitis."*[797] This would not appear to accord with either the Autopsy Request Form or the medical certificate of cause of death issued 24th October 1996.[798]

(vii) In answer to the question *"Will the cause of death be reviewed by the Belfast Royal Hospital ?"* the response is given at paragraph 10 *"Having brought Claire's case to the attention of the Medical Director, a review of Claire's case notes was carried out, with independent advice sought from Queens University Professor of Medicine. As a result of this review, the Coroner has been fully informed of the issues of concern. It will now be up to the Coroner to further review the medical aspects of Claire's case as he feels appropriate."*[799] The advice sought was not independent. Nor was the Coroner accurately informed as to the issues of concern.

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793 Ref: 089-006-012
794 Ref: 089-006-013
795 Ref: 089-006-013
796 Ref: WS-177-1 p.45
797 Ref: 089-006-015
798 Ref: 091-012-077
799 Ref: 089-006-015

418. It is for you Mr. Chairman to determine whether it was indeed appropriate for the RGH to transfer sole responsibility for proper investigation to the Coroner rather than conducting a simultaneous analysis itself which might then have assisted learning, H.M. Coroner, Mr. and Mrs. Roberts, the PSNI and this Inquiry.

419. As part of the process of informing the Coroner the *"comprehensive reply from Dr. Nichola Rooney on behalf of the Hospital dated 12th January 2005"* was forwarded to H.M. Coroner Mr. Leckey on 25th January 2005 with the observation that: *"I will leave it to you whether you wish to forward them to Dr Bingham to assist in compilation of his report."*[800] Further inaccuracies were thus supplied to H.M. Coroner, not in consequence of any independent investigation but rather, and in part on the basis of, Dr. Steen's own interpretation of Claire's case and the medical record.

420. By 9th February 2005 the Coroner had decided to hold an inquest into Claire's death regardless of the possibility that this Inquiry might consider Claire's case.[801] Mr. Leckey wrote to you Mr. Chairman on 18th April 2005 enclosing a copy of Dr. Bingham's report and advising that a further expert report from a specialist in emergency paediatric medicine was being commissioned from Dr. Iain Maconochie.[802] The PSNI had commenced its investigation by July 2005.[803]

Inquest

421. Mr. Walby's preparation for Inquest included consultations on 3rd April 2006 with Drs. Steen, Sands and Webb, together with the Trust solicitor, and on 7th April 2006 with Professor Young. The Inquest into Claire's death was opened on 4th May 2006 by the Coroner.

422. Dr. Bingham gave evidence that he considered that the admission diagnosis was reasonable and that acute encephalopathy (viral or ictal) was a likely cause of her presenting illness. He did not consider the serum sodium concentration of 132mmol/L a likely cause. He considered it reasonable to have given Claire IV fluid and noted that she was given the fluid used as standard in 1996 within the recommended volume for full maintenance fluid therapy. He believed that there were, however, reasons why Claire might have required fluid restrictions namely a lowered level of metabolism and possible reduced urinary output due to secretion of ADH which may accompany encephalopathy and nausea and vomiting. He concluded that if the reported sodium level of 121mmol/L was accurate then it was the likely cause of her deterioration and death.

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800 Ref: 090-048-152
801 Ref: WS-224-3p.34
802 Ref: 089-008-017
803 Ref: 097-058-349

423. Dr. Maconochie considered a diagnosis of encephalitis/ encephalopathy and/or non-convulsive status epilepticus to be quite probable given her past history of seizures. He regarded the management of these diagnoses to have been appropriate and did not comment on hyponatraemia. He considered Dr. Webb and other members of the team looking after Claire had given careful and informed advice. At the Inquest he gave his opinion as to cause of death as to be

(i) *"Cerebral oedema;*

(ii) *Encephalitis/encephalopathy and hyponatraemia and*

(iii) *Status epilepticus."*[804]

424. Dr. Bingham agreed with Dr. Maconochie's formulation of the cause of death and said that he considered her neurological illness had caused ADH secretion.

425. The Inquest Verdict gave as cause of death

(a) *"Cerebral oedema due*

(b) *Meningoencephalitis, hyponatraemia due to excess ADH production and Status epilepticus"*[805]

426. The Coroner found that the degree of hyponatraemia suffered contributed to the development of the cerebral oedema which caused her death but that meningoencephalitis and status epilepticus were also causes albeit that he could not determine the proportionate contribution of each to her death.

427. The Coroner's finding gave rise to new registration of death certificate on 10th May 2006 with the cause of death amended as to reflect the Coroner's Verdict at Inquest.

XXIII. Post Inquest

428. Mr. Walby was not altogether content with the Coroner's finding. He wrote to Brangam & Bagnall on 12th May 2006 to *"enclose a copy of the verdict on the Claire Robert's Inquest. It contains an important error which if allowed to stand will throw the case right into Mr. O'Hara's hands. H.M. Coroner states 'I accept the evidence of Dr. Heather Steen, Consultant Paediatrician, that the first blood test showing a serum sodium of 121mmol*

804 Ref: 091-007-028
805 Ref: 091-002-002

should have led to a clinical reassessment of Claire. That blood test should have been repeated and at the same time there should have been a reduction in fluid'. This is incorrect as there was a reduction in fluids as the Saline was reduced to two thirds of its value. I think H.M. Coroner meant to write '…there should have been a greater reduction in fluids.' To let this point go will create difficulty in the future I am sure and I would be grateful if you would take this up with H.M. Coroner please. Dr. Steen has been consulted and she feels it is important that we draw attention to it."[806]

429. Professor Young was able to agree with Mr. Walby: *"that the Coroner's verdict is misleading and that it would be rendered more accurate by the changes which you suggest"*[807] H.M. Coroner Mr. Leckey declined to make any changes to his Verdict on the basis that the Verdict accurately reflected Dr. Steen's evidence which was recorded by him and signed by her.[808] It would seem that Mr. Walby insisted to Brangam & Bagnall that: *"we need to make sure Mr. O'Hara is made aware of the error at the Inquest … It just could be that he determines to recommend inclusion of the Claire Roberts' case in his Inquiry, and if so it would be on the basis of this one error."*[809]

430. Dr. Scott-Jupp is of the clear view that the finding of the Coroner is nonetheless correct for the simple reason that calculations reveal that overall there was in fact an increase in fluids.[810] This view is shared by Dr. McKaigue.[811] Accordingly it would appear that it was Mr. Walby, Dr. Steen and Professor Young who may have been in error rather than the Coroner.

431. It is for you Mr. Chairman to determine whether the Litigation Management Office's attempt to change the Coroner's finding was motivated as much by a culture of defensiveness as a culture of analysis.

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806 Ref: 140-029-001
807 Ref: 139-010-001
808 Ref: 140-009-002
809 Ref: 139-006-001
810 Ref: 234-003-003 & 238-002-057
811 Ref: WS-156-2 p.4