Claire Roberts

Consolidated Report by Advisors August 14th 2012

This short report describes the main clinical issues that impacted on Claire's care during her hospital admission in October 1996 that they think require further examination by the Inquiry during the forthcoming Oral Hearings

In addition to all the relevant clinical, nursing & administrative records, the following statements & reports were used in the generation of this document:

1. Protocol & briefs for experts
2. Witness Statements & responses to questions; Dr Puthucheary, A&E SHO.
3. Witness Statements & responses to questions; Dr O'Hare, registrar in paediatrics.
4. Witness Statements & responses to questions; Dr Sands, registrar in paediatrics.
5. Witness Statements & responses to questions; Dr Webb, consultant paediatric neurologist.
6. Witness Statements & responses to questions; Dr Stevenson, paediatric SHO.
7. Witness Statements & responses to questions; Dr Hughes, paediatric SHO.
8. Witness Statements & responses to questions; Dr Stewart, paediatric SHO.
9. Witness Statements & responses to questions; Dr Bartholome, paediatric senior registrar.
10. Witness Statements & responses to questions; Dr Steen, consultant paediatrician
11. Witness Statements & responses to questions; S/N E A Jackson, staff nurse A&E.
12. Witness Statements & responses to questions; S/N McRandal, staff nurse, Allen Ward
13. Witness Statements & responses to questions; S/N Maxwell, staff nurse Allen Ward.
14. Witness Statements & responses to questions; S/N Jordan (nee Field) staff nurse, Allen Ward.
15. Witness Statements & responses to questions; S/N Taylor, staff nurse Allen Ward|
16. Witness Statements & responses to questions; S/N McCann, staff nurse Allen Ward.
17. Witness Statements & responses to questions; S/N Murphy, staff nurse Allen Ward.
18. Witness Statements & responses to questions; Sandra Ross, staff nurse PICU
19. Witness Statements & responses to questions; Margaret Wilkin, staff nurse PICU.
20. Witness Statements & responses to questions; Dr Clarke, registrar in anaesthetics.
21. Witness Statements & responses to questions; Dr McKaigue, consultant anaesthetist.
22. Witness Statements & responses to questions; Dr Taylor, consultant anaesthetist.
23. Witness Statements & responses to questions; Dr Savage, general practitioner.
24. Witness Statements & responses to questions; T Blue, triage nurse, A&E.
25. Witness Statements & responses to questions; Dr Gaston, consultant paediatrician.

26. Witness Statements & responses to questions; Dr Kennedy, registrar in radiology
27. Witness Statements & responses to questions; Dr Crean, consultant paediatric anaesthetist
28. Witness Statements & responses to questions; Dr Herron, senior registrar in neuropathology.
29. Witness Statements & responses to questions; Angela Pollock, sister, Allen Ward.
30. Witness Statements & responses to questions; Dr Mirakhur, consultant neuropathologist,
31. Witness Statements by members of the Roberts family
32. Depositions to Inquest
33. Witness statements/interviews PSNI
34. RHBSC case notes
35. Ulster Hospital case notes
36. Expert reports (2012) by Prof. Keith Cartwright, consultant clinical microbiologist.
37. Expert report (2012) by Prof Brian Neville, paediatric neurologist
38. Expert report (2011) by Prof. Brian Harding, neuropathologist.
39. Expert report (2012) Prof. Jeffery Aronson, pharmacologist.
40. Expert reports by Sally Ramsay (2011,2012) children's nurse
41. Expert report (2012) Dr Carol Landes, consultant paediatric radiologist.
42. Expert report (2012) Dr Scott-Jupp, consultant paediatrician.
43. Expert reports by Dr Waney Squier, consultant neuropathologist. Keeling, consultant paediatric pathologist (retired), 2011.
44. Expert report, Dr Roderick MacFaul, consultant paediatrician.
45. Expert report (2011) Bridget Dolan. Barrister at law
46. Expert report (2011) Steven Ramsden, former CEO

Summary

The list below summarises the matters for further consideration detailed in the chronological account which forms the bulk of this report. Those items marked *Key issue* are considered as potentially having had a significant effect on outcome.

A. Individual clinical failings identified in expert reports (not necessarily unanimously agreed by all experts)

Incomplete investigations on admission (Dr O'Hare)

Infrequent observations on admission to A&E and insufficient and incomplete observations following admission to the ward (S/N Jackson; S/N McRandal; S/N Field)

Failure to recognise the severity of illness on admission and during 22 October (Dr O'Hare; S/N McRandal; S/N Field & all staff involved on 22 October) *Key issue*

Failure to communicate the severity of illness to Claire's family (Dr O'Hare; S/N McRandal; S/N Field & all staff involved with Claire on 22 October)

Failure to establish a complete nursing care plan, revise this as Claire's condition changed and include sufficient detail regarding action taken as condition changed (S/N McRandal; S/N Field) *Key issue*

Use of dilute IV fluid in standard volume despite neurological signs (Dr O'Hare; Dr Sands; Dr Webb; Dr Steen; Dr Bartholome) *Key issue*

Failure to reassess Claire at or around 9-10 am on 22nd October (Dr Sands; Dr Steen)

Failure to measure accurate fluid balance (S/N McRandal; S/N Field)

Failure to repeat serum electrolytes on 22nd October (Dr Sands; Dr Stevenson; Dr Webb; Dr Hughes) *Key issue*

Failure to undertake EEG to confirm NCES (Dr Webb) *Key issue*

Failure to obtain CT scan during working hours on October 22nd (Dr Webb; Dr Steen)

Use of anticonvulsants despite lack of confirmation of NCES (Dr Webb)

Erroneous dose calculations (Dr Stevenson)

No reassessment of Claire by 'night' team 22nd October (Dr Hughes; Dr Bartholome; Dr Stewart; Dr Steen) *Key issue*

Failure to attend and/or failure to re-assess and take action at 9pm in response to nurse request (Dr Hughes or Dr Stewart) *Key issue*

Erroneous reporting of neuropathological findings (Dr Mirakhur; Dr Herron)

B. <u>Failures to consult more senior paediatrician</u>

On admission, when diagnosis uncertain and trainee apparently unaware of indicated investigations (Dr O'Hare)

Failure to involve Dr Steen or Dr Sands when hyponatraemia identified (Dr Bartholome) *Key issue*

C. <u>Absence of local clinical guidelines</u>

Investigation of children with impaired consciousness

IV fluid calculation in presence of encephalopathic illness

Frequency of electrolyte measurements in children receiving IV therapy *Key issue*

Indications for nurses to seek medical help in response to changes in neurological state

General guidance to medical trainees on when to seek consultant assistance

Prescribing guidance for junior doctors

D. <u>Issues regarding consultant responsibility</u>

Factual dispute over whether there was a post-take ward round by named consultant (Dr Steen) *Key issue*

Absence of consultant involvement in 'unwell' child (Dr Steen) *Key issue*

Absence of universally understood clear policies and procedures on interconsultant referrals and transfer of overall responsibility (Dr Steen; Dr Webb; Medical directorate generally) *Key issue*

Identification and remediation of trainee failings (re dosage calculations) (Dr Webb; Dr Steen)

E. <u>Handover arrangements</u>

Adequacy of handover by 'day shift' paediatric trainees to 'night cover' trainees *(Dr Sands; Dr Stevenson)* *Key issue*

Adequacy of briefing by consultant staff to 'night cover' trainees (Dr Webb) *Key issue*

F. Procedures after death

Incomplete and misleading information on death notice (Dr Steen)

Request for limited rather than full PM (implying failure to gain fully informed consent from Claire's parents) (Dr Steen; Dr Webb) *Key issue*

Failure to report unexpected death to HM Coroner (Dr Steen; Dr Webb)

Inadequate provision of information to parents when PM results available (Dr Steen; Dr Webb)

Absence of clinical summary completed by paediatric team

G. Clinical Audit processes

Failure to report drug errors as adverse incidents

Given that unexpected deaths are rare on a children's ward, adequacy of informal debrief processes

Apparent failure to review Claire's death both before and after PM information availability

No formal learning from the audit meeting that discussed Claire. *Key issue*

H. Possibly inadequate clinical services

Availability of emergency electroencephalography (EEG)

Availability of CT imaging

Laboratory 'turnround' of blood tests out of hours

I. Clinical Governance Issues

Degree of autonomy among nurses to initiate observations and other aspects of care

Adequacy of nursing assessment, care planning and written evaluation of care and actions taken

Procedures for post-take ward round/management of children, especially when lead consultant unavailable

Handover of consultant responsibility

Identification and management of junior staff errors in treatment/prescribing

Monitoring of medical staff workload

Reporting of Claire's death as an adverse incident

No apparent discussion with more senior clinical or managerial colleagues – policies for calling registrar/consultant.

No investigation into Claire's treatment in 1996 and in 2004 after UTV programme.

Adequacy of the Trust audit process

Adequacy of communication with Claire's parents during Claire's treatment, and after her death.

Adequacy of the response to Claire's parents' complaint in 2004.

Adequacy of the complaints process in the Trust.

The development of clinical guidelines for both medical and nursing management of children with neurological problems in the Trust

The robustness of the management arrangements in the Trust in 1996 and the clarity of responsibilities of the Clinical Director

J . Issues around communication with parents

Adequacy of the communication between clinical staff and Claire's family from Claire's admission to her death, including possible diagnoses, care plan and prognosis. *Key issue*

The adequacy of written records of discussions with Claire's family. *Key issue*

Adequacy of the Trust's guidance and training in communicating with families, particularly following the accreditation of the RBHSC by the King's Fund in 1995.

Adequacy and timeliness of information given to Claire's parents following her death and the outcome of the Post Mortem. *Key issue*

Chronological Account

1. Initial management in A&E and overnight 21/22 October

1.1 No criticism is made by the experts into the action of Dr Puthucheary, who made a reasonable diagnosis of encephalitis and competent referral to the paediatric team.

1.2 While Sally Ramsay criticises failure by nurses to monitor vital signs regularly in A&E, she states this did not affect outcome.

1.3 There are differences of opinion as to Dr O'Hare's initial management: Prof. Neville regards her diagnostic assessment as incomplete in not considering encephalitis, overwhelming infection, metabolic disorders (including hyponatraemia with cerebral oedema) and poisoning. Dr Scott-Jupp regards her history taking and examination as competent and her diagnosis ('viral illness') as no more than a preliminary assessment which does not exclude encephalitis.

1.4 Both are critical of the paucity of blood investigations undertaken, which meant that important causes of impaired consciousness, including liver failure and poisoning were not ruled out. However, this did not affect the outcome**. [234-002-002; 232-002-003/4]**

1.5 Dr Scott-Jupp gives as his opinion that, in 1996, urgent CT scanning was not mandatory because of the risks inherent in transfer to RVH, the possible need for anaesthesia or sedation and the poorer quality of imaging at that time. Dr Neville considers CT scanning should have been undertaken on admission, regardless of logistical difficulties and that he would have expected the registrar to discuss this with the consultant paediatrician on-call. **[232-002-004; 234-002-009]**

1.6 Sally Ramsay considers the nursing care plan drawn up after admission for overnight care was appropriate and comprehensive for a diagnosis of seizures and vomiting **(231-002-019)**. However, she stated that nursing documentation did not include the possibility of encephalitis, which was recorded in the A&E record. In addition, she stated that '*more frequent observation of some vital signs should have been made*' (**231-002-019**).

Matters for further consideration:

- Given that the experts considered investigations were incomplete and Dr Scott-Jupp has concerns about the safety and logistics of obtaining a CT scan (which Prof. Neville considered mandatory), we infer that the case was a complex one, possibly beyond a registrar's competence. Thus, the Inquiry might wish to know what policies or procedures governed when paediatric trainees should inform the responsible ('named') consultant in order to be involved in decision-making. Were trainees dissuaded in any way from calling consultants, especially 'out-of-hours'?

- Has that now changed and, if so, why and when?

- In view of the suggestion that observations of vital signs were not recorded sufficiently frequently in either A&E or the ward, what guidance and support was available then/is available now to nursing staff to determine frequency of observations?

- In 1996, whose responsibility was it to determine the frequency of observations?

2. <u>Initial IV fluid prescription</u>

2.1 Again, the experts are not in agreement: Dr Scott-Jupp considers the initial prescription of 65mls/hour of 0.18% saline in 4.5% dextrose was standard for 1996. **[234-002-002]**

2.2 Prof. Neville considers that at the time 'many' would have given a less dilute solution or restricted the volume of No 18 solution pending urgent review, changing the prescription once the serum sodium concentration was known (at midnight). **[232-002-004]**

2.3 Dr MacFaul states **[p18 of report**] that 'although [its] use for IV maintenance fluid was within the range of current practice for the time for management of ill children, at this time also ideal/high-quality practice for acute encephalopathy any causation [*sic*] should have led to choice of IV fluid with higher sodium concentration.' He added that a period of observation was necessary before a diagnosis of acute encephalopathy could be confirmed.

2.4 Also in his report, Dr MacFaul quotes a passage from the standard UK textbook of paediatrics (1984 edition) which advised fluid restriction in encephalopathy. We note that the 1992 edition does not include this passage.

Matters for further consideration:

- To what degree, in 1996, was the need to limit the use of dilute IV solutions in the presence of an illness which might involve the brain (encephalopathy) recognised?
- At the time, in RBHSC, what guidance was available to paediatric trainees with regard to IV maintenance in children with possible encephalopathy?
- What guidance is now followed? In this context, we note with concern Dr MacFaul's comment (**para 167 of report)** that 2006 guidance on treating children with impaired consciousness, endorsed by the Royal College of Paediatrics & Child Health and used as a basis of multi-site audit reported in 2011 *does not address the issue of IV fluid to be used.*
- What observations would have been required and over what period to make a diagnosis of acute encephalopathy?

3. <u>The serum sodium level</u>

3.1 This was reported at midnight as 132, just below the lower limit of the normal range (135). Dr Scott-Jupp points out that such a level is common in paediatric practice and does not, in itself, require a management change. However, he considers it did require checking about 12 hours later [which would have been at about the time of the morning ward round] because Claire was not improving. His opinion is that it is likely that a substantial fall would have been noted and 'it would have been possible to intervene before cerebral oedema became apparent.**'** **[234-002-003**

3.2 Prof. Neville considers it should have been checked after 6 hours, [about 4 a.m.] regardless of out-of-hours laboratory arrangements. **[232-002-005]**

3.3 Dr MacFaul quotes the standard paediatric text available in 1996 [which the advisors take to be 'Forfar & Arneil 4th edition p774] as advising 12 hourly electrolyte measurements in children with coma.

3.4 Dr Steen, named consultant for Claire states the electrolytes should have been checked on the afternoon of 22nd October **[WS 143/2 p6]**

3.5 We infer from the case notes that the serum sodium was not checked until sometime between 2100 and 2130 on 22nd October, about 24 hours after the previous test.

Matters for further consideration:

- Failure to recheck the serum sodium was a key error which the experts state had a major influence on outcome. Who was responsible for determining when to repeat the electrolyte measurements? (see sections below re 'ward round' and 'Dr Webb's involvement')

4. The morning ward round

4.1 This 'did not reach Claire until quite late into that morning' **[WS137-1 p19].** Mr Roberts remember this to be around 11.00 am **[WS 253/1, p6].** It was led by Dr Sands accompanied by Dr Stevenson (SHO) and Enrolled Nurse (E/N) Linsky **[WS 148/1 p4]**. At that time Dr Sands was 2 months into his first substantive post as a paediatric registrar, having previously been a locum registrar in paediatric cardiology for 3 months **[ibid p3].**

4.2 Sister Pollock stated that it would have been normal practice for herself or the nurse in charge in her absence to attend the ward round **[WS 125/1 p6]**. She is unable to recall when she was on duty during Claire's admission **[WS 225/1 p2]**. Similarly, Dr Steen is unable to recall events of 22 October, but has '*no reason to think that I did not take the ward round*' which was usually conducted around 10am on that ward. She postulated that '*there were other problems on the ward that morning delaying the round'* which might explain why Dr Sands saw Claire so late **[WS143/2 p8].**

4.3 Dr Sands described the history and examination at that time as 'felt to point to a major neurological problem' with the most likely diagnosis as epileptic status with encephalitis as a possible cause or complicating factor. **[ibid p10].** He stated the discussion would have included a plan to recheck blood electrolytes **[ibid p8].** He left the ward round to speak to Dr Webb about Claire, possibly at midday, including a discussion about a CT scan **[ibid p11 & WS137/2 p7**]. He stated that he informed Dr Steen by telephone, in the afternoon, of his consulting Dr Webb. **[WS137/1 p16**]. Following this he assumed Claire was 'under joint care between general paediatrics & paediatric neurology' **[WS137/2 p4]**

4.4 Dr Steen considers she was 'the named consultant paediatrician to oversee Claire's treatment and work with colleagues as required' (from admission to her death) **[WS143/1 p3]** and 'would normally have been in RBHSC 0845-1300 on 22nd October 1996 for the post-take ward round (from 0900-1100).' **[ibid p3 & p6]** but has no recollection of the day in question, except that 'I had been aware that Claire was in the ward at 9 am.' [**ibid p7].** We note that Dr Steen's second statement is more suggestive that she was on the ward round. "I have now no recollection of events. I assume I was informed by medical and nursing staff when I attended the ward prior to the ward round at approximately 8.45am on the 22nd October 1996." **[WS143/2 p2]**

4.5 Dr Scott-Jupp's opinion is that 'given that it was during the working day, it would have been reasonable for Dr Steen to have seen this child who was clearly unwell and causing diagnostic difficulties' **[234-002-005]**.

4.6 Prof. Neville's opinion is that 'the cause of Claire's brain illness was unexplained and the consultant [Dr Steen] should have been involved.' **[232-002-007]**

4.7 Dr MacFaul's opinion is that 'by the morning following her admission at latest Claire should have been seen by Dr Steen' and that while referral to Dr Webb was correct 'Dr Steen should have been involved in the decision making **[report para 91]**

4.8 No change was made in the nursing care plan following the ward round. Sally Ramsay considers that, in consequence, it did not reflect the potential severity of Claire's condition in that there should have been an entry regarding ongoing monitoring of the level of consciousness. **[231-002-019/021]**

4.9 Dr Sands states that, despite the absence of a note, he believes there would have been discussion about repeating the serum electrolytes and a plan to carry this out, **[WS137/1p8 WS137/2 p9]** and that it was for the SHO to carry this out. Dr Stevenson cannot recall whether there was a discussion. Dr Scott-Jupp states that had there been a request by Dr Sands to repeat any tests, he would have expected that to be recorded by the SHO in the case notes at the time and to be responsible for taking the blood and obtaining the result. **[234-003-006]**

Matters for further consideration

- If the Inquiry find as a fact that no consultant was present on the post-take round, it raises the question as to what was RBHSC policy regarding the role of the named consultant in undertaking post-take ward rounds (in 1996 and now).

- Why did the ward round apparently start so late (or at least, late to reach a newly-admitted and demonstrably unwell child)?

- Why was Claire not seen by a consultant until 16 hours after admission?

- Why were neurological observations not commenced until 13.00?

- In 1996, what degree of responsibility was given to paediatric trainees for managing children identified as being 'unwell' and/or having a major neurological problem and when were they required to inform the named consultant?

- Has the position with regard to consultant involvement changed and is this demonstrable in written policies or guidelines issued to trainees?

- What policies and professional guidance were (and are now) in place in regard to nursing staff autonomously adjusting care plans or changing the nature or frequency of observations in response to a child's condition?

- Why was no action taken to check the serum electrolytes?

- Were policies in operation for electrolyte measurement frequency in children having IV fluids? What is the position now?

5. <u>The initial involvement of Dr Webb</u>

5.1 The case notes show that from about 2 pm until 5 pm on October 22nd, Dr Webb saw and treated Claire three times. He believes Dr Sands first contacted him between 1 and 2 pm on that date **[WS 138/1 p4**] 'in the corridor at lunch time **[ibid p5**], being asked to provide a specialist opinion and 'He did not request me or my team to take over Claire's management and treatment' **[ibid p6]** and he did not do so **[ibid p8]**. He also states the encounter 'may have been after a hospital clinical meeting we both attended.'

5.2 Dr Scott-Jupp considers that Dr Webb should have made it clear at the time whether or not he had taken over care. **[234-002-007]**

5.3 Dr Webb diagnosed acute encephalopathy with non-convulsive status epilepticus (NCSE) possibly associated with viral infection and possibly meningoencephalitis. **[WS138/1 p20]** He believed, erroneously, that the sodium level of 132 had been measured the same day 'which would have made hyponatraemia a very unlikely cause of her symptoms…' **[ibid p21].** He accepts that her serum sodium should have been checked during the day of October 22nd 'but I did not think of this because I erroneously thought her serum sodium had been normal that morning.' [WS138/1p36]

5.4 Prof Neville's states that an EEG is the only method of confirming a diagnosis of NCES and, in Claire's case, needed as proof because 'it is not common and epilepsy was not prominent in this girl's recent history.' He considers cerebral oedema was a more likely cause, and that CT scanning should have been undertaken to confirm this. **[232-002-005 & 006].**

5.5 Dr Aronson, clinical pharmacologist agrees an EEG was desirable **[237-002-008].**

5.6 Dr Scott-Jupp is critical of Dr Sands not having repeated the serum sodium level [which would presumably have meant that Dr Webb would not have misled himself about the timing] but notes that he would have expected fluid management to be by the paediatric team, not the paediatric neurologist **[234-002-003/006]**. He is also critical of the failure to obtain an EEG but notes that his criticism might be unjustified in the light of Dr Webb's statement that there was no access to an emergency EEG service**. [234-002-004/WS138/1 p23].**

5.7 The advisors note, however, Dr Steen's statement that, in 1996, 'emergency EEGs were only with the authorisation of the consultant paediatric **neurologists [WS 143/1 pp 27, 29].**

5.8 We agree with the experts that there are major concerns regarding continuity of patient care and team-working between specialties which militated against competent management of Claire's case.

Matters for further consideration

- Why was Dr Webb not contacted immediately after the ward round in light of Dr Sands' belief **[WS 137/1 p11]** that Claire was very unwell?

- If Drs Sands and Webb met at a clinical meeting, was it one which Dr Steen attended or was expected to have attended?

- What arrangements were in place to ensure that all those involved in clinical care at RBHSC were aware of which consultant took ultimate responsibility for individual patients?

- What formal procedures were in place in regard to obtaining a specialist opinion and/or transferring responsibility for care?

- What training/guidance was given to trainee medical staff and nurses as to which consultant had overall responsibility for individual patients?

- Where more than one consultant was involved in patient care, what procedures were in place, and known to all concerned, regarding how to manage team-working and/or multidisciplinary care?

- Was it acceptable practice for RBHSC to provide paediatric neurology services without access to emergency electroencephalography (if Dr Webb, rather than Dr Steen is giving a factual account of what was the case)?

- What changes have been adopted since 1996 in relation to all the above?

6. Claire's medical care between 2pm and 5pm on October 22nd

6.1 Dr Webb prescribed a series of anticonvulsant medications, including phenytoin, midazolam and sodium valproate. Dosage errors were made by Dr Stevenson, SHO, who calculated the dose of phenytoin as 632 mg, whereas the dose ordered by Dr Webb amounted to 435 mg. Midazolam was ordered 'off-license' with a loading dose of 0.5 mg/kg (12mg) followed by about 2microgram/mg/minute. The drug administration chart appears to read 120 mg. There are no initials in the column used for denoting that dose was given but there is a nursing note referring to an intravenous dose (amount not stated) being given at 3.45pm.

6.2 Dr Aronson's opinion is that the overdose of phenytoin probably reduced her Glasgow Coma Scale score and so made assessment of her condition more difficult. The same is true for the combination of rectal diazepam acting in combination with the other drugs mentioned. **[237-002-010/016]**
6.3 It is Prof. Neville's view that phenytoin was not appropriate without proof of NCES but he does not consider the overdose materially altered outcome except that

it might have caused her GCS to fall at 3 pm (but not at 4 or 5 pm). For the same reason he considers the other anticonvulsants as inappropriate (except the diazepam administered by Dr Sands). **[232-002-006/009]**

6.4 Dr Scott-Jupp considers the overdose of phenytoin irrelevant; he does not criticise the use of anticonvulsants (deferring to expert neurological opinion) but states that the lack of improvement in Claire's conscious level should have prompted reassessment of the underlying cause. **[234-002-006]**

6.5 After pointing out that there was no licensed indication, in 1996 for midazolam in children with seizures, Dr Aronson adds that a dose of 120 mg would have caused major anaesthesia, coma, severe respiratory depression and possibly death. **[237-002-014]** Prof. Neville concurs with this assessment of outcomes and believes, therefore, that it was not given [**232-002-017**]. Dr Aronson also points out that a dose of 120 mg would have required the use of 12-30 ampoules, which the advisors consider highly unlikely for any doctor or nurse not to question, since it is way beyond what is normal in any IV drug administration.

6.6 In this respect, the advisors are aware of at least one publication in the medical literature of the use of high dose midazolam (as in the loading dose prescribed by Dr Webb) in treating refractory status epilepticus in children (Morrison G et al *Intensive Care Medicine* 2006;**32**:2070-6). Also it is universal practice in paediatrics to use drugs 'off licence', a fact regarded by paediatricians as of benefit to their patients and inevitable since many newer drugs have not been tested experimentally on children so cannot be licensed for their use.

6.7 Sally Ramsay considers that, by 3 pm when the GCS was 7, Claire needed 1:1 nursing care to facilitate continuous observation and monitoring **[231-002-021]**. She states that this level of care was often difficult to provide in a ward setting and that the GCS should have prompted discussion with more senior colleagues about admission to PICU **[231-002-031].** She states that the effect of the medications administered to control seizures indicated the need for half hourly recording of heart and respiratory rates from 2pm. This level of observation and '*increased general observation were best provided by 1:1 nursing care*' **[231-002-026]**. Therefore Sally Ramsay suggested that an increased level of care was indicated from 2pm on 22 October. However, there was no evidence from the nursing or medical records that 1:1 nursing/PICU was considered or discussed with more senior nursing staff.

6.8 Dr Scott-Jupp considers that, while in 1996, the need for ventilation was a pre-requisite for PICU admission, she should have been discussed with a PICU consultant who could then have assessed her and advised on management. [234-002-010]

6.9 Prof Neville states that cerebral oedema is, itself, an indication for ventilation and that had a CT scan and repeat electrolyte measurements been performed this 'would I think have been considered early on 22nd.' [232-002-012]
Matters for further consideration

- What were the reasons for Dr Webb's misunderstanding of the timing of the serum sodium estimation?

- Given the absence of EEG confirmation of NCES, was it reasonable to use repeated anticonvulsant doses from 2 pm onwards?

- What procedures were in place to instruct and test junior doctors in dosage calculations?

- What responsibility did prescribing doctors (in this case the consultant neurologist) have and what did they take in checking trainees' dose calculations and record keeping?

- In the light of the miscalculations and/or inadequate record keeping was any action considered or taken, at the time, to report these as 'adverse incidents' and or to offer further training to any of those involved (**WS 143/1 p36**)?

- What improvements have been introduced since 1996 in dealing with the last four issues above (**WS 143/1 p37 Q28dd**)?

- What policies, professional guidance and resources were in place to govern the intensity of nursing care ('1:1') and admission to PICU?

7. Responsibility for care after 5pm and before transfer to PICU

7.1 Dr Webb states that, after leaving the hospital at about 5 pm he expected to be informed of Claire's condition and any abnormal results as he was on-call. **[WS138/1p71]** He left instructions for a blood phenytoin level to be checked at about 9 pm but not regarding electrolytes as he believed 'this aspect of her care was being taken care of by the general paediatric team. **[WS138/11 p80]** He also states that he regarded Claire as 'a candidate for electrolyte imbalance' **[ibid p81]** and that 'Fluid management and routine biochemical investigations would usually be managed by the paediatric medical team in this situation.' **[WS138/1 p36]** Neither he nor any member of his team was told of the events at 7, 9 or 11.30 pm. His next contact being when she was considered brain dead. **[ibid p85].**

7.2 Dr Steen accepts she was the consultant responsible for Claire's care throughout. **[WS 143/1p7]**. However, in her deposition to the Coroner she stated that she contacted the ward – presumably at the end of her afternoon clinic – and was told Dr Webb had taken over care **[ibid p 84].** She expected Dr Webb to lead on investigations and management and she would 'have remained in support for any general paediatric issues on which Dr Webb wished to consult. **[143/2 p8].** She quotes 'custom and practice' at the time that if a child deteriorated the named consultant (at night the on-call consultant) would be contacted **[ibid p14].**

7.3 Sally Ramsay thought it reasonable that the nurses assumed that Dr Webb had responsibility for Claire's care.

7.4 Dr Webb's entry in the case notes (before he left the hospital) did not summarise Claire's condition and offered as a plan, administering an antibiotic and antiviral agent, albeit he did not think meningoencephalitis likely, checking stool, urine ,blood and throat swab cultures for viruses and adding intravenous sodium valproate. **[090-022-055]**

7.5 Dr Sands went off duty soon after 5 pm and was replaced by Dr Bartholome, senior registrar. She was first alerted to Claire at about 11.30pm when the SHO, Dr Stewart contacted her to seek advice when he discovered she was hyponatraemic.

7.6 She is not able to give details of any handover to her when she came on duty as such handovers were informal and not noted. **[WS 142/1 p25]** from Dr Sands. She does recall the consultant in charge of Claire as Dr Steen but does not recall which paediatric consultant was on-call that night.

7.7 Dr Scott-Jupp considers Dr Webb should have communicated his concerns about Claire to 'a senior on-call general colleague, either a consultant or experienced general registrar [in this case, Dr Bartholome] or alternatively made it quite clear that the neurology team were taking over her care. He should then have ensured that all of the neurology team on-call that evening was aware of the details of the case. **[234-002-007/8]**

7.8 Prof Neville states the hospital notes should have made clear if there had been a transfer of care. His reading of the case notes is that Dr Webb was making suggestions rather than taking over 'but I cannot be sure of this.'

7.9 Dr MacFaul is also critical of the apparent lack of handover, stating that Dr Sands should have handed over personally or by telephone to Dr Batholome and, given the severity of her illness, reviewed by the latter as a routine in the evening. **[p23]**

7.10 *The advisors consider a fundamental issue in this case is the lack of clarity as to who was responsible for Claire's care*. We are very concerned that those coming on duty at or after 5 pm may not have been properly briefed about the course of Claire's illness, the unresolved issues surrounding diagnosis, how to recognise deterioration and what to do if it occurred and what complications to which they needed to be alert.

7.11 We are equally concerned about apparent different understanding as between Dr Steen and Dr Webb as to who was responsible for biochemical monitoring and fluid therapy.

Matters for further consideration

- What arrangements were in place for medical staff going off duty at the end of the working day to apprise those coming on for the night shift of unresolved problems/ undiagnosed patients/ significantly ill patients etc.?
- How would the responsible resident paediatrician (in this case Dr Bartholome) or the SHOs working at night learn about the patients for whom they were now responsible?
- What, if any, arrangements were in place for consultants to brief the overnight staff on what was expected of them?
- How were these doctors made aware of which consultant was supervising management and investigations?
- How would the nurses know who were the responsible clinicians?
- How have procedures changed since 1996?

8. Claire's care between 5 pm and admission to PICU

8.1 The case notes contain no information until a nurse reported a 1 minute episode of teeth clenching and groaning at 7.15 and Nurse McCann reported a 30 second episode at 9 pm of screaming and drawing up of arms, pulse rate rising to 165 and seizure-like episode at 9pm, noting that a doctor was informed. **[090-042-144]** Nurse McCann is unable to remember which doctor; neither doctor on duty at the time, Dr Hughes **[WS140/1 p28]** nor Dr Bartholome **[WS142/1 p15]** has any recollection of this event.

8.2 A blood sample was taken at about 9.30 pm. None of the witnesses are able to state who took the sample, the result from which was reported to the duty SHO, Dr Stewart, at 11.30 pm and revealed significant hyponatraemia (sodium 121). He informed his registrar, Dr Bartholome who ordered a reduction in the rate of infusion and that a urine sample be sent to measure osmolality. **[090-022-056]**

8.3 Sally considers the episode at 7.00 pm should have led to a doctor being informed **[231-002-024/5].** She identified five events between 3.10pm and 9pm which should have been reported to a doctor. There was only evidence that one had been reported to a doctor. Sally Ramsay concluded that failure to record one significant event in the nursing evaluation was a failure in record keeping.

8.4 She is also concerned that there is no evidence of medical review at 9.30pm even though a doctor must have attended to take the blood sample.

8.5 Prof Neville is critical of Dr Bartholome: he considers appropriate action when the blood result was discovered at 2330 should have included: performing a neurological examination; induction of diuresis by mannitol or frusemide; elective ventilation to reduce partial pressure of carbon dioxide in order to reduce intracranial pressure. The consultant in charge should have been informed. He states also that the recorded fall in GCS at 9pm should have prompted contact with the registrar and/or consultant. **[232-002-011]**

8.6 Dr Scott-Jupp agrees that the registrar should have re-examined Claire, fluid restriction should have been greater – possibly stopping fluids altogether, to check blood and urine osmolality and 'undoubtedly' to involve a consultant.

8.7 Dr MacFaul is critical of the time taken in processing and reporting the blood test result (2 hours) and points out that, in fact, there was no reduction in total input because the reduction in No 18 solution infusion rate was matched by the fluids given to dilute the intravenous doses of acyclovir and phenytoin.

8.8 Dr Scott-Jupp, in attending to this point, notes confusing entries in the fluid balance chart which make retrospective calculation difficult, but agrees with Dr MacFaul that it is likely her IV fluid input was not reduced as intended.

8.9 *The advisors are very concerned about the lack of intervention in Claire's care at this period in her hospital admission:* lost opportunities for review, identified by experts, were:

> 'Routinely in the evening' (Dr MacFaul)
>
> At 7.00 pm if a nurse had reported the seizure-like event (Sally Ramsay)
>
> At 9pm when there was a fall in GCS/ seizure (Dr Neville; Dr Scott-Jupp)
>
> At 9.30 pm when a doctor attended to take blood (Sally Ramsay)
>
> At 11.30 pm (or earlier had the test result been communicated quickly), when Dr Bartholome should have attended and reassessed her as well as the consultant being informed (Prof Neville; Dr Scott Jupp); also the management of the hyponatraemia was inadequate (Prof. Neville, Dr Scott-Jupp, Dr MacFaul)

Matters for further consideration

- What procedures were in place for the night-shift registrar to routinely review ill patients as opposed to responding to urgent calls?

- What guidelines were there for nurses as to when to seek medical help in response to changes in neurological state?

- What guidance was given to registrars as to when to seek consultant assistance?

- Would intervention at 7.00pm or 9 pm (including clinical reassessment urgent estimation of electrolytes and appropriate treatment of hyponatraemia) have changed outcome?

- Would the same be true at 11.30 pm

- What local and professional guidance was available to nurses and junior doctors in relation to maintaining contemporaneous records of patient care?

- How was record keeping monitored in the trust in 1996 and now?

9. Her arrest and transfer to PICU

9.1 No expert has given an opinion that the arrest was mishandled or that PICU care was inadequate.

9.2 Prof Neville considers the arrest was a terminal event from which there was no hope of recovery. **[WS232-002-013]** Dr Scott-Jupp appears to consider that whatever action had occurred from 11.30 pm it was likely to have made little difference to outcome. Dr MacFaul is critical of retrospective record keeping following the arrest as no timings were documented. **[p27]**

We do not consider any matters for further consideration arise at this stage.

10. The death certificate, the post-mortem examination and reporting the death to the Coroner.

10.1 Dr Webb and Dr Steen saw parents following a CT scan of Claire's brain during the morning of October 23rd and were reported on a 'relative counselling chart' as stating that she had 'brain swelling…probably caused by a virus.' **[090-028-088]**

10.2 The notice of registration of death gave as the cause of death:
(a) Cerebral oedema (b) Status Epilepticus **[091-012-077]**
The death certificate was probably completed by Dr Steen **(WS-143-1 p74).** Under the current guidance (July 2010) in the Belfast Health & Social Care Trust (attached to Dr Steen's witness statement **[WS-143-1 page 123 – Para 8.7}**
'A doctor who had treated the patient in the last 28 days for a natural illness that caused their death may issue a Medical Certificate of Cause of Death'

10.3 A post-mortem examination limited to brain only was requested by Drs Steen and Webb, parents consenting.

10.4 Dr Steen states that, at the time, 'it was felt the sequence of events leading to her death was known and there were no areas of concern around her care' **[WS143/1 p73**]. Dr Steen maintains that there was no need to report the death to the Coroner, and there is no evidence that this was discussed with other doctors or with the Coroner's office. Bridget Dolan's expert report **[para 4.3, 1(b)(ii) p9]** states that the Coroner should be informed if 'the cause of death appears to be unknown'

10.5 Dr Mac Faul states that 'there was a strong case argument for referring Claire's death to the Coroner after her death but this did not take place until 2004'. **(report p11)**

10.6 Dr Herron, senior registrar in neuropathology conducted this autopsy on October 24th and undertook brain slicing (after fixation) on November 28th. He prepared a 'provisional anatomical summary'. Histology slides were created on January 23rd and a report issued by Dr Mirakhur on February 11th, although until 2011 Dr Herron wrongly believed he had been its author**. [WS224/1 p4; WS 224/3 p2, 15]**. Dr Mirakhur considers the report was a joint document. **[WS247/1 p6]**

10.7 Dr Herron states that the autopsy request form supplied to him gave as clinical problems: cerebral oedema; status epilepticus; inappropriate ADH secretion; and viral encephalitis. **[WS224/3 p13]**

10.8 The report identified brain swelling, 'low grade subacute meningoencephalitis' and that the cellular reaction in meninges and cortex was suggestive of a viral aetiology and a neuronal migration disorder. **[WS 247/1 p11]**

10.9 Prof. Brian Harding, paediatric neuropathologist examined brain sections and slides in 2006 at the request of the PSNI. His conclusion was that while there was cerebral oedema, there was no evidence of encephalitis or a neuronal migration defect. Subsequently Prof. Harding has reported that, had acute encephalitis been the cause of cerebral oedema over a course of 3 days, it is extremely unlikely that microscopic evidence of encephalitis would not be evident**.** **[235-002-001]**

10.10 Dr Waney Squier, neuropathologist examined brain tissue blocks and slides in 2012. She found signs of very severe brain swelling with no evidence of encephalitis and no evidence of a neuronal migration defect. The changes were recent; additionally there was evidence of older changes in the hippocampus and temporal lobe 'which are many weeks or even years old.' She suggests this might be related to febrile convulsions suffered by Claire when she was about 6 months old. There were no recent changes of the sort seen in status epilepticus. **[236-003-006/7]**

Matters for further consideration

- The death notice did not include known precipitants of death, including hyponatraemia, nor a presumed one – viral encephalitis. What audit was (and now is) conducted by RBHSC to ascertain the accuracy of death notices?
- Was it appropriate for Dr Steen to complete the death certificate?
- Given the uncertainties over the precise aetiology, why was a limited post-mortem requested
- Given that Claire's death was unexpected and the full diagnosis uncertain, why was there no consideration of reporting to HM Coroner
- Should the pathologist have challenged the type of post mortem, suggested clinicians contact the Coroner or discussed the case with the coroner himself?
- What instructions were given to consultant staff re referral to the Coroner?
- On what evidence did Dr Herron/Mirakhur conclude pathological findings, purporting to confirm certain of the clinically assumed causes of death but not confirmed by Prof Harding/Dr Squier?

11. Information to and communication with Parents

11.1 During Claire's illness, this appears to have been inadequate: Mr Roberts' statement to the Coroner of September 2005 **(091-004-006)** reported that he and his wife had been informed that Claire had a viral infection on the evening of admission on 21 October 1996. They '*asked about other illnesses and were relieved that doctors did not think Claire was in danger from meningitis'*. As Claire was settled they both went home for the night, believing Claire had a tummy bug and would be better the next day **[WS 253/1 p5,WS 257/1 p6]** . It would appear from the chronology in this statement that the parents were not aware of the possible diagnosis and complications of status epilepticus, as they went home on 22 October believing her to have a viral infection and that the '*medication was counteracting any viral infection Claire had and was having a sedation effect*'. However, in their witness statements both parents recall being told of 'internal fitting' **[WS 253/1 p6. WS 257/1 p 7].** In his comments in the statement to the Coroner, Mr Roberts stated that it was not until December 2004 that they had any knowledge that Claire was suspected to have had a condition other than a viral infection **(091-004-007)**. Mrs Roberts has stated in her witness statement that '*Dr Sands did not inform me that Claire's condition was in any way serious*' **[WS257/1 p8].** Mr Roberts raised the question of why he and his wife had not been informed of the medical staff concerns about Claire's illness.

11.2 When a child dies, In our experience, paediatricians generally accept that their duty of care includes discussing the death with parents once post-mortem findings become available. In Claire's case, Dr Steen wrote to parents on November 18th offering a meeting once the PM results became available 'after Christmas.' **[090-004-006]**

11.3 Dr Sands noted in the case notes that he discussed Claire's death with her parents on December 11th (which was before the results were available other than the provisional anatomical summary)**.**

11.4 Dr Steen wrote to the GP on 5th March 1997, when she would have been in receipt of Dr Mirakhur's (and or Dr Herron's) report. She quoted as the cause of death encephalomyelitis/meningitis and mentioned abnormal neuronal migration as a cause of learning difficulties. She made no mention of cerebral oedema, hyponatraemia or inappropriate ADH secretion. She stated she and Dr Webb had discussed the findings with parents but is now unable to recall when that was. **[090-002-002; WS 143/1 p99]**

11.5 Dr Webb wrote to parents giving the same diagnoses but also not mentioning the other more immediate causes.

11.6 Dr Steen states she has no recollection of what she discussed with Mr & Mrs Roberts. **[WS143-1 p70]** She confirms that her autopsy request form listed cerebral oedema, status epilepticus, inappropriate ADH secretion and possible viral encephalitis. **[ibid p72]**

11.7 Mr Roberts states; …'the post-mortem report also refers to a viral infection. Subsequent meetings with Dr Steen at the Belfast Royal Hospital continued to state a viral infection. At no time was hyponatraemia or falling sodium levels defined as a cause for the fluid build-up.' **[089-012-036]**

Matters for further consideration

- Why were parents not told in detail about the presumed course of events and the severity of Claire's illness, given that by the time of Claire's death it was known that she had cerebral oedema, that shortly before her collapse she was found to have hyponatraemia and by the time of the autopsy request form being completed a few days later, inappropriate ADH secretion was given as part of the process?

- What guidance was/is available to both doctors and nurses regarding recording discussions with families at the time and now?

- What formal procedures were in place amongst the clinicians at RBHSC to review child deaths?

- Why was no clinical summary produced and entered into the case notes (apart from the summary of PICU care)?

12. Reporting of Claire's death within the Trust

12.1 Dr Steen explains why the death wasn't reported to others in the Trust. **(WS- 143-1 p74)**
"at the time of Claire's death it was felt the sequence of events leading to her death was known and there were no areas of concern around her care"

12.2 There is no evidence that there was an adverse incident reporting procedure in the Trust at the time and no witness statements to suggest that Claire's death was discussed outside the clinical area.

12.3 Claire's case was reported to the Trust's audit coordinator and Claire's case was discussed at a paediatric audit meeting on 8 November 1996. **(DLS letters 24.11.2010 and 10.01.2011).** No records of this meeting are in evidence and nurses were unaware of any review of Claire's death, suggesting this was a medical audit meeting.

12.4 Dr MacFaul **(report p 31-33),** describes his views of the responsibilities of a Clinical Director in 1996. This includes, the availability and cover of medical staff, ensuring that clinical audit is in place, investigating adverse incidents and the development and updating of guidelines and protocols

12.5 There is no evidence that the Trust undertook an investigation of Claire's death following the inquest on 4 May 2006.

Matters for further consideration

- Would it be expected that Claire's death should have been reported to more senior clinician or management in the Trust?
- Were the Clinical governance arrangements in the Trust in 1996 insufficiently developed compared to other hospitals nationally?
- What was the role of the Clinical Director and Clinical Nurse Manager at the time when investigations into care were required? What has changed today?
- Why were there no actions or learning points arising from the audit meeting on 8 November 1996? Are such meetings now multi-disciplinary and documented?

13 Actions by the Trust

13.1 The Chief Executive William McKee stated that there was no formal mechanism or requirement to report lessons learned from inquests or incident reporting prior to 2004. **(W. McKee letter to Inquiry 26 July 2005 ref: 45487).** The Trust however had developed an Adverse Incident Reporting Policy in May 2000.

13.2 Stephen Ramsden's report to the Inquiry in respect of Adam Strain, **(6 October 2011 para 40 and 43)**, suggests that although risk management was in its infancy in 1995, he would have expected a more formal approach to lessons learned by the Trust.

13.3 Dr R MacFaul in his expert report **(July 2012 para 420 p 72),** states that in the mid-1990s most hospitals had a process for reporting serious adverse events concerning children receiving care, and logging them within the organisation.

13.4 The Trust (Drs Steen, Sands, Rooney and Professor Young) met Claire's parents at their request on 7th December 2004 following the UTV documentary. Professor Young (a consultant biochemist) had been asked by the Trust's Medical Director to review Claire's medical records and *'give an opinion on whether hyponatraemia may have contributed to Claire's death'*. **[091-002-062]**. Dr Rooney appeared to coordinate the meeting and provided the response from the Trust.
Mr Roberts wrote to the Trust on 8th December detailing his continuing concerns about the treatment of Claire to which Dr Rooney responded on 12 January 2005.

13.5 Dr MacFaul states that *'...in October 2004 the review of Claire's case and the meeting with the parents was not properly conducted in that an external independent opinion was not obtained. In a meeting held with parents incorrect information was given and incomplete information provided to the Coroner'*

Matters for further consideration

- Should the Trust have undertaken an investigation into Claire's treatment and death in 1996?

- In October 2004 following the UTV programmes, why did the Trust, not consider undertaking an investigation into Claire's treatment in accordance with guidance and practice at the time?

- Following Claire's parents contact with the Trust in October 2004, did the 'review' of Claire's case in late 2004 conform to the extant procedure (complaints, adverse incidents) at the time? Was the response from the Trust to Claire's parents reasonable?

- What action did the Trust take following Claire's inquest in May 2006?

- What lessons did the Trust learn from the review of Claire's death and contact with Claire's parents? What action was taken, including any amendment to Claire's case notes or statistical coding?

14 Other Issues

14.1 Workload of the paediatric registrar.
Dr Bartholome implies she could be on call at night for as many as 120 patients (if there was100% bed occupancy). **[WS142/1 p3]** Dr MacFaul raises the question of whether the workload of Dr Bartholome was excessive. **(Report para 50)**

14.2 Hospital guidelines
Dr MacFaul raises the question of the lack of hospital guidelines in RBHSC in 1997 and whether this was unusually late for a teaching hospital. **(Report para 49)**

14.3 The death of Adam Strain
Dr Webb in his statement **[WS-138-1 p93],** was not aware of the outcome of the Inquest into the death of Adam Strain prior to 26 Oct 1996

14.4 Children with learning disabilities
While there is no evidence that the clinicians' response to Claire was any the less because of her known learning disability, we are aware that such children are sometimes subject to less concern on the part of staff than are children of normal ability. The DH guidance on Welfare of Children and Young People in Hospital[1] stated that children with disabilities are '*doubly disadvantaged*' when admitted to hospital. It recommends that hospitals provide facilities and ensure staff are able to cope with the special needs of these children.

Matters for further consideration

- Did the Trust have adequate systems to monitor staff workload to ensure safe care?
- Should the Trust have communicated the outcome of the inquest into Adam Strain and any lessons learned?
- Had the Trust implemented the DH guidance and was there an extant policy or local guidance on providing care for children with known learning disabilities?
- What training was provided to staff working with children with disabilities in hospital in 1996 and now?

15 Remaining concerns regarding the causes of death

[1] DH (1991) Welfare of Children & Young People in Hospital (p20)

15.1 It is clear that different interpretations have been ascribed to the course of events leading to Claire's death. This is an attempt to synthesise those interpretations.

15.2 Viral infection (unspecified)
The clinical presentation is consistent with an acute viral infection. The fact that no laboratory confirmation or undisputed neuropathological evidence is available in no way rules out this possible precipitating cause. Prof Neville regards it as a reasonable suggestion

15.3 Encephalopathy
This is purely a descriptive term implying some pathological process occurring within the brain and does not infer any particular cause. As such it is unarguable given that Claire had acute neurological signs and symptoms.

15.4 Encephalitis/ Meningoencephalitis
This means inflammation of brain cells and in the latter case the membranes surrounding the brain and spinal cord, generally due to a virus invading those areas and provoking an inflammatory reaction. All experts agree it was reasonable to assume this as a provisional diagnosis on admission.

15.41 Prof. Cartwright considered the clinical presentation, illness progression and blood and CSF tests consistent with an acute and fulminating encephalitis. Some support for his view came from an interpretation of post-mortem CSF findings by Dr Dewi Evans, an expert for the PSNI. Dr Mirakhur (and/or Dr Herron) stated they had seen histological evidence of a subacute low-grade encephalitis but this is gainsaid on review of the brain tissues by Prof. Harding and Dr Squier. Furthermore, in response to a question from Prof. Cartwright, Prof Harding states that an acute and fulminating encephalitis causing cerebral oedema, coning and death in the space of 3 days could not occur in the absence of neuropathological changes.

15.42 In reconsideration, Prof Cartwright notes he cannot reconcile the opinions of Prof. Harding and Dr Dewi Evans but, in view particularly of the CSF findings, he maintains his opinion that encephalitis was likely.

15.43 Dr Scott-Jupp considers it plausible that the presenting illness was viral encephalitis. Prof Neville states the 'primary diagnosis' remains unknown

15.5 Hyponatraemia

There is no doubt that Claire became hyponatraemic with a minimally low sodium on admission and a dangerously low sodium when blood was next tested after about 24 hours.

15.51 Prof. Neville is of the opinion that hyponatraemia and brain oedema were present and caused her fits during the afternoon of October 22nd. He is certain that hyponatraemia was a major contributor to cerebral oedema but is unsure of the relative contributions of her IV fluids, inappropriate secretion of antidiuretic hormone (which can occur in any acute neurological illness) and the original illness 'whatever it was'.

15.6 Non convulsive status epilepticus

Dr Sands and Dr Webb stated this as a cause of her symptoms (albeit on the background of a non-specific viral infection or viral encephalitis in a child prone to epilepsy). Prof. Neville does not consider this diagnosis was likely because it is uncommon and epilepsy was not prominent in Claire's recent history, although it was acceptable as part of a differential diagnosis. He considers this diagnosis needs to be proved by obtaining confirmatory evidence from an EEG.

15.61 Dr Scott-Jupp considers it not unreasonable for Dr Sands to have made this diagnosis but within a differential diagnosis of encephalitis, encephalopathy or drug intoxication. He agrees EEG is necessary for an unequivocal diagnosis.

15.7 Inappropriate ADH secretion

As stated above, this is recognised to be a risk in any acute neurological illness. It can also complicate non-neurological illnesses, such as pneumonia. Dr Scott-Jupp notes that it might well be the cause of the frequently observed minor falls in serum sodium with a range of acute illnesses. It causes water retention so may precipitate cerebral oedema. Hypotonic fluid infusion can contribute to the latter as the presence of ADH prevents excretion of the water infused along with sodium and glucose. As stated above, Prof Neville cannot assess the degree to which the infusion might have contributed in Claire, given the amount was not excessive. However, Prof. Neville (and Dr MacFaul) point out that in the presence of an acute neurological illness, caution is necessary and either a more concentrated solution used and/or a lesser volume and rechecking electrolytes is mandatory.

15.8 Cerebral oedema

This was the final pathway leading to coning of the brainstem and death.

16 Interested Parties

16.1 Dr O'Hare: while we are not overly critical of this doctor, who was a junior trainee at the time, we note the experts' criticisms of failure to request EEG and CT, failure to investigate the possibilities of drug intoxication or acute liver disease and to consider hyponatraemia as part of the original differential diagnosis as well as not contacting her senior for advice.

16.2 Dr Sands: Dr Scott-Jupp considers the investigations he ordered as limited (as for Dr O'Hare); both experts are critical of the diagnosis of NCSE without recourse to EEG, the failure to recheck blood chemistry the morning after admission and not considering modification of the standard IV regime in view of the risk of SIADH, although Dr Scott-Jupp is less critical than Prof. Neville and Dr MacFaul. We are concerned at his actions at 1700h on 22nd October being limited to that of phlebotomy rather than reassessing Claire's case and deciding upon referral to the duty paediatrician. We are concerned that we have seen no evidence of a detailed handover to Dr Bartholome.

16.3 Dr Webb: he accepts error in assuming the sodium result of 132 was from the morning of October 22nd rather than the night before; experts point out he was thereby not in a position to consider hyponatraemia as a possible differential diagnosis; his use of anticonvulsants in the absence of EEG confirmation of diagnosis is criticised by Prof. Neville as is failure to obtain CT scanning. It is unclear whether or not Dr Webb contributed wittingly to any confusion about consultant responsibility. We are concerned about his failure to identify the drug error made by Dr Stevenson with regard to phenytoin for the reasons given in our report and, therefore, possible to prevent the further error with midazolam.

It is unclear what handover arrangements he made when leaving the hospital in the evening of October 22nd. Experts are concerned about the information provided to parents, before and after death, the documentation of the notification of death, the suggestion to parents that referral to the Coroner was not needed and the recommendation for a partial PM.

16.4 Dr Steen: Experts are critical of her failure to be involved in Claire's management before she attended at 0300h, shortly before admission to ICU, despite being the consultant responsible for her care. It is not clear why she did not conduct the ward round on the morning of October 22nd See comment in Para 4.3 or otherwise assist Dr Sands, who was relatively inexperienced as a paediatric registrar. The evidence from the case records suggests Dr Steen had primary responsibility for Claire throughout her stay, except for the period on PICU, when Dr McKaigue was presumably the primary consultant. We can find no evidence that she sought to make sure the medical and nursing staff understood whether it was she or Dr Webb who was the primary consultant. She is criticised by the experts in relation to information provided to parents, the information she stated on the notification of death, the decision not to refer to the Coroner and the suggestion for a partial PM. There is also a failure to deal with Dr Stevenson's drug dosage errors (see below) by appropriate remedial teaching.

16.5 Dr Bartholome: We are concerned that her role appeared to be 'fire-fighting' in that there is no evidence she took steps to assess Claire when she took over supervision at about 5.30 pm. Furthermore, Dr Scott-Jupp considers that she should have attended Claire when contacted by Dr Stewart with the very low sodium result at 11.30 pm and involved Dr Steen at this time. Prof Neville and Dr MacFaul are critical of what they consider is her lack of competent action at that time, albeit it might have been too late to change the outcome.

16.6 Dr Hughes: Nurse McCann noted that a doctor was informed about Claire's presumed fit at 9 pm on October 22nd and should have attended. There is no evidence that a doctor attended. Dr Hughes was on duty at that time so might have been the person contacted.

16.7 Dr Stevenson, because of concerns about the dose calculation error with phenytoin and the possible ten-fold error with midazolam.

16.8 Dr Mirakhur: she offered histological diagnoses of subacute low-grade encephalitis and a neuronal migratory defect. If Prof Harding and Dr Squier are correct, that neither of these were present, then her diagnoses misled Drs Webb and Steen and resulted in false information being transmitted to the family.

16.9 Dr Herron: we note that Dr Mirakhur claims the report of the above findings represented a joint conclusion with Dr Herron. If this is correct then the criticism voiced above is also attributable to him.

16.10 Staff Nurse Jackson, for failure to undertake regular observation of vital signs whilst Claire was in A&E. However, this had no impact on outcome.

16.11 Staff Nurse McRandal for not initiating frequent observation of some vital signs during the night of admission. In addition, she did not establish accurate fluid balance monitoring or record a ward based urine test.

16.12 Staff Nurse Field did not amend the care plan following the ward round by Dr Sands to reflect the changes in potential diagnosis and required changes in nursing care. In addition, she failed to recognise the severity of Claire's illness and ensure parents were informed.

16.13 Staff Nurse McCann for failing to recognise how unwell Claire was and escalate this information to more senior colleagues and for failing to amend Claire's care plan to reflect care provided.

16.14 Sister Pollock or her deputy, who were responsible for overseeing nursing care on the ward and ensuring an appropriate level of nursing care and observation.

16.15 The Director of Nursing at the time, in relation to the provision and availability of policies/guidance on measuring and recording fluid balance, other record-keeping, use of Care Plans, when to involve medical staff and management of untoward incidents.

16.16 The Medical Director/Clinical Director of Paediatrics/Clinical Director of Radiology/Clinical Director of Neurosciences (or their equivalents) at the time in relation to policies on consultant responsibilities and handover arrangements, availability of urgent CT and EEG respectively.

16.17 The Clinical Nurse Manager in relation to policies for monitoring and recording patient records and polices regarding investigations of serious incidents/unexpected deaths.

16.18 The Medical Director and CEO in their response to Mr & Mrs Roberts' concerns in 2004.

Gren Kershaw
Harvey Marcovitch
Carol Williams