BRIEF FOR CORONER

Introduction

1. Adam Strain, Claire Roberts, Raychel Ferguson and Conor Mitchell are four children who are the subject of a public inquiry being conducted by John O'Hara QC in Northern Ireland

2. All four children died in hospital and irrespective of where they were initially admitted, they were all ultimately admitted to the Royal Belfast Hospital for Sick Children ("the Royal"), which is Northern Ireland's leading teaching hospital. Briefly their details are:

   (1) Adam Strain was born on 4th August 1991 with cystic, dysplastic kidneys with associated problems with the drainage of his kidneys related to obstruction and vesico ureteric reflux. He was referred to the Royal from the Ulster Hospital in Dundonald. He died on 28th November 1995 in the Royal following kidney transplant surgery on 27th November 1995 from which he never recovered consciousness.

   The Inquest into his death was conducted on 18th and 21st June 1996 by John Leckey the Coroner for Greater Belfast, who engaged as experts: (i) Dr. Edward Sumner Consultant Paediatric Anaesthetist at Great Ormond Street Hospital for Sick Children ("Great Ormond Street"); (ii) Dr. John Alexander Consultant Anaesthetist at Belfast City Hospital; and (iii) Professor Peter Berry of the Department of Paediatric Pathology in St. Michael's Hospital, Bristol. The Inquest Verdict identified Cerebral Oedema as the cause of his death with Dilutional Hyponatraemia as a contributory factor (011-016-114). [Tab 1[1]]

   (2) Claire Roberts was born on 10th January 1987. She was admitted to the Royal on 21st October 1996 with a history of malaise, vomiting and drowsiness and she died on 23rd October 1996. Her medical certificate recorded the cause of her death as Cerebral Oedema and Status Epilepticus. That certification was subsequently challenged after a television documentary into the deaths of Adam and two other children (Lucy Crawford and Raychel Ferguson).

   The Inquest into Claire's death was carried out by John Leckey on 4th May 2006 who engaged as experts Dr. Robert Bingham (Consultant Paediatric Anaesthetist at Great Ormond Street) and Dr. Ian Maconochie (Consultant in Paediatric A&E Medicine at St Mary's, London). The Inquest Verdict

[1] The tabbed documents are provided in the accompanying Core Files

found the cause of Claire's death to be Cerebral Oedema with Hyponatraemia as a contributory factor.

(3) Raychel Ferguson was born on 4th February 1992. She was admitted to the Altnagelvin Area Hospital on 7th June 2001 with suspected appendicitis. An appendectomy was performed on 8th June 2001. She was transferred to the Royal on 9th June 2001 where brain stem tests were shown to be negative and she was pronounced dead on 10th June 2001. The Autopsy Report dated 11th June 2001 concluded that the cause of her death was Cerebral Oedema caused by Hyponatraemia.

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

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

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

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

after the Inquest Verdict. In that correspondence, Dr. Sumner described the fluid management regime as 'sub-optimal'.

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

3. The impetus for this Inquiry was a UTV Live Insight documentary 'When Hospitals Kill' shown on 21st October 2004.[2] The documentary primarily focused on the death of a toddler called Lucy Crawford (who was subsequently also found to have died in hospital in 2000 because of hyponatraemia) and what was presented as significant shortcomings of personnel at the Erne Hospital. She was transferred to the Royal on 13th April 200 where brain stem tests were shown to be negative and she was pronounced dead on 14th April 2001.

4. In effect, the programme alleged a cover-up and it criticised the hospital, the Trust and the Chief Medical Officer. The programme also referred to the deaths of Adam and Raychel in which hyponatraemia had similarly played a part. At that time, no connection had been made with the deaths of Claire and Conor.

Original Terms of Reference

5. The Inquiry was established under the Health and Personal Social Services (Northern Ireland) Order 1972, by virtue of the powers conferred on the Department by Article 54 and Schedule 8 and it continues pursuant to the Inquiries Act 2005.

6. The original Terms of Reference for the Inquiry as published by Angela Smith (then Minister with responsibility for the Department of Health, Social Services and Public Safety) on 1st November 2004 were to:

> To hold an Inquiry into the events surrounding and following the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson, with particular reference to:
>
> i. The care and treatment of Adam Strain, Lucy Crawford and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
> ii. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson.
> iii. The communications with, and explanations given to, the respective families and others by the relevant authorities.
>
> In addition, Mr O'Hara will:
>
> (a) Report by 1 June 2005 or such other date as may be agreed with the Department, on the areas specifically identified above and, at his discretion, examine and report on any other relevant matters which arise in connection with the Inquiry.

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2 See DVD of the programme with the accompanying Core Files

(b) Make such recommendations to the Department of Health, Social Services and Public Safety as he considers necessary and appropriate.

Changes

7. There have been a number of significant changes in the Inquiry since 2005. Firstly there was the receipt of Revised Terms of Reference from the Minister following the wish of the Crawford family to have Lucy excluded from the Inquiry's work:

1. The care and treatment of Adam Strain and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.

2. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain and Raychel Ferguson.

3. The communications with and explanations given to the respective families and others by the relevant authorities.

In addition, Mr O'Hara will:

(a) Report by 1 June 2005 or such date as may be agreed with the Department, on the areas specifically identified above and, at his discretion, examine and report on any other matters which arise in connection with the Inquiry.

(b) Make such recommendations to the Department of Health, Social services and Public Safety as he considers necessary and appropriate.

8. Secondly, Claire Roberts and Conor Mitchell were included into the Inquiry's work by the Chairman due to the cause of Claire's death and the apparent fluid mismanagement in Conor's case so soon after the implementation of Guidelines on Hyponatraemia which stressed the importance of fluid management.

9. The effect of the Revised Terms of Reference has been to exclude all explicit references to Lucy Crawford. The Chairman has interpreted the Revised Terms of Reference insofar as Lucy is concerned in the following way:

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

10. The case of Claire Roberts is being investigated according to precisely the same terms as those of Adam Strain and Raychel Ferguson. The investigation of Conor will address more limited issues in view of the fact that hyponatraemia

was not thought to be a cause of his death (if anything he developed hypernatraemia). Similarly, the fluid mismanagement referred to by Dr. Sumner was not considered to have been a cause of his death. The Chairman has stated:

> It is obviously a matter of concern if guidelines which have been introduced as a result of a previous death or deaths and which are aimed at avoiding similar events in the future, are not properly communicated to hospital staff and followed. It is relevant to the investigation to be conducted by the Inquiry whether and to what extent the guidelines had been disseminated and followed in the period since they were published. Another matter of interest is whether the fact that Connor was being treated on an adult ward rather than a children's ward made any difference to the way in which it appears that the guidelines may not have been followed.
>
> Accordingly, the Inquiry will investigate the way in which the guidelines had been circulated by the Department, the way in which they had been made known to hospital staff and the steps, if any, which had been taken to ensure that they were being followed. While this is an issue of general importance, it will be informed by an examination of the way in which the guidelines had been introduced and followed in Craigavon Area Hospital by May 2003.

Background

11. The law and practice involving Coroners in Northern Ireland is governed by the Coroners Act (Northern Ireland) 1959 (as amended) and the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963 (as amended). The current Coroner for Northern Ireland is Mr John Leckey, who conducted the Inquests into the deaths of all four children (together with the death of Lucy).

12. In terms of the reporting of deaths to the Coroner by medical practitioners, the relevant law is section 7 of the 1959 Act:

> Every medical practitioner, registrar of deaths or funeral undertaker and every occupier of a house or mobile dwelling and every person in charge of any institution or premises in which a deceased person was residing, who has reason to believe that the deceased person died, either directly or indirectly, as a result of violence or misadventure or by unfair means, or as a result of negligence or misconduct or malpractice on the part of others, or from any cause other than natural illness or disease for which he had been seen and treated by a registered medical practitioner within twenty-eight days prior to his death, or in such circumstances as may require investigation (including death as the result of the administration of an anaesthetic), shall immediately notify the coroner within whose district the body of such deceased person is of the facts and circumstances relating to the death.

13. A 'Memorandum of Understanding' entitled "*Investigating patient or client safety incident (Unexpected death or serious untoward harm)*" was produced by the Department of Health, Social Services and Public Safety, the Police Service of Northern Ireland, the Coroners Service and the Health and Safety Executive for Northern Ireland in February 2006. In Appendix 1, there is a section on 'Reporting Deaths to the Coroner', which repeats section 7 above, and adds an explanation of its implications:

"In essence this means a requirement to report:

- All deaths from unnatural causes. ***It is the underlying cause that determines the need to report rather than the terminal event eg bronchopneumonia due to immobilisation due to a fractured neck of femur.*** For example, homicidal deaths; deaths following assault, road traffic accidents or accidents at work; deaths associated with the misuse of drugs (whether accidental or deliberate); any apparently suicidal death; deaths from the effects of hypothermia or where a medical mishap is alleged ***should always be reported.***

- Any death from natural illness or disease if the deceased has not been seen and treated by a medical practitioner within 28 days of death.

- All deaths from industrial diseases e.g. asbestosis. (It is advisable to ascertain the deceased's employment history before writing a death certificate as a means of ruling out any possible industrial link – a medical history of chest disease or mesothelioma in someone who had been employed *at any time* as a shipyard worker would raise the possibility of asbestos exposure.)

- All deaths on the operating table or under an anaesthetic. *NB There is no statutory requirement to report a death occurring within 24 hours of admission to hospital or of an operation – though it may be prudent to do so.* (Deaths which follow an operation necessitated by trauma should be reported to the coroner, but deaths which follow an operation necessitated by a natural illness need not be reported unless death took place before recovery from the anaesthetic.)

- The death of a patient or client who had an accident in the health or social care environment (e.g. a fall in the ward).

- The death of a patient or client where there is an allegation of negligence or of a medical or nursing mishap.

- The death of a patient in the course of, or following, any clinical procedure even where the possibility of death occurring was a recognised risk of the procedure."

14. The power of the Coroner to report is contained in Rule 23(2) of the 1963 Rules:

> "A coroner who believes that action should be taken to prevent the occurrence of fatalities similar to that in respect of which the inquest is being held, may announce at the inquest that he is reporting the matter to the person or authority who may have power to take such action and report the matter accordingly."

15. With regard to his power to report under Rule 23(2), the Coroner has stated in a letter to the Inquiry dated 26th October 2010 (Ref: INQ-0224-10) [Tab 2]:

> My understanding is that the Chief Medical Officer and Health Trusts would have a power but not a duty to disseminate information on the outcomes of inquests and lessons to be learnt. You will note that the provisions of Rule 23(2) empower a Coroner to make a report to the person or authority who may have power to take action to prevent a recurrence of similar fatalities, but the Coroner does not have any power to require that appropriate action is taken.

16. Rule 23(2) is equivalent to Rule 43 of the Coroners Rules 1984 in England & Wales prior to its amendment by the Coroners (Amendment) Rules 2008. Since

17th July 2008, Rule 43 in England & Wales now reads (with Rules 43A and 43B now added):

Prevention of future deaths

43.(1) Where—

(a) a coroner is holding an inquest into a person's death;

(b) the evidence gives rise to a concern that circumstances creating a risk of other deaths will occur, or will continue to exist, in the future; and

(c) in the coroner's opinion, action should be taken to prevent the occurrence or continuation of such circumstances, or to eliminate or reduce the risk of death created by such circumstances,

the coroner may report the circumstances to a person who the coroner believes may have power to take such action.

(2) A report under paragraph (1) may not be made until all the evidence has been heard except where a coroner, having adjourned an inquest under section 16 or 17A of the 1988 Act, does not resume it.

(3) A coroner who intends to make a report under paragraph (1) must announce this intention before the end of the inquest, but failure to do so will not prevent a report being made.

(4) The coroner making the report under paragraph (1)—

(a) must send a copy of the report to—

(i) the Lord Chancellor; and

(ii) any person who has been served with a notice under rule 19; and

(b) may send a copy of the report to any person who the coroner believes may find it useful or of interest.

(5) On receipt of a report under paragraph (4)(a)(i), the Lord Chancellor may—

(a) publish a copy of the report, or a summary of it, in such manner as the Lord Chancellor thinks fit; and

(b) send a copy of the report to any person who the Lord Chancellor believes may find it useful or of interest (other than a person who has been sent a copy of the report under paragraph (4)(b)).

Response to report under rule 43

43A. (1) A person to whom a coroner sends a report under rule 43(1) must give the coroner a written response to the report containing—

(a) details of any action that has been taken or which it is proposed will be taken whether in response to the report or otherwise; or

(b) an explanation as to why no action is proposed

within the period of 56 days beginning with the day on which the report is sent.

(2) On receipt of a response under paragraph (1), the coroner—

(a) must send a copy of the response to—

(i) the Lord Chancellor; and

(ii) except where paragraph (6) applies, any person who has been served with a notice under rule 19; and

(b) except where paragraph (6) applies, may send a copy of the response to any person who the coroner believes may find it useful or of interest.

(3) Except where paragraph (6) applies, on receipt of a response under paragraph (2)(a)(i), the Lord Chancellor may—

(a) publish a copy of the response, or a summary of it, in such manner as the Lord Chancellor thinks fit; and

(b) send a copy of the response to any person who the Lord Chancellor believes may find it useful or of interest (other than a person who has been sent a copy of the report under paragraph (2)(b)).

(4) A person giving a response under paragraph (1) may make written representations to the coroner about—

(a) the release, under paragraphs (2)(a)(ii) or (b) or (3)(b), of a copy of the response; or

(b) the publication, under paragraph (3)(a), of the response.

(5) Representations under paragraph (4) must be made to the coroner no later than the time when the response is given under paragraph (1).

(6) On receipt of representations under paragraph (4), the coroner may decide that the response should not—

(a) be released in full under paragraphs (2)(a)(ii) or (b) or (3)(b); or

(b) be published in full under paragraph (3)(a).

(7) If paragraph (6) applies—

(a) the coroner must prepare a summary of the response; and

(b) paragraphs (2) and (3) apply to the summary of the response prepared by the coroner as they apply to the response received under paragraph (1).

Extension of time

43B. A coroner may extend the period of 56 days mentioned in rule 43A(1) (even if an application for extension is made after the time for compliance has expired).".

Dissemination of lessons learned by the Royal

17. The procedure in place within the Royal Group of Hospitals to ensure that lessons and information learned from inquests attended by Trusts employees were/are disseminated within the Trust Hospitals was as follows (Ref: IWS 061/1, p.2)

(1) Prior to April 1993 all Unit General Managers were required to put in place appropriate reporting mechanisms to ensure that the Eastern Health and Social Services Board Board (EHSSB) received prompt notification of any 'untoward incidents'.

(2) Until 1999, the Director of Medical Administration was required to ensure the internal dissemination of lessons learnt from inquests and that appropriate action was identified to address any vulnerabilities identified.

(3) From January 1999 dissemination of lessons learnt from inquests have been the responsibility of the Associate Medical Director, both internally within the organisation and on occasion when wider issues were identified to the DHSSPS via the Chief Medical Officer.

The Royal adverse incident reporting and investigation arrangements were revised in 2000 and more recently with the introduction of the methodology of Root Cause Analysis in 2002 and the incorporation of this into the revised Investigation Policy and Procedure .

(4) Prior to July 2004 within Northern Ireland there was no formal mechanism or requirement to report lessons learnt from inquests or incident reporting to the wider Health Service within Northern Ireland or the United Kingdom. There was no mandatory requirement or formal mechanism for Trusts to report the death of patients to the DHSSPS unless there was concern that clinical practice or performance was impaired and likely to result in disciplinary action or referral to the General Medical Council or Nursing and Midwifery Council.

(5) In July 2004, the DHSSPS issued *"Reporting and Follow up on Serious Adverse Incidents - Interim Guidance"* (HSS (PPM) 06/04). Included in Annex A of the Guidance is a list of examples of serious adverse incidents. These include cases involving court proceedings, *"including Coroner's Inquests"*. The guidance states that serious adverse incidents

"should be reported immediately to the senior manager with responsibility for the reporting and management of adverse incidents within the organisation. If the senior manager considers that the incident is likely to:

- be serious enough to warrant regional action to improve safety or care within the broader HPSS;
- be of public concern;
- or require an independent review,

he/she should provide the Department with a brief report [...] within 72 hours of the incident.

The Department:

- will collate information on incidents reported to it through this mechanism and provide relevant analysis to the HPSS;
- may also, where appropriate, seek feedback from the relevant organisation on the outcome of the incident to determine whether regional guidance is needed;
- may, in independent reviews, provide guidance in relation to determining specialist input into such reviews."

18. The relevant facts and circumstances in relation to Adam, Claire, Lucy, Raychel and Conor are set out below. Whilst the circumstances of Lucy's death are no longer the subject of this Inquiry, the 'aftermath' and its implications for Raychel, are matters to be investigated as part of the Inquiry's work.

Adam Strain

19. Adam Strain died on 28th November 1995 and Dr Maurice Savage reported his death to the Coroner (Ref: 011-025-125). [Tab 3] Dr Alison Armour (State Pathologist's Department) carried out a post-mortem examination on 29th November 1995 in the instructions of the Coroner (Ref: 011-010-034). [Tab 4]

20. The Inquest Verdict dated 21st June 1996 identified Cerebral Oedema as the cause of his death with Dilutional Hyponatraemia as a contributory factor (Ref: 011-016-114). [Tab 5]

21. The Coroner expressed concern that the result of Adam's Inquest indicated a lack of awareness within the Royal of the importance of correct fluid management and its significance in avoiding hyponatraemia and cerebral oedema. He has since stated that he was under the impression that after the Inquest, lessons would be learned which would be suitably communicated:

> My understanding was that so far as the [Royal] was concerned, the hospital would 'learn' from what happened to Adam." He further stated, "[t]here was discussion at the inquest as to how the views of Dr Sumner could be disseminated amongst the medical profession in Northern Ireland. The consensus was that there was no effective means of doing so other than through the medical literature. (Ref: IWS 091, p.2) [Tab 6]

22. In relation to the role of the Chief Medical Officer, the Coroner stated that, "*I cannot recall anyone (myself included) querying whether the Chief Medical Officer had any "educational" role. The position then and now [in 2005] is that there is no formal interface between coroners and Chief Medical Officers.*" (Ref: IWS 091, p.2) [Tab 6]

23. Overall, the Coroner stated that, "*I had assumed that the [Royal] would have circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some "best practice" guidelines. Children are not always treated in a paediatric unit and, in the event of surgery, the anaesthetist may not be a paediatric anaesthetist*" (Ref: IWS 091, p.3) [Tab 6]

24. At the time of the Inquest, the Royal produced a draft statement (Ref: 011-014-107a) [Tab 7], which states:

> ... that in future all patients undergoing major paediatric surgery who have a potential for electrolyte imbalance will be carefully monitored according to their clinical needs ... intensive monitoring of their electrolyte values will be undertaken. Furthermore, **the now known complications of hyponatraemia** in some of these cases will continue to be assessed in each patient, and all anaesthetic staff will be made aware of these particular phenomena and advised to act properly. (Emphasis added)

25. It is not clear to whom (if anyone) those guidelines were circulated and if they were circulated the criteria for their dissemination.

26. After the Inquest, the Royal modified its paediatric renal transplant guidelines and issued recommendations on anaesthetic record keeping in December 1996. (IWS 061/1, p.2) (Tab 8) However, the dissemination of this material was limited to paediatric anaesthetists within the Royal as it was felt by those involved that *"[t]he development of hyponatraemia around Adam Strain's surgery was unique and not something which would be encountered by the non paediatric anaesthetists."* (Ref: IWS 013/1, p.2) (Tab 9)

27. There was no further contact between the Coroner and the Royal regarding hyponatraemia and lessons learned from Adam's death until after the death of Raychel Ferguson in June 2001.

Claire Roberts

28. In the interim, Claire Roberts died at the Royal on 23rd October 1996. The Case Note Discharge Summary completed on Claire's death gives the principal diagnosis as *"Cerebral Oedema"* with other diagnoses being *"Status Epilepticus"* and *"Hyponatraemia"* (Ref: 090-009-011). [Tab 10] The death certificate was issued within a few hours of Claire's death and records *"(1) cerebral oedema (2) status epilepticus"* (Ref: 090-022-061). [Tab 11] A hospital post-mortem was arranged for the next morning (Ref: 090-027-085). [Tab 12] The post-mortem was limited to the brain only and was performed by Dr Herron (Pathologist, Department of Neuropathology, Institute of Pathology in Belfast). The limited autopsy report was made available on 11th February 1997 (Ref: 090-003-003). [Tab 13] The findings were then discussed with Claire's parents, both in person (Ref: 090-002-002) [Tab 14] and in writing (Ref: 089-001-001). [Tab 15] **It is not clear whether the death was reported to the Coroner.**

29. Between 21st March 1997 and the broadcast of the UTV Live Insight documentary 'When Hospitals Kill' on 21st October 2004, there was no communication from the Royal to Claire's parents regarding their daughter's death. The UTV programme led Claire's parents to contact the Royal expressing concerns over her death. Dr. Michael McBride (Medical Director at the Royal) asked Professor Young (Professor of Medicine, Queen's University Belfast) to carry out a review of Claire's medical notes. Professor Young informed him that hyponatraemia may have contributed to the development of Claire's Cerebral Oedema and he advised that it would be appropriate to consider discussing the case with the Coroner.

30. Subsequently on 8th December 2004 the Claire's parents made a request to the Royal to have their daughter's case referred to the Coroner (Ref: 089-003-007), [Tab 16] which the Royal did on 16th December 2004 (Ref: 089-004-008). [Tab 17]

31. Mr Roberts made the Inquiry aware of Claire's death by a letter dated 17th January 2005 (Ref: 089-007-016). [Tab 18]

32. The Inquest into Claire's death was carried out by the Coroner on 4th May 2006. The Inquest Verdict found the cause of Claire's death to be Cerebral Oedema with Hyponatraemia as a contributory factor.

Lucy Crawford

33. Lucy Crawford was transferred to the Royal on 13th April 2000 from the Erne Hospital. She was certified dead at the Royal on 14th April 2000 at 1.15 pm. On the morning of 14th April, Dr Donnacha Hanrahan (Consultant in Paediatric Neurology, Royal) contacted Dr Michael Curtis, a Pathologist on behalf of the Coroner's Office, and discussed Lucy's case with him. As a result of that discussion, the Coroner's Office advised that a Coroner's post mortem was not required but that a hospital post mortem would help to establish the cause of death. Mr and Mrs Crawford consented to that post mortem. Mr Stanley Millar (Chief Officer, Western Health and Social Services Council) subsequently stated in a letter to the Coroner dated 27th February 2003 that *"I also contacted the Coroner's Service to ask about the arrangement of an Inquest but was told it was not necessary"* (Ref: 013-056-320). [Tab 19]

34. Dr Hanrahan certified Lucy's cause of death as being Cerebral Oedema due to dehydration and gastroenteritis, which cause was entered on her death certificate dated 4th May 2000 and signed by Dr D O'Donoghue of the Paediatric Intensive Care Unit at the Royal (Post-mortem report Ref: 036a-052-115). [Tab 20]

35. Prior to the pronouncement of Lucy's death at the Royal, Dr Jim Kelly (Medical Director, Erne Hospital) advised Mr Hugh Mills (Chief Executive of the Trust) of an 'adverse incident' regarding Lucy at 9am on Friday 14th April 2000 (Ref: 030-010-017). [Tab 21] Mr Mills was advised that there could be a situation where the wrong drug or the incorrect level of fluids had been prescribed (Ref: 030-010-017). [Tab 21]

36. An investigation into Lucy's 'untoward death' was instituted by Dr Kelly to be carried out by Mr Eugene Fee (Director of Acute Hospital Services, Sperrin).

37. Mr Fee wrote to Dr Quinn (Consultant Paediatrician, Altnagelvin Hospital) on 21st April 2000 seeking his opinion on certain aspects of Lucy's care (including fluid management) so as to assist in the internal review of her case (Ref: 075-013-050). [Tab 22] The Erne Hospital and Altnagelvin Hospital were in separate Trusts but were both within the Western Health and Social Services Board (as it then was).

38. The internal review into Lucy's case was conducted jointly by Mr Fee and Dr Anderson (Clinical Director of Women and Children's Services), with input from Dr. Kelly and *"external assistance and advice"* from Dr Quinn (Ref: 075-013-055). [Tab 23]

39. The opinion obtained from Dr Quinn is dated 22nd June 2000 (Ref: 075-013-051), [Tab 23] which appears to have been relied upon in the review. It is recorded in the report of that review as:

> Dr Quinn is of the view that the intravenous solution used and the total volume of fluid intake when spread over the 7½-hour period would be within the accepted range and has expressed his surprise if those volumes of fluid could have produced gross cerebral oedema causing coning. (Ref: 075-013-057) [Tab 23]

40. That report is dated 31st July 2000 and it concluded that there had been poor record keeping and communication difficulties (Ref: 075-013-055). [Tab 23] It did not conclude that Lucy received either the wrong fluid and/or too much fluid.

41. The Crawford family were dissatisfied with Lucy's treatment and unconvinced by the explanation given to them for her death. They lodged an official complaint on 22nd September 2000 (Ref: 015-014-114) [Tab 24] and a letter of claim dated 27th April 2001 for negligence against the Trust was sent on their behalf (Ref: 033-017-032).[3] [Tab 25]

42. Following the Inquest into Raychel Ferguson's death, which took place on 5th February 2003, Mr Stanley Millar (Chief Executive, Western Health and Social Services Council and who had assisted Lucy's parents) received a briefing on the events leading up to Raychel's death along with other members of the Council. He identified similarities between Lucy's death and that of Raychel and on 27th February 2003 (Ref: 013-056-320) [Tab 26] he wrote to the Coroner to raise two principal issues:

    (1) Whether there were direct parallels between the deaths of Lucy Crawford and Raychel Ferguson, and
    (2) Whether an Inquest into Lucy Crawford's death in 2000/2001 would have led to the recommendations from the Raychel Ferguson Inquest being shared at an earlier date, with the consequence that Raychel Ferguson's life may have been saved.

43. By letter of 25th April 2003 (Ref: 013-056c-325), [Tab 27] the Coroner advised Mr Millar that he had decided an Inquest should be held into Lucy's death. That Inquest was from 17th February to 19th February 2004. It concluded with a finding that the actual cause of death, as opposed to the cause certified by Dr Hanrahan in April/May 2003 was (Ref: 013-034-130) [Tab 28]:

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[3] Claims were also made by Adam's mother, Raychel's parents and Conor's mother.

(1) (a) Cerebral oedema
(b) Acute dilutional hyponatraemia
(c) Excess dilute fluid
(2) Gastroenteritis

44. At the conclusion of the Inquest, the Coroner announced that he would be reporting the circumstances of Lucy's death to the Chief Medical Officer for Northern Ireland, Dr Henrietta Campbell, and the General Medical Council. On 23rd February 2004, he wrote to the Fitness to Practice Directorate of the General Medical Council expressing very serious concerns about the quality of the medical care that Lucy had received from two of her doctors at the Erne Hospital. (Ref: 013-037-142) [Tab 29]

45. On 19th February 2004, the Coroner wrote to the Medical Director of Altnagelvin Area Hospital (Ref: 013-041-165). [Tab 30] He enclosed the expert reports from the Inquest. He also enclosed a copy of correspondence which the Crawford family had received from Sperrin Lakeland Trust to the effect that an independent review of the circumstances of Lucy's death did not suggest that the care provided to her was inadequate or of poor quality. Mr Leckey stated that if the review had been carried out by Dr Quinn and that statement about Lucy's care accurately reflected his views, then he believed that Dr Quinn should re-consider them in the light of the evidence at Raychel's Inquest in February 2003, including that of the three experts. Mr Leckey highlighted in particular the evidence given by Dr Auterson (Consultant Anaesthetist, Erne Hospital): *"the wrong fluid was given, too much of it was given and the rate of infusion should have been regulated, Lucy's care was not up to standard"*.

46. Mr Leckey continued by stating that he had not seen Dr Quinn's report and that it was possible that the letter from Mr Mills to Mr Crawford did not summarise Dr Quinn's views adequately. However, he said:

> I strongly believe that Dr Quinn and Altnagelvin Hospital (because of the death of Raychel Ferguson) should consider afresh the issues of fluid management of children in the light of the three enclosed reports. (Ref: 013-041-166) [Tab 30]

47. That letter was copied by Mr Leckey to Dr Henrietta Campbell, the Chief Medical Officer with a covering letter also dated 19th February 2004 (Ref: 013-046a-214) [Tab 32] stating that:

> My concern is that Dr Quinn may hold views as to the appropriate fluid management for children, which are at odds with "best practice". Accordingly, I am asking you to consider making inquiries with the Medical Director of Altnagelvin Hospital to obtain clarification of what views were contained in the report and the basis on which they were reached.

48. On 23rd February 2004 Mr Leckey wrote in more detail to Dr Campbell (Ref: 013-046-216) (Tab 31) advising her of the outcome of the Inquest and suggesting that

while the 'protocol' ('*Guidance on the Prevention of Hyponatraemia in Children*', March 2002, DHSSPS), which had already been issued had not been criticised at the Inquest and had in fact been praised, there may be merit in the Working Party examining the Inquest papers in relation to Lucy's death to see if any changes to the protocol might be required. Mr Leckey added:

> In addition, the evidence at the inquest highlighted serious shortcomings in medical record keeping and the understanding of the nurses as to the fluid regime that had been prescribed. Is it the responsibility of the medical director of a hospital to ensure that proper standards of medical record keeping are maintained? Is there any monitoring of the standard of medical record keeping? Are nurses now briefed on a regular basis as to the implications of the protocol? I pose these questions as they relate to issues which really do concern me.

49. In yet another letter to Dr Campbell dated 22nd March 2004 (Ref: 013-046b-218 – 220) [Tab 33] Mr Leckey raised a series of issues which arose in part from an interview which Dr Campbell had given to BBC Northern Ireland and commented on the reporting of hospital deaths and the 'interface' between her department and Coroners:

> All hospital deaths are now referred to ACC Sam Kincaid [Assistant Chief Constable, Crime Operations PSNI] who will appoint an investigating officer and that officer will arrange for the medical staff to be interviewed and statements taken ...
> On request I will provide you with a list of all hospital deaths in my district which are currently under investigation ...
> As you know the Government is at present considering which of the recommendations of the Fundamental Review and the Shipman Inquiry should be implemented. Recently, I drafted a protocol concerning the reporting of hospital deaths to my office. Therefore, there may be merit in developing a protocol addressing what the interface should be between your Department and coroners. Although I have always valued my dialogue with you and your colleagues, I suspect there is little or no dialogue between other coroners in Northern Ireland and your Department

50. In the course of that letter, he referred to the Home Office's Position Paper (Reforming the Coroner and Death Certification Service, A Position Paper, March 2004, Home Office) [Tab 34] and two recommendations for the appointment of a Medical Examiner and a Medical Adviser to the Chief Coroner and expressed concerns about whether such appointments would *"solve the sort of problems that arose in relation to the death of Lucy"*. He referred to the specialist medical issues that may arise and that the Consultant Surgeon in charge of Raychel Ferguson at Altnagelvin had said in evidence at her Inquest *"that he had never heard of hyponatraemia"*. He concluded by seeking her views on *"the way forward"*.

51. By letter dated 11th March 2004 (Ref: 013-041c-169), [Tab 35] Dr Nesbitt in Altnagelvin replied to Mr Leckey, advising him that:

> I met with Dr Quinn to discuss the issues identified in your letter of 19 February 2004. He has advised that his only involvement was to review the hospital notes and provide comment to assist the Sperrin Lakeland Trust in their review of the case. Dr Quinn advised

> that his case note review should not be used in any complaints procedure as he felt that an independent paediatric review would be more appropriate. ...
>
> In conclusion, I wish to stress that Dr Quinn did not carry out a review of the case, his comments were provided to Sperrin Lakeland to assist them in undertaking their review. The death of this child occurred one year prior to the tragic episode of Raychel Ferguson in Altnagelvin. It is unfortunate that the earlier death was not brought to our attention in order to cause the alert throughout Northern Ireland, which regrettably only occurred following Raychel's death.

52. On 19th March 2004, Mr Mills wrote to Mr and Mrs Crawford on behalf of Sperrin Lakeland Trust expressing *"our regret and apologies for the failings in our service at the time of Lucy's death in April 2000"* (Ref: 030-058-080). [Tab 36] He continued:

> These failings, not fully identified in our original review, became evident later in the process following another reported death in Northern Ireland. At that time we sought, through your legal representatives, to reach settlement under legal proceedings. We cannot presume to lessen the grief of your loss. However, please be assured that the procedures linked to Lucy's death were reviewed and changed. Furthermore, we fully intend to formally reflect on the findings of the Coroner to ensure that we, and others, learn the lessons of Lucy's tragic death.

Raychel Ferguson

53. Raychel Ferguson died on 10th June 2001, having been transferred from Altnagelvin Area Hospital. A post-mortem was ordered by the Coroner, which, was performed by Dr Herron, as in the case of Claire. The Autopsy Report dated 11th June 2001 concluded that the cause of her death was Cerebral Oedema caused by Hyponatraemia (Ref: 012-047-219). [Tab 37]

54. The Chief Medical Officer was informed of the circumstances of Raychel Ferguson's death by a telephone call on 22nd June 2001 from Dr Raymond Fulton (Medical Director, Altnagelvin Health and Social Services Trust at the time of Raychel's death). The Chief Medical Officer suggested that CREST (Regional Guidelines Group) could set up regional guidelines for publicising the dangers of hyponatraemia when using low saline solutions in surgical children (Ref: 012-039-180). [Tab 38]

55. On 1st May 2002, Dr Nesbitt (then Medical Director of Altnagelvin Health and Social Services Trust), wrote to the Chief Medical Officer enquiring if the death of a child some years previously from hyponatraemia in the Royal had been reported to the Department (it is assumed that this was a reference to the death of Adam Strain). Dr Nesbitt had become aware of the Royal case whilst investigating the death of Raychel Ferguson (Ref: 012-039-196). [Tab 38]

56. The Chief Medical Officer stated in a letter to the Medical Director of Altnagelvin Area Hospital dated 10th May 2002:

> Your letter referred to a Coroner's case five years ago in which the cause of death of a child was reported to be hyponatraemia. This Department was not made aware of the case at the time either by the Royal Victoria Hospital or the Coroner. We only became aware of that particular case when we began the work of developing guidelines following the death at Altnagelvin. (Ref: 012-039-197) Tab 37

57. The Inquest into Raychel's death was conducted on 5th February 2003 by John Leckey who once again engaged Dr. Edward Sumner as an expert. The Inquest Verdict found the cause of Raychel's death to be Cerebral Oedema with Acute Dilutional Hyponatraemia as a contributory factor (Ref: 012-026-139). [Tab 39] It also made findings that the Hyponatraemia was caused by a combination of inadequate electrolyte replacement following severe post-operative vomiting and water retention resulting from the secretion of anti-diuretic hormone (ADH).

Conor Mitchell

58. Conor Mitchell died on 12th May 2003, having been transferred from Craigavon Hospital on 8th May 2003 where he had been admitted with signs of dehydration and for observation. Dr. Herron again performed the autopsy. He was unsure what 'sparked off' the seizure activity and the extent to which it contributed to the swelling of Conor's brain but he considered that the major hypernatraemia occurred after brainstem death and therefore probably played no part in the cause of the brain swelling (Ref: 087-055-205). [Tab 40]

59. The Inquest Verdict of 9th June 2004 stated the cause of death to be Brainstem Failure with Cerebral Oedema, Hypoxia, Ischemia, Seizures and Infarction and Cerebral Palsy as contributing factors (Ref: 087-057-221). [Tab 41] Dr Sumner later went back on his comment in his expert report that the fluid management had been adequate (Ref: 087-056-220) [Tab 42] and instead described the basics of fluid management as 'neither well understood, nor properly carried out' (Ref: 087-062-247). [Tab 43]

60. The relevance of Conor's case is that, 2 years after the death of Raychel Ferguson, issues with the management of fluids in children and with their accurate recording appear still to have existed.

Requirements

61. In the period 1996-2006, four children died of hyponatraemia as a contributory factor, with a fifth death of a child with elements of fluid management.

62. Of those deaths, four of the five occurred after the conclusion of the Inquest into Adam Strain's death in June 1996 when the dangers of hyponatraemia and

inappropriate fluid management had been highlighted by the expert evidence of Dr Sumner. These occurred despite the Coroner's understanding that lessons would be learned from Adam's death.

63. There is a concern over whether there are appropriate (or any) procedures or guidelines to govern communications between the hospital where a child was treated and died and the Coroner, or between that hospital and other hospitals that might benefit from lessons learned. There is also a concern over the line of communication for lessons learned between the hospital where the child died, the Coroner, the Chief Medical Officer and the Department of Health, Social Services and Public Safety.

64. Claire and Lucy both died after Adam but before Raychel's death. Yet their Inquests, which also established hyponatraemia as a contributory factor, did not take place until her death. There is therefore an issue as to whether, if their deaths had been subject to an Inquest by the Coroner at an earlier date, the dangers of hyponatraemia might have been highlighted and lessons learned which might have prevented Raychel's death.

65. An important element of this investigation is therefore the extent to which any of these deaths might have been avoided if lessons learned had been effectively communicated to the relevant bodies, both in terms of deaths being promptly reported to and investigated by the Coroner, and in terms of lessons being communicated and learned by the appropriate bodies post-Inquest.

66. The Chairman is empowered by the Revised Terms of Reference to: *"Make such recommendations to the Department of Health, Social Services and Public Safety as he considers necessary and appropriate."*

67. The Inquiry Team would therefore like to receive your advice on the following issues:

    (i) Between 1995 to date, what was/is the system of procedures and practices in the UK for the reporting of unexpected deaths in hospitals to the Coroner? In addition, your comments and/or observations on the scope for improvement in the current system of procedures and practices would also be of benefit.

    (ii) Between 1995 to date what is/was the system of procedures and practices in the UK for the reporting and dissemination of information on the outcomes or lessons to be learned from unexpected deaths in hospitals, and particularly those examined by Coroner's Inquests, to the hospital where the patient was treated, other hospitals, the doctors and nurses, Trusts, Boards and the DHSSPS (Department of Health in England and Wales/Scottish Government Health Department) including the Chief Medical Officer? Again, your comments and/or observations on the scope

for improvement in the current system of procedures and practices would also be of benefit, together with any process to follow up on the action taken.

(iii) Between 1995 to date, what was/is the system of procedures and practices in the UK for ensuring that the information on the outcomes or lessons to be learned from Coroner's Inquests is/was analysed and feeds/fed into the teaching and training of doctors and nurses and the care of patients? Again, your comments and/or observations on the scope for improvement in the current system of procedures and practices would also be of benefit, together with any process to follow up on the action taken.

(iv) Between 1995 to date, what was/is the system of procedures and practices in the UK for following up on the actions taken after Coroner's Inquests? Again, your comments and/or observations on the scope for improvement in the current system of procedures and practices would also be of benefit.

(v) How, particularly with the advent of the amended Rule 43 and the Coroners and Justice Act 2009, does Coroners Law and Practice in Northern Ireland differ from that in England, Wales and Scotland in reference to the issues noted above, and what are the advantages and/or disadvantages of these differences?

Conclusion

68. It is of fundamental importance that the Inquiry receives a clear and fully reasoned opinion on these issues.

69. Your assistance on the Inquiry's requirements should be provided in the form of a fully referenced Expert's Report.

CHRONOLOGY

Adam Strain's death	4th August 1991
Adam Strain's Inquest verdict	21st June 1996
Claire Roberts' death	23rd October 1996
Lucy Crawford's death	14th April 2000
Raychel Ferguson's death	10th June 2001
Raychel Ferguson's Inquest verdict	5th February 2003
Conor Mitchell's death	12th May 2003
Lucy Crawford's Inquest verdict	19th February 2004
Conor Mitchell's Inquest verdict	9th June 2004
UTV documentary airs	21st October 2004
Claire Roberts' Inquest verdict	4th May 2006

INDEX OF KEY ACCOMPANYING DOCUMENTS

Inquiry Background

- Original Terms of Reference
- Revised Terms of Reference

Other relevant documents

- DVD of UTV Documentary "When Hospitals Kill", 21st October 2004
- 'Memorandum of Understanding' entitled "Investigating patient or client safety incident (Unexpected death or serious untoward harm)", Department of Health, Social Services and Public Safety, the Police Service of Northern Ireland, the Coroners Service and the Health and Safety Executive for Northern Ireland, February 2006, Appendix 1

- "Reporting and Follow up on Serious Adverse Incidents - Interim Guidance" (HSS (PPM) 06/04). DHSSPS, 7th July 2004
  http://www.dhsspsni.gov.uk/hss(ppm)06-04.pdf