OVERALL OPENING

THE ORAL HEARINGS IN THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Chairman: John O'Hara QC

Banbridge Court House, 20th February 2012

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(1) Introduction

1. I should like to start by saying that the whole Legal Team is very much aware that we are dealing here with the deaths of young children, some who were very young and some the only child or the only daughter. On behalf of us all, I should like to express our condolences to the families of the children.

2. However, this Inquiry is not just about the deaths in hospital of Adam Strain, Claire Roberts, Lucy Crawford, Raychel Ferguson and Conor Mitchell. Nor is it just about the role that Hyponatraemia and the intravenous administration of what has become known as 'Solution No.18' played in their deaths. Or about any other mechanism that might have led to the gross Cerebral Oedema and coning. Although it involves all of those matters, arguably, the 'legacy' questions which arise from them are:

   How should lessons be learned from the deaths of children in hospital so as to reduce the incidence of such deaths re-occurring? Who has the responsibility to ensure that those lessons are learned and practice is changed accordingly?

3. Nevertheless, the deaths of Adam, Lucy and Raychel were instrumental to the establishment of this Inquiry and the deaths of Claire and Conor are also crucial for the issues that the Inquiry is to consider and may well be so for the recommendations that you, Mr. Chairman, will make in due course.

4. I shall therefore start by briefly saying something about each of the children.

5. What I say now is not intended to be an opening into the issues concerning the cases of the individual Children. There will be separate openings for the cases of Adam, Claire and Raychel (which will include Lucy's death and its aftermath) and Conor. I also need to say that the Inquiry's investigations are continuing into some of the clinical issues in Adam's case and clinical issues in the cases of the other Children. Furthermore, the investigation into the governance issues for all of the Children's cases and the position of the Department is still continuing. Accordingly, what I can say in this General Opening will, to some extent, be constrained by the need to ensure that those investigations are not compromised.

(2) The Children

Adam:

6. Adam Strain was born on 4th August 1991. He was an only child. He was born with cystic, dysplastic kidneys with associated problems with the drainage of

his kidneys related to obstruction and vesico ureteric reflux. A Glossary of Medical Terms[1] has been compiled for Adam's case and there will be one for the cases of each of the other Children. As can be seen from the Glossary for Adam's case, the term 'dysplastic kidney'[2] and the condition of 'vesico ureteral reflux'[3] are defined. In general therefore, unless it is of particular significance to a matter in issue, I shall not provide a definition for medical terms and conditions. However, for present purposes, Adam's condition basically meant that his kidneys were abnormally formed before birth causing them to be small and to function poorly and improperly.

7. Despite his medical problems, his mother describes Adam as a 'very happy, content child who was full of energy and bore bravely the very many procedures he had to undergo'. He was his mother's only child and she has provided a handbook, 'Adam Strain and the Hyponatraemia Public Inquiry', as a tribute to him.[4]

8. Adam was placed on the kidney transplant register on 24th November 1994[5].

9. On 26th November 1995, there was an offer of a kidney for Adam and he was admitted to the Royal Belfast Hospital for Sick Children (RBHSC) that evening. Adam's kidney transplant surgery was commenced the following morning. His Consultant Nephrologist was Dr. Maurice Savage, who was Professor of Paediatrics, Queen's University, Belfast.[6] He was not available for the entirety of the surgery and cover was provided by another Consultant Nephrologist, Dr. Mary O'Connor. The transplant surgeon was Mr. Patrick Keane (Consultant Urologist at the Belfast City Hospital). He was assisted by Mr. Stephen Brown, Consultant Paediatric Surgeon who was also at the Belfast City Hospital.[7] The anaesthetist was Dr. Robert Taylor (Consultant Paediatric Anaesthetist). He was assisted by Dr. Terence Montague (Senior Registrar in Anaesthesia) who has since left the RBHSC.[8] Dr. Montague did not remain for the entirety of the surgery. There is an issue to be addressed in the Oral Hearing in Adam's case as to whether or not Dr. Montague was replaced and if so by whom.

10. A comprehensive List of Persons has been provided in Adam's case, which shows the title, grade and role of all of those involved in Adam's clinical case[9]. A similar list with be provided for each of the other Children's cases as well as for the governance issues. A companion document has been compiled

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1 Glossary of Medical Terms (Adam) – Ref: 303-002
2 Glossary of Medical Terms (Adam) – Ref: 303-002-022
3 Glossary of Medical Terms (Adam) – Ref: 303-002-047
4 Handbook on 'Adam Strain and the Hyponatraemia Public Inquiry'- Ref: 304-001-001
5 Kidney Transplant Register Form - Ref: 057-070-130
6 Professor Savage retired in July 2011
7 Mr. Brown retired in September 2002
8 Dr. Montague is now a Consultant in Anaesthesia and Intensive Care at Our Lady's Children's Hospital, Crumlin
9 List of Persons in Adam Strain's case (Clinical issues) – Ref:303-001-001

providing a Nomenclature & Grading for Doctors[10], together with a similar document for Nurses[11], so as to assist with the terminology in use over the period from 1995 to date. Unless it is of particular relevance to the issues, I shall not therefore deal with the grade or training of any particular clinician.

11. An important issue for the Inquiry in Adam's case, as with all the cases, is the nature of the intravenous fluids he received. Adam, and several of the other children, was administered an intravenous solution of '0.18% sodium chloride in 4% dextrose', known colloquially as Solution No.18. Over the course of his surgery, from the initial preparation for anaesthesia to the end of the surgery, Adam received 1500ml of this solution, along with approximately 1500ml of blood and other solutions. The type, volume and rate of administration of intravenous fluids are issues for the Inquiry in all the cases.

12. Adam did not recover from his transplant surgery and he died on 28th November 1995. An Autopsy was started on 29th November 1995 by Dr. Alison Armour[12] who was then a Senior Registrar in Forensic Science at the State Pathologist's Department, Belfast.[13] The extent to which she sought and received specialist assistance with it from Dr. Meenakshi Mirakhur (then Consultant Neuropathologist at the Royal),[14] Dr. Denis O'Hara (then Consultant Paediatric Pathologist, since deceased) or Dr. Chitra Bharucha (then a Consultant Haematologist at the Royal)[15] and the extent to which any such input is reflected in her Report on Autopsy are all matters to be addressed in the Oral Hearing in Adam's case.

13. Also on 29th November 1995, Adam's death was referred to Mr. John Leckey who was then the Coroner for Greater Belfast. He now holds the position of Senior Coroner for Northern Ireland. Mr. Leckey was also the Coroner for the Inquests into the deaths of all of the other Children.

14. An Inquest was conducted into Adam's death on 18th June and 21st June 1996 by the Coroner who engaged a number of experts to assist him:

    (i) Dr. John Alexander[16] (Consultant Anaesthetist at Belfast City Hospital). He is now retired. He concluded that: "The complex metabolic and fluid requirements of this child having major surgery led to the administration of a large volume of hypotonic (0.18%) saline which produced a dilutional hyponatraemia and subsequent cerebral oedema". He also expressed the

10 Nomenclature & Grading for Doctors – Ref: 303-003-048
11 Nomenclature & Grading for Nurses – Ref: 303-004-051
12 Report on Autopsy on Adam - Ref: 011-010-034
13 Dr. Armour has since left that position and is now a Consultant Pathologist at the Royal Preston Hospital, Preston
14 Dr. Mirakhur has since retired
15 Dr. Bharucha has since retired
16 Report of Dr. Alexander on Adam – Ref: 011-012-084

view that: "*the problem could not be recognised until the surgery was completed*".[17]

(ii) Dr. Edward Sumner[18] (then a Consultant Paediatric Anaesthetist at Great Ormond Street Hospital for Sick Children – 'Great Ormond Street'). He concluded: "*on a balance of probabilities Adam's gross cerebral oedema was caused by the acute onset of hyponatraemia … from the excess administration of fluids containing only very small amounts of sodium … This state was exacerbated by the blood loss and possibly by the overnight dialysis. A further exacerbating cause may have been the obstruction to the venous drainage of the head. If drugs such as antibiotics were administered through a venous line in a partially obstructed neck vein then it is possible that they could cause some cerebral damage as well*".[19] He went on to comment in his evidence to the Coroner: "*I believe that without the venous drainage problem, Adam may have survived provided [his serum sodium] level did not drop below 123[mmol/L]*".[20]

(iii) Professor Jeremy Berry[21] (Department of Paediatric Pathology in St. Michael's Hospital, Bristol). He had the benefit of histological slides and concluded that oedema was not conspicuous in the lungs, "*curious foci of clear cell change in heptocytes scattered throughout the liver substance*" the significance of which he did not know, and that the: "*The transplant kidney was infarcted (dead). The extent of the change suggested that this occurred at or before the time of transplantation*".[22]

15. Dr. Sumner was also appointed by the Coroner as an expert in the Inquests into the deaths of all of the other Children, save for Claire whose Inquest was held in 2006. Accordingly, the Coroner had the benefit of Dr. Sumner's view of the relationship between the administration of excessive amounts of low sodium fluids, hyponatraemia and gross cerebral oedema in the cases of four of the Children, all with different presentations and spanning a period of eight years. The significance (if any) of that consistency of view is a matter being considered by the Inquiry.

16. The Verdict on Inquest[23] identified Cerebral Oedema as the cause of Adam's death with Dilutional Hyponatraemia and impaired cerebral perfusion as contributory factors: 1(a) Cerebral Oedema due to (b) Dilutional Hyponatraemia and Impaired Cerebral Perfusion during Renal Transplantation Operation for Chronic Renal Failure (Congenital Obstructive Uropathy). The Coroner found that the onset of cerebral oedema was caused by the acute onset of hyponatraemia from the excess administration of fluids containing only very

17 Final page, Report of Dr. Alexander on Adam – Ref: 011-012-087
18 Report of Dr. Sumner on Adam – Ref:011-011-053
19 Para.8, Report of Dr. Sumner on Adam – Ref:011-011-063 and 063
20 Deposition of Dr. Sumner – Ref: 011-011-049
21 Report of Professor Berry on Adam – Ref: 011-007-020
22 Penultimate page, Report of Professor Berry on Adam – Ref: 011-007-022
23 Verdict on Inquest on Adam– Ref: 011-016-114

small amounts of sodium and this was exacerbated by blood loss and possibly the overnight dialysis and the obstruction of the venous drainage from the head. The Inquest Verdict is recorded on Adam's Death Certificate as the cause of death.[24]

17. The effect of the fluids that were administered to Adam, their content, infusion rate and total amount will be addressed in the Oral Hearing into his case. So too is the extent to which there was any obstruction of the venous drainage from Adam's head and if there was, how it occurred and what effect it had.

18. In the course of giving evidence to the Inquest, Dr. Taylor produced a "Draft Statement"[25] on future practice, the contents of which were reported in the media.[26] It seems that that Statement was the product of all of the Consultant Paediatric Anaesthetists at the time, namely Dr. Taylor, Dr. Peter Crean (Consultant in Paediatric Anaesthesia and Intensive Care, RBHSC) and Dr. Seamus McKaigue (Consultant Paediatric Anaesthetist, RBHSC), as well as being approved by Dr. Joseph Gaston (Consultant Anaesthetist and the Clinical Director for Anaesthesia, Theatres & Intensive Care at the Royal Hospitals Trust).[27]

19. The Coroner has expressed the view that he had assumed that the RBHSC would have circulated other hospitals in Northern Ireland with details of the evidence given at the Inquest and, possibly, some 'best practice' guidelines.[28] The reasons why he might have formed that view, precisely what happened to the Statement and, more generally, what happened as a result of Adam's death are all matters to be addressed during the Oral Hearing in Adam's case.

Claire:

20. Claire Roberts was born on 10th January 1987. She was the youngest of three children, and the only daughter. She is described by her father as a 'little girl who had overcome her early setback and was happy, active and much loved'. During her early childhood, she had suffered from convulsions for which she was prescribed Tegretol and then Epilim. However, her convulsions appear to have ceased from about September 1991 when she was four years old and she was weaned off the Epilim over a period of a few months from February 1995.

21. On 21st October 1996, Claire's GP, Dr. Savage, referred her to the RBHSC with a recent history of malaise, vomiting and drowsiness. She was admitted to Allen Ward under the care of Dr. Heather Steen (Consultant Paediatrician). She was seen there by a number of nurses and doctors including Dr. Andrew Sands

24 Adam's Death Certificate – Ref: 070-001-001
25 Draft Statement - Ref: 011-014-107a
26 Press Cuttings – Ref: 070-016-070
27 Dr. Gaston retired in May 2005, after a position as part-time Associate Medical Director.
28 Mr Leckey's Witness Statement to the Inquiry – Ref: WS-091-1, page 3

(Paediatric Registrar) who sought specialist assistance from Dr. David Webb (Consultant Paediatric Neurologist). Precisely which of those two Consultants, Dr. Steen or Dr. Webb, had the responsibility for Claire's care and treatment from approximately 14:00 onwards on 22nd and on 23rd October 1996, together with the implications of that, are matters being investigated by the Inquiry.

22. On admission on 21st October 1996, Claire was prescribed IV fluids by the admitting doctor, Dr. Bernie O'Hare, a Paediatric Registrar. Like Adam, she was administered Solution No.18, which she continued to receive during her time on Allen Ward. Again, the appropriateness of the type, rate and volume of fluid administered to Claire are issues to be considered by the Inquiry.

23. There are a number of other important aspects of the care and treatment that Claire received during the course of her stay on Allen Ward that are under investigation.

24. Early in the morning of 23rd October 1996 at approximately 02:30, and before she was seen by Dr. Steen, Claire suffered a respiratory arrest, and was transferred to the Paediatric Intensive Care Unit (PICU). She was seen there by Dr. Robert Taylor who was involved in Adam's kidney transplant surgery. Dr. McKaigue was the Consultant on call when Claire was admitted to PICU and Dr. Crean is noted as the Consultant on the Case Note Discharge Summary. Both of them were involved with Dr. Taylor in the production of the draft Statement on future practice that was produced after Adam's death.

25. Claire did not recover and she died in PICU on 23rd October 1996. Her death was not reported to the Coroner and a brain-only Autopsy was carried out on 24th October 1996 with the permission of Claire's parents. The basis on which such a decision was made and the reason for it are matters that are being investigated by the Inquiry.

26. The Pathologist on the Autopsy Report is shown to be Dr. Brian Herron[29] who was then a Senior Registrar in Neuropathology but the Report itself is unsigned. At that time, Dr. Meenakshi Mirakhur was his Consultant Neuropathologist. She is the same consultant whose involvement in the production of the Dr. Armour's Autopsy Report on Adam is in issue.

27. The Autopsy Report was not conclusive. It found that the features of the brain were: *"those of cerebral oedema with neuronal migrational defect and a low grade meninoencephalitis … The reaction in the meninges and cortex is suggestive of a viral aetiology, though some viral studies were negative during life and on post mortem CSF. With the clinical history of diarrhoea and vomiting, this is a possibility though a metabolic cause cannot be entirely excluded. As this was a brain only autopsy, it is not possible to comment on other systemic pathology in the general organs"*.[30]

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29 Dr. Herron is now a Consultant Neuropathologist.

30 Report on autopsy on Claire – Ref: 090-003-003

28. Claire's Death Certificate[31] showed the cause of her death as I(a) Cerebral Oedema and (b) Status Epilepticus.

29. That certification was subsequently called into question after a UTV television documentary into the deaths of Adam and two of the other children (Lucy and Raychel) that was aired on 21st October 2004.

30. Claire's parents watched that programme and it prompted them to contact the RBHSC about the circumstances of their daughter's death. During a meeting between RBHSC personnel and Claire's parents on 7th December 2004[32], a query was raised over the role that fluid management, especially low serum sodium, might have played in Claire's death. The reason why that was not appreciated sooner by the RBHSC is matter being investigated by the Inquiry.

31. The Coroner was notified and an Inquest into Claire's death was carried out by John Leckey on 4th May 2006. He engaged as experts to assist him:

    (i) Dr. Robert Bingham[33] (Consultant Paediatric Anaesthetist at Great Ormond Street). He pointed out that the current guidance to use fluid with higher sodium content was not in place when Claire was being treated in 1996. He referred to confusion over Claire's usual neurological status and the effects of that on diagnosis and treatment. He presented a mixed picture: *"The hyponatraemia was probably an associated feature of Claire's condition rather than the primary illness. It was most likely to have been a result of the combination of raised levels of anti-diuretic hormone together with the intravenous infusion of low sodium content although the volumes infused do not fully account for the sodium becoming so low. I think it is most likely that hyponatraemia was the cause of the neurological deterioration … It is not, however possible to completely exclude the possibility that the serum sodium result was an isolated artefact and the deterioration was due to acute encephalopathy"*.[34]

    (ii) Dr. Ian Maconochie[35] (Consultant in Paediatric A&E Medicine at St Mary's, London). He considered that the *"management plan to treat the possibility of non-convulsive status epilepticus was correct at the time of practice"* as was her subsequent management in terms of her neurological presentation.[36]

32. The Verdict on Inquest[37] found the cause of Claire's death to be 1(a) Cerebral Oedema due to (b) Meningo-Encephalitis, Hyponatraemia due to excess ADH production and Status Epilepticus. The Coroner also made findings, principally

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31 Claire's Death Certificate – Ref: 091-012-077
32 Report of meeting in Claire on 7th December 2004 – Ref: 089-002-002
33 Report of Dr. Bingham on Claire – Ref: 091-006-020
34 Final page, Report of Dr. Bingham on Claire – Ref: 091-006-027
35 Report of Dr. Maconochie on Claire – Ref:091-007-028
36 Final page, Report of Dr. Maconochie on Claire – Ref:091-007-034
37 Verdict on Inquest on Claire – Ref: 091-002

that the degree of hyponatraemia that she suffered (fall in her serum sodium level to 121mmol/L) contributed to the development of the Cerebral Oedema that caused Claire's death, but that Meningoencephalitis and Status Epilepticus were also causes albeit that he could not determine the proportionate contribution of the three conditions to her death.

33. The Coroner accepted Dr. Steen's evidence at Inquest that the blood test showing 121mmol/L should have been repeated and there should have been a reduction in her fluids. He noted Dr. Steen's evidence that now the fluid management of Claire would have been different. That latter point is a matter that is to be investigated by the Inquiry.

34. The Coroner's finding gave rise to a new registration on 10th May 2006 of the cause of Claire's death so as to reflect the Coroner's Verdict on Inquest.[38] The reissued Death Certificate does not appear to have been issued until 2nd February 2012. The circumstances in which there was a new registration and the issuance of a new Death Certificate are matters being investigated by the Inquiry.

Lucy:

35. Lucy was born on 5th November 1998. She was the youngest of her parents' three children and was described by her mother as a 'very special little girl'.

36. Lucy was admitted to the Erne Hospital in Enniskillen on 12th April 2000 at about 19:20 with a recent history of drowsiness and vomiting. She came under the care of Dr. Jarlath O'Donohoe (Consultant Paediatrician) and was also treated by Dr. Amerullih Malik (Senior House Officer in Paediatrics)[39] and a number of nurses.

37. It is understood that following admission Lucy was given a 100ml bolus of fluids and some juice and that she was started on IV fluids at approximately 22:30 – 23:00. The IV fluid was Solution No. 18 and it appears to have been accepted by clinicians and nursing staff that this was given at a rate of 100ml/hr.

38. At approximately 02:55 on 13th April 2000 Lucy suffered a seizure and was transferred to the intensive care unit at the Erne Hospital where steps were taken to stabilise her for transfer to the RBHSC.

39. She was taken to the RBHSC in a seemingly moribund state by ambulance accompanied by Dr. Jarlath O'Donohoe and was admitted to PICU in the RBHSC under the care of Dr. Peter Crean (Consultant in Paediatric Anaesthesia

[38] Claire's reissued Death Certificate – Ref: 303-015-297
[39] Dr. Malik has since left Northern Ireland and is apparently working in Pakistan

and Intensive Care). She was 'hand-bagged' throughout the 90-minute trip by either Dr. O'Donohoe or the nurse Siobhan McNeill who accompanied him. For those unfamiliar with the geography, the distance between the two hospitals can perhaps best be appreciated from the map 'Health and Personal Social Services Northern Ireland'.[40]

40. Lucy was seen at the RBHSC by Dr. Donncha Hanrahan (Consultant Paediatric Neurologist), Dr. Anthony Chisakuta (Consultant in Paediatric Anaesthesia and Intensive Care) and by a Specialist Registrar in Paediatrics, Dr. Caroline Stewart.

41. Lucy was declared dead at 13:15 on 14th April 2000 and her death was reported to the Coroner's office that day. It was decided that it was unnecessary to conduct a Coroner's post-mortem. Quite how that decision came to be made is a matter being investigated by the Inquiry.

42. Nevertheless, it was agreed, with the consent of Lucy's parents, but apparently without the knowledge of the Coroner's Office, that there would be a hospital post-mortem.[41] The Autopsy Request Form dated 14th April 2000 was sent by Dr. Caroline Stewart to Dr. Denis O'Hara. It recorded the following clinical diagnosis:

> *"Dehydration and hyponatraemia Cerebral oedema → acute coning + brain stem death."*[42]

43. Dr. O'Hara is the same pathologist who is referred to by the Coroner as having, along with Dr. Bharucha, seen certain slides in relation to Adam's autopsy and expressed certain views. He conducted the hospital post-mortem[43] on Lucy later that day.

44. Lucy's death was certified by Dr. Dara O'Donoghue (Clinical Fellow, Paediatrics, RBHSC) as being caused by cerebral oedema due to or as a consequence of dehydration and gastroenteritis.[44]

45. Lucy's Death Certificate[45] showed the cause of her death as I(a) Cerebral Oedema, (b) Dehydration and (c) Gastroenteritis.
46. On 14th April 2000, Lucy's death was notified to the Sperrin Lakeland Trust by Dr. O'Donohoe and on or about 18th April 2000 Mr. Eugene Fee (Director of Acute Hospital Services, Sperrin Lakeland Trust) took the decision to instigate a Review of the care that Lucy had received at the Erne Hospital. The following

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40 Health and Personal Social Services Northern Ireland - Ref: 300-001-001
41 Coroner's letter of 28th April 2003 to Mr. Peter Walby (Director of Risk & Litigation Management, Royal Victoria Hospital) – Ref: 013-053-291
42 Autopsy Request Form - Ref: 061-022-073
43 Post-mortem Report on Lucy – Ref: 013-017-054
44 Dr. Dara O'Donoghue's certification of Lucy's death – Ref: 013-008-022
45 Lucy's Original Death Certificate – Ref: 029-004-004

day on 19th April 2000, Mr. Hugh Mills (Chief Executive, Sperrin Lakeland Trust) informed Martin Bradley (Chief Nurse at the Western Health and Social Services Board) of the 'issues'.[46]

47. The Review was coordinated by Mr. Fee with Dr. William Anderson (Clinical Director of Women and Children's Directorate, Erne Hospital).

48. In addition, on 20th April 2000, Mr. Mills asked Dr. Murray Quinn (Consultant Paediatrician at Altnagelvin Area Hospital) to contribute to the Review by examining the fluid regime which was adopted with Lucy and providing an external paediatric opinion on the management of her care. Dr. Quinn was provided with Lucy's clinical notes and asked to provide his opinion on three issues[47]:

    (i) Significance of the type and volume of fluid administered

    (ii) Likely cause of the cerebral oedema

    (iii) Likely cause of the change in the electrolyte balance

49. At that time the Erne Hospital and Altnagelvin Area Hospital were in different Trusts (respectively, Sperrin Lakeland Trust and Altnagelvin Group of Hospitals Trust). However, as is clear from the map 'Health and Personal Social Services Northern Ireland',[48] they were both under the same Western Health and Social Services Board. The extent to which that may have been significant is something that is being investigated by the Inquiry.

50. Dr. Quinn provided a draft report,[49] which was incorporated into the final Review Report of Mr. Fee and Dr. Anderson dated 31st July 2000[50]. The Review Report rehearsed Dr. Quinn's view that the total volume of fluid intake was 'within the accepted range'. It also stated that:

> *"Neither the post-mortem result or the independent medical report on Lucy Crawford, provided by Dr. Quinn, can give an absolute explanation as to why Lucy's condition deteriorated rapidly, why she had an event described as a seizure at around 2.55am on 13 April 2000, or why cerebral oedema was present on examination at post-mortem."* [51]

51. Lucy's death was not reported to the Coroner's Office by the Erne Hospital or Sperrin Lakeland Trust. The significance of that, as is the failure to inform the

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46 Notes of Mr Hugh Mills - Ref: 030-010-017
47 Letter from Mr Eugene Fee to Dr. Murray Quinn dated 21st April 2000– Ref: 034-017-050
48 Health and Personal Social Services Northern Ireland - Ref: 300-001-001
49 Medical Report of Dr. Murray Quinn – Ref: 036a-048-103
50 Review of Lucy Crawford's case - Report – Ref: 033-102-260
51 Review of Lucy Crawford's case - Report – Ref: 033-102-265

Coroner that a hospital post-mortem was being carried out, are matters that are being investigated by the Inquiry.

52. The Review, Dr. Quinn's report and exactly what was done at the Erne Hospital as a result of Lucy's death was the subject of a critical UTV documentary broadcast in October 2004. It is also an issue to be investigated by the Inquiry, as is what happened at the RBHSC after Lucy's death.

53. Following the Inquest into Raychel's death on 5th February 2003, the circumstances of Lucy's death were referred to the Coroner, who applied to the Attorney General for Northern Ireland for a direction that an Inquest should be held into her death. On December 2003, the Legal Secretariat for the Attorney General's Chambers notified the Coroner that the Attorney General had made an Order directing him to carry out an Inquest into the circumstances surrounding Lucy's death.[52]

54. The Coroner invited Dr. O'Hara to convert his hospital Post-mortem Report of 17th April 2000 into a Coroner's Report. Dr. O'Hara furnished such a Report dated 6th November 2003[53] in which he expressed the view that there were two potential causes: *"Firstly, hyponatraemia causing cerebral oedema due to disturbance which occurs in the quantities of water moving into the brain. Secondly, bronchopneumonia both toxic and hypoxic affects and is also well known as a cause of cerebral oedema"*.[54] He concluded that it would be difficult to be certain what proportion of the cerebral oedema could be ascribed to each of those processes.

55. Unfortunately Dr. O'Hara is deceased and we have only his two Reports and his letter to the Coroner of 23rd October 2003[55] to assist us with his views on what happened, particularly in the light of the opinion of Dr. Edward Sumner who was engaged by the Coroner as an expert, namely:

> *"I have read Dr. Sumner's report and believe that this will pose difficulties in that he confuses matters of fact with matters of opinion and approaches the matter in a somewhat 'tunnel vision' way … There is a history of a presentation which would be entirely consistent with an infective condition and then there is, as pointed out by Dr. Sumner objective evidence of hyponatraemia. The problem is that both these conditions can bear directly on the brain and give rise to the problems of which were the ultimate cause of death namely the cerebral oedema with its affect on vital respiratory and cardiac centres."* [56]

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52 Direction of Attorney General in December 2003 for an Inquest in Lucy's case – Ref: 013-052e-285
53 Dr. O'Hara's Post Mortem Report for the Coroner dated 6th November 2003 – Ref: 013-017-063
54 Dr. O'Hara's Post Mortem Report for the Coroner dated 6th November 2003 – Ref: 013-017-065
55 Correspondence of Dr. O'Hara – Ref: 013-053f-296
56 Correspondence of Dr. O'Hara – Ref: 013-053f-296

56. That Inquest was conducted by John Leckey from 17th February to 19th February 2004. In addition to Dr. Edward Sumner's expert Report, [57] as an expert the Coroner also had the benefit of two other expert Reports:

    (i) Dr. Dewi Evans[58] (Consultant Paediatrician, Singleton Hospital in Swansea), engaged for Lucy's parents. He pointed out that if Lucy had been managed according to the basic standards of paediatric practice in a district general hospital then it was, in his opinion, extremely unlikely that she would have developed cerebral oedema, ie: "*Treating Lucy with the standard therapy for children with gastroenteritis would have prevented the cerebral oedema and prevented the neurological collapse*".[59]

    (ii) Dr. John Jenkins[60] (Senior Lecturer in Child Health and Consultant Paediatrician at Antrim Hospital), engaged by the Directorate of Legal Services for Sperrin Lakeland Trust. He pointed to the absence of: "*clear documentation regarding the fluid type and rate prescribed, together with clear records as to the exact volumes of each fluid which were in fact received by the child throughout the time period concerned*" and the "*confusion between the staff involved*".[61]

57. The implications of the observations of those experts for lessons learned, hospital management and indeed for governance generally, are matters being investigated by the Inquiry.

58. The Verdict on Inquest[62] found the cause of Lucy's death to be I(a) Cerebral Oedema (b) Acute Dilutional Hyponatraemia (c) Excess Dilute Fluid and II Gastroenteritis. The Coroner also made findings that the Dilutional Hyponatraemia was caused by a combination of an inappropriate fluid replacement therapy of 0.18% saline and a failure to properly regulate the rate of infusion. There were further findings in respect of the poor quality of the medical record keeping and the confusion amongst the nursing staff as to the fluid regime prescribed having compounded the errors in fluid management.

59. As a result of the Inquest, Lucy's Death Certificate was amended[63] to show the cause of her death as shown in the Coroner's Verdict on Inquest.

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57 Dr. Sumner's Report dated April 2002 – Ref: 013-036-136
58 Dr. Evans' Report dated 18th February 2001 – Ref: 013-010-025
59 Para.53 of Dr. Evans' Report dated 18th February 2001 - Ref: 013-010-036
60 Dr. Jenkins' Report dated 7th March 2002 – Ref: 013-011-037
61 Final page of Dr. Jenkins' Report dated 7th March 2002 – Ref: 013-011-039
62 Verdict on Inquest on Lucy – Ref: 031-067
63 Lucy's amended Death Certificate –Ref: 069A-005-007

Raychel:

60. Raychel Ferguson was born on 4th February 1992. She was her parents' only daughter and the sister to three brothers. Her mother describes her as a 'lively, chatty, outgoing girl who loved fashion and music'.

61. Raychel had never previously been admitted to hospital until she was admitted to the Altnagelvin Area Hospital on 7th June 2001 following her arrival in the Accident and Emergency Unit with a history of abdominal pain and complaining of dysuria (i.e. painful, including 'burning', urination or difficult urination) and nausea.

62. She was admitted to the children's unit of Altnagelvin Hospital and came under the care of Mr. Robert Gilliland (Surgical Consultant) although he did not see her during her admission to the Altnagelvin Area Hospital and apparently did not appreciate that a patient under his care had died until the day after her death.

63. Raychel was examined by Mr. Regai Reda Makar (Surgical, Senior House Officer) who considered that she had acute appendicitis. The earlier complaint of dysuria was not revisited and Mr. Makar took the decision to perform an appendectomy, which was performed late that night. The anaesthetists were Dr. Vijay Kumar Gund and Dr. Claire Jamison (both Senior House Officers). However, Dr. Jamison left before the completion of surgery.

64. The records show that Raychel was commenced on Solution No. 18 at 22:15 at an infusion rate of 80ml/hour. Mr. Makar had initially prescribed intravenous Hartmann's solution for Raychel in the Accident and Emergency department, but upon being informed by Staff Nurse Noble that this was inconsistent with common practice on the ward, Mr. Makar changed the fluid prescription to Solution No. 18.

65. The fluids were continued at this rate until in or about 23:00 when Raychel was taken to theatre. The records show that Raychel was recommenced on this fluid at this rate at 02:00 on 8th June 2001, after the completion of surgery. As with the other children, the administration of this particular fluid, at this rate and in this volume is an issue to be considered by the Inquiry.

66. Raychel was seen by a number of nurses and doctors, including Mr. M.H. Zafar (Surgical, Senior House Officer), Dr. Joe Devlin (Surgical, Junior House Officer) and Dr. Michael Curran (Surgical, Junior House Officer) who were called because of Raychel's continued vomiting. Raychel was also seen by Dr. Jeremy Johnston (Paediatrics, Senior House Officer) as a result of a seizure that she suffered in the early hours of 9th June 2001.

67. Following her subsequent collapse, Raychel was seen by a number of other clinicians including Dr. Bernie Trainor (Paediatric Senior House Officer), Dr. Brian McCord (Consultant Paediatrician on-call), Dr. Aparna Date (Specialist Registrar in Anaesthetics) and Dr. Geoff Nesbitt (Clinical Director, and Consultant Anaesthetist). Raychel's pupils were found to be dilated and unreactive, her oxygenation deteriorated to 80% oxygen and her respiratory efforts declined. CT scans were performed and she was transferred to ICU at Altnagelvin later that morning.

68. Later on 9th June 2001, Raychel was transferred to PICU in the RBHSC. Again, for those unfamiliar with the geography, the distance between the two hospitals can be seen from the map 'Health and Personal Social Services Northern Ireland'.[64] The transfer letter[65] from Dr. Berne Trainor (Senior House Officer, Paediatrics) and presented on her arrival at midday said: "*Very unwell - pupils dilated and unresponsive*". The note made of the examination of Raychel that was carried out shortly after her admission to PICU and prior to the brain stem tests being carried out, records: "*Overall there appears to be no evidence of brainstem function - her limb movements are not, in my opinion, of cerebral origin*."[66]

69. At PICU, Raychel came under the care of Dr. Peter Crean (Consultant Paediatric Anaesthetist) who had not only been involved in Lucy's case, but had knowledge of Adam's case and was noted in Claire's case. He considered that brain stem death had already taken place. She was also seen by Dr. Donncha Hanrahan, the Consultant Paediatric Neurologist who had been involved in Lucy's case.

70. Raychel did not recover and, following two brain stem tests, she was pronounced dead at 12:09 on 10th June 2001 and the Coroner's office was notified. At the request of the Coroner, a post-mortem examination was carried out by Dr. Herron (Consultant Neuropathologist) who had been involved in the 'brain only' post-mortem on Claire and Dr. Al-Husani (Pathologist) on 11th June 2001. Dr. Herron had carried out the initial post-mortem examination of Claire when he was a Senior Registrar in Neuropathology.

71. Prior to the completion of the post-mortem Report, and on 12th June 2001 a 'Critical Incident Inquiry' was established at the Altnagelvin Hospital by Dr. Raymond Fulton (Medical Director) in accordance with the hospital's Critical Incident Protocol.[67] One of the action points involved a review of the continued use of Solution No.18 post-operatively.[68]

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64 Health and Personal Social Services Northern Ireland - Ref: 300-001-001
65 Transfer letter – Ref: 063-005-011
66 PICU Clinical Notes - Ref: 063-009-022
67 Critical Incident Protocol - Ref: 022-109-338
68 'Agreed action following critical incident meeting 12/06.01' – Ref: 006-002-240

72. The post-mortem Report[69] was completed on 20th November 2001 with the clinical summary[70] completed on 4th December 2001. The post-mortem Report was provided on 21st December 2001 with input from Dr. Clodagh Loughrey (Consultant Chemical Pathologist).

73. Raychel's Death Certificate[71] shows the cause of her death as 1(a) Cerebral oedema and (b) Hyponatraemia.

74. The Inquest into Raychel's death was conducted on 5th February 2003 by John Leckey. He engaged Dr. Edward Sumner as an expert. He had reported in February 2002 that in his view:

> "*Raychel died from acute cerebral oedema leading to coning as a result of hyponatraemia. I believe that the state of hyponatraemia was caused by a combination of inadequate electrolyte replacement in the face of severe postoperative vomiting and the water retention always seen postoperatively from inappropriate secretion of ADH*".[72]

75. The Coroner also had the assistance of Dr. Jenkins who had once again been engaged by the Directorate of Legal Services.[73] He concluded that:

> *"… my impression is that they [the doctors and nurses] acted in accordance with established custom and practice in the Unit at that time. Raychel's untimely death highlights the current situation whereby one sector of the medical profession can become aware of risks associated with particular disease processes or procedures through their own specialist communication channels, but where this is not more widely disseminated to colleagues in other specialities who may provide care for patients at risk from the relevant condition."* [74]

76. The 'situation' that Dr. Jenkins highlighted is a matter that is being investigated by the Inquiry.

77. The Verdict on Inquest[75] found the cause of Raychel's death to be 1(a) Cerebral Oedema with (b) Hyponatraemia as a contributory factor. The Coroner 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).

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69 Raychel's post-mortem report – Ref: 014-005-006
70 Raychel's post-mortem report (Clinical Summary) – Ref: 014-005-012
71 Raychel's Death Certificate – Ref: 303-013-295
72 Dr. Sumner 's report – Ref: 012-001-001
73 Dr. Jenkin's report – Ref: 012-023-132
74 Dr. Jenkin's report – Ref: 012-023-133
75 Verdict on Inquest on Raychel – Ref: 012-026

Conor:

78. Conor Mitchell was born on 12th October 1987. He was subsequently diagnosed with spastic tetraplegia, a severe form of cerebral palsy, and mild epilepsy. He was an only child who has been described by his family as 'upright, full of fun, very motivated and highly intelligent'.

79. On 28th April 2003 Conor was taken to Dr. Patterson at Moores Lane Surgery in Lurgan with a sore throat and he had been vomiting. Over the next few days he continued to be unwell and was vomiting although the precise cause was unclear. Ultimately, on 8th May 2003 Dr. Doyle at the same Moores Lane Surgery examined Conor and advised that he should be taken to hospital for blood tests and 24 hours observation.

80. Conor was taken to Craigavon Area Hospital later on 8th May 2003 where he was admitted to the Accident & Emergency Department with signs of dehydration and for observation. At that time Conor was 15 years old and weighed approximately 22 kilos. He was of slim build and is described as having the "*body habitus of 8-9 yr old child*".[76] He was seen there by Dr. Suzie Budd (Staff Grade Doctor in Accident and Emergency) and Dr. Paul Kerr (Consultant in Accident and Emergency Department). He was then admitted to the Medical Admissions Unit, which is not a paediatric unit, by Staff Nurse Ruth Bullas for the purposes of observation. Conor was examined in the Medical Admission Unit by, variously, Dr. Catherine Quinn (Senior House Officer, Medical), Dr. Andrew Murdock (Medical Registrar) and Dr. Jill Totten (Junior House Officer).

81. The reasons why Conor was not admitted into a paediatric unit or onto a paediatric ward, and the implications of that for his care and treatment, are matters being investigated by the Inquiry.

82. Whilst Conor was admitted to the Medical Admission Unit, unlike the other children, he was not prescribed Solution No.18, but instead received a combination of Hartmann's solution and 'normal' saline (0.9% saline). The extent to which the care and treatment which Conor received, both in Craigavon Area Hospital and the RBHSC, was consistent with the then teaching/training on fluid management and record keeping, in particular the Guidelines on Hyponatraemia that were published by the Department in 2002, are matters being investigated by the Inquiry.

83. Over the course of the afternoon of 8th May 2003 and into the evening, Conor's condition deteriorated. Staff Nurse Bullas, who having transferred from the Philippines was in her final month of her six month preceptorship, noted that he had spasms and developed a pink rash on his abdomen and thighs.[77] Dr.

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76 In-Patient Follow-Up and Out-Patient Notes – Ref: 088-004-057

77 In-Patient Follow-Up and Out-Patient Notes – Ref: 088-004-092

Murdock was unable to find evidence of a rash. However, Conor's family queried whether he should be transferred to the RBHSC and it was agreed that a second opinion should be sought from the 'paediatric team' and Dr. Marian Williams (On-call Paediatric Registrar) was contacted.

84. At about 20.30 and, whilst he was being examined by Dr. Williams, Conor suffered two episodes of seizure activity in rapid succession and stopped breathing. Several doctors then attended Conor in a short period of time including Dr. Murdock, Dr. Michael Smith (Consultant Paediatrician), and Dr. Aoibhin Hutchinson (Specialist Registrar in Anaesthesia). Conor required intubation and ventilation, following which a CT scan was conducted, which showed a very abnormal scan and a subarachnoid bleed.

85. Conor was then admitted to the ICU of the Craigavon Area Hospital, under the care of Dr. William McCaughey (Consultant Anaesthetist). He is recorded as being unresponsive on arrival, with pupils that were fixed and dilated. The following day Conor was making no spontaneous effort breathing. The In-Patient Follow-up Notes record: "*All appearances are that this unfortunate young fellow is brain stem dead*".[78]

86. He was transferred to the PICU at RBHSC on 9th May 2003 under the care of Dr. James Patrick McKaigue (Consultant Paediatric Anaesthetist). The reasons why and the process by which Conor was admitted into PICU at RBHSC are matters being investigated by the Inquiry, as are the implications of that admission for his care and treatment.

87. Subsequent brain stem tests were shown to be negative and he was pronounced dead on 12th May 2003.

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

89. The clinical diagnosis of Dr. Janice Bothwell (Paediatric Consultant) at the RBHSC was brainstem dysfunction with Cerebral Oedema related to viral illness, over-rehydration/inappropriate fluid management and status epilepticus causing hypoxia.[79] Dr. Herron from the 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 developed after brainstem death had occurred and that it therefore probably played no part in the cause of the brain swelling. He concluded in his Autopsy Report[80] that the ultimate cause of death was Cerebral Oedema.

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78 In-Patient Follow-Up Notes – Ref: 088-004-005 and 006
79 Autopsy Request Form - Ref: 087-137c-455
80 Autopsy Report - Ref: 087-055-199

90. Dr. Edward Sumner commented in his Report of November 2003[81] 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: *"total volume of intravenous fluids given was not excessive and the type of fluid was appropriate [Hartmann's/normal solution], but was the initial rate of administration too great for Conor? There was no pulmonary oedema, but his face did become puffy"*.[82] That query was raised in his correspondence shortly after the Inquest Verdict to Dr. Jenkins dated 11th June 2004 and copied to the Chief Medical Officer, Dr. Henrietta Campbell, and the Coroner:

> *"Having got home from Conor Mitchell's inquest, I feel I must communicate my great unease. This is the fourth inquest I have attended in Belfast where suboptimal fluid management has been involved …*
> *There was no calculation of the degree of dehydration nor the fluid deficit and no calculation of the maintenance fluids for a 22kg child.*
> *…*
> *My overall impression from these cases is that the basics of fluid management are neither well understood, nor properly carried out.*
> *Has this been your experience? What is the remedy?"* [83]

91. In his response of 28th June 2004, Dr. Jenkins referred to the results of a 'regional audit' that had assessed the implementation of the Hyponatraemia Guidelines issued in March 2002. He went on to refer to arrangements being made by the Chief Medical Officer for: *"a workshop at which issues of fluid management can be discussed between colleagues in relevant specialties within medicine, and indeed nursing"*. [84] He also referred to highlighting with the General Medical Council the issue of training in fluid administration and management and of drawing the matter to the attention to Northern Ireland Postgraduate Dean and Director of Undergraduate Medical Education.

92. The 'audit' on the implementation of the Hyponatraemia Guidelines was the subject of a paper by Dr. Jarlath McAloon and Dr. Raj Kottyal (respectively Consultant Paediatrician and Senior House Officer at the Antrim Hospital) published in the Ulster Medical Journal: 'A Study of Current Fluid Prescribing Practice and Measures to Prevent Hyponatraemia in Northern Ireland's Paediatric Departments'. In summary, the paper concluded that the *"evidence suggests that implementation has so far been incomplete"* and it highlights *"problem areas"*.[85] The extent to which the March 2002 Hyponatraemia Guidelines were being effectively implemented is an issue being investigated by the Inquiry as is the actions of the Chief Medical Officer and others in relation to the emerging issue of the appropriate intravenous fluid management of children in hospital.

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81 Report of Dr. Edward Sumner on Conor Mitchell - Ref: 087-056-213
82 Final page, Report of Dr. Edward Sumner on Conor Mitchell - Ref: 087-056-222
83 Letter from Dr. Sumner to Dr. Jenkins dated 11th June 2004 - Ref: 087-062i-247
84 Letter from Dr. Jenkins to Dr. Sumner dated 28th June 2004 – Ref: 087-062h-242 and 243
85 Ulster Med J 2005; 74(2) 93-97 – Ref: 303-027-362

93. The Verdict on Inquest[86] stated the cause of death to be I(a) Brainstem Failure, (b) Cerebral Oedema, (c) Hypoxia, Ischemia, Seizures and Infarction and II Cerebral Palsy. The Coroner also made findings. He was satisfied that there was seizure activity in the afternoon but found that there was no evidence that any clinicians had seen the series of 10-12 seizures, the increasingly vivid intermittent rash or heard the choking noises described by the family. He concluded that there was no evidence of any viral illness contributing to the underlying causes of Conor's death. The Coroner also found that: *"The fluid management at Craigavon Area Hospital was acceptable"*. [87]

(3) Hyponatraemia & Solution No.18

Hyponatraemia:

94. Throughout the Children's cases there is reference to hyponatraemia. What it means is relatively straightforward. A working definition simply for the purposes of this General Opening Mr. Chairman is:

> *"This is when the blood level of sodium is lower than normal either because of an excess excretion of sodium over intake and subsequent water intake and retention (hypovolaemic hyponatraemia) or by an excess of water intake over output diluting the serum sodium (dilutional hyponatraemia)."*[88]

95. To varying degrees, the extent to which these Children developed dilutional hyponatraemia, how and why they did so, whether it could have been avoided, whether it could have been arrested and reversed with appropriate treatment and, crucially, the extent to which it killed them are all matters that are the subject of the investigation into their respective cases.

Solution No.18:

96. 0.18% Sodium Chloride and 4% Glucose/Dextrose[89] intravenous fluid solution, or 'Solution No.18', is so-called because it comprises 4% Glucose and 0.18% Sodium Chloride (NaCl) with the remainder being 'free water'. This means that it contains one-fifth of the sodium and chloride ions than are found in an isotonic solution e.g. 0.9% NaCl. An isotonic solution, such as Hartmann's solution, contains approximately the same number of sodium and chloride ions as are in human blood.

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86 Verdict on Inquest on Conor – Ref: 087-057
87 Verdict on Inquest on Conor – Ref: 087-057-223
88 Expert report by Dr Coulthard - Ref: 200-002-037 and Expert report by Dr Gross – Ref:201-002-027 and 028
89 Glucose and Dextrose can be used interchangeably in this context

97. Solution No.18 was used intravenously with all of the Children (except Conor) and is at the heart of the criticisms made of their fluid management as its low level of sodium content has been connected with the development of dilutional hyponatraemia.

98. There is an issue, which the Inquiry is investigating, over the extent to which at the time of Adam's admission and for some time afterwards, Solution No.18 was a fairly standard intravenous solution for use with children. That investigation includes:

    (i) The purpose for which it was considered that Solution No.18 could appropriately be administered at the time when it was prescribed and administered to the Children. For example whether it should have been used as a 'maintenance' fluid (i.e. to match the fluids being lost) or a 'replacement' (i.e. to match fluids already lost). Alternatively, whether it should not have been used for either purpose.

    (ii) The extent to which the dangers of using too large a quantity of Solution No.18 or at too fast a rate should have been recognised. In other words, whether it should have been appreciated that such use would lead to a dilution of sodium in the body and a chain of events which, if unchecked, would culminate in dilutional hyponatraemia leading to cerebral oedema.

    (iii) The extent to which it is the presence of the low sodium in the Solution No.18 in combination with the 4% glucose that presents the problem in terms of dilutional hyponatraemia leading to fatal cerebral oedema or whether the same result would be produced with a similar quantity and rate of administration of: (a) water, or (b) glucose without sodium.

99. The precise mechanism by which dilutional hyponatraemia develops in children receiving intravenous fluids, together with its consequences and their significance, are matters that will be addressed in greater detail during the Oral Hearings for each of the Children.

Hyponatraemia Guidance:

100. Another important aspect of the work of the Inquiry is the impact of the 'Guidance on the Prevention of Hyponatraemia in Children' which the Department issued in 2002 before the Inquiry was established.[90]

101. It is possible that the need for such guidance was raised at a meeting on 18th June 2001 of Medical Directors, within days of Raychel's death. However, the

[90] Hyponatraemia Guidance – Ref: 007-003-004

Guidance was ultimately published on 25th March 2002,[91] after the deaths of all of the Children except Conor.

102. The Hyponatraemia Guidance starts with the warning that: *"Every child on IV fluids or oral rehydration is potentially at risk of hyponatraemia"*. It highlights the particular risks of the condition including those associated with post-operative patients, bronchiolitis and with vomiting. It addresses:
- Baseline assessment, specifically referring to urine and electrolytes
- Fluid requirements for both maintenance and replacement
- Choice of fluids
- Monitoring of the child's clinical state, fluid balance (input and output) and biochemistry
- Seeking advice

103. The circumstances giving rise to the formulation of the Hyponatraemia Guidance, its implementation, monitoring, auditing and evaluation are a fundamental part of the Inquiry's work and will be addressed in the Oral Hearings, particularly those dealing with hospital management and governance.

(4) Establishing the Inquiry

104. Turning now to the establishment of the Inquiry. On 21st October 2004, UTV aired an hour-long 'Insight Special' titled: 'When Hospitals Kill'. It featured the deaths of Adam, Lucy and Raychel and claimed that they had all died of the same cause, namely by hospitals accidentally administering too much of the wrong type of intravenous fluid. It also sought to expose what it claimed was a deliberate cover-up of the cause of Lucy's death.

105. The documentary prompted the Department to take action and, on 1st November 2004, Angela Smith MP, announced[92] that she had appointed John O'Hara QC to conduct a Public Inquiry into the issues that it raised. At that time, there was 'direct rule' from Westminster and Angela Smith was the Minister with responsibility for Health, Social Services and Public Safety in Northern Ireland.

106. The Department recognised that public confidence had been damaged and it wished the Terms of Reference for the Inquiry to be sufficiently broad to enable the concerns of not just the families but also the wider public to be fully addressed. In announcing the Inquiry the Minister stated: [93]

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91 CMO's letter of 25th March 2002 enclosing the Hyponatraemia Guidance – Ref: 026-019-046

92 Angela Smith's announcement on 1st November 2004 establishing the Inquiry – Ref: 008-032-093

93 Department News Release of 18th November 2004 – Ref: 021-010-022

"I believe it is of the highest importance that the general public has confidence in the quality and standards of care provided by our health and social services …

The death of any child is tragic and it is essential that the investigation into these deaths is independent, comprehensive and rigorous. The Terms of Reference that I have set for the Inquiry and the powers available to it are wide-ranging and should ensure that the Inquiry deals with all the issues of concern …

I have every confidence that Mr. O'Hara will conduct a thorough and rigorous inquiry and will establish what happened in these tragic cases."

107. The Terms of Reference were announced on 18th November 2004[94] as:

"In pursuance of the powers conferred on it by Article 54 and Schedule 8 to the Health and Personal Social Services (Northern Ireland) Order 1972, the Department of Health, Social Services and Public Safety hereby appoints Mr John O'Hara QC to hold an Inquiry into the events surrounding and following the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson, with particular reference to:

i The care and treatment of Adam Strain, Lucy Crawford and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
ii The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson.
iii The communications with and explanations given to the respective families and others by the relevant authorities.

In addition, Mr. O'Hara will:

a. Report by 1 June 2005 or such other date as may be agreed with the Department, on the areas specifically identified above and, at his discretion, examine and report on any other relevant matters which arise in connection with the Inquiry.
b. Make such recommendations to the Department of Health, Social Services and Public Safety as he considers necessary and appropriate."

108. As can be seen Mr. Chairman, the first part of the Inquiry's work under the Terms of Reference (and this is true of the Revised Terms of Reference since the structure remains the same) relates to the Children's treatment.

109. That part of the Terms of Reference requires an investigation into their care and treatment plain and simple. So for both Adam and Raychel that involves an investigation into the decisions over their surgery, when it was to be carried out and who was to do it as well as how it was actually performed.

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

110. However, that is not everything. Attention is drawn to the management of the Children's fluid balances. So, for example, in Adam's case that would involve the calculations that were made to arrive at the fluid management plan for his renal transplant surgery and any adjustments that were made to that plan during the course of his surgery. Attention is also drawn to the choice of intravenous fluids. So, for example, in Raychel's case that would involve the reason for and justification of the change from Hartmann's solution that had initially been prescribed for her during her surgery to Solution No.18 that was administered to her on the ward. The difference between those two intravenous solutions lies largely in the level of sodium, which for Hartmann's is 131mmol/l whilst for Solution No.18 it is 30mmol/l.

111. The second part of the Terms of Reference is very broad and the range of persons involved is constrained only by the requirement that they were 'concerned' in the procedures, investigations and events that followed the Children's deaths. At one level that would involve an investigation into the process by which the RBHSC Protocol on Renal Transplantation in Small Children' was revised in September 1996 following Adam's death. It extends to the nature and adequacy of the inquiry carried out at the Erne Hospital into the circumstances of Lucy's death, as well as to the conduct of the Chief Medical Officer at the time following Raychel's death.

112. It also takes in the means by which the Department's Guidance on the Prevention of Hyponatraemia in Children was produced, the process by which it was introduced into hospitals and the extent to which its enforcement was audited and evaluated, together with the quality of the governance exercised by the Department in relation to the occurrence of serious adverse incidents in hospitals. The Inquiry has compiling a chronology to summarise the events and lessons learned in relation to this aspect of its work: 'Chronology of the Response of the Department and Statutory Bodies: Governance and Lessons Learned', which is being updated to reflect the results of the investigation into the governance issues arising out of each of the Children's cases. It is intended that the first part of it will be provided prior to the start of the Oral Hearing on 'governance issues' in Adam's case.

113. There are of course other bodies whose conduct, in relation to the particular issues of concern, may fall within the scope of the Inquiry's work. For example:

    (i) School of Medicine, Dentistry and Biochemical Sciences at Queen's University Belfast, which provides undergraduate training and research facilities. The School has established Sub-Deaneries within the local Health Trusts to try and ensure greater integration between academic and clinical colleagues.

    (ii) Northern Ireland Medical and Dental Training Agency (NIMDTA) and its predecessor the Northern Ireland Council for Postgraduate Medical and

Dental Education. The task of both of those bodies was to ensure that doctors and dentists are effectively trained to provide patients with the highest standards of care.

(iii) Medicines and Healthcare Products Regulatory Agency (MHRA) and its predecessor Medicines Control Agency, which ensures that medicines and medical devices work and are acceptably safe. The Commission on Human Medicines (CHM) is a committee of the MHRA whose duties came into being on 30th October 2005.[95] For the purposes of this Inquiry and in relation to the use of Solution No.18, those duties include advising Ministers on matters relating to human medicinal products and promoting the collection and investigation of information relating to adverse reactions for human medicines for the purpose of such advice. Prior to its formation that function was carried out by Medicines Commission and the Committee on Safety of Medicines.

(iv) NHS National Patient Safety Agency, which co-ordinates the efforts of the entire country to report, and to learn from mistakes and problems that affect patient safety.

(v) HPSS Regulation and Quality Improvement Authority (RQIA), which promotes safe practice on the use of medicines and products and is Northern Ireland's independent health and social care regulator.

114. The third part of the Terms of Reference takes us back to the Children and their families. It encompasses a range of communications. For example, the nature and extent of the information given to Adam's mother about renal transplantation at the RBHSC, the accuracy and quality of the information given to the parents of the other Children as to why they became so ill and died, together with the degree to which the clinicians listened to the concerns of the parents in all the cases.

(5) Early stages of the Inquiry's Work

The approach:

115. The approach to the Terms of Reference was signalled almost immediately by your Statement Mr. Chairman of 18th November 2004: *"The Terms of Reference of the Inquiry which have been published today are very broad and I believe they will enable me to look at all the issues that need to be examined"*.[96] The commitment to investigating the 'broader issues' was reiterated by you Mr. Chairman in the Public Hearing on 3rd February 2005:[97]

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95 Medicines Act 1968 as amended by the Medicines (Advisory Bodies) Regulations 2005

96 Chairman's Statement of 18th November 2004 – Ref: 015-091-359

97 Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005-055

> *"I am determined to get to the heart of the issues which led to the Minister's decision to establish the Inquiry … Specifically, the public needs to know that our Health Service is managed and organised in such a way that when unfortunate events happen, as they inevitably will, lessons are learned to prevent their repetition. Nobody can reasonably expect that mistakes will not occur in our Health Service. What we all should expect, however, is that steps will be taken to help to minimise the risk to the health of others in the future. [p.2]*[98]
> …
>
> *Perhaps the single most important one [general issue] is what procedures have been in place to ensure that information and lessons which emerge from inquests are disseminated within the hospital concerned, within the Health Service in Northern Ireland and within the Health Service throughout the United Kingdom generally." [p.10]*[99]

116. Some of the heightened concern over the incidence of hyponatraemia-related deaths in Northern Ireland was generated by the discovery in December 2004 of Claire's death as a hitherto unknown child's death in which hyponatraemia was believed to be implicated (the Verdict on her Inquest on 4th May 2006 subsequently confirmed it). That discovery prompted an almost immediate Parliamentary Question from Iris Robinson (the then MP for Strangford) on 25th January 2005 to Angela Smith MP (the then Secretary of State for Northern Ireland) as to:

> *"… how many dilutional hyponatraemia-related deaths occurred in the Province in each of the last 20 years."*[100]

117. The answer was provided on 27th January 2005 by a table showing 6 deaths where the primary cause of death was 'hyponatraemia'/'fluid overload' and 55 deaths where an associated or secondary cause of death was 'hyponatraemia'/'fluid overload'.[101] As a result Mr. Chairman you wrote to the Department seeking the number of deaths in Northern Ireland in the last 25 years in which hyponatraemia had been identified as a primary or secondary cause of death.[102]

118. It also led to an announcement by you Mr. Chairman during the Procedural Hearing on 3rd February 2005 that: [103]

> *"Another issue which we want to address is what is the frequency of death as a result of hyponatraemia in Northern Ireland. Our understanding from figures which we have received recently from the Department is that in the last 20 years, there have been eight deaths which have been registered as directly attributable to*

98 Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005
99 Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005-065
100 Parliamentary Question from Iris Robinson MP - Ref: 073-019
101 Answer to Parliamentary Question from Iris Robinson MP – Ref: 073-019-093
102 Letter from the Chairman to the Department dated 27th January 2005 – Ref: 303-061-819
103 Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005-055

hyponatraemia; but that there have been 55 deaths registered with hyponatraemia as a secondary or contributory factor and 16 of those deaths were registered in 2002 and 2003. We want to inquire whether this is in keeping with equivalent figures for the rest of the United Kingdom; we want to inquire whether this is in keeping with other European countries; and whether it is or is not equivalent to other countries, is there any extent to which such deaths are avoidable." [p.11][104]

(Emphasis added)

119. I will return to the Inquiry's investigation into the incidence of hyponatraemia-related deaths in Northern Ireland and how it compares with the rest of the UK and Europe as, like other issues, it has not proved straightforward to investigate.

120. Another early 'broad issue' identified by you Mr. Chairman was the extent to which the risks of 'hyponatraemia' and the matters addressed in the Hyponatraemia Guidelines issued by the Department in 2002 were, or could reasonably have been expected to be have been, known to clinicians in Northern Ireland at the time of the treatment and deaths of Adam, Lucy and Raychel in 1995, 2000 and 2001 respectively. You made it quite clear Mr. Chairman at the Progress Hearing on 23rd June 2005 that:[105]

"We will also be looking at the education and training and at the continuing education and training of nurses and doctors [p.15]" [106]

121. I will deal later with how the Inquiry has pursued the investigation into that issue.

Progress of the work:

122. A first task for the Inquiry was to secure the relevant documents.

123. From December 2004, requests were sent to: (a) the Department (including the Chief Medical Officer's Office); (b) Royal Group of Hospitals HSST, (c) Sperrin Lakeland HSCT, (d) Altnagelvin HSST, (e) Coroner for Greater Belfast, (f) Ulster Television; and (g) the families of Adam, Lucy and Raychel. By February 2005 the Inquiry had received over 80 lever arch files.[107]

124. Thereafter the Inquiry published its initial procedures on the Inquiry's dedicated website dealing with: (a) 'Procedure of the Inquiry & Related

104 Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005
105 Transcript of the Public Hearing on 23rd June 2005 – Ref: 303-006-116
106 Transcript of the Public Hearing on 23rd June 2005 – Ref: 303-006-130
107 Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005-055

Matters', (b) 'Interested Parties', and (c) 'Context for the Involvement of Experts'.[108]

125. In order to assist the Inquiry with its work a team of expert Advisors was engaged and international experts from America, Canada and Australia were appointed to 'peer review' their work. Their professional details are included in Protocol No.4 on Experts,[109] which is published on the Inquiry's website. In summary their expertise includes: (a) Paediatric Anaesthesia, (b) Paediatrics, (c) Paediatric Intensive Care Nursing, (d) Health Service Management and Patient Safety.

126. One of the first tasks for the Advisors was to assist the Inquiry with the development of a 'List of Issues' to guide the investigation necessitated by the Terms of Reference as interpreted by the Chairman. The first List of Issues was published on the Inquiry's web site in June 2005.[110]

127. The scale of the investigation indicated in them was evident and shaped by the following factors:

(i) The clinical issues related to the care and treatment of Adam, Lucy and Raychel and the communications with their families.

The Children were all admitted with very different medical conditions, at different times and into different hospitals and they died in a period spanning from November 1995 to June 2001.

A proper assessment of the care and treatment they received on their admission, as required by the first part of the Terms of Reference could necessitate, in some instances, considering their previous clinical history, which in the case of Adam involves medical notes and records going back to when he was just a few months old and at the Ulster Hospital.

(ii) The management and governance issues relating to those clinical issues require the practices, procedures and systems in place over a lengthy period to be considered. In the case of the education and training of the clinical staff treating Adam, it amounts to a period from approximately 1975. Whereas in the case of the level of compliance with guidelines on hyponatraemia, it involves a period spanning 2002 to the present day.

In addition, and in relation to the events following the deaths of the Children, it meant investigating the practices of three separate hospitals, their respective Trusts and Area Boards, as well as the Department itself.

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108 'Procedure of the Inquiry & Related Matters' – Ref: 303-016-298; 'Interested Parties' – Ref: 303-017-306; and 'Context for the Involvement of Experts' – Ref: 303-018-308

109 Protocol No. 4 on Experts – Ref: 303-019-313

110 Initial List of Issues – Ref: 303-020-323

In particular, and as all three children ended up at the RBHSC, which is Northern Ireland's premier paediatric hospital and a teaching hospital, it would mean at least investigating the practices in place as at Adam's admission in November 1995 up to present day.

Further it would require an investigation into the reporting and management structure within the hospitals, Trusts and Area Boards, together with the dissemination of information amongst clinicians in different hospitals and the institutional linkages between the different Trusts, Area Boards, Department, Chief Medical Officer, Coronial Service and the Medical School at Queen's University Belfast.

(6) PSNI investigations

128. Shortly after the Inquiry was established, the Police Service of Northern Ireland ("PSNI") commenced an investigation into Lucy's death. In January 2005, Mr. Chairman the PSNI outlined the position to you as:

(i) It was estimated that their investigations would be completed in time for the file to be with the Director of Public Prosecutions by mid-April 2005. However, it was explained that there were issues that might delay progress such as uncovering evidence of 'an attempt to pervert the course of justice', which would require a more detailed examination of the very large number of documents released by the Sperrin and Lakeland Trust.

(ii) The PSNI was concerned that the Inquiry's investigation into the circumstances surrounding Lucy's death might compromise their investigation and therefore they wished the Inquiry to suspend its work on Lucy's case pending the completion of that investigation.

(iii) There were no plans to investigate the death of either Adam or Raychel and therefore the PSNI had no such objection to the Inquiry's work continuing in those cases.

129. Mr. Chairman, you therefore excluded from its work any investigation into the issues concerning Lucy and continued with its work into the other issues arising out of the Terms of Reference.

130. On 26th July 2005 the PSNI wrote to the Inquiry to advise that:[111]

(i) They were going to start an investigation into Adam's and Raychel's deaths.

111 Letter of PSNI to Chairman of 26th July 2005 – Ref: 094-193-943

(ii) The PPS had confirmed that no decision would be taken about any prosecutions in Lucy's case until all three files were with the DPP.

(iii) They wished the Inquiry: (a) to remove from its website any information that might be relevant to the police investigation, (b) to provide them with all Inquiry Witness Statements, and (c) not to seek any outstanding Inquiry Witness Statements or to generate any further such Witness Statements. In short they wished the Inquiry to suspend its work for the time being.

131. As a consequence a Press Release[112] was issued explaining the position and a Public Hearing convened for 7th October 2005. Mr. Chairman you announced at that Public Hearing that the work of the Inquiry was being suspended until you received the 'all clear' from the PSNI.[113]

(7) The intervening period

132. In the intervening period from 7th October 2005 until the Inquiry resumed its work in 2008, there were a number of significant developments.

Continuation of the PSNI investigations:

133. The PSNI investigations continued in the three cases of Lucy, Adam and Raychel. In addition, the cases of Claire and Conor also came to the attention of the PSNI and they commenced investigations into Claire's death in July 2005.[114]

134. On 20th October 2006, almost exactly a year after the Inquiry had suspended its work, the Public Prosecution Service (PPS) took the decision that the available admissible evidence was insufficient to meet the test for a prosecution against Dr. O'Donohoe and others for 'gross negligence manslaughter of Lucy and related offences'. Subsequently the PPS took the same decision in relation to Adam's case and on 1st February 2008 the PPS decided not to proceed with any prosecutions against anyone involved in Raychel's and Claire's cases.

135. In addition the PSNI decided not to proceed further with any investigations into Claire's death. Thereafter, in August 2008 the PSNI took the decision not to pursue any further investigations into Conor's death. Accordingly, his case was not referred to the PPS.

112 Press Release – Ref: 303-021-327
113 Transcript of hearing on 7th October 2005 – Ref: 303-007-159
114 E-mail from DS Cross to DI Nicholl re: death of Claire Roberts – Ref: 097-028-271

GMC and NMC prosecutions:

136. The Inquiry has also operated alongside investigations by the General Medical Council ("GMC") and the Nursing and Midwifery Council ("NMC") into the conduct of certain clinicians involved in some of the Children's cases. Those cases proceeded whilst the Inquiry's work was suspended and some of them are still ongoing. Mr. Chairman, in order not to fragment matters too much, I will explain here the current position in respect of those cases even though some of the developments occurred after the resumption of the Inquiry's work.

137. The first of those investigations was instigated by a report from the Coroner to the GMC on 23rd February 2004 following the conclusion on 19th February 2004 of the Inquest into Lucy's death. The referral concerned the conduct of Dr. Jarlath O'Donohoe and Dr. Amer Malik and was prompted by what the Coroner described as his *"very serious concerns about the quality of the medical care Lucy received whilst a patient in the Erne Hospital"*.[115] The result of those investigations was that on 27th September 2008 the case against Dr. Malik was cancelled.[116] On 30th October 2009, the Fitness to Practise Panel of the GMC found Dr. O'Donohoe guilty of serious professional misconduct.[117]

138. Mr. and Mrs. Ferguson made a formal complaint to the GMC on 6th November 2004[118] about a number of clinicians and officials:
- Dr. Henrietta Campbell (Chief Medical Officer for Northern Ireland over the relevant period),
- Dr. Murray Quinn (Consultant Paediatrician, Altnagelvin Hospital),
- Dr. Donncha Hanrahan (Consultant Paediatric Neurologist, RBHSC),
- Dr. John Jenkins (Consultant Paediatrician, Antrim Area Hospital and Department of Child Health, Queen's University Belfast),
- Dr. Geoffrey Nesbitt (Clinical Director of Critical Care, Altnagelvin Hospital)
- Dr. James Kelly (Medical Director, Sperrin and Lakeland Trust).

139. The Fergusons' complaint concerned what they regarded as a failure of those doctors to reveal the truth in the investigations into Lucy's death. They believed that the death of their daughter Raychel: *"could have been avoided if Lucy Crawford's death had been properly and independently investigated in 2000"*.

140. The case against Dr. John Jenkins and that against Dr. Geoffrey Nesbitt were closed on 23rd January 2009 and 3rd December 2009 respectively following decisions that no further action should be taken.[119] The case against Dr. Campbell was concluded on 27th May 2010 on the basis that no further action

115 Coroner's letter to the GMC dated 23rd February 2004 – Ref: 013-037-142
116 Decision of Professor Roger Green, Investigation Committee – Ref: 111-002-003 and Ref: 111-020-301
117 Decision of the Fitness to Practise Panel – Ref: 303-022-328
118 Fergusons' letter of 6th November 2004 to the GMC – Ref: 068-013-022
119 Case Examiner's reasons - Ref: 103-029-070, Ref: 103-012-028

should be taken but that she should *"reflect on this decision and the concerns expressed by the complainants"*.[120] The basis for those concerns forms part of the Inquiry's investigations.

141. The case against Dr. Hanrahan was concluded on the 5th October 2010 when he was notified that that no further action would be taken but that he should "*reflect on the lessons to be learnt from this case and to ensure that the Coroner is informed of the outcome of any hospital post-mortem in such circumstances in future.*" The case against Dr. Kelly is continuing.

142. On 9th November 2011, the GMC informed the Inquiry that Dr. Quinn had applied for 'voluntary erasure'. If granted, that would bring the case against him to an end with no findings but he would not be able to practise in the UK. He could subsequently apply to restore his name to the medical register but if he did so any outstanding fitness to practise issues would need to be addressed first. On 15th December 2011, the GMC refused the application for voluntary erasure on the basis that it was not in the public interest to dispose of his case in that way.[121] As a consequence, the case against Dr. Quinn is continuing.

143. There have been two sets of complaints to the NMC about the conduct of nurses.

144. The first set concerned complaints made in October 2004 by Lucy Crawford's parents in respect of Bridget Swift, Sally McManus, Bridget Jones and Teresa McCaffrey and their involvement in Lucy's case. Those complaints were all investigated in 2007 and closed in January 2007 on the basis of there being no case to answer.[122]

145. The other complaint was made in December 2009 by Ms. Judith Mitchell, Conor's grandmother, about Ruth Bullas and her involvement in Conor's case. On 13th July 2011, the Conduct and Competence Committee panel of the NMC found Ruth Bullas guilty of professional misconduct and her fitness to practise impaired. The first of the three charges concerned the failure to: *"document in the nursing notes, the reports you received from patient A's mother and grandmother that they had witnessed patient A suffering from seizures"*.[123] The second concerned a failure to escalate to a senior member of staff for a second opinion, the reports of such activity. The panel accepted the evidence of Sister Irene Brennan that no one had reported any seizures, spasms or twitchings to her concerning Conor and that if she had been informed of that type of activity she would have attended Conor herself. It found as part of its reasons for the finding of impairment:

120 Case Examiner's reasons - Ref: 104-029-560
121 GMC letter to Desmond J Doherty & Co Solicitors of 15th December 2011 – Ref: 303-023-341
122 NMC letter to the Inquiry of 2nd March 2010 – Ref: 303-024-343
123 NMC Reasons for the Substantive Hearing of the Conduct and Competence Committee – Ref: 303-025-344

> *"Health care records are a tool of communication within the team. You must ensure that the health care record for the patient … is an accurate account of treatment, care planning and delivery … It should provide clear evidence of the care planned, the decisions made, the care delivered and the information shared."* [124]

146. A 'striking off Order' was made.[125] The panel stated as part of its reasons for the sanction imposed:

> *"… responsibility for the deficiencies in the care provided to Conor at Craigavon Area Hospital should [not] be borne by her [Ruth Bullas] alone. The evidence before the panel revealed further wide-ranging and systemic deficiencies in Conor's treatment and care. These included the fact that the Registrant was delegated responsibility for Conor's nursing care with little or no ongoing support despite her lack of experience and the fact that she had not yet completed her preceptorship, inadequate handovers, briefings and reporting processes, a failure to provide Conor with nursing staff who were sufficiently and suitably qualified, and a lack of timely access to paediatric facilities and expertise."*
>
> (Emphasis added)

147. Whilst Mr. Chairman you have determined that the Inquiry is not investigating the cause of Conor's death and the conduct of the nurses or other clinicians in relation to his demise, you have nonetheless determined that the Inquiry is investigating the issue of record keeping. Accordingly, the Inquiry will investigate the significance (if any) of the findings and observations made by the panel in Ruth Bullas' case in relation to the knowledge of the nurses at Craigavon Area Hospital of appropriate record keeping and the Hyponatraemia Guidelines, together with the systems that the hospital instituted to introduce the guidelines, provide training on them and then ensure that they were being followed.

Alert No.22:

148. On 28th March 2007, the NHS National Patient Safety Agency (NPSA) issued its Alert No.22 for 1 month to 16 year olds[126] recommending the taking of action by 30th September 2007 to *"to minimise the risk of hyponatraemia in children"*.

149. That action by the NPSA was the culmination of a process that had been instigated as far back as 25th September 2001 by Dr. Taylor who reported to its predecessor organisation, Medicines Control Agency through the 'yellow card scheme', a suspected adverse drug reaction in respect of intravenous Solution 0.18%/4% glucose and the death of Raychel on 10th June 2001.[127] It was

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124 NMC Reasons for the Substantive Hearing of the Conduct and Competence Committee – Ref: 303-025-347
125 NMC Reasons for the Substantive Hearing of the Conduct and Competence Committee – Ref: 303-025-349
126 NPSA Alert No.22 of 28th March 2007 – Ref: 303-026-350
127 Suspected Adverse Drug Reactions Yellow Card Ref: WS-008/1 p.17-18

welcomed by the Medicines Control Agency as: *"an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of medicines"*.[128]

150. The progress of the investigation is summarised by Dr. Katherine Cheng of the Medicines Control Agency in her letter to Dr. Taylor of 26th November 2001.[129] The Working Group on Paediatric Medicines (the Working Group) conducted a review of 4% dextrose/0.18% saline and considered that although hyponatraemia is a risk to children during the use of 4% dextrose/0.18% saline, electrolyte imbalance is a risk with the use of all intravenous solutions.

151. The Working Group noted at its meeting on 21st November 2001 that careful monitoring of children after surgery is crucial and in particular, care should be taken not to overload patients with intravenous fluids if they were oliguric as part of the normal response to surgery. However, the Working Group considered that the issue of hyponatraemia related more to clinical practice rather than to medicines regulation and advised that there should be no changes to product information.

152. Then in 2006 Way and others published in the British Journal of Anaesthesia the results of a survey that had been carried out to assess the practice of postoperative intravenous fluid prescription by paediatric anaesthetists. The results showed, amongst other things, that 75.2 percent of anaesthetists prescribed hypotonic dextrose saline solutions in the post operative period. The authors suggested that national guidance was required, which led to Alert No.22 being issued.

153. Following on from the issue of Alert No.22, on 27th April 2007 Dr. Michael McBride (then Chief Medical Officer for Northern Ireland), Dr. Norman Morrow (Chief Pharmaceutical Officer for Northern Ireland) and Martin Bradley (Chief Nursing Officer for Northern Ireland) sent a joint letter to the Chief Executives of HSC Trusts informing them that:[130]

> *"HSC organisations are required to implement the actions identified in the Alert by 30 September 2007. Independent sector providers which administer intravenous fluids to children will also wish to ensure that the actions specified in the alert are implemented in their organisations within the same time scale."*

154. The actions identified included:
- Removal of 'Solution No.18' from stock and general use in areas that treat children;
- Production and dissemination of clinical guidelines for the fluid management of paediatric patients;

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128 Letter from Medicines Control Agency to Dr. Robert Taylor dated 1st October 2001 Ref: WS-008/1 p.16
129 Letter from Dr Katharine Cheng to Dr. Robert Taylor dated 26th November 2001 Ref: 064-010-038
130 Joint letter of 27th April 2007 – Ref: 303-028-367

- Provision of adequate training and supervision for all staff involved in the prescribing, administering and monitoring of intravenous infusions for children;
- Reinforcement of safer practice by reviewing and improving the design of existing intravenous fluid prescriptions and fluid balance charts for children
- Promotion of the reporting of hospital acquired hyponatraemia incidents via local risk management reporting systems;
- Implementation of an audit programme to ensure NPSA recommendations are adhered to.

155. Alert No.22, the circumstances in which it came about and the response to it will be addressed in detail later on. However, as can immediately be seen, it went further than the Hyponatraemia Guidance in that it recommended the removal of 'Solution No.18' from stock and general use in areas that treat children.

156. For completeness, the Commission on Human Medicines recently had a further review carried out of the use of Solution No.18 and the Inquiry awaits the publication of its results and their implications, if any, for its investigations.

157. The implementation required by Alert No.22 is to be found in the guidance published by the Department in September 2007, 'Parenteral Fluid Therapy (1 month – 16 years): Initial Management Guideline'.[131] The title of that guidance was amended and the guidance re-issued in February 2010 to, 'Parenteral Fluid Therapy for Children & Young Persons (aged over 4 weeks & under 16 years): Initial Management Guideline.'[132] That guidance is more comprehensive in respect of the management of fluid therapy that that provided in the Hyponatraemia Guidelines. The introduction of that guidance into hospitals in Northern Ireland and the effectiveness of the systems in place for monitoring compliance with them are matters being investigated by the Inquiry.

158. Again for completeness, prior to the publication of Alert No.22 the Chief Medical Officer wrote on 8th July 2004 to Dr. Jack McCluggage, who was the Postgraduate Dean of Medicine at Queen's University, Belfast at the time, to request that he consider *"training in Fluid Administration"* a priority.[133] Dr. McCluggage forwarded that request on to Senior Trainers within Paediatrics and other Medical Specialities on 20th July 2004.[134]

159. Dr. McCluggage remained the Postgraduate Dean until October 2004 when he was succeeded by Dr. Terry McMurray who wrote on 14th June 2005 to all Directors of speciality training committees, all Postgraduate Clinical Tutors, all Education Co-ordinators and to the Director of Postgraduate General Practice Education requesting evidence about training being delivered, and how it had

131 Department's September 2007 Guidance - Ref: 303-059-817
132 Department's amended Guidance issued in February 2010 - Ref: 303-060-818
133 Letter dated 8th July 2004 from the CMO to Dr. Jack McCluggage – Ref: 075-007-017
134 Dr. McCluggage's letter of 20th July 2004 – Ref: 303-054-766

changed.[135] Dr. McMurray then wrote on 21st May 2008 to all the Heads and Deputy Heads of the Schools of many of the key areas of practice including all Foundation Doctors specifically referring to the fact that the *"development of Hyponatraemia in previously well children undergoing surgery or with mild illness may not be well recognised by clinicians"*.[136] He enclosed the 'Regional Paediatric Central Fluid Therapy Chart' developed by the Department of Health as well as a 'Workforce Competence Statement' developed by the National Patients' Safety Agency to assist in 'implementing and embedding the training'. Dr. McMurray stressed: *"It is very important that training in this area is addressed by your speciality and I would be grateful if you can inform me as soon as possible how you mean to address this issue"*.

160. On 30th June 2008 the Associate Dean for Foundation Training contacted all Foundation Doctors and their educational supervisors, to advise them that completion of the BMJ e-learning module on Hyponatraemia was mandatory and that proof would be required of completion of the module within four weeks of them starting their F1 post.[137]

161. The precise communications, if any, amongst the Hospitals/Trusts, Department, Coroner and University in relation to the risks associated with low sodium and poor fluid management and their significance is something that is being investigated by the Inquiry.

RQIA:

162. The HPSS Regulation and Quality Improvement Authority (RQIA) was established by the Health and Social Personal Services (Quality Improvement & Regulation) (Northern Ireland) Order 2003. It has a role in relation to the inspection, regulation, investigation and review of performance within Health and Social Service organisations against five 'quality themes':
    - Corporate leadership and accountability;
    - Safe and effective care;
    - Accessible, flexible and responsive services;
    - Promoting, protecting and improving health and social well-being;
    - Effective communication and information.

163. The RQIA was asked to carry out an independent review to provide assurance to the Minister with regards to implementation of recommended actions outlined within the NPSA Alert No.22. In addition, the dissemination of the clinical guidelines and wall chart throughout HSC Trusts and independent hospitals was also reviewed.

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135 Dr. McMurray's letter of 14th June 2005 – Ref: 303-055-767

136 Dr. McMurray's letter of 21st May 2008 – Ref: 303-056-768

137 Email of 20th June 2008 from Dr. Terry McMurray forwarding an email from the Foundation Programme dated 2nd June 2008 - Ref: 303-057-769 and 770

164. The RQIA review Team reported in April 2008, 'Summary Report following Validation Visits to Trusts and Independent Hospitals throughout Northern Ireland'.[138] Thereafter the RQIA provided its full Report on 'Reducing the risk of Hyponatraemia when Administering Intravenous Fluids to Children' dated September 2008.[139] It was acknowledged in those Reports that all the Health and Social Care Trusts and independent hospitals that had been visited had undertaken considerable work to reduce the risks of hyponatraemia when administering intravenous fluids to children. Evidence was also found in all the areas visited of a commitment to achieve full compliance with the recommendations made in the NPSA Patient Safety Alert No.22 and to disseminate the Paediatric Parenteral Fluid Therapy clinical guidelines and wall charts.

165. However, some concern was expressed as to:

(1) The need to ensure that measures are consistently applied in adult wards where children are treated;
(2) The continued presence of Solution No.18 in stock on site;
(3) That the provision of fluid management training for non-paediatric staff caring for older children on adult wards was poor across all organisations visited by the review team;
(4) That there was little evidence of a reporting culture for incidents relating to intravenous fluids and hyponatraemia.

166. The RQIA review team published a follow-up report in May 2010, 'Report of actions taken by HSC Trusts and Independent Hospitals to implement Recommendations made in the Report: Reducing the Risk of Hyponatraemia when Administering Intravenous Fluids to Children' (RQIA, June 2008)'.[140] They found that Solution No.18 had been completely removed from all clinical areas where children were treated.

167. In addition, they found that members of staff were aware of the Clinical Guidelines and that nursing staff had attended training in paediatric fluid administration. There was some concern that generic adult fluid balance charts were still being used for some paediatric patients rather than dedicated paediatric equivalents and over the continuing risk associated with the administration of intravenous fluids to children on adult wards and clinical areas.

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138 RQIA 'Summary Report following Validation Visits to Trusts and Independent Hospitals throughout Northern Ireland' dated April 2008 – Ref: 303-058-771

139 RQIA Report on 'Reducing the risk of hyponatraemia when administering intravenous fluids to children' dated September 2008 – Ref: 303-030-376

140 RQIA Report of actions taken by HSC Trusts and Independent Hospitals to implement Recommendations made in the Report: Reducing the Risk of Hyponatraemia when Administering Intravenous Fluids to Children' (RQIA, June 2008)' dated May 2010 – Ref 303-031-415

168. That latter issue, which is referred to at page 15 of the May 2010 Report was a matter of concern in Conor's case when in May 2003 he was treated in an adult unit at Craigavon Area Hospital.

169. The extent to which the NPSA Alert No.22 has been implemented by Trusts and hospitals in Northern Ireland, and how they have responded to the reports of the RQIA, are issues to be considered by the Inquiry.

(8) Resumption of the Work of the Inquiry in 2008

170. The work of the Inquiry formally resumed with a Progress Hearing on 30th May 2008.[141] You announced then Mr. Chairman that there were to be no criminal prosecutions in any of the cases and therefore the way was clear for the Inquiry to resume its work. Mr. Chairman you also explained that the intervening years had brought about changes in that:
- The Inquiry team had changed;
- Mr. and Mrs. Crawford did not wish the Inquiry to continue to investigate Lucy's case;
- The work of the Inquiry was to be expanded to include Claire's case and aspects of Conor's case.

Addition of Claire and Conor:

171. In the exercise of your discretion Mr. Chairman, you added the case of Claire and aspects of Conor's case. Both deaths had come to your attention Mr. Chairman after the start of the Inquiry.

172. The Inquest into Claire's death took place on 4th May 2004 and hyponatraemia was found to be a contributory factor in her death.

173. The basis upon which Claire's case was included in the work of the Inquiry was explained by you Mr. Chairman during the Public Hearing on 30th May 2008:[142]

> *"In broad terms, however, my concern is about the apparent conflict between the initial explanation given to the Roberts' family and the subsequent explanation given to them after, but only after, they contacted the Royal following the television broadcast. I am also concerned whether more should have been learned from Adam's death and inquest and whether there should therefore have been better fluid management in the Royal for Claire a relatively short time later." [p.4]*

141 Transcript of Progress Hearing on 30th May 2008 – Ref: 303-008-173
142 Transcript of Progress Hearing on 30th May 2008, p.4 – Ref: 303-008-176

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

(i) Claire's care and treatment from her admission to the RBHSC on 21st October 1996 until her death in PICU on 23rd October 1996.

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

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

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

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

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

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

175. The Inquest into Conor's death took place on 9th June 2004. It did not conclude that hyponatraemia played a role in Conor's death. Nevertheless, there were criticisms of the fluid management and the record-keeping. Concerns were also raised about the extent to which the Hyponatraemia Guidelines had been followed and the significance of Conor being admitted to an adult ward even though he had a child-like physique.

176. Ultimately, on 4th February 2010[143] the Chairman decided to include certain elements of Conor's case into the Inquiry's work on the following basis:

> *"It is obviously a matter of concern if guidelines which have been introduced as a result of a previous death or deaths and which are aimed at avoiding similar events in the future, are not properly communicated to hospital staff and followed. It is relevant to the investigation to be conducted by the Inquiry whether and to what extent the guidelines had been disseminated and followed in the period since they were published. Another matter of interest is whether the fact that Conor was being treated on an adult ward rather than a children's ward made any difference to the way in which it appears that the guidelines may not have been followed.*
>
> *Accordingly, the Inquiry will investigate the way in which the guidelines had been circulated by the Department, the way in which they had been made known to hospital staff and the steps, if any, which had been taken to ensure that they were being followed. While this is an issue of general importance, it will be informed by an examination of the way in which the guidelines had been introduced and followed in Craigavon Area Hospital by May 2003." [p.1]*

177. Conor's case is therefore being investigated in relation to issues concerned with the Hyponatraemia Guidelines, for example issues such as whether the rate, choice and volume of fluid administration was appropriate in Conor's case, whether his fluid management was adequately monitored and recorded/ documented and whether if his fluid management was inadequate, what was done about it both at Craigavon Area Hospital and in the RBHSC from the perspective of governance and lessons learned.

Revised Terms of Reference:

178. On 26th May 2008 Mr. and Mrs. Crawford asked to have Lucy's case removed from the work of the Inquiry. They had their own personal and family reasons for doing so.

179. The then Minister of Health, Michael McGimpsey acceded to that request, which required a revision to the original Terms of Reference. On 17th November

143 Chairman's Note of 4th February 2010: 'Conor Mitchell' – Ref: 303-032

2008, he published Revised Terms of Reference, which excluded entirely Lucy's name:[144]

> *"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."*[145]

180. The then Minister informed you Mr. Chairman that he had not revised the Terms of Reference to add the names of Claire and Conor as it was unnecessary since you had the discretion to examine and report on any other matter that you saw fit and that you have already exercised your discretion in relation to the investigation of their cases.

181. The interpretation of those Revised Terms of Reference was left to you Mr. Chairman on the basis, as stated by the then Minister in his letter dated 4th December 2009, [146] that he was:

> *"… mindful of the independence of the Inquiry and the fact that your investigation may extend to officials, past and present, of my Department"*

182. Mr. Chairman, you then issued a consultation paper on 10th June 2009[147] and on 4th February 2010[148] published your decision, which was that:

> *"… 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*

144 Letter from the Minister to the Chairman dated 17th November 2008 – Ref: 303-033-460
145 Revised Terms of Reference – Ref: 303-034-461
146 Letter from the Minister to the Chairman dated 4th December 2009 – Ref: 303-035-462
147 Consultation Paper of 10th June 2009 - Ref: 303-036-463
148 Chairman's decision of 4th February 2010 - Ref: 303-037-466

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."[149]

183. Therefore, issues such as the steps taken by the RBHSC to ascertain the cause of Lucy's death, why a Coroner's post-mortem was not carried out and the adequacy of the Erne Hospital's investigation into her death, were all matters to be investigated by the Inquiry because of the possible impact they might have on the care and treatment provided to Raychel at the Altnagelvin Area Hospital just over a year later and her subsequent death at the RBHSC.

List of Issues:

184. Bringing together all of those developments, the Revised Terms of Reference and the exercise of your discretion Mr. Chairman in 2008 and 2010, has required the following matters to be investigated: [150]

(i) The care and treatment of Adam, Claire and Raychel, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids.

(ii) The circumstances of the death of Conor Mitchell[151] in the context of the guidelines on fluid management in children.

(iii) The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of:
   (a) Adam;
   (b) Claire;
   (c) Lucy[152] (in relation to the failure to identify the correct cause of her death and the alleged Sperrin and Lakeland cover up);
   (d) Raychel;
   (e) Conor[153] (in relation to the guidelines on fluid management in children).

(iv) The communications with and explanations given to the families by the relevant authorities, as well as the communications with and explanations given to others by the relevant authorities.

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149 Consultation Paper of 10th June 2009 - Ref: 303-036

150 Chairman's announcement at the Public Hearing on 30th May 2008, p.4 - Ref: 303-008-173 (in respect of Claire) and Chairman's announcement by letter dated 4th February 2010 – Ref: 303-037-466 (in respect of Conor)

151 Chairman's announcement at the Public Hearing on 30th May 2008, pgs.4-5 - Ref: 303-008-173

152 Chairman's decision of 4th February 2010 – Ref: 303-037-466

153 Chairman's announcement at the Public Hearing on 30th May 2008, p.5 - Ref: 303-008-173

(v) Recommendations to the Northern Ireland Department of Health, Social Services and Public Safety.

185. Those issues are reflected in the Inquiry's List of Issues. The List of Issues is a working document that is updated and revised as appropriate. The current List of Issues was published by the Inquiry on 14th February 2012.[154]

186. Taking first the clinical matters that are associated with the care and treatment provided to the Children, your interpretation Mr. Chairman of the Revised Terms of Reference has translated into the following by way of example:

(i) The underlying principles, the calculations, and the assumptions made, in relation to the prescription of intravenous fluids, before, during and after Adam's renal transplant surgery.[155]

(ii) The adequacy and frequency of the tests undertaken during Claire's admission and the tests which could have been carried out on her between 21st and 23rd October 1996 including blood and urine tests, a CT scan, an electro-encephalogram (EEG) and a MRI scan. [156]

(iii) How the cause of Lucy's death was established and agreed, including how and when the clinicians responsible for Lucy's treatment discussed and agreed on a cause of her death. [157]

(iv) Whether there was a delay on the part of the surgical team in responding to calls from the nursing team to see Raychel and if so, why that delay occurred, and whether nursing staff should have taken any further steps to secure the prompt attendance of a member of the surgical team. [158]

(v) Whether the nursing and medical teams who cared for Raychel adequately monitored her condition, and whether they provided her with appropriate treatment, both before and after she suffered a tonic seizure. [159]

(vi) To what extent the care and treatment which Conor received, both in Craigavon Area Hospital and the RBHSC, was consistent with the then teaching/training on fluid management and record keeping, in particular the Guidelines. [160]

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154 List of Issues published on 14th February 2012 – Ref: 303-038-478
155 List of Issues published on 14th February 2012 – Ref: 303-038
156 List of Issues published on 14th February 2012 – Ref: 303-038
157 List of Issues published on 14th February 2012 – Ref: 303-038
158 List of Issues published on 14th February 2012 – Ref: 303-038
159 List of Issues published on 14th February 2012 – Ref: 303-038
160 List of Issues published on 14th February 2012 – Ref: 303-038

187. Turning now to 'management and governance', it can be seen Mr. Chairman that your interpretation of the Revised Terms of Reference has meant a consideration of such issues at all levels from the Department (including the Chief Medical Officer) to the relevant Trusts and Boards, down to the management of the individual Hospitals and right down to the specific Hospital Divisions/Clinical Directorates. Those considerations deal, potentially, with a broad spectrum including the formulation of policy and guidance, the development of health strategy, and the establishment of governance structures, systems and procedures so as to enable the standard of healthcare being delivered to be properly monitored, audited, evaluated and improved. Examples of the extent of the range are:

(i) The procedures and practices that existed in Northern Ireland at the time of the Children's deaths for the reporting and dissemination of information to the Department of Health, Social Services and Public Safety of Northern Ireland (DHSSPS), and the medical community in general, of unexpected deaths in Hospital and outcomes of Coroners' Inquests. [161]

(ii) The teaching and training to medical students and student nurses in Northern Ireland on fluid management (with particular regard to hyponatraemia), record keeping and drug prescribing/administration as part of their qualification and to doctors and nurses as part of their induction, training and continuous professional development. [162]

(iii) The guidelines, procedures and practices that existed within the Altnagelvin Area Hospital, Craigavon Area Hospital and the RBHSC governing the provision of information to the parents of paediatric patients. [163]

(iv) The system of protocols, procedures and practices by which hospitals in Northern Ireland 'code' the causes of deaths and adverse incidents. [164]

(v) The accuracy and quality of information provided by the treating clinicians to the pathologists for post-mortem. [165]

Institutions involved:

188. In order to appreciate the scope of the investigation that has been and is being carried out, I should say something about the institutions and personnel involved.

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161 List of Issues published on 14th February 2012 – Ref: 303-038
162 List of Issues published on 14th February 2012 – Ref: 303-038
163 List of Issues published on 14th February 2012 – Ref: 303-038
164 List of Issues published on 14th February 2012 – Ref: 303-038
165 List of Issues published on 14th February 2012 – Ref: 303-038

189. At the time of Adam's admission to the RBHSC on 26th November 1995, Northern Ireland was under a period of 'direct rule' from Westminster with the Secretary of State for Northern Ireland responsible for the Departments of the Northern Ireland government. The Secretary of State for Northern Ireland at that time was Sir Patrick Mayhew. He was also in office at the time when Claire was admitted to the RBHSC on 21st October 1996. He was succeeded in 1997 by Mo Mowlam who was in turn succeeded in 1999 by Peter Mandelson.

190. Under 'direct rule', the Northern Ireland Department of Health was under the remit of the Parliamentary Under-Secretary of State at the Northern Ireland Office. The Minister responsible for health care in Northern Ireland at the time of Adam's admission was Malcolm Moss. The structure of the health service in Northern Ireland at the time of Adam and Claire's admissions to the RBHSC and their deaths there in 1995 and 1996 respectively is as shown in: 'Structure of the Health Service in Northern Ireland (pre-2007)'[166] and on the map: 'Health and Personal Social Services Northern Ireland'.[167] The present structure is as shown in: 'Structure of the Health Service in Northern Ireland – Commissioning of Services'.[168]

191. As you will appreciate Mr. Chairman, things changed fundamentally with the signing of the Belfast Agreement on 10th April 1998. It entered into force on 2nd December 1999 and ushered in a period of devolution. The significance of that so far as this Inquiry is concerned is that it resulted in the Departments (Northern Ireland) Order 1999, which established the Department of Health Social Services and Public Safety as a 'devolved Department'. The first Minister of the Department was Bairbre de Brún. Devolution has been suspended on four occasions starting with 12th February 2000.

192. The Ministers responsible for health and social care in Northern Ireland from 1994 (the year prior to Adam's death) until the present day, including through periods of direct rule are shown in a chart compiled by the Inquiry: 'Ministers responsible for Health and Social Care in Northern Ireland from 1994 to Present Day'.[169] The significance of those periods of direct rule, if any, is a matter that the Inquiry will consider in terms of its impact on any of the issues arising out of the Terms of Reference (or Revised Terms of Reference).

193. In June 2002, the Northern Ireland Assembly Executive launched the Review of Public Administration with a view to putting in place modern, accountable and effective arrangements for public service delivery. The final outcome was announced by the Secretary of State in November 2005. It led to a major reorganisation of health and social care, which was to take place in two phases.

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166 'Structure of the Health Service in Northern Ireland (pre-2007)' - Ref: 303-039-505

167 'Health and Personal Social Services Northern Ireland' – Ref: 300-001-001

168 'Structure of the Health Service in Northern Ireland – Commissioning of Services' - Ref: 303-040-506

169 'Ministers responsible for Health and Social Care in Northern Ireland from 1994 to Present Day' - Ref: 303-041

194. The first phase was the establishment of five new integrated Health and Social Care Trusts with effect from 1st April 2007. They replaced the Trusts that had been in operation during the cases of all of the Children. The original Health and Social Services Boards remained in place until the introduction of the second phase in April 2009 which involved their replacement by the Health and Social Care Board.

195. In addition, seven Local Commissioning Groups (LCGs) were created in April 2007 pursuant to the HSC (Reform) Act (NI) 2009 before being reduced to five with boundaries aligned to those of the Trusts in April 2009. Prior to that re-organisation the four Boards commissioned services from the Trusts. The functions of the LCGs are to assess and plan for current and emerging health and social care needs and to secure the delivery of health and social care to meet those needs.

196. The position as regards the Trusts and the LCGs between April 2007 and April 2009 and from April 2009 onwards is shown in a chart compiled by the Inquiry: 'Boards, Trusts, Hospitals & Commissioning Groups (pre-April 2007 and post-April 2009)'.[170] In addition the intermediate position which operated between 2007 and 2009 is shown on the map: 'Health and Social Care, Northern Ireland: Existing Acute, Local and Mental Health or Learning Disability Facilities'.[171] Whilst the final position is shown on the map: 'Health and Social Care Trust Boundaries showing location of Hospitals'.[172]

197. In broad terms, the function of those organisations, and therefore their relevance to the work of this is Inquiry, is that:

    (i) The Department of Health, Social Services and Public Safety (and its predecessor) has overall authority for health and social care services in Northern Ireland and to allocate government funding for that purpose. That authority includes the formulation of policy and legislation for hospitals.

    (ii) The Health and Social Care Board (and its predecessor Regional Boards) commissions the health and social care services.

    (iii) The five Trusts, of which three are particularly involved in the work of the Inquiry (and their predecessor Hospital Trusts), are responsible for the provision of the health and social care services. Each Trust manages its own staff and services and controls its own budget. The Royal Group of Hospitals Trust is of particular concern to the work of the Inquiry as it

170 'Boards, Trusts, Hospitals & Commissioning Groups (pre-April 2007 and post-April 2009)' - Ref: 303-042-509
171 'Health and Social Care, Northern Ireland: Existing Acute, Local and Mental Health or Learning Disability Facilities' - Ref: 300-002-002
172 'Health and Social Care Trust Boundaries showing location of Hospitals' – Ref: 300-078-149

includes the RBHSC where all the Children received their final care and treatment and ultimately died. The structure of that Trust as it was in 1995 and 1996 when Adam and Claire were admitted to the RBHSC is shown in: 'Royal Group of Hospitals Trust – Organisation Structure 1995/96'.[173] The Royal Group of Hospitals and therefore the RBHSC are now within the Belfast Trust, the structure of which is shown in a chart compiled by the Inquiry: 'Belfast Health & Social Care Trust: Organisation Structure (present day)'.[174]

(iv) The Hospitals within those Trusts is where health and social care services are actually delivered. The work of this Inquiry is particularly concerned with five of those Hospitals:
- RBHSC;
- Belfast City Hospital;
- Erne Hospital;
- Altnagelvin Area Hospital;
- Craigavon Area Hospital.

Personnel involved:

198. Turning now to the actual personnel involved. A large number of persons – clinicians, technicians and administrators - are involved in the investigation of both the 'clinical issues' and the 'management and governance issues'. Of particular relevance to the work of the Inquiry are those who:

(i) Were directly involved in the care of the Children during their final admission to their local hospital and, where relevant, following their transfer to the RBHSC;

(ii) Had the responsibility for communicating with the Children's families in respect of consent, aspects of the Children's care and/or the reason for their death;

(iii) Were involved in the post-mortem investigations into the cause of the Children's deaths and the provision of the Reports on Autopsy/Post-Mortem Reports on the Children;

(iv) Had the authority to require investigations into and reviews of the care and treatment of the Children and their deaths;

(v) Were involved in any such investigations;

173 'Royal Group of Hospitals Trust – Organisation Structure 1995/96' - Ref: 303-043-510
174 'Belfast Health & Social Care Trust: Organisation Structure (present day)' - Ref: 303-044-511

(vi) Were in the Coroner's office and involved in any decision in respect of the holding of an Inquest into any of the Children's deaths and the Coroner for the Inquest into each of the Children's deaths;

(vii) Were and are responsible for the development, implementation, audit, evaluation and revision of health policy, guidance and practices.

199. A number of the clinicians and pathologists were involved in more than one of the children's cases, which may be relevant for the investigation on 'lessons learned' and 'governance'. That raises its own issues, which are matters being investigated by the Inquiry, as to who had relevant knowledge and experience and the impact that should have had on the care provided to the Children and also what happened in the aftermath of their deaths. Those involved in that way in the key disciplines of Anaesthesia, Neurology and Pathology are set out in a chart compiled by the Inquiry: 'Clinicians and Pathologists involved in more than one of the Children's cases'.[175]

200. There is a similar 'overlap' in the case of the management at the Royal Hospitals, of which the RBHSC forms a part. Again, I have singled out the RBHSC as that is the hospital which alone saw and treated all of the Children immediately prior to their death. Mr. William McKee was the Chief Executive when each of the Children was admitted to the RBHSC. The position in relation to the Medical Director and the Nursing and Patient Services Director, which are both Executive Director positions, is a matter being investigated by the Inquiry. So too is the position in respect of the Directors of the key Directorates of: (i) Anaesthetics, Theatre and Intensive Care; (ii) Paediatrics; (iii) Surgical; (iv) Neurosciences; (v) Laboratories; (vi) Radiology; (vii) Medical Administration. That raises questions about the unique opportunities that the Royal Hospitals/RBHSC had for 'lessons learned' and the dissemination of any learning, which are matters being investigated by the Inquiry.

201. In addition to those who were directly involved in the sense just outlined, there are a number of others whose conduct and/or views are relevant to the work of the Inquiry. An example, are those who acted as experts, whether during an Inquest or during the investigations by the PSNI.

202. The evidence of all of those involved (whether directly or indirectly) will be provided in a variety of ways, including:
- Statements they provided to others such as their employer, Depositions given to the Coroner and Statements taken by the PSNI, together with any documentation that they supplied in support of their position;
- Depositions of Experts given to the Coroner together with Reports of experts whether engaged by the Coroner, the families or the PSNI;
- Witness Statements provided to the Inquiry and any documentation supplied in support of their views;

175 'Clinicians and Pathologists involved in more than one of the Children's cases' - Ref: 303-045

- Reports of Experts engaged by the Inquiry;
- Testimony in the course of these Oral Hearings.

(9) How the Work of the Inquiry has been carried out

The Legal Team:

203. The Legal Team comprises me as the Senior Counsel to the Inquiry, Jill Comerton and Martin Wolfe who are both Junior Counsel to the Inquiry, together with David John Reid, Junior Counsel, who has provided invaluable assistance. In addition, there is Anne Dillon, who is the Solicitor to the Inquiry, and Brian Cullen, Assistant Solicitor to the Inquiry.

204. I have also had the assistance of other Solicitors, in particular Fiona Chamberlain who was Solicitor to the Inquiry prior to its resumption in 2008.

Role of the Legal Team:

205. The role of the Legal Team, now that the Oral Hearings have commenced, is in large part (although not exclusively so) to focus on the evidence; to ensure that the examination of witnesses is rigorous and elicits all of the relevant evidence in a way that is not just fair to the witness and to the range of views held by the core participants but also bears in mind the public interest. It is my duty to act impartially, independently from you Mr. Chairman and to act in the public interest.[176]

206. The work of the Legal Team in relation to the evidence has been and is determined by the Inquiry's Revised Terms of Reference and the Lists of Issues that Mr. Chairman you have published.

207. It will be appreciated from what I have said so far Mr. Chairman about the Revised Terms of Reference, the expansion of the Inquiry's work following the addition of the cases of Claire and Conor, and the translation of the Revised Terms of Issues into the published List of Issues, that the consideration of issues of such breadth and depth has been a huge undertaking for the Legal Team and has taken time. Effectively we have been pursuing five inter-linked Inquiries or investigations into both clinical and governance matters.

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[176] Public Inquiries (2011) eds. Beer QC, J, Dingemans QC, J and Lissack QC, R (Oxford), para.4.91 and Justice Dennis O'Connor, 'The Role of Commission Counsel in a Public Inquiry' (2003) 1 Advocates' Society Journal 9

208. It is has been my job, assisted by the other members of the Legal Team, to investigate the evidence relating to the issues that arise from the Revised Terms of Reference for the Inquiry. That is the first part of our work which roughly corresponds to Stages A (Document Gathering)[177] and C (Witness Statements)[178] in the General Procedures which were published on the Inquiry's website.[179]

209. It has also included obtaining and analysing Expert Reports. This has been a particularly taxing exercise where there have been differences of view between eminent Experts. Such differences have made it necessary to test and probe the not only the underlying assumptions made by the Experts but also the clinical and evidential bases of their views. That is a crucial process and it has been time consuming. Unfortunately, it is not yet complete and there are outstanding reports from Experts on both clinical as well as hospital management and governance matters. The will be issued when received in accordance with the procedures that you have established Mr. Chairman.

210. It is a matter entirely for you Mr. Chairman what consideration and weight you place on the various forms of documentary evidence that the Legal Team has presented and will present to you, ranging from the:
    - Background Papers, which seek to provide a context and overview for some of the matters in question; to
    - Publications and guidelines that could or should have informed the conduct of those involved; to
    - Contemporaneous records and documents that may or may not have accurately recorded what was happening; to
    - Statements of those involved and the extent to which they are at variance, whether with each other or with other evidence; to
    - Reports of the various Experts and, again, the extent to which they agree with each other, are consistent with the contemporaneous materials and/or disagree with the views expressed in the Statements of those who were actually involved, whether as clinicians or managers.

211. The second part of the Legal Team's work requires testing that evidence through the questioning of Witnesses and Experts during the Oral Hearings.

212. It is my task, assisted by the rest of the Legal Team, to explore the issues during the Oral Hearings in a probing manner. It is not the task of the Legal Team to develop any particular theory of what happened or to support any particular version of events. Rather, our objective is to try and get to the bottom of what happened and why and to present the evidence to enable you Mr. Chairman to reach the most informed conclusions possible and thereafter to be able to make recommendations directed at improving matters.

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177 'Procedure of the Inquiry & Related Matters' – Ref: 303-016
178 'Procedure of the Inquiry & Related Matters' – Ref: 303-016
179 'Procedure of the Inquiry & Related Matters' – Ref: 303-016

213. Ultimately Mr. Chairman it will be for you to make determinations and findings on the issues arising out of the Revised List of Issues in the light of all of the evidence. That of course, is why it is crucial for me and the rest of the Legal Team to properly adduce for you all of the relevant evidence and to test it in a rigorous and balanced way.

Document gathering:

214. The call for documents has been ongoing since the resumption of the Inquiry's work. The search for documents, which continues, has and is being informed by guidance from the Inquiry's Advisors, from its Experts and from the responses to our requests for Witness Statements.

215. To date the Inquiry has received over 140 files of documents including:
- The Children's medical notes and records;
- Reports, scans, x-rays, photographs, correspondence and other documents generated by or for the hospitals and authorities concerned;
- Depositions from the Inquests and Reports commissioned by the Coroner;
- Documents held by the families of Adam, Claire, Raychel, Lucy and Conor;
- Correspondence and Transcripts from UTV plc;
- Statements from the PSNI investigations and Reports commissioned by the PSNI;
- Documents relating to the GMC proceedings, together with statements and transcripts concerning Dr. Jarlath O'Donohoe's case;
- Documents relating to the NMC proceedings, together with the transcript from Ruth Bullas' case;
- Documents from other bodies and organisations such as: (a) Department of State Pathology, (b) National Patient Safety Agency, (c) NHS Blood and Transplant, (d) Royal College of Paediatrics and Child Healthcare, (e) Medical and Dental Training Agency, (f) Attorney Generals Office, and (g) NHS Greater Glasgow and Clyde;
- Correspondence from DLS providing responses to the Inquiry's requests for information.

216. The Inquiry also received histological slides and other material in relation to some of the Children, which it has provided to its Experts for them to examine and provide Reports.

Publications:

217. The Inquiry has been referred to numerous publications by its Advisors, Experts, Witnesses and the legal representatives of the families. The Legal Team has compiled a bibliography of those publications which is being updated as

further authorities are cited. In addition, the Legal Team has compiled a bibliography of the relevant government and other publications in respect of health care management and governance that are relevant to the Children's cases and the Revised Terms of Reference generally.

Background papers:

218. The early concerns over the content of education and training in relation to fluid management and the incidence of paediatric death in Northern Ireland from hyponatraemia were addressed through commissioning 'Background Papers' from experts, which are published on the Inquiry's website.

219. The Chairman explained the purpose of doing so in relation to education and training during the Public Hearing on 9th March 2011:

> *"The reason for commissioning these papers and then circulating them is that we wanted to obtain a picture of the extent to which nurses and doctors have been taught about hyponatraemia and related issues over the last 30 or so years. The picture, as you will see when you receive the reports, the picture which emerges is a bit patchy, but we wanted to do that because it helps to set a background against which witnesses can be questioned at the oral hearings about the extent to which they were aware of hyponatraemia and what training they had received." [p.]*[180]

220. The Inquiry engaged Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust[181] and Professor Sir Alan Craft, Emeritus Professor of Child Health, Newcastle University Education[182] to provide a Background Paper on the training and continuing professional development of doctors in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2009. I do not propose to cite extensively from it but simply to draw attention to the following points that emerge from that work:

(i) Until recently, teaching was at the discretion of individual lecturers and tutors. Solution 18 was a commonly recommended fluid in paediatrics. Hyponatraemia and Syndrome of Inappropriate Anti Diuretic Hormone were understood but regarded as uncommon. There was no agreed protocol for the management of children on intravenous fluids. There were no recommendations for regular electrolyte testing.

(ii) More recently, teaching systems have become more accountable. Curricula have specific requirements for the teaching of the management of intravenous fluids in paediatrics. Medical students at Queen's University,

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180 Transcript for 9th March 2011 – Ref: 303-009-198

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

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

Belfast, for example are taught the prevention of hyponatraemia in adults based on the Clinical Resource Efficiency Support Team (CREST) guidelines. Alert No. 22 is specifically referred to in relation to the use of Solution No. 18. There are also guidelines for the management of children on intravenous fluids.

221. Professor Mary Hanratty, former Vice-President of the Nursing and Midwifery Council[183] and Professor Alan Glasper, Professor of Children and Young Person's Nursing, University of Southampton[184] were engaged by the Inquiry to provide a Background Paper on the training and continuing professional development of nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2011. The main points in which may be summarised as:

    (i) Maintaining fluid balance was often part of pre and post-registration nurse education programmes, but hyponatraemia itself was rarely specifically mentioned.

    (ii) On the whole, there was little attention paid to the Department of Health Guidance on the Management of Hyponatraemia that was circulated in 2002.

    (iii) This led to the RQIA assessment in 2008 finding that changes in practice were patchy.

    (iv) Every trust has since revised and updated the prescription, administration instructions and fluid intake and output documents reflecting the efforts to prevent the development of hyponatraemia in children.

222. The Inquiry engaged Dr. David Marshall, Senior Principal Statistician at Northern Ireland Statistics & Research Agency, to provide a Background Paper on the comparison of statistics of child hospital deaths in Northern Ireland from hyponatraemia or fluid overload with such deaths in the rest of the United Kingdom and Western Europe over the period 1979 to 2008. The salient points of which are:

    (i) There were 111 deaths registered in Northern Ireland between 1979 and 2008 where hyponatraemia or fluid overload was recorded as a cause of death. Of these 13 were coded as the underlying cause of death (none of which were children). For the remaining 98 deaths, hyponatraemia/fluid overload was recorded as a secondary cause of death and 5 of these deaths were to children aged less than 15 years.

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183 'Chronology of Nurse Education in Northern Ireland - Comparisons with UK mainland and Republic of Ireland - 1975 to date' (Professor Mary Bridget Hanratty) – Ref: 303-048-571

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

(ii) Initial analysis indicates a higher rate of child mortality in Northern Ireland than in selected other European countries, where hyponatraemia/ fluid overload is a factor in the cause of death

(iii) However, this analysis should be treated with caution due to: (a) the small number of registered deaths in Northern Ireland, (b) the fact the numbers are based on death certificate coding which can vary greatly from country-to-country and (c) the knowledge and awareness of a condition can also vary from country-to-country.

223. The difficulties in statistical comparison identified in the Background Papers from the Northern Ireland Statistics and Research Agency (NISRA)[185] were referred to by the Chairman at the Progress Hearing on 9th March 2011:

> *"In particular, one issue of concern which emerges is that there is a coding system for deaths, and a potential problem is the accuracy and reliability of the coding system. Unless the coding system is accurate and reliable it doesn't give you, whether in hyponatraemia or any other area, a truly accurate report on the incidence of various conditions such as hyponatraemia."[p.8]*[186]

224. The Inquiry is investigating the issue of the 'coding system' in Northern Ireland.

225. There were two other specialist areas where it was considered that it would be helpful to have an appropriate factual context within which to receive and consider the written and oral evidence of Witnesses, one related to Coroners and the other to post-mortems:

(i) Dr. Bridget Dolan, Barrister at Law and Deputy Coroner,[187] on the systems of procedures and practices in the United Kingdom for reporting and disseminating information on the outcomes or lessons to be learned from Coroner's Inquests on deaths in hospital (involving Hospitals, Trusts, Area Boards, Department of Health and Chief Medical Officer) Again, I do not propose to cite extensively from it but simply to draw attention to the following:

(a) The Coroner has the power to report the circumstances of an inquest case to an appropriate authority - a Rule 23 report in Northern Ireland (Rule 43 in England and Wales);
(b) In England and Wales, there was no national procedure or policy for dissemination of reports beyond the recipients of the Rule 43 report. There was no central collation of reports pertaining to healthcare

185 'Report to O'Hara Inquiry – Comparison of Mortality due to 'Hyponatraemia' between Northern Ireland and other European Countries' (NISRA) – Ref: 303-050-700 and 'Summary report for Inquiry into Hyponatraemia-related Deaths in Northern Ireland' (NISRA) – Ref: 303-051-707

186 Transcript for 9th March 2011 – Ref: 303-009-198

187 'Report to the Inquiry into Hyponatraemia-Related Deaths' (Dr. Bridget Dolan) – Ref: 303-052-715

issues by the Department of Health, nor any overview of Rule 43 reports received by NHS bodies;

(c) In Northern Ireland, there were no central figures for Rule 23 referrals;

(d) The amended Rule 43 power in England and Wales from 2008 increased the effect of a Rule 43 report. The Coroner has a wider remit for issuing them and anyone receiving a report must provide the Coroner with a written response, which must be sent to the Lord Chancellor and may be published. The Ministry of Justice now produces regular bulletins collating all Rule 43 reports in the previous six months;

(e) However, there were and still are no sanctions for failure to respond to a Rule 23 or indeed a Rule 43 report.

(ii) Dr. Jean Keeling, Paediatric Pathologist,[188] on the system of procedures for the dissemination of information gained by post-mortem examination following unexpected death of children in hospital. Some of the key points from her Background Paper are:

(a) Apart from the issuing of a Death Certificate, there is no standard practice in the UK for disseminating the information regarding an unexpected death in a hospital to other hospitals and bodies;

(b) Likewise, there is no common practice for internal analysis of deaths by hospitals, though many hospitals have meetings in which recent deaths are discussed;

(c) Coding is performed by clerks in hospitals based on information received from doctors. The likeliest source of error in coding is from the doctors involved, rather than the coders. Inaccurate coding could affect Government-generated statistics but is unlikely to affect analyses such as the National Confidential Enquiry into Perioperative Deaths (NCEPOD), where information is obtained on direct enquiry from the consultants concerned;

(d) There are no formal practices governing the dissemination of information from Coroner's Inquests to hospitals, Trusts and educational establishments.

Expert reports:

226. The Inquiry engaged experts to provide Reports, as advised by the Advisors, to address both general areas, such as the role of certain clinicians, as well as discrete issues, such as the interpretation of x-rays and CT scans.

[188] 'Dissemination of information gained by post-mortem examination following unexpected death of children in hospital' (Dr. J W Keeling) – Ref: 303-053-754

227. The Reports of the experts that have been received to date in Adam's case have all been made available to the Interested Parties and they will be published in due course.

228. The investigation into the cases of Claire, Lucy, Raychel and Conor is ongoing and the Reports of all the Experts involved in those cases will also be made available and published.

Witness statements:

229. The Inquiry has requested and received Witness Statements and Supplemental Witness Statements. The Legal Team has been guided in its questioning by:
- Advisors,
- Medical notes and records and other contemporaneous material,
- Subsequent documents received,
- Expert Reports,
- Previous statements made, whether through Depositions to the Coroner, Statements taken by the PSNI or Witness Statements to the Inquiry,
- Statements from others.

230. The Witness Statements that the Inquiry has sought and received cover the range from those whose involvement in the Children's cases was peripheral but whose evidence is required to establish some discrete point to those directly involved whether in the provision of medical care or in the management/governance of the provision of such care.

231. It is entirely possible for the evidence provided by Witness Statement to be sufficient and, particularly where it is not contradicted from any other source or challenged, to stand in lieu of oral evidence from that person. The Legal Team has prepared a Schedule, in the case of Adam, of those Witnesses that are not being called and whose Inquiry Witness Statement is being tendered as an unchallenged account. A similar Schedule will be prepared for each of the other Children's cases.

232. Some of the Witnesses that the Inquiry would wish to call have since died or are too ill to give evidence. For example the List of Persons involved that has been published for Adam's case shows that Dr. Fiona Gibson is too ill to assist the investigation. She was the Consultant Anaesthetist at the Royal Hospital who was asked in December 1995 to review the processes and equipment used in the RBHSC operating theatres. In the event that the evidence of such a witness is recorded in a Statement, whether a Deposition, PSNI Statement or Inquiry Witness Statement, - such as Dr. Gibson's PSNI Statement - then it will be a matter for you Mr. Chairman to determine what weight you will afford it in the light of all the other evidence.

Documents compiled by the Inquiry:

233. In order to assist in distilling the vast amount of information accumulated by the Inquiry in the course of its investigations the Legal Team has compiled a number of documents. Some of those documents are of general application, such as the maps showing the position the Trusts and Boards before and after the reorganisation in 2007 and 2009. I have already referred to some of those types of documents in the course of this General Opening. Some of the documents compiled by the Inquiry relate solely to a particular child's case, such as the 'clinical chronologies'. I will refer to those in the Openings of each Child's case.

234. The current categories of documents that are either compiled or are being compiled are set out in an Appendix to this General Opening. Since the investigations are continuing, it is possible that further such documents will be provided.

(10) The Oral Hearings

235. Mr. Chairman, I understand that you wish to address the matter of the Oral Hearings.

APPENDIX A

LIST OF ADVISORS & PEER REVIEWERS

Expert Advisors

(i) Dr. Peter Booker MB BS(Lond), FFARCS(Lond), MD (Liverpool) (Paediatric Anaesthesia)
(ii) Dr. Harvey Marcovitch MA(Cantab & Oxon) MB BChir FRCP(Lond) FRCPCH (Hon) DCH DObstRCOG (Paediatrics)
(iii) Ms. Carol Williams BA(Hons) MSc RGN RSCN (Paediatric Intensive Care Nursing)
(iv) Ms. Mary Whitty BA(Hons) (Health Service Management), whose subsequent ill-health meant that she had to retire
(v) Mr Gren Kershaw BA (Hons) FHSM CCMI (Health Service Management and Patient Safety), who replaced Mary Whitty

Peer Reviewers

(i) Professor Allen Arieff BA (Michigan) BS (Illinois) MD (North Western) MS (North Western) FACP of the University of California Medical School in San Francisco (Internal Medicine & Nephrology)
(ii) Dr. Desmond Bohn MB BCh FFARCS, MRCP, FRCPC of the Critical Care Unit at the Hospital for Sick Children in Toronto (Paediatric Anaesthesia)
(iii) Dr. Sharon Kinney Cardiothoracic Cert., Paed ICU Cert., BN (La Trobe), MN (Deakin), PhD (UniMelb) of the Intensive Care Unit and Clinical Quality and Safety Unit at the Royal Children's Hospital in Melbourne (Paediatric and Intensive Care Nursing)

APPENDIX B

CATEGORIES OF INQUIRY COMPILED DOCUMENTS

(i) Table of Ministers responsible for Health & Social Care from 1995 to date.

(ii) Maps showing the position of Health & Social Care bodies before and after the re-organisation in 2007.

(iii) Chronologies:
- Clinical chronology for each of the Children, giving for the period from admission to death: (a) the date and time of events, (b) a description of the event and those involved, (c) the source of the information together with the reference of any document;
- Hospital management and governance chronology for each of the Children, giving: (a) protocols, guidance, circulars & practices in force as at the time of admission, (b) dates of and reference for relevant publications, (c) events and those involved at the child's death and subsequently;
- Response of the Department and Statutory Bodies to the deaths of each of the Children, giving: (a) protocols, guidance, circulars & practices in force as at the time of admission, (b) dates of and reference for relevant publications, (c) events and those involved at the child's death and subsequently.

(iv) List of Persons Involved for each of the Children, showing for each child in relation to both 'clinical' and 'governance' matters:
- The person's name, position, role and the references for any Depositions, PSNI Statements, Inquiry Witness Statements,
- Whether or not the person is involved as an Expert,
- For those involved as Experts: (a) whether or not they are instructed by Inquiry or where retained by the Coroner, a family or the PSNI, (b) their position and title, (c) dates of their instructions and references for their Reports.

(vi) Table showing 'Clinicians involved in more than one Case'.

(vii) Table showing 'RBHSC Management involved in more than one Case'.

(viii) 'Glossary of Medical Terms' for each of the Children.

(ix) 'Nomenclature & Grading' to assist in understanding the relative grades and experience of the clinicians involved in the children's cases:

- Doctors 1948 – 2010,
- Nurses 1975 – 2012.

(x) Child-specific tables and schedules such as 'serum sodium measurements' and 'schedule of surgical procedures' for Adam.

(xi) For each of the Children, a schedule of those who are being called to give evidence at the Oral Hearings and those whose Statements are simply being tendered.

(xii) Schedule of visual aids to be available for use in the Opening in the Children's cases and/or the questioning of witnesses in the course of the Oral Hearings, such as: (a) maps, plans & diagrams, (b) photographs, x-rays & scans, (c) tables, graphs & schedules.

(xiii) Bibliographies for articles and papers in relation to clinical issues and publications in respect of management and governance matters.