

BRIEF FOR NEPHROLOGIST

Introduction

1. Adam Strain is one of 4 children who are the subject of a public inquiry being conducted by John O'Hara QC.
2. Adam Strain was born on 4th August 1991. He died on 28th November 1995 in the Royal Belfast Hospital for Sick Children ("the Royal") following kidney transplant surgery. The Inquest into his death was conducted on 18th and 21st June 1996 by John Leckey the Coroner for Greater Belfast, who engaged as experts: (i) Dr. Edward Sumner Consultant Paediatric Anaesthetist at Great Ormond Street Hospital for Sick Children ("Great Ormond Street"); (ii) Dr. John Alexander Consultant Anaesthetist at Belfast City Hospital; and (iii) Professor Peter Berry of the Department of Paediatric Pathology in St. Michael's Hospital, Bristol. The Inquest Verdict identified Cerebral Oedema as the cause of his death with Dilutional Hyponatraemia as a contributory factor.

3. The other 3 children are :

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

The Inquest into Claire's death was carried out by John Leckey on 4th May 2006 who engaged as experts Dr. Robert Bingham (Consultant Paediatric Anaesthetist at Great Ormond Street) and Dr. Ian Maconochie (Consultant in Paediatric A&E Medicine at St Mary's, London). The Inquest Verdict found the cause of Claire's death to be Cerebral Oedema with Hyponatraemia as a contributory factor.

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

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

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

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

The clinical diagnosis of Dr. Janice Bothwell (Paediatric Consultant) at the Royal was brainstem dysfunction with cerebral oedema related to viral illness, over-rehydration/inappropriate fluid management and status epilepticus causing hypoxia. Dr. Brian Herron 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 occurred after brainstem death and therefore probably played no part in the cause of the brain swelling. He concluded that the ultimate cause of death was Cerebral Oedema. Dr. Edward Sumner commented in his Report of November 2003 that Conor died of the acute effects of cerebral swelling which caused coning and brainstem death but he remained uncertain why. He noted that the volume of intravenous fluids was not excessive and the type appropriate but queried the initial rate of administration. That query was raised in his correspondence shortly after the Inquest Verdict. In that correspondence Dr. Sumner described the fluid management regime as 'sub-optimal'.

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

4. The impetus for this Inquiry was a UTV Live Insight documentary 'When Hospitals Kill' shown on 21st October 2004. The documentary primarily focused on the death of Lucy and what was presented as significant shortcomings of personnel at the Erne hospital. In effect the programme alleged a cover-up and it criticised the hospital, the Trust and the Chief Medical Officer. The

programme also referred to the deaths of Adam and Raychel in which hyponatraemia had also played a part. At that time no connection had been made with the deaths of Claire and Conor.

Original Terms of Reference

5. The Inquiry was established under the Health and Personal Social Services (Northern Ireland) Order 1972, pursuant to the powers conferred on the Department by Article 54 and Schedule 8 and it continues pursuant to the Inquiries Act 2005.
6. The original Terms of Reference for the Inquiry as published by Angela Smith (then Minister with responsibility for Health, Social Services and Public Safety) on 1st November 2004 were to:

To hold an Inquiry into the events surrounding and following the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson, with particular reference to:

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

In addition, Mr O'Hara will:

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

(Emphasis added)

Changes

7. There have been a number of significant changes since 2005. Firstly there was the receipt of Revised Terms of Reference from the Minister following the wish of the Crawford family to have Lucy excluded from the Inquiry's work:
 1. The care and treatment of Adam Strain and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
 2. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain and Raychel Ferguson.

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

In addition, Mr O'Hara will:

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

8. Secondly Claire Roberts and Conor Mitchell were included into the Inquiry's work by the Chairman due to Claire's cause of death and the apparent fluid mismanagement in Conor's case so soon after the implementation of Guidelines on Hyponatraemia which stressed the importance of fluid management.
9. The effect of the Revised Terms of Reference has been to exclude all explicit references to Lucy Crawford. The Chairman has interpreted the Revised Terms of Reference insofar as Lucy is concerned in the following way:

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

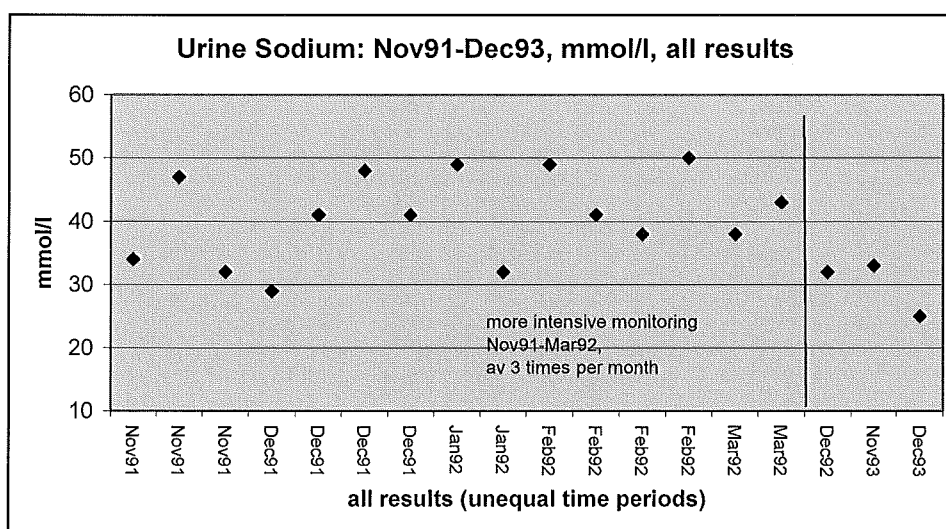
10. The case of Claire Roberts is being investigated according to precisely the same terms as those of Adam Strain and Raychel Ferguson. The investigation of Conor will address more limited issues in view of the fact that hyponatraemia was not thought to be a cause of his death (if anything he developed hypernatraemia). Similarly the fluid mismanagement referred to by Dr. Sumner was not considered to have been a cause of his death. The Chairman has stated:

It is obviously a matter of concern if guidelines which have been introduced as a result of a previous death or deaths and which are aimed at avoiding similar events in the future, are not properly communicated to hospital staff and followed. It is relevant to the investigation to be conducted by the Inquiry whether and to what extent the guidelines had been disseminated and followed in the period since they were published. Another matter of interest is whether the fact that Connor was being treated on an adult ward rather than a children's ward made any difference to the way in which it appears that the guidelines may not have been followed.

Accordingly, the Inquiry will investigate the way in which the guidelines had been circulated by the Department, the way in which they had been made known to hospital staff and the steps, if any, which had been taken to ensure that they were being followed. While this is an issue of general importance, it will be informed by an examination of the way in which the guidelines had been introduced and followed in Craigavon Area Hospital by May 2003.

Background to Adam

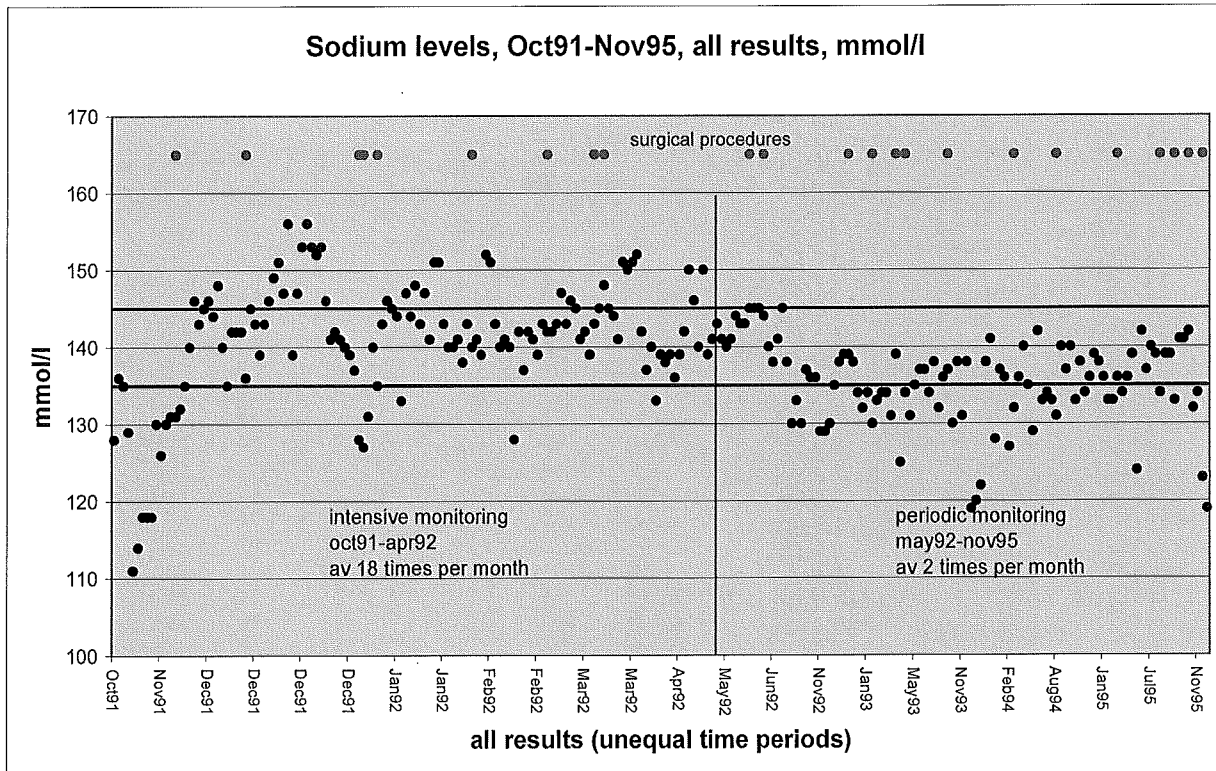
11. Adam Strain was born with cystic, dysplastic kidneys with associated problems with the drainage of his kidneys related to obstruction and vesico ureteric reflux. He was referred to the Royal from the Ulster Hospital in Dundonald and came under the care of Dr. Maurice Savage (Consultant Paediatric Nephrologist)¹ and Mr. Stephen Brown (Consultant Paediatric Surgeon).
12. Adam had multiple operations to his urinary tract, during which he was largely under the care of Mr. Stephen Brown. He had re-implantation of his ureters on 2 occasions and had nephrostomies performed during the early months of his life. On several occasions he was critically ill and required care in PICU and a brief period of dialysis due to acute renal failure. In addition a fundoplication procedure was carried out in 1992 when Adam was less than a year old, to relieve gastro-oesophageal reflux. Eventually he required all his nutrition by tube feeding and in 1993 he had a cystoscopy and percutaneous gastrostomy. In October 1995 there was a change of his gastrostomy.²
13. Adam was subject to recurrent urinary tract infections and his renal function deteriorated to the point where he required dialysis for uraemia. His mother was trained in the home peritoneal dialysis technique so that he could be dialysed at home. Adam was said to be polyuric but no measurements of total daily output are available. Biochemistry tests carried out when he was a few months old show the sodium content of his urine to range between 29 and 52mmol/L³



¹ Now Professor Maurice Savage

² A Schedule is attached showing all Adam's surgical procedures and their dates together with the surgeons and anaesthetists involved

14. According to his treating physician, consultant paediatric nephrologist, Dr. Maurice Savage,³ Adam had a potential for generating low serum sodium levels so was given extra sodium-containing feeds, namely 100mls normal saline and 50 mls 8.4% sodium bicarbonate daily. A graph of all recorded serum sodium concentrations is shown below.



15. The management of his sodium levels appears to have been largely carried out under the care of Messrs. Victor Boston and Stephen Brown, both Consultant Paediatric Surgeons. His recorded sodium levels for 1995, the year of his transplant surgery, show one very low result of 124mmol/l and a number below the normal range of 135-145mmol/l.

16. Adam was put on the waiting list for a kidney transplant once he was placed on dialysis. His gastrostomy feeds in the months prior to the transplantation surgery were detailed in June 1995 by his dietitian as 1700 mls daily but in the admission notes for 26 November 1995 as 2100 mls daily (1200 and 1500 mls respectively overnight). He passed an undocumented, so unknown, volume of urine but probably in excess of 1000 mls daily.⁴

³ See ref. 011-015-113. See also letter dated 17th January 1996 from Adam's Mother to the Coroner referring to the fact that it was commonly known that Adam had an ongoing problem with his sodium for which he had been treated the previous 4 years [ref: 011-041-174]

⁴ See ref: 059-006-121

17. Adam received the offer of a reasonably matched kidney on 26th November 1995. The donor kidney had been removed from a heart beating 16 year old donor with normal renal function at 1.42am on 26th 1995.⁵ Transplant surgery was scheduled for 7.00am on 27th November 1995.
18. At 11.00pm on 26th November 1995 Adam's serum sodium was recorded in the manuscript casenotes either as 134 mmol/l or as 139mmol/l (no printed laboratory report available) and Hb 10.5. As part of the preparation for his surgery his feeds were changed but it is not clear precisely how. According to contemporaneous charts he was fed 952 mls of 'clear fluid' after 11 pm with the aim of stopping 2 hours before going to theatre. The nursing records do not define the nature of this fluid. Some witnesses state it was Dioralyte but Dr Savage corrected his deposition to delete 'Dioralyte' and substituted 'N/S Saline Dextrose' [sic] {see ref 011-015-109.
19. His fluid intake was planned between Dr. Maurice Savage and Dr. Robert Taylor (Consultant Paediatric Anaesthetist) such that Adam should receive intravenous fluid (75ml/hr)⁶ after the tube feeds were discontinued and have his blood chemistry checked before going to theatre. In fact IV fluids did not start until anaesthesia was induced and electrolytes were not remeasured preoperatively after 11 pm. Suggested reasons were difficulty in achieving venous access and estimated delay in receiving results back from the lab. ("1-3 hours")
20. The main events surrounding Adam's transplant surgery are summarised in the following table:

Date	Event		Reference
26.11.1995	1.42am	Donor kidney removed by Mr. Casey at Southern General Hospital, Glasgow	058-009-025 (Kidney Donor Information Form)
	9.00pm	Adam admitted to Musgrave Ward at the RBHSC for possible renal transplant	011-009-001 (Deposition of Ms. Strain 18 th June 1996)
	9.30pm	Pre-op investigations for possible renal transplant carried out by Dr. Cartmill (Surgical SHO); Nursing admission details taken by SN Murphy	058-035-144 (Extract from Medical Notes and Records) 049-036-245 (Royal's Chronology of Care)

⁵ See Report of Mr. Geoff Koffman Consultant Surgeon for the PSNI dated 5th July 2006, ref: 094-007-027

⁶ See ref: 059-006-022

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	10.00pm	Evaluation Nursing Report taken by SN Murphy	049-036-245 (Royal's Chronology of Care)
	11.00pm	i.v. fluids commenced prescribed by Dr. Larkin (Community SHO); Results of investigations recorded by Dr. O'Neill (SHO) as haemoglobin 10.5g/dl, sodium 139 (or 134) mmol/l and urea 16.8; Dioralyte (or some form of dextrose/saline) instead of Nutrison gastrostomy feeds on Dr. Taylor's (Consultant Paediatric Anaesthetist) advice	<ul style="list-style-type: none"> • 049-036-245 (Royal's Chronology of Care) • 011-014 & 015 (Depositions of Drs. Savage and Taylor 21st June 1996) • 057-007-008 (blood chemistry charts) • 058-035-144 (Extract from handwritten Medical Notes and Records)
	11.30pm	Medical history and clinical examination taken by Dr. O'Neill (Senior House Officer): (i) temp. 36.4; (ii) pulse 97; (iii) blood pressure 108/56; (iv) weight 20.2kg	059-006-009 (Extract from Medical Notes and Records)
27.11.1995	1.30am	SN Murphy recorded i.v. infusion tissue and informed Dr. O'Neill	049-036-245 (Royal's Chronology of Care)
	5.00am	Unsuccessful attempts at IV cannulation between 11.00pm and 5.00am. 952mls of 'clear fluids' given via gastrostomy., ⁷ Peritoneal dialysis as usual(750ml 1.36% Dextrose solution – 8 cycles given before theatre)	<ul style="list-style-type: none"> • 049-036-246 (Royal's Chronology of Care) • 011-015 (Deposition of Dr. Savage 21st June 1996)
	7.00 am	GA induced in presence of Adam's mother. IV Dextrose-saline (0.18% in 4%) started by Dr. Taylor; 500 mls given by 7.30 am & 685 ml by 7.55 am. Lumbar epidural catheter inserted.	058-003-005(Anaesthetic record) 011-014 (Deposition of Dr Taylor 21.6.96)
	7.30am	Catheter inserted into right subclavian vein. Initial CVP reading taken at 0730 (as per Taylor) but probably 0755 (trend monitor) was 17mm.Hg (normal 2-7); transplant surgery started by Mr. Keane (Consultant Urologist); further 500ml of Dextrose saline fluids given up to 8.45am	<ul style="list-style-type: none"> • 011-014 -105(Transcript of Dr. Taylor 21st June 1996) • 058-003-005 (Anaesthetic Record)

⁷ Adam's mother informed the Coroner that only 600mls was given and that this figure, which was referred to Dr. Armour's Report on Autopsy, was an error. She also informed the Coroner that Adam was fed 2,100mls in total per day. Reference: 011-076-211.

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	8.30am	Donor kidney removed from ice; 400 colloid fluids (HPPF) given	<ul style="list-style-type: none"> • 058-009-027 (Kidney Donor Information Form) • 058-003-005 (Anaesthetic Record)
	8.45am	Rate of Dextrose saline fluids drastically slowed (500ml of given up to 11.00am) and 500ml Hartmann's solution commenced	<ul style="list-style-type: none"> • 058-003-005 (Anaesthetic Record) • 059-004-007 (Dr. Taylor's note to Mr. Brangam, Solicitor)
	9.15am	400 colloid fluids (HPPF) given	<ul style="list-style-type: none"> • 058-003-005 (Anaesthetic Record)
	9.32am	Results of pH Blood Gases and Electrolytes received, showing sodium at 123 mmol/l (normal being 135-145) and haematocrit at 18% (normal being 35-40%); 250ml packed red blood cells given	<ul style="list-style-type: none"> • 058-003-003 (BGE Report) • 058-003-005 (Anaesthetic Record)
	10.45am	200 colloid fluids (HPPF) and 250ml packed red blood cells given	058-003-005 (Anaesthetic Record)
	11.00am	Skin closure; neostigmine and glycopyrrolate administered by Dr. Taylor to reverse the neuromuscular blockade; blood loss recorded from swabs (328ml), suction (500ml) and other (300ml)	<ul style="list-style-type: none"> • Ref:011-014 (Transcript of Dr. Taylor 21st June 1996); • 058-003-005 (Anaesthetic Record)
	11.55 noon	Adam failed to wake, did not breathe and pupils fixed and dilated	011-014 (Deposition of Dr. Taylor 21 st June 1996)
	12.05pm	Adam transferred to PICU for ventilation of his lungs and assessment; puffy appearance with Central Venous Pressure reading of approx. 30 dropping to 11; Mannitol 50ml prescribed and reduction in fluids	<ul style="list-style-type: none"> • 058-005-013 (Drug record sheet) • 058-005-014 (Extract from Medical Notes and Records recorded by Dr. O'Connor) • 094-006-022 (Theatre log)
	12.15pm	Adam's appearance bloated	011- 009 (Deposition of Ms. Strain 18 th June 1996) 093-003 & 093-005 (PSNI witness statements of Adam's mother) Photographs
	7.35pm	First brain stem test carried out by Dr. Webb (Consultant Paediatric Neurologist)	058-004-009 (Brain Death Form)
28.11. 1995	9.10am	Second brain stem test carried out by Dr. Webb (Consultant Paediatric Neurologist)	058-004-009 (Brain Death Form)
	9.15am	Life pronounced extinct	011-010-011 (Report of Autopsy 29 th November 1995)

Issues

21. A post-mortem was carried out on 29th November 1995 by Dr. Armour (Senior Registrar State Pathologist's Department) who reported the cause of Adam's death as: 1(a) cerebral oedema due to (b) dilutional hyponatraemia and impaired cerebral perfusion during renal transplant.⁸
22. An Inquest was subsequently conducted into Adam's death on 18th and 21st June 1996. The Coroner, Mr. John Leckey, engaged Dr. Edward Sumner to prepare a Report on the circumstances of Adam's death. Dr. Sumner concluded in his Report dated 22nd January 1996:⁹

I believe that on a balance of probabilities Adam's gross cerebral oedema was caused by the acute onset of hyponatraemia (see reference) from the excess administration of fluids containing only very small amounts of sodium (dextrose-saline and plasma). 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. (reference: 011-011-063, emphasis added)

23. Dr. Sumner also gave evidence at Adam's Inquest and his Deposition of 18th June 1996¹⁰ records him as having expressed the following views:

All the fluids given after dialysis may have been given to increase central venous pressure. It may have had the effect of causing the dilution of the sodium in the body. Fluid balance in paediatrics is a more controversial area with a variety of views. With kidney transplants one gives more fluids than in other operations [*it is usual to be generous with fluids to maintain a CVP of 10-12 to optimise perfusion of the new kidney and to establish its urine-producing function*¹¹]. When the new kidney is perfused it is vital that sufficient fluids are available. I got the impression that Dr. Taylor was not believing the CVP readings he was getting. I believe they were probably correct but high. I think I would have believed them. A high CVO can mean too much fluid has been administered ... The low sodium was indicative of the hyponatraemia. Below 128 is a hyponatraemic state.

(reference: 011-011-049, emphasis and parenthesis)

⁸ See ref: 011-010-034

⁹ See ref: 011-011-053

¹⁰ See ref: 011-011-042

¹¹ See Dr. Sumner's Report of 22nd January 1996 at ref:011-011-059

24. Dr. Robert Taylor (Consultant Paediatric Anaesthetist) also gave evidence at the Inquest. His Deposition of 21st June 1996¹² shows that he disagreed with Dr. Sumner's principal finding:

I cannot understand why a fluid regime employed successfully with Adam previously, led on this occasion to dilutional hyponatraemia ... I believe that **the underlying cause of the cerebral oedema was hyponatraemia (not dilutional)** during renal transplant operation.

...
Adam was the only child with polyuric renal failure I have anaesthetised for renal transplant. He needed a greater amount of fluid because of the nature of the operation [*"All the more important in this case is the need to avoid dehydration that will deprive the donor kidney of sufficient fluid to produce urine"*¹³]. I believe the fluids given were neither restrictive or excessive. The new kidney did not work leading to a re-assessment of the fluids given. This made us think we have underestimated fluid and we gave a fluid bolus at 9.32.

(reference: 011-014-108, emphasis added)

25. The circumstances of the calculation of the fluids given to Adam and the actual amounts involved (bearing in mind his 'polyuric condition'¹⁴) are important issues for the Inquiry as they go to whether Adam's hyponatraemia might have been avoided by appropriate fluid management. Mr. Geoff Koffman (Consultant Surgeon at Guy's & St. Thomas Hospital and Great Ormond Street), was retained by the Police Service of Northern Ireland (PSNI)¹⁵ states in his Report of 5th July 2006 that: *"The sodium and potassium should have been repeated prior to start of surgery. The polyuric patient with poor renal function would pass large quantities of dilute urine and may have difficulty controlling the concentration of sodium and potassium in the blood"*.¹⁶
26. However, the fundamental difference between Dr. Edward Sumner and Dr. Robert Taylor is over whether Adam's condition permitted him to suffer from 'dilutional hyponatraemia'. That difference has been brought into sharp focus by the investigation conducted by the PSNI during which their comments on each other's views were sought by the investigating officers. The differences are evident from the transcript of Dr. Taylor's interview by the PSNI under caution. His underlying thesis was that Adam's condition and his performance under anaesthetic were known to him (but not to Dr. Sumner) and he was therefore able to state with confidence that Dr. Sumner was wrong in concluding that Adam developed 'dilutional hyponatraemia' as opposed to 'hyponatraemia':

¹² See ref: 011-014-108

¹³ See Deposition at ref:011-014-100

¹⁴ See letter dated 2nd March 1995 from Mr. Maurice Savage (Consultant Paediatric Nephrologist) to Dr. Scott (Adam's GP) explaining: *"The problem is he still needs about 2 litres a day because of his polyuric renal failure"*. Ref:057-072-134

¹⁵ The PSNI conducted an investigation into the deaths of all of the children over a period of about 2 years before deciding not to prosecute anyone in connection with their deaths

¹⁶ See ref: 094-007-032

- (1) See his comments on preparing Adam for the surgery: *"with paediatric anaesthesia there is a compromise to be made ... we knew from many times on dialysis that his blood chemistry and his water content of his blood were ... fixed so we could assumptions [sic], do we hurt him with needles or do we assume that this management of dialysis was the same as before."*¹⁷
- (2) See also his comments on the amount of fluids that Adam could tolerate: *"I agree with Drs. Sumner and Alexander that any other child would not have been given that quantity of fluid. Adam was very exceptional and I don't feel that those two individuals really understood Adam. Dr. Taylor confirmed that the 300mls given by Dr. Loan was given over one hour. The knowledge that Dr. Taylor had was that Adam could tolerate very high quantities of this fluid without any loss from his body and recover safely"*.

The reference to Dr. Loan's previous anaesthetic regime for Adam was relied upon by Dr. Taylor as establishing that *"Adam was not a normal child because a normal child could not cope with 300mls in one hour"*.¹⁸

- (3) See his comments on 'dilutional hyponatraemia' and its applicability to Adam: *"It was impossible for Adam to suffer from dilutional hyponatraemia contrary to the view of the Coroner and the experts because he could not concentrate urine. Therefore Adam could not fit Dr. Sumner's theory ... He stressed that dilutional hyponatraemia was only a theory, that cases had been described but only in children with intact kidneys."*¹⁹

See also: *"Dr. Taylor then contended that it was possible that if Adam was given 500mls he could pass 500mls in urine. No-one knew what his maximum output was, only that his minimum output was 200mls. Dr. Taylor's knowledge of the disease was such that he believed Adam could pass an unlimited amount of fluid. No one had established a maximum output for Adam."*²⁰

See also Mr. Geoff Koffman who refers in his Report for the PSNI to it being *"commonly agreed that he [Adam] was polyuric and could cope with an oral intake of in excess of 2 litres a day"*²¹ and who goes on to state in respect of the *"minority of patients that are polyuric"* that *"the bladder may be left on free drainage in these patients. It would not be particularly important to monitor the urine output in these patients."*²²

¹⁷ See ref: 093-035-094

¹⁸ See ref: 093-035-096

¹⁹ See ref: 093-035-102

²⁰ See ref: 093-035-103.

²¹ See ref: 094-007-029

²² See ref: 094-007-035

See further from Dr. Taylor: *"the theory of dilutional hyponatraemia was improperly applied to Adam and involved making the diagnosis for a known disease. He stated there was no evidence that a child like Adam could get dilutional hyponatraemia."*²³

See also his arguments on: (i) the figure of 124mmol/l²⁴ for Adam's sodium (at 9.32am during surgery) being unreliable; (ii) Adam having been as low as that before without a problem;²⁵ (iii) the rate of change in his sodium level being counteracted e.g. the protective effect of anaesthesia on the brain; (iv) the absence of any 'hyponatraemic symptoms'; and (iv) the administration of HPPF which contains some sodium and his criticism of Dr. Sumner for claiming that it did not.²⁶

Finally: *"Dr. Taylor had many patients in intensive care whose sodium is low at the time of death, whether that was the cause of death or the result of a dying process is debatable. He acknowledged that hyponatraemia was present but not that it caused his death. Police put to Dr. Taylor that he had said in a letter to a solicitor that 0.18% saline was isotonic, when in effect, its effect once infused is hypotonic. Dr. Taylor stated that depended on the metabolism of the patient, depending on how quickly he burned the glucose. Dr. Taylor explained that Adam did not need too much glucose as the body burns less under anaesthetic. This enhances the ability of the fluid to remain isotonic. This was another reason for the theory of dilutional hyponatraemia to be inapplicable – none of Arieff's patients had died on the table they had all died post-operatively."*²⁷

27. It may be worth noting that Dr. Edward Sumner does state in an undated Report for the PSNI: *"If Adam died from dilutional hyponatraemia and its acute cerebral effects, then, in my opinion it must have been the volumes of intravenous dextrose-saline which contributed to this"* (emphasis added). It is not clear from the papers why this qualification appears. The PSNI did send Dr. Sumner a detailed (but undated) series of questions that they wished him to answer,²⁸ some of which are relevant to the issues raised here:

19. Can we check if the 'fluid regime employed successfully with Adam' previously is true?

24. Is there value in comparing past operation notes with the relevant operation notes?

²³ See ref: 093-035-103. See also Dr. Alexander's Deposition to the Coroner in which he states: *"Adam's case is not an identical scenario to that in Arieff's paper. There the children had evidence of hypoxia and there is no evidence of that in Adam's case"*. See ref: 09-014-123

²⁴ Dr Taylor refers to a reading of 124 in error. The actual reading was 123mmol/l taken at 9.32am (see reference 058-003-003).

²⁵ See Adam's medical notes and records for 8th June 1995 ref: 058-041-197 and generally the Schedule above on Adam's sodium levels

²⁶ See ref: 093-035-106. Although in fact in his Report for the PSNI of September 2005, Dr. Edward Sumner refers to the *"excess administration of fluids containing only very small amounts of sodium."* See ref: 094-002-009. Dr. Sumner goes on to concede that HPPF does contain sodium: *"so would help to raise the serum sodium level, though this is usually given for blood volume replacement."* See ref: 094-004-014

²⁷ See ref: 093-035-110

²⁸ See ref: 094-009-042

50. What is the meaning of 'on the balance of probabilities'?²⁹ What other possible causes could there have been? How certain is this cause of death ie cerebral oedema caused by dilutional Hyponatraemia? Did any medical opinion dissent from that conclusion?
52. Dr. Alexander says he believes that renal failure may affect hyponatraemia and disagrees with you on that point.³⁰ Is he wrong and why?
28. To date we have not discovered the response from Dr. Sumner, whether in writing or in the form of any notes of a meeting(s) with the PSNI.
29. In addition the papers received by the Inquiry disclose a difference between the medical personnel over the condition and performance of the kidney transplanted into Adam. The condition of the donated kidney may be related to its storage time. Mr. Geoff Koffman makes the point in his PSNI Report dated 5th July 2006 that by the time the kidney was implanted into Adam it had had a total storage time of approximately 34 hours, which he claims is considerably longer than the average storage time of approximately 20 hours.³¹ He considers the possibility in his Report that the donated kidney was severely injured referring to "*acute tubular necrosis*" and noting that "*with a storage time in excess of 30 hours acute tubular necrosis and delayed graft function would be expected*".³²
30. The differences over the condition and performance of the kidney emerge principally from the following Statements and Reports:
- (1) Mr. Patrick Keane (Consultant Urologist) records in the Clinical History, Examination and Progress Report (which he signs sometime before 12.05pm on 27th November 1995): "*Kidney perfused reasonably well at end*"³³
- He expands upon that in a letter dated 11th December 1995 to the Complaints Officer at the Belfast City Hospital that the kidney: "*perfused quite well initially and started to produce urine. At the end of the procedure it was obvious that the kidney was not perfusing as well as it had initially done but this is by no means unusual in renal transplantation*"³⁴ See also his Deposition of 18th June 1996.³⁵

²⁹ A reference to Dr. Sumner's conclusion in his Report of the Coroner - see ref: 011-011-063

³⁰ See Dr. Alexander's Deposition to the Coroner ref: 011-012-083

³¹ See ref: 094-007-029

³² See ref: 094-007-034

³³ See ref: 058-035-135

³⁴ See ref: 011-026-127

³⁵ See ref: 011-013-093

In his Inquiry Statement of 20th June 2005 he states: *"At the completion of the surgery, the transplanted kidney had pulsatile flow in the artery and was perfusing"*. However, he goes on to state (which he had not done during the Inquest) that he left the theatre 10 minutes before the end of the anaesthesia and that Mr. Stephen Brown (Consultant Paediatric Surgeon), who was assisting him, closed the wound.

In his Statement to the PSNI on 7th September 2006 he states that: *"Initially the kidney that was transplanted into Adam perfused very well; after the kidney was placed in situ the kidney perfused less well but adequately; I could still feel blood flow in the renal artery. It is also my recollection that a little urine was produced before the ureter was connected to the bladder."*³⁶

- (2) Mr. Stephen Brown (Consultant Paediatric Surgeon, retired) stated in his Report for Dr. George Murnaghan (Director of Medical Administration) of 20th December 1995 that the *"perfusion of the kidney was satisfactory, although at no stage did it produce any urine"*³⁷

For reasons that are unclear, he did not give evidence at the Inquest but his Inquiry Witness Statement of 15th July 2005 states that: *"Following the vascular anastomosis the kidney appeared healthy and was good colour. My recollection was that it did not produce any urine during the course of the operation."*

In his statement to the PSNI he states: *"The kidney was a good colour, from what I can remember the kidney turned pink in colour when it was transplanted and the blood was put through it. As far as I can remember the kidney remained pink in colour"*. He acknowledged the difference between his account and that of Mr. Patrick Savage about the production of urine, stating that he could not explain it: *"I may be wrong about the urine. Though as far as I recall no urine was ever produced"*.³⁸

- (3) Dr. Robert Taylor refers in his Deposition of 21st June 1996 to the process of the calculation of fluids for Adam being *"complicated by the fact that the donor kidney did not appear well perfused after an initial period of apparently good kidney perfusion"*³⁹

In his evidence during the Inquest he states: *"The new kidney did not work leading to a re-assessment of the fluids given. This made us think we have underestimated fluid and we gave a fluid bolus at 9.32"*⁴⁰

³⁶ See ref: 093-010-029

³⁷ See ref: 20th December 1995

³⁸ See ref: 093-011-032

³⁹ See ref: 011-014-097

⁴⁰ See ref: 011-014-108

He expands upon that in his taped PSNI interview on 17th October 2006 given under caution, the transcript of which records: *"he was aware that the kidney did not 'pink up' easily and the impact on Dr. Taylor was to re-assess his fluids and worry that he was still in deficit and despite his best efforts that he had failed to increase the blood volume enough to perfuse the kidney. Dr. Taylor could not recall if the new kidney produced urine."*⁴¹

- (4) Nurse Gillian Popplestone (Registered Sick Children's Nurse) stated in her PSNI Statement of 31st January 2006 that: *"I also recall the surgeons discussing possible discolouration of the kidney at the time of the transplant. This concern appeared to subside as the operation progressed."*⁴²
- (5) Dr. Mary O'Connor (Consultant Paediatric Nephrologist) who was present towards the end of Adam's surgery stated in her PSNI Statement that: *"I have recorded that the kidney was 'bluish' at the end of theatre"*.⁴³ See the Clinical History, Examination and Progress Report, which she signed on 27th November 1995,⁴⁴ which also records: *"0 from tx kidney"*.⁴⁵ See also Eleanor Donaghy (Transplant Co-ordinator) who completed section 11 of the Kidney Donor Information Form recording at section 8, 'kidney damage', *"widely separated patch"* which was amended (but not by her) to *"widely separated arteries on 1 patch"*.⁴⁶
- (6) Dr. Alison Armour who carried out the autopsy on Adam at 2.40pm on 29th November 1995, the day after his death, states that there was *"complete infarction"* of the transplanted kidney.⁴⁷
- (7) Professor Peter Berry (Paediatric Pathology in the University of Bristol) stated in his Report for the Coroner dated 23rd March 1996 that: *"transplant kidney was infarcted (dead). The extent of the change suggested that this occurred at or before the time of transplantation."*⁴⁸ See also the letter from Professor Berry to the Coroner dated 25th March 1996 and his statement that *"I doubt this kidney would ever have functioned"*.⁴⁹ See further his PSNI Statement on 22nd March 2006 in which he explains his statement to the Coroner: *"By this I mean the microscopic changes were sufficiently well established that I estimated that the damage had occurred about 2 days previously, before or around the time of transplantation"*.⁵⁰

⁴¹ See ref: 093-035-108

⁴² See ref: 093-012-040

⁴³ See ref: 093-020-059

⁴⁴ See ref: 058-035-136

⁴⁵ See ref: 058-035-137

⁴⁶ See ref: 093-015-048

⁴⁷ See ref: 011-010-040

⁴⁸ See ref: 011-007-022

⁴⁹ See ref: 011-053-187

⁵⁰ See ref: 093-030-079

- (8) Professor Risdon (Consultant Paediatric Pathologist, Great Ormond Street) states in his Report to the PSNI dated 2nd June 2006: *"In my opinion the transplanted kidney must have suffered significant ischaemic damage prior to its insertion for this degree of ischaemic damage to be apparent at post-mortem"* and *"This opinion is supported by the fact that the other kidney from the same donor failed to function when transplanted to a different patient in Glasgow.⁵¹ This would suggest that both kidneys from this donor had suffered significant ischaemic damage before transplantation."⁵²*
- (9) Finally, Mr. Richard Donaldson (Renal Surgeon at Belfast City Hospital) comments in a report that seems to have been prepared for Adam's family: *"there is also back bleeding from the renal vein which could be thought to be proper perfusion – a few drops of urine from the ureter can sometimes be mistaken for early production of urine and is in fact residual donor renal pelvic fluid expressed on renal handling".⁵³*
31. The significance of that issue is that if the kidney was infarcted as Professors Berry and Risdon believe may have been the case, then it raises the question of whether Dr. Robert Taylor's calculation during surgery that more fluids were required was based on the false premise that he was dealing with a healthy kidney in dehydrated circumstances. In those circumstances an important question for the Inquiry would be whether such a mistaken basis for fluid calculations could have had implications for the hyponatraemia that Adam developed. Notably Dr. John Alexander considered that 'a compromised kidney was a factor in the onset of hyponatraemia' and therefore disagreed with Dr. Edward Sumner on that point.⁵⁴

Requirements

32. The Inquiry team requires your assistance with the following:
- (i) Analyzing the documents including the Reports and Statements
 - (ii) Understanding the medical process by which Adam came to die in the way that he did
 - (iii) Identifying areas where other Expert views should be sought
 - (iv) Determining the further matters to be addressed in Supplemental Witness Statements

⁵¹ The Inquiry has a letter dated 29th March 2005 from the Information Manager at UK Transplant which states that: *"we were notified that the transplant of the second kidney, which took place on 26 November 1995, had failed on day of transplant due to infection of the graft"*. However, Professor Risdon refers in his Report to a letter from the Director of Renal Transplantation at Greater Glasgow NHS. The Inquiry does not have that letter but will seek a copy of it.

⁵² See ref:093-031-083

⁵³ See ref: 094-013-066

⁵⁴ See Deposition to the Coroner, ref: 011-012-083

33. However, the most pressing matter is to receive your advice on the points raised in the section of this Brief titled 'Issues', the key points of which are summarised below under: 'Pre-Operative Period' and 'Operative Period':

Pre-Operative Period

- (1) Requirement for pre-operative measurement of electrolytes to be carried out after dialysis and before surgery, together with the likely significance of the absence of the information that would have been provided by those tests had they been carried out as requested by Dr. Maurice Savage.
- (2) The quality of record keeping and monitoring of fluids & electrolytes, including recording of dialysis cycles.
- (3) Respective roles of Dr. Robert Taylor, Mr Patrick Keane and Dr. Maurice Savage (and their respective teams) in the preparation of Adam for surgery.
- (4) Whether the assumptions made by Dr Taylor regarding Adam's preoperative fluid and electrolyte balance, urine output and hydration status were reasonable under the circumstances.
- (5) What would have been the implications for Adam's subsequent management if:
 - His usual overnight fluid intake was 1200 mls or 1500 mls
 - He had been fed 950 mls Dioralyte overnight (47mls/kg/24h) or the same volumes of normal saline or of 0.18% saline in 4% dextrose or water (alternatives quoted because of uncertainty as to nature of fluids actually given).
 - Adam had or had not received his normal saline supplements (100 mls normal saline and 50 ml 8.4% sodium bicarbonate in addition to the above.
 - Accurate fluid balance charts had been kept during dialysis
 - Adam had been catheterised and accurate hourly urine output measured and known preoperatively.

Operative Period

- (1) Significance of the volume and nature of IV fluids infused depending on whether he was dehydrated, properly hydrated or overhydrated at the point anaesthesia was induced; and whether these fluids were accurately documented.
- (2) Significance, if any, of the position of the central venous catheter, the starting and subsequent central venous pressure (CVP) measured intraoperatively and the implications for fluid management .
- (3) Implications of the 'tying off' of the left internal jugular vein in relation to CVP measurements and intraoperative fluid management.

You should be aware that whether or not it was 'tied off' is a contested matter. Dr. Alison Armour states in her Report of Autopsy that: "The autopsy revealed ligation of the left internal jugular vein." She explains the significance of that as: *"The catheter tip of the CVP was situated on the right side. This would mean that the cerebral perfusion would be less than that in a normal child. This would exacerbate the effects of the cerebral oedema and should be considered as a factor in the cause of death. Therefore the most likely explanation is that the cerebral oedema followed a period of hyponatraemia and was compounded by impaired cerebral perfusion."*⁵⁵

Adam's mother claims that Adam's left internal jugular vein was tied off at the same time as a Broviac central line, which had been inserted on 29th May 1992, was removed due to an infection. Adam's medical notes and records show that the Broviac central line was removed during a procedure on 9th February 1995.⁵⁶ However in a letter to the Inquiry dated 26th April 2005 from Brangam Bagnall & Co Solicitors for the, they claim that: *"There is no record of the left internal jugular vein being tied off in the RBHSC notes. It is the view of our client that this was not carried out and certainly not during the transplant on 27 November 1995."*

- (4) Difference in views between Dr Taylor and Dr Sumner on the diagnosis of Adam having developed 'dilutional hyponatraemia', including Dr. Taylor's comments on Professor Arieff's research on hyponatraemia.⁵⁷
- (5) The significance, if any, of Adam's history of episodes of abnormal sodium levels, including a measurement of 124 mmol/L recorded 4 months pre-operatively (8.6.95)

⁵⁵ See ref: 011-010-041

⁵⁶ See letter dated 26th April 2005 to the Inquiry from Brangam Bagnall & Co Solicitors for the Royal and the enclosed extracts from Adam's medical notes and records

⁵⁷ See ref: 093-035-102

- (6) Significance, if any, of the transplanted kidney not functioning, including any effect this might have had on the fluids administered to Adam and otherwise as a factor in the onset or exacerbation of his hyponatraemia. (with reference to the statements of Mr. Patrick Keane, Mr. Stephen Brown, Dr. Robert Taylor, Dr. Mary O' Connor and the expert reports of Professor Peter Berry, Professor Risdon and Mr. Geoff Koffman. It also would be helpful if you could comment on the quality of the material made available to Professors Risdon and Berry for their examination and reports, to the extent that there were any differences and if so, the significance of those differences.

Postoperatively

- (1) The significance of his 'bloated' appearance (presumably representing generalised oedema) noted by staff and mother immediately after the end of surgery and captured in photographs taken in ICU.
 - (2) Significance of the first few CVP readings taken in ICU.
 - (3) Significance of urine output measured in ICU immediately post-op.
34. You will need to consider all the Adam documents so as to carry out a thorough review of the evidence and form an opinion on the issues. However, to assist you we have included in the Core File the documents that would appear to be of especial significance:

*Coroner's papers (File 11):*⁵⁸

Depositions of:

- Dr. Maurice Savage (011-015, Tab 3a)
- Mr. Patrick Keane (011-013, Tab 3b)
- Dr. Alison Armour (011-010, Tab 3c)
- Dr. John Alexander (011-012, Tab 3d)
- Dr. Robert Taylor (011-014, Tab 3e)

Reports of:

- Professor Peter Berry (011-007, Tab 3f)
- Dr. Edward Sumner (011-011, Tab 3g)

⁵⁸ See Tab.3 of the accompanying File

*Inquiry papers:*⁵⁹

Witness Statements of:

- Dr. Maurice Savage (Tab 4a)
- Mr. Patrick Keane (Tab 4b)
- Mr. Stephen Brown (Tab 4c)
- Dr. Robert Taylor (Tab 4d)
- Mr. Victor Boston (Tab 4e)
- Dr. Joe Gaston (Tab 4f)
- Dr. Mary O'Connor (Tab 4g)
- Dr. Edward Sumner (Tab 4h)

Submission on the List of Issues on behalf of the Slavin family dated 2nd June 2005 (Tab 4i)

Correspondence:

- Inquiry to Dr. Peter Booker dated 1st July 2005 (Tab 4j)
- Dr. Booker to the Inquiry dated 4th July 2005 (Tab 4k)
- Inquiry to Dr. Harvey Marcovitch dated 1st July 2008 (Tab 4l)
- Dr. Marcovitch to the Inquiry dated 5th July 2008 (Tab 4m)

*PSNI papers (Files 93 & 94):*⁶⁰

Statements of:

- Dr. Maurice Savage (093-006, Tab 5a)
- Nurse Catherine Murphy (093-007, Tab 5b)
- Mr. Patrick Keane (093-010, Tab 5c)
- Mr. Stephen Brown (093-011, Tab 5d)
- Dr. Mary O'Connor (093-020, Tab 5e)
- Dr. Joe Gaston (093-023, Tab 5f)
- Professor Peter Berry (093-030, Tab 5g)
- Professor Risdon (093-031, Tab 5h)
- Transcript of Dr. Robert Taylor's interview under caution (included in the statement of DS William Cross (093-035, Tab 5i)

Reports of:

- Dr. Edward Sumner (094-022, Tab 5j)
- Mr. Geoff Koffman (094-007, Tab 5k).
- Medical opinion of Dr. Edward Sumner (094-001, Tab 5l)

⁵⁹ See Tab.4 of the accompanying File

⁶⁰ See Tab.5 of the accompanying File

Other documents:

- Correspondence between DS William Cross/PSNI and Dr. Edward Sumner and Professor Risdon (094-003 Tab 5m, 094-004 Tab 5n, 094-008 Tab 5o, 094-009 Tab 5p)
- Dr. John Burton's folder of documents (094-013, Tab 5q)

35. In addition the Chairman of the Inquiry has produced a note that includes a number of queries that he has in respect of hyponatraemia, which has been provided to the Inquiry's Panel of Experts. We also wish to have your comments on those queries. To assist, we have prepared a Schedule showing details of the recorded sodium results for all 5 children.
36. Finally and in the light of all the papers that have been provided to you, we seek your advice on additional questions that might usefully be put to Mr. Patrick Keane, Dr. Robert Taylor and any other practitioner identified as having been involved in the care of Adam.

Conclusion

37. It is of fundamental importance that the Inquiry receives a clear and fully reasoned opinion on the difference of view between Dr. Edward Sumner and Dr. Robert Taylor as to whether or not dilutional hyponatraemia played any part in Adam's death. If there is any possibility that Dr. Taylor's position could be correct then that would have serious implications for the lessons to be learned from what happened to Adam as well as the accuracy of the Coroner's Verdict.
38. Your assistance on those points should be provided in the form of a fully referenced expert report. In accordance with the Protocol on Experts your Report will be peer reviewed.