BRIEF FOR EXPERT ON CLINICAL GOVERNANCE
ADAM STRAIN

Introduction

1. Adam Strain is one of four children who are the subject of a public inquiry being conducted by John O'Hara QC.

2. Adam was born on 4th August 1991. He died on 28th November 1995 in the Royal Belfast Hospital for Sick Children ("RBHSC") 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 then 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 three children who are the subject of the Inquiry's work are:

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

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

   (2) 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 RBHSC 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. He 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).

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

The Inquest into Conor's death was conducted on 9th June 2004 by John Leckey, Coroner. He 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 RBHSC 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 a toddler called Lucy Crawford (who died in hospital in 2000 and whose death was subsequently also found to have been as a result of hyponatraemia). The programme makers identified what they considered to have been significant shortcomings of personnel at the Erne Hospital where Lucy had been initially treated before being transferred to the RBHSC. In effect, the programme alleged a cover-up and it criticised the hospital, the Trust and the Chief Medical Officer. The programme also referred to the deaths of Adam and Raychel in which hyponatraemia had similarly played a part. At that time, no connection was made with the deaths of Claire and Conor.

Original Terms of Reference

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

6. The original Terms of Reference for the Inquiry as published by Angela Smith (then Minister with responsibility for the Department of Health, Social Services and Public Safety) on 1st November 2004 included a reference a child Lucy Crawford. She was born on 5th November 1998, was admitted to the Erne Hospital in Enniskillen on ... and then transferred to the RBHSC where she was declared dead on 14th April 2000. Her Inquest was heard in February 2004 following which her death certificate was changed to include …

Changes

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

> "1. The care and treatment of Adam Strain and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
>
> 2. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain and Raychel Ferguson.
> 3. The communications with and explanations given to the respective families and others by the relevant authorities.
>
> In addition, Mr O'Hara will:

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

8. Secondly, Claire and Conor were included into the Inquiry's work by the Chairman due to the cause of Claire's death and a concern over the extent to which there had been compliance with the recently circulated Guidelines on Hyponatraemia.

9. The effect of the Revised Terms of Reference was to exclude all explicit references to Lucy. 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. Claire's case is being investigated according to precisely the same terms as those of Adam and Raychel.

11. The investigation of Conor will address more limited issues since hyponatraemia was not a cause of his death (if anything he developed hypernatraemia). 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."

Role of the Experts

12. There are 4 categories of expert assistance:

(i) Expert Advisers[1] appointed to assist the Inquiry in identifying, obtaining, interpreting and evaluating the evidence within their particular area of expertise, which currently comprises the following:
   (a) Consultant Paediatrician
   (b) Consultant Paediatric Anaesthetist
   (c) Paediatric Nurse, previously Consultant Nurse in Paediatric Intensive Care
   (d) National Health Service Hospital Management

(ii) Experts engaged on a case-by-case basis as Expert Witnesses.
In addition to your expertise as an expert on clinical governance, the Inquiry has also appointed Expert Witnesses in Adam's case on Transplant Surgery, Paediatric Nephrology, Hyponatraemia, Paediatric Nursing, Paediatric Anaesthetics, Radiology, Paediatric Neurology and Neuropathology.[2]
The Experts are required to provide their Expert opinion in the form of a Report incorporating an 'expert declaration' and attached to a Witness Statement. The Report will be made public. The Expert Witnesses may be required to attend the oral hearings and present their views.

(iii) Experts to provide commissioned 'Background Papers'[3]

(iv) Experts appointed as Peer Reviewers of the work of the Advisors[4]

13. You have been identified as an expert whose role falls within category (ii) above. This briefing paper contains some clinical issues on which we do not expect you to comment, but they are included to provide context and show the depth of the work of the Inquiry.

1 Dr. Harvey Marcovitch (Paediatrics); Dr. Peter Booker (Paediatric Anaesthesia); Carol Williams (Paediatric Nursing); Grenville Kershaw (Health Service Management and Patient Safety)

2 Dr. Malcolm Coulthard (Paediatric Nephrology); Professor Peter Gross (Hyponatraemia); Sally Ramsay (Paediatric Nursing); John Forsyth/Keith Rigg (Transplant Surgeons); Dr. Simon Haynes (Paediatric Anaesthetics); Dr. Caren Landes (Radiology); Professor Fenella Kirkham (Paediatric Neurology); Dr. Wayney Squier (Neuropathology)

3 To date the Inquiry has sought 'Background papers' on: (i) Education & Training of Doctors (Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust and Professor Sir Alan Craft, Emeritus Professor of Child Health, Newcastle University); (ii) Education & Training of Nurses (Professor Mary Hanratty, former Vice-President of the Nursing and Midwifery Council and Professor Alan Glasper, Professor of Children and Young Person's Nursiny, University of Southampton); (iii) Coroners (Dr. Bridget Dolan, Barrister-at-Law and Assistant Deputy Coroner); (iv) Dissemination of Information following Adverse Incidents (Dr. Jean Keeling, retired Consultant Paediatric Pathologist, New Royal Infirmary); (v) Adverse incidents and coding of deaths (Joy Trouton, retired Regional Coder for Northern Ireland); (vi) Statistics (Dr. David Marshall, Northern Ireland Statistics & Research Agency)

4 Professor Allen Arieff at the University of California Medical School in San Francisco (Internal Medicine & Nephrology), Dr. Desmond Bohn of the Critical Care Unit at the Hospital for Sick Children in Toronto (Paediatric Anaesthesia), Ms. Sharon Kinney at the Intensive Care Unit and Clinical Quality and Safety Unit at the Royal Children's Hospital in Melbourne (Paediatric and Intensive Care Nursing)

Background to Adam

14. Adam Strain was born with cystic, dysplastic kidneys. He developed problems with the drainage of his kidneys related to obstruction and vesico ureteric reflux. He was referred to the RBHSC from the Ulster Hospital in Dundonald when he was a few months old and came under the care of Dr. Maurice Savage (Consultant Paediatric Nephrologist)[5] and Mr. Stephen Brown (Consultant Paediatric Surgeon).

15. Thereafter, 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 urethers on 2 occasions and had nephrostomies, which were 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 dute to acute renal failure. In addition a fundoplication procedure was carried out in 1992 when Adam was less than a year old, to help prevent gastro-oesophageal reflux. Eventually he required all his nutrition through a gastrostomy tube and in 1993 he had a cytoscopy and PEG gastrostomy. The PEG was changed in October 1995 shortly before his transplant surgery.

16. Adam was subject to recurrent urinary tract infections and his renal function deteriorated to the point where, in 1994, he required dialysis for uraemia. His mother was trained in the home peritoneal dialysis technique so that he could be dialysed at home. His urine output was quite large but of poor quality and he was described as being polyuric.

17. According to his nephrologist, Dr. Maurice Savage, Adam had a potential for hyponatraemia and he received sodium supplements in his feeds. 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.

18. Adam was put on call for a kidney transplant once he was placed on dialysis. His tube feeds in the months prior to the transplantation surgery were slightly over 2 litres per day and he passed in excess of 1 litre of urine each day.

19. Adam received the offer of a reasonably matched kidney on 26th November 1995. The donor kidney had been removed in Glasgow from a heart-beating 16-year-old donor with normal renal function at 01:42 on 26th November 1995. Adam's Transplant surgery was scheduled for 06:00 on 27th November 1995, which was subsequently put back to 07:00.

20. At 23:00 on 26th November 1995, Adam's serum sodium was recorded in his medical notes as 139 mmol/l (ie within the normal band being 135 mmol/l to 45

[5] Now Professor Maurice Savage

mmol/l).[6] The Inquiry has not been provided with a copy of the laboratory report for that result. As part of the preparation for his surgery, his feeds were changed although there remains an issue as to exactly what they were changed to. According to his charts, he was given 952 ml of 'clear fluid' to stop 2 hours before going into theatre. The nursing records do not state the nature of the 'clear fluids' given. Some witnesses have said that fluid was Dioralyte (containing 60 mmol of sodium chloride/L). However, Dr. Maurice Savage corrected his Deposition to the Coroner to delete 'Dioralyte' and substitute 'N/S Saline Dextrose'. In any event, it is thought that he received just over 1 litre of fluids.

21. Apparently it was planned between Dr. Maurice Savage and Dr. Robert Taylor (Consultant Paediatric Anaesthetist) that Adam should receive intravenous fluid (75 ml/h) after the tube feeds were discontinued and have his blood chemistry checked before going to theatre. It seems that those checks did not take place. Although the Inquiry has very recently been provided with a laboratory result of a blood test taken some time on 26th November 1995 that measures Adam's serum sodium level at 133 mmol/l (ie below normal). Adam's notes do not record the time at which the sample was taken nor the result. To date no one has commented on or explained that result.

22. The clinicians have provided different explanations as to why, so far as they are concerned, the envisaged checks were not undertaken. On one basis, it was because it proved difficult to achieve venous access to obtain the necessary blood sample, whilst on another it was because of the potential delay in receiving results back from the laboratory and on yet another that it was not considered to be a priority.

23. Adam failed to waken at the end of his surgery at about 11:55 and his pupils were found to be fixed and dilated. Following 2 brain stem tests ventilatory support was withdrawn at 11:30 the following day on 28th November 1995.

24. The main events surrounding Adam's transplant surgery are summarised in the attached 'clinical' chronology. Also attached is a 'governance' chronology of events in the aftermath of his death.

25. A post-mortem was carried out on 29th November 1995 by Dr. Armour (Senior Registrar State Pathologist's Department) who reported her principle findings to the Coroner as "*cerebral oedema*" (Ref: 094-114-321). Her Report on Autopsy that was provided on 24th April 1996 (after 'fixing of the brain') states the cause

[6] There is no laboratory report for this result (which is incorrectly shown elsewhere in the notes as 134mmol/L). The Inquiry has since been provided with a laboratory report that although dated 27th November 1995 is referable to a sample taken on 26th November 1995 which shows the serum sodium level to be 133mmol/L. There is no reference to it in the notes.

of Adam's death as: 1(a) cerebral oedema due to (b) dilutional hyponatraemia and impaired cerebral perfusion during renal transplant (Ref: 011-010-034).

26. The Inquest that was subsequently conducted into Adam's death on 18th and 21st June 1996 recorded the Verdict that the cause of his death was:

> "1(A) Cerebral Oedema
> due to
> (B) Dilutional Hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy)
>
> Findings:
> The onset of cerebral oedema was caused by the acute onset of hyponatraemia from the excess administration of fluids containing only very small amounts of sodium and this was exacerbated by blood loss and possibly the overnight dialysis and the obstruction of the venous drainage to the head"

27. The Coroner, Mr. John Leckey, was assisted in reaching that Verdict by Dr. Edward Sumner (Consultant Paediatric Anaesthetist) who was retained to prepare a Report on the circumstances of Adam's death. Dr. Sumner concluded in his Report dated 22nd January 1996:

> "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."

28. Dr. Sumner also gave evidence at Adam's Inquest and his Deposition of 18th June 1996 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"]*. 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 CVP can mean too much fluid has been administered … The low sodium was indicative of the hyponatraemia. Below 128 is a hyponatraemic state."
>
> (Parenthesis added from p.6 of Dr. Sumner's Report – Ref: 011-011-059)

29. Dr. Robert Taylor (Consultant Paediatric Anaesthetist) gave evidence at the Inquest. His Deposition of 21st June 1996 (Ref: 011-014-096) 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"]*. 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."

30. The circumstances of the calculation of the fluids given to Adam and the actual amounts involved (bearing in mind his 'polyuric' condition) 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)[7] as an expert paediatric transplant surgeon and stated 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"*. The Inquiry's clinical Experts all address that issue and for the most part agree with him.

31. 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'. Dr. Taylor's underlying thesis was that Adam's condition and his performance under anaesthesia 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' (Ref: 011-014-108 and Ref: 093-038-238). As a result, Dr. Taylor stated in his Inquiry Witness Statement that he did not regard Adam's death certificate (which reflected the Verdict on Inquest) as accurate (Ref: WS-008/2, p.39).

Defining the Scope of Clinical Governance

32. The 'governance' issues arising out of the Inquiry's revised terms of reference are being considered at three 'levels': (i) hospital management and clinical governance; (ii) corporate or trust level; and (iii) government or departmental level within the Health and Social Care Services (HSC).

33. So far as 'clinical governance' is concerned, the Inquiry team has interpreted this as the system through which the HSC organisations are accountable for

[7] 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

continuously monitoring and improving the quality of their care and services and safeguarding high standards of care and services. This system largely operates at the clinical level, with reporting lines to Directorate and Trust managers.

34. The Inquiry team has adopted the term clinical governance is an 'umbrella' term which encompasses a range of activities in which clinicians should become involved in order to maintain and improve the quality of the care they provide to patients and to ensure full accountability of the systems to patients. On the management side, we understand that term embraces the leadership, procedures and systems that the organisation requires in order to maintain high quality services to patients and for which they are accountable.

35. In addition, the Inquiry team understands that clinical governance can be separated into the following main areas for the purposes of the Inquiry:

Clinical

(1) Clinical effectiveness and research:
- Adopting an evidence-based approach in the management of patients
- Changing your practice, developing new protocols or guidelines based on experience and evidence if current practice is shown inadequate
- Implementing NICE and professional College guidelines and adhering to HSC Service Frameworks and other national standards to ensure optimal care
- Conducting or reviewing research to develop the body of evidence available and therefore enhancing the level of care provided to patients in future

(2) Audit:
- Continuous monitoring of clinical practice, (mostly about groups of patients or services)
- Identifying deficiencies in relation to set standards of care and remedying them
- Identifying improvements required and instituting them

(3) Risk management:
- Instituting robust systems to identify, understand, monitor and minimise the risks to patients
- Complying with protocols
- Reporting and investigating adverse incidents, looking closely at complaints or legal cases etc
- Learning from mistakes and near-misses (informally for minor issues, formally for the more serious events)

- Assessing the risks identified for their probability of occurrence and the impact they could have if an incident did occur
- Assessing equipment and staffing requirements to ensure optimal care
- Promoting a blame-free culture to encourage everyone to report problems and mistakes.

(4) Education and training:
- Instituting appropriate support to enable staff to be competent in doing their jobs and to develop their skills so that they are up to date
- Promoting continuous professional development (CPD), regular assessment and appraisals

(5) Patient and public involvement:
- Ensuring that the services provided suit patients, that patient and public feedback is used to improve services into day-to-day practice to ensure an increased level of quality and suitability, and that patients and the public are involved in their care, the development of services and the monitoring of treatment outcomes

(6) Using information and IT:
- Patient data is accurate and up-to-date, both in case notes and electronically
- Confidentiality of patient data is respected
- Full and appropriate use of the data is made to measure quality of outcomes (e.g. through audits) and to develop services tailored to local needs

(7) Staffing and staff management:
- Appropriate recruitment and management of staff
- Ensuring that underperformance is identified and addressed
- Encouraging staff retention by motivating and developing staff and providing good working conditions

Management

(1) Strategic management – The developmental of aims and specific objectives, the planning of services, facilities and equipment
(2) General management – the day-to-day operational issues, including meeting objectives
(3) Finance – the effective use of resources
(4) Human Resources – all aspects of staff management
(5) Public Relations – communications on a wide range
(6) Information Technology – which normally embraces case notes recording

(7) Governance – ensuring the Board complies with statutory regulation and is accountable
(8) Clinical Governance – the quality of care (see above)

Requirements

36. The Inquiry team requires your assistance with the following:

(i) The provision of a detailed analysis and overview of the clinical governance issues arising from Adam's case, with particular regard to issues at a clinical level. Should your interpretation of the term 'clinical governance' and your view of its scope differ significantly from that of the Inquiry, as set out above, then please advise the Inquiry as to the basis upon which you consider the material might be more appropriately considered.

(ii) An analysis of the documents, including the Reports and Statements, in terms of the main areas of 'management and clinical governance' identified above.

(iii) The identification of any protocols, guidance, standards or practices (hereafter referred to throughout collectively as "guidance" save where the context indicates to the contrary) that were applicable to the issues raised in Adam's case in 1995 and which the RBHSC may have been expected to take cognisance of and/or comply with. They should include any available guidance in the UK generally on the provision of services to children in hospital and how they were applied at that time, together with an indication of how that guidance and its application has developed since then.

(iv) Consideration of the Inquiry's particular queries identified below, the details and circumstances in which they arise are expanded upon in the Appendix. You are not asked to determine any of the matters that are still in dispute or in respect of which there remain differences of view as that is ultimately a matter for the Chairman, but simply advise in the light of them.

(v) In addition, you are asked to identify and (only after approval by the Chairman) pursue any additional issues that arise from the papers provided but which are not raised in this Brief.

37. The particular queries that the Inquiry has identified are as follows and should be considered in the light of the matters set out in the Appendix:

Communications with the Family

(1) What published guidance was available in Northern Ireland and the rest of the UK with regard to consent in 1995?

(2) In Northern Ireland, Circular HSS (GHS) 2/95 was published on 6th October 1995 ("Circular HSS 2/95"). At the time of Adam's surgery, was the consent procedure governed by the provisions of this circular? How should that Circular have been cascaded to clinical teams and what action should have been required of them?

(3) If the provisions of Circular HSS 2/95 were not in operation at the time of Adam's surgery, then what standard should have been set in relation to consent and how should it have been communicated to clinical teams?

(4) Did the consent procedure that was followed in this case comply with the provisions of Circular HSS 2/95, and/or any other relevant guidance practice?

(5) By reference to any relevant guidance applicable in 1995, what measures should hospitals have had in place for determining whether any applicable guidance on consent was being complied with, and for enforcing compliance in the event of a departure from it?

(6) Insofar as you can comment from the materials currently available to you, advise whether the RBHSC had adequate measures in place for determining that the applicable guidance in respect of consent was being complied with, and for enforcing compliance in the event of failures.

(7) What (if anything) should have happened in the event of the matters described under 'Communications with Family' in the section titled 'Issues' coming to light? What is your assessment of the response of the RBHSC?

Recording and Monitoring

(8) By reference to any relevant guidance in 1995, describe the record keeping and monitoring which would have been expected from a hospital such as the RBHSC in relation to:
- Preparation of a patient for major paediatric surgery, and
- Steps taken during the conduct of major paediatric surgery.

(9) By reference to any relevant guidance applicable in 1995, what measures should such hospitals have had in place for determining whether the

guidance for record keeping and monitoring was being complied with, and for enforcing compliance in the event of departure from it

(10) Insofar as you can comment from the materials currently available to you, advise whether the RBHSC had adequate measures in place for determining that the applicable guidance on record keeping and monitoring was being complied with, and for enforcing compliance in the event of failures.

(11) What (if anything) should have happened in the event of the matters described under 'Recording and Monitoring' in the section titled 'Issues' coming to light? What is your assessment of the response of the RBHSC?

Services, Equipment and Facilities

(12) By reference to any relevant guidance in 1995, describe what would have been expected from a hospital such as the RBHSC in order to ensure that blood gas machines were:
- Properly maintained,
- Subject to risk assessments,
- Subject to appropriate quality control checks,
- Subject to guidance as to their reliability, and
- Used only by trained technicians, nursing or medical staff

(13) Insofar as you can comment from the materials currently available to you, advise whether the RBHSC complied with the relevant guidance applicable to the maintenance, risk assessment, quality control checks, guidance and use of blood gas machines, or whether the steps that they took were otherwise adequate.

(14) By reference to any relevant guidance applicable in 1995, describe what was expected from a hospital such as the RBHSC in relation to the conduct of laboratory testing during major surgery, and in particular what would have been regarded as an acceptable response time for the production of biochemical results during major surgery.

(15) Insofar as you can comment from the materials currently available to you, advise whether the RBHSC complied with the relevant guidance applicable to the conduct of laboratory testing and the production of biochemical results during major surgery, or whether the steps that they took were otherwise adequate.

(16) By reference to any relevant guidance applicable in 1995, describe the steps that a hospital such as the RBHSC would have been expected to adopt in

order to identify, inspect and report on equipment which had been used in theatre following which a patient had died.

(17) Insofar as you can comment from the materials currently available to you, advise on whether the RBHSC complied with the applicable guidance on equipment in the context of its examination of the Siemens Monitor, or whether the steps that they took were otherwise adequate.

(18) Insofar as you can comment from the materials currently available to you, advise on whether the RBHSC had adequate measures in place for determining that the applicable guidance on its services, equipment and facilities was being complied with, and for enforcing compliance in the event of failures.

(19) What (if anything) should have happened in the event of the matters described under 'Services, Equipment and Facilities' in the section titled 'Issues' coming to light? What is your assessment of the response of the RBHSC?

Dissemination of Information and Institutional Links

(20) By reference to any relevant guidance applicable in 1995, describe the procedures that a hospital would have been expected to have in place and to have followed after an adverse incident in which a patient has died unexpectedly in order to:

- Investigate the incident, including in Adam's case both before and after any Inquest
- Assess and develop the competence of the staff involved in the treatment which led to the death
- Assess and develop the competence of the staff involved in the investigation as to the cause of Adam's death
- Disseminate outcomes and lessons learned internally, including in Adam's case both before and after any Inquest
- Disseminate outcomes and lessons learned externally, including in Adam's case both before and after any Inquest

In addition, identify the post-holder(s) within the hospital organisation who would have been expected to carry out these steps.

(21) Insofar as you can comment from the materials currently available to you, advise on whether, in Adam's case, the RBHSC complied with the applicable guidance for:

- Investigating an adverse incident
- Assessing and developing the competence of the staff involved in the treatment which led to the death of Adam

- Disseminating outcomes and lessons learned internally both before and after the Inquest
- Disseminating outcomes and lessons learned externally both before and after the Inquest

(22) Insofar as you have not already addressed it, what (if anything) should have happened in the event of the matters described under 'Dissemination of Information and Institutional Links' in the section titled 'Issues' coming to light? What is your assessment of the response of the RBHSC? In particular, what (if anything) should have been done about Dr. Robert Taylor's rejection of Adam's Death Certificate as accurate

Conclusion

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

39. Your assistance on the Inquiry's requirements should be provided in the form of a fully referenced Expert's Report appended to the attached Witness Statement form. Your Report, and any supplemental or addendum Reports will be made public.

APPENDIX

CIRCUMSTANCES IN WHICH THE ISSUES IDENTIFIED BY THE INQUIRY ARISE

(a) *Communications with the family*

Communications between clinicians and Adam's family has been an important area of the Inquiry's work. The paragraphs below highlight some of the areas which are of potential concern.

The inquiry would welcome your comments from a clinical governance perspective on the standards that would have been expected in 1995 with regard to communications with Adam's family and the taking of consent.

(1) It may be noted that about that time the Royal was seeking Kings Fund accreditation. There are several references in the minutes of meetings of the Board of Directors of the Royal Hospitals Trust (Ref: INQ-0194-10):

- Mentioned in the Agenda for 24th November 1995 – the matter was then deferred to the meeting of 5th December 1995 where it was discussed. An accreditation survey was carried out in the week 13th to 17th November 1995.
- At the meeting of 19th April 1996 it was reported that the Trust had been awarded 'provisional Kings Fund accreditation', with an opportunity to pursue full accreditation through a re-survey.
- At the meeting of 2nd May 1996, it was reported that the re-survey was to take place in early 1997. This was confirmed at the meeting of 3rd October 1996 as being scheduled for 28th January 1997.

The Inquiry has been advised that Belfast City Hospital received Kings Fund accreditation in June 1997 and the Royal 'some time after that' (Ref: INQ-0372-11). King's Fund Organisational Audit, their standards and accreditation may have relevance to other issues in Adam's care, not just in communication.

(2) There were discussions with Ms. Slavin, Adam's mother, leading up to the transplant (Ref: 093-006-016 and Ref: 093-003-004), but there is no evidence as to whether there was a discussion with Adam's family regarding the choices available including the best hospital to undertake such a procedure. Attached are schedules compiled from NHS Blood and Transplant data showing the paediatric renal transplant experience of the RBHSC as compared with other renal transplant centres.

(3) There is a reference to Ms. Slavin's apprehension of 'such major surgery', but no detail about the reasons for her apprehension.

(4) There is no record of the surgeon, Mr. Patrick Keane, having spoken to Ms. Slavin about the surgical procedure. There is a reference in a statement by the anaesthetist Dr. Robert Taylor (Ref: WS-008/1, page 1) to him having met Ms. Slavin: *"At about 05.45hrs I met with Adam and his mother and reviewed all available information pre-operatively"* but earlier he stated in his Deposition to the Coroner that *"On this occasion I was unable to speak to Miss. Strain (Adam's mother) prior to surgery"* (Ref: 011-014-108). In any event there is no reference to a discussion of any risks associated with anaesthesia of fluid management and there is no record of the discussion that Dr. Taylor claims he had. Furthermore, Adam's mother has stated that she *'was not spoken to by any consultant on the morning of the operation'* (Ref: 093-003-005). However, she does say in her Inquiry Witness Statement of 20th June 2005: *"I was aware of risks associated with surgery, but I know I was completely unaware of the dangers of fluid mismanagement until after Adam's death"* (Ref: WS-001/1, page 4).

(5) Formal consent to the transplant procedure was signed by Ms. Slavin on the day of the surgery (Ref: 058-039-185). The consent form was also signed by Adam's nephrologist, Dr. Maurice Savage, which confirmed that he had *"explained to the child's parent/guardian the nature and purpose of this operation"*. There is no reference to any other individual being involved or to any explanation given to Adam's family of any associated risks with the surgery.

(6) Ms. Slavin did not know the identity of the surgeons who would be operating on Adam before the start of the surgery, and therefore did not know anything about their expertise. She comments in her Deposition to the Coroner (Ref: 011-009-026) and her statement to the PSNI (Ref: 093-003-004) regarding the surgeons: *"Also Mr Brown was assisting Mr Keane, but to be perfectly honest neither of these pleased me very much"*. She elaborates on that in her Deposition and in her Inquiry Witness Statement of 20th June 2005: *"I was unhappy about Mr. Brown due to a previous surgical procedure"* (Ref: 011-009-027) and *"I had no idea that Mr. Brown was going to be present. This would have been an issue for me because I had quite clearly stated in the past that I did not want Mr. Brown to be involved in any surgery with Adam because previous experience had left me with no faith in him"* (page 2). It seems that she went as far as seeking a second surgical opinion in March 1993, which was provided by Mr. Boston and (save possibly for a procedure on 20th April 1993) Mr. Brown ceased thereafter to have any involvement in Adam's care.

(7) The Belfast City Hospital confirmed in a letter dated 25th July 2005 (Ref: 094-013j-081) that Mr. Patrick Keane had performed four paediatric renal transplants prior to Adam's surgery (over the period 1st January 1990 to 31st December 1994). He was the only available surgeon at the time competent to perform Adam's transplant surgery, two other surgeons being on sick leave. Mr. Stephen Brown has acknowledged that he had not performed any. Dr. Robert Taylor and not been involved in any renal transplants at RBHSC before Adam's transplant surgery. Dr. Terence Montague, who was assisting him, was a Senior Registrar in Anaesthesia, who had only started in PICU that month and had no experience in anesthetising children. There is no evidence that the family had been informed of the level of expertise within the team.

(8) The quality of the information given to Adam's family generally is difficult to assess due to the very limited information available in the records; there are no records of what she was told when Adam was first placed on the transplant list, no records of what she was told when consent was taken and very little is recorded of what she was told following Adam's surgery. Mr. William McKee (Chief Executive, Royal Hospitals Trust) received a letter dated 6th October 1995 from the Chief Executive of the Health and Personal Social Services Northern Ireland (as did all other Trust Chief Executives) enclosing the handbook, 'A Guide to Consent for Examination or Treatment' (Ref: INQ-0379-11, p.4). The letter asked all Health and Social Services Boards/HSS Trusts to *"ensure that procedures are put in place to assure that consent is obtained along the lines set out in the handbook"* (Ref: INQ-0379-11, p.2). It is not clear what (if anything) had been done by the Trust in response to that letter prior to Adam's transplant surgery. It is also not clear what guidelines and protocols were in operation on the provision of information generally to the family of a child patient and/or the maintenance of a written record of such discussions with parents.

(b) *Recording and monitoring*

The recording and monitoring of Adam's care has been a significant issue for the Inquiry's work. The paragraphs below highlight some of the areas which are of potential concern.

The inquiry would welcome your comments from a clinical governance perspective on the standards that would have been expected in 1995 with regard to the recording and monitoring of Adam's treatment and care, supported by any national or professional guidance that was available.

(9) There is an issue over whether Adam's left internal jugular vein was 'tied off' either in surgery prior to the transplant or during the transplant procedure itself. Apparently, that issue cannot be resolved solely by

recourse to Adam's medical notes and records. The significance of that unrecorded (or mis-recorded) procedure (or inaccurate identification at post-mortem examination) is that it may have contributed to the increase in central venous pressure that was recorded during the transplant procedure. The 'findings' in the Inquest Verdict include the possible *"obstruction of the venous drainage to the head"* as an exacerbating factor in the onset of Adam's dilutional hyponatraemia.

(10) There is also an issue over the precise fluids that Adam was given on the evening before his transplant surgery. Adam's charts record that he was given 952 ml of 'clear fluid' but nowhere is the precise nature of that 'clear fluid' stated. In addition, fluid output was not recorded.

(11) There is also an issue in relation to the recording of certain measurements and results:

(i) Following his admission on 26th November 1995, Adam's weight was recorded at 23:30 as being 20.2kg. Dr. Maurice Savage recorded Adam's weight the following morning as 21kg (a gain of about 4 per cent). Those results were not recorded on Adam's weight chart or his admission evaluation sheet. However, according to his Deposition, Dr. Robert Taylor appears to have proceeded on the basis that Adam's weight was 20kg. The significance is that a weight gain (assuming the difference is accurate and not attributable to the use of different machines etc) could indicate a degree of fluid retention prior to his surgery.

(ii) The Renal Protocol required a pre-surgery chest x-ray. Adam's medical notes and records include a pre-surgery x-ray request form issued by Dr. Donagh O'Neill (SHO in Paediatrics). However, there is no radiological report and no such x-ray has been discovered. Doubt has been cast over whether such an x-ray ever took place (Ref: 301-0495).

(iii) Adam's medical notes include a record of blood being taken for testing at 21:00 on the evening before surgery, 26th November 1995 and the results being received at 23:00, which for serum sodium were 139 mmol/l (entirely within the normal range of 135 to 145 mmol/l). The Inquiry has not been provided with the corresponding laboratory report.

(iv) Very recently a mis-placed laboratory report of 27th November 1995 has been provided for a serum sodium result of 133 mmol/l (just below normal) in relation to bloods taken on 26th November 1995

(Ref: 301-081) There is no reference to that test, or the results, in the notes.

(12) Given the fact that some of Adam's test results were not placed with his medical notes, there is an issue over the system to ensure that all results and x-rays (especially those that arrive after a child's death) are placed in the medical notes so that any subsequent investigation (whether or not internal) can be fully informed.

(13) There is an issue as to venous access prior to Adam's surgery. Drs. Maurice Savage and Dr. Robert Taylor refer in their Depositions to the difficulty in gaining venous access. Nevertheless, Adam's notes record that at 01:30 on 27th November 1995 the i.v. cannula tissued and that Dr. O'Neill was informed. They also record the re-insertion of the cannula at 05.00 and Adam being transferred to theatre at 07:00. Nurse Catherine Murphy states in her PSNI Statement that: "*Although his patient notes say he had his cannula re-inserted at 5.00am I have a vague memory of the doctor having difficulty in inserting this and Adam going to theatre without i.v. access being obtained*" (Ref: 093-007-024). Notwithstanding her entry in the notes (for which there has been no explanation) Adam went to theatre without iv access having been re-established.

(14) There would appear to be a huge variability within Adam's notes. So whilst a fluid balance and i.v. prescription sheet was completed indicating fluid input and output, there was no actual measurement of his urine output nor were there any nursing records of his peritoneal dialysis for the 26th and 27th November 1995. Nevertheless, Professor Alexander (Consultant Anaesthetist at the Belfast City Hospital), who was engaged as an Expert by the Coroner, states in his Report that: "*Dr. Taylor is to be commended on the detailed notes and records he kept throughout the anaesthetic*". That praise is echoed by Drs. George Murnaghan (then the Director of Medical Administration at the Royal), and Dr. Joe Gaston (Clinical Director of Anaesthesia, Theatres and intensive care at the Royal), in their Inquiry Witness Statements (Ref: WS-015/1, p.3 and Ref: WS-013/1, p.3). However, the Inquiry has been advised that record keeping in relation to Adam's fluid and nutritional management and his dialysis may have been inadequate.

Adam's medical notes and records disclose three principal 'measurement'/'recording' issues:

- Initial calculations as to the 'deficit fluids' and the 'maintenance fluids' as part of the calculation of the 'fluid replacement' to be administered to Adam during surgery;
- Loss of fluids during the surgery (blood, urine etc);

- Response to developments during the surgery through altering the level and nature of the fluids

Dr. Robert Taylor continually refers in his statements to *"we"* or the *"team"*, but there is no record of any such 'joint' or 'team' decisions. Furthermore, Dr. Terence Montague informed the PSNI that Dr. Taylor sent him home at around the start of Adam's surgery (Ref: 093-037-117).

(15) There is also an issue of the precise composition of the 'team'. Dr. Robert Taylor claims that there was a 'anaesthetic nurse' and has recently claimed that Dr. Terence Montague was replaced by a 'trainee anaesthetist'. There is nothing in the medical notes and records to indicate the presence of an anaesthetic nurse or a 'trainee anaesthetist' and the investigation into the matter is ongoing.

(16) In addition, the Kidney Donor Information Form (Ref: 058-009-025) accompanying the donor kidney was completed in part at the Western Infirmary Glasgow and in part at Belfast. Section II of the form is supposed to be completed by the *"recipient surgeon"* (in Adam's case, Mr. Patrick Keane). However, it seems to have been completed by Eleanor Donaghy (the Transplant Co-ordinator) who stated that it is often the co-ordinator who completes the form although it remains the responsibility of the surgeon. Mr. Patrick Keane has not acknowledged providing the medical description of the condition of the donor kidney for the purposes of the Kidney Donor Information Form, namely that it had 2 arteries (rather than 1) which were widely separated. There is no indication on the Form as to who provided that information.

(17) There is also an issue over the accuracy of the information recorded in the Report on Autopsy of Dr. Alison Armour and the way in which that information was obtained:

(i) Dr. Alison Armour carried out the autopsy on Adam on 29th November 1995. The brain and spinal cord were removed to be described after 'fixation'. She recorded in her notes the weight of the brain as 1,320g (Ref: INQ-0319-11). Slides were made of the lungs, larynx, liver, native kidneys, transplanted kidney, spleen, and lymph node.

(ii) The brain was cut on 12th January 1996. Dr. Armour recorded in her Report of Autopsy (Ref: 011-010-035) the 'fixed' brain weight as 1,680g. She also recorded in it that the following slides were seen by Professor Berry (Paediatric Pathology at University of Bristol & Consultant Paediatric Pathologist) and Dr. Mirakhur (Consultant Neuropathologist at the Royal) as follows:

- Professor Berry:
  Lungs, Larynx, Liver, Native kidneys, Transplanted kidney, Spleen, Lymph node
- Dr. Mirakhur:
  Brain, Spinal code, Histology

(iii) Professor Berry's involvement was pursuant to a letter from Dr. Armour dated 22nd December 1995 that asked him to provide an expert opinion for the Coroner (Ref: 011-029-151). To do so he was provided with: (a) Adam's notes; (b) Consultant Anaesthetist's Report; (c) Consultant Paediatric Nephrologist's Report; (d) Report on equipment; (e) slides of the lungs, larynx, liver, native kidneys, transplanted kidney, spleen, and lymph node.

(iv) There is no record of any official referral from Dr. Armour to Dr. Mirakhur. The Inquiry has been advised that the normal procedure for requesting a neuropathplogy examination is by a formal letter to the Consultant Neuropathologist from the Pathologist who conducted the autopsy in the State Pathologist's Department. No report from Dr. Mirakhur has been identified or made available. It is not known exactly what information was provided by Dr. Mirakhur to Dr. Armour. However, Dr. Armour states in her Inquiry Witness Statement that: *"As far as I am aware what is written in my autopsy report was concurred[sic] by her"* (Ref: WS-012/1, p.2, Q2b)

(v) It would appear that on 7th December 1995 Dr. Armour also showed "*slides etc.*" to Dr. O'Hara (Consultant Paediatric Pathologist at the Royal) and Dr. Bharucha (Consultant Haematologist at Belfast City Hospital). It is not clear what slides where shown as the only evidence of this is a note made by the Coroner following his conversations with, amongst others, Dr. Armour (Ref: 011-025-125). Apparently, Drs. O'Hara and Bharucha both stated: "*there was clear evidence of hypoxia/anoxia/anaphylatic [sic] reaction*"**.** That note also records the process by which the Coroner decided that: (i) the anaesthetic equipment should be independently examined and (ii) that Professor Berry should be asked to provide an expert opinion.

(vi) Dr. Armour's Report on Autopsy was provided on 24th April 1996. It makes no reference to Drs. O'Hara and Bharucha. Nor did it include any reference to the: "*clear evidence of hypoxia*" that they are said to have identified. Rather it states: "*There was no evidence of terminal hypoxia*" (Ref: 011-010-040). It also made no reference to the brain weight of 1,320g, referring only to the 'fixed' brain weight of 1,680g.

(c) Services, equipment and facilities

Attached are schedules compiled from NHS Blood and Transplant showing the paediatric renal transplant experience of the RBHSC as compared with other renal transplant centres.

There are issues concerning the operation of the laboratory for the receipt of the electrolyte tests that Dr. Maurice Savage requested as part of the preparation for Adam's transplant surgery, as well as issues over the operation and accuracy of the blood gas machine as a means of measuring sodium, and the testing of the Siemens Monitor. The details of these concerns are highlighted below. The Inquiry would welcome any views from you on the standards expected at the time for laboratory and equipment support and what management action would be expected at this time.

(18) Laboratory:

- Dr. Robert Taylor states that a laboratory test for a blood sample from Adam during his transplant surgery would have taken 30 minutes to arrange in November 1995 (Ref: 093-038-224). He then claims that it would not have been practical to 'carry out electrolyte tests at the commencement of surgery' (Ref: 011-014-108), referring 'to the difficulties in getting samples to the lab – this would take between 1 – 3 hours and before the result was received it was out of date' (Ref: 093-038-247). However, Dr. Maurice Savage considered that: *"the normal turnaround time for laboratory analysis of a serum sodium in 1995, which was non-urgent and during working hours, I believe would probably have been 3-4 hours. This would have been similar out-of-hours, but in the case of urgent specimens, particularly from an operating theatre of intensive care unit where the urgency was made clear, I believe the turnaround time would have been less than one hour."* (Ref: WS-002/3, P.45).
- A recommendation drafted by Dr. Taylor and others refers to: *"The Trust will continue to use its best endeavours to ensure that operating theatres are afforded access to full laboratory facilities to achieve timely receipt of reports on full blood pictures and electrolyte values thereby assisting rapid anaesthetic intervention when indicated"* – suggesting that there was room to improve laboratory response times (Ref: 011-014-107a).
- By agreement in December 2009 with the Health and Social Care Board, Interim Management and Support (IMAS) visited the RBHSC in February 2010: *"with a view to impart best practice suggestions for its urgent and emergency care programme for children, and to identify opportunities for improvement and modernisation"*. A letter dated 5th March 2010 setting out their observations includes reference to: *"We were told that the emergency department had no porters or dedicated clerical staff. The pneumatic air tube system is unreliable and when it is down, there are long delays to get specimens to the laboratories. Even when the system is working, there are a shortage of*

pods. There is no near-patient testing available" – suggesting difficulties with times and laboratory testing (see attached).

(19) Blood gas machine:

- Dr. Taylor claimed that he would not rely on the blood gas machine *"to accurately analyse sodium levels"* and that it was *"common practice in the RBHSC"* not to rely on them (Ref: 011-014-108).
- The manufacturer has produced a statement explaining what the level of accuracy that can be achieved and how it can be maintained.
- Dr. Taylor also states that in 1995 a nurse could not do a blood gas analysis, as that required an anaesthetist or possibly a technician to operate the machine (Ref: 093-038-222 to 093-038-223). The significance is that he argues that he could not spare anyone to check a blood gas sample until 09:30.

(20) Siemens Monitor:

- The Coroner asked that the equipment used during Adam's surgery should be *"independently examined"* (Ref: 011-025-125). Messrs. Wilson and McLaughlin (Medical Technical Officers employed by the RBHSC) carried out an inspection of the Siemens Monitor on 2nd December 1995 that had purportedly been used in Adam's surgery and they provided a report. They have said that they were not told the purpose of their investigation. That inspection was carried out in the presence of Dr. Fiona Gibson, Consultant Cardiac Anaesthetist at the RBHSC, who had been asked by Drs. Murnaghan and Gaston to review and report on the processes and equipment used in Adam's operating theatre. Dr Taylor was present during the inspection.
- The reports were positive and provided to the Coroner as part of the Inquest on Adam's death.
- In particular, Dr. Gibson stated in her report, which she provided to Dr. George Murnaghan, that: *"The Protocols for monitoring, anaesthetic set-up and drug administration in this area are among the best on the Royal Hospitals site"*(Ref: 059-069-162). The Inquiry has since been advised that there were no such protocols and that: *"Dr. Gibson will have been referring to her perception of clinical practice in RBHSC and not to any written document"* (letters dated 24th February 2011 and 21st July 2011 from Directorate of Legal Services to the Inquiry - Ref: INQ-0263-11 and Ref: INQ-0346-11 respectively)

- Subsequently, following queries by the PSNI in 2006, it turned out that they had all inspected and reviewed the wrong Siemens Monitor, as the correct one had been out for repair shortly after Adam's surgery and was on 'test' in the Department (See letter from Dr. A.P. Walby to the PSNI, Ref: 094-210-999).

(d) Dissemination of information and institutional links

(21) Adam's Inquest took place on 18th and 21st June 1996. Dr. Robert Taylor stated in his Inquiry Witness Statement that, on 19th June 1996 (i.e. during the course of the Inquest and just before his evidence on 21st June 1996), he worked with Dr. George Murnaghan, (Director of Medical Administration, The Royal Hospitals Trust), Dr. Maurice Savage and Dr. Joe Gaston (Consultant Anaesthetist and Clinical Director of Anaesthesia, Theatres and Intensive Care), to develop a press statement regarding 'Draft Recommendations for Paediatric Surgery' (Ref: 060-018-036). The final statement was a revised version of the original and had amended *"major surgery"* to *"major paediatric surgery"* and focused on those with *"a potential for electrolyte imbalance"*, which was portrayed as a rare circumstance (Ref: 059-008-025). The original simply stated: *"the Royal Group of Hospitals wishes to make it known that the future management of patients undergoing paediatric surgery will be carefully monitored and re-appraised having regard to this information which is now available"* (Ref: 060-018-036).

(22) Dr. Murnaghan stated in his Inquiry Witness Statement that *"all elective major surgery on children and infants in Northern Ireland is conducted in the RBHSC"* (Ref: WS 015/1, p.2). No definition of 'major surgery' was given (although it would seem not to include the appendectomy undergone by Raychel Ferguson in the Altnagelvin Area Hospital). The significance of that statement would seem to be that it rendered consultation with medical personnel outside the RBHSC unnecessary. Dr. Murnaghan also made a note in relation to the Inquest proceedings that: *"Other issues identified which relate to structure and process of paed renal transplant services – agreed with IWC that should deal with this as RM [risk management?] issue & arrange a seminar"* (Ref: 059-001-001). It would seem the suggested invitees were to be restricted to RBHSC personnel.

(23) The suggestion that the 'lessons learned' from Adam's death may have been confined to RBHSC personnel would seem to be reinforced by the e-mail, on 20th September 2004, from Christine Stewart (Press and Public Relations Officer, the Royal) to the Department: *"I've just spoken with Dr. Bob Taylor, consultant anaesthetist in PICU, who was involved in the management of Adam Strain and gave evidence at the inquest. Following a detailed examination of the issues surrounding patient AS [Adam Strain] there were no new learning points, and therefore no need to disseminate any information"* (Ref: 023-045-105).

(24) The Coroner stated in his Witness Statement to the Inquiry dated 15th July 2005 that: *"I had assumed that the Royal Belfast Hospital for Sick Children would have circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some 'best practice' guidelines. Children are not*

always treated in a paediatric unit and, in the event of surgery, the anaesthetist may not always be a paediatric anaesthetist" (Ref: WS 091/1, p.3).

(25) Dr. Robert Taylor, who has teaching duties, does not accept Adam's Death Certificate as accurate: *"Adam's kidneys were unable to concentrate urine even in the presence of increased ADH secretion so therefore could not retain free water and get dilutional hyponatraemia, the mechanism described by Arieff. This means I felt his death certificate was not accurate"*. (Ref: WS 008/2, p.39) That view is contrary to the views of Dr. Maurice Savage, Adam's Consultant Nephrologist, and Dr. Alison Armour, the pathologist who carried out the Autopsy on Adam. It is also contrary to the opinion of Dr. Edward Sumner, the Coroner's Expert, and to the Coroner's Verdict on Inquest.

DOCUMENTS ATTACHED

1. There is a large amount of documentation on which the description of Adam's Care in this brief is based, including:

   (i) Contemporaneous documents:
   - Adam's Medical notes and records
   - Protocols relating to treatment
   - Reports on equipment
   - Report on Autopsy
   - Minutes of the Board of the RBHSC
   - Departmental Circulars

   (ii) Subsequent documents:
   - Inquest Depositions provided to the Coroner by Adam's mother, the treating clinicians, technical personnel and the pathologist. Also expert Reports obtained by the Coroner on clinical matters (Anaesthetists and a Pathologist)
   - PSNI Statements from Adam's mother, the nursing and medical staff, technical personnel, the pathologist, senior management at the RBHSC (Clinical Director for Anaesthetics, Theatres and Intensive Care and the Director of Medical Administration), together with a statement under caution from the treating Consultant Anaesthetist. Also, expert Reports obtained by the PSNI as part of their investigation (Anaesthetist, Pathologists, Surgeon)
   - Witness Statements provided to the Inquiry by Adam's mother, the nursing and medical staff, technical personnel, the pathologist, senior management at the RBHSC (Clinical Director for Anaesthetics, Theatres and Intensive Care and the Director of Medical Administration) and the Chief Executive

2. The documents and information set out below have been requested from the Departmental Legal Services and is outstanding. Please let us know if there is anything that you particularly wish to see for the purposes of preparing your report and we will seek to expedite matters.

1. Policies, Procedures, Protocols, Guidelines & Practices	
1(a) Complaints and litigation procedures from 1994 to date Other than: *Trust's 1998 Policy: 'Management of Formal & Informal Complaints (TP22/98) - (DLS letter 8th*	

September 2011 - Ref: INQ-0405-11)	
1(b) Clinical Governance Strategy (from 1994 or from earliest policy)	To include any written policies on: • Clinical Effectiveness, to include any policy about the implementation of good practice e.g. NICE, college guidelines • Clinical audit including morbidity & mortality audit • Risk management • Incident reporting • Patient and public involvement • Medical records, (including information on how case notes are managed and audited) • Medical and other staff appraisal process Also to include any monitoring procedures relating to these policies
1(c) Consent to treatment (from 1994 – to date): Other than: *'Patient Consent to Examination or Treatment' Ref: HSS (GHS) 2/95, 6th October 1995 & A Guide to Consent for Examination or Treatment, which were issued to the Chief Executives of all Trusts*	
1(d) Communication with patients and families guidance (from 1994 – to date)	
1(e) Management of children on dialysis (from 1994 onwards)	
1(f) Assessment and management of children in hospital (1994 onwards)	
1(g) The policy on/framework for assessment of competence in practice for nurses	This should include a competence assessment tool
1(h) Admission & Discharge policy (1994 onwards): Other than: *'Standard of Discharge letters' – Medical Audit Meeting 9th February 1996 (DLS letter 2nd August 2011 - Ref: INQ-0357-11)*	
1(i) Record keeping (1994 onwards) : *We have been advised that prior to December 2004 there was no specific guidance on destruction/retention of records of records other than Medical Records and Social Care*	

Records and the retention of other papers was subject to local practice influenced by storage issues. *We have also been advised that in December 2004 DHSS&PS issued the guidance 'Good Management Good Records', in response to which the Trust introduced its policy in March 2008 - (DLS letter 26th September 2011 - Ref: INQ-0419-11)*	
1(j) Monitoring & evaluation of adherence to policies, protocols, procedures, guidelines and practices, including the frequency of the review of such instruments	
2. Information	
2(a) *Any information on Adam Strain* or his case from November 1995 to November 1996 in any notes or minutes of the following meetings at (i) to (viii): NB. These may not be the precise titles of the meetings but they indicate the type of meetings in which the Inquiry is interested NB. All meeting minutes should include attachments/papers submitted to meetings, terms of reference, reporting structures (up and down the organisation) and the membership (role not named person) from October 1995 onwards	(i) Clinical Directorate/Directorate Management meetings in paediatrics
	(ii) Minutes of Paediatric Anaesthetics, Paediatric Surgical and Paediatric Renal Team meetings
	(iii) Management Executive Team meetings *We have been advised by DLS letter 18th October 2010 (Ref: INQ-0218-10) that minutes of these meetings were scanned in to the 'Hummingbird Document Management System' from 1998 and no minutes prior to that were retained*
	(iv) Trust Board meetings Other than: *Copies of: (a) Agendas and (b) Minutes of monthly meetings of Trust Board of Directors from*

	27th October 1995 to 9th January 1997 except for the meeting of 24th June 1996 for which it seems no minutes were taken (DLS letter 18th October 2010 - Ref: INQ-0218-10) *We have been advised that there are no minutes for meetings of the Board's Audit Committee before 1999 as these are kept in the Finance Department and only retained for 7 years as per 'the professional code' (DLS letter 18th October 2010 - Ref: INQ-0218-10)*
	(v) Post-graduate meetings
	(vi) Clinical Audit meetings *We have been advised that deaths are discussed at the Paediatric Directorate Clinical Audit Meetings but that no names or clinical details are ever given (DLS letter 18th October 2010 - Ref: INQ-0218-10)* *We have also been advised that the minutes of those meetings have been destroyed in accordance with Trust Policy but that a few 'random minutes have survived' eg. 8th November 1995 and 9th February 1996 (DLS letter 21st July 2011 - Ref: INQ-0347-11). A copy of those minutes has been provided – (DLS letter 2nd August 2011 – Ref: INQ-0357-11). A copy has also been provided of the minutes for the meeting on 10th December 1996 (attached to Dr. Murnaghan's Inquiry Witness Statement Ref: WS-015/1, p.5)*
	(vii) Complaints/litigation meeting
	(viii) Records management committee meetings
2(b) Organisational chart of the Management of the Royal Group of Hospitals & Dental Hospital Health & Social Services Trust in 1995, showing the position of RBHSC within it	*We have been given a brief and inadequate description of this - (DLS letter 22nd July 2011 - Ref: INQ-0350-11)*
2(c) Organisational chart of the Management of the Belfast Health & Social Care Trust as at 2011, showing the position of RBHSC within it	*We have been given a brief description of this - (DLS letter 22nd July 2011 - Ref: INQ-0350-11) but not an organisational chart*
2(d) Structure of the RBHSC and its specialist service departments including the laboratory, both in 1995 and as at 2011	
2(e) Structure of the Nephrology Department within RBHSC, including the	

Renal Transplant Centre, , both in 1995 and as at 2011	
2(f) Organisational Chart of the Management of the RBHSC including the Nephrology Department and the Renal Transplant Centre, both in 1995 and as at 2011	
2(g) Job descriptions for Night Sisters and Ward Sisters covering 1994 to current time	*We have been given the Job Descriptions of the Clinical Directors: (i) Paediatrics (Jan.2003), (ii) Anaesthetics (Nov.2010), (iii) Chief Executive (2010); (iv) Medical Director (Jan.2002).* *Also we have been advised that they did not have job descriptions in 1995 - (DLS letter 22nd July 2011 - Ref: INQ-0350-11)* *We have been given the job description (August 2007) of the equivalent to the 1995 Nurse Manager ie Childrens Services Manager – as the Trust cannot locate the personnel file for the Nurse Manager at the time (Audrey Lockhead) - (DLS letter 8th September 2011 - Ref: INQ-0407-11)*

3. We attach the following documents that are referred to in the Brief to provide a context and information for the preparation of your Report:

(i) DVD of 'When Hospitals Kill' – UTV documentary that was shown in 2004

(ii) Chronologies:
- Clinical
- Governance

(iii) Schedules compiled from NHS Blood and Transplant data showing the paediatric renal transplant experience of the RBHSC as compared with other renal transplant centres

(iv) Report on Autopsy (Ref: 011-010-034) and:
- Notification of autopsy findings (Ref: 094-114-321)
- Autopsy Request form signed by Dr. Taylor (WS-012/2 Page 26 – Page 29)
- Dr. Alison Armour's notes (WS-012/2 Page 18 – Page 25)
- Coroner's note (Ref: 011-025-125)
- Letter to Professor Jeremy Berry (Ref: 011-029-151)
- Email between State Pathologist's Department and the Royal (Ref: 306-057 (INQ-0486-11))

(iii) Coroner Depositions:
- Debra Slavin, Adam's mother (Ref: 011-009-025)

- Dr. Alison Armour, Pathologist (Ref: 011-010-030)
- Dr. Robert Taylor, Adam's Consultant paediatric anaesthetist, and the draft 'statement he produced dealing with 'lessons learned' (Ref: 011-014-096)

(iv) Papers collated by the Trust for the Coroner (file 59)

(v) Departmental Witness Statements

(vi) PSNI Witness Statements:
- Debra Slavin (Ref: 093-003-003)
- Dr Robert Taylor's PSNI interview transcript (Ref: 093-038-119)
- Dr Terence Montague, an anaesthetist who assisted Dr Taylor during Adam's surgery (Ref: 093-037-117)
- Catherine Murphy, Nurse (Ref: 093-007-024)
- Dr. George Murnaghan, Director of Medical Administration (Ref: 093-025-068)
- Dr Joe Gaston, Clinical Director for Anaesthetics, Theatres and Intensive Care (Ref: 093-023-066)

(vii) Inquiry Witness Statements & Expert Report:
- Debra Slavin
- Dr. Robert Taylor
- Dr Maurice Savage, Adam's consultant paediatric nephrologist
- Dr. Joe Gaston
- Dr. George Murnaghan
- Mr. William McKee, Chief Executive
- John Leckey, Senior Coroner
- Dr. Alison Armour, Pathologist
- Mr. David Wheeler, Business Manager for Critical Care & Clinical Chemistry Division – Instrumentaton Laboratory UK Ltd
- Expert Report of Simon Haynes on anaesthetics of 2nd August 2011 (p.21 et seq addresses: "How anaesthetists would deal with lessons learned following an 'adverse incident' or 'near miss' in 1995 (and now)" (Ref: 204-002-039)

(viii) Correspondence with Departmental Legal Service & Department of Health
- Ref: 305-016 (INQ-0194-10) – Minutes of Meetings of Board of Directors of the Royal Hospitals Trust
- Ref: 305-013 (INQ-0263-11) & Ref: 305-014 (INQ-0346-11) - correspondence regarding Dr Gibson's laboratory equipment report
- Ref: 305-001 (INQ-0372-11) – information regarding King's Fund accreditation

- Ref: 306-058 (INQ-0379-11) – copy of guidance note HSS(GHS)2/95 'A guide to Consent for examination or treatment', which was circulated on 6th October 1995
- Ref 301–081 (INQ-0450-11) - correspondence regarding mis-placed laboratory result
- Ref 301-095 (INQ-0494-11) – correspondence regarding missing pre-operative chest x-ray
- Ref: 306-059 - NHS correspondence to the RBHSC dated 5th March 2010 on NHS IMAS Intensive Support Team Visit together with HSC released on 25th January 2011 – 'IMAS Report: a overview'

(ix) Background Papers:
- Ms. Bridget Dolan – Coroners (including the extent to which any of the deaths might have been avoided if lessons learned had been effectively communicated to the relevant bodies, both in terms of deaths being promptly reported to and investigated by the Coroner, and in terms of lessons being communicated and learned by the appropriate bodies post-inquest)
- Dr. Jean Keeling – Dissemination of information gained by post-mortem examination following unexpected death of children in hospital

(x) Miscellaneous
- Consent form for Adam's renal transplant (Ref: 058-039-185)
- Kidney Donor Information Form (Ref: 058-009-025)
- Letter from Mr A P Walby, Associate Medical Director, Royal Hospitals Trust, to D/S Cross regarding testing of Siemens monitor (Ref: 094-210-299)
- Early draft of recommendations for the prevention and management of hyponatraemia arising during paediatric surgery (Ref: 060-018-036)
- E-mail from Christine Stewart, Press and Public Relations Officer, Royal Hospitals Trust, dated 20th September 2004, regarding her meeting Dr Bob Taylor (023-045-105)
- Number of paediatric renal transplants performed by Mr Keane (Ref: 094-013j-081)

4. Please contact the Inquiry Secretary to discuss any other or further documents that would be helpful for you to have in forming your views and providing your Report.