CLINICAL OPENING: ADAM DOB 4th August 1991

THE ORAL HEARINGS IN THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Chairman: John O'Hara Q.C.

Banbridge Court House, 26th March 2012

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I. Introduction

1. The hearing into Adam's case involves both 'clinical issues' and 'hospital management and governance issues'. The clinical issues are to be addressed first. There will then be another hearing concerning management and governance issues that I will open separately.

2. The purpose of this Opening is to open the hearing on the clinical issues and to:

   (i) Provide a context within which to consider the clinical evidence

   (ii) Draw attention to the investigation that has been carried out, the evidence that it has produced and its relevance to the Revised Terms of Reference and the List of Issues

   (iii) Highlight the main issues and identify in general terms the areas that the Legal Team considers require further testing and probing through questioning in the Oral Hearing.

II. Evidence Received

3. I am conscious that you will be making findings and recommendations on the basis of the totality of the evidence received and not just what is heard during the Oral Hearings, important as that aspect of the investigation is. I will therefore try and set out for you some of what has been received from all the categories described during the General Opening.

4. I will not presume to summarise everything as that would be an impossible task as well as being time consuming. Also you will have the complete set of the evidence that has been obtained.

5. During the General Opening on 20th February 2012[1], I explained that following the establishment of the Inquiry on 1st November 2004[2], requests for information and evidence were sent out to a number of bodies including, in relation to Adam's case:

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1 Ref: 'Opening Statement by Senior Counsel to the Inquiry' on the Inquiry website, under heading of 'Latest News'

2 Ref: 008-032-093

(i) Department of Health, Social Services and Public Safety

(ii) Royal Group of Hospitals HSST

(iii) Eastern Health & Social Services Board

(iv) Coroner for Greater Belfast

(v) Adam's family

6. The call for documents has been ongoing since the resumption of the Inquiry's work in 2008 and it is continuing. The search for relevant documents has and is being informed by guidance from the Inquiry's Advisors, from its Experts and from the responses to requests for Witness Statements.

Documents & Other Material

7. To date the Inquiry has received a vast amount of material in relation to Adam's case, including:

(i) Adam's medical notes and records[3]

(ii) Adam's developmental records[4]

(iii) Reports, scans, x-rays, photographs, correspondence and other documents generated by or for the Ulster Hospital in Dundonald ("Ulster Hospital"), Royal Group of Hospitals, including the Royal Belfast Hospital for Sick Children ("Children's Hospital")

(iv) Depositions[5] from the Inquest into Adam's death and Reports commissioned by the Coroner, including those from:

- Debra Strain[6]
- Dr. Alison Armour[7] (Pathologist, Institute of State Pathology, who was asked to provide a Report of Autopsy)

3 From Ref: 049-001-001 to 058-048-246
4 From Ref: 016-003-013 to 016-098-154
5 Throughout this Opening, the positions of those involved is given as it was at the relevant time, unless it is relevant to also identify their position at any other time
6 Deposition Ref: 011-009-025
7 Deposition Ref:011-010-030; Report of Autopsy Ref: 011-010-034

- Dr. John Alexander[8] (Consultant Anaesthetist, Belfast City Hospital, who was asked to provide an expert report on Adam's anaesthetic management)

- Dr. Edward Sumner[9] (Consultant Paediatric Anaesthetist, Great Ormond Street Hospital, who was asked to provide an anaesthetic opinion from a paediatric standpoint)

- Mr. Patrick Keane[10] (Consultant Urologist, Belfast City Hospital and the surgeon in Adam's case)

- Dr. Robert Taylor[11] (Consultant Paediatric Anaesthetist, Children's Hospital and the anaesthetist in Adam's case)

- Dr. Maurice Savage[12] (Consultant Paediatric Nephrologist, Children's Hospital and Adam's nephrologist)

- Professor Peter Berry[13] (Professor of Paediatric Pathology, University of Bristol, who provided a pathological report concentrating on the state of Adam's kidneys)

(v) Documents held by Adam's family[14]

(vi) Correspondence and Transcripts from UTV plc[15]

(vii) Documents from the investigations of the Police Service of Northern Ireland ("PSNI"), including:

- Statements from witnesses, including the transcript of an interview of Dr. Taylor taken under caution on 17th October 2006[16] .

- Reports they commissioned from Dr. Edward Sumner[17] (Consultant Paediatric Anaesthetist, Great Ormond Street Hospital) and Mr. Geoff Koffman[18] (Consultant Surgeon, and

8 Deposition Ref:011-012-079; Medical Report Ref: 011-012-084
9 Deposition Ref:011-011-042; Medical Report Ref: 011-011-053
10 Deposition Ref: Ref:011-013-093
11 Deposition Ref: 011-014-096
12 Deposition Ref: 011-015-109
13 Report Ref: 011-007-020
14 Contained at Ref: 070-001-001 to 070-024-293
15 Contained at Ref: 069-001-001 to 069B-044-294
16 Ref: 093-038-121
17 Medico-legal Report Ref: 094-002-002
18 Medico- legal Report Ref: 094-007-027

Surgical Head of Paediatric Unit, St. Thomas Hospital and Great Ormond Street Hospital, London), both as Experts

- Correspondence and other documents relating to Dr. John Burton[19] (Post-graduate Law Researcher) who offered the PSNI assistance in regard to the case

(viii) Documents from other bodies and organisations such as:

- Department of State Pathology
- National Patient Safety Agency
- NHS Blood and Transplant
- Royal College of Paediatrics and Child Healthcare
- Medical and Dental Training Agency
- NHS Greater Glasgow and Clyde

(ix) Correspondence from Directorate of Legal Service ("DLS") providing responses to the Inquiry's requests for information[20]

8. In addition, the Inquiry also obtained histological slides and other material in relation to Adam that was held by the State Pathologist's Office - to be examined and reported on by its Expert Neuropathologist Dr. Waney Squier. She also made her own slides from some of the material, all of which has been recovered by the Inquiry and is being securely held.

Publications

9. The Inquiry has been referred to numerous publications by its Advisors, Experts, Witnesses and the legal representatives of Adam's family. The Legal Team has carried out its own research and has compiled a bibliography of all of those publications, which is updated as further authorities are cited. The bibliography is available on the Inquiry website[21].

10. The majority of the articles in the bibliography concern the condition of hyponatraemia itself, including case studies, causative factors, the role of

[19] Medico – legal Report Ref: 094-013-053 & other correspondence and documents Ref: 094-013a, 013b, 013e, 013f, 013g, 013h, 013i, 013j, 013k & 013l.

[20] Contained at Ref: 301 (see all)

[21] Ref: 'Articles Index' under heading 'Key Inquiry Documents'.

hypotonic fluids, its effects and risk of morbidity. However, there are also other articles that cover areas as disparate as expected brain weights in children, the effect of heparin on blood gas analysis, the calculation bladder capacity to the development of posterior reversible encephalopathy syndrome (PRES).

11. As you will be aware, Mr. Chairman, the medical literature available on hyponatraemia has assumed even greater prominence given the debate amongst the Inquiry's Experts during their meeting of 22nd February 2012 and 9th March 2012 on the arguments over what the literature shows in relation to hyponatraemia, chronic venous sinus thrombosis and PRES. Indeed the issue of 'the literature' was on the agenda for both of the Experts' meetings.[22]

Background Papers

12. In the General Opening, I also referred to the commissioning of Background Papers by Experts to provide a context for the consideration of the evidence. Of particular relevance to the investigation into the clinical issues involved in Adam's case are the Background Papers of:

    (i) Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust[23] and Professor Sir Alan Craft, Emeritus Professor of Child Health, Newcastle University Education[24] on the training and continuing professional development of doctors in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2009

    (ii) Professor Mary Hanratty, former Vice-President of the Nursing and Midwifery Council[25] and Professor Alan Glasper, Professor of Children and Young Person's Nursing, University of Southampton[26] on the training and continuing professional development of nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2011

22 Ref: 307-007-073 (transcript of the meeting on 22nd February 2012) and Ref: 307-008-162 (transcript of the meeting on 9th March 2012)

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

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

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

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

(iii) Dr. Bridget Dolan, Barrister at Law and Assistant Deputy Coroner,[27] on the systems of procedures and practices in the United Kingdom for reporting and disseminating information on the outcomes or lessons to be learned from Coroner's Inquests on deaths in hospital (involving Hospitals, Trusts, Area Boards, Department of Health and Chief Medical Officer)

(iv) Dr. Jean Keeling, Paediatric Pathologist, on the system of procedures for the dissemination of information gained by post-mortem examination following unexpected death of children in hospital[28].

Expert Reports

13. The Inquiry has also engaged Experts, again as guided by the Advisors, to address generally the role of the Nephrologists, Anaesthetists, Surgeons and Nurses involved in Adam's case:

(i) Dr. Malcolm Coulthard (Honorary Consultant Paediatric Nephrologist, Royal Victoria Infirmary) whose Reports address issues such as the roles and responsibilities of the Nephrologists involved in Adam's case (Dr. Savage and Dr. O'Connor), an explanation as to Adam's renal function, as well as expert analysis of the management of Adam's fluid balance and electrolytes

(ii) Dr. Simon Haynes (Consultant in Paediatric Anaesthesia and Intensive Care - Freeman Hospital, Newcastle upon Tyne) whose Reports concern matters such as the role and responsibilities of the Anaesthetists involved in Adam's case (Dr. Taylor and Dr. Montague), the relationship between Surgeons and Anaesthetists in the operating theatre during transplant surgery, as well as providing analysis of Adam's fluid balance

(iii) Mr. John Forsythe (Consultant Transplant Surgeon, Royal Victoria Infirmary, and Honorary Professor of Surgery, University of Edinburgh) and Mr. Keith Rigg (Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust) who have provided joint Reports on amongst other matters the role and responsibilities of the Surgeons involved in Adam's case (Mr. Keane and Mr. Brown), the skills required and involved in a paediatric renal transplant including the techniques used for anastomoses, as well

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

[28] Paper to the Inquiry into Hyponatraemia-Related Deaths: 'Dissemination of information gained by post-mortem examination following unexpected death of children in hospital'- Ref: 303-053-754

as the relationship between the Surgeons and Anaesthetists during transplant surgery

(iv) Ms. Sally Ramsay (Independent Children's Nursing Advisor) has provided a Report on the nursing aspects of Adam's care

14. I will refer to some of their views later on in this Opening for the purposes of helping to identify the issues to be addressed during the Oral Hearing.

15. In addition the Inquiry engaged Experts to provide Reports on a number of specific issues, including:

(i) Professor Peter Gross M.D (Professor of Medicine and Nephrology) who has provided Reports on hyponatraemia and an analysis of Adam's fluid management

(ii) Professor Fenella Kirkham MB, BChir FRCPCH (Professor of Paediatric Neurology, Institute of Child Health, London and Consultant Paediatric Neurologist, Southampton General Hospital) who was asked by the Inquiry to give a neurological opinion into the effect of the infusion of fluids during surgery had on Adam's brain and the possible contribution, if any, of venous obstruction to Adam's cerebral oedema. As you are aware, Mr. Chairman, Professor Kirkham has since queried the exact role that dilutional hyponatraemia played in Adam's death, and has suggested cerebral venous thrombosis and PRES as alternatives. This issue was discussed at length by the Inquiry's Experts in their meetings on 22nd February 2012 and 9th March 2012.

(iii) Dr. Caren Landes (Consultant Paediatric Radiologist) who has examined and reported on chest x-rays taken of Adam at 13:20 on 27th November 1995 and 21:30 on 27th November 1995[29]

(iv) Dr. Waney Squier (Consultant Neuropathologist and clinical Lecturer, John Radcliffe Hospital, Oxford) who provided an expert Neuropathological opinion from histological slides that she made from the tissue blocks of Adam's brain. She also examined a sequence of photographs of Adam's brain taken at autopsy by the pathologist Dr. Alison Armour and received input from Dr. Philip Anslow on a post-surgical CT scan of Adam's brain

(v) Dr. Philip Anslow (Consultant Neuroradiologist, Radcliffe Infirmary, Oxford) who was brought in by Dr. Squier to assist in

[29] Ref: 207-005-010

interpreting CT scans taken of Adam's brain on 7th July 1995[30] and the post-surgical scan taken at approximately 13:15 on 27th November 1995[31]

16. The Reports of the Experts that have been received to date in Adam's case have all been made available to the Interested Parties and they will be published in due course in accordance with the Protocols and procedures that you have established Mr. Chairman.

Witness Statements

17. In addition to the Depositions that the Inquiry received from the Inquest[32] and the Statements from the PSNI investigation,[33] the Legal Team also requested and received a large number of Witness Statements and Supplemental Witness Statements from a variety of persons involved to varying degrees in Adam's case. The Legal Team has been guided in that task by:

    (i) The Inquiry's Advisors

    (ii) Medical notes and records and other contemporaneous material

    (iii) Previous statements made, whether through Depositions to the Coroner, Statements taken by the PSNI or Witness Statements to the Inquiry

    (iv) Statements from others

    (v) Subsequent documents received from the DLS and a variety of other sources

    (vi) Reports from the Inquiry's Experts

18. The Legal Team has compiled a list of all those involved in the Clinical area of Adam's case from all of the information received by the Inquiry [34]. It explains their position then and now, briefly summarises their role in Adam's case, and whether they have provided a statement and if so for whom. Importantly it also indicates the witnesses that it is proposed to call to give evidence during the Oral Hearing.

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30 Ref: 057-114-332
31 Ref: 058-038-182
32 Ref: 011-001-001 *et seq*
33 Ref: 093-001-001 *et seq*
34 List of Persons Involved: Adam (Clinical): Ref: 303-001-001

19. It is entirely possible for the evidence provided in a Witness Statement to be sufficient on any given issue. That is particularly the case where it is not contradicted by another Witness or information from any other source or where it is clear from an Expert Report that further probing of the Witness would not be useful. Should the evidence in a Witness Statement be regarded as sufficient, then it will stand in lieu of oral evidence from that Witness. The Inquiry Witness Statement, PSNI Statement or Deposition, as the case may be, of those who are not being called will be tendered as an unchallenged account.

20. In due course Mr. Chairman the Legal Team will compile a Schedule of all those whose evidence it is tendering to you in that way. It will be a matter for you Mr. Chairman whether you nonetheless wish the Witness to be called.

21. Unfortunately, there are Witnesses in respect of whom it has not been possible for the Legal Team to obtain an Inquiry Witness Statement or who are not available to give evidence at the Oral Hearing. For example, the Coroner records that on 7th December 1995 the pathologist Dr. Alison Armour showed histological slides of Adam to Dr. Denis O'Hara who was then Consultant Paediatric Pathologist, Royal Hospitals.[35] This was after Dr. Armour had conducted the autopsy. The Coroner's note of 8th December 1995 records that Dr. O'Hara and a Dr. Bharucha (to whom the slides were also shown, considered that *'there was clear evidence of hypoxia/anoxia/ anaphylatic [sic] reaction'*[36]. Dr. O'Hara is deceased and the Inquiry does not have a statement from him of any type since he was not called by the Coroner, nor did he give a Statement to the PSNI. As I indicated Mr. Chairman during the General Opening all we have of Dr. O'Hara's views is what was recorded by the Coroner in his note of 8th December 1995.

22. A further example is provided by Dr. Fiona Gibson (Consultant Anaesthetist, Royal Hospitals). She was asked by Dr. George Murnaghan (Director of Medical Administration) to visit the theatres in the Children's Hospital with Messrs Wilson and McLaughlin.[37] She provided a short report dated 4th December 1995 in which she concluded: *"The Protocols for monitoring, anaesthetic set-up and drug administration in this area are among the best on the Royal Hospitals site and I can see no reason to link these very sad cases into any pattern"*.[38] The Inquiry requested a Witness Statement from her in 2005 and it is quite possible that she would have been called to give

35 Ref: 011-025-125
36 Ref: 011-025-125
37 Ref: 011-005-017 & Ref: 093-026-069
38 Ref: 011-005-017

evidence at the Oral Hearing. Furthermore, the Inquiry subsequently received correspondence from the DLS that contradicts Dr. Gibson's reference to 'protocols', explaining that she might have meant 'practices' instead.[39] The Legal Team would have wished to pursue that issue with her both in relation to this part of Adam's case and that concerned with 'governance'. Unfortunately, Dr. Gibson is not available to the Inquiry for medical reasons. The only information that the Inquiry has on her views are those contained in her statement to the PSNI and her Report.[40]

23. It will be a matter for you Mr. Chairman to determine what weight you will afford the information that we have from those whom the Legal Team has not been able to pursue its inquiries.

Documents compiled by the Inquiry

24. It has been vital for the Legal Team to develop ways of distilling the vast amount of information accumulated by the Inquiry. Accordingly, the Legal Team has compiled a number of schedules and charts to try and provide that information to you Mr. Chairman in a more accessible way in relation to the issues. I will refer to such documents throughout this Opening Mr. Chairman and will explain their use and significance.

25. A list of all those compiled documents will be provided to you in due course. Since the investigations are continuing, it is possible that further such documents will be provided.

III. Adam & His Family

26. Adam Strain was born at 10:58 on 4th August 1991 at the Ulster Hospital in Dundonald by caesarean section[41]. We can see that hospital on the map 'Health and Personal Social Services Northern Ireland'[42] which shows the location of the hospital and how it relates to the Children's Hospital, where he was subsequently transferred.

27. Antenatally cysts had been noted in Adam's abdomen[43]. It was not clear what they were but an ultra sound scan performed after his birth showed that he had dysplastic kidneys with bilateral large cysts[44].

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39 Ref: 306-014-604
40 Ref: 011-005-017 and Ref: 093-026-069
41 Ref: 050-022-061
42 Health and Personal Social Services Northern Ireland - Ref: 300-001-001
43 Ref: 050-022-061
44 Ref: 050-022-061

28. Adam's clinical history and its possible relevance to what happened to him during his transplant surgery on 27th November 1995, will be set out in greater detail later on in this Opening. However, in summary, he developed problems with the drainage of his kidneys related to obstruction and vesico ureteric reflux[45]. He was referred to the Children's Hospital from the Ulster Hospital[46] when he was a few months old and came under the care of Dr. Maurice Savage (Consultant Paediatric Nephrologist) and Mr. Stephen Brown (Consultant Paediatric Surgeon).

29. Thereafter, Adam had multiple operations to his urinary tract for which he was largely under the care of Mr. Brown. He had re-implantation of his ureters on 2 occasions[47] and had nephrostomies[48], which were performed during the early months of his life. On several occasions, he was critically ill and required care in PICU[49] and he had a brief period of dialysis due to acute renal failure[50]. In addition, a fundoplication procedure was carried out in 1992[51] 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 cystoscopy[52] and PEG gastrostomy[53].

30. Adam was subject to recurrent urinary tract infections and his renal function deteriorated to the point where, in August 1994, he required dialysis for uraemia[54]. His mother was trained in the home peritoneal dialysis technique so that he could be dialysed at home[55]. According to Dr. Savage, Adam's urine output was quite large but of poor quality and he described him as being polyuric[56].

31. Also according to Dr. Savage[57], 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

45 Ref: WS-002-1 p.2
46 Ref: 049-025-061
47 Ref: 049-007-014 & Ref: 049-007-015 & Ref: WS-002-1 p.2
48 Ref: 051-023-112 & Ref: WS-002-1 p.2
49 Ref: 049-007-014
50 Ref: 049-007-014
51 Ref: 050-008-033
52 Ref: 055-053-108
53 Ref: 055-046-093
54 Ref: 056-029-061
55 Ref: 056-005-014
56 Ref: 053-021-066
57 Ref: WS-002-2 p.5 & p.26

result of 124mmol/l[58] and a number below the normal range of 135-145mmol/l[59].

32. Adam was put on call for a kidney transplant[60] once he was placed on dialysis. His tube feeds in the months prior to the transplantation surgery were slightly over 2 litres per day[61] and he passed in excess of 1 litre of urine each day.[62]

33. Of course Adam was so much more than a child with chronic kidney problems. His mother has written a moving tribute to him in a booklet provided by his family, 'Adam and the Hyponatraemia Public Inquiry':[63]

> *"When I had to go back to work part-time his nanny and granda looked after him, he adored them and they him. They would take him for walks along the beach and he would copy the way his granda walked with his hands behind his back. He enjoyed shopping with them in Holywood where he had his favourite shops and everyone knew him. His manners were impeccable - this was commented on by so many people and I was proud to take him anywhere.*
>
> *We were a very close family anyway but Adam brought us all closer, his aunties and uncles loved him dearly and were always there for him he never lacked attention. No matter what life threw at him he faced it with a smile he was such a happy little boy who endured more in his four short years than most people go through in a lifetime."*[64]

IV. The Children's Hospital Clinical & Nursing Personnel

34. In 1995, and today, the regional paediatric nephrology service for the province of Northern Ireland was provided by the Children's Hospital[65]. At that time the Children's Hospital was part of the Royal Group of Hospitals Health and Social Services Trust, which was part of the Eastern Health and Social Services Board. Today the Children's Hospital is part of the Belfast Trust which is part of the Health and Social Care Board[66].

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58 Ref: 058-041-197
59 For example - Refs: 057-103-212, Ref: 057-103-210 and Ref: 057-103-215 etc.
60 Ref: 016-042-078
61 Ref: 057-068-128
62 Ref: 300-077-141
63 Ref: 304-001-001
64 Ref: 304-001-007
65 Ref: 300-023-025
66 Ref: 300-023-036

35. However, renal transplants were originally provided solely from the Renal Unit of the Belfast City Hospital that was established in 1959. The first renal transplant to take place in Belfast occurred there in 1962[67].

36. Paediatric renal transplantation began in Northern Ireland in 1980 when Dr. Savage was appointed as Paediatric Nephrologist[68]. Initially, all paediatric transplants were carried out at the Belfast City Hospital, but from 1990 they began to take place at the Children's Hospital[69]. Nevertheless all the surgery was performed by renal transplant surgeons based at Belfast City Hospital. Generally those surgeons would be adult surgeons. For example Mr. Keane, who carried out Adam's transplant surgery, was an adult Consultant Urologist. On occasion a Paediatric Surgeon would be present.

37. The location of the two hospitals can be seen on the map 'Health and Personal Social Services Northern Ireland'[70] and the distance between the two can be appreciated from an aerial photograph[71]. From November 1982 Dr. Savage, who was Adam's Nephrologist, acted as a Consultant Paediatric Nephrologist for renal transplants taking place in Belfast[72]. A second Paediatric Nephrologist, Dr Mary O'Connor, who was also involved in Adam's case, took up a post at the Children's Hospital on 1st November 1995[73]. Since 1995, the majority of renal transplants on children under 14 years old have been performed at the Children's Hospital rather than Belfast City Hospital[74]. By 1998, seventy-seven renal transplants had been carried out in Belfast hospitals on patients younger than 18 years - Adam was the sixty-ninth. Of those seventy-seven, only two have died[75].

38. The organisation of the Children's Hospital in 1995 can be seen in the organisational chart compiled by the Inquiry Legal Team[76]. As can be seen paediatric renal transplantation, as with all surgery in 1995, fell under the Department of 'Anaesthetics, Theatre and Intensive Care'. The Clinical Director of that Department was Dr. Joseph Gaston. It can also be seen from the chart that in 1995 Dr. Connor Mulholland was the Clinical Director of the Department of Paediatrics (Acting). In addition and further

67 McGeown, "Clinical Management of Renal Transplantation" – Chapter 1, p.3-4
68 Mayes & Savage, "Paediatric renal transplantation in Northern Ireland", Ulster Medical Journal, [2000] 69(2) 90
69 Ref: 300-021-033
70 Health and Personal Social Services Northern Ireland - Ref: 300-001-001
71 Ref: 300-084-182
72 Ref: WS-002-2, p.29
73 Ref: WS-014-1, p.2
74 Ref: 300-021-033
75 Mayes & Savage, "Paediatric renal transplantation in Northern Ireland", Ulster Medical Journal, [2000] 69(2) 90
76 Ref: 303-043-510

up the tiers of management, Dr. Ian Carson was the Medical Director and Mr William McKee was the overall Chief Executive.

39. In addition to the List of Persons compiled by the Legal Team for Adam's case,[77] two companion documents have been compiled, 'Nomenclature & Grading of Doctors 1948 to 2012'[78] and 'Nomenclature & Grading of Nurses 1989 to 2012',[79] so as to assist with the terminology in use over the period from 1995 to date. Unless it is of particular relevance to the issues, I shall not therefore deal with the grade or training of any particular clinician.

40. Of particular note are those who were present during Adam's transplant surgery. I have already referred to Dr. Savage and Dr. O'Connor, who were both involved in Adam's transplant surgery as Consultant Nephrologists, and Mr. Keane and Mr. Brown who were involved as Surgeons. In addition, Dr. Robert Taylor acted as the Consultant Paediatric Anaesthetist during Adam's transplant surgery and he had previous experience of anaesthetising Adam. He was assisted by Dr. Terence Montague at the beginning, but not for the whole, of Adam's transplant surgery. There were also several nurses present – Staff Nurse ("SN") Patricia Conway who prepared the operating theatre and the instruments but left at 08:00. SN (Margaret) Janice Mathewson who was the Runner in the operating theatre and SN Gillian Popplestone who acted as Scrub Nurse during the transplant surgery. It seems that Mr. Peter Shaw was also present during Adam's transplant surgery as Medical Technical Officer.[80]

V. State Pathologist's Department

41. Adam's autopsy was performed by Dr. Alison Armour, who was a Senior Registrar Pathologist at the State Pathologist's Department.[81] At that time the State Pathologist's Department was headed by Dr. Jack Crane as the State Pathologist. He has remained the State Pathologist throughout the period of Adam's death until present day. Amongst the State Pathologist's responsibilities is the provision of an autopsy service to Coroners.[82]

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77 Ref: 303-001-001
78 Ref: 303-003-048
79 Ref: 303-004-051
80 Ref: Inquiry Witness Statement of Mr. Peter Shaw WS-106-1, p.2 and Ref: Inquiry Witness Statement of Mr. Tommy Ryan WS-125-1, p.2
81 Ref: WS-012-1, p.1
82 Ref: 306-008-004

42. In 1995 the State Pathologist was responsible to the Secretary of State for Northern Ireland but currently, following devolution, is responsible to the local Minister of Justice.[83]

43. In addition to the State Pathologist, who also acts as a Consultant Pathologist (along with his other duties), there was a Deputy and two Assistant State Pathologists, who are all Consultant grade pathologists, who assist in the conduct of Coroners' post-mortem examinations. Those pathologists take clinical responsibility for the autopsies they perform but the State Pathologist has overall responsibility for ensuring that all cases are carried out to the appropriate standard.

44. In 1995, the Department employed two trainees at Senior Registrar grade who worked under the supervision of the consultant pathologists.[84] Dr. Armour was one of those two trainees. The Legal Team is pursuing its investigations with the State Pathologist's Department.

VI. Context of Education & Training

45. The condition of hyponatraemia may be described as:

> "*This is when the blood level of sodium is lower than normal either because of an excess excretion of sodium over intake and subsequent water intake and retention (hypovolaemic hyponatraemia) or by an excess of water intake over output diluting the serum sodium (dilutional hyponatraemia).*"[85]

46. The medical literature contained a number of articles published prior to Adam's transplant surgery pointing to a possible connection between hyponatraemia in adults and certain effects on the brain, including death. Some of those from the late 1970s[86] and 1980s[87] are included in the Bibliography compiled by the Legal Team.

47. Then in 1992, Arieff, Ayus and Fraser published an article in the British Medical Journal entitled 'Hyponatraemia and death or permanent brain

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83 Ref: 306-008-004

84 Ref: 306-008-004

85 Expert report by Dr Coulthard - Ref: 200-002-037 and Expert report by Dr Gross – Ref:201-002-027 and 028

86 Arieff Al, Llach F, Massry SG, Kerian A. Neurological manifestations and morbidity of hyponatremia: correlation with brain water and electrolytes. Medicine (Baltimore) 1976; 55:121-9.

87 Ayus JC, Olivero JJ, Frommer JP. Rapid correction of severe hyponatraemia with intravenous hypertonic saline solution. Am7 Med 1982;72:43-8; Arieff Al. Hyponatraemia, convulsions, respiratory arrest, and permanent brain damage after elective surgery in healthy women. N Engl J Med 1986;314: 1529-35; Ayus JC, Krothapalli RK, Arieff Al. Treatment of symptomatic hyponatremia and its relation to brain damage. A prospective study. N Engl J Med 1987 ;317: 1190-5.

damage in healthy children'[88] dealing with the results of their study of a group of children. The objective of the study was to determine whether hyponatraemia causes permanent brain damage in healthy children. All of the 16 children (both male and female) in the clinical case study were hospitalised with seemingly minor illnesses or had minor surgery and they all subsequently suffered respiratory arrest with symptomatic hyponatraemia. The children either died or suffered permanent brain damage. All of them were found to have cerebral oedema following CT or MRI scans and nine of the ten who underwent post-mortem were found to have cerebral oedema with herniation. Brain weights of the patients were found to be, on average, more than 10 per cent higher than the normal values for children of the age range studied.

48. The conclusion drawn from that study and reported in the published paper was that generally healthy children with symptomatic hyponatraemia could abruptly develop respiratory arrest and either die or develop permanent brain damage. The authors recommended that hypotonic fluids (that is fluids with sodium concentrations of less than the concentration found normally in the blood) should not be used with hospitalised children unless there is a clear need to do so.

49. That article is mentioned repeatedly in the papers of all of the cases that are the subject of the Inquiry. It is often referred to simply as 'the Arieff article'. It has been cited in numerous publications, including an article by Dr. Armour on Adam's case, 'Dilutional hyponatremia: a cause of massive fatal intra-operative cerebral oedema in a child undergoing renal transplantation' that was published in the Journal of Clinical Pathology in 1997.[89]

50. An issue being investigated by the Inquiry is the extent to which the clinicians and nurses involved with Adam's case were aware of the dangers of hyponatraemia in paediatric cases and therefore the need for appropriate fluid management. In addition the Inquiry is investigating whether clinicians and nurses were receiving appropriate education and training in these areas.

51. The Legal Team has compiled schedules in relation to the specific clinicians and nurses who were involved in Adam's case, a 'Comparative Table of Education and Training of the Doctors' and a 'Comparative Table of Education and Training of the Nurses'.[90] Those schedules detail the

88 BMJ. 1992 May 9; 304(6836): 1218–22

89 Armour. Dilutional hyponatraemia: a cause of massive fatal intra-operative cerebral edema in a child undergoing renal transplantation. J Clin Pathol. 1997 May; 50(5): 444–446

90 Ref: 306-005-028 and Ref: 306-001-001

information that the clinicians and nurses have themselves provided as to their own knowledge from teaching and/or training of fluid management, hyponatraemia and proper record keeping:

(i) At undergraduate level

(ii) At postgraduate level

(iii) During their hospital induction

(iv) During Continued Professional Development (CPD) training

(v) In their experience as clinicians/nurses

52. In addition Dr. Robert Taylor accepted that he knew about the Arieff article in his Deposition.[91]

53. The Inquiry has not carried out any investigation to verify the accuracy of the information on those schedules provided and in some cases there would be no real means of doing so. Accordingly, it is a matter for you Mr. Chairman what weight you afford it.

VII. Adam's Diagnosis & Clinical History

54. I have already described Adam as having dysplastic kidneys with bilateral large cysts. It seems that Adam's condition carried with it a risk of him developing chronic renal failure.

55. The Legal Team has prepared a number of 'visual aids' to explain further Adam's condition. For example a diagram[92] which shows an outline of the organ systems making up the standard human anatomy. Also a diagram[93] which shows the kidneys in amongst the other organs such as the stomach and the pancreas. The kidneys, which are a pair, can be seen clearly marked on the diagram. As I am sure you are aware Mr. Chairman, the kidneys form a vital part of the body's renal system. They have many functions, but their primary role is to filter out the waste products from the blood and to excrete those waste products by the production of urine.

56. There are many medical terms, some highly specialist, referred to in Adam's papers particularly the Reports of the Inquiry's Experts. The Legal

91 Deposition to the Coroner: Ref: 011-014-108
92 Ref: 300-027-045
93 Ref: 300-028-046

Team has prepared a Glossary of Medical Terms[94] with the benefit of guidance from the Inquiry's Advisors. It is updated as further documents are received. In general therefore, unless it is of particular significance to a matter in issue, I shall not provide a definition for medical terms and conditions in this Opening. However, for present purposes, Adam's condition basically meant that his kidneys were abnormally formed before birth causing them to be small and to function poorly and improperly. The differences between a normal kidney[95] and a cystic dysplastic kidney[96] can be seen from two photographs obtained by the Legal Team. Neither of those photographs relates to Adam, they were obtained for illustrative purposes only.

57. As a result of his condition, Adam suffered with renal problems from birth. He was admitted to Musgrave ward at the Children's Hospital on 15th October 1991[97] under the care of Dr. Maurice Savage, Consultant Paediatric Nephrologist, who remained Adam's nephrologist throughout his life.

58. The Legal Team has compiled a Time Line of Main Events: Adam (1991-1995) ("Time Line")[98] with associated Summaries, Charts and Schedules, all of which serve to detail Adam's medical history from birth to death. The information for them has been extracted from Adam's medical notes and records. In general, the information included is that relevant to issues or risk factors that have been raised by the Inquiry's Experts, including incidences of the following which are all highlighted in red:

    (i) Low serum sodium (hyponatraemia) or of acute falls in serum sodium levels

    (ii) Low potassium (hypokalaemia)

    (iii) Low blood haemoglobin levels (anaemia)

    (iv) Polyuria

    (v) Dehydration

    (vi) Operations involving central lines

    (vii) Use of catheters

94 Ref: 303-002-011
95 Ref: 300-085-183
96 Ref: 300-030-048
97 Ref: 049-025-061
98 Ref: 307-001-002

(viii) Prescriptions of erythropoietin

(ix) Developmental issues

59. The contents of the Time Line,[99] together with the associated compiled documents, will obviate the need for me to go through all the details of Adam's clinical history prior to his admission for his transplant surgery.

60. Firstly, on the left hand side, Adam's admissions and surgical procedures are included for reference purposes. Important statements in his clinical or nursing notes are shown in red, such as the insertion of central lines and urethral catheters. The Legal Team has also compiled a separate Schedule of all Adam Strain's Surgical Procedures,[100] which details:

(i) Admissions to the Ulster Hospital and Musgrave Ward, Children's Hospital

(ii) The surgical procedures carried out including the relevant dates and the surgical and anaesthetic personnel involved

61. In addition there is an associated spread sheet, which identifies by a colour code Adam's day admissions, his admission date, the duration of his periods in hospital and also his discharge date.[101]

62. The next column on the Time Line is 'Fluids'. This details all records of the fluids Adam received during hospital admissions, and those lost, particularly as a result of diarrhoea or excess vomiting. Those details are derived from a separate Schedule.[102]

63. The next two columns detail any measurements of Adam's urine and serum sodium levels. The occasions highlighted in yellow are where Adam's serum sodium values are recorded as having fallen to below the normal range of 135mmol/l to 145mmol/L. Of particular note are those occasions when his serum sodium fell below 125mmol/l (severe hyponatraemia), where his serum sodium was higher than 155mmol/l (severe hypernatraemia) and where his serum sodium fell by 10 or more mmol/l in a period of 24 hours (an acute fall). All such instances are highlighted in red. They derive from a comprehensive Schedule that

99 Ref: 307-001-002
100 Ref: 300-060-107
101 Ref: 300-060 (all)
102 Ref: 300-059-090

records all Adam's serum sodium and urine sodium levels, which includes a graphical representation of the results.[103]

64. The next two columns show any measurements of Adam's serum potassium levels and his haemoglobin levels. The values outside the normal range are coloured pink and amber respectively, with those of particular note highlighted in red.

65. The final two columns show some of the medication that Adam received and the details of his dialysis over time. The details of medication are limited to:

    (i) Sodium and iron supplements

    (ii) Erythropoeitin

    (iii) Medication received between his admission for renal transplant on 26th November 1995 and his death on 28th November 1995

66. There is a Summary Time Line of Critical Events,[104] which shows in the appropriate colour blocks the incidence of only those acute or important items that are highlighted in red on the Time Line. A quick glance therefore provides an indication of when Adam was relatively free of such concerns. Indeed it can readily be seen that Adam had been in such a condition for a number of months before his transplant surgery. The two coloured blocks serving to show simply his erythropoietin medication and his dialysis prescription. That picture of Adam as gleaned from his medical notes and records contrasts with the description of him given by the pathologist Dr. Armour during her evidence to the Coroner on 18th June 1996: "*Adam was not a healthy child – he was a sick little boy*".[105]

67. The state of Adam's health, his general condition when he was admitted as well as his condition when he was anaesthetised, are all matters to which I will refer later on in this Opening. They will also be issues to be addressed in the Oral Hearing. So too will be the significance of Adam's state of health and his condition for the cerebral oedema that developed and his death.

68. Another issue from Adam's clinical history that has taken on a degree of significance is whether his left internal jugular vein was ligated. That arises because Dr. Armour's Autopsy Report identified under the section

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103 Ref: 300-059-079
104 Ref: 307-001-001
105 Ref: 011-010-033

on 'Internal Examination of Neck': *"a suture in situ on the left side of the neck at the junction of the internal jugular vein and the sub-clavian vein"*.[106] The relevance of that suture was described by her under the 'Commentary' section of the Report on Autopsy: *"Another factor to be considered in this case is cerebral perfusion. The autopsy revealed ligation of the left internal jugular vein. 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 also 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"*.[107] Dr. Armour reiterated that view in her evidence before the Coroner on 18th June 1996: *"There was impaired cerebral perfusion as there was a suture on the left side and a catheter tip on the right … The suture impaired the blood flow to the brain and the catheter tip on the right may have had a role to play. The suture had been there for some time"*.[108]

69. The structures being discussed by Dr. Armour can be seen on a diagram 'Anatomy of the Cervical Region (Neck)' that is included as part of the February 2012 joint Report of the Inquiry's Experts Messrs. Forsythe and Rigg.[109] That diagram has been extracted and enlarged for more convenient reference.[110]

70. The Inquiry carried out investigations to identify the particular surgical procedure that led to the ligation of Adam's left internal jugular vein. However, the Inquiry has been informed by the DLS that there is: "*no evidence the IJV [internal jugular vein] was ligated in RBHSC. The commentary section of the post mortem report is the only place where it is stated that the IJV is ligated. Ligation is not mentioned in the section on internal examination of the neck … in the 1980s and early 1990s it would have been considered standard practice in RBHSC to ligate the internal jugular vein during insertion of a Broviac or Hickman central venous catheter. In the early 1990s a new technique was introduced whereby the common facial vein was used in order to preserve the patency of the IJV. The typed theatre note of 29/5/92 clearly states that the common facial vein was used, thereby by definition preserving the left IJV … The removal of the [Broviac] line is a relatively simple procedure which would not have required exploration of the neck. The Broviac line is removed by traction at the exit site (in this case left anterior chest wall.) The anaesthetic record (057-077)*

106 Ref: 011-010-039
107 Ref: 011-010-041
108 Ref: 011-010-033
109 Ref: 300-087-185
110 Ref: 300-087-185

shows total anaesthetic time of 20 minutes. This would not allow time for an unrecorded surgical exploration of the neck with ligation of the IJV."[111]

71. The Inquiry's Experts Messrs. Forsythe and Rigg have considered the references to the insertion of a central line and have identified four occasions in their Report of February 2012 when that is recorded as having happened.[112] However, it was only the insertion of a Broviac line via the left common facial vein on 29th May 1992 that involved an incision being made in the left side of the neck.[113] The Schedule of Adam Strain's Surgical Procedures[114] shows the insertion of a Broviac line, Cystoscopy and Retrograde Pyelogram as having been carried out on that date by Messrs. Brown, McCallion and Stewart as Surgeons and Drs. Crean and McCarthy as the Anaesthetists. Adam's medical notes record the removal of a Broviac line on 9th February 1995[115] as having been carried out by Mr. Saad as the Surgeon and by Dr. Chisakuta as the Anaesthetist.

72. The Inquiry also requested Witness Statements from those involved in the surgery on 29th May 1992 and they have confirmed that the left internal jugular vein was not ligated during the surgery.[116] Mr. Brown has pointed out that he carried out the cystoscopy and that he was not involved in the insertion of the Broviac line, which was carried out by Messrs. McCallion and Stewart.[117] It is not clear whether they have accepted that Mr. Brown was not involved in the insertion of the Broviac line.[118] A recent Inquiry Witness Statement from Mr. McCallion dated 25th March 2012[119] and recent correspondence from the DLS dated 24th February 2012[120] have commented further, including an analysis of chest x-rays taken at the time of the surgery, and a year later. DLS and Mr. McCallion are adamant that the operation notes and the chest x-rays show that this operation did not involve a ligation of the left internal jugular vein.

73. The ligation of the internal jugular vein is a matter that will be pursued further during the Oral Hearing, in particular, as to whether it could have had the effect described by Dr. Armour or could in any other way have affected the development of Adam's cerebral oedema.

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111 Ref: 301-003-018 to Ref: 301-003-039, also Ref: 306-009-045 to Ref: 306-009-049– letter dated 26th April 2005
112 Ref: 203-008-106
113 Ref: 053-015-052
114 Ref: 300-060-107 and Ref: 057-102-189
115 Ref: 057-102-189
116 Ref: WS-228-1, pgs 2-3 (Mr. Stewart), Ref: WS-232-1, p.2 (Mr. McCallion) and Ref: Ws-007-4, p.2 (Mr. Brown)
117 Ref: WS-007-4, p.2
118 Ref: WS-228-1, p.2 and Ref: WS-232-1, p.2
119 Ref: WS-232-2
120 Ref: INQ-0771-12

VIII. Transplant Experience at the Children's Hospital

74. I turn now Mr. Chairman to the question of the experience of the clinicians and nurses at the Children's Hospital and Belfast City Hospital in handling paediatric renal transplant surgery.

75. To that end, the Inquiry has sought and received extensive statistical data from the NHS Blood and Transplant (NHSBT) and from DLS on the performance of renal transplant centres across the UK, including Belfast, since 1980 when renal transplants were first performed in Belfast.[121]

76. The Inquiry has compiled two Schedules from that data and three Charts to represent the information graphically and hopefully make it more readily accessible. The first Schedule 'UK Paediatric Kidney Only Transplants Deceased and Living) at Dedicated Paediatric Units, by Transplant Year, Transplant Unit and Age Group'[122] compares the number of paediatric renal transplants performed in the various UK centres with Belfast from 1980 to 2010, splitting the number of transplants into two age groups – those less than 14 years old, and those between 14 and 17 years old. It can be seen that the numbers are generally lower for Belfast, which serves a smaller population. That information is depicted in two Charts:

    (i) 'Paediatric Renal Transplants by Age, UK, 1990 – 2010'[123]

    (ii) 'Paediatric Renal Transplants by Centre and Age, Average 1990 – 2010'[124]

77. The relevance of experience in the provision of specialist services is described by Dr. Haynes in his Report for the Inquiry of August 2011: "*It is being increasingly recognised that there is a need to concentrate specialist services into a smaller number of centres, each with a greater throughput. This is for two reasons; firstly such that those involved in the provision of such services have a greater exposure to the difficulties encountered, allowing meaningful audit, research, development of skills and retention of skills, and secondly so that any one centre does not become overly dependent on a very small number of individuals.*"[125]

78. A similar point is made by Messrs. Forsythe and Rigg in their Report for the Inquiry of October 2011. They refer to the Report of the Working Party

121 Ref: 301-120-655
122 Ref: 300-021-033
123 Ref: 300-082-178
124 Ref: 300-082-179
125 Ref: 204-002-023

of the British Association for Nephrology: 'The Provision of Services in the UK for Children and Adolescents with Renal Disease' (March 1995) and to 3 million as being the minimum size of population to accumulate and maintain expertise so as to sustain a comprehensive paediatric renal service.[126] Concerns over the sustainability of the paediatric renal transplant service remain today as is shown by the extract from the 2011 Review of Renal Transplantation Services in Northern Ireland that has been provided to the Inquiry by the DLS.[127]

79. The Inquiry is investigating the relative experience, as at the time of Adam's transplant surgery, of the Surgeons at the Belfast City Hospital and the Anaesthetists at the Children's Hospital in carrying out paediatric renal transplants on young children.

80. A response dated 29th July 2005 by the Belfast City Hospital Trust to a Freedom of Information Request from Dr. John Burton[128] shows that between 1st January 1990 and 31st December 1994 there were a total of 49 paediatric transplants involving surgeons from the Belfast City Hospital,[129] of which 30 were performed at the Children's Hospital. The response identifies a total of fourteen Surgeons who were involved in those transplants but makes it clear that some cases involved two Surgeons and that not all the Surgeons were Consultants. Whilst the names of the Surgeons have been redacted, save for Mr. Keane and Mr. McCallion who are both associated with Adam, it can still be seen that there was at least one other Surgeon who had performed as many transplants as Mr. Keane. However, it also clear that none had extensive experience.

81. The position in relation to the Anaesthetists was less clear cut, as up until correspondence from the DLS dated 13th April 2012,[130] the figures provided by the DLS for the period 1st April 1993 to 13th October 2010[131] did not include any annual breakdown. So that although Dr. Taylor is shown has having been involved in seven paediatric renal transplants over that period and Dr. Chisakuta is shown as having been involved in eleven, it was not possible to compare their relative experience as at Adam's transplant surgery in November 1995. From the information now provided by the DLS it can be seen that the Anaesthetists with experience

126 Ref: 203-004-071
127 Section 14 and paragraph 18.3 at pages 25 and 33 respectively – Ref: 301-115-640 and Ref: 301-115-641
128 Ref: 094-013k-082
129 Ref: 094-013j-081
130 Ref: 301-124-682 and Ref: 301-124-683
131 Ref: 301-028-353

of paediatric renal transplants prior to Adam's transplant surgery were as follows:

(i) 7th October 1993: An unidentified Anaesthetic team

(ii) 27th September 1995: Dr. Peter Crean (Consultant in Paediatric Anaesthesia and Intensive Care)

(iii) 17th November 1995: Dr. Peter Crean and Dr. David Hill (Senior Registrar in Anaesthetics

82. I will return to this issue of expertise later in this Opening when I address the information provided to Adam's mother and the options that were explained to her. It is also an issue that will be considered from the 'governance' perspective.

83. The second Schedule compiled from the data provided by NHSBT and DLS, is 'Median Cold Ischaemic Time (hr) of UK Deceased Kidney Only Transplants at Dedicated Paediatric Units, by Transplant Year, Transplant Unit and Age Group'.[132] It compares the median cold ischaemic times for each of the UK centres from 1998 (being the earliest date that such data is available) to 2010. The third Chart, 'Median Cold Ischaemic Time of Deceased Donor Kidneys by Centre, Children, 1998 – 2010, Hours,[133] shows the position clearly with Belfast generally having one of the longest median cold ischaemic times.

84. Whilst there are demographic and geographic factors that might account for the differences between Belfast and the other centres, it can nonetheless be seen that the highest recorded period of cold ischaemic time, still falls considerably short of the 32 hours in Adam's case, namely from 01:42 on 26th November 1995 when the donor kidney was perfused with Baxter's solution[134] until approximately 10.30 on 27th November 1995 when the vascular anastomoses were unclamped.[135] Generally, the shorter the ischaemic time, the more likely the kidney is to work immediately and the better the long-term outcome.

85. I will return to the issue of the cold ischaemic time of the donor kidney offered to Adam later on in this Opening when I deal with the decisions to accept the donor kidney and to proceed with Adam's transplant surgery.

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132 Ref: 300-022-034
133 Ref: 300-082-180
134 Ref: 058-009-028 and Ref: 058-035-134
135 Ref: 059-006-012 and Ref: 058-009-027

IX. Facilities at the Children's Hospital

86. The Inquiry has had photographs taken of the Royal Hospital site, showing the layout and interior of the principal buildings involved. The photographs were taken in the past year and much has changed from 1995 when Adam was admitted for his transplant surgery. In particular a new building was opened in 1999 providing upgraded accommodation including for Theatres and Intensive Care Unit[136]. Nevertheless, the original structures and rooms remain albeit that their use has changed, and the photographs are still useful for showing location and distances. Indeed the set has been compiled as a 'walk through' starting with the old (and now disused) entrance and ending with the main laboratory[137] that would have been used during the first part of Adam's transplant surgery, before the laboratory at the Children's Hospital opened at 09:30.[138]

87. I should now like to turn to the site. A recent aerial photograph shows the proximity of the Children's Hospital to the Belfast City Hospital.[139]

88. A site layout from 1993 shows how the buildings were arranged on the Royal site at the time of Adam's transplant surgery.[140] Musgrave Ward can clearly be seen, as can the operating theatres, the laboratory for the Children's Hospital as well as the main laboratories for the Royal Hospitals as a whole.

89. The plan of the Ground Floor of the Children's Hospital from that period is also available.[141] It shows:

    (i) Musgrave Ward

    (ii) Operating theatre where Adam's transplant surgery took place as well as the other one in use that day

    (iii) Location of the blood gas machine

    (iv) PICU

90. It also shows the route that would have been taken by Adam from his entrance through the main entrance to the Children's Hospital, to his admission onto Musgrave Ward, his arrival at the Operating Theatre and

136 Ref: 300-023-036
137 Ref: 300-007-007 to Ref: 300-019-030
138 Ref: 301-018-332
139 Ref: 300-084-182
140 Ref: 300-003-003
141 Ref: 300-005-005

his transfer to PICU. The plan of the Lower Ground Floor of the Children's Hospital[142] shows the haematology laboratory where blood samples were analysed between 09.00 and 17:00.[143]

91. We can also see that route from the photographs, albeit that there have been significant changes since 1995. For example, the original entrance to the Children's Hospital from which Adam and his mother would have entered[144] and Musgrave Ward where he was admitted[145] at 21:00 by SN Catherine Murphy.[146]

92. Because of the new facilities at the Children's Hospital, many of the rooms used for Adam's surgery are now storerooms or vacant. A clear example is the Anaesthetic Room, in which Dr. Montague was preparing drugs and equipment when Adam arrived in theatre[147] for surgery, which is across the corridor from the operating theatre.[148]

93. The series of photographs also includes the Operating Theatre in which Adam's transplant surgery took place.[149] The whiteboard in the first photograph may well have been used to record blood loss. In addition the DLS has also provided two photographs taken of the Operating Theatre in 1997, which may help to provide a more accurate portrayal of how it was arranged and might have looked in November 1995.[150]

94. There were of course other operations going on at the time of Adam's transplant surgery. The Theatre Log for 27th November 1995[151] shows that Dr. Rosalie Campbell (Locum Consultant Anaesthetist) and Dr. David Hill (Trainee Anaesthetist) were working as anaesthetists in the neighbouring Operating Theatre.[152] The instruments from Adam's surgery would have been brought to a room known as the 'Dirty Room' where they would have been cleaned or disposed of.[153]

142 Ref: 300-006-006
143 Ref: 300-006-006
144 Ref: 300-007-007 and Ref: 300-007-008
145 Ref: 300-008-009 (as at 2011)
146 Ref: 057-013-017
147 WS-009-3 p.2 Q2(a)
148 Ref: 300-009-010 & Ref: WS-009-1 .6
149 Ref: 300-010-011, Ref: 300-011-012 and Ref: 300-011-013
150 Ref: 300-020-031 and Ref: 300-020-032
151 Ref: WS-117-2, p.10
152 Ref: 300-012-014 and Ref: 300-012-015
153 Ref: 300-013-016

95. The blood gas analyser that was used at 09:32 during Adam's surgery was kept in PICU and the place where it would have been located is shown in the photographs, albeit that it has since been removed.[154]

96. The Children's Hospital had its own laboratory, which has already been seen on the Lower Ground Floor plan.[155] It was close to the Operating Theatres in the Children's Hospital but was only available during the working hours of 09:00 and 17:00. Its proximity can be seen from the general layout and from the photographs.[156]Adam's transplant surgery was scheduled to start at 06:00 on Monday 27th November 1995 and was then put back to 07:00. Accordingly, it started considerably outside the hours of operation of the laboratory for the Children's Hospital. In those circumstances resort would have to be had to the main laboratory for the general Royal complex. That laboratory is in the Kelvin building and its location, the route to it and its distance from the Operating Theatre where Adam's transplant surgery was taking place, are shown on the 1993 Site Plan[157] and the aerial photograph.[158] There are a series of photographs taken from along the route to try and convey a sense of the distance between the Operating Theatres of the Children's Hospital and the main laboratory.[159]

97. The equipment and facilities required by a paediatric renal transplant centre are commented on by Dr. Haynes in his report of 2nd August 2011 where he particularly identifies:[160]

    (i) Access 24 hours a day to a blood gas machine within the operating theatre suite or in close proximity

    (ii) Adequate portering services for tasks such as the transport of specimens to the laboratory and the transport of blood for blood transfusion to the operating theatre

    (iii) Adequate numbers of suitably located telephones to allow easy contact with laboratories and other hospital resources

98. The significance of all of that is that until February 2012 Dr. Taylor consistently gave the lack of adequate facilities and services as a reason for the absence of any electrolyte results before the transplant surgery began

154 Ref: 300-014-017 and Ref: 300-014-018
155 Ref: 300-006-006
156 Ref: 300-015-019, Ref: 300-015-020 and Ref:300-015-021
157 Ref: 300-003-003
158 Ref: 300-017-027
159 Ref: 300-016-022, Ref: 300-016-023, Ref: 300-016-024, Ref: 300-016-025 and Ref:300-016-026
160 Ref: 204-002-022

and before the blood gas machine result at 09:32.[161] Dr. Taylor points out that test was not intended for Adam's electrolytes as he regarded the blood gas machine as incapable of providing accurate results, indeed he claims to have been warned not to rely on it for that purpose.[162] Rather, it was to enable him to check Adam's haemoglobin levels,[163] which had fallen to 6.1g/dL.[164]

X. Putting Adam on the Transplant List

99. Adam's renal function deteriorated to a level where he needed peritoneal dialysis. Peritoneal dialysis is a form of dialysis for children like Adam with severe chronic kidney disease. The process uses the patient's peritoneum in the abdomen as a membrane across which fluids and dissolved substances (such as electrolytes, urea, glucose, albumin and other small molecules) are exchanged from the blood. Fluid is introduced through a permanent tube in the abdomen and flushed out either every night while the child sleeps (automatic peritoneal dialysis) or via regular exchanges throughout the day (continuous ambulatory peritoneal dialysis).

100. Dr. Savage discussed Adam's deteriorating renal function and his need for dialysis with his mother during a Dialysis Clinic on 2nd November 1993.[165] It was Dr. Savage's plan to have Adam registered for a transplant at the same time as he went on dialysis, as he explained in a letter of 3rd November 1993 to Adam's GP Dr. Scott: "*Certainly if we get to the point where I feel he needs dialysis in the near future my plan would be to put him 'on call', before he needs dialysis, for a transplant*". [166]

101. As can be seen from the Schedule of Adam Strain's Surgical Procedures,[167] Adam had a continuous ambulatory peritoneal dialysis (CAPD) catheter inserted on 23rd March 1994.[168] Then in July 1994, Dr. Savage arranged to have Adam's tissue typing carried out with a view to putting him on call for a renal transplant[169] and he was registered as a possible recipient with

161 Ref: WS-008-3 p.8, Ref: Ws-008-3 p.20 and Ref: WS-008-3, p.24
162 Ref: 093-038-245 and Ref: WS-008-2, p.40
163 Ref: WS-008-2, p.13
164 Ref: 058-003-003
165 Ref: 016-055-096
166 Ref: 016-055-096
167 Ref: 300-060-107 to Ref: 300-060-114a
168 Ref: 055-010-017
169 Ref: 016-042-078

the United Kingdom Transplant Support Service Authority on 14th July 1994.[170]

102. It seems that Dr. Savage may have been the only Consultant clinician involved in the process of having Adam placed on the transplant register. The Inquiry Witness Statement of Adam's mother dated 10th January 2012 indicates that the provision of relevant information to her on renal transplantation for Adam was provided by Dr. Savage and she states that Dr. Savage was the person involved in assessing Adam before he went on the transplant list.[171]

103. I will return later in this Opening to the question of the process by which Adam was placed on the transplant register, who should have been involved in it and what should have been explained to his mother. Those will all be issues to be addressed in the Oral Hearing.

104. Adam was fully registered with the UKTSSA in November 1994 after tissue typing.[172] The UKTSSA Recipient Registration Form is a detailed document making provision for blood group and type, HLA data, the level of acceptable mismatching, sensitisation status and the person responsible for the information on the form.[173] The information on the form is what permitted UKTSSA to consider that the donor kidney from Glasgow Southern General Hospital was a sufficiently good match to offer to Dr. Savage for Adam.

105. Dr. Savage states in his Inquiry Witness Statement of 14th April 2011 that he explained the system of being on call for a kidney transplant to Debra Slavin, and the need for a fast response and immediate tissue cross-matching for the donor kidney if one became available.[174] He also stated that she received an explanatory booklet, 'Kidney Transplantation in Childhood: A Guide for Families' dated 1993 and compiled by the Paediatric Renal Unit at City Hospital, Nottingham.[175] The Guide states under 'What assessment is necessary': "*Placement on the transplant waiting list follows discussion with the kidney specialist and transplant surgeon*".[176] In any event, Adam's mother states in her Inquiry Witness Statement of 10th

170 Ref: 056-030-065
171 Ref: WS-001-2, pgs.5 and 6
172 Ref: 057-070-130
173 Ref: 057-070-131
174 Ref: WS-002-2, p.11 and Ref: WS-001-2, p.6
175 Ref: WS-002-3, p.124
176 Ref: WS-002-3, p.127

January 2012 that none of the information given to her on renal transplants was provided in written form.[177]

106. The Time Line shows[178] that Adam started his peritoneal dialysis on 24th August 1994 following his admission to insert the peritoneal catheter and that he was then receiving 11 cycles using 300mls of 1.36% solution.[179] Initially Adam received 6 cycles of 300ml volume overnight 5 days a week[180], then 8 cycles[181], and this was then increased to 10 cycles of 600ml volume overnight 6 times a week[182]. By the time of his transplant, 14 months after he was initially placed on the transplant list, he was receiving 15 cycles of peritoneal dialysis overnight using 750ml fills of 1.36% Dianeal solution.[183]

107. In the months leading up to the transplant, Adam received feeds through his gastrostomy tube. This consisted of 3 bolus feeds per day of 300mls each in the morning, early afternoon and evening, and then 1200mls over approximately 8 hours overnight[184]. These feeds were made up of 1000mls Nutrison, 50g of Maxijul, 50mls of Calogen and 100mls of Saline made up to 2100mls by water.[185] He would receive sodium and iron supplements in his feeds to prevent him having episodes of anaemia and low sodium.[186]

108. Adam's mother was trained in the use of the automatic dialysis cycling machine at the beginning of September 1994.[187] She maintained a detailed record of Adam's dialysis at home in a 'Dialysis Book'.[188] It included Adam's weight (before and after dialysis), first drain, manual drain and ultra filtrate. She also recorded his blood results, feeds as well as queries and observations of Adam – such as: *"Temperature drops Adam gets really twitchy and shakey"*.[189] Dr. Savage considered Adam's mother to be meticulous in her approach to Adam's home dialysis.[190]

177 Ref: WS-001-2, p.6
178 Ref: 307-001-033
179 Ref: 056-029-061
180 Ref: 057-101-176
181 Ref: 016-009-024
182 Ref: 057-084-159
183 Ref: 016-015-034
184 Ref: WS-001-2, p.4
185 Ref: WS-001-2, p.4
186 Ref: 057-013-017
187 Ref: 056-009-023
188 Ref: WS-001-2, p.20
189 Ref: WS-001-2, p.125
190 Ref: WS-002-2, p.10

XI. Adam's Admission & Pre-Surgical Events

109. Photographs taken of Adam just over a fortnight before his renal transplant surgery show him looking happy and well.[191] His mother described him by that stage, notwithstanding his renal problems, as "*being back on top form again. He was really well*".[192]

Receiving the Offer of a Kidney

110. We come now to the key period with regard to Adam's case, which starts with the offer of a donor kidney on 26th November 1995 and ends with his death on 28th November 1995. During that period there are the key events of Adam's admission to Musgrave Ward at 20:00,[193] his arrival at theatre at 07:00 on 27th November 1995 for his renal transplant surgery[194], his admission to PICU at the end of his surgery at around 12:00 noon,[195] and the withdrawal of ventilatory support at 11:30 on 28th November 1995.[196]

111. The vast majority of issues relating to Adam's case occurred during that period, particularly the management of his fluids during the peri-operative stage.

112. The Legal Team has compiled a Chronology of Events (Clinical) that details the clinical events that occurred over that period.[197] This document is compiled almost exclusively from Adam's medical notes and records. It does include some matters from other sources, such as Depositions or PSNI Statements and this is generally where there is no other source and the matter has not been queried or challenged.

113. The Inquiry has tried to ensure that the details in the Chronology are not contentious and that it can therefore act as a useful reference document when considering the various issues in Adam's case. To that end the Inquiry sent the Chronology out to all the Interested Parties on 5th January 2012 for comment. Since then, the Chronology has been updated, to reflect the subsequent receipt of documents. An example[198] is the query over whether the chest x-ray requested by Dr. O'Neill[199] was ever carried out and relates to correspondence received from DLS.[200] A further example[201]

191 Ref: 300-079-150
192 Ref: WS-001-1, p.2
193 Ref: 057-006-007
194 Ref: 058-039-185
195 Ref: 056-006-016
196 Ref: 058-035-142 and Ref: 058-038-162
197 Ref: 306-003-006
198 Ref: 306-003-008
199 Ref: 057-019-028
200 Ref: 301-118-650

is provided by the receipt of a laboratory report from DLS[202] dated 27th November 1995 but in respect of a blood specimen taken before midnight on 26th November 1995. The laboratory report shows a serum sodium level of 133mmol/L,[203] which is lower than the previous value of 139mmol/L from a blood specimen taken at 21:00.[204]

114. The structure of the Chronology is straightforward.[205] The date and time are on the left-hand side, the event is in the middle, and the reference for the source of the information is on the right-hand side. The footnotes contain the references for the Glossary of Terms, List of Persons Involved: Adam and any comments or clarifications.

115. In the circumstances, I do not propose to go through the Chronology in detail. However, I will refer to it as appropriate in dealing with the issues and will use it as a reference document during the Oral Hearing.

Trainee Anaesthetist

116. As is recorded in the Anaesthetic Record for Adam's transplant surgery, Dr. Robert Taylor was assisted by Dr. Terence Montague for the renal transplant. Dr. Terence Montague was a Senior Registrar in Anaesthesia at the time.[206] However, whilst the Anaesthetic Record might suggest that he was there for the duration of the surgery, in fact he claims that was not the case. Dr. Montague states in his PSNI statement of 30th November 2007 that he had been on call for the night of 26th November 1995 and that although he was present at the start and assisted with preparing Adam, including the epidural, Dr. Taylor sent him home just after the start of the transplant surgery.[207]

117. Dr. Taylor accepts Dr. Montague's account of events. In his Inquiry Witness Statement of 16th May 2011 he states: "*After the start of the surgery another trainee whose name I cannot remember came on duty to assist me and I was able to let Dr. Montague go home as he had been on call for 24 hours as he confirms in his statement*".[208] The precise time at which Dr. Montague left was not recorded and is uncertain but it seems that it was prior to 09:32 when the blood gas result was obtained.[209] It may have been around 08:30

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201 Ref: 306-003-009
202 Ref: 301-081-540
203 Ref: 301-081-547
204 Ref: 058-035-144
205 Ref: 306-003-006
206 Ref: 058-003-006
207 Ref: 093-037-117
208 Ref: WS-008-2, p.10
209 Ref: 093-037-117

to coincide with the Anaesthetic Registrars coming on duty on the Monday morning.[210]

118. Dr. Taylor is clear in his evidence to the Inquiry that Dr. Montague was replaced in the Operating Theatre, as he states in his subsequent statement dated 3rd October 2011 that: *"I would not have allowed [Dr Montague] to leave unless an appropriate substitute replaced him"*.[211] Dr Montague was asked about the possibility of him being replaced by another registrar and he stated: "*There would have been some of the other anaesthetic registrars starting work in theatres in RBHSC at approximately 08.30 and one of those registrars would have been available to assist Dr Taylor"*[212] and *"I don't know which registrar replaced me."*[213]

119. None of the other members of the Transplant team, and neither of the Consultant Paediatric Nephrologists, has mentioned the presence of a trainee Anaesthetist during the transplant surgery, other than Dr. Montague.

120. The correct identification of all those in the Operating Theatre, particularly anyone present from about 09:30 onwards, is a matter of importance to the Inquiry and it has pursued its investigations into the matter as far as possible.

121. The Inquiry subsequently received a letter dated 17th August 2011[214] from DLS providing a: "*list of junior Anaesthetic trainees who were attached to the Royal Group of Hospitals on the date of Adam Strain's transplant operation on 27th November 1995"*. They formed the pool of potential trainee Anaesthetists from which to identify the person whom Dr. Taylor says assisted him in the Operating Theatre after Dr. Montague's departure. All of those on the list were identified and the Inquiry sent each of them Witness Statement Requests to ascertain, in the first instance, whether any of them could have been present in the Operating Theatre on 27th November 1995 during Adam's transplant surgery. Witness Statements were received from all twenty-one[215] but none of them claimed to have been there.

122. The Inquiry has produced a 'Schedule of Possible Trainee Anaesthetists Assisting Dr. Robert Taylor in Adam's Transplant Surgery'.[216] It records

210 Ref: WS-009-1, p.6
211 Ref: WS-008-3, p.10
212 Ref: WS-009-1, p.6
213 Ref: WS-009-2, p.4
214 Ref: 301-051-419
215 Ref: Witness nos.185 through to 234
216 Ref: 306-002-004

those contacted by the Inquiry and summarised their responses. It can be seen from that Schedule that for the most part they confirm that they were not involved. For some of them this is because at that time they were either not in the jurisdiction or were not working for the Trust. For example: Drs. McNamee, Gilliland, Bunting, Trinder, Kelly and Kumar.

123. Drs. O'Neill, Bedi and Kerr do not recall Adam's case, although Dr. Kerr goes so far as to say that she believes that she would recall it if she had been involved. Dr. Bedi identifies Dr. McBrien as possibly being the 'on-call trainee'.

124. Dr. McBrien was contacted and has provided two Inquiry Witness Statements dated 30th September 2011 and 14th February 2012. In the first he states that: "*the theatre log for 27th November 1995 shows that I anaesthetised 2 cases at 18:30 and 20:05. It is my recollection that on a weekday such as this, the trainee anaesthetist on call overnight came on duty at 13:00. This would indicate that I was not in the hospital that morning*".[217] In his second Inquiry Witness Statement he explains that: "*The 'trainee anaesthetist on call overnight' went off duty sometime between 8 am and 9 am as it was deemed not safe for him to continue working after a night on call. The trainee anaesthetist starting at 1300 was routinely allocated to an elective list for the afternoon, taking over emergency duties in the evening after their afternoon list had finished*".[218]

125. The Theatre Log referred to by Dr. McBrien[219] shows the date of each operation carried out in the particular Operation Theatre, as well as:

(i) Patient's details

(ii) Diagnosis

(iii) Nature of the procedure/operation

(iv) Whether the classification of the operation as major, minor etc

(v) Name of the Surgeon

(vi) Name of the Anaesthetist

(vii) Particular ward from which the patient has come

(viii) Name of the Scrub Nurse

[217] Ref: WS-194-1, p.2
[218] Ref: WS-194-2, p.2
[219] Ref: WS-117-2, pgs. 10 and 11

(ix) Times of arrival and departure

126. The Theatre Log does include, in certain instances, the names of those who assisted. However, although the names of both Mr. Keane and Mr. Brown are entered as the Surgeons for Adam's transplant surgery, the name of the assistant Anaesthetist is not recorded - only Dr. Taylor's name is shown.

127. Accordingly, it is still unknown whether there was a trainee Anaesthetist who assisted Dr. Taylor in the Operating Theatre after Dr. Montague's departure and if so who it was. That is an issue which will also be pursued from a 'governance' perspective.

128. Dr. David Hill, who was also a trainee Anaesthetist at the time, provided an Inquiry Witness Statement dated 12th October 2011. Whilst he has been unable to further the investigation into the presence or identity of a trainee Anaesthetist in Adam's transplant surgery, he did open up the prospect of another person being in the Operating Theatre whilst Adam was still there. He described working with Dr. Rosalie Campbell (locum Consultant Anaesthetist) in the adjoining Operating Theatre to the one where Adam's transplant surgery was taking place.[220] He then stated that: "*my recollection is that at some stage during our work on the day in question, which was in an adjacent theatre, the consultant anaesthetist, who appears to have been Dr. Rosalie Campbell, left to assist Dr. Taylor because a patient, who I now understand to be Adam Strain, was slow to wake up*".[221]

129. Dr. Campbell has provided two Inquiry Witness Statements, one dated 7th April 2011 and the other 8th October 2011. The only issue in relation to Adam raised in the first of her Inquiry Witness Statements is with reference to assisting Dr. David Webb, as the second doctor, in the performance of the first set of brain stem testing.[222] She deals with the question of entering the Operating Theatre where Adam's transplant surgery was taking place in her second Inquiry Witness Statement and, in the main, responds to all such queries by stating that she has no recollection. [223]

130. The issues raised by Dr. Hill will be addressed during the Oral Hearing.

220 Ref: WS-181-1, p.3
221 Ref: WS-181-1, p.5
222 Ref: WS-117-1, p.2
223 Ref: WS-117-2, p.4

Anaesthetic Nurse

131. Dr. Taylor's evidence raises a further issue of 'identification', this time in relation to the presence of an Anaesthetic Nurse during Adam's transplant surgery. He stated in his Inquiry Witness Statement dated 18th July 2005, which he made just before the Inquiry's work was suspended, that: *"At 07.00 I worked closely with Dr. T Montague and the anaesthetic nurse to induce anaesthesia and provide all the technical skills necessary to secure the airway, breathing, access to intravenous lines, arterial access, central venous access and epidural catheter placement."*[224]

132. The issue was raised during the course of the PSNI investigations which started in Adam's case in about July 2005.[225] Dr. Taylor was asked about his statements on the presence of an Anaesthetic Nurse during the course of his interview under caution on 17th October 2006. He stated that: *"My knowledge is there has to be 3 nurses present before an anaesthetic is commenced"*.[226]

133. As a result of Dr. Taylor's evidence, both SN Gillian Popplestone and SN Janice Mathewson made PSNI Statements. SN Popplestone stated: *"I cannot be certain, however, from my experience it is possible that the anaesthetists had the assistance of a nurse and possibly an operating technician."*[227] Whilst SN Mathewson stated: *"I can say from my experience that in an operation such as a renal transplant on a child, as well as the surgeons and anaesthetists I would have expected a scrub nurse, a runner and a theatre technician with probably an anaesthetic nurse as well."*[228]

134. The Inquiry pursued the matter. Under cover of a letter dated 5th September 2011[229] DLS provided a list of Theatre Nurses employed by the Royal Group of Hospitals Trust as at 27th November 1995. The Inquiry located them all and sent out Inquiry Witness Statement requests to ascertain whether they could have acted as an Anaesthetic Nurse for Dr. Taylor during Adam's transplant surgery. Although the Inquiry received responses from all of them, none claimed to have been the Anaesthetic Nurse.[230]

135. The Legal Team has compiled a Schedule of Possible Anaesthetic Nurses Assisting Dr. Robert Taylor in Adam's Transplant Surgery contacted by

224 Ref: WS- 008-1 p.4
225 Letter dated 26th July 2005 from the PSNI to the Inquiry Chairman – Ref: 094-193-943
226 Ref: 093-038-143
227 Ref: 093-012-040
228 Ref: 093-013-042
229 Ref: 301-055-427
230 Ref: Witness nos.206 through to 222

the Inquiry and in which their responses are summarised[231]. None of those contacted stated that they were the anaesthetic nurse. As with the trainee Anaesthetists, some of them confirm that they were not involved on the basis variously of not being on duty, only being an Auxiliary Nurse at the time or working elsewhere. Others simply cannot recall.

136. Accordingly, it is still unknown whether there was a dedicated Anaesthetic Nurse and if so who it was. That is an issue which will also be pursued from a 'governance' perspective.

Fluid Balance

137. The management of fluid balance and the choice and administration of intravenous fluids is a key element of the Terms of Reference.[232] It has therefore been the subject of detailed queries from the Inquiry in Witness Statement Requests as well as Briefs to the Inquiry's Experts.

138. This is an area that is far from straightforward and the arguments made by the clinicians and the Experts is to a large extent dependent on the assumptions they have made about the clinical information, which is not available, such as Adam's serum sodium level at the start of the anaesthetic and his urine output during the surgery. Furthermore, the clinicians and the Inquiry Experts have not all presented their calculations in a way that easily permits comparison.

139. In an effort to bring some consistency to the various approaches and permit where the differences really lie and why to be more readily seen, the Legal Team developed a standard table, 'Adam's Perioperative Fluid Balance', to display the essential elements of the fluid balance calculations and sent it to Dr. Taylor and the Inquiry Experts Dr. Coulthard, Dr. Haynes and Professor Gross. They were all asked to display their calculations on that standard table. The completed tables of Dr. Coulthard and Dr. Haynes were provided as part of their further Reports.[233] Professor Gross provided the data[234] which has subsequently been inserted into a table[235] and has been accepted by him. Dr. Taylor's completed table[236] is provided as part of his Inquiry Witness Statement

231 Ref: 306-002-003

232 Ref: 021-010-024

233 Dr. Coulthard provided an original table - Ref: 300-062-119 and subsequently revised his figures and provided a revised table – Ref: 200-020-247. The main revisions concern his view that Adam's native kidneys might actually have 'shut down' at some point during surgery and produced no urine at all and his view that the relevant fluid volume and rate is that of the administration of 'free water'. Ref: 300-063-122 (Dr. Haynes)

234 Ref: 201-008-188 *et seq*

235 201-008-203

236 Ref: 300-061-117

dated 9th January 2012.[237] Dr. Savage also provided a table[238] as part of his Inquiry Witness Statement dated 20th March 2012.[239]

140. The Legal Team has compiled a comparison table[240] from all of those individual tables showing the underlying assumptions and calculations of Dr. Taylor, other clinicians and the Inquiry's Experts. Its purpose is to clarify the key differences between each of them and why and how they are able to come to their conclusions.

141. We start with a display of Adam's Daily Fluid Balance.[241] This shows the position of each of the Inquiry's expert witnesses – namely Dr. Haynes, Professor Gross and Dr. Coulthard, as well as Dr. Sumner who was an expert witness at Adam's inquest, and Dr. Taylor and Dr. Savage in relation to what each of them believed to be Adam's daily input and output of fluids prior to his surgery. Firstly, there is the assumption by each of them as to his weight and surface area, which are used in the calculation of losses. All are agreed that Adam's daily fluid intake was 2100ml. His fluid losses are divided into 4 areas – firstly, losses from perspiration and water vapour in breath. These are known as 'insensible losses' as they cannot be accurately measured and can only be estimated. Secondly, fluid lost in the course of dialysis. Thirdly, faecal loss. Finally, urine output, which can be seen to be the substantial loss per day. Each of the experts and witnesses calculates the urine output by subtracting the insensible, dialysis and faecal losses from the daily intake of 2100mls. It can be seen that the estimated urine outputs vary from approximately 55ml/hr (Professor Gross and Dr. Haynes) to approximately 80ml/hr (Dr. Taylor).

142. Notably Dr. Taylor's calculation of urine output here is significantly reduced from his earlier assertion that Adam would pass around 200mls per hour of dilute urine. He commented in his last witness statement to the Inquiry that having "*reflected on this*" he now recognises that Adam had a fixed urine output of around 70-80mls per hour.[242] He further stated that: "*The intraoperative fluid that I administered was based on this incorrect assumption and I therefore administered a hypotonic fluid, 0.18NaCl/4% Glucose, at a rate in excess of his ability to excrete it, particularly in the first hour of anaesthesia.*"[243]

237 Ref: WS-008-5, p.5
238 Ref: WS-002-5, p.7
239 Ref: WS-002-5, p.1
240 Ref: 300-077-141 *et seq*
241 Ref: 300-077-141
242 Ref: WS-008-6, p.3
243 Ref: WS-008-6, p.3

143. The remainder of the comparison table shows Adam's fluid balance between 22:00 and his arrival in theatre at 07:00 on 27th November 1995, and during the course of his surgery until its conclusion and his admission to PICU at 12:15. The calculations and assumptions of each of the Inquiry expert witnesses mentioned plus Dr. Taylor in each of the time periods is displayed.

144. Each of the experts and Dr. Taylor also give their comments on the concentration of sodium (Na) in each of the solutions that Adam received and any reasons why planned fluid infusion, whether its content or the infusion rate, should change due to changes in his estimated loss.

145. An important additional factor to consider here is that of blood loss. Dr. Taylor calculates Adam's blood loss during surgery to 1128ml.[244] Examining the blood loss record and swab count[245], this figure is based on the difference in weight between dry and blood soaked swabs (411ml), the volume of liquid in the suction bottle (500ml) and a visual estimation of the amount of blood on the surgical towel. However, Mr Keane has subsequently estimated the blood loss to have been only 468ml.[246] He bases this on the fact that 600 ml would be made up of urine, peritoneal dialysis fluid and slushed ice used to cool the kidney until the vascular anastomoses were complete.[247]

146. The issue of what the surgical blood loss was, and whether Dr. Taylor estimated the blood loss appropriately during the surgery, and responded appropriately to it regarding Adam's fluid management, is one that that the Inquiry will investigate during the Oral Hearings. In addition, it will investigate whether this blood loss was reasonable in the circumstances.

XII. Inducing Anaesthesia & Adam's Transplant Surgery

147. The factual details of what happened over this period, covering anaesthetising Adam and his transplant surgery, and the sources of that information, are set out in the chronology compiled by the Legal Team, 'Inquiry Chronology of Events: Adam (Clinical)'.[248]

244 Ref: 011-002-004
245 Ref: 058-007-021
246 Ref: WS-006-3, p. 18
247 Ref: 011-013-093 and Ref: WS-006-2, p.10
248 Ref: 306-003-011 *et seq*

148. The Legal Team has also summarised the information known about Adam's condition going into surgery from his medical notes and records in the chart Adam's Pre-Surgical State.[249] It includes his:

(i) Weight / height

(ii) Temperature

(iii) Heart rate (bpm)

(iv) Respiration

(v) Feed and other fluids

(vi) Dialysis

(vii) Blood pressure

(viii) Haemoglobin

(ix) White cell count

(x) Serum sodium

149. In addition the Legal Team has compiled Schedules of the results of the recordings made during the peri-operative period, which is the period between Adam's arrival in and departure from the Operating Theatre. Those Schedules show:

(i) Adam's vital signs

(ii) Drugs administered

(iii) Temperature and central venous pressure

(iv) Fluids administered and lost

(v) Oxygen saturation and end tidal carbon dioxide

(vi) Serum sodium and haemoglobin levels[250]

150. That information has been depicted in a number of corresponding Charts.[251] The information in relation to fluids appears most strikingly in

[249] Ref: 306-006-040
[250] Ref: 307-006-063 *et seq*
[251] Ref: 307-006-064 *et seq*

Chart 3 showing the fluids administered and fluids lost and Chart 4 showing his hourly and cumulative fluid balance. The urine figure in Chart 3 is an estimate based on Adam's average hourly output and no estimate for his insensible losses has been included. The question of Adam's likely urine output during the transplant surgery is an issue under consideration by the Inquiry's Experts. Furthermore, the cumulative fluid balance in Chart 4 deals with all fluids and not simply 'free water', which has been the subject of recent debate amongst the Inquiry's Experts.

151. It is hoped that presenting the information in this way will make it easier to explore the various aspects of Adam's fluid management during the Oral Hearing.

XIII. Adam's Death & Investigations into its Cause

152. There are three photographs of Adam which were taken by a nurse on 28th November 1995 in PICU.[252] A fourth photograph was taken just after Adam's life support was switched off.[253] The significance of these for the Inquiry is to enable the Experts to factor Adam's appearance into their views on the extent to which he was 'fluid overloaded' at his death, notwithstanding the treatment which he had received to deal with that overload.

Report to Coroner & Autopsy

153. Adam's death was reported by Dr. Maurice Savage to the Coroner on 28th November 1995, stating that the death was 'totally unexpected'. On the instructions of the Coroner, a post-mortem was carried out on 29th November 1995 in the Mortuary, Royal Victoria Hospital, Belfast by Dr. Alison Armour.[254] Dr. Armour was a trainee forensic pathologist at Senior Registrar grade employed within the State Pathologist's Department in 1995.[255] She worked under the supervision of the Consultant Pathologist(s) within the State Pathologist's Department. The Consultant grade pathologists took 'clinical' responsibility for the autopsies they performed but the State Pathologist, Professor Jack Crane, had overall

252 Ref: 300-080-152
253 Ref: 300-080-155
254 Ref: 011-010-034
255 Ref: WS-021-1 p.1

responsibility for ensuring that all cases were carried out appropriately and to a high standard.[256]

154. Dr Armour had available to her 10 files of medical notes and records and the clinicians' notes.[257] She summarised Adam's clinical history, particularly: the fluids he received (1500mls of Solution No.18) during the first 90 minutes of surgery, that there was blood loss of approximately 1200ml by the end of the surgery, that a blood gas result at 09.32 showed a serum sodium of 123mmol/l and a haematocrit of 18% and that his CVP during surgery rose to 30mmHg. She noted that after surgery, he had a CT scan at 13:15 which showed gross cerebral oedema and a chest X-ray revealed pulmonary oedema with the CVP catheter tip in a neck vessel.

155. She then performed an external examination of Adam's body.[258] Adam's weight is noted as 20kg. A diagrammatic representation and explanation of Dr. Armour's external examination has been compiled from a diagram that the Inquiry's Expert on Anaesthesia provided with his Report of 20th February 2012.[259] Dr Armour did not specifically note any external appearance of swelling during her external examination.

156. She then commenced an internal examination,[260] weighing various organs including the brain, heart (which was 120g), liver and lungs. The brain on autopsy has to be 'fixed' before it can be examined. Contemporaneous notes of her autopsy[261] show that she recorded the 'unfixed' weight of the brain as either 1,302g or 1,320g.[262] These weights (along with the weight of the lungs at 190g and 290g respectively) were not recorded in her final Report on Autopsy.

157. She internally examined the neck, noting there was no evidence of congestion or obstruction and that there was a suture in situ on the left side of neck at the junction of the left internal jugular vein and the sub-clavian vein.[263] The particular area can be seen from the diagram 'Anatomy of the Cervical Region (Neck)' that is included in the Report of Messrs. Forsythe and Rigg dated February 2012. [264]

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256 Ref: 306-008-004
257 Ref: 011-010-033
258 Ref: 011-010-037
259 Ref: 300-090-189
260 Ref: 011-010-038
261 Ref: WS-012-2 p.25
262 Ref: WS-012-2, p.25
263 Ref: 011-010-039
264 Figure 1: 'Anatomy of the Cervical Region (Neck)' in the Report of Messrs. Forsythe and Rigg dated February 2012: Ref: 300-087-185

158. She then examined the brain after fixation, which was cut on 12th January 1996. She described the brain as being 'grossly swollen with loss of sulci and uncal swelling'. On the cut section there was 'massive brain swelling and constriction of the ventricles' and 'severe white matter congestion'.[265] She also noted the fixed weight of the brain as 1,680g, with the average weight for a boy of Adam's age being 1,300g.[266] A sequential set of photographs were taken of Adam's brain during the autopsy but not of his body or the suture referred to in the neck.[267] Photographs of Adam's brain which were taken at autopsy.[268] Dr Squier has also provided photographs of the brains of other children with oedema for comparison with Adam's brain.[269]

159. Dr. Armour then examined histological slides of the organs under a microscope.[270] This revealed 'complete infarction of the transplanted kidney' and 'massive cerebral oedema of the cortex and white matter' of the brain, but 'no evidence of terminal hypoxia'.[271]

160. In her commentary at the end of the report, Dr Armour referred to Arieff's 1992 article, although she distinguished it as referring to healthy children undergoing operations like tonsillectomies and who therefore had *"normally functioning kidneys which was not the situation in this case"*[272]. However, she stated that the most likely explanation for Adam's death was *"cerebral oedema followed by a period of hyponatraemia and was compounded by impaired cerebral perfusion"*.[273] Dr Armour reported the cause of Adam's death as: 1(a) cerebral oedema due to (b) dilutional hyponatraemia and impaired cerebral perfusion during renal transplant.[274]

161. For the purposes of her Report, Dr. Armour had available to her the opinion of Professor Jeremy Berry (Professor of Paediatric Pathology) on the histological slides.[275] He was engaged by the Coroner and was sent slides of amongst other areas, Adam's native kidneys and the donor

265 Ref: 011-010-039
266 Ref: 011-010-040
267 Ref: 011-010-039 and 300-081-156, 300-075-138
268 Ref: 300-081-160 and Ref: 300-081-161
269 Ref: 300-058-076
270 Ref: 011-010-039
271 Ref: 011-010-040
272 Ref: 011-010-041
273 Ref: 011-010-041
274 Ref: 011-010-034
275 Ref: WS-012-1 p.13

kidney. He concluded that the transplanted kidney was dead (infarcted) at or before the time of transplantation.[276]

162. Dr. Armour claims to have also sought an opinion on the brain and related material from Dr. Meenakshi Mirakhur (Consultant Neuropathologist).[277] She sent her the brain, spinal cord and histological slides and tissue blocks. Dr. Armour claims that Dr. Mirakhur's views were consistent with her Report on Autopsy in relation to her description of and comments on the brain. It seems though that no formal request for a neuropathological report was received by Dr. Mirakhur nor was any such report provided by her. Dr. Mirakhur denies any knowledge of her opinion having being sought or seeing any slides and she claims not to have seen the Report on Autopsy until the Inquiry referred her to it when seeking a Witness Statement from her.[278]

163. In addition, according to a note made by the Coroner dated 8th December 1995[279], Dr Armour also showed slides to Dr. Denis O'Hara (Consultant Paediatric Pathologist) and a Dr. Bharucha. There is some degree of uncertainty of the particular Dr. Bharucha in question, whether Dr. Chitra Bharucha who provided an Inquiry Witness dated 12th January 2012[280] or Dr. Hoshang Bharucha who has provided an Inquiry Witness Statement dated 10th April 2012.[281] As can be seen neither remembers or accepts any involvement in Adam's case. However, according to the Coroner's note, both Dr. O'Hara and Dr. Bharucha stated that there was clear evidence of hypoxia evident. Dr. Armour stated in her Autopsy Report that there was no evidence of hypoxia[282]. As you know Mr. Chairman, Dr O'Hara is now deceased and the Drs Bharucha cannot presently recall their involvement.

164. Dr. Armour wrote to Professor Jack Crane, State Pathologist, on 8th December 1995[283] stating that she had been dealing with the case of Adam Strain and further: "*I am willing to attend any meeting about this case, including a meeting with clinicians, administrative staff, H.M. Coroner and whoever else wishes to attend. As I was the pathologist who carried out the autopsy I feel my opinion on the case is relevant to such a meeting and as such the case could be discussed in full.*"

276 Ref: WS-18-1 p.4
277 Ref:011-010-040
278 Ref: WS-223-1 p.2
279 Ref: 011-025-125
280 Ref: WS-229-1, p.1
281 Ref: WS-249-1, p.1
282 Ref: 011-010-040
283 Ref: 011-023-123

165. This letter was prior to the provision of her Autopsy Report, and was copied to the Medical Protection Society, Mr. Calvin Spence of the British Medical Association, Mr. George Murnaghan, Hospital Administration and the Coroner. The reason for such a proposed meeting is something that will be pursued further.

166. It is not clear whether anyone at the State Pathologist's Department saw Dr. Armour's Report on Autopsy before it was sent to the Coroner. However we know that both Dr. Savage and Dr. Taylor were present at some point while the Autopsy was being carried out. The Coroner's papers also indicate that Dr. Armour discussed Adam's death and its possible causes with Drs. Taylor, O'Hara and Bharucha. It is also clear from her subsequent evidence at the Inquest that the extent of Adam's cerebral oedema 'was the worst she had ever seen'.[284]

167. Dr. Armour's autopsy report is undated.[285] So whilst it is known that a copy of it was sent out by the Coroner on 22nd April 1996[286] to Adam's mother, his experts Dr. Sumner and Dr. Alexander and to Dr. George Murnaghan at the Royal, it is not clear when Dr. Armour finalised her Autopsy Report.

168. The way in which Dr. Armour carried out the autopsy and prepared her Report is something that will be addressed during the Oral Hearing. It will also be considered from a 'governance' perspective.

Coroner's Investigation

169. The Coroner wrote to Dr. John Alexander, Consultant Anaesthetist on 30th November 1995, asking him to prepare an anaesthetic report on Adam's case for use at the Inquest. He stated that Dr. Alison Armour informed him that she found gross cerebral oedema, the worst she had ever seen in an autopsy on a child. He identified the clinicians involved as Dr. Robert Taylor and Messrs. Stephen Brown and Patrick Keane. He also stated:

"… the child was healthy and considered to be an ideal candidate for transplant surgery. No complications were anticipated."[287]

170. On Dr. Alexander confirming he would provide a report, the Coroner contacted Dr. George Murnaghan seeking statements from the clinicians involved as soon as possible. He also stated:

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284 Ref: 011-010-033
285 Ref: 011-010-035
286 Ref: 011-059-124
287 Ref: 011-018-116

"*it would be useful to have a statement from the technician responsible for the equipment in theatre confirming that it was functioning properly. The statement should cover the frequency of checks and whether such checks were carried out before and after surgery in this instance.*"[288]

171. Dr. Armour contacted the Coroner on 1st December 1995 and indicated that she was becoming ever more convinced that there was a question mark over the anaesthetic equipment used, as nothing in the anaesthetic readings during surgery had indicated a problem.[289] The Coroner spoke to Dr. George Murnaghan and asked that the equipment used during Adam's surgery should be "*independently examined*".[290]

172. Messrs. Wilson and McLaughlin (Medical Technical Officers employed by the Royal Victoria Hospital) 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.[291] They have said that they were not told the purpose of their investigation.[292] That inspection was carried out in the presence of Dr. Fiona Gibson, Consultant Cardiac Anaesthetist at the Children's Hospital, who had been asked by Dr. Murnaghan and Dr. Gaston to review and report on the processes and equipment used in Adam's Operating Theatre. Dr. Taylor was present during the inspection.[293]

173. The report provided to the Coroner as part of the Inquest on Adam's death, indicated that "*all cylinders were removed from the Lamtec... [and] five pins were discovered to be loose and could be removed*".[294] The report further states that: "*the anaesthetist using the machine is also expected to sign the log before commencing the list but this does not happen on most occasions. A reason for this omission should be requested*".[295]

174. The findings in that report and its significance will also be considered from a 'governance' perspective.

175. As I have already mentioned, 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*".[296] The Inquiry has since been advised in letters from

288 Ref: 059-073-166
289 Ref: 011-025-125
290 Ref: 011-025-125
291 Ref: 011-028-147
292 Ref: WS-109-1 p.2 and Ref: WS-110-1 p.2
293 Ref: 094-075-276
294 Ref: 093-028-077b
295 Ref: 093-028-077c
296 Ref: 059-069-162

Directorate of Legal Services dated 24th February 2011 and 21st July 2011 respectively that there were no such protocols and that: *"Dr. Gibson will have been referring to her perception of clinical practice in the Children's Hospital and not to any written document"*.[297]

176. 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.[298] That indeed was a possibility raised in the report of Messrs. Wilson and McLaughlin.

177. The conduct of the investigation of the equipment for the Coroner by Messrs Wilson and McLaughlin, and Dr. Gibson's review for Dr. Murnaghan and Dr. Gaston is a matter that will be pursued from a 'governance' perspective.

178. The Coroner met with Dr. Murnaghan, Dr. Gaston and Dr. Lyons on 3rd December 1995 and it was suggested by Dr. Lyons that it was important to have another paediatric anaesthetic opinion apart from Dr. John Alexander as he did not have extensive paediatric experience. The Coroner subsequently telephoned Dr. Edward Sumner who agreed to provide an opinion for the Inquest.[299] Professor Jeremy Berry also agreed to provide an expert report regarding the condition of the transplanted kidney.[300]

179. Dr. Alexander sent his report to the Coroner on 3rd January 1996[301]. In it he claimed that there was: *"very little firm available information concerning dilutional hyponatraemia (low serum sodium) in children"*.[302] He referred to Arieff's paper: 'Hyponatraemia and death or permanent brain damage in healthy children' referring to how: *"generally healthy children with symptomatic hyponatraemia (101-123mmol/l) can abruptly develop respiratory arrest and either die or develop permanent brain damage"*.[303]

180. He summarised his opinion as:

> *"The complex metabolic and fluid requirements of this child having major surgery led to the administration of a large volume of hypotonic (0.18%) saline which produced a dilutional hyponatraemia and subsequent cerebral oedema … Dr.*

297 Ref: 305-013-599 and Ref: 305-014-604 respectively
298 Ref: 094-210-999
299 Ref: 011-027-128
300 Ref: 011-032-164
301 Ref: 011-012-084
302 Ref: 011-012-086
303 Ref: 011-012-086

Taylor is to be commended on the detailed notes and records he kept throughout the anaesthetic".[304]

181. Dr. Sumner produced his report for the Coroner on 22nd January 1996[305] Referring to Arieff's 1992 article, he concluded that:

"*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."[306]

182. Professor Jeremy Berry sent a letter to the Coroner dated 25th March 1996 enclosing his Report of 23rd March with the comment: "*I am unable to throw any light on the cause of this child's death. I suspect the answer lies in precise details of his clinical management and the examination of his brain … I doubt this kidney would ever have functioned*". [307]

183. In his report, he noted that on microscopy *"the [transplanted] kidney shows almost complete infarction"* and that *"the transplant kidney was infarcted (dead). The extent of the change suggested that this occurred at or before the time of transplantation"*.[308]

Adam's Inquest

184. Adam's Inquest opened on 18th June 1996 before Mr. John Leckey, HM Coroner. Evidence was heard from Constable Tester,[309] Ms. Strain,[310] Dr. Alison Armour,[311] Dr. Edward Sumner,[312] Dr. John Alexander[313] and Mr. Patrick Keane[314] before being adjourned to 21st June 1996, when evidence was heard from Dr. Taylor[315] and Dr. Savage.[316] Of the team involved in

304 Ref:011-012-087
305 Ref: 011-011-053
306 Ref: 011-011-063
307 Ref: 011-053-187
308 Ref: 011-007-022
309 Ref: 011-008-024
310 Ref: 011-009-025
311 Ref: 011-010-030
312 Ref: 011-011-042
313 Ref: 011-012-079
314 Ref: 011-013-093
315 Ref: 011-014-096

Adam's transplant, neither Dr. Montague, Mr. Brown, Peter Shaw (the Medical Technical Officer) nor any of the nurses were called to give evidence. The Coroner did not have available to him the expertise of an Expert Paediatric Neurologist.

185. Dr. Armour in her evidence stated that she found *"massive cerebral oedema"*[317] that she had *"never come across anything of similar degree"*.[318] She also stated that Adam had experienced *"substantial blood loss"* and that *"he was a sick little boy"*.[319] She further stated that there was *"impaired cerebral perfusion as there was a suture on the left side and a catheter tip on the right"* and that this suture *"had been there for some time"*.[320]

186. Dr. Alexander in his evidence stated that *"there was a fluid deficit' between 5.00am & 7.00am"*[321] and that he would not have been *"particularly alarmed" with a drop 123mmol/L.*[322] He did not: *"entirely concur with Dr. Sumner's view that a compromised renal function is not a factor in the onset of hyponatraemia"*.[323]

187. Dr. Sumner in his evidence stated that *"without the venous drainage problem, Adam may have survived provided the level did not drop below 123mmol/L"*[324] and that *"fluid balance in paediatrics is a very controversial area with a variety of views"*.[325]

188. Dr. Sumner gave evidence before Dr. Taylor and Dr. Savage.[326] He did not therefore have an opportunity to hear and comment upon their evidence. Dr. Taylor states that he spoke to Dr. Sumner and Dr. Savage during a lunch break at the Coroners' Inquest and explained that Adam had high-output renal failure and so could not respond to ADH by concentrating urine and retaining water.[327] He had earlier made such a claim in his PSNI Statement under caution on 17th October 1995: *"They both acknowledge that the cause of the papers on dilutional hyponatraemia couldn't have happened*

316 Ref: 011-015-109
317 Ref: 011-010-033
318 Ref: 011-010-033
319 Ref: 011-010-033
320 Ref: 011-010-033
321 Ref: 011-012-083
322 Ref: 011-012-083
323 Ref: 011-012-083
324 Ref: 011-011-049
325 Ref: 011-011-049
326 Ref: 094-013f-072
327 Ref: WS-008-2, p.40

Adam and yet in court they say it did"(sic).[328] He acknowledged that he was 'frustrated' that in court they said that it could.[329]

189. The cause of Adam's death is recorded on the Verdict on Inquest[330] as:

> *"I(A) Cerebral Oedema*
>
> *Due to*
>
> *(B) Dilutional hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy)"*

190. The findings made by the Coroner in respect of the cause of the cerebral oedema reflect the summary at p.10 of Dr. Sumner's Report[331] and can be broken down as:

(i) Acute onset of hyponatraemia from excess fluids containing very small amounts of sodium

(ii) Exacerbated by blood loss

(iii) Possibly also exacerbated by:

- overnight dialysis and
- obstruction of the venous drainage to the head

191. The Coroner's Verdict on Inquest was not accepted by Dr. Taylor.[332] He disagreed with Dr. Sumner's principal finding in his deposition of 21st June 1996.[333]

> "*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*

328 Ref: 093-038-252
329 Ref: 093-038-251
330 Ref: 011-016-114
331 Ref: 011-011-063
332 Ref: 094-013e-071
333 Ref: 011-014-108

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."[334]

192. Dr. Taylor also set out his objections to Dr. Sumner's report and Dr. Armour's autopsy report in correspondence dated 2nd February 1996[335] and 8th May 1996[336] respectively.

193. The Verdict on Inquest is also not entirely accepted by the Inquiry's Experts, the reasons for which will addressed by them in their evidence during the Oral Hearing.

PSNI Investigation

194. As I stated in my General Opening, having begun an investigation into the events surrounding the death of Lucy Crawford, the PSNI wrote to the Inquiry on 26th July 2005[337] to advise that they were going to start an investigation into Adam's and Raychel's deaths.

195. In doing so, they sought statements from a large number of those contained in the List of Persons for Adam's case. In particular, they conducted a PACE interview under caution with Dr. Robert Taylor, the transcript of which is available.[338]

196. However, the Public Prosecution Service (PPS), on reviewing the evidence generated by the PSNI, subsequently took the decision, as with the other cases, not to proceed with any prosecutions against anyone involved in Adam's case.

XIV. Revised Terms of Reference in relation to Adam

197. As you are aware, and as I commented in the General Opening, the Terms of Reference of the Inquiry have changed since they were first published in November 2004. However, the effect of the change by then Minister of Health, Michael McGimpsey on 17th November 2008, to exclude entirely Lucy's name[339], has not affected the Terms of Adam's case which remain unchanged from the original Terms:

334 Ref: 094-013e-071
335 Ref: 059-053-108
336 Ref: 059-036-072
337 Ref: 094-193-943
338 Ref: 093-038-121 to 093-038-288
339 Ref: 303-033-460

> *In pursuance of the powers conferred on it by Article 54 and Schedule 8 to the Health and Personal Social Services (Northern Ireland) Order 1972, the Department of Health, Social Services and Public Safety hereby appoints Mr. John O'Hara QC to hold an Inquiry into the events surrounding and following the deaths of Adam Strain and Raychel Ferguson, with particular reference to:*
>
> 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* [340]

198. However, the addition of the case of Claire Roberts has affected the way in which Adam's case will be dealt with. The investigation of her death requires an investigation into whether the way in which the aftermath of Adam's death and his Inquest were handled had any impact on Claire's subsequent care and treatment at the Children's Hospital. It will be appreciated that Adam died at the Children's Hospital in November 1995 and the verdict in his Inquest was given in June 1996. In the case of his death, this was almost one year before Claire was admitted to the Children's Hospital and, in the case of his Inquest, almost exactly four months before she was admitted there. This will, however, generally be considered from a 'governance' perspective in relation to Adam.

XV. List of Issues in relation to Adam

199. The issues raised by the Terms of Reference are reflected in the Inquiry's List of Issues. The List of Issues is a working document that is updated and revised as appropriate.[341] The current List of Issues was published by the Inquiry on 14th February 2012. In relation to the clinical area of Adam's case, they particularly fall into four areas:

    (i) Investigation into the relevance of the care and treatment that Adam Strain received at the Children's Hospital

[340] Ref: 021-010-024
[341] Ref: 303-038-478 *et seq*

(ii) Investigation into the care and treatment that Adam received on 26th, 27th and 28th November 1995, especially in relation to the management of his fluid and electrolyte balance

(iii) Investigation into the quality of the information on Adam provided to Adam's next of kin from when the possibility of placing Adam on the renal transplant list arose in 1994 until the announcement of the Inquiry in 2004

(iv) Investigation into the experience of the Transplant team including surgeons, anaesthetists and nurses

XVI. Selection of Issues to be addressed through the Oral Hearing

200. All the evidence received by the Inquiry, the categories of which I have already described, forms part of the material upon which Mr. Chairman you will in due course make findings. As has been seen it is a substantial volume of material for you to consider and not all of what has been received is consistent.

201. There are also gaps in the information received. In some instances it seems clear that those gaps cannot, at this remove, be filled. For example, the Inquiry has been informed by DLS that there is no longer a complete set of staff rotas. Whilst the Inquiry will seek to have a Witness address the policy on the destruction of documents, most usefully for the purposes of 'hospital management and governance', it is unlikely that will assist the Inquiry in better identifying who was doing what when in areas where that remains an issue.

202. Some gaps may be filled by evidence during the Oral Hearing. For example, it is unclear whether the chest x-ray that Dr. O'Neill records in Adam's notes[342] as having been ordered was actually carried out and if not why not. It may be that issue can be clarified and the gap filled during the Oral Hearing.

203. In addition to providing for you Mr. Chairman such missing elements in the narrative of what happened, the matters to be addressed during the Oral Hearing will essentially concern four categories of as yet unresolved issues, dealing with differences between:

(i) The documents and the evidence of a witness

342 Ref: 057-019-028, Ref: WS-004-1, p2 and Ref: WS-004-2, pgs.2,6

(ii) The evidence of witnesses, whether between the accounts given by a witness or between the accounts of different witnesses

(iii) The evidence of a witness and the views of an expert

(iv) The views of the Experts on a particular issue

204. Those categories apply to the entire period that is relevant to Adam's case but most particularly from 14th July 1994[343] when, as can be seen from the 'Time Line of Main Events',[344] arrangements were being made to put him on call for renal transplant simultaneous with the start of dialysis, up until the autopsy on 29th November 1995.

205. For the purposes of this Opening, Mr. Chairman I will highlight the main issues leading up to the Report on Autopsy in relation to four main periods:

(i) Pre-Operative, which spans the period from when it was decided to place Adam on the transplant register right up until the morning of his transplant surgery.

(ii) Peri-Operative, which deals with the period from the start of the anaesthesia for his transplant surgery until his transfer to PICU

(iii) Post-Operative, which deals with the period from Adam's transfer to PICU up until his death

(iv) The period following Adam's death, which deals with the autopsy until the Verdict on Inquest

206. The events that took place in those periods are to a certain extent reflected in some of the documents that have been compiled by the Legal Team to which I will refer as appropriate to explain matters. In particular:

(i) 'Time Line of Main Events: Adam (1991-1995)',[345] the Schedule of Surgical Procedures[346] and the charts on 'Serum Sodium Levels' and 'Urine Sodium Levels'[347] – all in relation to the entirety of the period

343 Ref: 016-042-078
344 Ref: 307-001-032
345 Ref: 307-001-002
346 Ref: 300-060-108
347 Ref: 300-059-079 and Ref: 300-059-080

(ii) 'Inquiry Chronology of Events: Adam (Clinical)' [348] - in relation to the period from his admission on 26th November 1995 until the Autopsy on 29th November 1995

(iii) 'Adam's Pre-Surgical State'[349] - for the period from his admission on 26th November 1995 to 07.00 on 27th November 1995

(iv) 'Charts of Adam's Peri-operative Period'[350] - covering the period from 07:00 on 27th November 1995 to 12:00 on 27th November 1995

207. I am anxious not to compromise the evidence that is to be given during the Oral Hearing, particularly where there is an issue concerning differences in the versions of those who were directly involved with Adam's case or queries over some aspect of his management over the period from 26th November 1995 to 28th November 1995. I will address such issues with care and in some instances not at all.

208. However, an example that I can give without compromising matters concerns the differences and inconsistencies in the evidence of Dr. Taylor. In particular, the explanations that he gives in his interview under caution by the PSNI on 17th October 2006[351] in relation to his preparation for Adam's transplant surgery and his management of Adam during it. The PSNI have provided a transcript of that interview. Mr. Chairman, it is a lengthy document which bears close examination by you. That is so notwithstanding, indeed possibly because of, Dr. Taylor's most recent and unsolicited Inquiry Witness Statement of 1st February 2012 in which he acknowledges a number of errors that: *"led to a lower standard of care [for Adam than he] would normally provide"*.[352]

209. There are also issues other than matters arising out of Dr. Taylor's evidence, especially in relation to his most recent Witness Statement, that will be addressed from a 'governance' perspective in Adam's case.

210. The Reports of the Experts that were engaged in previous investigations into Adam's case, whether by the Coroner for the purpose of the Inquest or by the PSNI for the purpose of its investigation and recommendations on prosecution, have all been published. Furthermore, the Reports received to date from the Experts engaged by the Inquiry have been provided to the Interested Parties and will in due course be published.

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348 Ref: 306-003-006
349 Ref: 306-006-040
350 Ref: 307-006-063
351 Ref: 093-038-121
352 Ref: WS-008-6, p.3

211. As can be seen Mr. Chairman, there are clear differences between the Experts and Adam's clinicians as there are amongst the Experts themselves. I will try and highlight some of those differences for you Mr. Chairman in the course of this Opening.

212. There is also an important area of disagreement between the Experts that is worthy of especial mention, which relates to the role of dilutional hyponatraemia in Adam's death. It is obviously of fundamental importance. It has been the subject of considerable debate amongst the Inquiry's Experts and has generated a number for further Reports from them, not all of which were received by the Inquiry at the start of this Opening on 26th March 2012. I deal now with how that debate arose.

213. Until the preliminary Report provided by Professor Kirkham on 16th February 2011[353] the shared view of the Inquiry's Experts was that dilutional hyponatraemia was the major cause of the acute cerebral oedema that led to Adam's death. That is not to say that there were not some differences amongst them, principally in relation to the role of a possible ligation of Adam's left internal jugular vein as described in Dr. Armour's Report on Autopsy[354] and its contribution to any obstruction to the venous drainage from the head as referred to in Dr. Sumner's Report of 22nd January 1996[355] and his evidence on 18th June 1996.[356]

214. The Report of Professor Kirkham signalled a change to there being a common view on dilutional hyponatraemia amongst the Inquiry's Experts. She introduced in her preliminary Report the explanation that: *"on the balance of probabilities, chronic venous sinus thrombosis was a likely cause of Adam's previous rather subtle neurological problems"* and that it was likely that: "*further acute thrombosis in the venous sinuses was associated with acute posterior cerebral oedema during the operation*".[357] She also expressed the view that the: "*development of PRES [posterior reversible encephalopathy syndrome, for which Adam had at least 3 risk factors (anaemia, blood transfusion, immunosuppression) contributed to the rapid development of mainly posterior cerebral oedema*".[358]

215. Professor Kirkham then does go on to deal specifically with dilutional hyponatraemia at paragraph 54 of her preliminary Report, in which she summarises and addresses in turn the bases of the argument that: "*Adam's acute cerebral oedema and brain death was caused by dilutional*

353 Ref: 208-002-017
354 Ref: 011-010-034
355 Ref: 011-011-063
356 Ref: 011-011-049
357 Ref: 208-002-035
358 Ref: 208-002-037

hyponatraemia".[359] She concludes with: *"Although it is possible that the compensatory mechanisms were overwhelmed because of the rapidity of the fall in sodium and the associated shift of water into the brain along an osmotic gradient, on the balance of probabilities the rapid development of fatal posterior cerebral oedema was secondary to acute on chronic cerebral venous thrombosis, probably with the additional development of posterior cerebral oedema similar to that seen in cases of PRES"*.[360]

216. Since Professor Kirkham's preliminary Report, the Inquiry's clinical Experts have had two lengthy meetings, one on 22nd February 2012 and one on 9th March 2012. Both meetings were recorded and a transcript has been provided for each one.[361] Professor Kirkham's preliminary Report and those two meetings have generated a considerable number of Reports from the Experts as they explore and challenge their differences and the bases for them:

(i) Dr. Anslow:

- Note of 18th February 2012[362] dealing with certain queries raised by Professor Kirkham, prior to the completion of her preliminary Report

(ii) Dr. Coulthard:

- Report of 15th March 2012[363] on CVP presenting his arguments as to an error in zeroing
- Report of 15th March 2012[364] dealing with the two papers cited by Professor Kirkham in her preliminary Report, namely: (a) Paut et al: 'Severe hyponatraemic encephalopathy after paediatric surgery: report of seven cases and recommendations for management and prevention'; and (b) Sicot & Laxenaire: 'Death of a child due to posttonsillectomy hyponatraemic encephalopathy', together with a third paper
- Report of 16th March 2012[365] on free water balances, which corrected his Report on the same subject earlier that day and

359 Ref: 208-002-038
360 Ref: 208-002-039
361 Ref: 307-007-073 and Ref: 307-008-162
362 Ref: 208-004-051
363 Ref: 200-019-226
364 Ref: 200-018-222
365 Ref: 200-021-254

includes 2 pages of calculations based on Dr. Taylor's statement of 1st February 2012

- Report of 16th March 2012[366] providing responses to queries raised during the Experts' meeting on 9th March 2012 and Dr. Taylor's statement of 1st February 2012,[367] as well as recalculating his own table, 'Adam's perioperative fluid balance',[368] and those originally produced by Dr. Haynes,[369] Professor Gross[370] and Dr. Taylor[371]

- Report of 16th March 2012[372] in response to the queries raised during the Experts' meeting of 9th March 2012 and other issues including matters raised by the Professor Gross and others

- Report of 17th March 2012[373] providing his final views from the perspective of a paediatric nephrologist

(iii) Professor Gross:

- Report of 18th March 2012 on the Experts' meeting of 22nd February 2012[374]

(iv) Dr. Haynes:

- Report of 20th February 2012 responding to the Report of Professor Kirkham dated 16th February 2012[375]

- Supplementary Report of 6th March 2012[376]

- Report of 18th March 2012[377] on his final position having regard to the Expert Reports to date and the two meetings of Experts

- Summary Report of 18th March 2012[378]

(v) Dr. Squier:

366 Ref: 200-020-232
367 Ref: WS-008-6, p.1
368 Ref: 300-062-119
369 Ref: 300-063-122
370 Ref: 201-008-203
371 Ref: 300-061-117
372 Ref: 200-020-232
373 Ref: 200-021-254
374 Ref: 201-015-215
375 Ref: 204-008-353
376 Ref: 204-009-361
377 Ref: 204-012-378
378 Ref: 204-013-389

- Report of 17th February 2012 responding to Professor Kirkham's Report of 16th February 2012[379]

- Report of 15th March 2012[380] on her final position.

217. Following the adjournment of the Hearing on 27th March 2012, the following additional Reports were received from the Inquiry's Experts:

(i) Professor Gross:

- Report of 23rd March 2012 on the Experts' meeting of 9th March 2012[381]

(ii) Professor Kirkham

- Final report of 28th March 2012[382]

218. The debate amongst the Inquiry's Experts deals with complex medical issues, some of which may well be being developed out of research that is still ongoing.

219. However, even that is not accepted by all of the Inquiry's Experts. On the one hand Dr. Coulthard states at page 3 of his Report of 20th February 2012 that he does not consider that there is anything new in PRES but that it is simply a radiological description for acute hypertensive encephalopathy, which is something that all Nephrologists know they need to manage.[383] Whilst on the other hand Dr. Haynes acknowledges at paragraph 25 of his Report,[384] also of 20th February 2012, that PRES is increasingly recognised as an entity and believes he has come across some cases. He also agrees in that Report that PRES can be considered where there is no obvious underlying cause for the cerebral oedema, albeit that in Adam's case there was such a cause, namely the dilutional hyponatraemia.[385] As a pathologist, Dr. Squier approached the issue of PRES from a different perspective. She explains in her Report of 22nd February 2012 that PRES is not yet a condition diagnosed pathologically[386] and Dr. Anslow states in his Note of 18th February 2012 responding to certain queries raised by Professor Kirkham that: *"PRES is a diagnosis best*

379 Ref: 206-006-113
380 Ref: 206-010-120
381 Ref: 201-016-284
382 Ref: 208-007-068
383 Ref: 200-014-207
384 Ref: 204-008-353
385 Ref: 204-008-353
386 Ref: 206-006-114

made on MRI".[387] However, Dr. Squier nonetheless comments at paragraph 50 on PRES as being *"a very interesting condition that was well worth consideration"*. [388]

220. The ongoing research and study on the matters being considered and debated by the Inquiry's Experts is well illustrated by the published literature they cite in their Reports which is being included to update the Bibliography compiled by the Legal Team.

XVII. Issues to be addressed - Pre-Operative Stage

Putting Adam on the Transplant Register

221. As can be seen from the 'Time Line of Main Events: Adam (1991-1995)' ("Time Line"),[389] arrangements were made to have Adam registered for a transplant as soon as his condition deteriorated to the extent that he required dialysis.[390] He was registered with the United Kingdom Transplant Support Service Authority (UKTSSA) in November 1994.[391]

222. The main members of the 'Transplant team', together with the Inquiry's Experts (Dr. Coulthard, Dr. Haynes and Messrs. Forsythe and Rigg), were all asked to complete a template for a Table for Paediatric Renal Transplant: Showing the Involvement of Personnel in the Various Phases'. Their completed Tables show who they regard should be involved at any particular stage from the first mention to the family of transplant as an option to communicating the child's death.[392] The table also indicates the importance of that involvement to that stage.

223. There are issues to be explored in the Oral Hearing as to the way in which the decisions were made relating to placing Adam on the transplant register. Those issues include:

    (i) The information and options that were given to Adam's mother on the most appropriate transplant centre and also the possibility of a living donor.

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387 Ref: 208-004-051
388 Ref: 206-006-114
389 Ref: 307-001-032
390 Ref: 016-042-078 and Ref: 056-030-065 and
391 Ref: 057-070-131
392 Ref: 300-064-124 (Dr. Savage), Ref: 300-065-125 (Dr. Taylor), Ref: 300-066-127 (Mr. Keane), Ref: 300-067-128 (Dr. Coulthard), Ref: 300-968-129 (Dr. Haynes), Ref: 300-069-131 (Messrs. Forsythe & Rigg). Dr. Montague also provided a completed table (Ref: WS-009-3, p.9) with his Inquiry Witness Statement of 16th September 2011 (Ref: WS-009-03, p,1)

Dr. Savage discusses in his Inquiry Witness Statement of 28th September 2011[393] what he told Debra Slavin, whilst acknowledging that the information he provided to her is not recorded in Adam's notes. Debra Slavin refers to the particular issues of 'options' and 'living donor' in her Inquiry Witness Statement.[394] She also addresses the issue of the transplant booklet in her Witness Statement[395].

Dr. Coulthard's comments on the information that he considers should have been provided to Debra Slavin at page 13 of his Report dated 7th November 2011[396] and at page 12 of his Report dated 16th February 2012. [397]

(ii) The extent to which the decision to place Adam on the transplant register should have been informed by a multi-disciplinary team to include a transplant surgeon.

Dr. Savage refers in his Inquiry Witness Statement dated 14th April 2011 to the 'multi-disciplinary team' for renal transplants, which he describes as comprising, in addition to the nephrologists: "*renal nurses, dieticians, psychologists and social workers*".[398] He expands on that a little in his Inquiry Witness Statement dated 28th September 2011 by identifying SN Joanne Clingham as the senior renal nurse at the time of Adam's transplant surgery and Mrs. Janet Mercer as the dietician.[399] He also makes it clear that the: "*transplant surgeon did not participate in these multi-disciplinary team meetings, except by special arrangement, as he worked not on the Royal Victoria site but on the Belfast City site*".[400]

Messrs. Forsythe and Rigg comment on the issue of 'transplant assessment' in their Report of June 2011 at paragraph 2.1,[401] paragraph 3.1[402] and at paragraph 4.1.[403] They are clearly of the view that a Consultant Transplant Surgeon should be involved prior to placing the child on the transplant register, for the purposes of carrying out a physical examination of the child and

393 Ref: WS-002-3, p.10, Q.(b)
394 Ref: WS-001-2, p.5
395 Ref: WS-001-2
396 Dr. Coulthard's Report - Ref: 200-007-122
397 Ref:**:** 200-013-188
398 Ref: WS-002-2, p.11
399 Ref: WS-002-3, p.19
400 Ref: WS-002-3, p.19
401 Ref: Messrs. Forsythe and Rigg's Report – Ref: 203-002-026
402 Ref: 203-002-029
403 Ref: 203-002-032

explaining to the family the procedure together with the risks and benefits involved.

Dr. Coulthard also comments upon this phase in his Report dated 7th November 2011 and the involvement of Surgeons in the process: *"I believe that the final decision to plan to undertake a transplant should not be made by the paediatric nephrologist alone, but jointly by the paediatric renal team and the transplant surgeons."*[404] Dr. Coulthard develops these points at page 5 of his Report dated 7th November 2011. [405]

(iii) Whether such a multi-disciplinary team should have developed a 'plan' for Adam's surgery that could be implemented by the available clinicians if and when a donor kidney became available.

Messrs. Forsythe and Rigg refer at paragraph 4.1.5 of their Report of June 2011 to discussing options at a 'transplant assessment clinic' and not in an emergency situation when decision making can be pressured.[406] They then go on to say: *"Having a plan to transfer Adam's care to a larger paediatric centre would have been a realistic option for them to consider, although there are logistical difficulties with such an option."* [407]

Dr. Coulthard also considers that a specific plan should have been formulated for Adam's transplant surgery. He makes the point at page 4 of his Report of 7th November 2011: *"One important role of having such a meeting and assessment by a transplant surgeon and paediatric nephrologist is to formulate a specific plan for that particular child, and to record it in their case notes. The importance of this is that it may not be that particular surgeon who is available to operate at the time a kidney becomes available, and it allows a calmly considered plan to be used at the time, instead of considering these details under a last-minute time-pressure"*.[408]

He returns to that point on the following page of that Report: *"we would see it as good practice for them to meet the transplant surgeons at least once before listing them, and for them to receive advice in that way … (c) the paediatric nephrologist should liaise with the transplant surgeons … before listing the child. At that point, any particular specific decisions about management should be recorded for future reference. Also*

404 Ref: 200-007-113 and Ref: 200-007-114
405 Ref: 200-007-113
406 Ref: 203-002-034
407 Ref: 203-002-034
408 Ref: 200-007-113

at that point they should jointly decide on the level of urgency … This has major implications for the choice of kidneys that would be accepted".[409]

224. The issues in relation to the arrangements for placing Adam on the transplant register together with the information that was provided to Adam's mother at the time, are all matters that will also be considered from a 'governance' perspective.

Accepting the Offer of the Donor Kidney

225. Turning now to the period that commences with the perfusion of the donor kidney at Glasgow Southern General Hospital at 01:42 on Sunday 26th November 1995.[410] Ms. Eleanor Donaghy, who was the Transplant Coordinator at the Belfast City Hospital at the time of Adam's transplant surgery, explains the process of donor kidney retrieval, offer and acceptance in her Inquiry Witness Statement of 22nd September 2011.[411] She refers to a protocol that she drew up in July/August 1992 with a Senior Sister in the Belfast City Hospital transplant ward: *"setting out agreed roles between nursing staff on the Transplant Ward and myself when a transplant was being arranged in BCH"*, which she states is out of date and no longer exists.[412] She goes on to state that no such protocol existed for the Children's Hospital.[413]

226. Some of the issues raised by Eleanor Donaghy's Inquiry Witness Statement will be considered from a 'governance' perspective.

227. The Inquiry's Experts Messrs. Forsythe and Rigg also describe the organ retrieval and offering process in their joint Report of June 2011.[414] They also explain in that Report the significance of that period for the 'cold ischaemic time' of the donor kidney.[415] They return to the issue of 'cold ischaemic time' and discuss also 'warm ischaemia' in their joint Report of October 2011.[416]

228. Dr. Savage's name appears on Adam's Registration Form.[417] Accordingly, he was the person to be notified of a possible donor kidney for Adam.

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409 Ref: 200-007-114
410 Ref: 306-007-042
411 Ref: WS-100-3, p.2 *et seq*
412 Ref: WS-100-3, p.5
413 Ref: WS-100-3, p.5
414 Ref: 203-002-026
415 Ref: 203-002-026
416 Ref: 203-004-066 and Ref: 203-004-061
417 Ref: 057-070-131

229. Dr. Savage has described in his Inquiry Witness Statement of 14th April 2011 what actually happened, insofar as he can recall it, in relation to Adam's case.[418] He expands upon that in his Inquiry Witness Statement of 28th September 2011 to address the role of the surgeon in accepting the donor kidney as well as collecting it from the Belfast City Hospital and bringing it to the Children's Hospital.[419] However, there are still some issues to be pursued during the Oral Hearing.

230. The time at which Dr. Savage received the offer of the donor kidney for Adam is unclear but it would have been sometime before 20:00 as that was the time when it is recorded that Adam was admitted into the Children's Hospital.[420] Dr. Savage believes that he had one conversation with the UK Transplant Service when they would have informed him:

(i) That a kidney, which had a reasonable tissue match, was available for Adam. The match was a 3 out of 6 tissue types

(ii) Of the cause of death of the donor

(iii) Of the time at which the kidney had been donated

(iv) Of the age, blood group and tissue type of the donor

(v) Of any significant medical history

(vi) Of any significant anatomical detail of the donated kidney for example that there were 2 arteries on a patch. Dr. Savage has no recollection of being told that the 2 arteries were *"widely separated"*.[421]

231. Dr. Savage should therefore have known that:

(i) Given the donor was 16 years old, the donor kidney was essentially the size of an adult kidney

(ii) It had 2 arteries, which might be a surgical issue

(iii) As at Adam's admission, the donor kidney would have a cold ischaemic time of about 19 hours

418 Ref: WS-002-2, p.2 *et seq*
419 Ref: WS-002-3, p.20
420 Ref: 057-006-007
421 Ref: WS-002-3 p. 36 Q31(d), p.22 Q20(h), p.21 Q20

232. On the basis of that information Dr. Savage, after speaking to Mr. Keane[422] and Adam's mother, took the initial decision to accept the donor kidney for Adam[423] and had his mother bring him in.[424] Mr. Keane states that he had no input or involvement in the decision to accept the kidney from UK Transplant.[425] It has since been confirmed by correspondence from DLS to the Inquiry dated 13th February 2012 that there were actually three arteries on the patch one of which is queried as having been tied off.[426] The Inquiry's Experts Messrs. Forsythe and Rigg have confirmed to the Inquiry that this: "*does not change the facts of their report but re-emphasizes the need for the surgeon to have been involved in the decision to accept the kidney and the need to inspect the kidney and to do the benchwork before the patient was anaesthetised.*"[427]

233. Those issues will be addressed further during the Oral Hearing, particularly in relation to the issue of taking consent from Adam's mother and proceeding on with the transplant surgery. However, it is worth noting at this stage that a 'cold ischaemic time' of 19 hours, which is what it would be by the time Adam was brought into the Children's Hospital, was getting quite close to the 24 hour "*optimal time*" within which to commence surgery to which Dr. Savage refers in his Inquiry Witness Statement of 28th September 2011.[428]

234. The way in which Dr. Savage made the decision to accept the donor kidney for Adam and the matters that he took into account are matters that will be dealt with in the Oral Hearing.

Compiling the Transplant Team

235. Dr. Savage was responsible for putting together the principal members of the team for Adam's transplant surgery, namely the Anaesthetist and the Surgeon.[429]

236. Dr. Taylor was the Consultant Paediatric Anaesthetist on call over Friday 24th November 1995 to Sunday 26th November 1995[430] when the offer of a donor kidney was received by Dr. Savage. It may be that is how he came to be included, rather than anything to do with his particular experience,

422 Ref: WS- 002-3 p. 20 Q19 (g), p.21 Q20(c) & (d), p. 23 Q 20(h)
423 Ref: WS-002-2, p.11, Q.5
424 Ref: WS-002-2, p.2, Q.2, p.12, Q.6
425 Ref: WS-006-3 p.23 Q42.
426 Ref: 301-121-656 and the enclosure Ref: 301-121-656
427 Ref: 203-009-111
428 Ref: WS-002-3, p.8
429 Ref: WS-002-2, p.3, Q.(2), Ref: WS-002-2, p.14, Q.(8), Ref: WS-002-2, p.15, Q.(9), Ref: WS-002-2, p.17, Q.(10)
430 Dr. Taylor's Inquiry Witness Statement – Ref: WS-008-1, p.2, Q.(i)

the extent of which I have already described. Dr. Taylor himself states in his first Inquiry Witness Statement dated 17th July 2005: "*I only agreed to provide general anaesthesia for Adam with an experienced senior registrar, Dr. T Montague, experienced theatre nursing staff and the ready access to experienced surgeons, and nephrologists who were in theatre dress and present beside me in theatre for large parts of the procedure*".[431]

237. The significance of that statement is something that will be addressed during the Oral Hearing.

238. Mr. Keane was at the time a Consultant Urologist, having been appointed to his Consultant post in March 1994.[432] It is not clear whether he was contacted by Dr. Savage simply because he was the Surgeon on call. Dr. Savage states in his Inquiry Witness Statement dated 14th April 2011 that: "*From the surgeon on call list for renal transplants held in the Renal Unit in the BCH, the transplant surgeon was identified. On this occasion Mr. Patrick Keane confirmed that he was available and willing to carry out a paediatric transplant*".[433] However, Mr. Keane does not believe that he was on call.[434] Rather, he thinks that he was contacted by Dr. Savage because he was the only available surgeon trained in transplantation.[435] It seems from Mr. Keane's Inquiry Witness Statement of 20th September 2011 that the other surgeons, Messrs. Donaldson and Kernohan, may have been on sick leave at the time.

239. Furthermore, it also seems from Mr. Keane's Inquiry Witness Statement of 20th September 2011 that at the time of Adam's transplant surgery there were only three Surgeons who performed paediatric renal transplants and had Mr. Keane "*been away, there would have been no one capable of doing the transplant*".[436] I have already referred to Mr. Keane's own experience in carrying out such surgery.

240. The implications of the statements of both Dr. Taylor and Mr. Keane are matters that will be addressed in the Oral Hearing in relation to the extent of the suitable expertise available to Dr. Savage.

241. The depth of the experienced resources required for the provision of a proper paediatric renal transplant service as at 1995 is something that will be addressed from a 'governance' perspective.

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431 Ref: WS-008-1, p.4, Q.(i)
432 Ref: WS-006-3, p.2
433 Ref: WS-002-2, p.14, Q.(8)
434 Ref: WS-006-2, p.8, Q.(9)(d)
435 Ref: WS-006-2, p.8, Q.(9)(d)
436 Ref: WS-006-3, pgs, 10 & 11, Q.(18)

242. In addition to Dr. Taylor and Mr. Savage, Mr. Brown may be considered to have been a significant member of the team due to his experience as a Consultant Paediatric Surgeon who had operated on Adam previously. I have already referred to his experience. However, exactly how Mr. Brown came to be included in the Transplant team as Surgical Assistant to Mr. Keane is not clear from the Inquiry Witness Statements of Dr. Savage,[437] Mr. Keane[438] or even Mr. Brown himself.[439] In recent correspondence from the DLS to the Inquiry dated 13th April 2012 it seems that: *"The Trust believes that the primary reason Mr. Brown was in theatre on the morning of 27th November 1995 was to perform his routine operating list which in order to assist Mr. Keane he delegated to his surgical trainee and he performed only the last operation on his own list at 12:15"*.[440] Mr. Brown's list, which started at 09:10 and ended with a procedure at 12:15, can be seen on the theatre log for 27th November 1995.[441]

243. Another explanation may be that his prior involvement in surgery on Adam was considered helpful. Certainly, Dr. Savage says that it is likely that he informed Adam's mother that: *"a paediatric surgeon would also be involved in the surgery who had knowledge of Adam's previous surgery who would therefore be available instantly during the transplantation procedure"*.[442] The extent of that involvement can be seen from the 'Schedule of Adam Strain's Surgical Procedures' as can the experience of the other Paediatric Consultant Surgeons with Adam.[443]

244. The result of those early surgical procedures, some of which involved Mr. Brown, is described in Adam's notes in:

    (i) ICU Discharge Summary dated 20th January 1992 by Dr. Craig, Senior House Officer in Intensive Care Unit: *"He had a ureteric reimplantation on the 23.11.91 which obstructed leading to acute renal failure"*.[444] That was one of the procedures performed by Mr. Brown.[445] As can be seen from the Schedule of Serum Sodium Levels there followed a period of hyponatraemia with Adam's sodium levels reaching as low as 111mmol/L and not getting back

437 Ref: WS-002-2, p.12, Q.(6)(b) and Ref: WS-002-2, p.14, Q.(8)
438 Ref: WS-006-2, p.4, Q.(4) and WS-006-3, p.3
439 Ref: WS-007-2, p.4, Q.(5)(d)
440 Ref: 301-124-684
441 Ref: 300-094-194 – This document has been compiled by te Inquiry from four separate pages for ease of reference (Ref: 094-006-021 *et seq*)
442 Ref: WS-002-2, p.12
443 Ref: 300-060-107
444 Ref: 050-013-045
445 Ref: WS-007-2, p.3

into the bottom of the normal range (ie 135mmol/L to 145mmol/L) until 28th November 1991.[446]

(ii) Undated operation note by Mr. Victor Boston, Consultant Paediatric Surgeon,[447] of a procedure on 8th December 1991:[448] "*Previous re-implantation of both ureters. Subsequently developed renal failure necessitating bilateral ureterostomies. The left kidney which appeared to be the best biochemically unfortunately displaced as demonstrated by tube nephrostogram. At no stage was there drainage into the bladder and it was presumed that there was an obstruction at the lower end of both ureters … the old wound was opened … and it was clear that the ureter had necrosed about 2cms above the bladder*".[449]

(iii) Letter dated 12th May 1992 from Dr. Savage to Dr. Scott who was Adam's GP at the time**:** "*He was operated on at the Ulster Hospital and here in the Children's Hospital by Mr. Brown. He has ended up with one ureter attached to the other and then the single, lower part of the ureter draining into the bladder. We are not entirely happy that this drains completely freely but it is felt by our surgical colleagues that this is the best result that can be achieved at the minute and they are loath to interfere again because he has had five operations in this area*".[450]

(iv) Letter dated 2nd April 1993 from Mr. Boston to Dr. Savage: *"he had a bilateral re-implant in November 1991, and lapsed into renal failure necessitating bilateral T-tube drainage. In December 1991 it was obvious that the left ureter was not draining and he ended up with a left sided ureterostomy. This was followed by a left ureteral ureterostomy to try and solve the problem of drainage of his left renal tract. He had a fundoplication in 1992 for GOR … An attempt at retrograding in January failed to identify the right ureteric orifice*".[451]

245. On 4th December 1992 Adam's mother asked Dr. Savage to obtain from Mr. Boston a second surgical opinion.[452] Mr. Boston refers to Mr. Brown having agreed to that[453] and on 30th March 1993 Mr. Boston saw Adam and his family.[454] It seems from Adam's notes that the last surgical procedure performed by Mr. Brown on Adam was a cystoscopy on 8th

446 Ref: 300-059-079
447 Ref: 050-008-031
448 Ref: 049-034-237
449 Ref: 050-008-031
450 Ref: 016-085-127
451 Ref: 016-062-104
452 Ref: 054-057-151
453 Ref: 016-062-104
454 Ref: WS-011-1, p.2

February 1993.[455] Thereafter, Mr. Boston and a number of others operated on Adam as can be seen from the Schedule of Adam Strain's Surgical Procedures.[456] Adam's mother states that she had made it quite clear that she: "*did not want Mr. Brown to be involved in any surgery with Adam because previous experience had left me with no faith in him*".[457]

246. For the sake of completeness, the other members of the 'Transplant team' were the assistant Anaesthetist, the Theatre Nurses and the Medical Technical Officer, who were included in the following way:

(i) On 26th November 1995 Dr. Montague, Senior Registrar in Anaesthesia, was the resident on call for both the Labour Ward and Theatres. That was a 24 hour shift that was due to end at 09:00 on Monday 27th November 1995, the morning of Adam's transplant surgery.[458] According to his Inquiry Witness Statement of 4th April 2011,[459] he had started as a Senior Registrar in Anaesthesia at the Children's Hospital in November 1995 and had never been involved in a renal transplant procedure in a child prior to Adam's transplant.[460] He was brought into the 'team' by Dr. Taylor as Assistant Anaesthetist for a limited period until the end of his shift.[461] Dr. Montague is now a Consultant in Anaesthesia and Intensive Care at Our Lady's Children's Hospital in Dublin and interestingly he comments in his Inquiry Witness Statement of 4th April 2011 that: "*I believe such complex cases need to be managed by an experienced multidisciplinary transplant team which manages sufficient numbers of cases*".[462]

(ii) Dr. Savage contacted the theatre[463] and thereafter the Theatre Nurses for Adam's transplant surgery, SNs Conway, Popplestone and Mathewson were those who were on duty at that time. Specifically, SN Conway was on-duty on Sunday 26th November 1995 and handed over to SN Mathewson at 8.00am on Monday 27th November 1995.[464] SN Popplestone claims to have also come on duty at 08:00 on Monday 27th November 1995.[465] However, SN Conway states in her Inquiry Witness Statement dated 21st May

455 Ref: 054-027-065
456 Ref: 300-060-107
457 Ref: WS-001-1, p.2
458 Ref: WS-009-1, p.2, Q.(1)
459 Ref: WS-009-1, p.2 and p.4
460 Ref: WS-009-1, p.4
461 Ref: WS-009-1, p.2, Q.(1)
462 Ref: WS-009-1, p.11
463 Ref: WS-00-2, p.2, Q.(2)
464 Ref: WS-060-1, p.2, Q.(1)
465 Ref: WS-010-1, p.2, Q.(1)

2011 that SN Popplestone came in early to prepare her instruments and set up as Scrub Nurse for Adam's surgery.[466] She also states that she was joined by SN Popplestone at approximately 07:00 on 27th November 1995.[467]

(iii) Similarly, Peter Shaw, who acted as the Medical Technical Officer for Adam's transplant surgery, was simply the Medical Technician on duty for Monday 27th November 1995.[468]

247. In addition, Dr. Taylor claims that he was assisted by an Anaesthetic Nurse, indeed that he would not have administered the anaesthetic without three nurses being present: "*My knowledge is there has to be three nurses present before an anaesthetic is commenced*".[469] He also claims that Dr. Montague was replaced in the Operating Theatre at the end of his shift by a Trainee Anaesthetist.

248. There are issues to be explored in the Oral Hearing as to exactly how the Transplant team was put together, who was in it and what information about the principal members of the team was given to Adam's mother both prior to and following the taking of her consent for his transplant surgery. In addition , those issues concern:

(i) The reasons for Mr. Brown's involvement, together with the significance for the transplant surgery of his particular knowledge of Adam

(ii) Whether there was an Anaesthetic Nurse to assist Dr. Taylor and if not why not

(iii) Whether Dr. Montague was replaced by an Anaesthetic Trainee and if not why not and if he was replaced then at what stage and by whom

249. Some of those issues will also be dealt with from a 'governance' perspective.

Adam's Care & Discussions amongst the Transplant Team

250. Adam was admitted onto Musgrave ward under the care of Dr. Savage[470] who acknowledges in his Inquiry Witness Statement dated 14th April 2011

466 Ref: WS-060-1, p.2, Q.1
467 Ref: WS-06-2, p.3, Q.2
468 Ref: WS-106-1, p.2, Q.(1)
469 Ref: 093-038-143
470 Ref: 057-013-017

that he was responsible for satisfying himself that the Renal Transplant Protocol was followed (which included the measurement of his electrolytes), that Adam was properly managed, that he was fit for his transplant surgery and that he was in the best condition possible when he was taken to theatre.[471]

(i) See: Dr. Coulthard's comments in his Report of 7th November 2011 on Dr. Savage's role in the management of Adam's pre-operative fluids and in delivering Adam to the operating theatre in appropriate condition[472].

(ii) See too: Dr. Coulthard's reference in his Report of 4th December 2010 to the Newcastle guidelines and explains why a repeat blood test is not included in them[473]. He also responds to the different view expressed by Mr. Koffman in his Report for the PSNI of 5th July 2006[474]. Dr. Coulthard returns to the issue of the circumstances under which a repeat blood test was either desirable or mandatory in his Report of 7th November 2011[475].

251. The issue of whose responsibility it was to have carried out the repeat blood test referred to in the Renal Protocol for the Children's Hospital, whether and when it should have been done and its significance is something I will turn to later on but in any event it is a matter that will be addressed in the Oral Hearing.

252. The management of Adam's peritoneal dialysis over night was a part of Dr. Savage's responsibility, which he concedes in his Inquiry Witness Statement of 28th September 2011 – although he acknowledges that no dialysis records have been identified.[476]

(i) See: Dr. Coulthard's comments in his Report of 7th November 2011 on Dr. Savage's role in the management of Adam's pre-operative fluids and his dialysis[477].

(ii) See: Dr. Haynes, states in his Report of 2nd August 2011 that the nursing staff on the ward should have kept meticulous details of Adam's fluid balance while being dialysed (volume of urine produced, precise details of all fluid administered to or taken in by

471 Ref: WS-002-2, p.3, Q.(2) and Ref: WS-002-2, p.13, Q.6
472 Ref: 200-007-116
473 Ref: 200-004-082
474 Ref: 094-007-032
475 Ref: 200-007-116
476 Ref: WS-002-3, p.16, Q.12
477 Ref: 200-007-116

Adam) and the anaesthetist should have reviewed that information before Adam's transfer to theatre.[478] Clinical examination would have given a guide as to whether Adam was dehydrated or fluid overloaded. Adam should have been weighed at the end of dialysis and the ward nurses would have been responsible for recording all of that information under the direction of the Nephrology team. Dr. Haynes states that adequate information in this respect does not appear to have been made available to Dr. Taylor[479]

(iii) See: Sally Ramsay states that the record-keeping fell below the expected standard as more elements of care required more detailed documentation. For example:

- There was no nursing care plan;
- The dialysis details were not recorded including the number of cycles, the volume of fluid removed post-dialysis and the post-dialysis weight
- There was no prescription for dialysis detailing the dialysate (type of fluid), volume for each cycle, the number of exchanges and the dwell time
- The prescription chart, nursing and medical records did not make clear any intention to administer fluids of 75mls/hr when the feeds stopped at 05.00 on 27th November 1995; there was no prescription for the initial infusion at the rate of 20mls/hr, of which 18mls was delivered, despite the cannula having been inserted by a doctor, who would have been able to write the necessary prescription; there is no record of the actual type of gastrostomy feed or whether there were bolus feeds, no individual hourly recordings merely a running total which is incomplete
- If *"clear fluids"* meant dioralyte, there was no prescription written for that fluid; prescriptions for medicines should have been signed to confirm they had been given; vital signs were not recorded post dialysis, Adam's height was not measured contrary to the Admission Protocol.

(iv) See: Sally Ramsay states that renal nurses, as nurses working in a specialist area, would have been able to initiate urinary

478 Ref: 204-002-024
479 Ref: 204-002-024.

measurement or ask a doctor whether urine was to be measured. Adam's nappies could have been weighed to estimate his urine output, as a child in chronic renal failure about to undergo major surgery. Sally Ramsay's overall impression is that the care given to Adam pre-operatively lacked structure, and this resulted in omissions in his care.[480]

(v) See: Dr. Coulthard's reference in his Report of 4th December 2010 to the effect of dialysis on imbalances in biochemistry and Adam's condition arriving at theatre. The effect of Adam's dialysis, on his fluid balance and serum sodium levels, including the fact that he received only 8 of his usual 15 cycles, is a matter that was the subject of discussion during the Experts' meeting on 9th March 2012 as can be seen from the transcript.

253. Dr. Savage also liaised with Dr. Taylor in relation to his particular requirements of 'clear fluids'[481] and the cessation of fluids in relation to safely anaesthetising Adam[482] and ensuring that was prescribed by junior staff (i.e. Drs. Cartmill[483] and O'Neill[484]). In addition Dr. Savage describes himself as liaising with Mr. Keane and Dr. Taylor to formulate a 'plan' for the arrangement and conduct of Adam's renal transplant.[485]

(i) See: Dr. Coulthard on the fluid-management information that Dr. Savage should have provided to Dr. Taylor[486]

(ii) See too: Dr. Coulthard on the matters that Dr. Savage should have discussed with Mr. Keane[487]

254. It seems that Dr. Savage took the decision to accept the donor kidney once the transplant cross-matching process was complete at about 01:00 on 27th November 1997[488] indicating a half-match.[489]

(i) See: Dr. Coulthard, for example: *"a child who was thriving happily on dialysis […] would be listed to have an especially well matched and in other ways extremely suitable kidney"*[490] See too: *"The range of issues to*

480 Ref: 202-002-018 (Report dated 10th February 2011).
481 Ref: 058-035-144
482 Ref: WS-002-2, p.18 et seq, Q.11
483 Ref: 058-035-144, Ref: 057-010-013
484 Ref: 057-019-028, Ref: 058-035-131
485 Ref: WS-002-3, p.4, Q.(2).
486 Ref: 200-007-116 & 200-007-124 *et seq*
487 Ref: 200-007-129
488 Ref: 058-035-133
489 Ref: 059-006-012
490 Ref: 200-007-114

consider include the size and age of the donor, their medical condition before retrieval, the time since the organ was harvested, any anatomical issues such as multiple arteries, and the degree of tissue-type mismatch".[491]

255. Compliance with the 1990 Children's Hospital Guidelines on paediatric Renal transplant:

(i) The Protocol for paediatric renal transplants that was in operation at the time of Adam's surgery was 'Renal Transplantation in Small Children',[492] that had been introduced by Dr. Savage in September 1990. The examinations and investigations on admission included a chest x-ray. Adam's notes include a request by Dr. O'Neill for such an x-ray[493] but there is no record of the corresponding radiological report indicating that one was actually carried out.

(ii) Correspondence from the DLS dated 28th October 2011 queries whether there ever was a pre-surgical chest x-ray.[494] The absence of such an x-ray would obviously mean that the post-surgical x-rays that were taken at 13:20[495] and at 21:30[496] on 27th November 1995 could not be considered with reference to Adam's state before the administration of 1500mls of hypotonic fluids during his surgery.

256. The apparent absence of a pre-surgical chest x-ray is an issue that will be addressed during the Oral Hearing both in relation to compliance with the Protocol and adequate record-keeping.

257. The absence of a pre-surgical chest x-ray is only one issue in relation to record-keeping that will be pursued during the Oral Hearing. At 23:00 Dr. O'Neill records Adam's serum sodium level from bloods taken at approximately 21:00 as 139mmol/L.[497] However, there is no corresponding laboratory report and it is not clear how that result was achieved. In the absence of a print-out, his hand-writing is misread by Dr. O'Connor who records Adam's serum sodium level as 134mmol/L on the Transplant Form.[498] Subsequently, the Inquiry received a set of laboratory results from the DLS in October 2011[499] that included a laboratory report

491 Ref: 200-007-115
492 Ref: WS-002-3, p.67
493 Ref: 057-019-028, Ref: WS-004-1, p2 and Ref: WS-004-2, pgs.2,6
494 Ref: 301-118-650
495 Ref: 058-035-140
496 Ref: 058-035-142
497 Ref: 058-035-144
498 Ref: 057-007-008 and WS-014-2, p.8
499 Ref: 301-081-540

dated 27th November 1995 in respect of a blood specimen taken sometime on 26th November 1995. That report recorded Adam's serum sodium level as 133mmol/L. There is no reference to it in Adam's notes and records and it is not clear whether, at the time, any one appreciated that over the evening Adam's serum sodium level had fallen to a level that was just below the normal range of 135mmol/L to 145mmol/L and if so whether or not it was of any significance.

258. The Protocol also provided for electrolyte testing[500] and this did not happen. The witness statements of Dr. Montague and Dr. Taylor provide the explanation– Adam was upset and a decision was made to leave him alone until the morning**.**

259. Thereafter, Dr. Taylor also did not consider a pre-surgical electrolyte check a priority although his reasoning is not always clear. However, in his most recent statement of 1st February 2012, he accepts that he should have sent a sample to the laboratory for electrolyte analysis before the surgery commenced.[501]

(i) Dr. Haynes is of the view that serum electrolyte measurement was strongly indicated at the completion of dialysis and at an absolute minimum once Adam was anaesthetised. The reason for doing so was that any abnormal results would have guided fluid and electrolyte administration.[502]

(ii) Dr. Coulthard took a different view largely it seems, because of what he considered the consequences of the process of dialysis to be.

260. The basis of the explanations that Dr. Taylor gave in his prior statements for not having carried out a serum sodium test before the one at 09:32 and why he gave them are matters that will be pursued during the Oral Hearing. So too is the question of the likely effect of peritoneal dialysis on both Adam's hydration and his serum sodium levels.

Timing of the Surgery & Cold Ischaemic Time

261. It seems from Adam's notes and records that before the results of the tissue cross-matching were received at 01:42[503] a decision had been made for the transplant surgery to start at 06:00 on Monday 27th November

500 Ref: WS-002-2, p.52
501 Ref: WS-008-6, p.3
502 Ref: 201-002-023 & 024
503 Ref: 059-006-012

1995.[504] It is not clear when that decision was made but it should have been known by those making it that as at 06:00 the cold ischaemic time of the donor kidney would be approximately 29 hours. In fact the start of surgery was put back to 07:00[505] and the donor kidney was not perfused with Adam's blood until about 10:30[506] following an apparent anastomoses time of 120 minutes. The total cold ischaemic time was therefore approximately 32 hours.

262. It is clear from Dr. Savage's Inquiry Witness Statement of 14th April 2011 that he incorrectly believed when making this statement, that putting back Adam's surgery to 07:00 would constitute only 16 hours after the kidney had been donated. His Inquiry Witness statement shows that he had assumed that the kidney had been donated at 1.42pm on Sunday 26th November 1995, as opposed to early in the morning at 01:42.[507] Thereafter, he states in his Inquiry Witness Statement of 28th September 2011 that the error as to ischaemic time was one he made in his April 2011 statement and was not an error that he made at the time of surgery.[508] He went on to state that: "*I would have undoubtedly considered the cold ischaemic time and would have been unlikely to accept the kidney if I believed we were unlikely to be able to perform the transplant within 24 hours of it being donated*"[509] – i.e. by 01:42 on Monday 27th November 1995.

263. However, Mr. Keane has expressed the view in his Inquiry Witness Statement of 20th September 2011 that: *"We would have transplanted a kidney up to 36 hours as I had been trained to do in the Royal Postgraduate Medical School"*.[510]

264. The cold ischaemic time of the donor kidney is referred to by Mr. Koffman in a letter to the Inquiry dated 7th July 2010. He notes that the average 'cold storage time' in the UK is about 20 hours but goes on to state that he had been involved in "*transplanting organs from older donors with cold storage times greater than 48 hours with a great deal of success*".[511] The particular circumstances of those surgeries have not been provided to the Inquiry and are a matter that will be explored during the Oral Hearing. Mr. Koffman goes on to state that the longer the cold storage time, the more likely there is to be acute tubular necrosis, which can affect the blood circulation of the kidney and might explain the description of the donor

504 Ref: 058-035-133
505 Ref: 058-035-133
506 Ref: 058-035-134
507 Ref: WS-002-2, p.16, Q.(f)
508 Ref: WS-002-3 p.37 Q.34(a)
509 Ref: WS-002-3, p.21, Q.(c)
510 Ref: WS-006-3, p.12
511 Ref: 205-002-009

kidney not looking *"so well perfused in the later stages of the operation"*.[512] It will be recalled that Dr. Taylor expressed the view in his Deposition at the Inquest that the: *"new kidney did not work leading to a re-assessment of the fluids given"*.[513]

265. The significance of the cold ischaemic time of the donor kidney is also addressed by Messrs. Forsythe and Rigg in their Report of June 2011. They associate a prolonged cold ischaemic time with delayed kidney function,[514] which can increase the risk of thrombosis in children.[515] They also refer to the seeming 2 hours of 'warm ischaemic time' involved in preparing and transplanting the donor kidney, which they consider over-long and was very likely to have caused it irrevocable damage.[516]

266. The cold ischaemic time of the donor kidney, particularly in relation to the decisions that were made by Dr. Savage, Dr. Taylor and Mr. Keane during the pre-surgical period and its infarction, are issues that will be addressed in the Oral Hearing.

267. The condition of the transplanted kidney was examined at autopsy and Dr. Armour made a number of histological slides that she provided to Professor Berry who was engaged by the Coroner. He examined them and expressed the view in his Report of 23rd March 1996 that: *"The transplant kidney was infarcted (dead). The extent of the change suggested that this occurred at or before the time of transplantation. This could be resolved by enquiries about the fate and function of the donor's other kidney after transplantation"*.[517]

268. Dr. Armour concluded then in her Autopsy Report that there was *"complete infarction"* of the transplanted kidney.[518]

269. Professor Risdon, who was engaged by the PSNI, examined a number of tissue samples from the transplanted kidney for the purpose advising on the likely time of its infarction. He concluded that the changes seen in the transplanted kidney were more advanced than would be expected after only 24 hours of non-perfusion. The starting point for that calculation would be some time after the completion of the vascular anastomoses at

512 Ref: 205-002-009
513 Ref: 011-014-108
514 Ref: 203-002-037
515 Ref: 203-002-034
516 Ref: 203-002-030
517 Ref: 011-007-022
518 Ref: 011-010-040

10:30 and the perfusion of the transplanted kidney with Adam's blood[519] and would extend to the removal of ventilatory support at 11:30.[520]

270. Professor Risdon goes on to state in his Report: *"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"*.[521] He also referred to the other kidney from the donor and drew support for his conclusion from the fact that it too had failed.

271. The Inquiry made enquiries about the fate of the other kidney. NHS Blood and Transplant responded in a letter dated 3rd June 2010[522] explaining that the other donor kidney, which had been transplanted on 26th November 1995, failed due to *"poor recipient arteries"* and was subsequently removed. However, there is no information as to whether it was examined on removal or whether anything can properly have been inferred about its condition prior to it being transplanted.

272. There are issues to be addressed during the Oral Hearing in relation to the timing of the transplant surgery, the cold ischaemic time of the donor kidney transplanted into Adam, whether its condition had any effect on events during the transplant surgery, as well the ultimate cause of its infarction. Having said that, it is important to note that none of the Experts have stated that the infarction of the transplanted kidney, whenever and however it occurred, contributed to Adam's death.

Taking Consent for Adam's Transplant Surgery

273. Dr. Savage assumed sole responsibility for taking consent from Adam's mother for Adam's transplant surgery.[523] He also states that in 1995 it was not uncommon for *"initial consent to be obtained by someone other than the surgeon carrying out the procedure"*.[524]

274. This is commented upon by Professor Koffman in his report of 5th July 2006 for the PSNI where he states: *"It appears from the records that consent for the operation was not performed by the surgeons but probably by the paediatric nephrologist Dr. Savage and this would be normal accepted practice for the mid 1990s"*.[525] He then goes on to state: *"It would be important to view the*

519 Ref: 059-006-012 and Ref: 058-009-027
520 Ref: 058-035-142
521 Ref: 093-031-083
522 Ref: 306-007-042
523 Ref: WS-002-2, p.13, Q.6, Ref: WS002-3, p.5, Q.(iv) and Ref: 058-039-185
524 Ref: WS-002-3, p.27
525 Ref: 094-007-031

consent form and if possible the topics that were discussed with Adam's mother including the risk of death and serious adverse events from the procedure".[526]

275. Dr. Coulthard also expresses the view that in 1995 it was common for the *"final written consent for a child's kidney transplant to be undertaken by the consultant paediatric nephrologist"*[527] . However, that is put in the context of a surgeon having been previously involved, explaining: *"that in our local arrangements, the parents will always have met a transplant surgeon in advance of the surgery, and will have covered the relevant issues then".*[528]

276. Mr. Keane deals at length with the taking of consent in his Inquiry Witness Statement of 20th September 2011, explaining that: *"In 1995 it was not considered necessary for consultant surgeons to take consent as long as a doctor capable of explaining the risks and benefits of the procedure explained the issues to the patient. I had and have full confidence that Dr. Savage could do that".*[529] Indeed he goes on to state that he would not know the technical details until he operated and to that extent he was in no better position than Dr. Savage.[530] Furthermore, he states: *"Dr. Savage would have more knowledge of the risks of paediatric transplantation than I did".*[531]

277. Messrs. Forsythe and Rigg note in their Report of June 2011 that consent was taken by Dr. Savage who was not capable of carrying out the transplant operation.[532] They then express a different and very firm view to that of Mr. Koffman and Dr. Coulthard that: *"It is the role of the transplant surgeon to gain consent from a paediatric patients' parents and that this was the case in 1995 as well as now".*[533] Dr. Haynes also considered it *"inappropriate"* for the written consent for Adam's transplant surgery to have been taken by a nephrologist.[534] He states in his Report of 2nd August 2011: *"This should have been taken by a member of the surgical team. It is generally the case that consent is taken by an individual capable of carrying out a procedure or operation him or herself".*[535] See also Dr. Haynes' Report of 7th October 2011 in which he disagrees with Mr. Koffman and claims that the taking of consent by someone other than the surgeon: *"is not now, and was not then considered to be good practice".*[536]

526 Ref: 094-007-031
527 Ref: 200-007-117
528 Ref: 200-007-117
529 Ref: WS-006-3, p.20
530 Ref: WS-006-3, p.20
531 Ref: WS-006-3, p.20
532 Ref: 203-002-029
533 Ref: 203-002-032
534 Ref: 202-002-037
535 Ref: 202-002-037
536 Ref: 204-004-160

278. There are a range of matters that Dr. Savage believes he communicated to Adam's mother prior to or at the time that her consent was taken, although he acknowledges that he did not record the information that he gave her:[537]

(i) The donor kidney was an *"adult kidney"*[538]

(ii) A paediatric surgeon would be involved who had *"knowledge of Adam's previous surgery who would therefore be available instantly during the transplant procedure"*[539]

(iii) Several units of blood would need to be cross-matched because of the risk of blood loss during surgery

(iv) Adam's normal overnight feeds would need to be changed so that his stomach was empty at the time he received his anaesthetic

(v) Once Adam's tube feeds had ceased, some intravenous fluids would be given to him up until he got to the operating theatre

279. The issues relating to consent which will be addressed at the Oral Hearing will include:

(i) The information that should have been provided to Adam's mother, particularly in relation to risks, and those who should have been involved in explaining that information to her for the purpose of obtaining her consent to Adam's transplant surgery on 27th November 1995

(ii) The information that was actually provided to Adam's mother and the explanation for it

280. The issue of consent is a matter that will be considered from a 'governance' perspective, including consideration of the extent to which the form used complied with any current requirements.

Information Gathering by the Transplant Team

281. The value of this exercise for the Transplant team is largely dependent on the quality and accessibility of the information compiled on Adam once he was placed on the transplant register.

537 Ref: WS-002-2, p.12
538 Ref: WS-002-2, p.12
539 Ref: WS-002-2, p.12

282. Dr. Haynes states that as Adam was such a complex patient, a medical summary should have been prepared when he was placed on the transplant waiting list and placed in a prominent place in the case notes.[540] This is important because the surgeon involved in that initial assessment may not be the actual surgeon performing the transplant operation. The depth and efficacy of the information gathering process at the initial assessment stage to go onto the transplant list and thereafter on any reviews prior to the offer of a donor kidney lay the foundation for a well planned and successful transplant. It is this information together with Dr. Savage's briefing to the surgeon and anaesthetist pre-operatively which forms the basis of the plan for transplant surgery.

283. By 26th November 1995 Adam's medical notes were contained within 10 files.

284. Dr. Haynes would have expected the anaesthetist to have sifted through Adam's RBHSC notes to gain an understanding of the pathology involved and to identify particular problems, as well as introduced himself to Adam and Mrs. Slavin and to examine Adam as required. Dr. Haynes states that: *"preoperative assessment is an integral part of an anaesthetist's duties ... If not performed adequately mistakes will inevitably be made"*.[541] Dr. Haynes would have expected Dr. Taylor to have:

    (i) Ascertained the nature of Adam's renal pathology

    (ii) Noted Adam's current normal fluid balance and electrolyte requirements including his fluid intake, normal insensible fluid losses; usual volume loss during peritoneal dialysis, and Adam's average urine production

    (iii) Noted that Adam required sodium supplements to maintain normal sodium serum levels, and that he could not regulate urinary sodium losses.

285. Dr. Haynes states that the anaesthetist should have:

    (i) Realised that sodium had to be given as a constituent of all fluid administered and that repeated tests on Adam were required to ensure that the sodium serum concentration was acceptable

[540] Ref: 204-004-163
[541] Ref:204-004-163

(ii) Ascertained the detail of the postoperative course following major surgery e.g. December 1991 to January 1992, ascertained the details of Adam's normal peritoneal dialysis regime

(iii) Read medical correspondence after nephrology outpatients' visits, noted any difficulties arising in previous anaesthetics and to have noted any other features regarding Adam's health[542]

286. Mr. Forsythe and Mr. Rigg state that a transplant surgeon from the multi-disciplinary team ought to have met Adam and his family when Adam was being assessed for transplant and prior to going on the transplant list, and that the operating transplant surgeon should see the patient and parents again before surgery (preferably early in the pre-operative period) to reassess the patient and become fully aware of all active problems and any relevant past medical and surgical history.[543]

287. They also state that the transplant surgeon should have been aware of Adam's current condition, active problems, past medical and surgical history and recent and current results of investigations, and should also have examined Adam's abdomen.[544] There appears to be no record of a transplant plan for Adam.

288. The 'Time Line' also highlights a number of factors from Adam's notes and records that may have been relevant for the Transplant team to have known or appreciated before embarking on the transplant. For example:

(i) Adam's previous fluid balances, his episodes of hyponatraemia, the level to which his serum sodium levels fell and the rate at which they did so - See also the chart of Serum Sodium levels[545]

(ii) The details of his previous surgeries, especially those involving central lines and urethral catheters – See also the Schedule of Surgical Procedures[546]

289. Dr. Savage was familiar with Adam's notes and records as he had been in charge of Adam's care since his admission to Musgrave Ward in October 1991. Both Dr. Taylor[547] and Mr. Keane[548] read Adam's notes and records prior to the surgery.

542 Ref: 204-004-163 and 204-004-164
543 Ref: 203-002-032
544 Ref: 203-002-036
545 Ref: 300-059-079
546 Ref: 300-060-107
547 Dr. Taylor's Inquiry Witness Statement – Ref: WS-008-3, p.3, Q.(4)

290. The Inquiry's Expert Dr. Haynes refers in his Report of August 2011 to the "*central importance*" of Dr. Taylor knowing about Adam's past history of hyponatraemia with serum sodium results of below 120mmol/L and its implications for his fluid management.[549]

291. The Inquiry's Experts Messrs. Forsythe and Rigg also deal in their Report of June 2011 with the importance of Mr. Keane being aware of Adam's history of hyponatraemia and of current condition as well being aware of Adam's "*active problems, past medical and surgical history, and recent and current results of investigations*".[550] They state that Mr. Keane should have seen the following documents before commencing surgery[551]:

    (i) The operation consent form; the kidney donor information form; the admission notes from 26th and 27th November 1995 including results of investigations performed

    (ii) An investigation summary sheet to know what the trend for results of investigations had been in the pre-operative period

    (iii) Recent clinic letters and knowledge of Adam's previous abdominal surgical procedures

292. There are therefore issues to be explored during the Oral Hearing as to the information that the Transplant team had going into Adam's transplant surgery, including what they understood from his notes and records, what they could have learned from them, its significance and the extent to which it might have affected the conduct of the transplant surgery.

293. The 'Time Line' also highlights from Adam's notes and records periods of: (a) dehydration/polyuria; (b) anaemia/iron deficiency; and (c) the administration of erythropoietin.[552] Whilst there is agreement amongst the Inquiry's Experts[553] that those constitute risk factors for chronic venous thrombosis, they disagree over whether any of them operated so as to expose Adam to the risk of developing chronic venous thrombosis. [554]

294. The issue of whether Adam was likely to have or did develop chronic venous thrombosis and its relevance to the development of his cerebral

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548 Mr. Keane's Inquiry Witness Statement – Ref: WS-006-3, p.5 *et seq*, Q.(6) & (7)
549 Dr. Haynes' Report of August 2011 – Ref: 204-002-023
550 Report of Messrs. Forsythe and Rigg of June 2011 – Ref: 203-002-036
551 Ref: 203-008-109
552 Ref: 307-001-002
553 Transcript of Experts' Meeting on 22nd February 2012, p.35 *et seq* – Ref: 307-007-073
554 Transcript of Experts' Meeting on 22nd February 2012, p.38 *et seq* – Ref: 307-008-162

oedema and death is a matter to be addressed further by the Inquiry's Experts during the Oral Hearing.

XVIII. Issues to be addressed - Peri-Operative Stage

295. This stage commences with Adam being anaesthetised at 07.00[555] on Monday 27th November 1995 and ends with his transfer to PICU at about 12.00 noon.[556]

296. What happened factually during that period is recorded in Adam's medical notes and records,[557] which have been incorporated into the 'Inquiry Chronology of Events: Adam (Clinical)'[558] It is also the subject of numerous statements from those directly involved in his care and treatment, as well as Reports from the Inquiry's Experts Dr. Coulthard, Professor Gross, Dr. Haynes and Messrs. Forsythe and Rigg.

297. The identity of those who were directly involved in Adam's care during the peri-operative stage, the particular nature of their involvement, the statements they have made and the Reports of the Inquiry's Experts are all to be found on the Schedule compiled by the Legal Team, 'List of Persons Involved: Adam'.[559]

298. The Legal Team has sought to analyse Adam's condition at the start of the peri-operative stage primarily by reference to two charts that it has compiled and to which reference has already been made.

299. The first chart is 'Adam's Perioperative Fluid Balance',[560] which distils the information on and calculations by the clinicians Dr. Savage and Dr. Taylor[561] as well as the Inquiry's Experts Dr. Haynes,[562] Professor Gross[563] and Dr. Coulthard in respect of Adam's fluid balance. Reference has already been made to that chart, the information for which is taken from the individual charts provided by those clinicians and Experts.

300. As you will have appreciated Mr. Chairman, the comparative chart seeks to provide a comparative analysis of, amongst other things, Adam's fluid

555 Ref: 057-014-019
556 Ref: 058-035-135
557 Ref: 057-001 to 057-115, Ref: 058-001 to 058-048 & Ref: 059-001 to 059-073
558 Ref: 306-003-011 to Ref: 306-003-016
559 Ref: 303-001-001 *et seq*
560 Ref: 300-077-142 to Ref: 300-077-144
561 Ref: WS-008-5, p.5
562 Ref: 300-077-141
563 Ref: 201-008-188

balance at the start of his transplant surgery based on the assumptions made by those clinicians and Experts about:

(i) Adam's surface area

(ii) Adam's fluid losses including, insensible, urine, dialysis, faecal

(iii) The effect of the dialysis on Adam's serum sodium level and his fluid balance

301. The purpose of that analysis is to try and establish, so far as it can be done in the absence of any actual measured values for Adam's serum sodium level and urine output,[564] his fluid balance at the start of his anaesthesia at 07.00 and the administration of 0.18% saline/4% dextrose intravenously.[565] It is hoped that such a starting point will assist in the understanding of what happened during the peri-operative stage, ie his transplant surgery, as well as the further queries that need to be raised with the medical and nursing witnesses in respect of Adam's care and treatment.

Adam's Condition and Risk Factors Pre-Surgery

302. The second chart is 'Adam's Pre-Surgical State',[566] which has also already been presented to you Mr. Chairman as setting out certain pre-admission details as well as summarising Adam's condition going into surgery according to a variety of factors.

303. In addition there is the 'Time Line of Main Events: Adam (1991-1995)'[567] compiled by the Legal Team and which you have already seen, that includes summary details of Adam's blood work up on 26th November 1995, as well as the 'Summary Time Line of Critical Events',[568] which highlights the extent to which Adam was relatively free of significant factors in the period leading up to his admission on 26th November 1995.

304. The view of Adam's mother of his condition is set out in her first Inquiry Witness Statement:

564 There are two serum sodium values of 139mmol/L (Ref: 058-035-144) and 133mmo/L (Ref: 301-081-547) believed to relate to blood taken at be taken at 21.30 and some time before midnight on 26th November 1995 respectively
565 Ref: 058-003-005
566 Ref: 306-006-040
567 Ref: 307-001-002
568 Ref: 307-001-001

"*Adam had been ill all that summer and he was now back on top form again. He was really well at that point. But I was told that I wouldn't know when another kidney would come up and that this was a really good match.*"[569]

305. Dr. Savage also considered that Adam was 'fit and well' going into his transplant surgery as is evident from his correspondence with Adam's GP Dr. Scott.[570]

306. Such a view seems to have been generally accepted at the time and is reflected by the Coroner in a letter dated 30th November 1995 that he sent to Dr. John Alexander seeking an expert Anaesthetist Report from him: "*I understand that the child was healthy and considered to be an ideal candidate for transplant surgery. No complications were anticipated.*"[571] That view is echoed in the statements of Dr. Coulthard during the Experts' meetings in Newcastle, especially:

"*… if you put all the evidence together as to what condition he was in when he went to theatre, everything else [other than the CVP reading] points to him being in a relatively good condition*" [572]

307. Dr. Taylor provides a slight discordant note to that when he states in his PSNI interview under caution that Adam was: "*In good health however his chronic status of congenital nephritic[sic] syndrome did not make him a perfect candidate*".[573] Although when pressed to explain the basis of his view of Adam's status, he resiled from it stating in his Inquiry Witness Statement of 16th May 2011 that: "*His [Adam's] diagnosis was 'bilateral dysplastic kidneys with large cyst' as diagnosed by Dr Savage (049-029-075) and 'Reflux nephropathy' by* Dr *O'Connor (058-035-143) not as I suggested*".[574]

308. Furthermore, there remains the as yet unresolved issue raised by Professor Kirkham in her Reports[575] as to whether Adam nonetheless arrived for his surgery with risk factors for the development of chronic

569 Ref: WS-001-1, p.2
570 Ref: 016-025-049 (18th August 1995), Ref: 016-018-039 (12th October 1995) and Ref: 016-004-014 (4th December 1995)
571 Ref: 011-018-116
572 Ref: 307-008-184 (Transcript of Experts' meeting on 9th March 2012, p.22)
573 Ref: 093-038-162
574 Ref: WS-008-2, p.28
575 Ref:208-002-017 *et seq* (Preliminary Report dated 16th February 2012) and Ref:208-007-068 *et seq* (Final Report dated March 2012)

venous sinus thrombosis,[576] the instances of which are recorded on the Time Line:[577]

(i) Administration of Erythropoietin[578]

(ii) Anaemia at least in part secondary to iron deficiency[579]

(iii) Polyuric and intermittently at the risk of dehydration[580]

(iv) Ligation of the left internal jugular vein with the CVP catheter in the other side of his neck[581]

309. In addition to those risk factors, which she considers were present in Adam when he arrived for his transplant surgery, Professor Kirkham considered that he developed an additional risk factor for chronic venous sinus thrombosis when Methylprednisolone was administered in the Operating Theatre as an immunosuppresent drug. [582]

310. Alternatively, Professor Kirkham considers that Adam may have arrived at the Operating Theatre for his transplant surgery with a compromised ability to deal with the Cerebral Oedema that he subsequently developed. She refers in her Reports[583] to the compensatory mechanisms in the brain of:

(i) Increase in the venous drainage; and

(ii) Increase in the re-absorption of Central Spinal Fluid (CSF)

311. To assist, the Legal Team has provided two diagrams showing schematic representations of the contents of the brain,[584] both of which are also appended to the Inquiry Witness Statement of Dr. Leslie Dyer. Fig 1a shows the normal intracranial contents of brain matter and Central Spinal Fluid together with arterial supply and venous drainage. Fig 1b shows the position during raised intracranial pressure.

576 Ref: 208-002-034 (Preliminary Report dated 16th February 2012) and Ref:208-007-091(Final Report dated March 2012)
577 Ref: 307-001-001
578 Ref: 208-002-034 (para.48 of 16th February 2012) and Ref: 208-007-091 (para 64 of 28th March 2012)
579 Ref: 208-002-034 (para.48 of 16th February 2012) and Ref: 208-007-092 (para 64of 28th March 2012)
580 Ref: 208-002-034 (para.48 of 16th February 2012) and Ref: 208-007-091 (para 64 of 28th March 2012)
581 Ref: 208-002-034 (para.48 of 16th February 2012) and Ref:208-007-093 (para 64 of 28th March 2012)
582 Ref: 208-002-034 (para.48 of 16th February 2012) and Ref: 208-007-092 (para 64of 28th March 2012)
583 Ref: 208-002-039 (para.55 of 16th February 2012) and Ref: 208-007-094 (para 64of 28th March 2012)
584 Ref: 300-088-186

312. Professor Kirkham also provided a diagram with both of her Reports[585] taken from page 646 of Rogers (1996) Textbook of Paediatric Intensive Care, which shows the Monroe-Kellie Principle.[586] The diagram shows the same three intracranial components of brain, blood (arterial and venous) and Central Spinal Fluid. Professor Kirkham uses the diagram and others to demonstrate how if:

"The volume of one of these components increases eg there is cerebral oedema leading to increased volume of the brain, there is some reserve capacity related to: (i) reduction of venous blood by compression and/or drainage into the jugular veins and (ii) reduction of CSF volume by increased absorption in the subarachnoid space over the brain and around the spinal cord."[587]

313. Professor Kirkham considered it a possibility that the efficacy of those compensatory mechanisms in Adam's brain were likely to have been reduced by reduced jugular venous drainage due to a combination of:

(i) The possible ligation of Adam's left internal jugular vein as noted by Dr. Armour in her Report on Autopsy,[588] referred to in her evidence to the Coroner on 18th June 1996[589] and confirmed in her Inquiry Witness Statement dated 29th November 2011 [590]

(ii) The position of the central venous line catheter in the right jugular vein[591]

314. She stated in her Preliminary Report of 16th February 2012 that such a combination would have: *"reduced the opportunity for compensating for increasing cerebral oedema by drainage of blood into the jugular veins"*.[592] She reiterates this in her Final Report of 28th March 2012.[593]

315. In addition, Professor Kirkham expresses the view in her Final Report of 28th March 2012[594] that such a compromising effect was possibly exacerbated by Adam's position during surgery, which was supine (head down) and turned to one side.

585 Ref: 208-002-039 (16th February 2012) and Ref: 208-007-103 (28th March 2012)
586 Ref: 300-092-192
587 Ref: 208-002-039 (16th February 2012) and Ref: 208-007-103 (28th March 2012)
588 Ref: 011-010-034
589 Ref:011-010-030
590 Ref:WS-012-2 p.6
591 Ref: 208-002-040
592 Ref:208-002-036 (para.49)
593 Ref: 208-007- 094
594 Ref: 208-007- 094

316. As you will already have appreciated Mr. Chairman, whether Adam had any risk factors going into his transplant surgery and if he did whether they played any part in the development of his fatal cerebral oedema, has been and continues to be a matter of considerable debate amongst the Inquiry's Experts Professor Kirkham, Dr. Coulthard, Professor Gross, Dr. Haynes and Dr. Squier.

317. Accordingly, Adam's condition going into his transplant surgery and its significance, are issues that will require to be explored during the Oral Hearing.

Responsibilities of the Members of the Transplant Team

318. As you are aware Mr. Chairman, Dr. Savage accepted that the responsibility for getting Adam to the Operating Theatre in an appropriate condition for his transplant surgery rested to a large extent with him.[595]

319. As you are also aware Mr. Chairman, the Anaesthetic team for Adam's transplant surgery comprised, at the outset, Dr. Taylor as the Consultant Paediatric Anaesthetist and Dr. Terence Montague who assisted him, having started as a Senior Registrar in Anaesthesia at the Children's Hospital in November 1995.[596] Dr. Taylor has accepted that in large part the responsibility for Adam's well being during this peri-operative stage rested with the Anaesthetic team generally and him, as the Consultant, in particular.[597] However the extent to which the assistant anaesthetist(s) assisting and working under the supervision of Dr. Taylor had an obligation to intervene so as to advise on and help to correct mistakes being made by Dr. Taylor during Adam's surgery, is a matter which will be considered during the Oral Hearing.

320. The Inquiry's Expert Dr. Haynes has described in his Report of 2nd August 2011 the nature of that responsibility:

> *"The consultant anaesthetist would be responsible for assessing the preoperative condition of the patient, including liaison with referring clinicians (paediatric nephrology in this case). This would include ensuring that appropriate fluid management took place in the hours leading up to the operation, that the appropriate investigations had taken place and the results were obtained and noted. The impact of previous surgical procedures (e.g. central line insertion) would be assessed.*

595 Ref: WS-002-2 p.2-3
596 Ref: WS-009-1, p.2
597 Ref: WS-008-2 p.2

The consultant anaesthetist would decide on the conduct of anaesthesia (including fluid and electrolytes administered). He/she would either carry out the necessary technical procedures himself (anaesthetic drug administration, venous cannulation, arterial cannulation, central venous cannulation, epidural catheter insertion, urinary catheter insertion etc) or delegate them to a trainee under his direct supervision. It would be incumbent on the consultant anaesthetist to appraise the surgeon of any difficulties encountered (e.g. in Adam's case with central venous line insertion), and an alternative strategy (e.g. surgical cutdown) agreed.

…

If present, a trainee anaesthetist would assist the consultant anaesthetist with the roles described above within his/her capabilities, the consultant being responsible for the actions of a trainee."[598]

321. Indeed Mr. Chairman you will recall from the 'Table for Paediatric Renal Transplant' that Dr. Taylor[599] and the other lead members of the Transplant team, Dr. Savage[600] and Mr. Keane,[601] together with the Inquiry's Experts, Dr. Coulthard,[602] Dr. Haynes[603] and Messrs. Forsythe and Rigg,[604] have all set out what consider should have been the level of involvement of the medical and nursing personnel in the various phases of the transplant process.

322. Dr. Taylor has provided a number of Inquiry Witness Statements, in addition to his evidence to the Coroner and his PSNI statement under caution, in which he sets out how he went about discharging that responsibility.[605] In addition his conduct over the period 26th November 1995 until Adam failed to wake from his transplant surgery at about noon on 27th November 1995 has been commented upon and criticised by Dr. Sumner as an expert for the Coroner and PSNI[606] and the Inquiry's Experts Dr. Coulthard, Professor Gross and Dr. Haynes in numerous Reports.[607]

323. Nevertheless, there remain outstanding matters concerning the way in which Dr. Taylor sought to discharge his responsibilities to Adam during this peri-operative stage and the possible consequences of his conduct.

598 Ref: 204-002-026
599 Ref: 300-065-125
600 Ref: 300-064-124
601 Ref: 300-066-127
602 Ref: 300-067-128
603 Ref: 300-068-129
604 Ref: 300-069-131
605 Ref:WS-008-1p.2 to WS-008-1 p.6
606 Ref: 011-011-053 & 094-002-002
607 Ref: 200,201 & 204

Those issues will be the subject of further probing during the Oral Hearing.

Preparation of the Operating Theatre & Equipment

324. Dr. Taylor acknowledges that the preparation of the Operating Theatre is largely a matter for the Anaesthetic team as assisted by the Medical Technical Officer.[608] He states in his Deposition to the Coroner of 21st June 1996 that he was familiar with all the anaesthetic equipment used and that it was checked prior to the start of its use for Adam's transplant surgery.[609] In his Inquiry Witness Statement of 16th May 2011 he confirms that the equipment was checked on 27th November 1995 prior to the start of the transplant surgery and goes on to make the following points:[610]

(i) Checking the equipment involved: *"Checking the pipes were securely plugged in, backup cylinders were full, oxygen delivery and FiO2 monitors were attached, patient monitors were in working order, airway equipment and drugs and resuscitation equipment"*[611]

(ii) Dr. Montague was with him when he made those checks[612]

(iii) Neither the checks nor the results were recorded as they were 'routine checks'[613]

325. The report provided by Messrs. McLaughlin and Wilson to the Coroner as part of the Inquest on Adam's death, indicated that *"all cylinders were removed from the Lamtec ... [and] five pins were discovered to be loose and could be removed"*.[614] It is not clear when that happened or whether that was the condition of the equipment at the time of Dr. Taylor's inspection and if it was whether it could and should have been noted by him.

326. The report also states that: *"the anaesthetist using the machine is also expected to sign the log before commencing the list but this does not happen on most occasions. A reason for this omission should be requested"*.[615] Again, it is not clear whether Dr. Taylor signed the log as he was expected to do and if not why not.

608 Ref: 300-065-125
609 Ref: 011-014-102
610 Ref: WS-008-2, p.30
611 Ref: WS-008-2, p.30
612 Ref: WS-008-2, p.30
613 Ref: WS-008-2, p.30
614 Ref: 011-004-014
615 Ref: 011-004-014

327. Those issues in respect of the checking of the equipment will be addressed further during the Oral Hearing and also from a governance perspective.

Inducing Anaesthesia

328. The main starting point for the peri-operative stage is the anaesthetising of Adam.

329. According to Dr. Montague's Inquiry Witness Statement of 4th April 2011 the Anaesthetic Room was not used to anaesthetise Adam who was brought directly into the Operating Theatre with his mother to be anaesthetised there.[616] The location of the Operating Theatre used for Adam and its adjacent Anaesthetic Room can be seen on the Site Plan.[617]

330. The Nursing Notes record that Adam was transferred to the Operating Theatre at 07.00.[618] Adam's mother puts it a little earlier than that in both her draft statement to the Coroner of 17th January 1996[619] and her Inquiry Witness Statement of 10th January 2012.[620]

331. Dr. Montague claims in his Inquiry Statement of 16th September 2011 that he was in the Anaesthetic Room preparing drugs and equipment when Adam was brought into the Operating Theatre.[621] Adam is recorded as having arrived in the Operating Theatre crying[622] and Dr. Taylor claims in his Deposition to the Coroner of 21st June 1996 that Adam was anaesthetised in the presence of his mother.[623]

332. Dr. Taylor was in the Operating Theatre when Adam was brought in and whilst Dr. Montague states in his Inquiry Witness Statement of 4th April 2011 that he does not recall who else was present he does state: *"Normally one of the theatre nurses helped the anaesthetist. I do not recall which nurses were there"*.[624] Adam's mother states in her Inquiry Witness Statement of 10th January 2012 that theatre staff were present when she arrived with Adam in the Operating Theatre. Also, whilst she concedes that she does not know whether there were any nurses specifically assisting Dr. Taylor in anaesthetising Adam, she is clear that: *"There were nurses in the room"*.[625]

616 Ref: WS-009-1, p.6
617 Ref: 300-005-005
618 Ref: 057-014-019
619 Ref: 011-006-018
620 Ref: WS-001-2, p.11
621 Ref: WS-009-3, p.2
622 Ref: 058-003-057
623 Ref: 011-014-096
624 Ref: WS-009-1, p.6
625 Ref: WS-001-2, p.12

333. Dr. Montague also claims in his Inquiry Statement of 16th September 2011 that he did not go into the Operating Theatre until Adam was asleep as he considered that it would be less upsetting for him if there were fewer strangers about.[626] He goes on to state: *"Dr. Taylor did not need me for the induction of anaesthesia"*.[627]

334. As you know Mr. Chairman there is an unresolved issue as to whether an Anaesthetic Nurse was required to be and or was present assisting Dr. Taylor with the anaesthesia and, if such a nurse was there, who she was. Those are matters to be pursued further during the Oral Hearing.

335. The Anaesthetic Record shows anaesthesia commencing at 07:00 with the intravenous administration of[628] Atropine (0.3mg), Sodium Thiopentone (STP) (125mg) and Atracurium (10mg).[629] Adam's mother states in her Inquiry Witness Statement of 10th January 2012 that he told Dr. Taylor that he wanted to be anaesthetised by the *"butterfly"* and not the *"mask"*.[630] Dr. Taylor confirms in his Deposition to the Coroner that Adam was anaesthetised through a 25G butterfly needle in his right antecubital fossa.[631]

336. No criticism is made of the conduct of Adam's anaesthetic by the Inquiry's Expert Dr. Haynes. He describes it in his Report of 4th October 2011 as *"satisfactory"*.[632]

337. As part of the arrangements to provide Adam with appropriate pain relief during the transplant surgery, Dr. Montague also cited an epidural once Adam was anaesthetised. The purpose of the epidural was also to assist with Adam's post-operative pain management.[633] It seems that Adam's mother was unaware that an epidural would be administered and first learned of it when Dr. Savage updated her on his way to perform his other duties. She states in her Inquiry Witness Statement that she was unhappy about it as Adam had experienced considerable pain the last time an epidural had been used.[634]

338. A number of things then happened prior to the surgery, which are recorded on the 'Chronology' as including:

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626 Ref: WS-009-03, p.2
627 Ref: WS-009-3, p.2
628 See the Glossary of Terms for the meaning and use of these drugs
629 Ref: 058-003-005
630 Ref: WS-001-2, p.12
631 Ref: 011-014-096
632 Ref: 204-004-162
633 Ref: 058-003-006, Ref: WS-009-1, p.6 and Ref: 011-014-096
634 Ref: WS-001-2, p.3

(i) A cannula was inserted into a peripheral vein in Adam's left hand and Dr. Taylor started an infusion of 500mls 0.18% saline/4% dextrose,[635] which he recorded as being: *"Fluids as per Dr. Savage"*.[636]

- The fluid calculations that Dr. Taylor made and the principles which he applied in relation to the replacement of the fluid deficit in the first hour and addressing the ongoing renal losses associated with Adam's native kidneys are discussed later on.

(ii) Arterial access was gained with a fine catheter into the right radial artery to continue to monitor arterial blood pressure.[637]

- Dr. Savage appreciated at the outset that there was an opportunity to check Adam's electrolytes. In a letter from Dr. Savage to Dr. Murnaghan dated 7th June 1996, Dr. Savage stated *"I understand that venous access was readily achieved in theatre and therefore it would have been possible to check the electrolyte picture at that stage"*.[638] The matter is further addressed in Dr. Savage's Witness Statement to the Inquiry, when he states: *"I made it clear to Dr. Taylor that it was important that his sodium and electrolytes were checked immediately prior to theatre"*.[639]

- Mr. Keane's own view as stated in his Inquiry Witness Statement of 16th March 2011 is that: *"I cannot explain why Adam's electrolytes were not checked when the central line was inserted. He should have had his electrolytes checked once the central or arterial lines were inserted"*.[640]

- Dr. Taylor, in his PSNI statement under caution, sets out his view that the checking of electrolytes was not a *'priority'*. When asked whether it was accurate to say that this was not a priority, Dr. Taylor agreed but with an added element of explanation, namely that "*we had knowledge that his sodium didn't vary*".[641] Dr. Taylor also addresses this matter in his Witness Statement to the Inquiry, in which he states:

635 Ref: 058-003-005
636 Ref: 058-003-006
637 Ref: 011-030-155
638 Ref: 059-003-006
639 Ref: WS-002-3 p.14
640 Ref: WS-006-2, p.13
641 Ref: 093-038-231

> *"When I commenced Adam's anaesthetic at around 07.00 on the 27th November 1995 I appear to have become pre-occupied with the anaesthetic procedures; endotracheal intubation, insertion of a peripheral intravenous line, arterial line, central line and epidural and omitted sending a blood sample for electrolyte analysis to the laboratory as I should have. I accept that I should have sent the electrolyte sample before starting the operation. I should also have sent other samples as necessary and used those results to adjust the rate and type of the intravenous fluids".*[642]
>
> It should further be noted that it is stated in correspondence from the DLS, that it would have been necessary to use the main RVH laboratory in the Kelvin building for electrolyte testing, as the Paediatric Clinical Biochemistry laboratory in the Children's Hospital did not open until 09:00[643]

- Dr. Haynes reiterates in his Report of 7th October 2011[644] the view that he expressed in his first Report of 2nd August 2011 that a sample of Adam's blood should have been sent off to the laboratory for 'assay' as soon as he was anaesthetised as well a sample being retained for testing with the blood gas analyser for a speedy result.[645] He goes on to state: *"This would have been a priority"*.[646]

(iii) A triple lumen central venous catheter was inserted into the right subclavian vein.[647] The Legal Team has provided a photograph of typical lumen lines including the triple one that was used with Adam.[648]

- The Legal Team have also provided a diagrammatic representation of marks found on Adam's body at Autopsy which was compiled from the Expert Report of Dr. Haynes.[649] This representation will assist with identifying where the central venous catheter was inserted into Adam's chest, and can be seen as Box 4: *"needle puncture mark in left upper chest in region of the subclavian vein"*.[650] It is also necessary to refer to a chest x-ray that

642 Ref: Ref: WS-008-6 p.3
643 Ref: 301-018-332
644 Ref: 202-004-150
645 Ref: 202-002-024
646 Ref: 204-004-150
647 Ref: 011-030-155
648 Ref: 300-026-044
649 Ref: 300-090-189
650 Ref: 300-090-189

was taken of Adam post-operatively[651] which clearly shows the catheter tip turning away from the heart and up towards Adam's neck.

- Dr. Taylor states in his Deposition for the Coroner of 21st June 1996 that: *"a central venous catheter [was] placed without undue difficulty"*.[652] It should be noted however that this statement is in contrast with Dr. Taylor's comments made within the same Deposition: *"a central venous line was attempted on 3 occasions in the left subclavian, once in the left internal jugular, and then successfully in the right subclavian"*.[653]

- It should be further noted that Mr. John Wilson, the Chief Medical Technical Officer for Anaesthetics, Theatres, and Intensive Care for the Royal Group of Hospitals, explains in his Statement to the PSNI of 24th April 2006[654] how the CVP transducer is connected and calibrated. He explains how to check the reading for accuracy and how to deal with any anomalies, including the 're-zeroing' and replacing the 'transducer'. He claims that both operations can be performed quickly with the latter taking about a minute.

Insertion of a Urinary Catheter

339. In addition to the failure to have Adam's electrolytes measured once Adam was anaesthetised and arterial access was gained, there was also a failure to insert a catheter so that Adam's urine output could be monitored and measured during the surgery.

340. The Inquiry's Experts Messrs. Forsythe and Rigg have provided diagrams of the three urinary catheters in their Joint Report of February 2012 and they discuss their different characteristics.[655] Those three catheters are 'Urethral Catheter', 'Suprapubic Catheter' and 'Ureteric Catheter'.[656] As will be appreciated only the first two involve the drainage of urine and therefore provide a means of monitoring urine output.

651 Ref: 300-073-136
652 Ref: 011-014-096
653 Ref: 011-014-099
654 Ref: 093-027-072 *et seq*
655 Ref: 203-008-109
656 Ref: 300-037-055

341. The Inquiry's Expert Dr. Haynes has included the insertion of a urinary catheter as a task for the Anaesthetic team.[657]

342. Dr. Taylor states in his Inquiry Witness Statement of 3rd October 2003 that he believes that Adam's bladder was not catheterised at the outset so as to permit it to be as full as possible.[658] He goes on to state that: *"I suspect it was as a result of discussion with the surgeons although I cannot remember. A catheter would have provided me with information on urine output and the surgeon with an empty bladder. Without it there is no information on urine output but the surgeon has a full bladder"*.[659]

343. Mr. Keane is quite clear in his Inquiry Witness Statement of 20th September 2011 that: *"It was my decision not to catheterise and I believe [sic] was the correct decision. I decided to allow the bladder to distend naturally"*.[660]

344. The insertion of a catheter for the monitoring of urine output during transplant surgery is discussed by Dr. Haynes in his Report of 2nd August 2011 in which he states: *"Adam produced significant volumes of urine and his urinary output should have been monitored when possible during the operation and a urinary catheter should have been inserted following induction of anaesthesia prior to commencing surgery"*.[661] He cites in support of that 'Guidelines for Anaesthesia for Paediatric Renal Transplantation' (1998) which state under monitoring: *"All patients have bladder catheters inserted prior to surgery"*.[662]

345. Dr. Haynes then goes on to give the reason for doing so: *"It was known that his [Adam's] native kidneys produced large volumes of poor quality urine, and measurement of urine production during the initial part of the operation whilst his native kidneys were still perfused would have guided fluid therapy"*.[663] He expands upon this in his Report of 7th October 2011 when referring to the fact that Adam's previous extensive surgeries meant that his transplant surgery prior to the reimplantation of the transplanted ureter might be lengthy and involve significant blood loss: *"To allow safe management of intravenous fluid therapy, the anaesthetist needed to know as best he could, the volume of urine produced, especially in a patient such as Adam where urinary*

657 Ref: 204-002-026
658 Ref: WS-008-3, p.2
659 Ref: WS-008-3, p.12
660 Ref: WS-006-3, p.13
661 Ref: 204-002-031
662 Ref: 204-002-067
663 Ref: 204-002-031

losses, because of the underlying disease, may not reflect his circulatory state. This is done be[sic] noting urine volume drained from the bladder catheter".[664]

346. Although Mr. Koffman refers to the bladder being left "*on free drainage*" with polyuric patients in his report for the PSNI of 5th July 2006,[665] Dr. Haynes claims that Mr. Koffman is considering the monitoring of urine from the surgical perspective of ascertaining the function of the engrafted donor kidney and not from the perspective of the anaesthetists: "*need to consider the patient's condition during the initial phase of a transplant operation*".[666]

347. Messrs. Forsythe and Rigg express similar views to those of Dr. Haynes, albeit in more trenchant terms, in their joint Report of June 2011: "*A urethral catheter will always be placed at the beginning at [sic] the operation, unless it is not technically possible*".[667] Mr. Keane has confirmed in his Inquiry Witness Statement of 16th March 2011 that there was no contraindication to inserting a urinary catheter immediately after Adam was anaesthetised.[668] However, when pressed about why one was not inserted he states in his subsequent Inquiry Witness Statement of 20th September 2011 that: "*Adam's urethra was very small and in my opinion urethral catheterisation was unnecessary. I wanted the bladder full*".[669]

348. Messrs. Forsythe and Rigg go on to address Mr. Keane's requirement for distension of the bladder in their joint Report of October 2011 in which they disagree that it needs to be achieved through the accumulation of urine:

> "*Professor Alexander states in paragraph ii) [Ref: WS-120-03] 'During renal transplantation, the urinary bladder is allowed to fill, so that it is easy to identify when it is time to transplant the ureter into the bladder. This is normal practice.' This is not, and has not been, the normal practice of either of us or the units in which we have worked. If a urethral catheter has been placed then, as noted above, it may be clamped during the first part of the surgical procedure to allow the bladder to distend … However this is a controlled situation rather than leaving the bladder to fill in an uncontrolled way when one is not sure of the urinary output of that individual.*"[670]

664 Ref: 204-004-156
665 Ref: 094-007-035
666 Ref: 204-004-157
667 Ref: 203-002-027
668 Ref: WS-006-2, p.6
669 Ref: WS-006-3, p.9
670 Ref: 203-004-063

349. They also deal with Mr. Keane's claim that Adam's urethra was *"very small"* in their joint Report of November 2011: *"Adam's urethra was very small because he was young. We are not aware of any reason why his urethra would have been smaller than usual"*.[671]

350. The following issues are therefore all matters that will be addressed during the Oral Hearing:

(i) Whether or not a urethral catheter should have been inserted at the outset and the significance, if any, of it not having been done

(ii) Whether Mr. Keane's requirement for the lack of a catheter at the outset so that Adam's urine output might be used as a means of distending his bladder was appropriate the circumstances

(iii) What type of discussion, if any, should there have been between the Anaesthetic and Surgical teams over the insertion of a urethral catheter at the outset

(iv) Whose requirements, as between the Anaesthetic and Surgical teams, should have prevailed in the circumstances of Adam's transplant surgery

(v) The significance of the size of Adam's urethra for the insertion of a urethral catheter prior to the start of the transplant surgery, including whether his urethra was small for his age and size

Monitoring Adam

351. Before I deal with the issues raised in the monitoring of Adam during his transplant surgery it may be helpful to have some appreciation of the arrangement of a typical Operating Theatre during such an operation. The Legal Team has provided photographs showing: (a) general view of Operating Theatre showing renal transplant in progress;[672] (b) renal transplant in progress showing the personnel involved including the circulating nurse (or runner) in the foreground;[673] (c) renal transplant in progress with scrub nurse to the right;[674] and (d) renal transplant in progress with scrub nurse to the left.[675] It is possible from those photographs, none of which have anything to do with Adam or his transplant surgery, to gain some sense of the proximity of the various

671 Ref: 203-006-089
672 Ref: 300-046-064
673 Ref: 300-047-065
674 Ref: 300-048-066
675 Ref: 300-049-067

members of the Transplant team to each other, as well as the positions of the monitors and the strong operating lights used.[676] I will refer later on in relation to the conduct of the transplant surgery to the effect of those operating lights on the temperature of the donor kidney prior to its anastomoses.

Anaesthetic assistance for Dr Taylor

352. Dr. Taylor accepts in his Inquiry Witness Statement of 16th May 2011 that the monitoring of Adam throughout his transplant surgery was the responsibility of the Anaesthetic team and that he had the *"lead role"* in the: *"Monitoring of vital signs and fluid/blood management"*.[677] As you know Mr. Chairman there is an unresolved issue about whether Dr. Taylor had the benefit of an assistant Anaesthetist for the duration of Adam's transplant surgery, which is an issue that includes when exactly Dr. Montague left the Operating Theatre and whether and if so when and by whom he was replaced. It is far from clear from the Statements of the various Witnesses when Dr. Montague left the Operating Theatre:

(i) Dr. Montague states in his PSNI Statement of 30th November 2007 that he was there at the start but then was sent home by Dr. Taylor (as he had been on call that night), which he believed was prior to 09:32[678]

(ii) Dr. Montague states in his Inquiry Witness Statement of 4th April 2011 that his 24 hour shift was due to end at 09:00 on Monday 27th November 1995 and that he would then have been free to go home.[679] He goes on to state that at the time he left the surgery had started but the donor kidney had not been transplanted.[680]

(iii) In his Inquiry Witness Statement of 22nd July 2001, Dr. Montague states that he cannot recall whether he was still in the Operating Theatre when the third bag of 0.18 NaCl/4% Glucose was erected at about 08:43[681] but that: *"I think I am likely to have left around 08.30 when the anaesthetic registrars would have started their normal day"*.[682]

(iv) Dr. O'Connor states in her Inquiry Witness Statement of 11th April 2011 that she arrived at work at approximately 09:00 on 27th

676 See in particular the photograph at Ref: 300-049-067
677 Ref: WS-008-2, p.2
678 Ref: 093-037-117 to Ref: 093-037-118
679 Ref: WS-009-1, p.2
680 Ref: WS-009-1, p.6
681 Ref: 058-003-005
682 Ref: WS-009-2, p.4 – see also Ref: Ws-009-2, p.5

November 1995.[683] She then states in her Inquiry Witness Statement of 22nd September 2011 that Dr. Taylor and Dr. Montague were the anaesthetists that she saw in the Operating Theatre and regarded as the Anaesthetic team.[684] She goes on to state in that Statement that Dr. Montague was present when she arrived in the Operating Theatre but that she cannot recall if was present for the whole procedure or if there were any other Anaesthetists.[685]

(v) Dr. Taylor is unable to clarify matters in his Inquiry Witness Statement, as apart from anything else it is not until his Inquiry Witness Statement of 16th May 2011 (after the publication of Dr. Montague's PSNI Statement) that he discloses that Dr. Montague was replaced by an as yet unidentified Trainee Anaesthetist. He states in that Statement that *"surgery had just commenced"* when he let Dr. Montague go.[686] He then goes on to state in his Inquiry Witness Statement of 3rd October 2011 that he would accept that Dr. Montague went home around the expected changeover time of 09:00.[687]

353. The particular significance of all of that Mr. Chairman is that Dr. Taylor accepts that he left the Operating Theatre from time to time[688] which, in the absence of an assistant Anaesthetist would leave the responsibility of monitoring Adam during that period to the Medical Technical Officer Mr. Shaw and the as yet unidentified Anaesthetic Nurse.

Monitoring issues

354. The Inquiry's Expert Dr. Haynes explains in his Report of 2nd August 2011 that the purpose of the Anaesthetic team monitoring Adam was really a means of them: *"ensuring adequate depth of anaesthesia, and maintaining stability of respiratory and cardiovascular systems"*[689] all the time that Dr. Taylor, as the Consultant, retained responsibility for Adam, which was until he handed over Adam's care to PICU or, as the case may be, high dependency care or the ward staff.

355. The monitoring of Adam was carried out by <u>four</u> principle means:

683 Ref: WS-014-2, p.16
684 Ref: WS-014-3, p.3
685 Ref: WS-014-3, p.5
686 Ref: WS-008-2, p.10
687 Ref: WS-008-3, p.10
688 Ref: WS-008-2, p.9
689 Ref: 204-002-027

(i) Continuous monitoring of Adam's vital signs, namely ECG, blood pressure, temperature, heart rate and blood pressure – including Central Venous Pressure

(ii) Periodic checks and tests including measurements of his blood loss by weighing swabs and towels and noting the administration of fluids and medication e.g. as shown on the anaesthetic record[690] and the blood swab count[691]

(iii) Other checks and tests including blood gas analysis to check haemoglobin and haematocrit levels and/or serum sodium concentration

(iv) Continuous visual observation as referred to by Dr. Taylor on a number of occasions during his PSNI Statement under caution, eg: (a) *"when continuously reassessing Adam's fluid replacement we used all the information available from the anaesthetic monitors as well as visualising the impact on the surgical field"*;[692] (b) *"But there would have been a watchful [Anaesthetist's] eye … at the surgical field … and at the monitors … constantly … So I would have been aware of everything that happened"*;[693] (c) *"So we [Anaesthetists] must position ourselves in a place as well as looking at our technology … To actually see what's happening in real time with the patient blood doesn't be lost[sic] as maybe you can see in the swab count n a very teady[sic] manner"*[694]; (d) that visualising the impact in the surgical field relates to blood loss and the colour of the blood;[695] (e) "*the general look at his veins are his veins dilated or shrunken … does the wound look moist … or dehydrated"*[696]

356. As I stated earlier, the Inquiry has compiled Schedules[697] and charts[698] of the results of the recordings made during the peri-operative period showing:

(i) Adam's vital signs

(ii) Drugs administered

(iii) Temperature and central venous pressure

690 Ref: 058-003-003
691 Ref: 058-007-020
692 Ref: 093-038-128
693 Ref: 093-038-142
694 Ref: 093-038-145
695 Ref: 093-038-147
696 Ref: 093-038-205
697 Ref: 307-006-063 *et seq*
698 Ref: 307-006-064 *et seq*

(iv) Fluids administered and lost

(v) Oxygen saturation and end tidal carbon dioxide

(vi) Serum sodium and haemoglobin levels.

357. There are a number of issues which arise in respect of the peri-operative monitoring of Adam during his surgery on 27th November 1995. These matters will be considered during the Oral Hearing, and to assist the Legal team has compiled a Schedule of these issues, 'Schedule of Issues Arising from Peri-Operative Monitoring'.[699] It is intended that the contents of this Schedule, together with the associated compiled documents, will obviate the need for me to go through all the details of Adam's peri-operative monitoring during his transplant surgery.

358. The Schedule is a summary of the following principal issues identified by the Legal Team in respect of Adam's peri-operative monitoring on 27th November 1995:

(i) Checking of serum electrolytes prior to Adam being taken to the operating theatre

(ii) The turnaround of serum electrolyte laboratory result

(iii) The failure to insert a urinary catheter after anaesthetic

(iv) The accuracy of CVP monitoring

(v) The subsequent blood testing by Blood Gas Analyser

(vi) Whether there was regular monitoring, review and regulation of Adam's fluid intake to keep up with his fluid losses

(vii) Visual observations

(viii) The significance of Adam being 'swollen', 'puffy' and 'bloated' at the end of surgery

(ix) Compliance with the 1990 RBHSC Guidelines for Renal Transplantation in Small Children[700]

359. Beside each of these identified issues, which are set out in the left-most column, are further columns containing any relevant comments by Dr.

699 Ref: 306-015-120
700 Ref: 201-006-177

Taylor and Mr. Keane, as members of the Transplant team, as well as the Inquiry's Experts Dr. Coulthard, Professor Gross and Dr. Haynes. The purpose is to provide a ready comparison between the views of members of the transplant team and those of the Experts. A final column to the far right includes the relevant comments of any other expert such as Dr. Sumner who advised both the Coroner and the PSNI.

Administration of Fluids & Response to Adam's Condition

360. As you are aware Mr Chairman, the appropriateness or otherwise of the intravenous fluids that Adam received during surgery is one of the key areas of investigation by the Inquiry. This is reflected by the Terms of Reference:

"especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case."[701]

361. The Legal Team has therefore gone to some length to investigate that issue. Reference has already been made to the fluid management comparison table. This reflects the questioning of Dr. Taylor, and the in-depth analysis offered by the Inquiry's experts, namely Dr. Coulthard, Professor Gross and Dr. Haynes.

362. Dr Taylor stated in his first witness statement to the Inquiry in 1995 that his pre-operative fluid calculations were based on the following factors:

"1. *Replace fluid deficit (mainly dilute urine)*
2. *Provide fluid maintenance requirements each hour in theatre*
3. *Replace any blood loss*
4. *Further fluid management would depend on BP, HR, CVP and organ perfusion*
5. *The need to ensure that Adam's blood volume was certainly not deficient BUT with careful monitoring was actually increased in order to adequately perfuse the new, adult sized donor kidney."*[702]

363. The issues relating to Adam's fluid management can therefore be usefully considered in relation to:

(i) Adam's pre-surgical condition, including whether Adam was in 'deficit' prior to surgery, and the effect of dialysis on fluid and sodium balance

701 Ref: 021-010-024
702 Ref: WS-008-1, p.4

(ii) Adam's maintenance requirements including urine output

(iii) Adam's blood loss during surgery

(iv) Whether the fluids chosen were appropriate in terms of their sodium and glucose content

(v) The volume of fluids administered, and the reasons for doing so

Adam's Pre-surgical Fluids

364. At the time of Adam's transplant, he was receiving 3 bolus feeds of 300mls each during the day and 1200ml of Nutrison over 8 hours every night as his feeds through his gastrostomy tube.[703] On his admission to the Children's Hospital on 26th November 1995, Dr. Jacqueline Cartmill prescribed two amounts of 500mls iv fluids of 0.18% sodium chloride/4% dextrose to run at a rate of 75 ml/h – described as *"maintenance"*[704]. At 22:00 when fluids were actually started, 180ml/h of *"clear fluids"* were to be administered through his gastrostomy tube. Dr. Savage has said that the 'clear fluids' administered were in fact Dioralyte[705]. This was in addition to his iv fluids now reduced to 20 ml/h.[706] However, the IV cannula tissued at 01.42 and Dr. Daragh O'Neill therefore prescribed an increase in Adam's gastrostomy fluids to 200 ml/h. That uncertainty is a lack of clarity over whether the cannula was re-inserted at 05:00.[707] The Nursing Notes indicate that it was but in her PSNI Statement SN Catherine Murphy queries whether that actually happened.[708] This is an issue to be addressed during the Oral Hearing.

365. The Inquiry's experts and Professor Savage have stated that Dioralyte contains 57-60mmol/L of sodium[709]. However, Dr. Taylor in his deposition to the Coroner stated that "*Diaoralyte (sic) = 0.18NaCl/4% Glucose solution*"[710] and has stated that it contains only 35mmol of sodium,[711] although he states elsewhere that it contains 60mmol/L of sodium.[712] This is an issue to be further addressed during the Oral Hearing.

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703 Ref: 057-068-128
704 Ref: 057-010-014
705 Ref: 011-002-005
706 Ref: 057-010-013
707 Ref: 057-014-019
708 Ref: 093-007-024
709 Ref: 300-077-141
710 Ref: 011-014-098
711 Ref: 300-077-141
712 Ref: WS-008-2, p.21

366. According to Adam's overnight fluid balance sheet, he received a total of 952ml of Dioralyte and 18ml of '5/N' (Solution 18).[713] His feeds were stopped at 05:00 because of pre-surgical fasting. From 05:00 until his transfer to surgery for anaesthetic preparation at 07:00 he received no fluids.

Effect of Dialysis on Fluid Balance & Plasma Sodium

367. There is an issue as to the effect of dialysis on fluid balance and plasma sodium, and particularly whether it is able to 'fix' fluid and/or sodium imbalance.

368. Dr. Coulthard has stated that in his experience peritoneal dialysis tends to buffer the impact of variations in fluid status that would otherwise result in children becoming either dehydrated or fluid overloaded. The dialysis would remove less fluid overnight if the child was dehydrated and more if they are overhydrated.[714] He states that because of the dialysis, Adam's overall fluid balance: *"was unlikely to have been significantly perturbed by the events in the few hours prior to his transplant"*.[715]

369. Likewise, he states that peritoneal dialysis tends to correct any imbalances that may exist in the plasma sodium because the dialysate contains sodium at normal plasma concentrations (in Adam's case 132mmol/L). Dr. Coulthard says that sodium will diffuse down its concentration gradient from fluid to plasma if the plasma sodium is low, or from the plasma to the fluid if they are hypernatraemic. Thus, he states that: "*the plasma sodium in the morning after an overnight dialysis session is almost guaranteed to be normal if the child starts off with a near-normal value.*"[716]

370. Although Adam received 8 cycles rather than his usual 15, Dr. Coulthard does not think this would have made a substantial difference to his fluid balance, although it may have reduced the change the dialysis had on the sodium balance.[717]

371. Dr Savage, in his most recent statement to the Inquiry of 20th March 2012, has stated that peritoneal dialysis "*tends to normalise*" both plasma sodium concentration and fluid balance status.[718] However, in earlier Inquiry Witness Statements of 14th April 2011 he states: *"The effect of receiving 952mls of clear fluid after admission rather than the usual 1.5 litre of Nutrison*

713 Ref: 057-010-013
714 Ref: 200-002-050
715 Ref: 200-009-149
716 Ref: 200-002-050
717 Ref: 307-007-108
718 Ref: WS-002-5, p.3 and p.4

feed and a small volume of intravenous fluids (58mls) meant that Adam was in relative deficit of 500mls compared to previous days. He would therefore have been less well hydrated than usual and it is possible that this may have resulted in some degree of haemoconcentration which would have the possible effect of increasing his serum sodium concentration. In normal circumstances this deficit would have been addressed by replacing the deficit by extending his tube feed at 200mls per hour over 2-3 hours"[719]

372. As regards the issue of 8 rather than 15 cycles of peritoneal dialysis, Dr. Savage says in his Inquiry Witness Statement of 28th September 2011: *"Furthermore Adam was having a short period of dialysis and some tube and IV fluids overnight and again I thought it would be wise to check that his electrolytes had remained in the normal range".*[720]

373. Dr. Taylor agrees that "*it was usual for Adam's electrolytes to remain stable following dialysis for 24 hours*"[721] and that his dialysis "*did not lead to deranged electrolytes*".[722]

374. The issue of the effect on Adam's sodium levels of his 8 cycles of peritoneal dialysis, as opposed to his usual 15 cycles, is something that will be addressed further in the Oral Hearing.

Fluid Deficit

375. The fact that Adam received less fluid overnight than his usual 1200ml, and the fact that he received no fluids between 05:00 and 07:00 has raised the issue regarding whether Adam was in a 'deficit' of fluid and/or was dehydrated on his arrival to surgery at 07:00, and if so, what the degree of that deficit was.

376. Dr. Taylor has stated that he believed that Adam was in fluid deficit and therefore planned the administration of fluid in the early part of the surgery to replace this deficit. In his deposition, he judged this deficit to be between 300mls and 500mls, and stated that there was some evidence to suggest that Adam may have been dehydrated prior to surgery.[723] In a witness statement to the Inquiry, he has stated that:

719 Ref: WS-002-2, p.19
720 Ref: WS-002-3, p.29
721 Ref: WS-008-1, p.2
722 Ref: WS-008-2, p.28
723 Ref: 011-014-099

"[A] total of 970 mls had been given over 6 hours. I calculated that he should have received 1200mls over these 6 hours and therefore he not had to receive in excess of 200ml/hr to provide for this planned fluid administration."[724]

377. In addition to believing there was a deficit, Dr Taylor also considered that there was "*an urgency to replace this deficit so that Adam did not become dehydrated or suffer from low blood circulation prior to transplant*."[725] and that he wished to ensure that "*no potential deficit remained as we began the process of increasing Adam's circulating blood volume (hypervolaemia) in preparation for his kidney transplant*"[726]

378. Professor Savage agrees that the fact that Adam received 952mls of Dioralyte plus a small amount of IV fluids rather than his usual 1.5 litre Nutrison feed meant that Adam would have been less well hydrated than normal.[727] He stated that the deficit was important to address so as to provide a good intravascular volume prior to the removal of the vascular clamps and therefore addressing the deficit over 1-2 hours would seem to be reasonable.[728] In his Inquiry Witness Statement of 28th September 2011 Dr. Savage states: *"The amount of fluid deficit which I believe was required to be corrected by IV infusion during Adam's surgery was approximately 500mls. This was based on the fact that he normally received 1500mls gastrostomy feeds overnight, but on the night in question, he only received 970mls"*[729]

379. However, in his most recent statement to the Inquiry of 20th March 2012, he states that he estimates Adam was 300-500mls in deficit.[730]

380. Dr Alexander at the Inquest agreed that there was a fluid deficit between 05:00 and 07:00.[731]

381. Dr. Coulthard disagrees that Adam was in fluid deficit before surgery, and asserts that he would have arrived in theatre at approximately normal salt and water balance.[732] He believes that Adam arrived in theatre "*somewhere between being in precise water balance, and being about 300 ml overloaded"* and that he: "*would certainly exclude him having been water deficient."*[733]

724 Ref: WS-008-2, p.6
725 Ref: WS-008-1, p.3
726 Ref: WS-008-2, p.31
727 Ref: WS-002-2, p.20-21
728 Ref: WS-002-2, p.21, p.40
729 Ref: WS-002-3, p.39 and see also Ref: WS-008-3, p.43
730 Ref: WS-002-5, p.4
731 Ref: 011-012-083
732 Ref: 200-007-134
733 Ref: 200-009-150

382. Professor Gross agrees that it was unlikely that Adam was dehydrated prior to surgery pointing to the fact that Dr. Taylor was able to place a right subclavian access at his first attempt.[734]

Urine Output

383. There is significant disagreement between the Witnesses and the Inquiry's Experts as to the level of Adam's urine output, which is a crucial issue for you Mr. Chairman as it is one of the major factors taken into account when clinicians are calculating the rate of fluid administration.

384. Of particular significance is the position of Dr. Taylor, which has altered since the beginning of the Inquiry's investigations. Prior to January 2012, Dr. Taylor appears to have made the assumption that Adam would pass around 200mls per hour of dilute urine.[735] This was despite the note of 9th November 1995 in Adam's medical notes by Dr. O'Connor:[736] "*PU++ how much? 1-2 litres*"[737] i.e. that he passed 1-2 litres of urine per day.

385. Dr. Savage's position is that Adam passed 1.5 litres of urine a day[738] and that he had planned with Dr. Taylor that Adam should receive intravenous fluid at 75ml/hr after his tube feeds.[739]

386. Dr. Taylor also believed that Adam could tolerate large quantities of Solution No.18 as he had received 300mls in one hour in a previous operation on 18th October 1995. He stated in his PSNI interview that this showed that "*Adam was not a normal child cause normal children shouldn't cope with 300 mls over an hour. [...] Adam was exceptional*."[740] He further stated that Adam's body operated "*like a hole in a bucket*", and that he "*had to get that bucket filled up*".[741] In addition, he stated that his knowledge of Adam and his kidney disease was such that he considered the 200ml/hr to be a "*minimum loss*" and that it may well have been "*unlimited*", and that "*no-one had established maximum output*".[742] As a result, it seems that Dr Taylor did not believe that Adam could retain 'free water' and so could not suffer from dilutional hyponatraemia.[743]

734 Ref: 200-007-125
735 Ref: WS-008-2, p.6 (16th May 2011) and Ref: WS-008-3, p.12 (3rd October 2011)
736 Ref: WS-014-2, p.3
737 Ref: 058-035-143
738 Ref: WS-002-5, p.4, WS-002-1, p.3
739 Ref: WS-002-1, p.3
740 Ref: 093-038-193
741 Ref: 093-038-195
742 Ref: 093-038-242
743 Ref: WS-008-2, p.39

387. Crucially, Dr. Coulthard disagrees with this assumption, describing it as "*without foundation*".[744] He states that dysplastic kidneys in end-stage failure will have a relatively fixed urine output, as regulation of individual renal functions such as urine concentration or water re-absorption will have failed by this stage. He therefore believes that, prior to his surgery in November 1995, Adam produced about 1.5 litres per day of urine (60-65ml/hr) and that this was near both his maximum and minimum volume capacity. In effect, his kidneys were always working 'flat out'.[745] Therefore, if he was administered more than the rate he was able to excrete, he would simply retain the rest in his body. [746]

388. As highlighted by his most recent witness statement, Dr. Taylor has since reflected on this and 'recognised' that Adam had a fixed urine output of around 70-80mls per hour, and has admitted that, based on his incorrect assumption, he administered Solution No.18 to Adam: "*at a rate in excess of his ability to excrete it, particularly in the first hour of anaesthesia*".[747] He has yet to accept that Adam suffered from dilutional hyponatraemia. Dr. Coulthard has commented that the fluid regime would have been inappropriate even if Adam could have excreted it at the rate previously assumed by Dr. Taylor.[748]

389. Adam's urine output was not measured during his surgery until a suprapubic catheter was inserted by Mr. Keane later in the operation at around 10:30.[749] There is a result of 49ml for urine output from the surgery and Dr. Taylor considers this measurement begins only after the insertion of the catheter.[750] Mr. Keane seems to suggest that there was urine produced during the surgery: "*In Adam's case, we allowed the bladder to distend naturally and not measure his urine output but depended on his CVP measurements, which is the parameter of most value to a surgeon*".[751] In contrast, Dr. Coulthard in fact believes that Adam probably produced the noted 49ml at the beginning of the procedure, and that his general condition during anaesthesia after the first period resulted in his very vulnerable kidney function slowing or actually stopping during the rest of the procedure. Whether and how much urine Adam produced during the course of the surgery is an issue that will be addressed during the Oral Hearing.

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744 Ref: 200-002-056
745 Ref: 200-009-151
746 Ref: 200-002-045
747 Ref: WS-008-6, p.3
748 Ref: 200-013-180
749 Ref: WS-006-3, p.8
750 Ref: WS-008-2, p.42
751 Ref: WS-006-2, p.10

Free Water

390. Before we discuss the choice of fluids, I should take a moment to discuss the meaning of the term 'free water'. This has been used by several of the Inquiry's Experts, most notably Dr. Coulthard and Professor Gross. Dr Coulthard explains it as follows:

"*If you give a solution which is less strong than normal saline you can calculate it as if you had given a volume of normal saline and the rest of it as pure water, whereas in reality you may have given it in different combinations. So for example, one litre of fifth normal saline is the equivalent of 200mls of normal saline and 800mls, four fifths of it as water.*"[752]

391. Dr. Coulthard has taken the Inquiry's comparative fluid balance table and calculated the amount of free water given to Adam based on each of the contributors' fluid calculations.[753]

392. The issue of 'free water' and its significance for Adam's fluid management and the development of his hyponatraemia is something that will be addressed further during the Oral Hearing.

Choice of Fluids

393. Adam received a total of 1500mls of Solution No.18 during his transplant surgery. As I mentioned during my General Opening, the intravenous solution 0.18% Sodium Chloride and 4% Glucose/Dextrose (or 'Solution No.18') comprises 4% Glucose and 0.18% Sodium Chloride (NaCl) with the remainder being 'free water'. This means that it contains one-fifth of the sodium and chloride ions than are found in an isotonic solution e.g. 0.9% NaCl. An isotonic solution, such as Hartmann's solution, contains approximately the same number of sodium and chloride ions as are in human blood.

394. Since Solution No.18 contains one-fifth of the sodium content of normal saline, Professor Gross comments that, given that Adam received a total of 1500mls of Solution No.18 during his transplant surgery, this was the equivalent of him receiving 300mls of normal saline and 1200mls of 'free water'.[754]

395. As I also mentioned in my General Opening, NPSA Alert No.22 has directed hospitals across the U.K. to remove Solution No.18 from stock and general use in areas that treat children. There is an issue in Adam's

752 Ref: 307-007-098
753 Ref: 200-021-258
754 Ref: 201-006-176

case as to whether it was the appropriate fluid to be administered: (a) as a maintenance fluid; (b) as a replacement fluid for any fluid deficit Adam may have had; (c) at all**.** Those are issues to be pursued at the Oral Hearing both in relation to the position in 1995 and now.

396. Dr. Taylor has stated that Solution No.18 was the *"standard iv maintenance fluid in paediatric practice"* and that it was *"used widely for replacement fluid in dehydration."*[755] He also said that he would use it for maintenance in healthy infants and children undergoing surgery.[756]

397. In addition, Dr. Taylor has stated that because of Adam's inability to concentrate urine, he produced very dilute urine with a low concentration of sodium. In assessing this, he relied on urine biochemistry results from almost 4 years prior to Adam's transplant surgery which showed his urine to have a sodium content of 29-52mmol/L.[757] He has since estimated the concentration of Adam's urine as 30-40mmol/L.[758] Professor Gross and Dr. Haynes consider Adam's urine concentration to be similarly at about 30 and 40mmol/L respectively.[759] Dr. Taylor states he therefore chose Solution No.18 with its sodium content of 30mmol/litre as the fluid which most closely represented the fluids lost.[760]

398. Dr. Coulthard has commented that because Adam's renal function would have changed over time, particularly with him starting dialysis in 1994: "*previous [urinary sodium] measurements have no relevance to the situation that pertained at the time of his death*".[761] He estimated Adam's urinary sodium content to have been about 75mmol/L.[762]

399. As mentioned previously, Dr. Taylor also believed that Adam's urine sodium content resembled the sodium concentration of his night feeds and Dioralyte, although Dr. Savage and the Inquiry's experts disagree with that. In addition, Dr. Taylor states that he used Solution No.18 because of its glucose content and the need to provide sufficient sugar for Adam's metabolic requirements[763] and to prevent hypoglycaemia.[764]

400. Adam also received other solutions. He received 1000mls Human Plasma Protein Fraction (HPPF) and 500mls of packed blood cells to replace blood

755 Ref: 059-004-007
756 Ref: WS-008-3, p.24
757 Ref: WS-008-1, p.2
758 Ref: WS-008-5, p.7
759 Ref: 204-002-035
760 Ref: WS-008-1, p.3
761 Ref: 200-002-045
762 Ref: 200-004-134
763 Ref: WS-008-1, p.5
764 Ref: WS-008-2, p.29

lost during surgery. HPPF contains 130-150mmol/L of sodium and is accepted as having a similar electrolyte profile to blood. He also received 500mls of Hartmann's solution which has a sodium content of around 130 mmol/L of sodium, which is also similar to that of blood.

401. Dr Taylor has accepted that there were other intravenous solutions available in the Children's Hospital in November 1995:

(i) 5% glucose

(ii) 10% glucose

(iii) 0.9% sodium chloride (normal saline)

(iv) Hartmanns solution[765]

402. The first two solutions contain no sodium chloride at all, which is why Dr. Taylor did not use them.[766] The latter two are both 'balanced' salt solution,[767] but Dr. Taylor says that had he used them instead of Solution No.18, Adam would have had a "*dangerously low blood sugar*" at the end of surgery.[768]

403. Dr. Haynes comments that hyponatraemia is the inevitable consequence of the administration of Solution No.18 in significant volumes.[769]

404. Dr. Coulthard states that his default replacement fluid would be 0.5% Dextrose Saline (75 mmol/L) rather than the 0.18% Dextrose Saline used with Adam, though it would not be unreasonable to use the latter to replace only the insensible and urine losses.[770] However, he states that to use this fluid to 'replace Adam's deficit' or to 'increase Adam's circulating volume to perfuse the transplant' was "*simply wrong*".[771] He also states that half-normal saline (0.45% NaCl) and normal saline (0.9% NaCl) are both routinely available on general paediatric wards with glucose contents of 4% or 5%.[772]

765 Ref: WS-008-2, p.29
766 Ref: 059-004-007
767 Ref: WS-008-3, p.24
768 Ref: 059-004-007
769 Ref: 204-002-035
770 Ref: 200-002-051
771 Ref: 200-002-053
772 Ref: 200-005-095

Rate of Fluids Given

405. Dr. Taylor decided that Adam required 600mls in the first hour of his transplant surgery to address what he had calculated was his fluid deficit of approx 400mls and also Adam's maintenance requirements. He therefore administered 500mls of Solution No.18 to Adam during the first 30 minutes of surgery and a second bag of 500mls was started thereafter.[773] Dr. Taylor has accepted that Adam received approximately 750mls of Solution No.18 in the first hour of his transplant surgery.[774]

406. In his deposition, Dr. Taylor states that the rate of Solution No.18 administration was calculated to restore the deficit, and "*supply maintenance 150ml/hr (in view of the polyuria) and insensible losses (large area of abdominal cavity exposed).*"[775] In his first statement to the Inquiry, he describes Adam's fluid maintenance requirements as 200mls/hr[776] which he repeated in his PSNI interview.[777] He explained that his assessment of 200ml/hr for the maintenance rate was based on Adam's overnight maintenance rate of 200mls/hr.[778] He therefore administered 500mls of Solution No.18 to Adam during the first 30 minutes of surgery and a second bag of 500mls was started thereafter.[779]

407. There is an issue as to the appropriateness of Dr. Taylor's rate of administration to be addressed further during the Oral Hearing. Several of the experts believe that the rate of administration led to an acute fall in Adam's serum sodium level, which was dangerous. Professor Gross states that there is a "*significant difference*" between 'acute' hyponatraemia and 'chronic' hyponatraemia.[780]

408. Dr. Coulthard agrees that the quantity of low sodium concentration infused into Adam was "*simply vast*" and "*dramatically fast*" in a very short period of time.[781] He believes that: "*absolutely critical element of management is about how quickly or how slowly you allow the sodium to fall*" and that "*letting the sodium fall quickly leads to cerebral oedema and brain death*".[782] He contextualises this by referring to the literature of three children who died having been administered free water at rates of between 3-7 ml per kg

773 Ref: WS-008-1, p.4
774 Ref: WS-008-5, p.5
775 Ref: 011-014-101
776 Ref: WS-008-1, p.4
777 Ref: 093-038-186
778 Ref: WS-008-2, p.31
779 Ref: WS-008-1, p.4
780 Ref: 300-007-104
781 Ref: 200-002-054
782 Ref: 307-007-102

hourly.[783] In contrast, Adam received 31.6ml/kg of free water. He has stated that: "*there are no compensatory mechanisms in the body that can come into play anywhere quickly enough to prevent brain swelling in the face of such an inappropriate and massive [administration of fluid]*".[784]

409. Dr. Taylor has explained that he also wanted to give Adam fluids to make him hypervolaemic (that is to increase his circulating blood volume) and to increase Adam's blood pressure as this was 'vital' to allow perfusion of the vital organs and the donor kidney.[785] This fluid was the HPPF to which I have already referred. Dr Taylor has commented that his fluid management of Adam was going according to his pre-surgery plan up until about 09:00, when Adam's blood loss became problematic.[786]

Blood Loss

410. There is an issue, and some disagreement, particularly between Dr. Taylor and Mr. Keane, as to the volume of blood Adam lost during the surgery. This is a matter that will be pursued further during the Oral Hearing.

411. Dr. Taylor stated in his Deposition to the Coroner that there was 'substantial ongoing blood loss from the surgery'.[787] He stated that the haemoglobin fell from 10.5g/dl to an estimated 6.1g/dl during the surgery which confirmed "*significant blood loss*"[788] and that there was 328mls of blood loss in the swabs (which started off light but increased in size[789]), 500mls of blood in the suction bottle and an unknown amount in the towels and drapes (which he estimated as being greater than 300mls[790]). Dr. Taylor has several estimates for the total blood loss including 1128mls[791], 1211mls[792], "*>1211mls*"[793] and 1411mls[794].

412. Mr. Keane disagrees, stating that "*there was no major bleeding in Adam's case*"[795] as no more than two units were used to replace blood loss. In addition, "*the blood loss of 1200cc*" was not all blood but contained approximately 600mls of urine, peritoneal dialysis fluid and slushed ice

783 Ref: 200-022-271
784 Ref: 200-022-271
785 Ref: 011-014-100, WS-008-3, p.29
786 Ref: 093-038-187
787 Ref: 011-014-096
788 Ref: 011-014-101
789 Ref: WS-008-1, p.5
790 Ref: WS-008-3, p.18
791 Ref: 011-014-097
792 Ref: WS-008-5, p.2
793 Ref: 011-014-101
794 Ref: WS-008-1, p.7
795 Ref: WS-006-2, p.14

used to cool the kidney until the vascular anastomoses were complete.[796] He also states that Adam received between 250 and 350mls of blood,[797] not 500mls as stated by Dr. Taylor.

413. Dr. Haynes, having examined the records and the statements of Dr. Taylor and Mr Keane, suggests the blood loss was somewhere in between 528 and 1128ml, most probably 750-1000 mls, although he concedes that this "*remains an estimate, little better than an informed guess*".[798]

CVP

414. Central venous pressure is a measure of the pressure of blood in one of the main veins draining into the heart and offers a guide to the amount of blood returning to the heart and the ability of the heart to pump that blood out into the arterial system. It is affected by various events, including whether or not the circulation needs more fluid in it for the heart to pump blood effectively or the opposite, whether the circulation is overloaded, so putting a strain on the heart. Dr. Haynes has commented that "*a continuous display of central venous pressure would be required in a patient such as Adam*".[799] The Legal Team has provided a photograph of a monitor to indicate the continuous display.[800] This shows neither the actual monitor used in Adam's case nor even the particular model but it is provided simply for illustrative purposes. The Legal Team has also provided a diagram to explain CVP waveform or 'trace'.[801]

415. Central Venous Pressure (CVP) recording was commenced at just prior to 08:00 with a reading of 17mmHg. It rose to over 20mmHg by 09:00 and reached 30mmHg about 10:00, which can be seen from the monitor printouts of his surgery.[802] It can also be seen from the monitor printout of when he was in PICU[803] and the Intensive Care Unit Daily Record Sheet [804] that Adam's central venous pressure fell to about 11mmHg on his transfer to PICU at about noon and did not rise to beyond about 14mmHg on 27th November 1995.

796 Ref: WS-006-2, p.10
797 Ref: WS-006-2, p.14
798 Ref: 204-006-337
799 Ref: 204-002-030
800 Ref: 300-036-054
801 Ref: 300-035-053
802 Ref: 094-192-908
803 Ref: 058-008-022
804 Ref: 057-008-010

416. It should be noted that those printouts do not show the 'real-time' CVP readings, but instead a compressed version of them to produce a graph of the average CVP readings over the period of his surgery.

417. Dr. Taylor stated in his Deposition to the Coroner that: *"there were both cardiac and respiratory patterns to the waveform confirming correct intravascular placement."*[805]

418. Mr. Wilson describes that printout in his PSNI Statement of 24th April 2006:[806] *"I note that the calibration is checked within 15 minutes, again at 0900 hours, again at 0915 hours and again at 1000 hours. In the latter two cases, more time was taken in checking the calibration. I note in each case the trace returned to its previous reading and between calibrations the nature of the trace is as I would expect to see from a functioning transducer, although the levels which I see is[sic] elevated. I also note that the CVP trace rises in correspondence with a rise in the main arterial pressure. I see no evidence that the transducer was faulty."* [807]

419. Dr. Haynes comments at the Meeting of Experts on 9th March 2012 that in his opinion and contrary to Dr. Taylor's view: "*there never was a proper venous wave form during the operation obtained through that central venous line*".[808] He reiterates that view in his Report of 18th March 2012 where he discusses in more detail the issues of the CVP waveform and the recorded CVP values.[809]

420. Dr. Coulthard states in his Report of 4th August 2010 that: *"if respiratory pressure waves were registered on the CVP trace, either due to respiratory movements or chest compression, then the CVP should be assumed to be correctly reading. I would consider that if there was doubt about the validity of the CVP trace this problem should have been solved at the time because of the great importance of the values in directing safe management. I cannot accept that that it is good practice to assume that a monitoring system is not working, and to make clinical decision s that appear to conflict with its read-outs".*[810]

421. There is an issue to be addressed during the Oral Hearing as to the nature of the 'waveform' pattern produced during the transplant procedure and its significance if any for the monitoring and management of Adam's fluid balance.

805 Ref: 011-014-099
806 Ref: 093-027-071
807 Ref: 093-027-072
808 Ref: 307-008-180
809 Ref: 204-012-382 *et seq*
810 Ref: 200-002-055

422. Dr. Taylor's fundamental position in respect of the CVP values that were being displayed on the monitor was that they were in accurate because the CVP catheter was in the wrong place, namely as he states in his Deposition to the Coroner of 21st June 1996: *"not in close relation to the heart"*.[811] He goes on to describe the CVP in his PSNI Statement under caution of 17th October 2006 as *"measuring a dead end road"*.[812] He confirms in that Statement that he nonetheless regarded the values of, for example, 17mmHg and 21mmHg as accurate figures *"at the end of the catheter"* just not reflective of the Adam's central venous pressure.[813]

423. Dr. Taylor goes on to say in his Inquiry Witness Statement of 3rd October 2011 that he examined the dynamic trace and it was non-pulsatile which: *"confirmed [his] clinical findings that the tip had gone into neck"*.[814] Therefore, he states that he accepted the 17mmHg as a marker to look for relative change rather than an absolute measure.[815] He confirms in his PSNI Statement of 17th October 2006 that such a use would enable him to increase the CVP by: *"5 to 10 centimetres above the initial level to ensure adequate blood flow to the new or donor kidney"*.[816]

424. He expands upon the use that might still be made of the CVP readings in his Inquiry Witness Statement of 3rd October 2011: *"The reading was higher then expected because it was obstructed. However it was still in a central vein and changes in his circulating blood volume would be reflected in changes to this pressure. Thus a relative increase in his circulating blood volume would lead to an increase in the CVP relative to the initial level."*[817] Furthermore, and due to its 'unreliability', Dr. Taylor explained in that Statement that other measurements such as heart rate and blood pressure were taken into consideration when deciding whether Adam was hypervolaemic.[818]

425. During the course of the Meeting of Experts on 9th March 2012 Dr. Haynes stated that the CVP values were: *"of no real guidance and it should have been recognised that they could not possibly have been correct in the circumstance"*.[819] He reiterates that in his Report of 18th March 2012: *"I am absolutely certain that the CVP reading obtained during Adam's transplant operation could not be relied on either as an absolute number or as a trend monitor"*.[820]

811 Ref: 011-014-099
812 Ref: 093-038-215 and Ref: 093-038-212
813 Ref: 093-038-211
814 Ref: WS-008-3, p.13
815 Ref: WS-008-1, p.5
816 Ref: 093-038-128
817 Ref: WS-008-3, p.13
818 Ref: WS-008-3, p.14
819 Ref: 307-008-180
820 Ref: 204-013-395

426. During the course of the Meeting of Experts on 9th March 2012, Dr. Coulthard agrees with Dr. Haynes' *"speculation that CVP as high as Adam had at the onset of surgery, or had recorded as the onset of surgery, is not at all compatible with what we think his physical state was at that time. To me it seems that the most likely … problem [is] there is an error"*.[821] He goes on to conclude that *"the most likely error is one of zeroing"*.[822]

427. Dr. Coulthard has since stated in his recent Report of 17th March 2012 that he believes: *"the CVP readings were all about 8-10mmHg too high in theatre, due to a zeroing mistake … If Dr. Taylor had taken the time to zero the CVP properly, he wouldf have had a reliable measure of Adam's vascular fullness and would thus have been alerted to the fact tha he did not need any more extra fluid"*.[823]

428. Dr. Coulthard also expresses the view in his Report of 16th February 2012 that if the CVP catheter was lodged into a vein and obstructed (ie in the dead end road referred to by Dr. Taylor) then he would expect the Anaesthetist to: *"insert his central line elsewhere, such as into the inferior vena cava through one of [Adam's] femoral veins"*.[824] Although, he recognises that would need to be: *"discussed with the transplant surgeons, as it would be ideal if the femoral vein was used on the opposite side to the planned kidney insertion"*.[825]

429. Professor Gross also comments on the CVP readings in his Report of 2nd January 2011 in which he states: *"Assuming that the catheter might have travelled in a retrograde fashion by perhaps 3cm this alone would however not explain a high reading such as 17mmHg"*.[826] He refers to Professor Von Kummer, Professor of Diagnostic Radiology/Neuroradiology and Chief of the Department of Neuroradiology at the University of Dresden,[827] who he states has: *"suggested that he could not think of a venous obstruction between the tip of the catheter and the heart that would have increased the CVP artificially to 17mmHg"*.[828]

430. The Legal Team has provided a diagram of the general area to assist in appreciating the option suggested by Dr. Coulthard[829] and The Inquiry's

821 Ref: 307-008-182
822 Ref: 307-008-182
823 Ref: 200-022-267
824 Ref: 200-013-182
825 Ref: 200-013-182
826 Ref: 201-004-137
827 See his short form curriculum vitae - Ref: 201-003-091
828 Ref: 201-004-137
829 Ref: 300-028-046

Experts Messrs. Forsythe and Rigg have also provided a 'close up' diagram.[830]

431. There are issues to be addressed during the Oral Hearing in relation to the CVP including:

(i) What the CVP catheter was measuring over the course of Adam's transplant surgery

(ii) The use that might properly have been made of the CVP readings during the course of Adam's transplant surgery

(iii) Whether Dr. Taylor should have continued on with a CVP that he did not consider to be providing correct readings

(iv) Whether Dr. Taylor should have relied upon or otherwise reacted to the CVP readings that he received, and if he should have reacted otherwise then what that might have involved

432. Dr Taylor also stated in his deposition to the Coroner that there was a "*sudden increase in CVP to 28mmHg when the table was raised 5-6 inches for surgical reasons.*"[831]

433. The issue of raising the surgical table on CVP, who requested it and why, together with what consideration if any should have been given to its possible implications, will be addressed at the Oral Hearing.

434. Mr. Keane has no recollection of being made aware of any problems with the CVP.[832] He has stated that: **"***central venous pressure (CVP) was the most important parameter I would rely on. I would want his CVP to be 10-12 when the clamps came off*".[833] He also claims not to have been aware that the CVP was recorded as being 17mmHg at the start of surgery. He expresses the view that such a value could be attributed to misplacement, kinking of the line or over-hydration and states that if he had been aware of the 17mmHg: *"I would have asked the Anaesthetist to ensure the CVP reading was truly 17. It is normal to subtract 5 from the reading in a ventilated patient. If it was truly 17 then seek medical input (from Savage). I would have checked the position and flow in the line and, if this was a true reading, restricted Adam's fluids and considered giving a diuretic"*.[834]

830 Ref: 300-070-133
831 Ref: 011-014-100
832 Ref: 093-010-030
833 Ref: WS-006-3, p.13
834 Ref: WS-006-3, p.14

435. There is therefore an issue to be addressed at the Oral Hearing as to whether Mr. Keane cold or should have known Adam's CVP was registering at levels of 17mmHg, over 20mmHg and as high as 30mmHg.

436. Dr. O'Connor claims that she discussed the CVP with Dr. Taylor as she *"had noted a high reading of 30 mmHg perioperatively"* and he informed her that *"the reading had been 17 mmHg at the time of the insertion of the line"* and that as *"this was clinically unlikely in a child who had received overnight dialysis he had presumed the reading to be inaccurate"*.[835] Dr. O'Connor formed the view that due to the *"high initial CVP the accuracy of recordings was uncertain … I assumed that he [Adam] may have had one of his external jugular veins tied off as this was common practice at the time of insertion of central lines in RBHSC in 1995"*.[836]

437. She expands upon that a little in her subsequent Inquiry Witness Statement of 22nd September 2011: *"I noted that the CVP reading was 30mmHg and expressed my concern about this to Dr. Taylor. He informed me that the CVP line had been difficult to insert and that the recording had been 17mmoHg at the time of the insertion of the line as this was clinically unlikely in a child who had received overnight dialysis and who had not received his full normal quota of fluids, I understood that he presumed the reading to be inaccurate as the line could be malpositioned."*[837]

438. Whether Dr. O'Connor dealt appropriately with the issue of the CVP reading being high, and whether she said or should have said anything about this to Mr. Keane, Dr. Taylor or to both of them, is a matter that will be pursued at the Oral Hearing.

Blood Gas Result at 09:32

439. Dr. Taylor sent a blood sample to be analysed at the blood gas machine located nearby in PICU. He gives his reason for doing so in his Inquiry Witness Statement of 28th September 2011 as: *"to assess his [Adam's] pH, pO_2 and haematocrit"*.[838] He received the results of a blood gas analysis on Adam at 09:32, which showed haematocrit of 18% and a sodium level of 123mmol/L.[839]

440. Dr. Taylor states in his Inquiry Witness Statement of 3rd October 2011 that he had been told that the blood gas machine did not produce reliable results for serum electrolytes, mainly because the dilutional effect of

835 Ref: Ws-014-2, p.8
836 Ref: WS-014-1 p.2
837 Ref: WS-014-3, p.5
838 Ref: WS-008-3, p.33
839 Ref: 058-003-003

adding liquid heparin to the syringe would tend to produce artefactually low serum electrolyte concentrations.[840]

441. The Inquiry obtained a Witness Statement dated 8th September 2011 from David Wheeler from Instrumentation Laboratories, the manufacturers of the blood gas analyser used in Adam's case. He states that although they do not recommend sodium heparin for use as an anticoagulant: *"because doing so will increase sodium levels by 1 to 3mmol/L even in the presence of the correct proportion of heparin and blood"*.[841]

442. Dr. Haynes disagrees with Dr. Taylor stating in his Report of 2nd August 2011 that the measurement should have been believed and steps taken to correct the abnormality as well as any cerebral oedema that may have ensued as a result.[842] He also states that he would have considered ceasing immediately the administration of any intravenous fluid containing less than 131mmol/L of sodium and would have given a dose of 0.5g/kg of Mannitol.[843] In addition, Dr. Haynes states that he would have considered administering hypertonic saline solution, *"typically as 3% solution"*.[844] He was of the view that: *"frequent blood samples would be required to monitor the corrective progress"*.[845]

443. Dr. Coulthard calculates in his Report of 4th August 2010 that the *"plasma sodium reading of 123mmol/L measured then is likely to be correct"*[846] and he states in his Report of 4th December 2010 that it should have initiated an urgent serum sodium measurement from the hospital laboratory.[847] He reiterates that view in his Report of 16th February 2012.[848]

444. Accordingly, the following issues will be pursued in the Oral Hearing:

(i) Whether Dr. Taylor had been told that the serum sodium result from the Blood Gas Analyser should not be relied upon and if so in what circumstances

(ii) Irrespective of what he had been told, whether the blood gas sodium result should have been relied upon by Dr. Taylor and the other members of the Transplant team and for what purpose

840 Ref: WS-008-3, p.15
841 Ref: WS-180-1, p.3
842 Ref: 204-002-033 and Ref: 204-002-034
843 Ref: 204-002-034
844 Ref: 204-002-034
845 Ref: 204-002-034
846 Ref: 200-002-053
847 Ref: 200-004-085
848 Ref: 200-013-181

(iii) How Dr. Taylor and the other members of the Transplant team should have reacted to that result in terms of their treatment and management of Adam during the peri-operative stage

Physical Appearance

445. At the end of the transplant surgery, Dr. Taylor stated that he noticed that Adam's face, hands and feet were swollen when the sterile towels were removed[849]. Professor Gross has suggested that Adam may perhaps have been "*fluid overloaded to such a degree that he manifested edema of the skin as a sign of increased extracellular fluid*".[850] In addition, Dr. Haynes, on seeing the photographs taken of Adam on 28th November 1995 in PICU[851], comments that these photographs, in his opinion, showed "*very marked swelling*" of Adam's head and arms.[852]

446. The significance of Adam's appearance is an issue that will be considered during the Oral Hearing.

Conduct of the Transplant Surgery

447. As you are aware Mr. Chairman, the Surgical team for Adam's transplant surgery comprised Mr. Keane as a Consultant Urologist and Mr. Brown as a Consultant Paediatric Surgeon to assist him.

448. Mr. Keane sets out the steps in the transplant surgery in his Inquiry Witness Statement of 16th March 2011 as being:[853]

(i) Incision, identification and exposure of the vessels which are to be used and the approach to same

(ii) Isolation of the vessels in preparation for clamping

(iii) Cleaning and preparation of the donor kidney

(iv) Vascular and ureteric anastomoses

(v) Wound closure

849 Ref: WS-008-2, p.45
850 Ref: 201-004-143
851 Ref: 093-005-008
852 Ref: 204-006-333
853 Ref: WS-006-2, p.5

Timing of the Surgery

449. It is not entirely clear when the actual transplant surgery, 'knife to skin', commenced. The time is not recorded in Adam's medical notes and records and only appears by way of the statements of those involved, principally Mr. Keane.

450. In his Deposition to the Coroner on 18th June 1996, Mr. Keane states that: *"The operation started at 7:30am"*.[854] However, in response to questions during the Inquest he states that: *"The operation would have started between 7.15 and 8.00am"*.[855] Subsequently, he states in his Inquiry Witness Statement of 16th March 2011 that the surgery 'knife to skin' started at: *"Approximately 7.15am"*.[856] When pressed to explain the basis of that time he states in his subsequent Inquiry Witness Statement of 20th September 2011 that: *"Having reflected on this and considering the evidence, it would now appear that the surgery started at around 8.00am"*.[857]

451. The position on timing is made even less clear when in that Inquiry Witness Statement of 20th September 2011, he deals with the times that 'steps in the procedure' were taken, stating that between approximately 07:00 and 08:00 on 27th November 1995 he: *"would have scrubbed and prepared the kidney"*[858] but then states that: *"The surgery started at approximately 8.00am. I made an incision in the right iliac fossa and opened the peritoneum"*.[859]

452. The timing issues in relation to the preparation of the donor kidney and the actual start of the surgery 'knife to skin', are matters that will be addressed further during the Oral Hearing.

Condition of the Kidney and Ischaemic Time

453. The significance of the preparation time is its contribution to what I have previously referred to as the 'warm ischaemic time'. Mr. Keane describes in his Inquiry Witness Statement of 20th September 2011 what he did by way of preparing the donor kidney and states that it would have taken *"several minutes"*:[860]

(i) Excising the perinephic fat

854 Ref: 011-013-093
855 Ref: 011-013-093
856 Ref: WS-006-2, p.10
857 Ref: WS-006-3, p.12
858 Ref: WS-006-3, p.6
859 Ref: WS-006-3, p.6
860 Ref: WS-006-3, p.7

(ii) Clearing the artery and vein of all adventitia

(iii) Joining the two arteries on a single patch

454. The Legal Team has provided photographs showing: (a) the transportation box for a donor kidney;[861] (b) the donor kidney in its bag being removed from the container;[862] and (c) the surgeon preparing the donor kidney for transplant,[863] cleaning and testing it.[864] In the latter photograph it can be seen that the donor kidney has two arteries, which the surgeon is working on. None of these photographs relate to Adam or his transplant surgery, they are provided simply for illustrative purposes.

455. Mr. Keane states in his Inquiry Witness Statement of 20th September 2011 that:

> *"The kidney is kept in swabs wrapped in slushed ice during the 'preparation' and returned to the ice water solution at the end of the preparation. I cannot state the time of the vascular anastomoses but the kidney is kept wrapped in ice soaked swabs during the time taken to perform the anastomoses. The true warm ischaemic time ie when the renal vein clamp is removed to removal of the arterial clamp was seconds as there was no need to reapply them"*.[865]

456. Messrs. Forsythe and Rigg describe the process in their joint Report of October 2011 explaining that the donor kidney is in a sterile bowl containing ice and cold fluid whilst the surgeon is working on it. They acknowledge that the time for the surgeon to inspect, trim, clean and separate the blood vessels varies and: *"will be longer when there is complex anatomy or there is damage to repair"*.[866] However, they state that: *"Typically [the preparation time] takes 20-30 minutes to do [and that] It is recognised good practice to do this before the patient is anaesthetised in case the kidney is unusable and the transplant cannot proceed"*.[867]

457. As you know Mr. Chairman the UKSSTA Transplant Form shows that the donor kidney had:[868]

(i) Two arteries

(ii) Three arteries on patches

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861 Ref: 300-041-059
862 Ref: 300-042-060 and Ref: 300-043-061
863 Ref: 300-044-062
864 Ref: 300-045-063
865 Ref: WS-006-3, p.7
866 Ref: 2003-004-065
867 Ref: 2003-004-065
868 Ref: 058-009-027

(iii) One branch tied

(iv) *"?Third artery tied off + cut off patch"*

458. The fact that the donor kidney actually had three arteries, one of which is queried as *"?Third artery tied off + cut off patch"* is something that has only recently come to light in correspondence from DLS dated 10th February 2012 and with the provision of a clearer copy of the relevant page of the UKSSTA Transplant Form.[869] As previously mentioned, the Inquiry's Experts Messrs. Forsythe and Rigg have confirmed to the Inquiry that this: "*does not change the facts of our report, but re-emphasizes the need for the surgeon to have been involved in the decision to accept the kidney and the need to inspect the kidney and to do the benchwork before the patient was anaesthetised."*[870]

459. The likely effect, if any, of those features of the donor kidney on its 'preparation time' is something that will be addressed during the Oral Hearing.

460. The Legal Team has also provided photographs showing the process of anastomoses referred to by Mr. Keane, namely: (a) donor kidney about to be transplanted;[871] (b) donor kidney held in a swab and being sutured in place;[872] and (c) attached donor kidney with blood beginning to flow as shown by the 'pinked up' areas.[873] Once again, none of the photographs relate to Adam or his transplant surgery but are for illustrative purposes only.

461. Messrs. Forsythe and Rigg also address in their joint Report of October 2011 the issue of the 'warm ischaemic time' of the donor kidney and the views expressed by Mr. Keane in respect of it:

869 Ref: 058-009-027 and correspondence from the DLS to the Inquiry dated 10th February 2012 – Ref: 301-121-656
870 Ref: 203-009-111
871 Ref: 300-050-068
872 Ref: 300-051-069 and Ref: 300-052-070
873 Ref: 300-053-071

"The first period of warm ischaemic time occurs at the time of organ retrieval and is the time from when circulation to the kidney stops until the kidneys are cooled by the instillation of cold perfusion fluid … it was zero minutes for Adam's donor. The second warm ischaemic time starts from when the kidney is removed from the cold and finishes when the recipient blood is perfused into the kidney."[874]

462. They go on to deal with the 'anastomosis time', which they state is the same as the second warm ischaemic time, and to address in particular the extent to which the donor kidney may become 'warmed up' during anastomosis:

"It begins when the kidney is removed from the cold and ends when the recipient's blood is perfused into the kidney. During this time the assistant surgeon holds the kidney in a manner which facilitates the operating surgeon in performing the anastomosis (the join between the vein of the kidney and the veins of the recipient plus the artery of the kidney and the artery of the recipient). Because of this position the kidney is in direct contact with both the recipient and also the gloved fingers of the surgeon. These two forms of contact, the ambient temperature and the energy of the strong operating lights[875] *mean that the kidney gradually warms, rising to a core temperature above 10°C at approximately 20 minutes".*[876]

463. In their joint Report of June 2011 Messrs. Forsythe and Rigg state that: *"The anastomosis time will usually be under 30-40 minutes and in our combined experience a time over 60 minutes would be exceptional and be due to intra-operative technical difficulties".*[877] Their view echoes that of Mr. Koffman who states in his Report of 5th July 2006 for the PSNI that: *"anastomosis times may vary from approximately 20 minutes to 60 minutes in the case of a difficult anastomosis".*[878]

464. Messrs. Forsythe and Rigg go on in their joint Report of June 2011 to state that: *"Two hours of warm ischaemic time is very likely to cause irrevocable damage to a kidney".*[879] In fact the UKTSSA Transplant Form records the donor kidney as having been removed from the ice in Belfast at 08:30 on 27th November 1995 and perfused with Adam's blood at 10:30[880] which, according to Messrs. Forsythe and Rigg, means that the warm ischaemic of the donor kidney or the anastomoses time was two hours.

874 Ref: 203-004-061
875 See for example the photograph at Ref: 300-049-067
876 Ref: 203-004-064
877 Ref: 203-002-028
878 Ref: 094-007-035
879 Ref: 203-002-030
880 Ref: 058-009-027

465. The length of the warm ischaemic or anastomoses time is something that will be pursued further in the Oral Hearing. So too will the question of what effect, if any, that time is likely to have had on the condition of the donor kidney at or after its transplantation.

Surgical Approach

466. As to the actual method of anastomoses used, Mr. Keane's approach was to join the renal vein of the donor kidney to Adam's external iliac vein and the two renal arteries of the donor kidney on a common patch to Adam's iliac artery.[881] Messrs. Forsythe and Rigg have provided with their joint Report of October 2011 a diagrammatic representation of Mr. Keane's approach as Figure 2B.[882] As can be seen the external iliac artery that was used by Mr. Keane is a considerably narrower vessel than either the common iliac artery or the aorta. Similarly the external iliac vein that he used is considerably narrower that either the common iliac vein or the inferior vena cava.

467. Mr. Keane explains in his Inquiry Witness Statement of 20th September 2011 that:

"I considered using aorta common iliac but it was my judgment that Adam's iliac vessels were satisfactory in calibre. No surgical complication occurred …

I considered the common iliac and vena cava but my judgment was that the external iliac vein was suitable. No surgical complication occurred."[883]

468. Mr. Koffman considered Mr. Keane's approach in his report for the PSNI of 5th July 2006:

"… the major decision would have been about whether to anastomoses the transplant renal vessels (artery and vein) to the iliac vessels as in adults or because of Adam's small size to choose larger blood vessels such as the aorta and vena cava for these anastomoses which would entail a different approach. In the event they chose to use the iliac vessels and although this is not the approach I would use normally for a 4 year old, 20 kg, it is used by some surgeons carrying out paediatric transplants. Therefore I would not criticise the use of this approach."[884]

469. He goes on to state: *"There were considerable difficulties experienced during this operation chiefly because of the previous surgery but also partly because of*

881 Ref: 059-006-012 and Ref: WS-006-1, p.3
882 Ref: 203-004-083
883 Ref: WS-006-3, p.26
884 Ref: 094-007-032

Adam's age and weight. It is impossible to ascertain from the operation note whether the anastomoses were performed in a technically sound way."[885] The significance of the anastomoses is explained by his comment: *"The likelihood is that the kidney was viable at the time of implantation into Adam but there was a subsequent thrombosis of the artery or the vein either due to technical factors or due to low blood flow secondary to acute tubular necrosis or due to some hypercoagulable."*[886] Mr. Koffman reiterates those comments in a letter dated 7th July 2010 that he provided to the Inquiry:

"I cannot be certain that there was not a technical error in the performance of the arterial or venous anastomosis, or in the positioning of the kidney before closure."[887]

470. Messrs. Forsythe and Rigg take a rather different view in their joint Report of June 2011, for whilst they agree with Mr. Koffman that they would not have performed the anastomoses in the way that Mr. Keane did, they disagree that it was nonetheless an acceptable method in view of Adam's size and the effectively adult-size of the donor kidney being transplanted:

"Children under 5 years of age or under 20kg do require special consideration in terms of surgical approach. The surgical approach would usually be an extraperitoneal approach in the right iliac fossa, with a view to using the common iliac artery or the aorta (main artery of the abdomen) for the arterial anastomosis; and the common iliac vein or inferior vena cava (the larger veins) for the venous anastomosis …

… in a young child aged 5 years of age it is unacceptable to use the external iliac artery. This would significantly increase the chance of renal artery thrombosis and loss of the kidney. Conventional practice both in 1995 and now would be to use the larger common iliac artery or aorta."[888]

471. Furthermore, they state in their joint Report of October 2011 that Mr. Keane's reference to Adam's iliac vessals being of satisfactory calibre is in appropriate as: *"a normal calibre external iliac artery is not suitable to use in a five year old child"*.[889]

472. <u>As has I have stated earlier Mr. Chairman, none of the Experts have stated that the infarction of the kidney contributed to Adam's death. Nevertheless Professor Gross states in his Report of 2nd January 2011:</u>

885 Ref: 094-007-034
886 Ref: 094-007-037
887 Ref: 205-002-010
888 Ref: 203-002-038
889 Ref: 203-004-075

"The malfunctioning transplant in itself did not contribute to Adam's hyponatraemia, since it was the renal failure of his native kidneys that prevented excretion of major amounts of free water. However if the transplant functioned well, it is likely that it would have begun to excrete free water, which could have reduced the degree of hyponatraemia in Adam."[890]

473. There are therefore issues which will be addressed in the Oral Hearing as to the way in which the anastomoses was carried out, the adequacy of the justification for the method adopted and the possible consequences for the viability of the donor kidney.

Communication between the Anaesthetic and Surgical Teams

474. There is also an important issue to be addressed during the Oral Hearing in terms of the adequacy of the communication between the Anaesthetic and Surgical teams. A number of the experts identify its importance for a successful procedure. However, a real query has been raised by some of the experts over whether the two teams communicated appropriately with each other over the course of the transplant surgery and if they did not do so then what effect, if any, that had. See for example, Dr. Haynes' comments in his Reports of 7th October 2011 and of 1st November 2011:

"Communication between surgeon and anaesthetist, especially with regard to the volume of blood loss during the operation does not appear to have been good."[891]

"My overall impression is that there appears to have been a failure of the senior clinicians involved in Adam's transplant operation to work effectively as a team."[892]

"Reading and re-reading the various witness statements does not reassure me that surgeon and anaesthetist were working effectively together as a team, communicating well with each other."[893]

475. The differences amongst the members of the Transplant team will be pursued during the Oral Hearing.

Role of the Nephrologists during Surgery

476. The role performed by Nephrologists during surgery is also an issue to be considered during the Oral Hearings.

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890 Ref: 201-004-142
891 Ref: 204-004-162
892 Ref: 204-004-162
893 Ref: 204-006-334

477. Dr Savage states that it was his "*habit*" to "*observe the procedure intermittently and always be present close to the theatre for consultation should information be required by the transplantation team.*"[894] He states that he *"would have been changed into theatre scrubs but would not have been gowned as an observer"*.[895] He states he left around 09.00 to undertake some duties in his role as Senior Lecturer, Queen's University, Belfast. [896]

478. Dr O'Connor states that Adam's surgery was in progress when she arrived that morning and made herself available to attend to Adam's post-operative care[897]. She states that she was present in theatre towards the end of the operation, and also that she went into theatre on several occasions as she was keen to know how quickly the operation was progressing.[898]

479. Dr. Coulthard considered this in his Report to the Inquiry dated 7th November 2011. In that Report he described Consultant Paediatric Nephrologists as the *"main medical carers"*[899] for children with end stage renal failure. He further states, in respect of their presence in the theatre during surgery, that the Consultant Paediatric Nephrologist should *"visit the operating theatre intermittently during a child's transplantation whenever this is practical"* but that this *"does not constitute a formal part of the paediatric nephrologist's role; it is more a 'social' aspect of providing holistic care to these children and their families"*.[900]

480. The issue of the role of the Nephrologist in the Operating Theatre whilst the transplant surgery is ongoing is something that will be addressed further during the Oral Hearings.

End of the Transplant Surgery

481. Turning now to the issues that arise in relation to the end of the transplant surgery. Just as the time of Mr. Keane actually commencing the surgery 'knife to skin' is not recorded in Adam's medical notes and records, so the time of his departure from the Operating Theatre and the time of the closure of the wound signalling the end of the operation, are not recorded there. So although the Anaesthetic record ends at 11:00[901] with Dr. Taylor administering Neostigmine and Glycopyrrolate to reverse the

894 Ref: WS-002-2, p.22
895 Ref: WS-002-2, p.22
896 Ref: WS-002-2, p.22
897 Ref: WS-014-1, p.2
898 Ref: WS-014-2, p.5
899 Ref: 200-007-111
900 Ref:200-007-117
901 Ref: 058-003-005

neuromuscular blockade[902] and Adam's medical notes record that he was admitted to PICU at 12:05,[903] we are nonetheless dependent upon the statements of those who were directly involved for the actual time of Mr. Keane's departure and the end of the surgery.

482. There is no reference in Mr. Keane's Deposition and evidence to the Coroner on 18th June 1996 of him not staying until the end of the transplant surgery or of Mr. Brown fulfilling any particular task in relation to Adam's surgery. However, Mr. Keane states in his Inquiry Witness Statement of 20th June 2005 that he left *"10 minutes prior to the end of the anaesthesia"* to attend to an emergency leaving Mr. Brown to close the wound.[904] Mr. Brown provided a report to the Coroner dated 20th December 1995 but it makes no reference to him closing the wound or to Mr. Keane leaving before the end of the transplant surgery.[905] Indeed he refers to it in less than categorical terms in his PSNI Statement of 4th September 2006: *"It would appear to be the case that Mr. Keane left myself to sew up the wound. I do not have any recollection of the end of the operation or the anaesthetist trying to bring Adam round"*.[906]

483. Subsequently in his Inquiry Witness Statement of 16th March 2011, Mr. Keane puts the time that he left the Operating Theatre at: *"approximately 10-30am"*.[907] He claims that at that stage there was: *"pulsatile flow in the artery, the ureter had been connected successfully and the kidney was reasonably well perfused"*.[908] However earlier, in his Deposition to the Coroner, he stated: *"At the end of the procedure it was obvious that the kidney was not perfusing as well as it had done"*.[909]

484. The views of the other witnesses are not entirely consistent on the condition of the donor kidney. For example, Dr. O'Connor has recorded in Adam's medical notes and records that: *"Kidney – looked 'bluish' at end of theatre"*.[910] SN Popplestone who was in the Operating Theatre as the scrub nurse states in her PSNI Statement of 31st January 2006 that: *"I also recall the surgeons discussing possible discolouration of the kidney at the time of transplant. This concern appeared to subside as the operation progressed"*.[911] Whilst Mr. Brown states in his PSNI Statement of 4th September 2006:

902 Ref: 058-003-005
903 Ref: 059-006-013
904 Ref: WS-006-1, p.3
905 Ref: 059-060-146
906 Ref: 093-011-032
907 Ref: WS-006-2, p.7
908 Ref: WS-006-2, p.7
909 Ref: 011-013-093
910 Ref: 059-006-014
911 Ref: 093-012-040

"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".[912] Dr Taylor commented in his deposition to the Coroner that the donor kidney at around 10am "*was not looking good*" and not producing urine.[913]

485. Furthermore, although Mr. Keane states in his Inquiry Witness Statement of 16th March 2011 that: *"A minute or so after completion of the vascular anastomoses. A few drops [of urine were produced"*.[914] Mr. Brown has never been of that view. In his first statement, which appears to have been his report to the Coroner dated 20th December 1995, he states: *"The profusion[sic] of the kidney was satisfactory, although at no stage did it produce any urine"*.[915] He repeats that in his PSNI statement of 4th September 2006.[916]

486. It seems that the pressure for Mr. Keane to leave the Operating Theatre was, as he explains in his Inquiry Witness Statement of 16th March 2011, a telephone call from the Belfast City Hospital that: *"a patient who was undergoing a percutaneous nephrolithotomy, was bleeding heavily in the operating theatre there and they needed help urgently."*[917]

487. However Ms. Donaghy, the Transplant Coordinator, states in her PSNI Statement of 28th April 2006 that she went into the Operating Theatre at the end having spoken with SN Clingham (now Sharratt) who told her that Adam might be brain stem dead and was still in the Operating Theatre. She describes the mood as very sombre and believed that the surgeons were still at the table although she did not know what stage they were at or what time it was.[918] However, SN Clingham claims in her PSNI Statement of 4th September 2006 that: *"I do not recall any conversations in respect of the progress of the operation during the surgery"*.[919] Nevertheless Ms. Donaghy made a further Statement to the PSNI on 21st June 2006 in which she is very clear:

"I can only say that I remember Patrick Keane (surgeon) being at the table. There was another surgeon, however, I do not recall who it was. There were other staff present in the operating theatre; however I do not recall who they were. I remember when I was in the theatre wondering why they were continuing with

912 Ref: 093-011-032
913 Ref: 011-014-101
914 Ref: WS-006-2, p.11
915 Ref: 059-060-146
916 Ref: 093-011-032
917 Ref: WS-006-2, p.7
918 Ref: 093-015-048
919 Ref: 093-017-051

the procedure if the child was supposed to be brain stem dead; however, I would not be able to say what part of the procedure they were at".[920]

488. Ms. Donaghy's Inquiry Witness Statements are in the same vein. For example, in the one dated 22nd September 2011 she states in respect of her entry into the Operating Theatre that she remembers: "*two surgeons standing at opposite sides of the operating table. There was an anaesthetist and nursing staff in theatre*".[921]

489. The narrative of what actually happened will be further explored during the Oral Hearing. So too will be the issue of the condition of the donor kidney, particularly in view of the Report of Professor Berry for the Coroner dated 23rd March 1996 in which he states: "*The transplant kidney was infarcted (dead). The extent of the change suggested that this occurred at or before the time of transplantation*".[922] Also the Report of Professor Risdon for the PSNI dated 2nd June 2006 in which he states: "*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*".[923]

490. Messrs. Forsythe and Rigg state in their joint Report of June 2011 that: "*thrombosis of the kidney happened soon after implantation due to poor positioning of the kidney, the use of a smaller external iliac artery inflow or due to a surgical technical problem*".[924] The possible technical problems to which they refer are set out in their subsequent joint Report of October 2011.[925] Mr. Koffman expresses the view in his letter to the Inquiry dated 7th July 2010 that it is possible that there was a technical error in the "*positioning of the kidney before closure*".[926]

491. Mr. Brown claims in his Inquiry Witness Statement of 23rd September 2011 that: "*Wound closure has no influence on the position of the transplanted kidney*".[927]

492. The issue of the position of the transplanted kidney and the closure of the wound, including the fact that Mr. Brown, who had never previously been involved in a paediatric (or adult) renal transplant was left to do it, will be considered further during the Oral Hearing.

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920 Ref: 093-016-049
921 Ref: WS-100-3, p.2
922 Ref: 011-007-022
923 Ref: 093-031-083
924 Ref: 203-002-041
925 Ref: 203-004-076
926 Ref: 205-002-010
927 Ref: WS-007-3, p.6

493. It would seem that skin closure occurred at about 11:00. Over a further 30 to 40 minutes, Adam was prepared for transfer to PICU and unsuccessful attempts were made to waken him, largely by Dr. Taylor as Mr. Brown claims in his Inquiry Witness Statement of 25th March 2011 that he had already left[928]. Indeed the theatre log for the other Operating Theatre shows Mr. Brown was involved in surgery that started at 12:15 and finished at 12:50, with Dr. Campbell as the anaesthetist[929]. During that period and at about 11:30, blood was taken from Adam for laboratory testing. The results of this sample were not received until about 13:00,[930] when they showed that his serum sodium levels had fallen further to 119mmol/L.[931]

494. The turn around time on that sample in those circumstances is a matter that will be pursued during the Oral Hearing and from a governance perspective.

Record Keeping

495. Dr. Alexander in his report for the Coroner states that: "*Dr. Taylor is to be commended on the detailed notes and records he kept throughout the anaesthesia*".[932]

496. Messrs. Forsythe and Rigg in their joint Report of October 2011 refer to the operative record being brief and the key points being there.[933] Nonetheless, they go on to identify further information that should have been included in order to produce a "*complete record*" and these will be considered during the Oral Hearing: [934]

(i) Confirmation that an extraperitoneal approach had been used, and if so, whether had the peritoneum been breached

(ii) Further detail or a diagram in relation to the reference to "*Arteries on widely separated patch joined with 6/0 Prolene*"[935] as to how it was done as the note could be interpreted in a number of ways

(iii) Inclusion of time at the beginning and end of the anastomosis and ideally the cold ischaemic time - the single time of vascular anastomosis that is unsigned and not attributable is inadequate

928 Ref: WS-007/2, p.6
929 Ref: 094-006-023 and 024
930 Ref: 058-035-138
931 Ref: 058-040-186
932 Ref: 011-012-087
933 Ref: 203-004-078
934 Ref: 203-004-078
935 Ref: 059-006-012

(iv) Better comment on the perfusion of the kidney after the vascular clamps had been removed, the existing note simply states *"Kidney perfused reasonably at [illegible]"*[936]

(v) Post-operative management plan should have been included

497. Ms. Ramsay considers the peri-operative record keeping from the nursing point of view in her Report of 10th February 2011. She notes that Adam arrived in the operating theatre with no Care Plan.[937] Nevertheless she concludes that the Operating Theatre nursing records: *"are of an acceptable standard"*.[938]

498. The absence of a formal Care Plan will be addressed during the Oral Hearing, so too will the fact that the Anaesthetic Record (although possibly for the post-surgical period) was neither completed nor signed.[939] Ms. Ramsay notes in her Report of 21st June 2011 that it: *"was poor practice to fail to sign records"*.[940]

Keeping Adam's Family Informed

499. Adam's mother states in her Inquiry Witness Statement of 10th January 2012 that she left Adam in the Operating Theatre with Dr. Taylor at about 06:45[941] to wait in Musgrave Ward with her sister Glenda Thompson. As has been commented upon that time differs slightly from the times referred to by the clinicians and the start of the Anaesthetic Record. She further states that she was told that she would be kept informed about Adam by Dr. Savage and Dr. O'Connor. [942]

500. Adam's mother goes on to state in her Inquiry Witness Statement of 10th January 2012 that she was notified of Adam's progress on two occasions, at 09:30 by Dr. Savage who was leaving for other duties and at 10:30 by Dr. O'Connor.[943] In her first Inquiry Witness Statement, which was provided in 2005, Adam's mother states that: *"Dr. Savage and Dr. O'Connor were very good at keeping me informed of what they understood was happening in theatre. At 9.30am I was told things were progressing well and … that Mr. Brown was assisting Mr. Keane. Sometime after 10.00am I was told the operation was taking longer than expected because of Adam's previous surgery and because*

936 Ref: 059-006-013
937 Ref: 202-002-027
938 Ref: 202-002-021
939 Ref: 058-003-004
940 Ref: 202-004-071
941 Ref: WS-001-2, p.11
942 Ref: WS-001-2, p.12
943 Ref: WS-001-2, p.12

of Adam's weight. At around 12.00noon I was told Adam was out of theatre".[944] However, she also states that she was completely unaware, and by inference uninformed, of the dangers of fluid mismanagement until after Adam's death.

501. In her Inquiry Witness Statement of 10th January 2012, Adam's mother states that during her discussion with Dr. Savage at 09:30 she learned for the first time that Adam had received an epidural and: *"I was not happy because Adam had an epidural before and he had been in a lot of pain and I did not want this to happen again"*.[945] In addition she reiterates that Dr. Savage told her that all was well. In the same Inquiry Witness Statement she states that she was told that Adam's bladder was enlarged and that after the transplant he she would need to catheterise him several times a day.[946]

502. It seems that nothing was said to Adam's mother about his low serum sodium measurement at 09:32.

503. According to her Inquiry Witness Statement of 11th April 2011, Dr. O'Connor does not recall talking to Adam's mother at all.[947] Whilst according to his Inquiry Witness Statement of 14th April 2011, Dr. Savage does not believe that he was in the Operating Theatre at 09:32 or that he was aware of the serum sodium value of 123mmol/L.[948] Rather he thinks that he left when he handed over to Dr. O'Connor at about 09:00.[949]

504. An issue to be explored during the Oral Hearing is exactly when Dr. Savage and Dr. O'Connor knew about Adam's low serum sodium at 09:32. The question of whether Adam's mother should have been informed about it and, generally, the extent to which she was kept adequately informed about Adam's condition whilst he was in the Operating Theatre and the progress of his transplant surgery.

Response to Adam's Failure to Wake

505. Dr. O'Connor claims in her Inquiry Witness Statement of 19th July 2005 that she was present in the theatre towards the end of Adam's operation: *"I was aware that at the end of the surgery Dr. Taylor discovered Adam to have fixed, dilated pupils"*.[950] It seems that she had arrived at the Children

944 Ref: WS-00-1, p.4
945 Ref: WS-001-2, p.13
946 Ref: WS-001-2, p.13
947 Ref: WS-014-2, p.6
948 Ref: WS-002-2, p.3
949 Ref: WS-002-3, p.2
950 Ref: WS-014-1 p.2

Hospital at approximately 09:00 on 27th November 1995[951] and was asked by Dr. Savage to *"supervise post-operative care and fluid management for Adam"* as he intended to go to the University later that morning.[952]

506. Dr. David Hill states in his Inquiry Witness Statement of 12th October 2011[953] that in or around the same time he was assisting Dr. Rosalie Campbell, who was a locum consultant anaesthetist in the Children's Hospital, in a theatre adjacent to that in which Adam was being operated on. He states that at some point during the course of their theatre list Dr. Campbell *"left to assist Dr. Taylor because a patient, which I now understand to be Adam Strain, was slow to wake up"*.[954] While the theatre log records Dr. Campbell's attendance in the adjacent theatre throughout both the morning and afternoon lists, Dr. Campbell has said that she does not *"recall entering the theatre during his [Adam's] transplant"*[955] and that she has no recollection of *"being asked for or offering advice"*.[956]

507. The issues of whether Dr. Campbell left the Operating Theatre in which she was working to go and assist Dr. Taylor and if so in what circumstances and to what effect will be addressed during the Oral Hearing.

XIX. Issues to be addressed – Immediate Post-Operative Stage

Treatment following Surgery

508. Dr. O'Connor describes in her Inquiry Witness Statement of 19th July 2005 her role in PICU immediately following Adam's surgery as being *"to make a clinical assessment of his condition, to request any necessary investigations and to prescribe any necessary fluids and drugs"*.[957] It should be noted that Dr. O'Connor at this point also contacted Dr. Savage *"to inform him of the situation and he returned immediately from the University"*.[958]

509. Dr. O'Connor's notes from the time record that she first examined Adam at 12:05 on 27th November 1995[959] (following his transfer to PICU by Dr.

951 Ref: WS-014-2 p.4
952 Ref: WS-014-2 p.3
953 Ref: WS-181-1, p.1
954 Ref: WS-181-1 p.5
955 Ref: WS-117-2 p.4
956 Ref: WS-117-2 p.5
957 Ref: WS-014-1, p.2
958 Ref: WS-014-1, p.2
959 Ref: 058-035-135 to 137

Taylor[960]) and these confirm that *"he did not breathe following surgery and that his pupils were observed to be fixed and dilated"*.[961] On examination Dr. O'Connor noted haemorrhages on both his right and left fundi and that his disc margins were indistinct.[962] She also observed him to be *"puffy"*,[963] his CVP measurement to be *"11cm of water"*[964] and that there had been *"no recorded output to date from the transplanted kidney"*[965].

510. Dr. O'Connor's notes queried two causes for his neurological abnormalities: whether he had *"'coned' due to cerebral oedema"* and that *"he had high fluid intake and possible abnormal cerebral venous drainage"*.[966] Her immediate plan of action was to give Mannitol *"in an effort to decrease any possible cerebral oedema"*[967] and to *"restrict his fluid intake"*[968]. She is also noted as agreeing with Dr. Taylor's *"management of hyperventilation"*[969] and urgently requested urea and electrolyte profiles, and a neurology opinion.[970]

511. Dr. Haynes, in his Report dated 7th October 2011[971], provides comment on the use of Mannitol rather than hypertonic saline as a first-line therapy for hyponatraemia. He states that Mannitol is *"an osmotic agent"* and therefore a consequence of its administration is that water *"leaves swollen brain cells to enter the circulation"*.[972] He further states that he would *"be more likely to administer Mannitol as initial therapy"* if he *"suspected the presence of cerebral oedema in a patient- the urgency is to reduce potential injury to brain cells"*.[973]

Communications with Adam's Family

Adam's mother saw him for the first time since he had been anaesthetised at about 12:15 once he had been transferred from theatre directly to PICU, and she became immediately concerned *"how bloated he was"*.[974] She states in her Witness Statement to the Inquiry that *"this was something I had never seen following his previous operations but this did not appear to be an issue for*

960 Ref: WS-008-01, p.7
961 Ref: WS-014-1 p.3
962 Ref: WS-014-1 p.3
963 Ref: WS-014-1 p.3
964 Ref: WS-014-1 p.3
965 Ref: WS-014-1 p.3
966 Ref: WS-014-1 p.3
967 Ref: WS-014-1 p.3
968 Ref: WS-014-1 p.3
969 Ref: WS-014-1 p.3
970 Ref: 093-020-058
971 Ref: 204-004-159
972 Ref: 204-004-159
973 Ref: 204-004-159
974 Ref: WS-001-1 p.2

any of the hospital staff present".[975] It was at this stage that she was informed by Dr. Taylor that something was *"drastically wrong"* and that it was a *"one in a million thing"*.[976]

512. It was the view of Dr. O'Connor that as Dr. Savage knew the family well *"he was best placed to speak with them"*.[977] As soon as the situation became clearer Dr. Savage, accompanied by Dr. Taylor and SN Beattie, sat down with Adam's mother and the family and explained that: *"Adam had cerebral oedema with a swollen brain causing pressure on his vital centres"*[978] and indicated that he thought *"the hope of recovery was remote"*.[979] He also explained that they did not yet understand why this had occurred other than *"there had been an imbalance of fluids in his body"*.[980]

513. None of the surgeons were present for any of the discussions with Adam's mother. Mr. Keane claims to have left by that stage having been called away to an emergency at the Belfast City Hospital. [981] On that basis he was unable to visit Adam's mother immediately after Adam's surgery. He does, however, state that he would have spoken to Adam's family in accordance with his *"customary practice"*[982] and that *"in my absence I expected Mr. Brown to speak to Adam's family"*.[983] When Mr. Brown was asked why he did not take responsibility to speak to Adam's mother after the surgery, he stated in his Inquiry Witness Statement of 23rd September 2011 that: *"This was not a paediatric surgery operation, but a transplant. As I have emphasized my role was a technical one of acting as assistant to the surgeon. I did not take any other responsibility either before or after the operation"*.[984]

514. Dr. Coulthard deals with speaking to Adam's mother in his Report of 7th November 2011 where he states that in a case such as Adam's he would: *"expect the anaesthetist to join the nephrologist, as the patient's general management and support would be his/her primary responsibility at the time, but in most cases I think that the surgeon would usually join the discussion as well"*.[985]

975 Ref: WS-001-1 p.2
976 Ref: WS-001-1 p.4
977 Ref: WS-014-2 p.4
978 Ref: WS-002-1 p.4
979 Ref: WS-002-1 p.4 and Ref: 059-006-016
980 Ref: 058-038-181
981 Ref: WS-006-2 p.6
982 Ref: WS-006-2 p.7
983 Ref: WS-006-2 p.7
984 Ref: WS-007-3 p.6
985 Ref: 200-007-118

515. The issue of who should have spoken to Adam's mother after the surgery and in what terms is something that will be addressed during the Oral Hearing.

CT Scan

516. The emergency CT scan sought by Dr. O'Connor was ordered by Dr. Taylor on a form in which he queries *"Oedema"* and *"Bleed"*.[986] It was carried out at 13:15 and the Radiological Report prepared by Dr. Abdusamea Shabani and Dr. Charles McKinstry states: *"The lateral ventricles are very small. The third ventricle is not clearly seen. There is no mid-line shift. The brain appears swollen. No focal parenchymal lesion can be seen"*.[987] The results are also recorded by Dr. McKinstry in Adam's notes as: *"marked generalised cerebral swelling with compression of the … ventricles, basal cisterns and cortical sulci"*.[988]

517. It should be noted however that Dr. Anslow, in his Report to the Inquiry[989] indicates that the swelling in Adam's brain, rather than being *'generalised'*, was most *"severe in the posterior fossa"*.[990] Furthermore Professor Kirkham, in her most recent Report to the Inquiry of 28th March 2012, takes a similar view that the development of acute cerebral oedema particularly involved the *"posterior cerebral structures"*.[991] The difference that may exist between the views of the Experts regarding the significance of that CT scan is a matter which will be pursued during the Oral Hearing.

Chest x-rays

518. At approximately 13:20[992] the chest x-ray sought by Dr. O'Connor was obtained. Dr. Savage recorded in Adam's notes at 20:30 that: "Repeat CXR at bedtime to see if pulmonary oedema cleared".[993] In his Deposition to the Coroner he states that the: *"chest x-ray showed pulmonary oedema"*.[994] The chest x-ray is also recorded by Dr. Armour in Adam's notes with reference to the CVP catheter: *"central venous line was seen going up through his neck vessels rather than downward toward the heart"*.[995] Dr. O'Connor queried in Adam's notes[996] whether that: *"may have caused some obstruction*

986 Ref: WS-111-2, p.6
987 Ref: WS-111-2, p.8
988 Ref: WS-014-1 p.3 and Ref: 058-035-138
989 Ref: 206-005-109
990 Ref: 206-005-111
991 Ref: 200-007-081
992 Ref: 058-035-138
993 Ref: 058-035-140
994 Ref: 011-015-110
995 Ref: WS-014-1, p.3
996 Ref: 058-035-138

of venous return". She also refers to the position of the CVP catheter in her Inquiry Witness Statement of 19th July 2005.[997]

519. Dr. Landes has examined that x-ray and a subsequent one taken later that evening at 21:30,[998] which was ordered by Dr. Savage: *"to see if pulmonary oedema cleared"*.[999] Dr. Landes reaches a different view regarding the presence of pulmonary oedema, which she sets out in her Report to the Inquiry of 29th November 2011: *"both x-rays are taken in expiration, but the lungs are clear in both radiographs"*.[1000]

520. Subsequently, the Inquiry received from the DLS a Witness Statement dated 28th February 2012 from Dr. Louise Sweeney. She is a Consultant Paediatric Radiologist at the Children's Hospital and she states in that Inquiry Witness Statement: *"there has been an increase in heart size and a deterioration in the appearance of the lungs due to an increase in pulmonary oedema in both lungs"*.[1001]

521. The interpretation of those two x-rays and their significance, if any, will be considered during the Oral Hearing.

Possible Venous Obstruction

522. The issue of a possible venous obstruction is also a matter of some debate. Dr. Armour develops this matter further in her Autopsy Report, when she states: *"Another factor to be considered in this case is cerebral perfusion. The autopsy revealed ligation of the left internal jugular vein. 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 also be considered a factor in the cause of death"*.[1002]

523. Dr. Haynes takes the issue further and states that *"central venous cannulation in small children frequently leads to thrombosis (clot formation) in proximity to a cannnula with subsequent obstruction of veins"*[1003] and that this leads him to *"suspect that there might have been some narrowing of Adam's great veins caused by previous central line insertion"*.[1004]

997 Ref: WS-014-1 p.3
998 Ref: 058-035-142
999 Ref: 058-035-140
1000 Ref: 200-004-007
1001 Ref: WS-242-1 p.2
1002 Ref: 011-010-041
1003 Ref: 204-006-327
1004 Ref: 204-006-327

524. The extent to which the catheter tip located on Adam's right side compromised to any relevant degree the venous drainage from Adam's brain is a matter to be pursued at the Oral Hearing.

525. Dr. O'Connor has set out her analysis of the post-operative period in the following terms in her Inquiry Witness Statement of 19th July 2005:

> *"that the cerebral oedema was likely to be related to the drop in serum sodium from a pre-operative level of 139mmol/L on 26th November 1995 to a post-operative level of 119mmol/L at 1pm on 27th November 1995. I assumed that his normal polyuric state complicated his fluid management and that his possible abnormal cerebral venous drainage may have made him more susceptible to cerebral oedema".*[1005]

526. Whether or not Adam's cerebral drainage was abnormal is a matter to be further pursued during the Oral Hearings.

527. The Nursing Care Plan records the administration of further doses of sublingual Nifedipine to relieve hypertension, a continuation of dopamine, and no spontaneous respiration.[1006] At 17:10 Adam was noted as having *"some decerebrate movement"*[1007] but a short time later was recorded as having fixed and dilated pupils and *"no movement apart from shrugging of shoulders to nail bed stimuli".*[1008]

Neurological Observation and Brain Stem Tests

528. Dr. David Webb states in his Inquiry Witness Statement of 12th April 2011 that sometime after Adam had his CT scan he was informed that Dr. Savage wished him to: *"see a boy who had had a renal transplant earlier that morning and had not woken up following the procedure. He had been found to have fixed dilated pupils and papilloedema (optic nerve swelling) and had evidence of coning (brain herniation) on a CT scan".*[1009] Dr. Webb states in his PSNI statement of 28th April 2006 that he attended Adam at 19:00.[1010] He goes on to state in his Inquiry Witness Statement of 12th April 2011 that he found evidence for an *"osmotic disequilibrium syndrome that was though to occur because of shifts in urea concentration between blood and brain and was associated with brain swelling".*[1011]

1005 Ref: WS-014-1, p.3
1006 Ref: 058-038-153 & 058-005-012
1007 Ref: 058-035-139
1008 Ref: 058-038-160
1009 Ref: WS-107-1 p.3
1010 Ref: 093-021-060
1011 Ref: WS-107-1 p.5

529. Dr. Webb has, however, provided a subsequent Witness Statement dated 23rd August 2011 in which he expresses a different view: *"I am fairly sure that no one informed me that the sodium level was so low, because if I had of been aware of the low sodium I would have considered Hyponatraemia to be the likely cause of the fluid shift"*.[1012]

530. Shortly afterwards he undertook two clinical assessments of Adam's coma and brain stem function,[1013] the first of which was at 19:30 and witnessed by Dr. Campbell,[1014] and the second undertaken the following morning and witnessed by Dr. O'Connor.[1015] It was following the latter of these two assessments that Dr. Webb recorded that the brain stem test criteria were fulfilled.

531. It should be noted that, during the Expert's meeting held on 9th March 2012, Dr. Haynes was asked what the appropriate protocol would be in terms of brain stem testing, with specific reference to Adam's sodium level, and he stated that he would have expected to have seen *"more active steps"*[1016] to bring Adam's sodium within normal range. Professor Kirkham, who was present at the same meeting agreed that: *"you'd certainly want to have a normal metabolic range"*.[1017]

XX. Period Following Adam's Death

532. It was after the second brain stem assessment was carried out by Dr. Webb on 28th November 1995 that Adam's mother was told that the situation was hopeless and that consent was sought and obtained from her to switch off his life support systems.[1018]

533. In her first Witness Statement to the Inquiry Adam's mother states that "*I knew that the cause of Adam's death was the swelling of his brain, but at no time do I recall anyone telling me that this had happened because he had been given too much fluid*".[1019] It was at this point that Adam's mother enquired about the possibility of organ donation.[1020] Dr. Savage informed her that because Adam had died following surgery there would have to be an Autopsy and

1012 Ref: WS-107-2 p.4
1013 Ref: 058-004-009
1014 Ref: 058-004-009 & WS-107-1 p.5
1015 Ref: 058-004-009 & WS-107-1 p.5
1016 Ref: p.107 of the 9th March 2012 Expert's Meeting on the Inquiry website
1017 Ref: p.107 of the 9th March 2012 Expert's Meeting on the Inquiry website
1018 Ref: WS-001-1 p.4
1019 Ref: WS-001-1 p.4
1020 Ref: 059-066-018

Inquest.[1021] The Coroner, who was informed of the position by Dr. Savage, records that he spoke to Professor Crane the State Pathologist about donation and he: "felt that the organs might have been damaged by what happened but in any event it would be preferable if they were available for inspection by the pathologist".[1022] Ultimately, Professor Crane agreed that the heart valves might be used. [1023]

534. Adam's mother she was informed that it would *"only be possible to donate his heart valve and his eyes"*[1024] for which she gave her consent.

535. Thereafter, Dr. Armour appears from her Report on Autopsy to have removed Adam's heart, weighed it, recorded its weight at 120gm and noted: *"The organ was taken for transplant"*.[1025] It appears that the heart itself was not examined, although the pericardial sac and the aorta were described as *"Normal"*, Dr. Armour did not carry out an examination of the heart and its surrounding vessels. There is no comment on the weight of the heart. Dr. Sweeney refers to an *"increase in heart size"* between the taking of the chest x-ray at 13:20 and that at 21:30 on 27th November 1995[1026] but it is not known how the size of Adam's heart compared with that of a normal 4 year old boy like Adam, ie of about 20kgs in weight and 104cms in height.

536. It should also be noted that on 1st April 2012 the Inquiry received a Preliminary Report from Professor Sebastian Lucas, a Consultant Histopathologist, dated 1st April 2012 regarding the Autopsy and its performance, and in it he comes to the view that *"in the context of current practice in London, this removal would not take place in a case that would be regarded as high profile: the unexpected post-operative death of a young child in hospital"*.[1027] The Inquiry is clarifying with Professor Lucas the extent to which current practice reflects the practice in 1995.

537. The issue of what should have been done about Adam's heart in respect of autopsy will be addressed during the Oral Hearing and will also be considered from a governance perspective.

538. At approximately 11:30 ventilatory support was withdrawn from Adam and in her presence[1028] the fluids and monitors were discontinued and all

1021 Ref: WS-001-1 p.4-5
1022 Ref: 011-025-125
1023 Ref: 011-025-125
1024 Ref: WS-001-1 p.4
1025 Ref: 011-010-038
1026 Ref: WS-242-1, p.2
1027 Ref: 209-001-006
1028 Ref: 058-035-142

lines removed.[1029] Then at 13:00 all nursing observations were discontinued.[1030] Constable Stephen Tester was then made aware of the death of Adam Strain and Adam's mother identified his body to him.[1031] Adam's death was thereafter reported to the Coroner.

Conduct of the Autopsy and Provision of the Report on Autopsy

539. I have already explained the involvement of Dr. Armour in the post-mortem examination of Adam and that the way in which she carried out the autopsy and prepared her Report is something that will be addressed during the Oral Hearing.

540. The Inquiry instructed Dr. Waney Squier, Consultant Neuropathologist, John Radcliffe Hospital, Oxford to provide an expert Neuropathological opinion from the histological slides that she made from the tissue blocks taken by Dr. Armour of Adam's brain.[1032]

541. Throughout the Inquiry's investigations, the issue of whether a thorough and accurate post-mortem was carried out into Adam's death has risen in importance, particularly in light of the recent discussion amongst the Inquiry's Experts as to the cause of Adam's death. The Inquiry had sought advice from Dr. Squier regarding some of the issues that have arisen regarding the autopsy. She has assisted with the neuropathological issues and in general terms with issues of autopsy of practice.

542. The Inquiry has since briefed Professor Sebastian Lucas. He is Professor of Clinical Histopathology and a Consultant Histopathologist to Guys and St Thomas' Hospitals Trust, London. He provided a Preliminary Report on 1st April 2012.[1033]

543. The issues that have arisen regarding the autopsy conducted by Dr. Armour, and which will be matters to be pursued at the Oral Hearing and also (in some cases) from a governance perspective, include:

(i) Whether Dr Armour had the requisite experience as a trainee forensic pathologist to perform Adam's autopsy, and/or whether she should have been supervised by a Consultant pathologist. Professor Lucas found Dr Armour's autopsy to have been "*performed competently*" and was "*internally consistent*".[1034] He stated

[1029] Ref: 058-038-162
[1030] Ref: 058-038-164
[1031] Ref: 011-008-024
[1032] Ref: 206-002-001
[1033] Ref: 205-001-005
[1034] Ref: 205-001-005

that he would regularly review coronial autopsy reports, and he would grade Dr Armour's as "*good*" as it '*addressed the central issue and produced a coherent answer*'.[1035]

- That is not a view entirely shared by Dr. Squier who states in her Report of 28th January 2012 that: *"It is impossible to answer [the question of whether the suture was causing venous obstruction] from the description given. Dr. Armour writes that there was no congestion or obstruction of the jugular veins but that the left internal jugular vein was ligated. These statements are not consistent with one another".*[1036]

(ii) Whether there was ligation of the left internal jugular vein. I have explained this in detail previously, and do not propose to explain it again. It is suffice to say that there is a disagreement between the Trust and Dr Armour as to whether such a suture was present.

- Professor Lucas has stated that the autopsy description of the ligature apparently found in Adam's left neck as "*sub-optimal*" since it was not then and has not since become clear whether or not there was really a ligature that obstructed the venous outflow of the left internal jugular vein. He stated that: "*this lack of clarity is an important criticism of the autopsy and the report.*"[1037]

- Dr Squier agrees that Dr Armour's report is "*unclear on this matter*"[1038] and that her report is inconsistent when addressing the question whether the suture was causing venous obstruction.[1039] She states that Dr Armour could have made further investigations to see how long the suture had been present, including sampling for histology.[1040]

(iii) Whether the donor kidney was infarcted. Dr. Armour examined histological slides of the internal organs under a microscope which allegedly revealed 'complete infarction of the transplanted kidney'.[1041] She sent Professor Berry histological slides of: (a) the native kidneys and the donor kidney; (b) spleen; (c) lungs; (d) liver; e) lymphnode. He noted that there was unexplained cellular change in the hepatocytes scattered throughout his liver but he did not know the significance of it. He concluded that the transplanted

1035 Ref: 205-001-006
1036 Ref: 206-004-024
1037 Ref: 205-001-005
1038 Ref: 206-004-023
1039 Ref: 206-004-024
1040 Ref: 206-004-024
1041 Ref: 011-010-039

kidney was infarcted (dead) at or before the time of transplantation.[1042]

- Professor Lucas has criticised Dr Armour for failing to pursue the issue of the cellular change in the liver, and her omission to carry out any histopathological investigation of why the transplanted kidney had infarcted. [1043]

(iv) Differences between her contemporaneous notes and the final autopsy report. Dr. Armour made notes in order to assist her with the provision of her Report, which would necessarily have to be provided some time after the Autopsy. This was to allow for the brain to be 'fixed' and histological slides examined as well as to receive the reports from the experts that the Coroner had retained in Paediatric Pathology and Paediatric Anaesthesia – Professor Berry and Dr. Sumner respectively. Those notes provide information which she did not include in her final autopsy report, such as:

- The fresh unfixed brain weight is recorded as *"1,302gms"*, but this figure is partially struck out and reads *"1,320gms"*. The reason for the amendment of the weight in unknown nor is it known when the amendment was made.

- "*Lungs: The left weighed 190gms and the right lungs weighed 290gms. Both were moderately oedematous throughout*".[1044]

  Dr. Armour cannot explain why this comment was not included in the final autopsy report other than the non-inclusion of the weights of the lungs was a typographical error.[1045]

- Further information on the pleural cavities[1046] and the trachea & main bronchi.[1047]

(v) What the weight of Adam's brain was at post-mortem. I have just mentioned the contents of Dr. Armour's contemporaneous notes of the brain weights. These weights were not recorded in her final Report on Autopsy. The fixed weight was noted as 1,680g.[1048] Dr

1042 Ref: 011-007-020 (Report)
1043 Ref: 205-001-006
1044 Ref: WS 012-2 p.24
1045 Ref: WS 012-2 p. 11
1046 Ref: WS 012-2 p. 24
1047 Ref: WS 012-2 p.24
1048 Ref: 011-010-040

Armour has since said that the 'unfixed' weight she noted must have been an error and that 1,580g would be a more accurate unfixed brain weight.[1049] Professor Lucas has criticised the uncertainty of the weight of the brain, although the swollen nature of the brain is also apparent from the CT scan.[1050]

(vi) The appropriateness of the description of the brain in the Report on Autopsy and in Dr. Armour's evidence to the Coroner. Dr. Armour describes it in her Report as: *"The brain was grossly swollen with loss of sulci and uncal swelling"*[1051] and in her evidence to the Coroner as: *"This was massive cerebral oedema and I have never come across anything of a similar degree"*.[1052]

- The extent of the swelling is discussed by Dr. Squier in her Report of 28th January 2012 and she does not appear to describe it in equivalent terms to Dr. Armour. She states: *"The external appearances of the brain at the vertex show mild swelling with compression of the sulci but the shape of the gyri is relatively well preserved. At the base of the brain the cerebellar tonsils are haemorrhagic and appear damaged … In some slices [taken of the brain] gyri are flattened and sulci compressed, in others the gyri are beter preserved. Pictures of the cerebellum show this to be extremely swollen, no spaces are seen between the folds of the cerebellar cortex"*.[1053]

(vii) The involvement of Dr Mirakhur. Dr. Armour claims to have sought a second opinion on the brain and related material from Dr. Meenakshi Mirakhur who was a Consultant Neuropathologist at the Royal and also claims to have provided her with the brain, spinal cord and histological slides. There is no record of a Neuropathological Report being requested by Dr. Armour nor is there any record of such a report being provided by Dr. Mirakhur. Nevertheless, Dr. Armour claims that Dr. Mirakhur's views were consistent with the description of and comments on the brain that she included in her Report on Autopsy.[1054] However, Dr. Mirakhur denies any knowledge of her opinion being sought or of seeing any slides and she claims not to have seen the Report on Autopsy until the Inquiry referred her to it in seeking a Witness Statement from her.

1049 Ref: WS-012-2, p.11
1050 Ref: 205-001-006
1051 Ref: 011-010-039
1052 Ref: 011-010-033
1053 Ref: 206-004-026
1054 Ref: 011-010-034

- Dr. Squier states in her Report of 28th January 2012 that: *"in a case such as this where the cause of death was thought to have been in the brain and was potentially the result of a hospital procedure (surgery and anaesthesia) best practice would have been to ask a Neuropathologist to undertake a formal and complete brain examination. This is particularly important as Dr. Armour was not at the time fully qualified as a consultant pathologist. I am surprised that her report was not countersigned by a consultant supervisor".*[1055]

(viii) The involvement of Drs O'Hara and Bharucha to provide a second opinion on the histological slides, and the lack of a paper trail in regard to their assistance and findings. The Coroner made a note dated 8th December 1995 that:

"Today Dr. Armour showed slides etc to Dr. O'Hara and Dr. Bharucha. Both stated that there was clear evidence of hypoxia/anoxia/anaphylactic reaction. Those are virtually all the same thing."[1056]

- Dr. O'Hara was a Consultant Paediatric Pathologist and Dr. Armour states in her Inquiry Witness Statement that the slides would have been shown to both him and Dr. Bharucha for their opinion.[1057] In the event, Dr. Armour recorded in her Report on Autopsy that: *"There was no evidence of terminal hypoxia"*[1058] and *"Generalised cerebral oedema in children has many causes including hypoxia. In this case this has been excluded"*.[1059] This is reiterated in her Inquiry Witness Statement in which she states that there was no evidence of: *"hypoxia/anoxia/anaphylactic reaction"*.[1060]

- The basis upon which she formed a different view from Dr. O'Hara and Dr. Bharucha is not known and is a matter that will be pursued in the Oral Hearing.

- Dr Squier has suggested that in a complex case such as Adam's *"specialist assistance should have been sought formally and the reports of those specialists included as signed reports within the final pathology report"*.[1061]

1055 Ref: 206-004-025
1056 Ref: 011-025-125
1057 Ref: WS-012-2 p.12, Q24
1058 Ref: 011-010-040
1059 Ref: 011-010-041
1060 Ref: WS-012-2, p.13 Q24(d)(ii)
1061 Ref: 206-004-030

There is now an issue as to the identity of Dr. Bharucha. The Inquiry had written to a Dr. Chitra Bharucha, who was a Consultant Haematologist at Belfast City Hospital in November 1995 regarding her involvement in Adam's case. In her Inquiry Witness Statement dated 12th January 2012, she denied any knowledge of the case.[1062] DLS contacted the Inquiry on 22nd March 2012 to indicate that this may have been a case of mistaken identity and in fact the correct person may have been her husband Dr. Hoshang Bharucha, a Consultant Pathologist at the Royal Victoria Hospital in November 1995. A request for an Inquiry Witness Statement was been sent to him and the Inquiry has sought an explanation of why it was not notified earlier of the correct identity of Dr. Bharucha.

(ix) Whether the lungs were oedematous. I have already commented that there is an issue between the Inquiry's expert radiologist Dr. Landes and Dr. Sweeney's statement provided by DLS (as well as several of the clinicians involved) as to whether Adam's lungs were oedematous according to his chest x-rays. Dr. Armour reports that a chest x-ray revealed pulmonary oedema.[1063] It is unclear whether Dr. Armour examined the x-rays herself or relied upon the description in Adam's medical notes and records. Similarly it is unknown whether Dr. Armour examined the CT scan of Adam herself or relied upon the description thereof in Adam's medical notes and records.

(x) No examination of heart or comment on its weight of 120gms. The heart was removed before autopsy for transplantation. As already stated, Professor Lucas has said that it should have been examined "*for certainty*" in such a high profile death.

(xi) Whether Dr Armour should have asked for an expert opinion on the CT scans of 27th November 1995 and 7th July 1995 and whether that would have been required in 1995 by either acceptable or best practice

(xii) The conduct of the autopsy on the hospital site. Dr Squier has stated that "*where there is a question regarding the conduct of the treating clinician it would today be most unusual for the autopsy to be performed in the same hospital. It would be normal for the body to be*

[1062] Ref: WS-229-1, p.1
[1063] Ref: 011-010-036

removed to another hospital so that there can be no question of conflict of interest."[1064]

(xiii) Whether it was appropriate for Dr Taylor and/or Dr Savage to be present during the autopsy. Dr Savage stated in a letter to Adam's GP dated 4th December 1995 that *"I have since attended a post-mortem when no new information was obtained that would explain the events during his surgery but confirmed the presence of gross cerebral oedema."*[1065] Dr Armour also mentioned at Adam's Inquest that "*Dr Taylor advised me at the autopsy of the calculation he made to replace blood loss*."[1066] Professor Lucas has criticised Dr Armour for providing "*too much*" "*non-pathology information*" in her Autopsy Report.

(xiv) The reason for Dr. Armour's letter of 8th December 1995 to Professor Jack Crane, which she copied to the Medical Protection Society, Mr. Calvin Spence of the British Medical Association, Mr. George Murnaghan, Hospital Administration and the Coroner, that she had been dealing with the case of Adam Strain and that:

"*I am willing to attend any meeting about this case, including a meeting with clinicians, administrative staff, H.M. Coroner and whoever else wishes to attend. As I was the pathologist who carried out the autopsy I feel my opinion on the case is relevant to such a meeting and as such the case could be discussed in full."* [1067]

Cause of Adam's Cerebral Oedema & Death

544. As has been seen the cause of Adam's death is recorded on the Verdict on Inquest[1068] as:

"*I(A) Cerebral Oedema*

Due to

(B) Dilutional hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy")

The findings made by the Coroner were that:

[1064] Ref: 206-004-029
[1065] Ref: 016-004-015
[1066] Ref: 011-010-033
[1067] Ref: 011-023-123
[1068] Ref: 011-016-114

"*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*"

545. The Inquiry will note the debate regarding the cause of Adam's cerebral oedema and death, including:

(i) The role of dilutional hyponatraemia

(ii) Any other causes or contributing factors including:
- Chronic cerebral venous sinus thrombosis
- Acute cerebral venous sinus thrombosis
- Thrombosis of the paravertebral plexus
- Reduced jugular venous drainage or possible venous obstruction
- Cerebral blood flow, anaemia and reduced cerebral O2 delivery/low CO_2
- Posterior Reversible Encephalopathy Syndrome (PRES) during surgery
- Hypoxia
- Seizure(s) during surgery
- Halothane in anaesthetic
- Pre-existing central nervous system condition

546. I have already mentioned the debate amongst the Inquiry's Experts regarding the cause of Adam's death and their lengthy meetings on 22nd February 2012 and 9th March 2012, and the reports produced by those experts in the aftermath of the meetings. To assist matters, the Legal Team has produced two Schedules – 'Summary of Key Point: Pre-Experts' Meetings'[1069] and 'Summary of Key Points: Post-Experts' Meetings'[1070] – that set out in summary form the positions of each of the Inquiry's key experts on the issues (Professor Kirkham and Professor Gross and Dr. Squier, Dr. Haynes and Dr. Coulthard) before the their Expert Meetings on 22nd February 2012 and 9th March 2012 and after those meetings.

547. The 'key points' included in the Schedules are:

(i) Adam's development

(ii) The medical literature

[1069] Ref: 306-016-130
[1070] Ref: 306-017-146

(iii) The risk factors for chronic / acute venous thrombosis

(iv) Venous sinus thrombosis

(v) The effect of reduced jugular venous drainage

(vi) PRES

(vii) Adam's presentation during surgery

(viii) Arguments on brain death caused by dilutional hyponatraemia

548. I do not propose to go through those Schedules in detail now, as the Transcripts of the two Experts' Meetings have been made available on the Inquiry's web site, their Reports have been provided to the Interested Parties and will also be published in due course according to the Inquiry's Protocols and Procedures and, of course, the Experts will be giving evidence at the Oral Hearing.