

Witness Statement Ref. No. 006/02

**NAME OF CHILD: Adam Strain**

**Name: Patrick Keane**

**Title: Consultant Urologist**

**Present position and institution: Consultant Urologist, Belfast HSC Trust**

**Previous position(s) and institution(s):**

*[Since your Witness Statement of 20<sup>th</sup> June 2005]*

N/A

**Membership of Advisory Panels and Committees:**

*[Identify by date and title all of those since your Witness Statement of 20<sup>th</sup> June 2005]*

**1996-2003 Lead Clinician in Urology, Belfast City Hospital.**

**1996-1998 Postgraduate Tutor at Belfast City Hospital**

**1997-2003 Programme Director in Urology, Belfast City Hospital**

**2003 to date - Member of the Scientific Reference Group of the Prostate Cancer Risk Management Programme**

**2005 to date - Specialist Advisory Committee in Urology**

**2008 to date - Clinical lead for NICAN in Urology**

**2010 to date - Council of the British Association of Urological Surgeons**

**Previous Statements, Depositions and Reports:**

*[Identify by date and title all those since your Witness Statement of 20<sup>th</sup> June 2005]*

N/A

**OFFICIAL USE:**

**List of previous statements, depositions and reports attached :**

<b>Ref:</b>	<b>Date:</b>	
011-003	11.12.1995	Statement
011-013	18.06.1996	Deposition at the Inquest on Adam Strain
006/1	20.06.2005	Witness Statement to the Inquiry on Hyponatraemia
093-010	07.09.2006	Statement to PSNI

**IMPORTANT INSTRUCTIONS FOR ANSWERING:**

Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number. If the document does not have such a number then please provide a copy of the document.

**I QUERIES ARISING OUT OF YOUR INQUIRY WITNESS STATEMENT**

With reference to your Witness Statement dated 20<sup>th</sup> June 2005, please provide clarification and/or further information in respect of the following:

**(1) Response to position and institution: "Consultant Urologist Belfast City Hospital Trust"**

- (a) Describe your work commitments to the Royal Belfast Hospital for Sick Children (RBHSC) from the date of your appointment as a Consultant and particularly over the period 26<sup>th</sup> November to 28<sup>th</sup> November 1995**

I had an Honorary Contract at RBHSC and had close working relationships with the surgeons there. I was involved in setting up the Stone Service for children and the continuing care through adolescence of the paediatric urological population. With reference to transplantation, I was involved in teaching the surgeons at the RBHC how to perform the procedure, hence Mr Brown's involvement. I lectured at the RBHSC and dealt with unusual cases and transplants.

- (2) State what you considered to be your role in relation to and responsibilities towards Adam over the period from learning on 26<sup>th</sup> November 1995 of a potential donor kidney for him until 28<sup>th</sup> November 1995 when ventilatory support was withdrawn, and in particular:**

- From Adam's admission to RBHSC until his arrival in theatre
  - While Adam was in theatre until his admission to PICU
  - From admission to PICU until his death
- To acquaint myself with the clinical situation and to make the necessary arrangements to get the team together;
  - To perform the transplant procedure and deal with any complications arising;
  - Nil

- (3) Answer to Question 1 at p.2**

*"Prior to the transplant surgery of Adam I spoke on several occasions to Dr. Savage ... who was responsible for Adam's pre-operative and post-operative dialysis treatment ... I believe that our conversations would have included reference to Adam's medical condition; the cause of Adam's renal problems; Adam's medical history; Adam's mother's consent and planning and setting up the transplant procedure ...*

*Prior to the surgery I believe I would also have spoken with Mr. Brown ... it is likely that I would have spoken to him about Adam's case and the timing of the surgery ...*

*I would also have spoken with Dr. Taylor ... I consider it likely ... that I would have spoken to him about Adam's surgery and the timing of the anaesthetic ... In summary, I sought all relevant clinical*

*information from these clinicians and discussed the preparation for and timing of the transplant."*

(a) Describe and explain your contribution to Adam's preoperative management

As detailed above (in my witness statement dated 20<sup>th</sup> June 2005).

(b) State when and where your discussions with Dr. Savage took place and describe the content of them, including in relation to:

- Adam's medical condition
- cause of Adam's renal problems
- Adam's medical history
- consent from Adam's mother
- planning and setting up the transplant surgery
- preparation for and timing of the transplant surgery

As detailed in my witness statement dated 20<sup>th</sup> June 2005, I discussed all of the above with Dr Savage by telephone on 26<sup>th</sup> November 1995. At 16 years remove, I cannot remember specific details.

(c) State when and where your discussions with Mr. Brown took place and describe the content of them, including in relation to:

- Adam's case
- preparation for and timing of the transplant surgery

I spoke with Mr Brown by telephone on 26<sup>th</sup> November 1995. The content of the conversations is as detailed in my witness statement dated 20<sup>th</sup> June 2005. At 16 years remove, I cannot remember specific details.

(d) State when and where your discussions with Dr. Taylor took place and describe the content of them, including in relation to:

- Adam's surgery
- preparation for and timing of the transplant

I spoke with Dr Taylor by telephone on 26<sup>th</sup> November 1995. The content of these conversations is as detailed in my witness statement dated 20<sup>th</sup> June 2005. At 16 years remove, I cannot remember specific details

(e) Describe and explain "*all relevant clinical information*" that you sought from those clinicians (ie Dr. Savage, Dr. Taylor and Mr. Brown) and what you received in response.

I discussed the following:

- Adam's medical condition
- cause of Adam's renal problems
- Adam's medical history
- consent from Adam's mother
- planning and setting up the transplant surgery
- preparation for and timing of the transplant surgery

These were telephone conversations and, at 16 years remove, I cannot remember specific details

- (f) Explain when, by whom, and in what circumstances, it was agreed that Adam's transplant surgery would take place at 7.00am as opposed to the 6.00am originally included in his medical notes and records (Ref: 059-006-011)

The operation was scheduled for 6.00 am. I only operate when the patient is safely anaesthetised, which, in Adam's case, was at approximately 7 am

- (g) Explain what determined the timing of Adam's transplant surgery

Adam needed dialysis to prepare for the operation. He would not have been ready for the operation until midnight or beyond on 27<sup>th</sup> November 1995, meaning we could not start until the early hours of the morning. In my opinion, operating on Adam in an exhausted state during early hours of 27<sup>th</sup> November 1995, would not have been appropriate, for reasons of patient safety.

- (4) Answer to Question 1(i)(ii) at p.2

*" Prior to the surgery I believe I would also have spoken with Mr. Brown"*

- (a) Describe when, why and in what circumstances Mr. Brown came to act as assistant surgeon to you for Adam's transplant surgery

As detailed above, I was teaching the paediatric surgeons at RBHSC about transplant surgery and had assisted Mr Boston in one procedure. Mr Brown was also interested in learning and had previously operated on Adam and, therefore, had a personal interest in his care.

- (b) Identify the on-call surgical Registrar at the time of Adam's surgery

I am unable to do so and this question should be addressed to the RBHSC/Belfast HSC Trust.

- (c) Describe and explain all occasions prior to 27<sup>th</sup> November 1995 on Mr. Brown acted as your surgical assistant

Never.

- (d) Specify the date and time when it was agreed that Mr. Brown would assist you with Adam's transplant surgery

On 26<sup>th</sup> November 1995. At 16 years remove, I am unable to provide details of the time.

- (5) Answer to Question 2(i) at p.2-3

*" ... my contemporaneous operation note reads as follows: ...  
Procedure 2 arteries on widely separated patch joined with 6/0 prolene  
Vein (renal) to external iliac (vein)  
Arterial patch sutured to external iliac (artery) with 6/0 prolene ..."*

(a) Describe and explain what you did throughout the period of surgery (on a half hourly basis)

Surgeons do not record procedures in half hourly units of time. However, the steps in the procedure are as follows:

- Incision, identification and exposure of the vessels which are to be used and the approach to same;
- Isolation of the vessels in preparation for clamping;
- Cleaning and preparation of the donor kidney;
- Vascular and ureteric anastomoses;
- Wound closure

All technical parts of the operation were achieved and no surgical complications occurred

(b) State the identity of the person that collected the donor kidney and explain who was responsible for the completion and accuracy of the accompanying 'Kidney Donor Information Form' (Ref: 058-009-027), including the:

- identity of the person who provided the information for the completion of the Section II details at items 3, 4 and 8, 9 and state when those entries were made
- identity of the person who amended the entry at Section II item 8 by deleting "patch" and adding "arteries on 1 patch" and state the time at which this amendment was made

I am unable to do so, and this question should properly be directed to the RBHSC/Belfast HSC Trust.

(c) State whether you checked the completed form

I cannot remember whether, or not, I checked the completed form, however, I left the RBHSC after the transplant as I had been called to a life threatening emergency at Belfast City Hospital.

(d) Explain what happened to the 'Kidney Donor Information Form' on its completion

I do not know in Adam's case, however, it is normally handed to the Transplant Coordinator.

(6) Answer to Question 2(i) at p.2-3

*" ... my contemporaneous operation note reads as follows: ...*

*Ureter reimplanted by small submucosal tunnel*

*(size) 8 Feeding tube (splint for ureter)*

*(size) 14 Malecot (bladder catheter)"*

(a) Describe and explain in relation to the insertion of the bladder catheter and the donor ureteric catheter:

- identity of the person who inserted each catheter
- time of their insertion volume of urine that drained when the bladder catheter was first inserted

I inserted the catheters. The time was not recorded but close to 10.00 am. The volume of urine was not recorded.

(b) Explain whether there was any contra-indication to inserting a urinary catheter immediately after induction of anaesthesia

No contraindication.

(c) State the volume of urine in Adam's bladder when opened

Not recorded

(7) Answer to Question 2(i) at p.2-3

*" ... my contemporaneous operation note reads as follows: The operation note is written in the clinical notes and not on a separate sheet as was the practice at that time ...  
Kidney perfused reasonably at end"*

(a) Explain your meaning of "at end"

At the end of the transplant procedure.

(b) State when did you make the entry, "Kidney perfused reasonably well at end" and signed same in Adam's notes (Ref: 058-035-135 )

At the end of the transplant procedure.

(c) Describe and explain the circumstances in which you made that entry

I was called to the Belfast City Hospital to say that a patient, who was undergoing a percutaneous nephrolithotomy, was bleeding heavily in the operating theatre there and that they needed help urgently. I had finished the transplant, there was pulsatile flow in the artery and the kidney was reasonably perfused. I asked Mr Brown to close the wound, made a quick operation note and rushed to Belfast City Hospital to deal with the problem there.

(d) State whether there any discussion in theatre about the colour of the donor kidney, and if so, identify those involved and describe when and to what end those discussions took place

Mr Brown and I discussed the colour of the kidney at the end of the transplant. We were both happy with the perfusion of the kidney at the end of the transplant procedure.

(8) Answer to Question 2(iii) at p.3

*" At the completion of his surgery, Adam was in a satisfactory condition. I was called to an emergency at the Belfast City Hospital and Mr. Brown, Consultant Paediatric Surgeon, closed Adam's wound. Adam was stable when I left, 10 minutes prior to the end of the anaesthesia"*

(a) State at what time and for how long were you in theatre during the Adam's transplant procedure

From the start of the operation to after the successful transplant. I was absent for approximately 10-15 minutes required to close the wound.

- (b) State whether you left theatre at any time before your ultimate departure from the theatre, and if so, state at what time you left theatre during surgery and for how long.

I did not leave the theatre at any time before my ultimate departure.

- (c) Describe the nature of the emergency at Belfast City Hospital which caused you to leave the operating theatre and at what time and how you were alerted to it

Belfast City Hospital telephoned before the end of Adam's transplant, to say that a patient, who was undergoing a percutaneous nephrolithotomy, was bleeding heavily in the operating theatre there and that they needed help urgently.

- (d) State at the time at which you left the theatre on 27<sup>th</sup> November 1995

At approximately 10-30 am.

- (e) Describe and explain what was left for Mr Brown to do in relation to the transplant surgery at the time you left the operating theatre

Close the wound.

- (f) Identify the persons present in theatre whilst you were there

At 16 years remove, I am unable to recall, however, I believe that Mr Brown, Dr Taylor and other medical and nursing personnel (whose names I cannot remember) were present.

- (g) Explain what you mean by "*in a satisfactory condition*"

There was pulsatile flow in the artery, the ureter had been connected successfully and the kidney was reasonably perfused.

- (h) State whether there was a designated anaesthetic nurse in theatre during the transplant procedure, and if so, identify that person.

I cannot recall and believe that this question should be directed to the RBHSC/Belfast HSC Trust.

- (i) Describe and explain what you considered your responsibilities to be on 27<sup>th</sup> November 1995 (if anything) in relation to speaking to Adam's family after surgery and before you left RBHSC.

I would have, in accordance with my customary practice, spoken to Adam's family, if I had not been called away to an emergency at Belfast City Hospital. In my absence, I expected Mr Brown to speak to Adam's family.

- (j) Describe your discussions (if any) with Adam's mother on 27<sup>th</sup> November 1995.

None. As above, I would have, in accordance with my customary practice, spoken to Adam's

mother/family, if I had not been called away to an emergency at Belfast City Hospital.

## II QUERIES ARISING OUT OF YOUR DEPOSITION

With reference to your Deposition to the Coroner taken on 18<sup>th</sup> June 1996, please provide clarification and/or further information in respect of the following:

(9) *"I was asked to transplant this 4 year old boy on Monday 27 November 1995."* (Ref: 011-013-093)

(a) State when and by whom were you first informed about the possibility of renal transplant surgery for Adam

Dr Savage on Sunday, 26<sup>th</sup> November 1995.

(b) State when and who at the RBHSC first received the offer of the donor kidney for Adam

I am not aware of this information and believe that this question should be raised with the RBHSC/Belfast HSC Trust.

(c) State when and by whom you were first asked to perform renal transplant surgery upon Adam

Dr Savage on Sunday, 26<sup>th</sup> November 1995.

(d) Explain the reasons why were you chosen to perform the renal transplant for Adam Strain on 27<sup>th</sup> November 1995. State whether you the surgeon on call on that date.

I do not hold a copy of the on call rota for November 1995, however, at 16 years remove, I do not believe that I was on call on 27<sup>th</sup> November 1995. I was contacted by Dr Savage on 26<sup>th</sup> November 1995 with a request that I perform the transplant, as I understood that I was the only appropriately trained surgeon who was available and capable of performing the procedure.

(e) Identify who was responsible for co-ordinating the arrangements for Adam's renal transplant surgery

Dr Savage and the Transplant Co-ordinator, Eleanor Donaghy.

(f) Identify who collected the donor kidney, when and from where

I am not aware of this information and, therefore, this question should be raised with the RBHSC/Belfast HSC Trust.

(g) Following receipt of the offer of the kidney for Adam, describe and explain the process by which it was brought to the RBHSC

I am not aware of this information and, therefore, this question should be raised with the RBHSC/Belfast HSC Trust. However, I believe that the kidney was flown to Northern Ireland and transported by taxi to the RBHSC.

(h) State when were you first informed that Adam had been admitted to the RBHSC for



possible renal transplant surgery

Sunday, 26<sup>th</sup> November 1995.

(i) State when and in what circumstances you first saw:

- the Kidney Donor Information Form (Ref: 058-009-025)
- the "Transplant Form" (Ref: 057-007-008)

At 16 years remove, I cannot recall, however, my customary practice would have been to look at them pre-operatively.

(10) "In this case the kidney being transplanted had been removed within a normal time before surgery" (Ref: 011-013-093)

(a) State your understanding of the ischaemic time of the donor kidney to be when the transplant surgery was being discussed over 26<sup>th</sup> and 27<sup>th</sup> November 1995 and the basis for this understanding

Perfusion started at 01.42am on Sunday, 26<sup>th</sup> November 1995. At 16 years remove, I have no recollection of the timing of discussions on ischaemic time.

(b) State what you understood the actual ischaemic time of the donor kidney to be when you commenced transplant surgery

Approximately 29 hours.

(c) Describe the basis upon which you believed that the donor kidney "had been removed within a normal time before surgery"

The Kidney Donor Information Form

(d) Explain "a normal time before surgery" and:

The kidney was still transplantable in terms of its cold ischaemia time.

- identify the person who informed you of this  
At 16 years remove, I am unable to recall, but I would have discussed it with Dr Savage and the transplant co-ordinator.
- state when and where were you informed of this  
At 16 years remove, I am unable to recall
- what time you understood that the donor kidney had been removed, and the basis of your understanding  
Perfusion started at 01.42am on Sunday, 26<sup>th</sup> November 1995. This information was gleaned from the Kidney Donor Information Form.
- state whether your understanding changed at any point prior to Adam's death, and if so, when, what was the change in understanding and state why your understanding changed  
My understanding did not change.
- state the date and time on/at which you first saw the donor kidney  
At approximately 6am on the morning of the operation on Monday, 27<sup>th</sup> November 1995

(11) *"The operation would have started between 7.15 and 8.00am."* (Ref: 011-013-093)

(a) State when the surgery 'knife to skin' started.

Approximately 7.15am.

(b) Given the surgical note records that *"vascular anastomosis - 10.30am"* (Ref: 058-035-134), state at what time the bladder was catheterised.

Within a few minutes of 10.30am.

(12) *"The blood loss of 1200cc was not all blood but contained fluid as well"*. (Ref: 011-013-093)

(a) State the amount of "fluid" contained in the *"blood loss of 1200cc"*

Approximately 600cc made up of urine, peritoneal dialysis fluid and slushed ice used to cool the kidney until the vascular anastomoses are complete.

(13) *"Monitoring of urine during a transplant procedure is never done"* (Ref: 011-013-093)

(a) Clarify whether you mean urine produced by the native kidney, the donor kidney or both

Urine from the donor kidney is never monitored before the ureteric reimplantation and the end of the procedure.

(b) Explain why urine is not monitored during a transplant procedure

Generally patients are anuric or oliguric. To reimplant the ureter in adults, normally, 300 cc of water is instilled into the bladder to distend it. 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.

(c) State by what means urine produced by Adam's native kidneys was to be collected and measured during the course of the operation on 27<sup>th</sup> November 1995

It was not to be collected, but allowed to distend Adam's bladder in preparation for ureteric reimplantation.

(d) Identify who was responsible for collecting and measuring the urine produced by the native kidney during the transplant surgery

See (c) above.

(e) Describe what was done with the urine produced by Adam's native kidneys

Sucked into a bottle and soaked into swabs.

(f) State by what means was urine produced by Adam's donor kidney to be collected and measured during the course of the operation on 27<sup>th</sup> November 1995

It was not to be measured until the ureteric reimplant had been done and then by catheter.

- (g) Identify who was responsible for collecting and measuring the urine produced by the donor kidney during the transplant surgery

No one, because the urine from the donor kidney was not being monitored and would not be monitored until the transplant was over.

- (h) Describe what was done with the urine produced by the donor kidney

Soaked in swabs and sucked into a bottle.

- (14) *"...the kidney... perfused quite well initially and started to produce urine. At the end of the procedure it was obvious that the kidney was not perfusing as well as it had initially done, but this is by no means unusual in renal transplantation."* (Ref: 011-013-093)

- (a) State when the donor kidney *"started to produce urine"*, and describe how much urine was actually produced

A minute or so after completion of the vascular anastomoses. A few drops.

- (15) *"It was some time after the end of surgery that the problem with Adam was noticed"* (Ref: 011-013-093)

- (a) Explain your reference to *"the end of surgery"*

It was my understanding that, at the end of surgery and when the anaesthetist was waking Adam up, they noticed he was unresponsive, unable to breathe and had fixed dilated pupils, that is, he was brain dead.

- (b) State when you were first notified that *"a problem"* had occurred with Adam following his surgery and explain what you did about it.

I was telephoned (I cannot remember by whom) in the ante room of Theatre 6 at Belfast City Hospital after completing the emergency operation there, to be told Adam was brain dead.

- (16) *"I was not aware of Arieff's paper. In the light of Adam's experience the factors in that paper would be carefully considered in future surgery of a similar nature"* (Ref: 011-013-093 to Ref: 011-013-094)

- (a) State how Arieff's paper on hyponatraemia ought to have been *"carefully considered"* following Adam Strain's death and also following Adam Strain's Inquest

To change paediatric practice in relation the use of Solution 18 and outline what measures should be taken when it hyponatraemia is detected.

- (b) Describe how that paper has actually been considered

It is not relevant to adult urological practice. All of the issues dealt with in the Arieff paper

have been common knowledge in urology for 30 years.

- (c) Explain the reasons for your view that the factors in Arieff's paper would be restricted to being *"carefully considered in future surgery of a similar nature"*

That is not my view. Arieff's paper applies to general paediatric practice.

- (d) State what difference, if any, Arieff's paper has made to your practices since November 1995.

None. Adam's death deeply affected me and so I chose not to involve myself in paediatric transplantation after 27<sup>th</sup> November 1995.

### III QUERIES ARISING OUT OF YOUR PSNI STATEMENT

With reference to your PSNI Statement dated 7<sup>th</sup> September 2006, please provide clarification and/or further information in respect of the following:

- (17) *"In 1995 I was a consultant Urologist, at the time I would have performed somewhere in the region of 250-400 transplant operations"* (Ref: 093-010-029)

- (a) Prior to 27<sup>th</sup> November 1995:

- Describe your experience and involvement in performing paediatric renal transplants, the dates of those renal transplants and the hospital where they took place

Precise numbers should be obtained from RBHSC/Belfast HSC Trust, however, I believe that I had performed three paediatric renal transplants before Adam's, although I had assisted on a number of others.

- Describe your experience in performing paediatric renal transplants in children who were polyuric

None before Adam.

- Describe your experience in assisting with paediatric renal transplants

Small numbers over a 4 year period as Senior Registrar at the RBHSC.

- Describe your paediatric urological experience in terms of the average number of children per month aged less than 6 years that you operated on in 1995

0.1-0.2 per month approximately

- State the number of children, aged less than 6 years, you had performed a renal transplant on before Adam?

I believe three, although I had assisted in a number of others.

(b) Since 27<sup>th</sup> November 1995:

- Describe your experience and involvement in performing paediatric renal transplants, the dates of those renal transplants and the location where they took place
- Describe your experience in performing paediatric renal transplants in children who were polyuric
- Describe your experience in assisting with paediatric renal transplants
- Describe your paediatric urological experience in terms of the average number of children per month aged less than 6 years that you operated on
- State the number of children, aged less than 6 years, you had performed a renal transplant on since Adam

None. Adam's death deeply affected me and so I chose not to involve myself in paediatric transplantation after 27<sup>th</sup> November 1995.

(18) *"I would have expected that Adam's electrolyte levels would have been checked either just before or just after the operation started"* (Ref: 093-010-030)

(a) Describe your understanding of Adam Strain's serum sodium level over 26<sup>th</sup> and 27<sup>th</sup> November 1995 prior to his surgery and explain the basis of it

His sodium level was normal at the end of dialysis pre-operatively.

(b) Explain the reasons why you would have expected *"Adam's electrolyte levels to have been checked either just before or just after the operation started"*

He was polyuric and his feeding regime had changed in preparation for the transplant. Once anaesthetised the difficulty in venesection would not arise.

(c) State your understanding of the reason why Adam Strain's electrolyte levels were not checked *"just before or just after the operation started"*

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.

(19) *"During the course of the operation I do not recall any discussions regarding sodium levels"* (Ref: 093-010-030)

(a) State whether Dr. Taylor informed you of any problem with Adam's serum sodium concentrations during the transplant operation and if so describe what you were informed and the response to the problem

He did not.

(20) *"I was not made aware of any problems during the operation in relation to blood pressure or central venous pressure ... I have no recollection of being made aware of any problems with the CVP"* (Ref: 093-010-030)

(a) Describe and explain any discussion in theatre in relation to CVP, identify those involved

and describe any action taken

Approximately 15 minutes before I thought the vascular anastomoses would be complete, I would, in accordance with my customary practice, ask the anaesthetist what the CVP was and to preload the child if necessary. I do this in every case, however, I have no specific recollection in this particular case.

(21) *"During the operation there was very little blood loss"* (Ref: 093-010-030)

(a) Explain the basis on which you concluded that there was *"very little blood loss"*

Surgeons are very aware of blood loss and will communicate concerns to the anaesthetist. There was no major bleeding in Adam's case. His Haemoglobin was 10 at the start and 10 at the end and he received between 250 and 350 cc blood.

(b) Describe and explain any concerns relating to blood loss expressed to you by Dr. Taylor, when he alerted you to them and for what purpose

Dr Taylor did not communicate any concerns about blood loss to me.

(c) Describe what (if anything) you agreed with him in respect of the administration of a second infusion of Human Plasma Protein Fraction (HPPF) and when that happened

I had no discussion with Dr Taylor on fluid management during this procedure. I do not discuss fluid management, other than blood loss, when a consultant anaesthetist is involved in a case.

(22) *"It is also my recollection that a little urine was produced before the ureter was connected to the bladder"*. (Ref: 093-010-029 to Ref: 093-010-030)

(a) State the basis of your *"recollection"*

I saw a few drops of urine.

(b) Explain what was done with this urine, including:

- whether it was collected and measured
- and if so, the volume produced

Nothing was done with the urine.

(23) *"I made my record in the clinical notes as the Hospital for Sick Children did not have specific operation notes to my knowledge at the time"*. (Ref: 093-010-030)

(a) In November 1995, did you make your record in the *"specific operation notes"* in your work elsewhere?

Yes. Most hospitals have a specific page to write an operation note. In RBHSC in 1995, they wrote in the continuation notes and did not have a specific 'operation note'.

(b) What information would be recorded on the *"specific operation notes"* and who would be

responsible for recording that information on those notes?

The surgeon or his assistant, anaesthetist and the details of the operation.

#### IV ADDITIONAL INFORMATION

- (24) Describe any discussion between you or Dr. Brown and Dr. Taylor relating to Adam's fluids during the surgery, and state the time at which those took place.

There was no such discussion. Please see 21 (c) above.

- (25) Describe in detail the education and training you received in fluid management (in particular hyponatraemia) and record keeping through the following, providing dates and names of the institutions/bodies:

(a) Undergraduate level: 1975-8 University College Galway Clinical lectures and practical experience in wards and passing final MB

(b) Postgraduate level: Practical experience in paediatric surgery in Galway which was part of the adult workload. Lectures and passing the FRCS examination. I was paediatric Surgical Registrar in Temple Street for a year in 1982-3. I was an examiner in the primary and Fellowship examinations of the Royal College of Surgeons in Ireland. I am an examiner in the iMRCS exam and also an examiner in the FRCS(Urol) examination. Fluid management in surgical patients is an integral and important subject in those examinations. In 1992 I wrote a chapter 'Insertion of the Kidney' in a book entitled Clinical Management of Renal Transplantation edited by Professor McGeown. The intraoperative fluid management and management of hyponatraemia in transplantation, relevant at the time of Adam's transplant, are dealt with in Chapters 14 and 20 by Drs. Alexander and McNamee respectively

(c) Hospital induction programmes: I was Postgraduate Tutor in the Belfast City Hospital from 1997-9 and Lead Clinician in Urology for 7 years 1995-2003. I was Programme Director in Urology for 7 years and responsible for the postgraduate education of all trainees in Northern Ireland. Hyponatraemia is a very common problem in urology and its diagnosis and management were dealt with by me on multiple occasions and it is a continuing and important part of the urology curriculum. As a member of the Specialist Advisory Committee in Urology, I was editor of the urology curriculum nationally for 2 years 08-10, the curriculum outlines the knowledge on fluid and electrolytes required by urologists.

(d) Continuous professional development

See above. I have also attended the Good Clinical Practice course.

- (26) Prior to 26<sup>th</sup> November 1995, describe in detail your experience of dealing with children:

(a) With hyponatraemia, including:

- the estimated total number of such cases, together with the dates and where they took place

It is impossible to say how many children I dealt with with hyponatraemia but, as a paediatric surgical registrar, I was directly responsible for the fluid management of at least 20 surgical patients day and daily for a year.

- the number of the children who were aged less than 6 years old

In a year I would estimate 100's and with hyponatremia of Adam's severity, less than 5

- the nature of your involvement

Post operative management of fluids in surgical patients and on a small number of patients' intensive care management.

- the outcome for the children

In my year in paediatric surgery no patient died of hyponatraemia.

(27) Since 27 November 1995, describe in detail your experience of dealing with children:

(a) With hyponatraemia, including:

- the estimated total number of such cases, together with the dates and where they took place
- the number of the children who were aged less than 6 years old
- the nature of your involvement
- the outcome for the children

None. Adam's death deeply affected me and so I chose not to involve myself in paediatric transplantation after 27<sup>th</sup> November 1995.

(28) Describe in detail your role in the care and treatment of Adam prior to 26<sup>th</sup> November 1995, including:

(a) Date of each occasion and the procedure/surgery undergone by Adam

(b) The hospital concerned

(c) The fluid management regime employed on each occasion

I had no involvement in Adam's care prior to 26<sup>th</sup> November 1995.

(d) The lessons that you learned from your treatment of Adam and his death

Adam had very complicated medical issues to deal with. There were no surgical issues involved in his death. Adam died of hyponatraemia, which I believe was due to the administration of solution 18. I was part of a team but as a team we had had a catastrophic outcome. I decided to have no further part in provision of paediatric transplantation after Adam's death.



- (29) Identify any 'Protocols' and/or 'Guidelines' which governed Adam's renal transplant surgery and those which currently govern such procedures

None at the time. I am not aware of current Protocols or Guidelines as I have not been involved in paediatric transplants since 27<sup>th</sup> November 1995.

- (30) Identify precisely from Adam's medical notes and records the entries that you made or which were made on your direction and state below:

The operation note (AS - Royal 058-035-134 and 058-035-135)

- (a) When each of the identified entries was made

My entry was made immediately on completion of the transplant procedure and just before I went to Belfast City Hospital to attend to the emergency detailed above.

- (b) The source of the information recorded in the entry

The operation.

- (c) Identify the person who recorded "*vascular anastomosis - 10.30am. 27/11/95*" in Adam's medical notes and when this entry was made.

I am unable to attribute the handwriting to any person.

- (31) Provide any further points and comments that you wish to make, together with any documents, in relation to:

- (a) The care and treatment of Adam from his admission for the renal transplant surgery on 26<sup>th</sup> November 1995 to his death on 28<sup>th</sup> November 1995

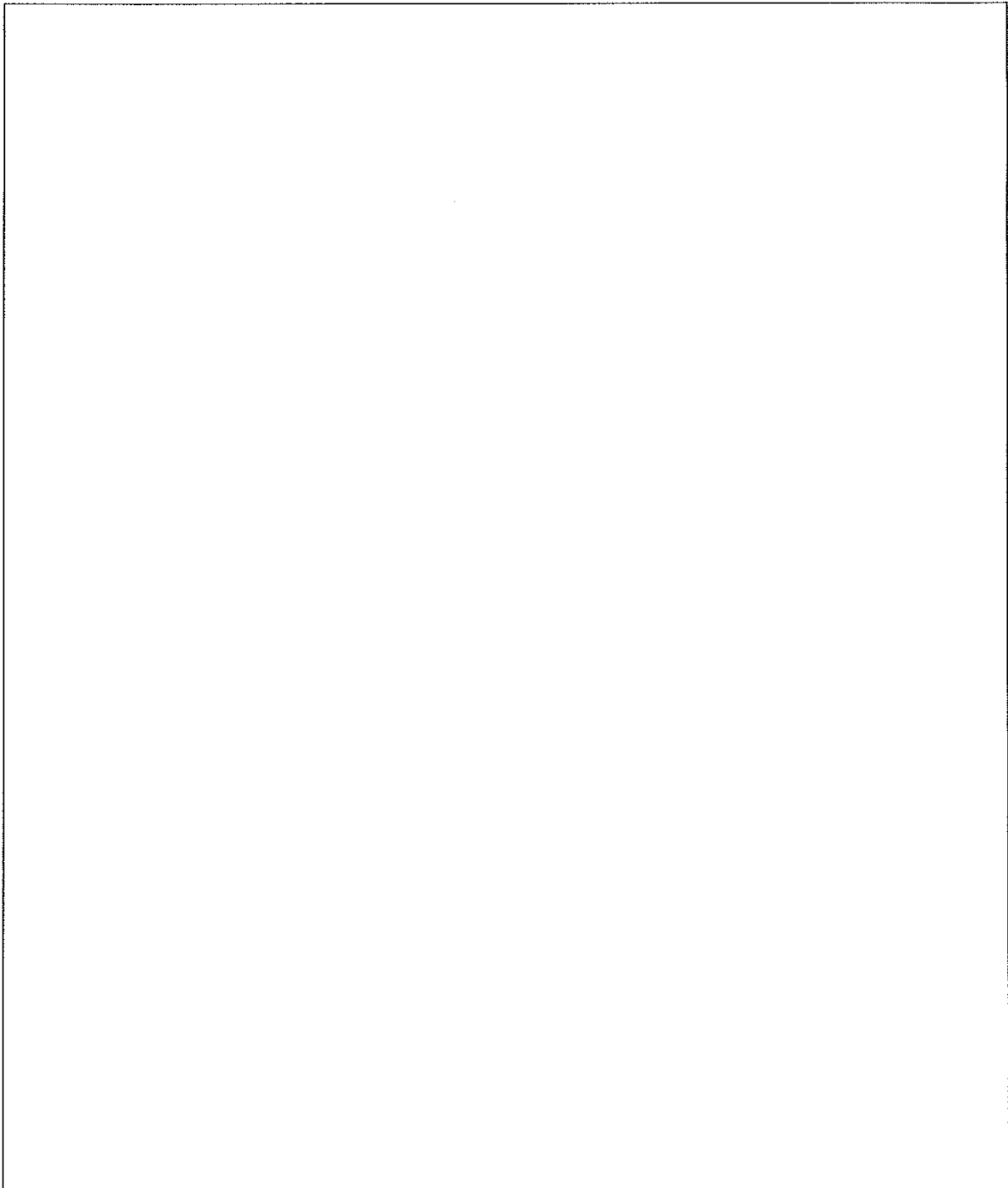
- (b) Record keeping

- (c) Communications with Adam's family about his care and treatment in respect of the renal transplant surgery

- (d) Lessons learned from Adam's death and how that has affected your practice

- (e) Current Protocols and procedures

- (f) Any other relevant matter



**THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF**

**Signed:**

*Fabrizio J. Leone*

**Dated:**

*16/3/11*