

Witness Statement Ref. No.

126/1

NAME OF CHILD: Adam Strain

Name: John Forsythe

Title: Consultant Transplant Surgeon and Honorary Professor

Present position and institution:

Consultant Transplant Surgeon, Royal Infirmary of Edinburgh
Honorary Professor of Surgery, University of Edinburgh

Previous position(s) and institution(s):

January 1992 – June 1995
Consultant Surgeon (Royal Victoria Infirmary) with special interest in renal transplantation
Visiting Surgeon (Alnwick Infirmary)
Honorary Lecturer in Surgery (University of Newcastle upon Tyne)

Membership of Advisory Panels and Committees:

Specialty Advisor, Chief Medical Officer (transplantation and organ donation), 1999
Chairman, Scottish Transplant Group, 2001 - present
President, British Transplantation Society, 2005 - 2007
Non-executive Board member, NHS Quality Improvement Scotland, 2002 - 2007
Non-Executive Board member, NHS Blood & Transplant, 2005 - present
Chairman, Advisory Committee on the Safety of Blood, Tissues & Organs (Advisory Committee to all Ministers of Health in the UK), 2007 - present
General Secretary, European Society of Transplantation, 2009 - present
Lead Clinician for Organ Donation & Transplantation Scotland, 2008 - present

Previous Statements, Depositions and Reports:

OFFICIAL USE:

List of reports attached:

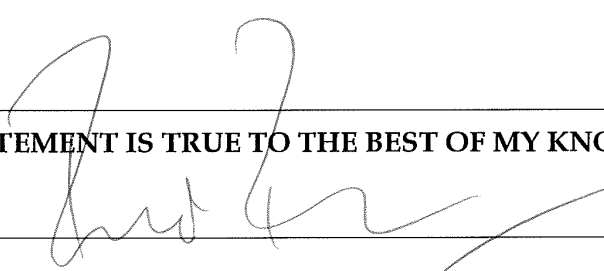
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Particular areas of interest:

John Forsythe specializes in abdominal organ transplantation including liver, kidney and pancreas transplants. He has served on a number of advisory committees as noted above and taken part in 3 external reviews across the UK.

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

Signed:



Dated:

29/6/2011

NAME OF CHILD: Adam Strain

Name: Keith Rigg

Title: Mr

Present position and institution:

Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust (1992 to date)

Previous position(s) and institution(s):

Training positions in General and Transplant Surgery, Newcastle upon Tyne Hospitals 1984-1992

Membership of Advisory Panels and Committees:

Human Tissue Authority (2005 to date)

British Transplantation Society (2001-2011: Ethics Committee, Training committee, Council Member, Vice-President and President)

Department of Health EU Organ Donation Directive Steering Group and Implementation Steering Group (2009 to date)

Chair, Transplant 2013 (2010 to date)

Paediatric Nephrology Networks, Working Party of Royal College of Paediatric and Child Health (2010-2011)

Vice-Chair, Trust Donation Committee, Nottingham University Hospitals NHS Trust (2010-date)

Previous Statements, Depositions and Reports:

None

OFFICIAL USE:

List of reports attached:

Ref:

Date:

Ref:	Date:	

Particular areas of interest:

Adult and paediatric kidney transplantation

Ethics, law and public policy relating to transplantation

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

Signed:



Dated:

20 | 6 | 11



*Expert Witness Report
For
Public Enquiry*

JUNE 2011

K Rigg
KEITH RIGG
20/6/11

John Forsythe
John Forsythe
23/6/2011

**Authors
Keith Rigg
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1 Authors

Keith Rigg has been a Consultant Transplant Surgeon at Nottingham University Hospitals NHS Trust since 1992. He has been actively involved with adult and paediatric kidney transplantation, including small children, during that time. He is immediate Past President of the British Transplantation Society and is a member of the Human Tissue Authority.

John Forsythe was appointed as a Consultant Transplant Surgeon in Newcastle upon Tyne in 1992 and was actively involved in adult and paediatric kidney transplantation in that post. In 1995 he moved to become Consultant Transplant Surgeon at the Royal Infirmary of Edinburgh. For the first few years of that post he continued to be involved in paediatric renal transplant, but is now restricted to adult intra-abdominal transplantation. He is Past President of the British Transplantation Society, General Secretary of the European Society of Organ Transplantation, and Chairman of the Advisory Committee for the Safety of Blood, Tissue and Organs.

2 Review of standard practice (1995 and current)

The patient pathway for a paediatric patient is considered and standard practice described below and where there are significant differences between practices in 1995 and now, these are highlighted.

2.1 Transplant assessment

- Prior to going onto the transplant list it would be expected that the patient and their parents would have been seen by a consultant paediatric nephrologist and a consultant transplant surgeon. This consultation would include a physical assessment, an explanation of the procedure, the risks and benefits involved, and an opportunity for the family to ask any questions.

2.2 Organ retrieval and the offering process

- The organs would be retrieved in standard fashion which involves exposure, inspection and mobilisation of the relevant organs; cross clamping of the major vessels followed by perfusion with cold preservation fluids; removal of organs with inspection prior to packing in cold preservation fluid on ice prior to transport to the recipient centre. The time that the major vessels are cross clamped and organs perfused was recorded on the UKTSSA form in 1995 (this form has been updated subsequently with request for further detail added since then) and the cold ischaemic time starts from this time until the point the kidney is re-perfused with the recipient's blood. The quality of the initial perfusion is (and was) also recorded on this form.
- Once the kidneys were removed and the anatomy and quality of the organs were identified they would be offered according to the national allocation scheme run in 1995 by UKTSSA. This is now run by NHSBT and a provisional offer is now made before the retrieval operation starts, with confirmation once the anatomy and quality of the organ has been seen, in an attempt to reduce cold ischaemic time.
- The offering process involves talking to the designated contact person at the relevant transplant unit which was usually the donor co-ordinator, but is now most often a recipient co-ordinator. This person would discuss the offer with the Consultant Transplant Surgeon and Consultant Paediatric Nephrologist. The decision to accept an organ would be based on donor factors such as size and age, anatomy and cold ischaemic time; recipient factors such as age, size, current medical condition; and recipient hospital resources such as beds and availability of a surgeon with appropriate experience.
- Once the organ has been accepted transport arrangements from the donor hospital to the recipient hospital are made; in the case of kidneys coming to Belfast this would require air travel.

2.3 Recipient assessment

- After the kidney has been accepted the child will be called into hospital for assessment prior to transplantation going ahead. This will include taking a history, performing an examination and performing routine pre-operative investigations. It would be expected to know the results of the urea and electrolytes and a full blood count immediately prior to the operation for the anaesthetist and surgeon to be aware of these.
- When the kidney arrives in the hospital, samples from the donor travelling along with the kidney and including blood samples from the recipient would be taken to the laboratory for a cross-match test which normally takes about four hours. Contemporary practice is evolving whereby a virtual cross-match can be performed in selected patients such that a conventional cross-match is not required and time is saved. A virtual cross-match means characterisation of antibody levels ahead of the organ offer which allows an accurate prediction of the cross-match result and reduces cold ischaemic time by up to 4 hours.
- The operating theatre would be booked by either the donor co-ordinator (1995) or recipient co-ordinator (current) or surgeon; the consultant anaesthetist contacted and asked to assess the patient. An estimated time for theatre should be planned.
- The patient will be seen and assessed by the transplant surgeon, the procedure explained to the child and parents and consent taken.

2.4 Timing of surgery

- Theatre is normally planned for when a negative cross-match test is due to be received and provided all pre-op investigations are satisfactory. It is preferable not to perform kidney transplants between the hours of 0000 and 0600, but if the cold ischaemic time is likely to be over 24 hours (in 1995) or 20 hours (current)[Ref 1,2] then consideration should be given to performing the operation overnight.

2.5 Operative procedure and intra-operative management

- The kidney would normally be inspected by the surgeon prior to commencement of anaesthesia to check for damage and to prepare for surgery.
- The anaesthetist would then anaesthetise the child and place the necessary invasive monitoring such as a central line and arterial line.
- A urethral catheter will always be placed at the beginning at the operation, unless it is not technically possible
- Children under 5 years of age or under 20kg do require special consideration in terms of surgical approach and fluid balance. 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 (the 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. An intra-abdominal approach may occasionally be required

[Ref 3]. There is evidence to confirm better outcomes when larger vessels are used [Ref 4]. 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.

- Once the kidney has been re-perfused with the patients blood the kidney will become pink and enlarge and small amounts of clear fluid may be seen to pass from the ureter, although this does not always happen and in particular if there has been a prolonged cold ischaemic time or anastomosis time. The early passage of fluid is not a predictor of function [Ref 5]. If the kidney becomes mottled or bluish it implies that perfusion is sub-optimal. Any deterioration in perfusion of the kidney should prompt the surgeon to check the flow in the renal vessels, the position of the kidney and to check the blood pressure and central venous pressure readings with the anaesthetist.
- The fluid balance would be the prime responsibility of the anaesthetist, but in more complex patients, the consultant paediatric nephrologist would be involved. The surgeon may request a higher blood pressure or a fluid challenge if they are worried about the perfusion of the organ, but the prime responsibility would remain with the anaesthetist.
- Before closure of the abdomen careful positioning of the kidney is always required, but particularly when a large kidney is placed in a small child where proper positioning for best perfusion of the kidney can be challenging. Contemporary practice includes the option of delayed closure of the wound for 48 hours.

2.6 Post-operative management

- The child would return to either intensive care or a high dependency ward setting for close monitoring.
- It is recognised that renal artery or venous thrombosis will occur in up to 5% of transplants, but that this risk may be higher in small children, with kidneys with multiple arteries and with prolonged cold ischaemic time [Ref 6-9]

3 Issues raised by the documentation

In considering the case of Adam Strain we have been provided with a large number of documents by the officers acting for the Public Inquiry, which we understand to be a subset of the total documents available in this case. We confirm that we have asked for some further information and that has been provided. In reviewing the documentation we would wish to highlight the following issues, before dealing with the specific issues raised by the Inquiry team:

3.1 Transplant assessment

- No transplant surgeon appears to have been involved in the initial assessment and listing for transplantation for Adam. This is against best practice. Although this practice does not appear to have been followed, it is unlikely to have had any effect on the ultimate outcome.
- It is recognised that polyuric kidney failure is very rare in the adult setting and even unusual in the paediatric setting. Most renal patients on dialysis have a decreased native urine output.

3.2 Organ retrieval and the offering process

- There were no specific difficulties identified in the retrieval process of the 16 year old donor and the kidneys were removed in a satisfactory manner. The perfusion of the kidneys was described as 'good'.
- It is unclear from the documentation who in Belfast received the offer for the kidney, with whom it was discussed and who made the final decision to accept the kidney.
- Many units would have concerns in accepting a kidney for a small child with complex problems that would have a cold ischaemic time in excess of 30 hours and with multiple arteries.
- It is also unclear why there was a delay between the kidneys being removed and arriving in Belfast. Possible explanations include travel delays, the kidney having been offered to another centre first or lack of appreciation of the significance of the prolonged ischaemic time within the transplant centre.

3.3 Recipient assessment

- A transplant surgeon did not see the child and his mother prior to surgery and did not take consent. Consent was taken by Dr Savage, the consultant nephrologist, who was not capable of doing the operation.
- In view of the complex nature of Adam's fluid balance management it would have been expected that he would have a urea and electrolyte estimation repeated on the morning of surgery and for the result to be available prior to commencement of anaesthesia and surgery.

3.4 Timing of surgery

- As mentioned above it is unclear why there was a delay between 0142 on 26 November 1995 and Adam arriving at 2100 later that day. During this time one might have expected that the kidney could have been transported to Belfast, the recipient prepared, cross-match test performed, and the transplant completed by the late evening of 26 November 1995. In fact by the time the cross-match test had been performed and the result made available, the earliest the operation could have gone ahead would have been 0200 and it was therefore reasonable for the operation to be scheduled for 0600.

3.5 Operative procedure and intra-operative management

- Conventional practice would be to insert a urethral catheter before the commencement of surgery, but in this case it was not done.
- In a larger teenage child it would be acceptable to use the external iliac artery for the anastomosis, but in a young child aged under 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.
- The anastomosis time is recorded on the UKTSSA form as 120 minutes; if this is correct this is a major concern, but it may reflect inaccurate recording. It is unclear from the documentation when the preparation of the kidney and arteries was undertaken. Whilst it would be best practice to do this before the start of anaesthesia, it may be that this is what is recorded as happening at 0830 on the UKTSSA form. Two hours of warm ischaemia is very likely to cause irrevocable damage to a kidney.
- We would concur that Adam's transplant surgery would have been more difficult because of multiple previous procedures and that a greater than usual blood loss may have occurred. Estimations of the loss vary in the evidence presented to us, but the relevant perioperative form has the following: blood loss =500ml suction (approx.), swabs =411.1ml. To this some of those involved have added approximately 200ml for 'soaked drapes'. There is evidence that not all of this fluid measured will be blood loss and will instead be urine or the fluid used to cool the kidney. A significant proportion of this is likely to be urine because Adam's bladder was not catheterised at the start of the operation (by the evidence of the surgeon) and that Adam's mother was told immediately after the operation that he had a 'big bladder' which would have been opened to attach the ureter. [The bladder is opened during standard renal transplant operations and any urine in the bladder then escapes into the wound, and will then be removed by suction.]
- In children with complex fluid balance issues or who are having problems with surgery it is often helpful for the consultant paediatric nephrologist to be present in theatre to give further advice to the anaesthetist. There is conflicting evidence in the reports in that Dr Savage says he was not called until after the operation was finished, whilst Mr Keane recalls Dr Savage 'walking in and out' of theatre.

- In the documentation there were conflicting reports as to whether perfusion was satisfactory at the end of the operation and whether perfusion was worse at the end of the procedure than at initial reperfusion of the kidney. There is no documentary evidence that the significance of this change has been appreciated, or that the steps detailed above were put into place, or it may be that the passage of time since the event means that there no accurate recollection as to whether the change in colour was really significant. It may be that this was the beginning of the process of ischaemia and subsequent infarction.
- We note the witness statement of Eleanor Donaghy and her recollection of events in theatre appear very different to those of Mr Keane, Mr Brown and Dr Taylor. This may reflect the difficulty in remembering events of 11 years ago and we do not feel able to comment further.
- Whilst recognising that the operating surgeon had to leave before the end of the procedure to deal with a surgical emergency elsewhere, it is recognised that best practice is for the surgeon to stay for the closure of the wound to ensure optimal positioning of the kidney. The surgeon should also be available in the immediate post-operative period in case of concerns or complications.

4 Issues raised by the enquiry team

4.1 The role of the transplant surgeon in discussing with the patient's family the risk of death and adverse events from the transplant surgery

- A transplant surgeon from the team should see the patient and parents in the transplant assessment clinic, prior to going on the transplant list, which allows full discussion regarding the operation, the risks and benefits of transplantation, and allows discussion about individual patient issues. The operating transplant surgeon should see patient and parents again prior to surgery and reassess the patient and ensure they are fully aware of all active problems and relevant past medical and surgical history. They should also be responsible for taking or confirming consent. It is also good practice for the surgeon to see the patient and parents/carer in the early post-operative period.

4.1.1 The quality of the communication by the transplant surgeon with Adam's family (particular Adam's mother)

- There is no documented evidence of any communication between the transplant surgeon (indeed any surgeon) and Adam's family at initial transplant assessment or prior to surgery.

4.1.2 The role of the transplant surgeon in gaining consent from the paediatric patient's parents (both in 1995 and now)

- 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. In 1995 it may have been more usual to delegate this responsibility to surgical trainees if they were available; however the overall responsibility lay with the operating surgeon. Now there is clear guidance set out from the GMC, Department of Health and Royal College of Surgeons about the role of the surgeon in gaining consent and in what circumstances this can be delegated.
- The following points are made in Section 26 and 27, Responsibility for seeking patients consent – in the General Medical Council, '*Consent Guidance*' published in 2008 [Ref 10].

26. If you are the doctor undertaking an investigation or providing treatment, it is your responsibility to discuss it with the patient. If this is not practical, you can delegate the responsibility to someone else, provided you make sure that the person you delegate to:

- a. is suitably trained and qualified
- b. has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved
- c. understands, and agrees to act in accordance with, the guidance in this booklet.

27. If you delegate, you are still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before you start any investigation or treatment.

The following points are made in Section 5, Who is responsible for taking consent – in the Department of Health, *'Good practice in consent implementation guide: consent to examination or treatment'* published in 2001 [Ref 11].

1. The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.

3. The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

The following points are made in Section 4.1 of the Royal College of Surgeons of England, *'Good Surgical Practice'* published in 2008 [Ref 12]

In addition, surgeons must:

- establish whether a patient has a supporter as early as possible in the relationship and mark this clearly on their notes;
- meet with the patient prior to surgery to discuss operation and implications;
- ensure that patients, including children, are given information about the treatment proposed, any alternatives and the main risks, side effects and complications when the decision to operate is made. The consequences of non-operative alternatives should also be explained;
- provide time for patients and their supporters to discuss the proposed procedure and provide an opportunity for the patient to make a fully informed and unharassed decision to agree to the treatment suggested and to indicate by signature their willingness to proceed

4.1.3 Any particular risks that were apparent in Adam's case that should have been explained by the transplant surgeon to Adam's mother before the transplant surgery.

The particular risks for Adam were

- His age and size (children aged under 5 years of age or less than 20kg do require special consideration) [Ref 8-9]
- The multiple previous operations he had had which would have led to adhesions and increase the duration of surgery and likelihood of blood loss

- A prolonged cold ischaemic time which would have most likely resulted in a delay to the kidney functioning and which increases the risk of thrombosis in children [Ref 9]
- Multiple vessels which do increase the risk of thrombosis [Ref 7]
- The match of the donor kidney, which was a half match, which may have resulted in a slightly higher risk of rejection

4.1.4 Whether (both in relation to 1995 and now) patients and their families are regularly informed of the identities of their surgical team, and if they are unhappy with a particular surgeon, whether alternatives are made available.

- It is expected that patients and their families will have met a surgeon at their initial transplant assessment and at that stage they can express any preference for a particular surgeon, although in practice it is uncommon for this to be stated. If a transplant is being performed out of hours the preferred surgeon may not always be available and the patient and their family will be able to make a choice as to whether to proceed or not.

4.1.5 Whether there were any other options to immediate renal transplant surgery that should have discussed and/or recommended, such as:

- ***delaying transplant surgery until Adam was older***
- ***having Adam taken to a centre with greater experience of paediatric renal transplant***
- ***having the transplant carried out by a more experienced team***
- Ideally these options should be discussed at the initial transplant assessment clinic, and not in an emergency situation where decision-making can be pressured.
- In respect of the specific options:
 - Delaying transplant surgery until Adam was older would not have been in his best interests as quality of life and life expectancy would be improved with a successful transplant as opposed to dialysis.
 - 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. The evidence that we have seen shows that the Belfast performed a mean of 4.2 transplants per year in patients aged under 14 years of age during the period 1990-1995, and 3.3 transplants per year for the period 1990-2004.
 - It is always preferable to have the most experienced team available

4.2 The extent to which the transplant procedure in Adam was complex (due to his previous surgery, age and weight)

Adam's transplant procedure was complex for the reasons previously stated, namely:

- His age and size (children aged under 5 years of age or less than 20kg do require special consideration)
- The multiple previous operations he had had which would have led to adhesions and increase the duration of surgery and likelihood of blood loss

- A prolonged cold ischaemic time which would have most likely resulted in a delay to the kidney functioning
- Multiple vessels in the donor kidney, a fact which does increase the risk of thrombosis

4.3 The level and type of surgical experience that was warranted in the circumstances

- The surgical experience that was warranted was a consultant transplant surgeon who was experienced in dealing with children aged under 5 yrs or weighing under 20kg requiring a kidney transplant. In addition an experienced surgical assistant would be required.

4.4 The level and type of surgical experience of the surgical team that actually operated on Adam Strain

- From the documentation it appears that the operating consultant surgeon was a very experienced adult transplant surgeon, but who had limited paediatric experience (particularly in small children). According to the documentary evidence he had only personally performed three paediatric transplants at that stage and subsequently stopped doing them altogether. The surgical assistant was a consultant paediatric surgeon who had previously operated on Adam, but had limited transplant experience.

4.5 Whether the Royal Belfast Hospital for Sick Children had the facilities and resources, both in terms of clinical experience and technological services, to carry out such a surgery in November 1995

- As it is now 16 years since the event and with the documents we have at our disposal it is not possible to make a robust statement about this. In particular we have not been made aware of the paediatric transplant experience of the other consultant transplant surgeons on the rota at that time.
- A review of paediatric renal transplantation for the period 1984-1998 was published in 2000 [Ref 13] and 77 patients had been transplanted in that time. The results were stated to be comparable to other centres with 5 year graft survival of 64%, two patients dying after transplantation and 13% of kidneys failing within the first 30 days.
- It was noted that John Forsythe was recently involved in a review of transplant services in Northern Ireland commissioned by Dean Sullivan, Director of Commissioning. Most of the focus during that review was on the adult renal transplant service but comments were also made about the paediatric service. It is acknowledged that the review was carried out many years following this particular case but some of the comments in the review might be considered to be pertinent.
- Keith Rigg has been a member of a working party of the Royal College of Paediatric and Child Health and a document titled 'Improving the standard of care of children

with kidney disease through paediatric nephrology networks' will be published later this year. The recommendation about paediatric transplant units will state: 'A paediatric transplant unit should offer the full range of deceased and live donor transplants, including ABO incompatible transplantation, to all appropriate patients. There should be a full multi-professional team with appropriate support services and robust transition processes in place. Each unit should have at least two surgeons who have expertise particularly in the younger child.'

4.6 The frequency of blood and electrolyte results that should have been sought including whether, as a matter of good practice, the surgeons should have sought up to date information on Adam's electrolyte levels prior to commencing the transplant procedure and, if so, the practical significance of not having such information prior to commencing the transplant procedure

- In view of the complex nature of Adam's fluid balance management it would have been expected to have a urea and electrolyte estimation repeated on the morning of surgery and for the result to be available prior to commencement of anaesthesia and surgery. It is our view that it is primarily the responsibility of the consultant anaesthetist to have seen the result, but it would also have been good practice for the surgeon to be aware. By going ahead with anaesthesia and surgery without knowing the electrolytes, and in view of Adam's past medical history, the team were risking significant electrolyte disturbances during the intra-operative period.

4.7 The significance for the surgeons (if any) of the fact that Adam had a past history of occasional hyponatraemia (with serum sodium results of below 120mmol/L)

- It was important for the surgeons to be aware of the history of hyponatraemia, but it would have been the primary responsibility of the anaesthetist to monitor this and act on abnormalities during anaesthesia. From the documentary evidence Dr Savage had highlighted this particular issue with both Dr Taylor and Mr Keane.

4.8 The information that the surgeons should have sought about Adam's medical condition and his physical state before commencing the transplant procedure, and the reasons for them seeking it

- 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. They should also have examined the patient's abdomen. Evidence was presented to suggest that some of these key factors in Adam's condition had been conveyed by telephone from Dr Savage to Mr Keane. The reason the surgeon should be aware of these was to ensure the procedure was performed in a safe and effective way.

4.9 The significance for the surgeons (if any) of the fact that the donor kidney was perfused at 01:42am on 26th November 1995 and the transplant surgery was not scheduled to start until 07:00am on 27th November 1995

- The transplant surgeon should have been aware that the cold ischaemic time would have been in excess of 30 hours by the time the kidney was re-perfused with blood during the transplant procedure, and that a prolonged cold ischaemic time is associated with delayed kidney function. It is preferable not to perform kidney transplants between the hours of 0000 and 0600 because of potential surgical fatigue in a potentially complex case and reduced levels of ward staffing. If the cold ischaemic time is likely to be over 24 hours then consideration should be given to performing the operation overnight. In 1995 cold ischaemic times were kept below 24 hours where possible, but there is now evidence that cold ischaemic times of greater than 20 hours are associated with delayed kidney function and poorer long term outcome. [Ref 1-2]

4.10 The likely viability of the transplant kidney prior to it being transplanted into Adam, and commenting on the views of:

- (a) *Dr. Alison Armour who carried out the post-mortem*
- (b) *Professor Peter Berry*
- (c) *Professor Rupert Risdon*

- From the documentary evidence provided it is our view that the kidney was viable when removed from the donor initially at 0142 on 26 November 1995, and was still viable when removed from ice and when re-perfused with blood at 1030 on 27 November 1995. This is based on the UKTSSA form which records good perfusion of the donor kidney and the fact that no other witness comments in a negative fashion about the appearance of the kidney prior to implantation.
- Dr Alison Armour comments that at post-mortem the transplanted kidney was totally infarcted. It is our view that infarction occurred sometime between re-perfusion of the kidney and withdrawal of life support in Adam after brain stem death tests had been performed.
- We have read the report of Dr Peter Berry and his supplemental statement, along with Professor Risdon's view and subsequent response from Dr Berry.
- A kidney that has had been removed and stored at a cold temperature with no blood supply for over 30 hours will show signs of damage after re-perfusion (acute tubular necrosis). If a kidney then completely loses its blood supply shortly after the transplant procedure it will then appear completely infarcted. The pathologists acknowledge that it is hard to be completely accurate in timing this latter event, therefore our judgement remains that the kidney was viable right up to the time it was re-perfused with Adam's blood.
- We note that the paired kidney also infarcted and failed. In the documentary evidence it states that the blood vessels of this recipient (of this paired kidney) were of poor quality and thin and attenuated, which may have contributed to this kidney infarcting. As noted above renal vascular thrombosis is a recognised complication of

transplantation, particularly in the small child. It is unfortunate that this complication has occurred in both kidneys from one donor.

For us it is inconceivable that a donor surgeon and his assistant, plus an operating surgeon and his assistant and the anaesthetist, would fail to notice an infarcted kidney and carry on with the transplant operation. No infarcted kidney 'pinks' up after re-perfusion.

4.11 The effect (if any) of the viability of the transplant kidney on the impact of the volume and rate of fluid infused into Adam

- As noted above if there is any evidence of poor perfusion then after taking note of the blood pressure and central venous pressure readings, further intravenous fluids may be given as a bolus.

4.12 The extent to which the administration of fluids in response to the concerns over the quality/perfusion of the transplant kidney could have had an effect on the development of the hyponatraemia.

- We are not best qualified to answer this question, except to comment that a surgeon who is worried about perfusion of a transplanted organ will ask the anaesthetist for optimisation of the central venous pressure and blood pressure.

4.13 The appropriateness of the approach adopted by the surgeons to anastomosis the transplant renal vein to the external iliac vein and the two transplant renal arteries on a common patch to the iliac artery, as opposed to choosing larger vessels for the anastomoses such as the aorta and vena cava having regard to Adam's age and size (4 years old and approximately 20kg)

- 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. An intra-abdominal approach may occasionally be required.
- In a larger teenage child it would be acceptable to use the external iliac artery for the anastomosis, but in a young child aged under 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.

4.14 Whether there was a surgical error in the performance of the arterial or venous anastomosis and or in the positioning of the kidney before closure

- From the documentary evidence it is not possible to say if there was a surgical error in the performance of the arterial or venous anastomoses or in the positioning of the kidney before closure. However there is concern that there was discolouration of the kidney before closure which may have been relatively benign as is sometimes seen a short time after re-perfusion. On the other hand it may have been indicated an evolving ischaemia of the kidney either for positional reasons or due to reduced flow in the renal artery particularly as the smaller external iliac artery was used.

4.15 The implications (if any) for the transplant procedure and its success of the fact that the total storage time of the donor kidney was about 34 hours by the time it was implanted into Adam and perfused with blood

- We have addressed the issue of cold ischaemic time above and that a kidney with 34 hours of cold ischaemic is likely to have a period of delayed kidney function, which should recover. In our combined experience we have transplanted kidneys into adults with prolonged cold ischaemic times of up to 40 hours and have seen functioning kidneys after a variable period of delayed kidney function.
- We have noted our concerns about the time recorded to perform the arterial and venous anastomoses and if this really was 120 minutes then this would impact negatively upon the outcome of the transplant procedure.

4.16 The relationship between the surgeons and the anaesthetists during transplant procedure in respect of the administration of fluids, including:

- a) How the surgeons and anaesthetists work as a team in the operating theatre*
- b) How the surgeons and anaesthetists work as individuals in the operating theatre*
- c) The need for the surgeons to be aware of Adam's blood pressure, central venous pressure measurement and sodium levels during the transplant procedure*

- Our experience is that surgeons and anaesthetists do work together as a team in theatre, but that they have different roles and responsibilities. The surgeon is primarily responsible for performing the procedure and keeping the anaesthetist and the rest of the theatre team fully apprised of progress and any unexpected events. The anaesthetist is primarily responsible for the induction and maintenance of anaesthesia, analgesia and fluid balance; and for informing the surgeons if there are unexpected events. The shared priority of the surgeon and anaesthetist is the safety of the patient.
- We are unable to comment from the evidence available on how the surgeons and anaesthetists looking after Adam worked both as a team and individuals in the operating theatre.

- This was a difficult operation and the surgeons would have been concentrating primarily on performing the operation, and although they should have been aware of Adam's blood pressure, central venous pressure and sodium readings, these were the primary responsibility of the anaesthetist.

4.17 As between the surgeons and the anaesthetists, where the primary responsibility lies for ensuring that the appropriate balance is achieved between excessive venous filling which would be dangerous to Adam and under filling which would be dangerous to the transplanted kidney

- Fluid balance and central venous pressure monitoring is the primary responsibility of the anaesthetist, and the optimal management of the patient should always come before that of the kidney. The surgeon will be aware of the state of the kidney and if it is showing signs of poor perfusion will request intervention to effect a higher blood pressure and central venous pressure reading. Again, we feel that good teamwork is important and we agree with this statement concerning the good management of fluids and haemodynamic factors around the time of reperfusion of a transplant kidney "we consider a constant dialogue with the anaesthesia service of paramount importance in this regard". [Ref 14]

4.18 The likely requirement by the surgeons for the anaesthetist to provide extra fluid input where a transplanted kidney becomes discoloured and/or perfusion becomes sub-optimal

- See answers to 4.17, 4.11 and 4.12

4.19 Whether any production of urine by the donor kidney would be incompatible with the donor kidney being infarcted

- Early after re-perfusion one cannot categorically state that any fluid produced by the kidney is urine. Following a live donor transplant large amounts of urine may be produced when a kidney works immediately and effectively after re-perfusion. When a few drops of fluid are produced following re-perfusion in a deceased donor kidney there is no predictive factor either for short or long term outcomes. An infarcted kidney looks mottled and discoloured, and the presence or absence of a few drops of fluid are irrelevant.

4.20 Whether back bleeding from the renal vein can be mistaken for proper perfusion and whether residual donor renal pelvic fluid expressed on renal handling can sometimes be mistaken for early production of urine

- Back bleeding from the renal vein can be mistaken for proper perfusion.

- Residual donor renal pelvic fluid expressed on renal handling can sometimes be mistaken for early production of urine.
- In Adam's case there is not enough evidence presented to allow us to say whether these statements are pertinent in his transplant procedure.

4.21 The extent to which the poor function of the donor kidney may have been due to:

- (a) Low blood pressure*
 - (b) Surgical error in the anastomosis or the positioning of the new kidney before closure reducing the flow of blood to it*
 - (c) Development of acute tubular necrosis*
 - (d) Some other cause (and if so what that cause is)*
- A large number of deceased donor kidneys do not pass urine initially and have delayed kidney function due to damage to the kidney tubules, called acute tubular necrosis. These kidneys usually recover in days or weeks and the ultimate prognosis is good. The absence of urine immediately after re-perfusion in a deceased donor kidney (especially one with a cold ischaemia time of greater than 30 hours) would not be an immediate matter for concern.
 - Clearly from the reports of the three pathologists the kidney lost its blood supply and infarcted. It is our view 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.
 - A low blood pressure can result in both acute tubular necrosis and renal vascular thrombosis, but there was no evidence from the anaesthetic record that Adam's blood pressure was low. Adam had a satisfactory blood pressure, for his age and size, throughout the operation.

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Statement of Truth

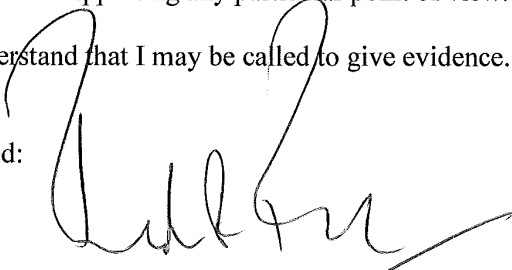
I understand that my duty as an expert is to provide evidence for the benefit of the Inquiry and not for any individual party or parties, on the matters within my expertise. I believe that I have complied with that duty and confirm that I will continue to do so.

I confirm that I have made clear which facts and matters referred to in my report(s) are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which I refer, having studied all the relevant documents supplied to me.

I confirm that I have no conflict of interest of any kind, other than any disclosed in my report(s). I do not consider that any interest that I have disclosed affects my suitability as an expert witness on any issue on which I have given evidence. I undertake to advise the Inquiry if there is any change in circumstances that affects the above. I have no personal interest in supporting any particular point of view.

I understand that I may be called to give evidence.

Signed:



JOHN FORSYTHE

Date:

31/8/2011

Statement of Truth

I understand that my duty as an expert is to provide evidence for the benefit of the Inquiry and not for any individual party or parties, on the matters within my expertise. I believe that I have complied with that duty and confirm that I will continue to do so.

I confirm that I have made clear which facts and matters referred to in my report(s) are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which I refer, having studied all the relevant documents supplied to me.

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I understand that I may be called to give evidence.

Signed:



Date: 31st August 2011

Mr Keith Rigg