



**QUESTIONS FOR PROFESSOR JOHN
FORSYTHE & MR. KEITH RIGG**

**ARISING OUT OF CONSULTATION NOTE
DATED 14TH JUNE 1996**

RE: ADAM STRAIN

August 2012

**Authors
Keith Rigg
John Forsythe**

Keith Rigg 1/8/12
John Forsythe 3/8/2012.

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RE: ADAM STRAIN

We have answered those questions which are within our areas of expertise.

Timings of the surgery

- (1) Please set out, from the consultation document, and your knowledge of the medical notes, what you consider to be the approximate timings of the surgery, including the timing of:
- (a) The veins being connected to the donor kidney
 - (b) The kidney being placed in situ
 - (c) Vascular anastomosis being completed
 - (d) The sewing up of the wound
 - (e) The reversal of the anaesthetic

From the anaesthetic record (Ref:058-003) the anaesthetic commenced at 0705 and finished at 1100, and there is no comment on that record of what time surgery started or finished. There are no accurate timings of when the vascular anastomoses were completed in the operative record (Ref:058-035); although there is a non-attributable entry that the vascular anastomosis was completed at around 1030. The consultation document (Ref:122-001) states 'In this case the kidney was in at around 9.30am. The vein was in and the arteries were being finished.'

It is not possible from the evidence available to give actual timings as these have not been recorded, but from the consultation document the anastomosis of the donor renal vein to the recipient external iliac vein would have been completed before 0930. At around 0930 the anastomosis of the renal arteries to the external iliac artery was being finished. The phrase 'the kidney was in' means to us that both the venous and arterial anastomoses have been fully completed and the kidney reperfused; whereas in this document it refers to a time before the vascular anastomoses had been completed. There is no accurate information about when the wound would have been closed except that it would likely have been at some time between 1030 and before 1100. The reversal of the anaesthetic would have been around 1100.

- (2) What is the normal period of time from 'knife-to-skin' for:
- (a) The veins being connected to the donor kidney
 - (b) The kidney being placed in situ
 - (c) Vascular anastomosis being completed
 - (d) The sewing up of the wound (including how long this would take)

The duration of a kidney transplant operation is very variable and will depend on factors that relate to the recipient, to the donor organ and to the surgeon. Most kidney transplants will

be performed within a period of 75-150 minutes, but may be longer if there are difficulties at any stage. Indicative times for the different stages of the operation are as follows:

- Time from initial incision to exposure of blood vessels ready for anastomosis: 30-60 minutes
- Time for venous and arterial anastomoses and reperfusion of the kidney: 20-40 minutes
- Time to check for bleeding and for ureteric anastomosis: 15-30 minutes
- Closure of the wound: 10-20 minutes

(3) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"Dr Taylor pointed out it was very possible that this kidney could have been in place within an hour."* (Ref: 122-001-002)

It depends what Dr Taylor means by 'in place', but if this were to mean the venous and arterial anastomoses being completed and the kidney perfused then it would be possible within an hour in a straightforward kidney transplant. In Adam's case this was not a straightforward kidney transplant and it is likely that the initial part of the operation would have taken longer because of the adhesions present and the need to reconstruct the two arteries on a widely separated patch.

(b) *"In this case the kidney was in at around 9.30am. The vein was in and the arteries were being finished. At this stage Dr Taylor did a blood gas assessment and based on the results of this then started to give the blood. Once the blood was being put through the clamps were released and further blood was given at a later stage."* (Ref: 122-001-003)

(i) What may be meant by:

- *"the kidney was in at around 9.30am"?*
- *"The vein was in"?*

(emphasis added)

As described above our understanding of the kidney being 'in' would be when the venous and arterial anastomoses were completed and the kidney being reperfused with blood. The description from the document describes the kidney being 'in' when the venous anastomosis was complete, but whilst the arterial anastomosis was not yet finished. As the venous anastomosis was complete the kidney would be attached to the recipient vein and therefore may be described as being 'in situ', but we would assert that a more accurate description of the kidney being 'in' would be the one we have given above. Our understanding of the vein being 'in' would be when the anastomosis of the donor renal vein to the recipient external iliac vein had been completed.

(ii) What would be the time period between the vein being "in" and the "arteries [...] being finished"?

As described above, the time for the venous and arterial anastomoses to be completed would normally be in the order of 20-40 minutes. As each normally takes approximately the same period of time, the time between completion of the venous anastomosis and the completion of the arterial anastomosis (or the time taken to complete the arterial

anastomosis) would be of the order of 10-20 minutes depending on the complexities involved.

- (iii) What would have been the implications for Adam's fluid management when the "kidney was in" and the "arteries were being finished"?

At this stage of the operation and prior to reperfusion of the kidney it is important that the patient is well filled with fluid as evidenced by a CVP reading in the target range for that unit and a good blood pressure. This will usually require the administration of intravenous fluids to reach this state.

- (c) *"this procedure was planned to last 1-1 ½ hours."* (Ref: 122-001-003)

As described above a straightforward transplant operation can be completed in 75-90 minutes, but in a complex patient such as Adam this would be over optimistic and an operative duration of 120-180 minutes would be more realistic.

Condition of the donor kidney

- (4) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

- (a) *"A query was also raised about whether the new kidney had been properly perfused. The kidney was not performing well and it was felt that more fluids were required. It was pointed out that one can get a situation where the new kidney just simply does not work and in fact perhaps 5-10% of transplanted kidneys will not work."* (Ref: 122-001-005)

The 5-10% figure relates to the percentage of transplanted kidneys that fail within the first year; and it is generally accepted that 5% of transplants will fail because of arterial or venous thrombosis. However it would be extremely unusual for the transplant to fail at the time of operation. If there was concern about the blood supply to the newly transplanted kidney various manoeuvres would normally be tried to improve the blood supply, and if despite those the blood supply could not be restored then the kidney would usually be removed at the time. There was no reference made to any of this within the operative record.

- (b) *"During the surgery when this kidney was failing to operate a needle was put into the artery and no blood came out and clearly the kidney was not working when the operation site was closed however, the performance of the kidney was no longer relevant at this stage."* (Ref: 122-001-005)

- (i) What was the purpose of putting a needle into the artery?

The purpose of putting a needle into the artery is to determine if there is blood flow into the kidney. If blood comes out of the needle then the surgeon is reassured that there is blood getting to the kidney; but if there is no blood, and the surgeon is happy that the needle is in the lumen of the artery, then this means there is no inflow of blood to the kidney.

- (ii) Is this commonly done in transplant surgeries?

In our experience this is very uncommon, and is only done when there is concern about whether there is a blood flow in the artery when no pulse in the artery can be felt.

(iii) What is the significance of no blood coming out?

If no blood comes out of the needle and the surgeon is happy that the needle is in the lumen of the artery then this means there is no inflow of blood to the kidney. The consequence of this is lack of blood to the kidney and the process of infarction (death of the kidney tissue) would begin.

(iv) What might "the performance of the kidney was no longer relevant at this stage" have meant?

This would suggest to us that the surgical and anaesthetic teams must have recognised the seriousness of Adam's condition and of his very poor prognosis. In normal situations where a kidney had no blood supply and it couldn't be rectified then the kidney would be removed, but if time was of the essence for the patient's overall clinical condition, then the kidney may be left in situ. However if this route was followed the kidney would need removing over the next 24-48 hours before it caused harm, unless of course the patient had died within that time frame.

(v) Is this procedure consistent with the evidence that you have seen and heard to date and if not in which way is it inconsistent?

This course of events is not consistent with what is recorded in the case notes, within the witness statements or the oral evidence given, with perhaps the exception of those given by Eleanor Donaghy.

Specifically there is no mention in the operative record that there was any concern about the perfusion and Mr Keane wrote in the operation note, albeit as a separate entry, that 'the kidney was perfused reasonably at the end'. If a needle has been placed in the artery and there was good flow of blood then it would be reasonable for that not to be recorded; if however the needle had been placed and there was no flow of blood and the 'kidney was clearly not working' (and in this context this implies there was no blood supply) then this should have been recorded. This is at odds with the written operative record that states the kidney was perfused reasonably at the end.

(vi) How significant a procedure is it in terms of describing what was happening?

As stated above: If a needle has been placed in the artery and there was good flow of blood then it would be reasonable for that not to be recorded; if however the needle had been placed and there was no flow of blood and the 'kidney was clearly not working' (and in this context this implies there was no blood supply) then this should have been recorded.

(vii) Should it have been recorded in Adam's notes and records and if so where?

Yes at a minimum there should have been a record in the operation note, and a note of the concerns in the anaesthetic record.

Blood loss

(5) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) "To replace blood one must provide 2½ times the volume of blood lost" (Ref: 122-001-001)

- (b) *"The first packed cell was given after the blood gas readings had been checked. It is generally the situation that they prefer not to give blood if this is avoidable particularly with children as it may contain viruses."* (Ref: 122-001-002)
- (c) *"The low haematocrit level could be explained either by blood loss or over transfusion of water. If this was explained by an over transfusion of water one would have expected the haemoglobin level to be very high at the end of the procedure whereas in fact it was normal at the end of the procedure suggesting that the haematocrit low level had been due to blood loss."* (Ref: 122-001-003)
- (d) *"The blood loss was measured as approximately 1,200 mls. Only 500 mls of packed cells were given but these actually are equivalent to double the amount of fluid."* (Ref: 122-001-003)
- (e) *"It was also pointed out that some of what was thought to be blood loss could in fact have been a mixture of urine and blood. However, the haemoglobin at the end of the procedure was fine showing that the sums to compensate for this had been correct."* (Ref: 122-001-004)
- (f) *"There had also been a query raised that there was a delay in providing blood replacement. The doctors considered the following to be of guidance:- If one has lost 10% of blood volume then you could provide a drip of platelets and fluid. If 15-20% of blood volume was lost then one could give blood."* (Ref: 122-001-005)
- (g) *"However it was felt not to be as clear cut as to when one would start to replace the lost blood volume and it was commented that some people would bleed down to 30% prior to surgery. They said that the anaesthetist monitoring the situation would look at all factors and may not rush straight in to replace blood depending on the situation."* (Ref: 122-001-005)

These seven questions would best be answered by a paediatric anaesthetist.

CVP

- (6) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:
 - (a) *"The CVP readings although showing as 17 were felt to really provide a base of 12 because of the gradient between the jugular and the heart which was assessed at around 5 cms. For this procedure one would push up the CVP as high as one would dare ie around 5 cms. Therefore one would allow it to go up to 22 when starting with the base of 17."* (Ref: 122-001-003)
 - (b) *"Dr Taylor pointed out that his practice would tend to be to have the CVP on a pole and to keep the transducer well away from the dialysis tube."* (Ref: 122-001-005)
 - (c) *"Dr Taylor would have the transducers, arterial and CVP clipped onto the drip stand rather than attached to the table. In either situation when the table surface, that the patient is lying on, is tilted the CVP would have to be recalibrated and indeed in this particular case the table was moved and Dr Taylor recalibrated the settings."* (Ref: 122-001-007)

These three questions would be best answered by a paediatric anaesthetist.

Urinary catheter

(7) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"It was pointed out that one would not routinely catheterise patients going to theatre simply to measure their urinary output."* (Ref: 122-001-002)

As explained in our written evidence (Ref: 203-004-061/062/063) it would be normal practice to catheterise the patient prior to starting the operation, but not for the purpose of measuring urine output.

(b) *"It was pointed out that it was of vital importance that one was not able to measure the urine output during the procedure as the bladder was open. Normally one would be able to measure urinary output during operation every 5 mins except for a short period when the bladder was open. However during this procedure the bladder was opened immediately and was opened for some 2 hours so it was not possible to measure the urinary output and this child was known to have high urine output."* (Ref: 122-001-004)

(i) Please explain what *"the bladder was open"* means and why *"it was not possible to measure the urinary output"*.

The description of the bladder being open means that during the initial incision and exposure that the bladder was opened by cutting into it. It is likely that this was done inadvertently and not deliberately. As a consequence any urine produced by the kidneys that made its way to the bladder would have leaked out into the operative field, mixing with blood. As the urine was mixed with the blood it was not possible to accurately measure the urine output alone.

Additional Comments

(8) Please provide any further points and comments that you wish to make, together with any documents

It is noted that Mr Keane was not present at the consultation (Ref:122-001) and therefore there is no surgical perspective on the contents of the document. However the contents of this were more contemporaneous than subsequent witness statements or oral evidence.

We also note that Mr Keane commented in his operation note that the kidney was perfused reasonably at the end, although the entry in the ITU notes (?Dr O'Connor – ref 058-035-136) states that the kidney was bluish at the end. It is not stated whether this observation was a personal one or relayed by someone else who had been in theatre, but the two statements do not seem to us to be compatible with each other. The kidney was either reasonably perfused at the end or it was bluish – it could not be both.