CLARIFICATION BRIEF FOR EXPERTS ON PAEDIATRIC SURGERY: JOHN FORSYTHE & KEITH RIGG

ADAM STRAIN

The Inquiry has some queries arising out of your Report dated June 2011 and some further queries on which your assistance is sought. We should be grateful if you would provide clarification and address the following matters:-

Page 4

1. Review of standard practice (1995 and current) (section 2):

   "The patient pathway for a paediatric patient is considered and standard practice below …"

   (i) This section goes through the various stages: (i) Transplant assessment; (ii) Organ retrieval and the offering process; (iii) Recipient assessment; (iv) Timing of surgery; (v) Operative procedure and intra-operative management; (vi) Post-operative management.

   (ii) It would be helpful if there are any guidelines, protocols and/or other literature which reflects/sets out the 'pathway' and 'standard practice' that you describe. If so, please identify that material.

Page 5

2. Timing of surgery (para.2.4):

   "It is preferable not to perform kidney transplant between the hours 00:00 and 06:00, 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"

   (i) Your first reference is to *'UK Transplant unpublished data'*. It would helpful to know what that data is and how the Inquiry can obtain a copy of it.

3. Operative procedure and intra-operative management (para.2.5):

"The kidney would normally be inspected by the surgeon prior to commencement of anaesthesia to check for damage ..."

(i) Please be more explicit regarding that comment. For example, do you mean that the kidney would have been taken out of its surrounding cold preservation fluid?

(ii) Following on from the query at 3(viii) above and for the purposes of calculation, at what point in time does the warm ischaemia period start?

"A urethral catheter will always be placed at the beginning of the operation, unless it is not technically possible"

(iii) Please identify the source of this statement - i.e. whether it is based on experience and/or on a survey of the literature, and if the latter please identify the relevant material.

(iv) Explain the reasons for the necessity of placing this catheter, both generally and also specifically in Adam's case.

(v) Explain the reasons for the need to place that catheter at the beginning of the operation both generally and also specifically in Adam's case.

(vi) Was it reasonable in Adam's case for the urethral catheter not to have been placed at the beginning of the operation if there were no contraindications?

(vii) Was it reasonable in Adam's case for the urine output not to have been measured between the start of the operation and occlusion of the urethral catheter to allow the bladder to fill up prior to anastomosis?

(viii) Do you regard the decision as to whether to insert a urinary catheter at the beginning of such a case to have been the responsibility of the surgeon or the anaesthetist?

(ix) Is the insertion of a urinary catheter at the beginning of such a case done by the anaesthetist or the surgeon?

(x) In this particular case, if Dr. Taylor had stated to you (as the surgeon) that he had not inserted a urinary catheter because he had felt it unnecessary, would you then have inserted one? If not, why not?

(xi) We refer you to paragraph 2.8 and 3.8 of Mr. Koffman's Report [Ref: 094-007-030 and Ref: 094-007-035] as well as a Report of Professor Alexander that he provided to the Coroner [Ref: 011-012-083] together with his Inquiry Witness Statement [Ref: WS-120-03], all of which address those issues of catheters and monitoring/measuring. Please:

(a) Comment in detail on the views that they express and their applicability to Adam's case
(b) Explain what *"free drainage means"* and what happens to the urine of a polyuric patient when the bladder is left on *"free drainage"*

Page 6

"The anastomosis time will usually be under 30-40 minutes and in our combined experience a time of over 60 minutes would be exceptional and due to intra-operative technical difficulties"

(xii) Please define exactly what you mean by *"the anastomosis time"*.

Page 7

4. Organ retrieval and the offering process (para.3.2):

"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"

(i) Please expand upon this and explain why they would have concerns and whether that would mean they would decline to accept it.

Page 8

5. Operative procedure and intra-operative management (para.3.5):

"It is unclear from the documentation when the preparation of the kidney and arteries was undertaken."

(i) What exactly is involved in *"preparation of the kidneys and arteries"*? How long should this have taken? When should it have been performed?

(ii) How do you interpret the comment on the transplant form about 2 (multiple) arteries on patch? – i.e. how many vascular anastomoses had to be performed?

"A significant proportion of this is likely to have been 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"

(iii) What is the normal capacity of the bladder in a child of 20 kg?

(iv) Would you have expected Adam's bladder to have had a larger capacity than normal? If so, how much larger?

Page 10

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

"It is the role of the transplant surgeon to gain consent from a paediatric patient's 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."

(i) Please identify any material documenting or explaining this role of the operating surgeon in 1995.

Page 11

7. The particular risks for Adam (para.4.1.3):

(i) Are the *"particular risks for Adam"* that you have identified confined solely to surgical risks - we note that you have not included, for instance, polyuria and a history of recurrent acute hyponatraemia?

(ii) In your view should the surgeons have recorded any of these 'risk factors' in Adam's notes?

(iii) Again in your view, should the surgeons have discussed these risk factors and their significance and if so: (a) when, (b) with whom, and (c) to what end?

Page 12

"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"

(iv) It would be helpful for this to be expanded upon so that the reason for the increased risk of thrombosis in children is more fully explained, together with the possible effects of a thrombosis.

"Multiple vessels which do increase the risk of thrombosis."

(v) The Kidney Donor Information Form (Ref: 058-009-025) refers to 'multiple arteries on patch'. You refer to that increasing the risk of thrombosis. Again, it would be helpful for this to be expanded upon so that the connection between the 'multiple vessels' and the incidence of thrombosis is more fully explained - perhaps with a diagram to show the 'multiple vessels' in question.

(vi) In your view, should the surgeons have assessed and discussed the condition of the blood vessels before the surgery?

"The match of the donor kidney, which was a half match, which may have resulted in a slightly higher risk of rejection"

(vii) It would helpful if you could explain what *"half match"* means and the likely extent of the *"slightly higher risk of rejection"*

Page 13

8. The level and type of surgical experience that was warranted in the circumstances (para.4.3):

"a consultant transplant surgeon who was experienced in dealing with children aged under 5 years or weighing under 20 kg requiring a kidney transplant. In addition an experienced surgical assistant would be required"

And the level and type of surgical experience of the surgical team that actually operated on Adam Strain (see all of para. 4.4).

The information provided to the Inquiry indicates as follows in respect of the surgical team:

(a) Mr. Keane:
- He was a Consultant Urologist at the time of Adam's transplant surgery and may have been the on-call transplant surgeon. According to him, he *"was the only appropriately trained surgeon available and capable of performing the [renal transplant] procedure"* on Adam on 27th November 1995 [Ref: WS-006-02, p.8]
- Between 1st January 1990 and 31st December 2004, Mr. Keane was involved in 4 paediatric renal transplants at Belfast City Hospital (it is unclear if he was the lead surgeon or assisted in these operations) [Ref: 094-013-082 & Ref: 094-013-083].
- Prior to Adam's transplant, Mr. Keane had performed 3 renal transplants involving children aged less than 6 years old (whilst assisting in others), the most recent of which prior to Adam was at the RBHSC on 17th

November 1995 involving a 3 year old child and with Mr. Victor Boston (Consultant Paediatric Surgeon) [Ref: WS-006-02, p12, Ref: 094-163-769 and Letter from the Directorate of Legal Services to the Inquiry dated 2nd August 2011]
- Mr. Keane has performed no paediatric transplants since Adam's surgery [Ref: WS-006-02, p.13]

(b) Mr. Brown:
- He was a Consultant Paediatric Surgeon who assisted Mr. Keane in Adam's transplant surgery
- Mr. Brown had not performed nor been involved in any transplant operation prior to Adam's renal transplant [Ref: 093-011-031]
- Mr. Brown does not recall if he was involved in any other transplant operation after Adam's death [Ref: WS-007-02, p.5]. He believes that if he had, they would have been very few [Ref: 093-011-031]
- Mr. Brown does recall ever having previously assisted Mr. Keane [Ref: WS-007-02, p.5]

(i) Explain whether in your view Messrs. Keane and Brown represent a sufficiently experienced team to carry out the renal transplant surgery on Adam (given his risk factors and the donor kidney provided)

(ii) Please define what you mean by *"an experienced surgical assistant"*, including the nature/level of expertise he or she should have

(iii) It would be helpful for you to expand on the particular role of the assistant surgeon, dealing especially with why you consider an *"experienced surgical assistant"* was required in Adam's case

9. 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 on Adam in November 1995 (para.4.5)

"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"

We refer you to and attach the following:
- Report of a Working Party of the British Association for Nephrology: 'The provision of services in the UK for children and adolescents with renal disease' (March 1995)
- November 1998 British Transplantation Society: 'Towards Standards for Organ and Tissue Transplantation in the United Kingdom'

- The Report of the Working Party to Review Organ Transplantation; The Royal College of Surgeons (January 1999)
- 1999 Department of Health & Social Services: 'Paediatric Surgical Services in Northern Ireland: Report of a Working Group'
- 2 tables provided by the NHS Blood and Transplant Agency showing for Belfast and other Transplant Centres the figures for: (a) 1990 - 2010 paediatric renal transplants by year and age group; and (b) 1998 - 2010 median cold ischaemic time by years and age group
- Letter from the Liaison Officer of Belfast City Hospital Trust to Dr. Burton dated 29th July 2005, with the enclosed schedule showing the number of paediatric transplants carried out by identified surgeons at the Belfast City Hospital site (BCH) over the period 1st January 1990 to 31st December 2004 [Ref: 094-013-082 & Ref: 094-013-083]
- Letter from the Publications Manager of the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust to Dr. Burton dated 17th May 2005, with the enclosed 2 schedules showing the dates of paediatric renal transplants for children under 14 years at both the RBHSC and BCH for the period January 1990 to December 2004 [Ref: 094-163-766 to Ref: 094-163-768]
- Email from the Publications Manager of the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust to Dr. Burton of 11th July May 2005 stating the numbers of renal transplants carried out by identified surgeons at the RBHSC over the period 1st January 1990 to 31st December 2004 [Ref: 094-163-769]

(i) Please comment on the extent to which those documents refer to or explain the 1995 position.

(ii) Please expand upon this part of your report to the extent that those documents, together with the information that you already have, enable you to do so. If you require any specific information to complete this part of your report, then please identify it so that we can try and obtain it for you.

"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 comments in the review might be considered to be pertinent."

(ii) Please provide a copy of the Review or advise the Inquiry as to how a copy can be obtained.[1]

[1] For your information and comment if appropriate, we attach a copy of: (i) 2002 Review of Renal Services commissioned by the Northern Ireland Minister for Health, Social Services and Public Safety (which may have been the precursor to your Review); (ii) British Transplantation Society 2003: 'Standards for Solid Organ Transplantation in the United Kingdom'; and (iii) May 2010 Department of Health, Social Services & Public

(iii) Please identify the comments in that review that *"might be considered pertinent"* and explain why.

"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 ... 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."

(i) Please explain exactly what constitutes *"a full multi-professional team with appropriate support services and robust transition processes"*

(ii) Please explain in detail what constitutes the level of *"expertise particularly in the younger child"* being recommended

(iii) Please describe and explain the extent to which that recommendation reflects views held about paediatric transplant units in 1995 in the UK, provide the basis for your view together and identify any literature in support of it

(iv) To the extent that there are any differences between what was considered acceptable for a paediatric transplant unit in 1995 and now, please explain the basis for that difference and identify any literature in support of your view

Page 16

10. 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 the vena cava having regard to Adam's age and size (4 years old and approximately 20kg)

We attach a copy of a section of 'Clinical Management of Renal Transplantation', a textbook compiled by Dr Mary McGeown with assistance from, amongst others, Mr Keane, and which was a current text in Northern Ireland at the time of Adam Strain's surgery.

Health: 'Improving Services for General Paediatric Surgery - Policy and Standards of Care for General Paediatric Surgery in Northern Ireland (together with the 2009 Consultation Document)

From the information available to you, including this section, and Adam's medical notes and records (which refer to his previous procedures) together with the statements of Mr. Keane, please provide:

(i) An annotated diagram of Adam's abdominal cavity prior to transplantation including the:
- site of his native kidneys
- right iliac fossa
- spleen
- bladder
- colon
- ureter
- renal arteries
- aorta
- common iliac artery
- external iliac artery
- vena cava
- renal vein
- external iliac vein
- common iliac vein
- inferior vena cava

(ii) An annotated diagram of Adam's abdominal cavity following transplantation of the donor kidney including the:
- site of his native kidneys
- site of the transplanted donor kidney
- right iliac fossa
- spleen
- bladder
- 2 catheters
- colon
- ureter
- renal arteries
- aorta
- common iliac artery
- external iliac artery
- vena cava
- renal vein
- external iliac vein
- common iliac vein
- inferior vena cava

(iii) An annotated diagram showing any differences between (ii) and the views that you have expressed in your report and/or a more usual/appropriate approach

(iv) Your further comments on the 'appropriateness of the approach adopted by the surgeons' in light of the views expressed by Mr. Keane in the chapter on 'Clinical Management of Renal Transplantation' that he provided for the textbook

Page 18

11. 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 (para.4.17)

"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" See also your paragraphs 2.5 and 4.12

(i) If the anaesthetist had informed you at the beginning of the case that the CVP as placed was not going to be able to provide accurate or reliable readings, what would your reaction have been?

(ii) Do you think that further attempts at inserting a CVP catheter should have been made in the light of Adam's increased surgical risk factors and his polyuria?

(iii) If so, on the balance of probabilities, would a further delay of, say, 30 minutes have made a significant negative impact on the postoperative functioning of the donor kidney?

Page 19

12. The extent to which the poor function of the donor kidney may have been due to ... (para.4.21)

"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 problem"

(i) Please explain which of the following three possible causes of renal artery thrombosis was most likely: (a) poor positioning of the kidney,(b) the use of a smaller external iliac artery inflow, or (c) due to a surgical technical problem

(ii) Explain the type of *"surgical technical problem"* (other than those referred to at para.10(i)(a) and (b)), which could have caused the renal artery thrombosis

(iii) Please define what you mean by *"soon after implantation"*

13. If Mr Brown had seen, during the course of wound closure, that the appearance of the kidney had changed and that it was now looking as if its perfusion was inadequate. In those circumstances, what should he have done?

Other queries

14. A relatively recent review[2] of paediatric renal transplants has suggested that about 10 per cent of recipients will suffer from overt pulmonary oedema in the postoperative period. In the light of your own experience, what are your views on that figure for 1995 and now?

15. What do you consider was the role, if any, of a 'low dose' dopamine infusion during and/or after paediatric renal transplantation in 1995?

16. What is your view of the quality of the operative record? What information, if any, should have been included that was omitted?

17. What practical steps should Mr. Keane have taken before Adam's surgery, other than those already set out in your report dated June 2011, and state the reasons why.

18. State whether the lead surgeon in Adam's case should have examined Adam's medical notes before surgery, and if so, state what medical notes you would have expected Adam's surgeon to have examined prior to his surgery, the reasons why and when he should have examined these notes. If not, state the reasons why not.

19. Attached is a table detailing Adam's surgical procedures from his birth to the date of his death. Please state what Mr. Keane might usefully have learned from an examination of Adam's medical notes pre-operatively, in particular from the details of Adam's previous surgeries, and how that should have affected his preparation and the conduct of Adam's surgery.

20. Attached is a table showing the various phases in a paediatric renal transplant operation. Please modify it, as you consider appropriate, so that it reflects what you consider should have happened and identify under those phases the personnel who you consider should have been involved.

---

[2] Coupe N et al. Pediatric Anesthesia 2005; 15: 220-8