NOTE FOR MR. GEOFF KOFFMAN
RE: ADAM STRAIN

Background

1. Adam Strain, Claire Roberts, Raychel Ferguson and Conor Mitchell are 4 children who are the subject of a public Inquiry established under Article 54 of the Health and Personal Social Services (Northern Ireland) Order 1972 and being conducted in Northern Ireland by John O'Hara QC. The current terms of reference of the Inquiry are:

> To hold an Inquiry into the events surrounding and following the deaths of Adam Strain and Raychel Ferguson, with particular reference to:
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> 1. The care and treatment of Adam Strain and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.
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> 2. The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain and Raychel Ferguson.
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> 3. The communications with and explanations given to the respective families and others by the relevant authorities.
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> In addition, Mr O'Hara will:
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> (a) Report by 1 June 2005 or such date as may be agreed with the Department, on the areas specifically identified above and, at his discretion, examine and report on any other matters which arise in connection with the Inquiry.
>
> (b) Make such recommendations to the Department of Health, Social services and Public Safety and report on any other relevant matters which arise in connection with the Inquiry.
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> (b) Make such recommendations to the Department of Health, Social Services and Public Safety as he considers necessary and appropriate.

The cases of Claire Roberts and Conor Mitchell have been added to the Inquiry's work by the Chairman under his discretionary power to examine and report on any other matters which arise in connection with the Inquiry

2. Adam Strain was born on 4th August 1991 with cystic, dysplastic kidneys with associated problems with the drainage of his kidneys related to obstruction and vesico ureteric reflux. He was referred to the Royal from the Ulster Hospital in Dundonald. He died on 28th November 1995 in the

Royal following kidney transplant surgery on 27th November 1995 from which he never recovered consciousness.

3. The Inquest into his death was conducted on 18th and 21st June 1996 by John Leckey the Coroner for Greater Belfast, who engaged as experts: (i) Dr. Edward Sumner Consultant Paediatric Anaesthetist at Great Ormond Street Hospital for Sick Children ("Great Ormond Street"); (ii) Dr. John Alexander Consultant Anaesthetist at Belfast City Hospital; and (iii) Professor Peter Berry of the Department of Paediatric Pathology in St. Michael's Hospital, Bristol. The Inquest Verdict identified Cerebral Oedema as the cause of his death with Dilutional Hyponatraemia as a contributory factor.

4. An investigation was subsequently carried out by the Police Service of Northern Ireland ("PSNI") into the death of Adam Strain and the other children. The PSNI engaged a number of Experts to assist them with their investigation into Adam's death. In addition to you, they also engaged Dr. Edward Sumner Consultant Paediatric Anaesthetist and Professor R.A Risdon Consultant Paediatric Pathologist at Great Ormond Street.

5. All of the Experts engaged by the Coroner and the PSNI produced Reports.

The Inquiry

6. The Inquiry has appointed a Panel of Experts[1] to assist it in its investigations in respect of all 4 children. It has also engaged Experts to deal with a number of discrete issues that are child-specific.

7. The work of all the Inquiry's Experts is peer reviewed by a team of international Experts.[2]

8. One of those issues concerns the donor kidney that was transplanted into Adam. Those issues first arose during the Inquest and continued to be

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1 Dr. Peter Booker (Paediatric Anaesthesia), Dr. Harvey Marcovitch (Paediatrics), Ms. Carol Williams (Paediatric Intensive Care Nursing), and Health Service Management and Patient Safety

2 Professor Allen Arieff at the University of California Medical School in San Francisco (Internal Medicine & Nephrology), Dr. Desmond Bohn of the Critical Care Unit at the Hospital for Sick Children in Toronto (Paediatric Anaesthesia), Ms. Sharon Kinney at the Intensive Care Unit and Clinical Quality and Safety Unit at the Royal Children's Hospital in Melbourne (Paediatric and Intensive Care Nursing)

addressed during the investigation by the PSNI. The references to them in the Depositions, Witness Statements and Reports may be summarised as:

(1) Mr. Patrick Keane (Consultant Urologist) records in the Clinical History, Examination and Progress Report (which he signs sometime before 12.05pm on 27th November 1995): *"Kidney perfused reasonably well at end"*[3]

He expands upon that in a letter dated 11th December 1995 to the Complaints Officer at the Belfast City Hospital that 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"*[4] See also his Deposition of 18th June 1996.[5]

In his Inquiry Statement of 20th June 2005 he states: *"At the completion of the surgery, the transplanted kidney had pulsatile flow in the artery and was perfusing"*. However, he goes on to state (which he had not done during the Inquest) that he left the theatre 10 minutes before the end of the anaesthesia and that Mr. Stephen Brown (Consultant Paediatric Surgeon), who was assisting him, closed the wound.

In his Statement to the PSNI on 7th September 2006 he states that: *"Initially the kidney that was transplanted into Adam perfused very well; after the kidney was placed in situ the kidney perfused less well but adequately; I could still feel blood flow in the renal artery. It is also my recollection that a little urine was produced before the ureter was connected to the bladder."*[6]

(2) Mr. Stephen Brown (Consultant Paediatric Surgeon, retired) stated in his Report for Dr. George Murnaghan (Director of Medical Administration) of 20th December 1995 that *the "perfusion of the kidney was satisfactory, although at no stage did it produce any urine"*[7]

For reasons that are unclear, he did not give evidence at the Inquest but his Inquiry Witness Statement of 15th July 2005 states that: *"Following the vascular anastomosis the kidney appeared healthy and was*

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3 See ref: 058-035-135 at Tab. 1 of the accompanying File
4 See ref: 011-026-127 at Tab. 2 of the accompanying File
5 See ref: 011-013-093 at Tab. 3 of the accompanying File
6 See ref: 093-010-029 at Tab. 4 of the accompanying File
7 See ref: 059-060-145 at Tab. 5 of the accompanying File

good colour. My recollection was that it did not produce any urine during the course of the operation."

In his statement to the PSNI he states: *"The kidney was a good colour, from what I can remember the kidney turned pink in colour when it was transplanted and the blood was put through it. As far as I can remember the kidney remained pink in colour"*. He acknowledged the difference between his account and that of Mr. Patrick Savage about the production of urine, claiming that he could not explain it: *"I may be wrong about the urine. Though as far as I recall no urine was ever produced"*.[8]

(3) Dr. Robert Taylor refers in his Deposition of 21st June 1996 to the process of the calculation of fluids for Adam being *"complicated by the fact that the donor kidney did not appear well perfused after an initial period of apparently good kidney perfusion"*[9]

In his evidence during the Inquest he states: *"The new kidney did not work leading to a re-assessment of the fluids given. This made us think we have underestimated fluid and we gave a fluid bolus at 9.32."*[10]

He expands upon that in his taped PSNI interview on 17th October 2006 given under caution, the transcript of which records: *"he was aware that the kidney did not 'pink up' easily and the impact on Dr. Taylor was to re-assess his fluids and worry that he was still in deficit and despite his best efforts that he had failed to increase the blood volume enough to perfuse the kidney. Dr. Taylor could not recall if the new kidney produced urine."*[11]

(4) Nurse Gillian Popplestone (Registered Sick Children's Nurse) stated in her PSNI Statement of 31st January 2006 that: *"I also recall the surgeons discussing possible discolouration of the kidney at the time of the transplant. This concern appeared to subside as the operation progressed."*[12]

(5) Dr. Mary O'Connor (Consultant Paediatric Nephrologist) who was present towards the end of Adam's surgery stated in her PSNI Statement that: *"I have recorded that the kidney was 'bluish' at the end of*

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8 See ref: 093-011-032 at Tab. 6 of the accompanying File
9 See ref: 011-014-096 at Tab. 7 of the accompanying File
10 See ref: 011-014-108 at Tab. 7 of the accompanying File
11 See ref: 093-035-108 at Tab. 8 of the accompanying File
12 See ref: 093-012-040 at Tab. 9 of the accompanying File

theatre".[13] See the Clinical History, Examination and Progress Report, which she signed on 27th November 1995,[14] which also records: *"0 from tx kidney"*. [15] See also Eleanor Donaghy (Transplant Co-ordinator) who completed section 11 of the Kidney Donor Information Form recording at section 8, 'kidney damage', *"widely separated patch"* which was amended (but not by her) to *"widely separated arteries on 1 patch"*.[16]

(6) Dr. Alison Armour who carried out the autopsy on Adam at 2.40pm on 29th November 1995, the day after his death, states that there was *"complete infarction"* of the transplanted kidney.[17]

(7) Professor Peter Berry (Consultant Paediatric Pathologist in the University of Bristol) states in his Report for the Coroner dated 23rd March 1996 that the: *"transplant kidney was infracted (dead). The extent of the change suggested that this occurred at or before the time of transplantation."*[18] See also the letter from Professor Berry to the Coroner dated 25th March 1996 and his statement that *"I doubt this kidney would ever have functioned"*.[19] See further his PSNI Statement on 22nd March 2006 in which he explains his statement to the Coroner: *"By this I mean the microscopic changes were sufficiently well established that I estimated that the damage had occurred about 2 days previously, before or around the time of transplantation"*.[20]

(8) Professor Risdon (Consultant Paediatric Pathologist, Great Ormond Street) states in his Report to the PSNI dated 2nd June 2006: *"In my opinion the transplanted kidney must have suffered significant ischaemic damage prior to its insertion for this degree of ischaemic damage to be apparent at post-mortem"* and *"This opinion is supported by the fact that the other kidney from the same donor failed to function when transplanted to a different patient in Glasgow.*[21] *This would suggest that both kidneys*

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13 See ref: 093-020-059 at Tab. 10 of the accompanying File
14 See ref: 058-035-136 at Tab. 11 of the accompanying File
15 See ref: 058-035-137 at Tab. 12 of the accompanying File
16 See ref: 093-015-048 at Tab. 13 of the accompanying File
17 See ref: 011-010-040 at Tab. 14 of the accompanying File
18 See ref: 011-007-022 at Tab. 15 of the accompanying File
19 See ref: 011-053-187 at Tab. 16 of the accompanying File
20 See ref: 093-030-079 at Tab. 17 of the accompanying File
21 The Inquiry has a letter dated 29th March 2005 from the Information Manager at UK Transplant (Tab 18 of the accompanying file) which sates that: *"we were notified that the transplant of the second kidney, which took place on 26 November 1995, had failed on day of transplant due to infection of the graft"*. However, Professor Risdon refers in his Report to a letter from the Director of Renal Transplantation at Greater Glasgow NHS. The Inquiry does not have that letter but will seek a copy of it.

from this donor had suffered significant ischaemic damage before transplantation."[22]

(9) Finally, Mr. Richard Donaldson (Renal Surgeon at Belfast City Hospital) comments in a report that seems to have been prepared for Adam's family: *"there is also back bleeding from the renal vein which could be thought to be proper perfusion – a few drops of urine from the ureter can sometimes be mistaken for early production of urine and is in fact residual donor renal pelvic fluid expressed on renal handling".*[23]

9. The Inquiry has appointed Dr. Malcolm Coulthard as an Expert in Paediatric Nephrology to assist its investigation in respect of the renal issues.

10. However, the Inquiry's Panel of Experts has advised that we revert to you with certain queries that they have arising out of your Report for the PSNI.

Queries

11. The Panel of Experts has referred to paragraph 2.7 of your Report for the PSNI dated 5th July 2006[24] where you indicate that the transplant kidney produced urine. It would appear from paragraph 3.12 of your Report that your comment is based upon the Deposition of Mr. Patrick Keane. The Panel of Experts have reported that:

(i) *It would be useful to seek clarification from Mr. Koffman as to whether, if the kidney was infarcted at operation as suggested by the pathologists, this was possible*

(ii) *Additionally, Mr. Koffman might elaborate on his belief the kidney must have been viable at the start of the operation and how this ties in (or not) with the opinion of the pathologists*

12. The Panel of Experts has also noted that you offered an opinion in your Report at paragraph 3.2 on the significance of not having a sodium measurement immediately prior to the operation:

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22 See ref:093-031-083 at Tab. 19 of the accompanying File
23 See ref: 094-013d-065 at Tab. 20 of the accompanying File
24 See ref: 094-007-027 at Tab. 21 of the accompanying File

NOTE

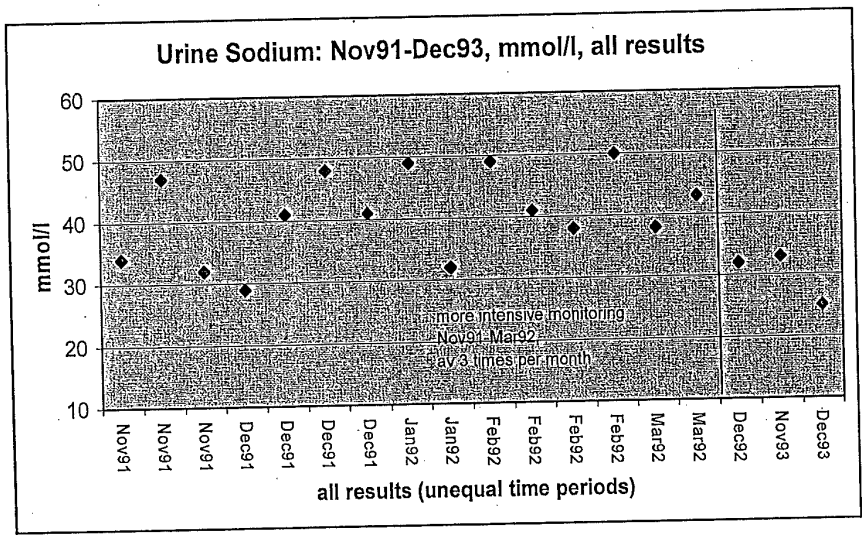
The sodium and potassium should have been repeated prior to start of surgery. The polyuric patient with poor renal function would pass large quantities of dilute urine and may have difficulty controlling the concentration of sodium and potassium in the blood. The importance of this measurement would not have been obvious to the medical teams looking after Adam at the time.

13. The Panel of Experts have reported that:

(i) *It would be helpful to know whether or not it had been made known to Mr. Koffman in his instructions that Adam had a past history of occasional hyponatraemia*

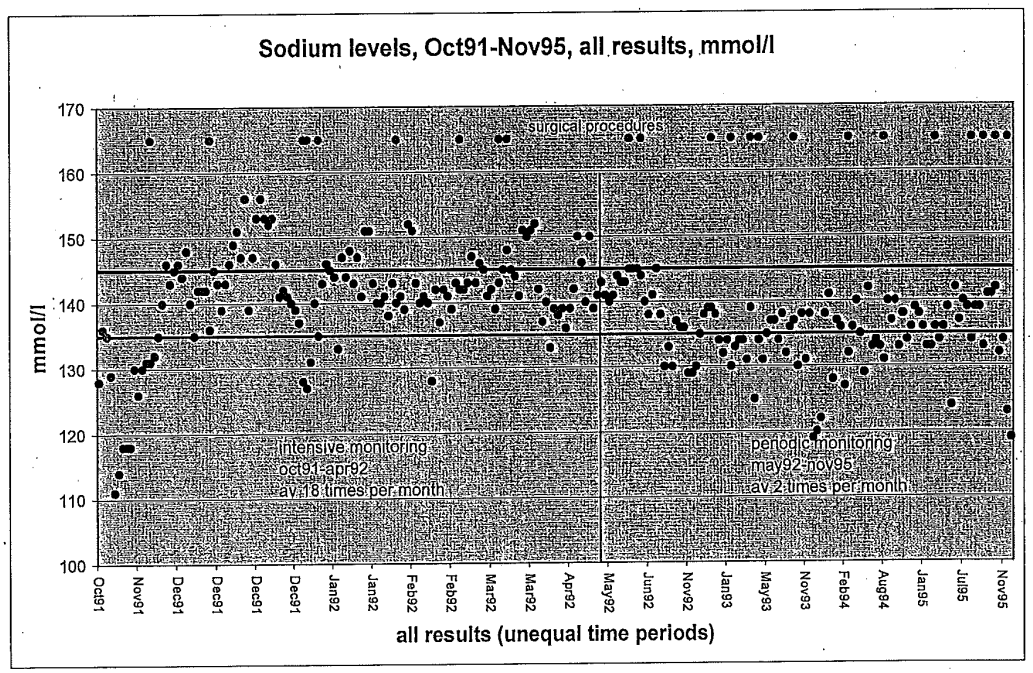
(ii) *If not, it would be helpful to know whether the knowledge that Adam had such a past history (of which the transplant 'team' were aware) changes his view and if so, his view in the light of that information*

14. For your convenience the information on Adam's recorded sodium results is provided below in 2 graphs compiled from a table of Adam's recorded results.[25]



[25] See Tab.22 of the accompanying File for the table of serum sodium results and surgical procedures(Tab.23) together with the table of urine sodium results (Tab.24)

NOTE



15. Your response will be provided to the Inquiry's Panel of Experts together with its Expert Nephrologist, Dr. Malcolm Coulthard.