Witness Statement Ref. No. 015/1

NAME OF CHILD: Adam Strain

Name: George Murnaghan

Title: Dr

Present position and institution:

Associate Dean, The Irish Committee on Higher Medical Training (ICHMT)

The Royal College of Physicians of Ireland, 20-22 Lower Hatch Street, Dublin 2

Previous position and institution:
[As at the time of the child's death]
Director of Medical Administration, The Royal Hospitals Trust, Belfast, BT12 6BA

Membership of Advisory Panels and Committees:
[Identify by date and title all of those between January 1995-December 2004]

Previous Statements, Depositions and Reports:
[Identify by date and title all those made in relation to the child's death]

OFFICIAL USE:
List of previous statement, depositions and reports attached:

Ref:	Date:	

Particular areas of interest
[Please attach additional sheets if more space is required]

1. Describe the steps that were taken (and by whom) following the death of Adam to draw attention to the cause of his death and lessons that might be learned from it:
(i) within the hospital ;
(ii) within the Trust; and
(iii) to others.

Following Adam Strain's death the Coroner for Greater Belfast was notified. He ordered a post mortem; this was performed by Dr Alison Armour of the State Pathologist's Department. Following this and her oral report to the Coroner he contacted me be telephone. Subsequently, both by telephone and by letter (059-073-166) he notified me that he would be holding an Inquest and seeking an independent medical/anaesthetic report from Dr John Alexander. At the same time he asked that the anaesthetic equipment be checked for proper function. I arranged this and a report (059-068-157 to 160) was prepared by two medical technical officers at the Royal Hospitals. This examination observed the equipment was "found to be in satisfactory condition".

Additionally, and following consultation with the Clinical Director of Anaesthesia and Intensive Care Services, Dr J Gaston a further report into the correct functioning and maintenance of the anaesthetic equipment was provided by Dr Fiona Gibson (059-065-151,152 and 059-069-161,162). This reports states that there was no evidence of a problem relating to the equipment "but identified a problem relating to the pin indexing which the whole hospital will now address". This was a matter dealt with directly within the Anaesthetic Directorate. Subsequently, when Dr Armour reported to the Coroner, he sent me, in accordance with his usual practice, a copy of Dr Armour's report (059-035-068). No steps were taken apart from the direct involving of the clinicians in discussion with pathologists and the anaesthetic technical staff in attempting to clarify the cause of death and thereby to assist the Coroner in his proper duties where possible until the Inquest was held on 18th and 21st June 1996. However, the consultant anaesthetists providing paediatric services in the RBHSC prepared a draft press statement which was then submitted to me and in turn entered into the record at the inquest on 21st June 1996 (059-008-025 and 060-019-037,038 - redacted) and published in the Belfast Telegraph (070-016-073) and Irish News (070-016-070). This particularly addressed the complication of hyponatraemia in patients undergoing renal transplantation. The particular monitoring requirements identified during expert evidence were to be brought to the attention of all anaesthetic staff working in the RBHSC.

2. Describe the steps that were taken (and by whom) following the Inquest into the death of Adam to ensure that information and lessons learned from the Inquest were disseminated:
(i) within the hospital;
(ii) within the Trust; and
(iii) to others.

As an introduction to this response it is proper to indicate that all elective major surgery on children and infants in Northern Ireland is conducted in the RBHSC. This means that they come under the care of one of the three consultant paediatric anaesthetists in Northern Ireland who provided this service at the RBHSC. Such surgery was confined to the RBHSC. It was not performed elsewhere in the Royal Hospitals Trust. It was not performed elsewhere in Northern Ireland.

Within the hospital and following a review of all the expert evidence provided by H M Coroner a statement was prepared by Dr Gaston and those consultant anaesthetists in conjunction with this witness (060-018-035,036). This statement indicated that all paediatric anaesthetic staff within the Trust would be made aware of the particular phenomena associated with electrolyte imbalance, the need for careful monitoring and in particular the monitoring of their electrolyte balance.

Particular areas of interest (Contd)

The paediatric nephrologists, who manage the medical condition of children requiring renal transplants, reviewed and modified their guidelines (RGH 2.6 - copy attached). These were only relevant, in the Northern Ireland context, in the RBHSC as this was the only hospital providing patient care for these children. It did not need to be shared elsewhere within the Trust or elsewhere outside the Trust.

The importance, value and relevance of good record keeping as exemplified by the casenotes for Adam Strain was subsequently highlighted by Dr Gaston at an ATICS Clinical Audit meeting on 10th December 1996 (RGH 2.2 - copy attached). Such a topic is a regular and recurring feature of all clinical audit meetings held throughout Northern Ireland Hospitals and, as such, while this example was noteworthy for its detail and precision, it was not highlighted outside the ATICS Directorate which encompasses and includes all the anaesthetic staff that practice with the Royal Hospitals Trust. In keeping with normal practice a copy of this minute was copied to all members of the Directorate so that those who were unable to attend were kept informed.

Other points you wish to make including additions to any previous Statements, Depositions and or Reports
[Please attach additional sheets if more space is required]

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

Signed: G A Cunningham **Dated:** 30th June 2005

RGH.C.C.

CONFIDENTIAL

ROYAL GROUP HOSPITALS

ANAESTHETICS DIRECTORATE CLINICAL AUDIT MEETING

Date: 10 December 1996

Venue: Lecture Theatre 2 School of Radiography

Attendance: See Register

Morbidity & Mortality

Two cases were presented: Atypical Ventricular Fibrillation
Airway obstruction in a child

Education

Sevoflurane Update was presented.

Audit

Topic: *Anaesthetic Record Keeping*

Two problems were identified - Inadequate Records and no records at all.
The two obvious reasons for good record keeping are medicolegal and Clinical.
Common areas of inadequate information were found to be in:

- Pre-op assessment
- Difficult intubation
- Drug and Fluid administration
- Untoward Events

Taking one of the above areas ie Difficult intubation, the presenter showed how improvements could be made eg. *Why was intubation difficult*
How difficult was it
How was the patient intubated
Other information - was airway easy to maintain
was saturation maintained
any cuts to lips - was everything okay when completed
were there any special precautions when extubating the patient

A handout titled Anaesthetic Record Set - Suggestions as to a reasonable content was given to everyone present. This document had been jointly produced by the Association of Anaesthetists of Great Britain & Ireland and the Society for Computing & Technology in Anaesthesia.

The Anaesthetic Chart Review which is ongoing will tie into this and will be discussed further at a later date.

Topic *Review of Acute Pain Service*

The Acute Pain Service in the main hospital of the Royal Hospitals oversees the use of patient-controlled analgesia (PCA) for some 1,500 patients per year. This audit relates to 2,300 patients seen by the Pain Control Nurse between April 1995 and September 1996. Morphine was administered in 99% of cases, with an initial PCA dose of 1mg for 97.5% of patients. Only 0.5% of these patients required a subsequent increase in the PCA dose to 1.5mg.

1 .4hr consumption of morphine was less than 50mg for over 50% of patients and between 51 and 100mg for approx. 30% during the first 2 days of PCA and thereafter tended to decrease. Eight percent of patients consumed more than 100mg in 214 hrs. Possible reasons for this included major complex surgery, chronic opoid intake preoperatively and a history of drug dependence or misuse.

Regardless of surgical speciality 40-60% of all patients required PCA for 2-3 days, and only 1% of patients continued with PCA for 8-18 days. Early discontinuation of PCA was recorded for 19% of all patients but was as high as 42% for those patients who had had spinal surgery. The indications for early cessation of PCA in the latter group were: - no need for potent analgesia (25%), nausea (20%), vomiting (13%), inadequate patient use of PCA (15%) and inadequate analgesia, despite satisfactory use of PCA (14%).

The overall incidence of postoperative nausea/vomiting for patients on pCA was 16% on day 1 and 8% by day 2. Other complications which occurred within the first 48hrs of PCA use included pruritis (3%), urinary retention (2%) and hallucinations (1%). These complications were associated with a relatively high mean 24hr consumption of morphine. The incidence of CNS depression , sedation or bradypnoea was less than 1%. Of note 4/14 patients had bradypnoea were significantly sedated and only 4/16 oversedated patients had bradypnoea.

Over 90% of general surgical patients had satisfactory analgesia at rest during the first 3 postoperative days. However, pain relief on movement was inadequate for 70% of patients on day 1 and over 30% of patients on day 2.

Epidural analgesia was employed for 122 patients between January 1996 and November 1996. The average duration of its use was 2-3 days. The mean infusion rate of fentanyl (5mcg/ml) and bupivacaine 0.1% was 6ml/hr for both lumbar and low thoracic epidurals. Hip flexion was preserved in 63% of patients and only 1 patients was restricted to ankle flexion during the first 24 hrs postoperatively. On day one pain scores were satisfactory for 90% of patients at rest and 66% of patients on movement. The incidence of nausea or vomiting was 20%. Only 3 patients with lumbar epidurals became hypotensive during the first 24 hrs, the upper level of sensory block being T7-T12. Respiratory depression occurred in 2 patients, but only 1 patients required intravenous naloxone One patient developed hallucinations. There were no major complications of epidural analgesia.

Comments:
The use of both PCA and epidural analgesia are well established methods of postoperative analgesia for adult patients in the Royal Hospitals, the latter technique providing superior analgesia on movement. there is a low incidence of respiratory depression with either method of analgesia and no other major complications of epidural analgesia have occurred. Nausea and vomiting are the most common undesirable complications associated with these perioperative analgesic techniques

MUSGRAVE WD   KCH · L6.   Copy from M. Savage 13/12/04

RBHSC RENAL TRANSPLANT GUIDELINES

CHECK LIST ON ADMISSION

A) HISTORY:-

Function of native kidneys - volume output.
Recent contact with infectious diseases.
When last dialysed.
Vaccination history.
CMV status donor/recipient.
Cytotoxic antibody status.
Tube feeds - what and how much.
What central line sites used previously.
List drugs.

B) EXAMINATION:-

State of nutrition.
State of hydration.
BP
Height and weight, surface area.
Catheter exit site appearance.

C) INVESTIGATIONS (insert peripheral cannula at same time)

Clotted sample - 5 ml by taxi to Ward 11N, BCH for tissue typing X-match (telephone 7-111-2455).
FBP, DWCC, coag screen, U/E, creat, Ca, albumin.
Group and X-match 4 units WBC depleted CMV -ve blood.
Virology for Hep A, B and C, CMV, measles, chickenpox, HIV, EBV.
PD fluid and urine for culture.
Urine for U/E and creatinine.
CXR
ECG if on antihypertensives.

PLAN:-

1. Fast and consent.

2. Shower.

3. Dialysis if k+ > 5.

4. Peritoneal Vancomycin loading dose (500 mg/l)
   Leave x 4 hours and drain pre Theatre.

5. If prolonged fast - maintenance IV fluids (give insensible losses (= 300 ml/m) and output) as 0.18% saline, 4% dextrose. D/W Consultant if Na < 133. Repeat U/E at time of going to Theatre.

6. Acyclovir - if either donor or recipient CMV positive.
   800 mg PO 2-6 hours pre-op.
   800 mg PO 24 hours post-op.

   Thereafter according to GFR

> 25 ml/min/1.73	6 hourly	800 mg PO
10-25 ml/min/1.73	8 hourly	800 mg PO
< 10 ml/min/1.73	daily	800 mg PO
Dialysis dependent	12 hourly	800 mg PO

   (Half dose in < 2 years old)

7. Complete "Check List" for Theatre.

IMMUNOSUPPRESSION

1. CYCLOSPORIN
   Start 3 mg/kg/12 hrs/IV by syringe pump infusion pre-op.
   (Alternative if decided by Consultant =
   3 mg/kg IV slow bolus over 4 hours pre-op or
   10 mg/kg orally 4 hours pre-op)

2. AZATHIOPRINE
   2 mg/kg/IV in 50 ml saline and given over 20 min pre-op.

3. For highly sensitized patients, ie > 70% cytotoxic antibiotics
   - Antithymocyte globulin (see separate protocol).

IN THEATRE

Assess hydration, check electrolytes and ABG x 2 hourly.
IV Augmentin on induction.
S/C Heparin with surgeons consent after induction.

< 15 kg	1000u tds
15-20 kg	1500u tds
20-40 kg	2500u tds
> 40 kg	5000u tds

Triple lumen CVP catheter.
IA line in small children.
If Hb < 10 g/dl give packed cells to bring it up to 10 g/dl.
Start Dopamine 2-3 mcg/kg/min.
Use N.saline, plasma, or blood (as appropriate) to raise CVP to 8-10 mm mmHg prior to removal of vascular clamps. Keep CVP here.

10-15 MINS PRIOR TO
RELEASE OF CLAMPS - 0.5 g/kg (2.5 ml/kg) 20% Mannitol
(alternative 4 mg/kg Frusemide)

- 10 mg/kg Methylprednisilone (max 500 mg)

POST-OPERATIVE

1. FLUIDS

Replace urine output and insensible losses (300 ml/m /day) EACH HOUR as 0.45% saline 2.5% dextrose (subtract volume of infusions).

Boluses of N.saline or HPPF (5-10 ml/kg) over 20 mins to maintain CVP and BP.

2. OBSERVATIONS

a. CVP between 5-10 mmHg.
b. BP decided on individual basis.
c. Optimal urine output to be decided on an individual basis. In polyuric patients this will be around 4 ml/kg/hr initially, falling to 2 ml/kg/hr when stable. In previously anuric patients far lower outputs may be acceptable if ATN has occurred. Check transplant troubleshooter for management guidelines on output and BP.

3. DRUGS

Immunosuppression

a. Cyclosporin 6 mg/kg/24 hrs written up as continuous infusion via syringe pump 3 mg/kg/12 hrly (not stable for longer). This will be converted to Cyclosporin 12 mg/kg/day orally given as bd dosage. Stop infusion 12 hours after first oral dose.

b. Methylprednisilone 60 mg/m /day as bd dose for first 5 days and then reduce (see separate sheet).

c. Azathioprine 1 mg/kg/day from D1 post-op - IV or oral, for monitor WCC. Stop after one month if no rejection.

Prophylaxis

d. Dopamine 2-3 mg/kg/hr.

e. Ranitidine 1 mg/kg bd IV, oral 2 mg/kg bd (Until minimum steroid dose achieved)

f. Nifedipine 5-20 mg bd as Cyclosporin toxicity prevention.

g. Septrin 120-480 mg orally bd Mon, Wed, Fri for 3-6 months.

h. Heparin 1000-2500 s/c tds for 5-10 days.

i. Acyclovir if CMV +ve donor or recipient (see above).

Analgesia

j. Epidural
or
k. Morphine 10-20 mcg/kg/hr infusion (half BW (kg) in mg in 50 ml at 1-2 ml/hr).

INVESTIGATIONS

1. U/E, creatinine, glucose, Ca x 6 hourly for 24 hours.
   x 12 hourly next 24 hours.
   x daily thereafter (+ phosphate).

2. Doppler renal USS post-op if possible and repeat PRN (? daily)

3. FBP, DWCC, (and CD3 count if on ATG) daily.

4. CXR daily for 2-3 days.

5. Urine - culture, U/E and creatinine daily.
   - protein/creatinine ratio x twice daily.

6. Cyclosporin levels analysed Tue and Fri (RVH Ext 3334). When on oral drugs send daily for 10 days and thereafter Tue and Fri.

IMMUNOSUPPRESSION POST TRANSPLANT

1. STEROIDS

Day 1-5	Methylprednisolone 60 mg/m /day as bd dosage x 5 days (may be changed to same dose oral Prednisolone as soon as tolerated).
Day 6	Prednisilone 30 mg/m^2/day as 2 divided doses.
Day 14	Prednisilone 20 mg/m^2/day as 2 divided doses.
Day 21	Prednisilone 10 mg/m^2/day as 2 divided doses.
Week 4-8	Prednisilone 10 mg/m^2 DAILY as one daily dose.
Week 8-12	Prednisilone 5 mg/m^2 DAILY.
Week 12+	Prednisilone 10 mg/m^2 alternate days.

2. AZATHIOPRINE

If no severe rejection STOP at 4-6 weeks. Do not give if neutrophils < 1000 or total WCC < 3000.

3. CYCLOSPORIN

Always as NEORAL

Levels -	Weeks 0-4	150-250 ng/ml
	Weeks 4-12	150-200 ng/ml

FOLLOW UP

After discharge	-	alternate days x 1 week
Until week 6	-	twice weekly
Week 6-10	-	weekly
Week 10-12	-	fortnightly
> 3 months	-	monthly
> 1 year	-	6-8 weekly

NB. See within 1 week of any DOSE CHANGES

REJECTION

ASSESSMENT OF REJECTION

> 10% rise in serum creatinine is a significant change. It could be due to:-

1. Laboratory error.
2. Rejection.
3. Cyclosporin toxicity.
4. Other drug toxicity (especially Acyclovir).
5. Infection (especially UTI).
6. Obstruction - exclude with renal USS.

All such rises in creatinine should be reported to the Consultant and repeated immediately. If a 10% rise is confirmed and rejection suspected then initial treatment would be:

Methylprednisolone 15 mg/kg/IV for 3 days (maximum 500 mg). (100 mls N SALINE) over 4 hrs.

This should only be prescribed after discussion with Consultant.

Other causes of a rise in creatinine should be excluded and diagnosis confirmed whenever possible with a renal biopsy.

For patients who have received renal transplant > 1 month previously, oral Prednisolone 3 mg/kg/day is given for 3 days (maximum 150 mg).

ANTI-THYMOCYTE GLOBULIN (MERIEUX-RABBIT)

Given for steroid resistant rejection or as prophylaxis when recipient > 75% cytotoxic antibodies or second transplant when first graft lost early with rejection.

Test dose: 0.1 ml (0.5 mg) in 10 ml N.Saline over 1 hour via central line.

ANAPHYLAXIS treated with:

Hydrocortisone 100 mg IV
Chlorpheniramine 5-10 mg IV
Adrenaline (0.01 ml/kg of 1 in 1000, 1 m)

Prior to theraputic dose give Chlorpheniramine IV and Hydrocortisone IV.

Theraputic Dose:

< 30 kg - 2.5 mg/kg/day

> 30 kg - 1.25-2.5 mg/kg/day

Diluted in 100 ml saline central line over 8 hours.
Chills, fevers and arthralgia common.

ATG Monitoring

Aim absolute lymphocyte count 200-400 (omit if < 200).

CD3 count daily

(Send 0.5 ml EDTA blood to RVH immunology,
arrange with extension 2689,
ask for lymphocyte markers profile I which includes CD3).

Aim level 100-300 (omit if < 100).

Updated Sept 96
M Savage/M O'Connor

THEATRE CHECK LIST FOR TRANSPLANT PATIENT

NAME:

Ht: Wt: SA:

CMV status: Donor Recipient

Acyclovir: Yes/No

Pre theatre:

Na	Hb	PT
K	WCC	PTTK
Urea	Plats	
Creat		
Ca		
Albumin		

Drugs:

Drugs in ward pre-transplant:

Azathioprine Dose

Cyclosporin Dose

Drugs in Theatre:

Augmentin (on induction) (30 mg/kg, max 1.2 g) =

Methylprednisolone (10 mg/kg, max 500 mg) =

Mannitol 20% (0.5 g/kg = 2.5 ml/kg) =

Amount of blood to bring Hb up to 10 g/dl =

NURSING CHECK LIST FOR TRANSPLANT

NAME:

Height

Weight

BP

MSU and urine U/E

Shower

PD sample for microscopy and culture

PD Vancomycin 500 mg/l and run in usual fill volume and drain one hour pre theatre.

Pre-op Cyclosporin

Azathioprine

? ATG

Acyclovir if CMV +ve donor or recipient

TRANSPLANT TROUBLESHOOTER

OUTPUT

If urine output falling < 2 ml/kg/hr give volume to correct low BP or CVP.

Volume — 5-10 ml/kg/stat of N.saline or HPPF
(or blood if appropriate)
May need repeated frequently in first 24 hours leading to positive fluid balance > 1-3 litres.

BP

If high - Hydralazine 0.2 - 1.0 mg/kg/IV stat followed by hourly infusion at same rate.

If low - Volume or Dobutamine (0-20 mg/kg/min)

TEMPERATURE

After first 24 hours may signify rejection.
Check creatinine, blood cultures, urine culture, CXR.

SUDDEN ONSET OLIGURIA/ANURIA

Catheter blocked?

Anastomotic leak?

Urine leak?

IF IN DOUBT CALL CONSULTANT NEPHROLOGIST