Witness Statement Ref. No. 013/2

NAME OF CHILD: Adam Strain

Name: Joseph Gaston

Title: Dr.

Present position and institution: Retired June 2005. Moved to England May 2007. I no longer have any medical role.

Previous position and institution:
[As at the time of the child's death]

Clinical Director, Anaesthetics, Theatre & Intensive Care- Royal Group of Hospitals ("RGH") / Director of Anaesthetics- Royal Belfast Hospital for Sick Children ("RBHSC").

Membership of Advisory Panels and Committees:
[Identify by date and title all of since your Witness Statement dated 15th July 2005]

Previous Statements, Depositions and Reports:
[Identify by date and title all those made in relation to the child's death since your Witness Statement dated 15th July 2005]

093-023-064 25-04-06 Statement to PSNI

OFFICIAL USE:
List of previous statements, depositions and reports:

Ref:	Date:	
013/1	15.07.05	Witness Statement to the Inquiry
093-023-064	25.04.06	Statement to PSNI

IMPORTANT INSTRUCTIONS FOR ANSWERING:

Please attach additional sheets if more space is required. Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number.

If the document does not have an Inquiry reference number, then please provide a copy of the document attached to your statement.

I. QUERIES IN RELATION TO YOUR MEDICAL QUALIFICATIONS, EXPERIENCE, TRAINING AND RESPONSIBILITIES

(1) Please provide the following information:

(a) State your medical qualifications as of 1995;

MB, BCh, BAO, DA, FRCA, LMCC, FRCPC

(b) State the date you qualified as a medical doctor;

July 1967

(c) Describe your career history before you were appointed Clinical Director for Anaesthetics, Theatres & Intensive Care/ Director of Anaesthetics- RBHSC;

Trained in RAF Anaesthetic Service, Hammersmith Hospital, London and Royal Victoria Hospital, Belfast. Appointed Consultant Anaesthetist Waveney Hospital Ballymena 1974.
Moved to Canada December 1976 - Specialist Anaesthetist Dr Everett Chalmers Hospital, Fredericton, New Brunswick, Canada Jan 1977 - Sep 1987.
Moved to Saudi Arabia September 1987 - Consultant Anaesthetist, King Fahad National Guard Hospital, Riyadh 1987- September 1990.
Moved to Belfast - Consultant Anaesthetist, Royal Hospitals, November 1990 - June 2005.

(d) Describe your work commitments at the RBHSC from the date of your appointment to November 1995;

Responsible for the management of the Anaesthetic Service only. Responsible for the recruitment and appointment of Consultant Paediatric Anaesthetists and ensuring staffing of anaesthetic service to provide appropriate cover. Day to day running of the service delegated to one of the paediatric consultant anaesthetists. I think that consultant was Dr P Crean during my time as Clinical Director.

(e) Was there a written job description for your post in 1995? If so please provide copy of the same. If not, what were the functions and responsibilities of the post?

I have no recollection of having a job description

(f) **Describe the accountability of the Clinical Director for Anaesthetics, Theatres & Intensive Care and the Director of Anaesthetics- RBHSC at that time.**

I was responsible for the management of all aspects of the anaesthesia, theatres and intensive care on the Royal Site and for anaesthesia only on the Royal Maternity, School of Dentistry, Cardiac Surgery and RBHSC.

(g) **What is your view of the role of a Director of Anaesthetics in 1995?**

Having had experience of management in Canada and a JCAH accredited Hospital in Saudi Arabia I saw my role as clearly a managerial role.

(h) **What was your experience of renal paediatric transplant surgery in 1995?**

While I worked in a number of renal failure/renal transplant units I have no recollection of anaesthetising a paediatric patient for an actual transplant.

II. QUERIES ARISING FROM YOUR PREVIOUS STATEMENT (WS-013/1)

(2) ***"I did express my views at a number of meetings to discuss the management of the case".***

(a) **When were those meetings held?**

(b) **Where were those meetings held?**

(c) **Who was present at those meetings?**

(d) **What was discussed at those meetings?**

(e) **Were those meetings documented in any way? If so please provide, if not please explain why?**

(f) **What views did you express at those meetings?**

(g) **What was the outcome of those meetings?**

(h) **What was the consequence of those meetings?**

(i) **Did you consider Adam's case history to have potential for learning?**

I have no detailed memory of any of these meetings. I suspect most were held in Dr Murnaghan's office and would have involved a number of medical staff. It certainly was my opinion that lessons could be learned and I am fairly certain this was discussed. I think that the seminar highlighted X1V 46 was planned to do this in a multi-professional way but as I state later I have no recollection of this seminar ever taking place.

(3) *"I wrote a draft document on a policy for managing hyponatraemia in children having surgery. This was written in consultation with the paediatric consultant anaesthetists" (Ref: 060-018-035-036).*

(i) **Please state whether document (Ref: 060-018-036) was ever finalized beyond draft stage?**

(ii) **If so to whom was it distributed, how and when?**

(iii) **If it was not distributed why not?**

(iv) **What were the relevant considerations in respect of dissemination of these recommendations?**

(v) **Did this draft document become a policy? If so was it substantive? If not why not?**

(vi) **Had you read the Arieff et al paper (BMJ 1992) at the time you drafted this document?**

(vii) **Please state why, given the content of the Arieff et al paper and its relevance to hyponatraemia in healthy children, you confined your recommendations to children undergoing major surgery?**

(viii) **Please state whether you considered drafting guidance for managing hyponatraemia in healthy children?**

(ix) **What was the primary purpose of drafting this document?**

(x) **Did you consult with others in drafting this document? If so please identify those individuals and state their areas of expertise?**

I was asked to prepare a draft document by Dr Murnaghan, I believe at the request of the Coroner. I did this in close co-ordination with the Consultant Paediatric Anaesthetists. The only further involvement I had was to forward this to Dr Murnaghan. I do not know what happened after that. I had full knowledge of the Arieff et Al paper when I wrote this document.

(4) *"I arranged for a report on the equipment used during the operations in the operating theatres".*

(a) **Which *"operations"* and which *"operating theatres"* were you referring to?**

(b) **Why did you not arrange for independent examination of the equipment?**

(c) **Did you ask Dr. Fiona Gibson to attend at the time of the inspection?**

(d) **What information did you give Mr. McLaughlin and Mr. Wilson?**

(e) **Did you inform Mr. McLaughlin and Mr. Wilson as to which *"operations"* and which *"operation theatres"* you were concerned with?**

(f) **What steps were taken to identify the equipment to be examined as the equipment used during Adam Strain's surgery?**

(g) **What steps did you take to have the correct monitors examined and when?**

(h) **At that time were you aware of PEL (93) 36 recommendations at Annex B on reporting adverse incidents and defects in medical equipment?**

I arranged for the report on the equipment in consultation with Dr Murnaghan, I think but I have no record or memory of the process. I would have been aware of PEL (93)36 since the information was widely publicised at the time. Neither Dr Gibson, Mr Wilson or Mr McLaughlin worked in RBHSC and therefore I would have considered them independent. I have no recollection of the process of asking them to undertake the inspection. My recollection is that Dr Murnaghan possibly at the request of the Coroner asked for the inspection to rule out any common clinical theme or equipment issue in the three cases. The only documented evidence I am aware of with regards to this section are the reports from Dr Gibson, Mr Wilson and Mr McLaughlin.

(5) *"Dr. Taylor came to speak to me about the case and how upset he was about his death and we talked through the circumstances and I assured him of my support and understanding of what had been a very complex and challenging anaesthetic".*

(a) **Were these discussions documented in any way? If so please provide.**

(b) **Are there any records as to broader discussions relating to lessons to be learned from Adam's death?**

(c) **Given Dr. Taylor's view that dilutional hyponatraemia was not the cause of Adam's death- do you think that this could have constrained broader discussion as to the issues arising and lessons to be learned and shared in the case of Adam Strain?**

I have no memory of the detail of this conversation beyond that which I detailed in previous statements and I have no written record now. It would have been my policy at that time to make a short note of our conversation, however with the lapse of time I no longer have any records.

(6) *"I highlighted the importance of detailed documentation of fluid management in patient's notes at the ATICS Audit meeting on 10th December 1996 (REF: RGH 2.2)".*

(a) **In the minutes of the ATICS Audit meeting which you attached to your statement, it is stated that a handout entitled *"Anaesthetic Record Set- Suggestions as to a Reasonable Content"* was given to everyone present. Please supply a copy and state who was responsible for drafting the same.**

I enclose a copy of the Anaesthetic Record Set.

III. **QUERIES ARISING FROM YOUR PSNI STATEMENT (Ref: 093-023-064)**

(7) *"At the time it was my opinion that learning from this case was primarily in paediatrics, however, it was very limited in general anaesthetics due to the unique nature of Adam's case"*(Ref: 093-023-064)

(a) **Please explain why you took this view?**

(b) **You state that this was your opinion "at the time". Please state if your opinion has changed, and if so, please state when and give reasons for your change of opinion;**

(c) **Please state why, if the *"learning from this case was primarily in paediatrics"* that you drafted the document Ref: 060-018-036 with Consultant Anaesthetists for Consultant Anaesthetists?**

I do not now have any further detail to add to my original statement.

IV. INTERNAL CONTROL

(8) **Were professional Codes of Conduct incorporated into the contracts of those healthcare professionals involved in the care and treatment of Adam Strain in 1995?**

I have no information now to either confirm or state that this was in place or not in place.

V. HEALTH AND SAFETY

(9) **Had the RBHSC taken any steps to implement guidance for children, including that in:**

(a) **Welfare of Children and Young People in Hospital', Department of Health (1991), HMSO IBSN 0113213581?**

(b) **'Children First – A Study of Hospital Services', Audit Commission (1993) HMSO IBSN 0118860968?**

If so:

(i) **What were those steps?**

(ii) **When were they instituted?**

(iii) **Was their implementation monitored and if so please provide record of the same?**

(iv) **Who was responsible in the RBHSC for implementing such guidance for children?**

I had no role in the day to day management of the RBHSC Theatres or ICU or wards therefore I cannot comment on this section.

(10) **From a 1995 risk management perspective, what should have been expected in respect of:**

(a) **The composition of a paediatric operating theatre team;**

(b) **The minimum staffing requirements thereof;**

(c) **The experience of anaesthetist and surgeon in paediatrics;**

(d) **The appraisal of anaesthetic staff after an unexpected death;**

(e) **The monitoring of anaesthetic set up and drug administration;**

(f) **The documentation and record keeping in respect of anaesthetic equipment;**

(g) **The content of operation notes.**

I had no role in the day to day management of the RBHSC Theatres or ICU or wards therefore I cannot comment on most of this section. In relation to:
C - Consultant Paediatric Anaesthetists had to have one year of specialty training in paediatric anaesthesia before appointment.
D - There was no policy in place for this appraisal at that time
E, F &G - While I cannot confirm this I am confident that all three of these did take place regularly.

VI. KINGS FUND ORGANISATIONAL AUDIT

(11) What knowledge do you have of the King's Fund accreditation process?

(12) If you participated in that process, specify the steps that you took?

(13) Identify any changes in practice which occurred as a result of engaging with the Kings Fund process, both in respect of improving systems of risk management at a clinical and corporate level, and in any other respect?

(14) Where these steps considered sufficient to obtain full accreditation and if not, why not?

11-14 I was a Kings Fund Organisational Audit, and its successor, Health Quality Service Surveyor from 1992-2008. I was also a member of the Trust's steering group. I have no recollection of the details, conclusion or follow up of the survey and no relevant documentation.

VII. CLINICAL/MEDICAL AUDITS

(15) In 1995, what arrangements did the RBHSC have in place for ensuring that regular and systematic medical and/or clinical audits took place?

If the RBHSC did have a system in place for conducting medical and/or clinical audits, please address the following:-

(a) Was there a Clinical Audit Committee? If so, what was its remit?

(b) What were the rules that regulated the operation of the Clinical Audit Committee?

(c) Who formed the Clinical Audit Committee?

(d) Did you play a role in connection with the Clinical Audit Committee, and if so what?

(e) Who was responsible for ensuring that medical and/or clinical audits were carried out?

(f) Who was responsible for carrying out medical and/or clinical audits?

(g) Under what procedures were medical and/or clinical audits carried out?

(h) **To whom were the results of medical and/or clinical audits sent?**

(i) **What kinds of action could be taken on foot of the results of medical and/or clinical audits?**

I have no knowledge relevant to this section since I had no role in this area within RBHSC.

(16) **Please particularise all steps taken by the Trust/ RBHSC to investigate the unexpected death of Adam Strain.**

I have no recollection of any steps taken and no relevant information or documentation.

(17) **Was there any procedure or system in place in 1995 to audit the quality, clarity and completeness of operation notes?**

There was a system in place within anaesthesia to audit operation notes (related to anaesthesia in both the Trust and RBHSC). My memory is that Paediatrics had the highest standard or documentation and compliance with the standards.

(18) **If there was no system in place for conducting medical and/or clinical audits in 1995, please clarify whether there was any other system in place for quality assuring the safe provision of clinical care?**

There was a system of medical/clinical audit in place within the individual specialties but multiprofessional and multispeciality audit was rare in my recollection.

(19) **Was there a system of independent external scrutiny in place to review patterns of performance in the RBHSC, and if so please provide details of the same?**

I had no remit in this area and therefore cannot comment.

(20) **What steps were taken to achieve the objectives outlined in HPSS Management Plan 1995/96-1997/98 with particular reference to paragraph 4.4.11 and the adoption of a policy of clinical audit as part of a program to improve service quality and state when each such step was taken?**

I had no remit in this area and therefore cannot comment.

VIII. CONSENT

(21) **In 1995 did the RBHSC have guidance, policy or procedures in place which governed the issue of patient 'consent'?**

If so,

(a) **Provide a copy of the guidance, policy or procedure;**

(b) **Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;**

(c) Describe its main features;

(d) State how the guidance, policy or procedures was distributed to clinical staff;

(e) State how the guidance, policy or procedures was monitored for compliance.

(22) With respect to the recommendations deriving from:

(a) Guide HC (90) 22, a Guide to Consent for Examination or Treatment;

(b) Circular HSS (GHS) 2/95.

Please state what steps the Trust took to:

(i) Disseminate this guidance and to whom;

(ii) Monitor and record compliance with the same;

(iii) Enforce compliance.

(23) What arrangements were in place in order to notify the Trust that Circular HSS (GHS) 2/95 had been disseminated, and that there was a system in place to monitor compliance with the Circular?

(24) If it is correct that the RBHSC did not commence using the new model consent forms recommended in HSS (GHS) 2/95 until early in 2000, please state the reasons for this delay. If not, please advise date of introduction of new consent forms.

I cannot comment on any aspect of 21-24 because it was not part of my role. I cannot remember as in Section 22 and 23.

IX. RECORD KEEPING

(25) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the issue of clinical record keeping?

If so,

(a) Provide a copy of the guidance, policy or procedures;

(b) Describe its main features;

(c) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(d) State how the guidance, policy or procedures were distributed to clinical staff;

(e) State how the Trust satisfied itself that the guidance, policy or procedures was being complied with by members of clinical teams;

(f) State whether there was/ is any protocol or procedure governing the destruction of any clinical records created in 1995, and if so please identify the same;

(g) Whether there is/ was any protocol or procedure governing the identity of those individuals permitted to sign for and signify safe receipt of transplant organs;

(h) In respect of the composition and documentation of clinical and surgical teams engaged in specific operations.

(26) In 1995, had the RBHSC established a Medical Records Committee?

If so, please address the following:

(a) Who formed the membership of this committee?

(b) Did you play a role in connection with the committee?

(c) What rules regulated the operation of this committee?

(d) What was the purpose of the committee?

(e) Was its operation governed by any policy/procedure?

(27) With respect to the recommendations deriving from:

(a) Department of Health Circular HC (89)20;

(b) Department of Health Circular HSG (94)11;

(c) HSC 1999/053- 'For the Record-Managing Records in NHS Trusts and Health Authorities;

(d) The 1995 Audit Commission study 'Setting the Records Straight, a study of hospital health records';

(e) The Royal College of Surgeons of England Guidelines for Clinicians on Medical Records and Notes (1990, revised 1994).

Please state what steps the Trust took to:

(i) Disseminate this guidance and to whom;

(ii) Monitor and record compliance with the same;

(iii) Enforce compliance.

(28) What guidance was provided to medical/ nursing staff in respect of:

(a) **The monitoring and recording of intra-operative fluid balance?**

(b) **Recording weights in children?**

(c) **Monitoring effectiveness of peritoneal dialysis?**

(d) **The completion of patient records?**

(29) **What procedures or protocols were in place in 1995 for monitoring compliance with professional standards for record keeping?**

I had no involvement in the area of record keeping within RBHSC and I have no recollection of the actions taken in relation to 27, 28 and 29.

X. COMMUNICATION

(30) **In 1995 did the RBHSC have guidance, policy or procedures in place which governed the issue of communications with next of kin and the provision of information during, before and after surgery; and after an unexpected death?**

If so please provide:

(a) **A copy of the guidance, policy or procedures;**

(b) **Describe its main features;**

(c) **Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so please identify this guidance;**

(d) **State how the guidance, policy or procedures were distributed to clinical staff;**

(e) **State how the Trust satisfied itself that the guidance, policy or procedures was being complied with by members of clinical teams.**

(31) **Were there any procedures in place in 1995 for communication with next of kin when aspects of care had not gone to plan and had resulted in harm to the patient?**

I had no involvement in any of these areas and therefore I cannot comment.

XI. BLOOD GAS MACHINES

(32) **In 1995 did the RBHSC have guidance, policy or procedures in place which governed the use of blood gas machines?**

If so, please address the following:

(a) Provide a copy of the relevant guidance, policy or procedures.

(b) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) State how the RBHSC's guidance, policy or procedures were distributed to clinical staff;

(d) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams.

(33) In 1995 what did the guidance, policy or procedures associated with the use of blood gas machine say about the following matters:

(a) Maintenance;

(b) Inspection;

(c) Risk assessment;

(d) Quality control checks;

(e) The personnel entitled to use the machines;

(f) Documenting and recording keeping in respect of same.

(34) In 1995 was there established within the RBHSC a committee, group or team to oversee the safe use of blood gas machines?

If so, please address the following:

(a) Who formed the membership of this committee, group or team?

(b) Did you play a role in connection with the committee, group or team?

(c) What rules regulated the operation of this committee, group or team?

(d) What was its purpose?

(e) Was its operation governed by any policy/procedure?

(35) With respect to the recommendations deriving from:

(a) DHSS NI (Hazard Notice 24/89/76);

(b) Joint Working Group Guidance on Quality Assurance (1993);

(c) HEI 98- Management of Medical Equipment And Devices (revised 1991);

(d) Guidelines for implementation of Near-Patient Testing (September 1993), Joint

Working Party of the Association of Clinical Biochemists and the Royal College of Pathologists, ACB, London;

(e) Management Executive Circular of 27th July 1994 Ref: PEL (93)36 Annex B.

Please state what steps the Trust took to:

(i) Disseminate this guidance and to whom;

(ii) Monitor and record compliance with the same;

(iii) Enforce compliance.

32-35 I had no involvement in any of these areas and therefore I cannot comment.

XII. LABORATORY TESTING

(36) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the conduct of biochemical laboratory testing during major surgery?

If so, please address the following:

(a) Provide a copy of the relevant guidance, policy or procedures;

(b) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) State how the RBHSC's guidance, policy or procedures were distributed to clinical staff;

(d) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams;

(e) Did the RBHSC seek to apply a response time in respect of biochemical laboratory testing during major surgery, and if so, what was this response time?

(f) If so, what guidance, policy or procedure informed such attempts?

I had no involvement in any of these areas and therefore I cannot comment.

XIII. THEATRE EQUIPMENT

(37) In 1995 did the RBHSC have guidance, policy or procedure in relation to,

(a) The purchase;

(b) Maintenance; and

(c) Replacement of theatre equipment, and if so,

(i) Provide a copy of the relevant guidance, policy or procedure;

(ii) Was the guidance, policy or procedure adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(iii) State how the RBHSC's guidance, policy or procedures was distributed to clinical staff;

(iv) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams.

(38) In 1995 did the RBHSC have guidance, policy or procedure in relation to equipment which had been used in theatre when a patient had died?

If so, please address the following:

(a) Provide a copy of the relevant guidance, policy or procedure;

(b) Was the guidance, policy or procedure adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) State how the RBHSC's guidance, policy or procedures was distributed to clinical staff;

(d) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams.

(39) If, in 1995, the RBHSC did have guidance, policy or procedures in relation to equipment which had been used in theatre when a patient had died, please also address the following:

(a) How was that guidance, policy or procedures applied in relation to the theatre equipment used during Adam's surgery;

(b) In Adam's case, what steps were taken in relation to the guidance, policy or procedures;

(c) Who took those steps;

(d) What conclusions were reached?

(40) What steps were taken in Adam's case in relation to the following:

(a) To identify the theatre equipment used during his renal transplant surgery;

(b) To inspect that equipment;

(c) To report on it.

Describe fully any steps that were taken in respect of any of these matters and state,

(i) When the steps were taken; and

(ii) By whom they were taken.

(41) In relation to the Coroner's direction that steps should be taken to ensure that the Siemens Monitor used during Adam's surgery was the subject of independent examination, please address the following:

(a) Who was responsible for acting on the Coroner's direction?

(b) What steps did this person take?

(c) When did he/ she take them?

(d) Was a report produced?

(e) To whom was the report directed?

(f) What conclusions did it reach?

(g) Was any action taken by the RBHSC/ Trust on foot of the report?

(h) Was the Coroner provided with a copy of the report?

(i) What steps did the RBHSC/ Trust take to ensure that the Coroner's requirements were complied with?

(42) Professional Estate Letter (93)36 (27th July 1994) provided the HSS Trusts with a hazard reporting procedure. Was this procedure applied in Adam's case?

If so,

(a) Explain fully how it was applied;

(b) Who applied it?

(c) What steps were taken by reference to this procedure?

(43) Did the RBHSC comply with the guidance contained in HEI 98- Management of Medical Equipment and Devices (revised January 1991) and referenced in *'Anaesthetic related equipment, purchase, maintenance and replacement, the Association of Anaesthetists of Great Britain and Ireland in November 1994 (PEL (93) 36)'*, and if so what steps did it take to comply?

37-43 I had no involvement in any of these areas and therefore I cannot comment.

XIV. DISSEMINATION AND INSTITUTIONAL LINKS

(44) In 1995 did the RBHSC have guidance, policy or procedures in place governing issues arising out of a serious untoward incident or an adverse incident such as the death of a patient following surgery?

If so, please address the following:

(a) Provide a copy of the relevant guidance, policy or procedures.

(b) Was the guidance, policy or procedures adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;

(c) State how the RBHSC's guidance, policy or procedures were distributed to clinical staff;

(d) State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams;

(e) How was the guidance, policy or procedures applied in Adam's case?

I had no involvement in these areas.

(45) Did the RBHSC take any steps, whether by way of an internal investigation or otherwise, to establish whether lessons could be learned from the death of Adam Strain?

If no such steps were taken, please explain why not?

If steps were taken, please address the following:

(a) What steps were taken to learn lessons from the death of Adam?

(b) Under what policy or procedures were these steps taken?

(c) Identify the person(s) who took steps to establish whether lessons could be learned from Adam's death?

(d) When were those steps taken?

(e) What lessons were learned from the death of Adam?

(f) What lessons were learned from the Inquest into the death of Adam?

(g) What measures were taken to review matters arising from the Inquest?

(h) What steps, if any, were taken to disseminate outcomes and lessons internally (within the RBHSC/ Trust)?

(i) What steps, if any, were taken to disseminate outcomes and lessons externally (outside the RBHSC/ Trust)?

(j) What steps, if any, were taken to assess and develop the competence of staff involved in the treatment that led to Adam's death?

I had no involvement in these areas.

(46) Following the Inquest into Adam's death it was agreed that the *"other issues identified"* at the Inquest would be dealt with and that a seminar would be arranged for that purpose and would involve the following clinicians: Doctors Mulholland, Gaston, Hicks, O'Connor,

Savage, Taylor, and Mr. Keane (Ref: 059-001-001).

Please address the following:

(a) Did that seminar take place? If it did not take place, please explain why it didn't take place?

Upon the assumption that it did take, place please provide any record associated with the meeting or its conclusions and address the following:

(i) When did it take place?

(ii) Who attended?

(iii) What was discussed?

(iv) What conclusions were reached?

(v) Were these conclusions disseminated, and if so, when and to whom?

I have no recollection of this seminar taking place.

(47) Dr. Taylor indicated his disagreement with the cause of death indicated on Adam's death certificate. State whether any steps were taken by the RBHSC/ Trust to address Dr. Taylor's views?

If so, please address the following:

(a) What steps were taken to address Dr. Taylor's views?

(b) When were those steps taken?

(c) Who took those steps?

(d) What conclusions emerged from this process?

I have no recollection if this happened or not.

(48) Please state your view on whether it would have been easier to use Adam Strain's case history as a vehicle for learning had there been agreement as to the role dilutional hyponatraemia played in Adam's death?

I do not feel I can make a judgement on this now so many years later.

(49) Please confirm whether or not you received a report in writing of or into the death of Adam Strain in 1995?

I would have expected to receive a report but cannot confirm this.

(50) Please state whether there existed a formal approach to:

(a) Assessing and developing the competence of the staff involved in the treatment that led to Adam's death;

(b) Disseminating outcomes and lessons learned internally both before and after the Inquest;

(c) Disseminating outcomes and lessons learned externally both before and after the Inquest?

I have no recollection of any formal approach to a, b or c.

XV. INTERNAL REVIEW

(51) Did the RBHSC conduct an internal review in respect of any of the following matters after Adam's death:

(a) The procedures governing consent, and whether they were complied with in Adam's case;

(b) The records kept/made relating to the pre, intra and post operative care of Adam;

(c) The records kept/ made of communications with Adam's parents;

(d) The use of equipment before and during Adam's surgery;

(e) Lessons to be learned from the treatment which led to his death;

(f) The competence and training needs of those who cared for Adam.

If so, please address the following:

(i) What steps were taken in respect of each matter?

(ii) When were those steps taken?

(iii) Who took those steps?

(iv) What policies or procedures were used when taking those steps?

(v) What conclusions emerged in respect of any of these matters?

(52) Did the RBHSC have a policy for investigating adverse incidents in 1995?

51-52 I cannot remember whether this took place or not.

XVI. OTHER

(53) In respect of the clinical negligence action commenced 25th April 1996 and settled 29th April

1997 please state:

(a) Did the litigation restrict the scope of explanation offered to Adam's parents?

(b) Did the litigation restrict the scope of dissemination of information in respect of learning outcomes, both internally and externally?

(c) Were the clinical staff involved in Adam's case kept informed of all aspects of the outcome of the clinical negligence case?

I have no recollection of the details of the settlement and therefore I cannot comment on a, b or c.

(54) Has any consideration been given to viability of the RBHSC renal transplant facility and if so:

(a) When?

(b) Why?

(c) By whom?

(d) What was considered?

(e) With what outcome?

(f) In the light of the publication of the *'Provision of Services for Children and Adolescents with Renal Disease'* (Working Party Report in March 1995).

I was never party to such discussions.

(55) Were any child patients transferred from the RBHSC to any other hospital in the UK for surgery before Adam's death, and if so please state:

(a) Date of transfer;

(b) Hospital to which child was transferred;

(c) Age of child when transferred;

(d) Identity of Consultant in charge of child prior to transfer;

(e) Reason for the transfer;

(f) Whether there existed any policy, protocol, procedure or guidelines in relation to the transfer of children to hospitals outside of Northern Ireland for surgery.

I had no involvement in these areas and therefore I cannot comment.

(56) Were there any procedures, protocols or practices in 1995 governing paediatric renal transplant surgery? If so, please address the following:

(a) **Provide a copy of the relevant guidance, policy or procedure;**

(b) **Was the guidance, policy or procedure adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;**

(c) **State how the RBHSC's guidance, policy or procedures was distributed to clinical staff;**

(d) **State how the Trust satisfied itself that the guidance, policy, or procedures was being complied with by members of clinical teams;**

(e) **Was there a system for periodic review and updating of any such policy, protocol or guidance?**

I had no involvement in these areas and therefore I cannot comment.

(57) **Please identify those procedures and protocols governing the reporting and dissemination of information to the DHSSPS and the wider medical community in 1995 and now relating to:**

(a) **Unexpected/ unexplained deaths in RBHSC;**

(b) **Outcomes of Coroner's Inquests**

and further please address the following:

(i) **Identify those individuals responsible for the implementation of the same;**

(ii) **Was the procedure/ protocol as adopted by the RBHSC, modeled on or informed by any published guidance, and if so, identify this guidance;**

(iii) **State how the Trust satisfied itself that the procedures and protocols where complied with;**

(iv) **To what extent were the procedures and protocols followed in Adam's case?**

(v) **What information was supplied in Adam's case?**

(vi) **Whether the procedures and protocols were consistent with guidance in both Northern Ireland and the UK in 1995.**

I had no involvement in these areas and therefore I cannot comment.

(58) **Please indicate what teaching and/ or training was provided to nursing and/ or medical teams in and before 1995 in respect of:**

(a) **Fluid management (with particular reference to hyponatraemia);**

(b) **Record keeping.**

I had no remit in these areas and therefore I cannot comment.

(59) **Please state what steps had been taken by November 1995 to implement the recommendations of the NCPOD report in respect of out of hours paediatric surgery.**

I had no remit in these areas and therefore I cannot comment.

(60) **Please state what action you took following the Inquest into Adam's death. If you took no action please explain why.**

I had no remit in these areas and therefore I cannot comment.

(61) **Explain why no contact was made by the RBHSC with other hospitals to inform them of the amendment of the renal transplant guidelines by the anaesthetic, theatre and intensive care directorate.**

I had no remit in these areas and therefore I cannot comment.

XVII. EDUCATION, TRAINING AND EXPERIENCE.

(62) **Describe in detail the education and training you received in fluid management (with particular reference to hyponatraemia) and record keeping through the following, providing dates and names of institutions/ bodies:**

(a) **Undergraduate level;**

(b) **Postgraduate level;**

(c) **Hospital induction programs;**

(d) **Continuous Professional Development;**

I cannot remember my undergraduate teaching but I was fortunate to have good teaching at postgraduate level. I do not remember ever having fluid management as part of my induction. I also had excellent training in America in preparation for my FRCPC.

(63) **Prior to 26th November 1995, describe in detail your experience of dealing with children with hyponatraemia, including:**

(a) **The estimated total of such cases, together with the dates and where they took place;**

(b) **The number of children who were aged under 6 years;**

(c) **The nature of your involvement;**

(d) **The outcome for the children.**

I have never to the best of my recollection been involved in a case of hyponatraemia in a paediatric patient though it was not routine to keep such information during most of my career. I was however fully aware of a small number of cases involving children who died following tonsillectomy who had

received low or non sodium containing fluids. These cases were in Atlantic Canada. It was routine in every hospital where I worked to use balanced salt solutions as replacement fluid in both adult and paediatric patients.

XVIII. GENERAL

(64) Please provide any further comments you may wish to make.

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

Signed: [signature] Dated: 22 May 2012

Anaesthetic Record Set

Suggestions as to a reasonable content

PRE-OPERATIVE INFORMATION

PATIENT IDENTITY
- Name / ID No. / gender
- Date of birth

ASSESSMENT & RISK FACTORS
- Date of assessment
- Assessor, where assessed
- Weight (kg), [height (m) optional]
- Basic vital signs (BP, HR)
- Medication, incl. contraceptive drugs
- Allergies
- Addiction (alcohol, tobacco, drugs)
- Previous GAs, family history
- Potential airway problems
- Prostheses, teeth, crowns
- Investigations
- Cardiorespiratory fitness
- Other problems
- ASA ± comment

URGENCY
- Scheduled - listed on a routine list
- Urgent - resuscitated, not on a routine list
- Emergency - not fully resuscitated

PEROPERATIVE INFORMATION

CHECKS
- Nil by mouth
- Consent
- Premedication, type and effect

PLACE & TIME
- Place
- Date, start and end times

PERSONNEL
- All anaesthetists named
- Operating surgeon
- Qualified assistant present
- Duty consultant informed

OPERATION PLANNED/ PERFORMED

APPARATUS
- Check performed, anaesthetic room, theatre

VITAL SIGNS RECORDING/CHARTING
- Monitors used and vital signs (specify)

DRUGS & FLUIDS
- Dose, concentration, volume
- Cannulation
- Injection site(s), time & route
- Warmer used
- Blood loss, urine output

AIRWAY & BREATHING SYSTEM
- Route, system used
- Ventilation: type and mode
- Airway type, size, cuff, shape
- Special procedures, humidifier, filter
- Throat pack
- Difficulty

REGIONAL ANAESTHESIA
- Consent
- Block performed
- Entry site
- Needle used, aid to location
- Catheter: y/n

PATIENT POSITION & ATTACHMENTS
- Thrombosis prophylaxis
- Temperature control
- Limb positions

POSTOPERATIVE INSTRUCTIONS

Drugs, fluids and doses
Analgesic techniques
Special airway instructions, incl oxygen
Monitoring

UNTOWARD EVENTS
- Abnormalities
- Critical incidents
  - Pre-op, per-op, postoperative
  - Context, cause, effect

HAZARD FLAGS
- Warnings for future care.

Commentary

BACKGROUND

This document is produced jointly by the Royal College of Anaesthetists, The Association of Anaesthetists of Great Britain & Ireland and the Society for Computing & Technology in Anaesthesia. Work has been going on for some years to standardise the data kept about anaesthetic episodes. This is worth striving for several reasons: not only would there be a welcome agreement about what requires to be written down, but terms such as 'Start time' would be defined, and therefore reports derived from the data would be comparable.

A meeting was set up by the Society for Computing and Technology in Anaesthesia (SCATA) at the Association of Anaesthetists of Great Britain & Ireland in 1990, attended by representatives from the Royal College of Anaesthetists, and some terms used in the dataset were defined. [1] The next move was to define the content of the anaesthetic record. All concerned recognised that there is no ideal content - that what is appropriate for cardiac anaesthesia or a manipulation of a wrist are totally different, and the appropriate content must increase with the complexity of the anaesthetic. We therefore agreed to list the fields that could be included, and will later deal with the issues of what should be added. It was also fully recognised that datasets and content are continually changing; we expect that as thinking and requirements change, we will need to reissue this guidance at reasonable intervals. We also recognise that several of these definitions are contentious, and fully anticipate further serious discussion.

We have *not* attempted to design a form, but rather to show what information might be presented.

COMMENTS ON PARTICULAR FIELDS

Many items will be present 'by association' - in other words, already present in the patient's notes, and making it pointless to rewrite them. This does not diminish the need for key items of anaesthetic relevance to be copied on occasion - to emphasise that the anaesthetist was aware of them, but defining precisely which these are is not sensible.

URGENCY

This is a long debated issue, probably the most contentious in the whole set. The problem is that CEPOD uses a four division classification, *Elective, Scheduled, Urgent* and *Emergency*, and the difference between Elective and Scheduled is a purely surgical one not discernible by the anaesthetist. The CEPOD definitions were used in the dataset published in 1994.

Elective - Operation at time to suit both patient and surgeon.

Scheduled - An early operation but not immediately life-saving. Operation usually within 1-3 weeks.

Urgent - Delayed operation as soon as possible after resuscitation. Operation usually within 24 hours.

Emergency - Immediate operation, resuscitation simultaneous with surgical treatment. Operation usually within one hour.

Because of the difficulties with this classification, the 'Classes' of listed and unlisted were introduced.

Listed - An operation published on a scheduled list

Unlisted - Not published on a scheduled list

We are now recommending that these two classifications are amalgamated to make a more anaesthetically realistic classification that reflects daily life.

Scheduled - listed on a routine list
Urgent - not on a routine list, but fully resuscitated
Emergency - not fully resuscitated

PATIENT POSITION & ATTACHMENTS

The way in which a patient was lying during anaesthesia should be recorded, including the position of the limbs and any special precautions taken against injury.

UNTOWARD EVENTS

There is a whole series of terms developing in this field - critical incidents, complications, abnormalities, negative outcomes, recovery room impact events, and more. Thinking in this field is changing sufficiently rapidly so being dogmatic about which terms to use is not sensible.

In general terms, the need is to record events so that anaesthesia may be safer in the future; to record, therefore, not only things that went wrong (complications), but also that nearly went wrong (critical incidents). We should also record 'abnormalities' such as a difficult intubation, which are not preventable, both for the patient's future safety, and for educational reasons. The severity of the incident should also be recorded.

HAZARD FLAGS

Any important abnormalities (drug sensitivities, errors of metabolism etc.) affecting the patient clearly should be flagged both on the record and in the notes.

Reference

1. Lack, J.A., Stuart-Taylor, M.E., and Tecklenburg, A. An anaesthetic minimum dataset and report format. The Society for Computing and Technology in Anaesthesia (SCATA), The European Society for Computing and Technology in Anaesthesia (ESCTAIC). *British Journal of Anaesthesia* 1994; 73(2): 256-260.

Further copies may be obtained from
Professional Standards Directorate
Royal College of Anaesthetists
Tel: 0171-813 1900

APRIL 1996

A revised anaesthetic record set

Professor A P Adams, Chairman, Record Working Party

In 1990 following a meeting organised by the Society for Computing and Technology in Anaesthesia (SCATA) attended by a representative of the College and the Association, a set of terms of use for anaesthetic records was defined[1]. Further meetings held with representatives from the college, AAGBI and SCATA defined the content for an anaesthetic record. Whilst no record is ideal - what is needed for cardiac surgery may well differ greatly from that needed for a simple manipulation under anaesthesia - there is a need for a starting set. The list is a start. The Working Party recognises that changes will be needed with time and intends to reissue the guide at reasonable intervals. It did not attempt to design a form but aimed to show what information might be presented. The set has been discussed and approved by the Council of the College.

Some of the items in the lists will already be present in the patient's notes and it may appear pointless to rewrite them. But several items of key information should appear on the anaesthetic chart. Four points are worthy of special note:

Urgency

There is a problem in that CEPOD uses a four-division classification - Elective, Scheduled, Urgent and Emergency. The distinction between the first two classes is purely surgical. A second classification uses: Listed and Unlisted. The Working Party proposes a more anaesthetically related classification:

- *Scheduled* - a patient listed on routine list.
- *Urgent* - a patient not on a routine list but fully resuscitated.
- *Emergency* - a patient not fully resuscitated.

Patient position and attachments

The record should note the position of the patient and the limbs together with any special precautions taken against injury.

Untoward events

There are many terms such as critical incidents, complications and negative outcomes which describe events during the perioperative period. Thinking in this field is still developing. The aim should be to make anaesthesia safer in the future by recording events where things went wrong (complications) and where they nearly did (critical incidents). Abnormalities such as difficult intubations need to be recorded.

Hazard flags

Any important abnormality such as a drug sensitivity or an error of metabolism which affects the patient should be flagged both on the anaesthetic record and in the notes.

Reference

1 Lack JA, Stuart-Taylor M, Tecklenburg A. SCATA and ESCTAIC. An anaesthetic minimum data set and report format. British Journal of Anaesthesia 1994;73:256–260.

ANAESTHETIC RECORD SET

Suggestions as to a reasonable content

The record set can be divided into groups:

PRE-OPERATIVE INFORMATION

Patient Identity

Name/Identity Number/Gender

Assessment and Risk Factors

Date of Assessment
Assessor and where assessed
Weight (kg), [height (m) optional]
Basic vital signs (BP and Heart Rate)
Medication including contraceptive drugs
Allergies
Addiction (tobacco, alcohol, drugs)
Previous general anaesthetics
Family history
Potential airway problems
Prostheses, teeth, crowns
Investigations
Cardiorespiratory fitness
Other problems
ASA status ± comment

Urgency

Scheduled – listed on a routine list
Urgent – resuscitated, not on routine list
Emergency – not fully resuscitated

PER-OPERATIVE INFORMATION

Checks

Nil by mouth
Consent to operation
Premedication, type and effect

Place and Time

Place
Date of operation
Time started and finished

Personnel

All anaesthetists named
Qualified assistant present
Operating surgeon
Duty consultant informed

Operation planned/performed

Apparatus

Checks performed, anaesthetic room and theatre

Vital Signs Recording/Charting

Monitoring used and vital signs (specify)

Drugs and Fluids

Doses, concentrations and volume
Cannulation
Injection site(s), time and route
Warmer used
Blood loss, urine output

Airway and Breathing System

Route, system used
Ventilation: type and mode
Airway type, size, cuff and shape
Special procedures, humidifier, filter
Throat pack
Difficulty

Regional anaesthesia

Consent
Block performed
Entry site
Needle used, aid to location
Catheter: yes/no

Patient Position and Attachments

Thrombosis prophylaxis
Temperature control
Limb positions

POSTOPERATIVE INSTRUCTIONS

Drugs, fluids and doses
Analgesic techniques
Special airway instructions
Oxygen therapy
Monitoring

UNTOWARD EVENTS

Abnormalities
Critical Incidents
Pre-, per- or post-operative
Context, cause and effect

HAZARD FLAGS

Warnings for future care