Witness Statement Ref. No. 106/3

NAME OF CHILD: Adam Strain

Name: Peter Shaw

Title: Mr

Present position and institution: Retired

Previous position and institution:
[Since your Witness Statement of 13th August 2011]

Membership of Advisory Panels and Committees:
[Identify by date and title all of those since your Witness Statement of 13th August 2011]

Previous Statements, Depositions and Reports:
[Identify by date and title all those since your Witness Statement of 13th August 2011]

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

Ref:	Date:	
093-014	02.05.2006	PSNI Witness Statement
106/1	08.04.2011	Inquiry Witness Statement
106/2	13.08.2011	Second Inquiry Witness Statement

IMPORTANT INSTRUCTIONS FOR ANSWERING:
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 such a number then please provide a copy of the document.

I. QUERIES ARISING OUT OF YOUR PSNI WITNESS STATEMENT

With reference to your PSNI Witness Statement dated 2nd May 2006 (Ref: 093-014-045), please provide clarification and/or further information in respect of the following:

(1) *"During the operation my role was to assist the anaesthetists in their duties and if needed to act as a second runner."* **(Ref: 093-014-045)**

(a) In your role as "*a second runner*", state whether you could have been available to transport a blood sample from theatre to the laboratory and/or the blood gas machine for analysis or to make arrangements for transportation of such a sample. If so, state when you could have done so. If not, state the reasons why not.

The second runner has to stay in theatre until the runner returns.

(b) In your role as "*a second runner*", state whether you would have been available to transport a blood sample from theatre to the laboratory and/or the blood gas machine for analysis or to make arrangements for transportation of such a sample. If so, state when you would have done so. If not, state the reasons why not.

The second runner has to stay in theatre until the runner returns.

(2) *"In doing that I started fluid through the transducer not under pressure to clear any air bubbles, then the fluid bag was put under pressure at 300 mmHg, then the transducer was plugged into the monitor, a tap was turned to atmosphere and the zero button on the monitor was pressed and if the transducer was working a straight line marked zero was produced. Then I used to switch the tap from atmosphere to the patient, I used to tap the transducer looking at the monitor and if it was working I could see a corresponding wave form on the monitor."* **(Ref: 093-014-046)**

(a) State whether the *"wave form"* of the CVP for Adam conformed to one where pressure was being accurately recorded by the monitor, giving your reasons. If not, state the reasons why not.

This is the anaesthetist's role.

(b) Describe and explain what is being shown on that print-out, including:

(i) what the axis on left hand side is measuring and the range of values on that axis, in particular whether the maximum value is 60 mmHg or 40 mmHg
(ii) what is meant by the reference to "PAS" and "PAM"
(iii) what is indicated by the box on the left hand side entitled "Trend Menu"
(iv) what is meant by the reference to "Alarms", what type of event would trigger an alarm and what would happen in the event of an alarm

This is the anaesthetist's role.

(c) **Explain how the document at Ref: 094-037-211 was produced**

It is a printout produced by the Patient Monitoring machine used in the course of the operation.

(d) **Explain what could cause the configuration of the CVP measurement that appears on the print-out (Ref: 094-037-211), including:**

(i) **the start before 0730 and running below zero until just before 0800**

I would have tested the transducer was working.

(ii) **the 'returns to zero' at about 0800, 0915 and 1000**

I do not know.

(e) **State whether prior to or since Adam's transplant surgery you had encountered CVP values as high as those shown on the print-out and if so, state in what circumstances.**

I cannot recall. As I have stated previously I took part in many operations since 1980.

II. QUERIES ARISING OUT OF YOUR INITIAL INQUIRY WITNESS STATEMENT DATED 8th APRIL 2011

With reference to your Inquiry Witness Statement dated 8th April 2011, please provide clarification and/or further information in respect of the following:

(3) **Answer to Question 2(d) at p.4:**

"My responsibilities would have been to clean and check all the machinery and generally make sure that the machinery is ready for the next operation. The entire operating theatre would be cleaned exhaustively and the machines checked and replenished and left in full working order."

(a) **State exactly what checks you would have carried out at the end of surgery on the Siemens Patient Monitor model 1281:**

(i) **to *"make sure that the machinery is ready for the next operation."***

(ii) **so that it was *"left in full working order."***

Wipe the monitor, leads and screen and check the leads.

(b) **If there had been any fault with the said Patient Monitor including a 'dim display', state whether this would have been evident from the checks normally carried out on that Monitor at the end of surgery.**

This would have been evident.

III. QUERIES ARISING OUT OF YOUR INQUIRY WITNESS STATEMENT DATED 13th AUGUST 2011

With reference to your Inquiry Witness Statement dated 13th August 2011, please provide clarification and/or further information in respect of the following:

(4) Answer to Question 2(a) at p. 3:

"(i) I was not aware of anyone's concerns in relation to accuracy of the blood gas machine in providing electrolyte results.
(ii) Anaesthetists relying on the results would have been aware that addition of heparin to the serum sample would have altered serum electrolyte readings."

(a) You have failed to state *"whether you had any concerns, about: (i) the accuracy of the blood gas machine(s) in providing near-patient measurement of serum electrolytes; and (ii) relying upon the results of those machines."* Please answer the question adequately.

This was not my function. This was the function of the Anaesthetist.

(b) State how *"the addition of heparin to the serum sample would have altered the serum electrolyte readings"* (i) generally in November 1995 and (ii) in Adam's surgery. In particular, state whether the addition of heparin to the serum sample would have raised or lowered the sodium concentration result.

I cannot state that. This is a specialist function and not within my knowledge.

(c) State how and when *"anaesthetists... would have become aware that addition of heparin to the serum sample would have altered serum electrolyte readings."* In particular, identify who would have informed them and whether this would have been done orally or in writing. If in writing, please identify the relevant document.

So far as I am aware the Anaesthetist would have been aware of this information at all times as part of his professional training.

(d) As *"[a]naesthetists relying on the results would have been aware that addition of heparin to the serum sample would have altered serum electrolyte readings"*, state what guidance or instructions would have been given to the anaesthetists prior to 27 November 1995:

(i) on the use of heparin with Blood Gas analysers so as to minimise its effects on the serum electrolyte readings
(ii) in relation to factoring that knowledge into their interpretation of the serum electrolyte readings produced by the Blood Gas analysers

This matter is for the professional training of the Anaesthetist.

(e) State the type of heparin that was added to Adam's serum samples during his transplant surgery on 27th November 1995 together with the form of heparin used i.e. liquid or solid If you cannot recall specifically, state:

(i) what type and form of heparin would likely have been used at that time
(ii) whether the heparin used was sodium heparin, lithium heparin or lithium heparin balanced with calcium, potassium and sodium

I do not know.

(f) By the time you retired in 2005, state whether the type or form of heparin added to the serum sample changed, and if so, state to what, when and the reasons why.

I do not know.

IV. ADDITIONAL QUERIES

(5) Describe the portering service available on 26th and 27th November 1995 to the theatre in RBHSC for tasks including the transporting of specimens to the laboratory.

A telephone request would be made to the porter's office for a specimen to be taken from theatre to the laboratory.

(6) State whether a pneumatic tube system was available in RBHSC on 27th November 1995 for samples from the theatre to be sent directly to the laboratory.

So far as I can recall it was not.

(7) State whether, in November 1995, the RBHSC had, or had access to, any *portable* blood gas analyser machines e.g. iSTAT blood gas analyser, to measure sodium, potassium, urea, and creatinine. If so:

- **(a) Identify the type of *portable* blood gas analyser available at that time and describe where it was located**
- **(b) State what arrangements would have been required for the use of that blood gas analyser in Adam's transplant surgery**
- **(c) State the accuracy of the results for sodium compared to:**
  - **(i) the static blood gas analyser**
  - **(ii) laboratory blood tests**

No.

(8) Describe the system in place in November 1995 for the transportation of blood samples from the theatre in RBHSC to the laboratory and/or the blood gas machine for analysis.

Blood samples would be taken by porter to the laboratory, or by the MTO or anaesthetist to the blood gas analyser.

(9) State whether it would have been possible to carry out a pre-operative X-ray on 27th November 1995 to check the CVP line position. If so, state whose responsibility it would have been to arrange the x-ray:

This was not my function and I cannot comment on it.

(10) State what X-ray equipment was available during Adam's transplant procedure on 27th November 1995 had the anaesthetist/s wished to confirm the position of the CVP catheter tip, and how long would it have taken to have arranged and performed such an X-ray.

X-rays were available in theatre but I did not have any involvement with the equipment.

(11) If, as the subsequent X-ray showed, the CVP line was going up a neck vessel, state from your experience what you believe could and should have been done to address that problem. during the course of the transplant surgery. State who should have taken the responsibility to take that action, if any.

This is not my function nor was within my competence.

(12) State from your experience the likely effect of the CVP line going up a neck vessel, in particular on the accuracy and reliability of the initial CVP reading and any relative changes to it.

I cannot comment.

(13) **State from your experience what options you believe were available to achieve accurate and reliable information on Adam's CVP and who you believe should have considered and exercised those options**

To the best of my knowledge this is within the professional competence of the anaesthetist.

(14) **State whether you were involved in transferring Adam from theatre to PICU on 27th November 1995 and identify the other theatre staff and clinicians who were also involved in that transfer. If you do not recall specifically whether you were involved in this transfer to PICU, state whether this was normally/likely part of your role as anaesthetic assistant/theatre staff and whether you were normally/likely accompanied in this transfer, and if so, by whom.**

I was probably involved. Normally there would have been three persons involved – anaesthetist, nurse and myself. I cannot identify the personnel involved.

(15) **Describe in detail the process of how Adam was transferred from theatre to PICU. If you cannot recall specifically, describe how a paediatric renal transplant patient would likely/normally have been transferred from theatre to PICU in November 1995.**

Normally the patient would have been transferred to a PICU bed and taken to the PICU with all the equipment and a monitor attached. I cannot recall the exact details of this particular transfer.

(16) **Describe in so far as you can recall Adam's appearance after surgery and on his transfer to PICU.**

I cannot recall.

(17) **State whether you remained in PICU to assist with the transfer of the lines to the PICU monitors. If you do not recall this specifically, state whether you would normally/likely have done this as part of your role as anaesthetic assistant/theatre staff.**

I cannot recall but I would have remained to assist. This would have been part of my normal function.

(18) **Identify the consultant and nurse/s in PICU to whom the care of Adam was transferred on arrival on 27th November 1995.**

I cannot identify the personnel involved.

(19) **Identify who carried out the handover to the PICU clinician and PICU nurses on arrival on 27th November 1995, and state what information was given, or if you do not recall specifically, what information was likely/normally given, during that handover to :**

(a) The PICU consultant/clinician

(b) The PICU nurses

About:

- **Adam**
- **his renal transplant surgery**
- **the reasons for his failure to breathe spontaneously and his fixed dilated pupils post operatively**
- **Adam's serum sodium concentration**
- **Adam's fluids regime during the transplant procedure**
- **the position of the CVP line both during and on completion of the transplant procedure, the CVP readings during the transplant procedure and the explanation for those CVP readings, any concerns relating to the CVP line, whether the CVP line was**

functioning effectively and reliably

I cannot recall the identity of the personnel. In normal circumstances the patient case notes plus the anaesthetic sheet would have been placed on the bed and given to PICU personnel.

(20) **Identify any guidance or protocols in November 1995 relating to the transfer from theatre to PICU of paediatric patients and the handover to PICU staff.**

I cannot identify such guidance or protocols.

(21) **State whether the position of the CVP line had been adjusted between approximately 11.30 on 27th November 1995 and the transfer of the CVP line to the PICU monitors, and if so, when, how, by whom and identify where this is recorded. If you do not recall specifically, state whether it was likely/normal that the CVP line was adjusted during that period and if so, by whom.**

I cannot recall but it would not have been normal practice to adjust the CVP line unless an anomaly was shown on the monitor screen.

(22) **Describe your normal practice for managing a CVP line when admitting a child to PICU from theatre. How would you ensure that readings were accurate and reliable?**

If there was drip stand on the trolley/bed, or a mobile stand, the transducers would be attached to the stand by a clamp, and re zeroed.

(23) **At the time of Adam's death and now, were there any guidelines available to ward, anaesthetic, theatre and/or PICU staff on the management of CVP lines?**

I do not know if there were guidelines.

(24) **State whether the attached Hazard notice HC (Hazard) (89) 31 *'Blood Gas Measuring: The need for reliability of results produced in extra laboratory areas'* was ever brought to your attention, and if so when, by whom, in what circumstances.**

(a) **If this Hazard Notice was not brought to your attention, state the reasons why not.**

(b) **State whether you brought this hazard notice to the attention of anyone in RBHSC, and specifically whether this included Dr. Taylor, Mr. Keane, Mr. Brown, Dr. Montague, and if so, when did you do so? If you did not do so, state the reasons why not.**

(c) **State what action, if any, was taken by you as a result of this hazard notice and when this action was taken.**

(d) **State what action, if any, was taken by others as a result of this hazard notice and when this action was taken.**

(e) **If no action was taken, explain the reasons why not.**

(f) **State whether there was a written operational protocol for the blood gas analyser machine used on 27th November 1995 at approximately 09.32, and if so, state whether it was available to the user and was attached to the machine. If there was no written operational protocol, state the reasons why not. If there was a written operational protocol but it was either not available to the user, or was not attached to the machine, state the reasons why not.**

(g) **State what steps were taken by RBHSC prior to 27th November 1992 to ensure that the**

results of the blood gas analyser machine used at 09.32 in relation to Adam were comparable with those produced by a quality-controlled laboratory-based instrument.

I cannot answer any of these particulars at this stage. It was not my function to bring information to the attention of the medical and PICU nursing staff who were professionally competent. I cannot recall if the Hazard Warning Notice was given to me personally or when but if it was it would have been given to all staff in Department.

(25) **State if there was a Point of Care Testing (POCT) policy for blood gas analysers in RBHSC on 27th November 1995. If so, state what it was. If not, state why there was not such a policy.**

So far as I can recall, we did Quality Control testing every day without fail.

(26) **State whether: (i) the paediatric Clinical Biochemistry Laboratory in RBHSC and (ii) the main Royal Victoria Hospital Laboratory in the Kelvin Building had Clinical Pathology Accreditation (CPA) on 26th November 1995. If so, state when that accreditation was obtained and exactly what it entailed. If not, describe the standards to which each Laboratory operated and identify the document/s where those standards are recorded.**

I do not know.

(27) **Describe what equipment was available in RBHSC in November 1995 to measure serum sodium concentration, other than the blood gas analyser in the corridor between PICU and the PICU staff room, and state where this equipment was located. (and how long it took to analyse the blood sample at that time.)**

I am not aware of what equipment was available in the RBHSC Biochemistry laboratory.

(28) **State whether you were aware of any application by the RBHSC to be an accredited institution with the King's Fund Organisation Audit (KFOA) Programme and standards in 1995. If so, state whether you believe the care and treatment of Adam complied with the KFOA standards, and explain the basis for your belief. If not, explain the respects in which it did not comply.**

I do not know.

(29) **State whether you were aware of any discussions relating to Adam's death and his inquest involving the Trust, clinical or managerial staff concerning the lessons that could be learned and/or action that should be taken.**

(a) **If so, state when those discussions took place, who participated in them and what the outcome was.**

(b) **State, in particular, the extent to which you were involved in any such discussions and/or action.**

(c) **If you were not involved in either discussions or action, explain why not.**

I am not aware.

(30) **State whether you had any discussion within RBHSC, outside the context of renal transplant and/or renal surgery, about the benefits of regularly monitoring electrolytes and the use of fluids with a higher sodium content. If so, identify those involved and when such discussions took place.**

I had no such discussions.

(31) **Describe the procedure for clinical audit at RBHSC in November 1995 and identify any relevant documents**

(a) Describe the procedure for clinical audit at RBHSC at the date of your retirement and identify any relevant documents

(b) Describe what you did in terms of a 'clinical audit' of Adam's case, and provide any relevant documents

(c) State whether your actions relating to a clinical audit of Adam's case would differ in 2011 or at the date of your retirement and if so, how. If not, explain why not.

This was not part of my function. These are matters for the clinician's involvement.

(32) **State whether there has been any audit or assessment of renal transplant surgery at the RBHSC or of Belfast as a renal transplant centre. If so,**

(a) State when such audits or assessments occurred (in both cases)

(b) Identify who conducted them

(c) Describe your role, if any, in them

(d) Identify any report resulting from such audits and assessments, and if available, provide a copy

This question should be directed to the medical staff with the appropriate professional qualifications.

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

Signed:  **Dated:** 17 - 10 - 2011

HEALTH CIRCULAR

HAZARD

HC(HAZARD)(89)31

17 October 1989

DEPARTMENT OF HEALTH
HEALTH SERVICES MANAGEMENT

To:
Regional Health Authorities)
District Health Authorities) for action
Special Health Authorities)

BLOOD GAS MEASUREMENTS: THE NEED FOR RELIABILITY OF RESULTS PRODUCED IN EXTRA-LABORATORY AREAS

SUMMARY

A recent incident has indicated that the use of blood gas analysers by untrained staff, without adequate management supervision of the equipment and without the use of quality control procedures, can give rise to misleading results, having the potential to affect adversely the treatment of patients.

ACTION

This information should be brought to the attention of all who need to know or be aware of it. This will include **pathology laboratory staff and any medical, nursing, operating department and special care baby unit staff or others with direct access to blood gas analysers.**

General advice on the management of equipment was published in Health Equipment Information, Number 98, January 1982. The advice given should be followed in the management of extra-laboratory analytical equipment and systems.

Careful and systematic selection of appropriate equipment is essential. It is particularly important to ensure that equipment has been designed for use by non-laboratory staff.

When purchasing consumables care should be taken to ensure reliable performance in conjunction with instrumentation. It is also recommendad that the pathology laboratory is involved in the purchase, and maintenance, of all extra-laboratory equipment.

All staff who perform extra-laboratory blood gas measurements must be adequataly trained.

There should be a written operational protocols for the equipment, which should be available to the user and preferably be attached to the equipment.

Routine maintenance of extra-laboratory analytical equipment is essential. Procedures should be in accordance with the equipment manufacturer's instructions and include a function of quality control check.

Independent quality control procedures on all extra-laboratory measurements should be carried out regularly, in collaboration with the pathology laboratory, to ensure that competence is maintained by all users and that the results are comparable with those produced by a quality-controlled laboratory-based instrument.

BACKGROUND

1. An investigation into an incident involving a neonate has shown that clinically-misleading results can be produced if blood gas analysers are not used exactly as specified by the manufacturer. In particular, where capillary samples are taken, it is essential that the capillary tube is completely filled. Failure to do this could give rise to unreliable results.

2. Such clinically-misleading results are particularly likely to occur where quality control programmes are lacking and where there is no formal training of staff, systematic maintenance or calibration of such equipment.

ENQUIRIES

3. Photocopies of Health Equipment Information, Management of Equipment, Number 98, January 1982 can be obtained from **Mr J Nash at the address shown below.**

4. Enquiries regarding this Circular should be addressed to **Mr A N Horn, DH, NHS Procurement Directorate, 14 Russell Square, London WC1B 5EP (Tel: 01 636 6811 Ext 3231; Fax: 01 637 8990).**

From:

NHS Procurement Directorate
14 Russell Square
London WC1B 5EP
(Tel: 01 636 6811 Ext 3328; Fax 01 637 8990)

.....

for health authority use as instructed locally.

TITLE: **BLOOD GAS MEASUREMENTS: THE NEED FOR RELIABILITY OF RESULTS PRODUCED IN EXTRA-LABORATORY AREAS**

HC(Hazard)(89)31

17 October 1989

Sent to department responsible for action: Date .....

Action completed: Signature ..... Location ..... Date .....

Comments on action taken:

Return to after completed action: Date .....