Witness Statement Ref. No. 125/3

NAME OF CHILD: Adam Strain

Name: Tommy Ryan

Title: Mr

Present position and institution: Retired

Previous position and institution:
[Since your Witness Statement of 21 July 2011]

Membership of Advisory Panels and Committees:
[Identify by date and title all of those since your Witness Statement of 21 July 2011]]

Previous Statements, Depositions and Reports:
[Identify by date and title all those since your Witness Statement of 21 July 2011]]

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

Ref:	Date:	
125/1	04.05.2011	Inquiry Witness Statement
125/2	21.07.2011	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 INQUIRY WITNESS STATEMENT DATED 21 JULY 2011

With reference to your Inquiry Witness Statement dated 21st July 2011, please provide clarification and/or further information in respect of the following:

(1) Answer to Question 3(b) at p. 3:

"I have no recollection of any concerns regarding accuracy of any parameter at that time. We started using Lithium heparin in PICU and Theatres but I can't remember when. As a hospital policy we introduced pre-heparinised dry lithium syringes and issued these to all wards and departments from the Internal store in RBHSC but again I cannot recall when this started."

(a) State what type and form of heparin was used in RBHSC theatres prior to the introduction of *"Lithium heparin"*, and in particular:-

(i) Identify the records that would show there was a change *to "Lithium heparin"* and state when and why this change occurred.
(ii) State the reasons why *"[w]e started using Lithium heparin in PICU and Theatres"*.

Sodium Heparin. I do not know of any records that would show when and why the change to Lithium heparin was made to avoid sodium heparin altering the blood sodium readings.

(b) State what type and form of heparin was used in RBHSC theatres prior to the *"introduc[tion of] pre-heparinised dry lithium syringes"*.

Lithium heparin in vials.

(i) Identify the records that would show there was a change to *"pre-heparinised dry lithium syringes"* and when and why this change occurred.

There are no records but it must have been approved as I would not have had the authority to change any patient oriented system.

(ii) (State the reasons why *"we introduced pre-heparinised dry lithium syringes"*.

It was introduced mainly because samples which sometimes came from the wards had either no heparin in them (which caused a blockage) or far too much heparin (on one occasion half a ml) which caused very inaccurate results.

(c) Please clarify whether RBHSC *"started using Lithium heparin"* in the form of *"pre-heparinised dry lithium syringes"* or whether Lithium heparin was used in some other form initially which then changed to the *"pre-heparinised dry lithium syringes"*. If so, please state the form of lithium heparin used initially.

Originally it came in Vials from the pharmacy, when this happened I cannot remember. The preheparinased syringes were first sourced in approx year 2000 and kept centrally (in the in house Medical and Surgical store) for general issue in the hospital

(d) State how did heparin affect the accuracy of the blood gas machine serum sodium measurement and what information or guidance did you provide to anaesthetists about the use of heparin and any effect it may have on the accuracy of sodium level analysis by blood gas machines.

Sodium heparin would have given a high sodium reading. I cannot remember who advised we change to the lithium heparin, it may have been the equipment company at the time or it may have been the medical staff. I am sorry I just don't remember.

(e) State whether you issued any instructions against relying upon blood gas machine serum sodium results. If so:

(i) state when you issued these instructions, to whom, in what circumstances

I would have informed senior Medical staff as soon as I found out.

(ii) describe the nature of your instructions and what happened as a result of having issued them

It would have been verbally.

(iii) identify any documents containing or referring to those instructions

There are no records.

(f) State how anaesthetists:

(i) used or might have used those serum sodium blood gas results

I am not medically competent to answer that question.

(ii) did or might have factor/ed the use of heparin and any effect it may have upon their interpretation of the blood gas machine sodium measurement.

I cannot answer this question.

(g) By the time you retired, state:

(i) the type and form of heparin that was being added to the serum sample for analysis
Preheparinised syringes

(ii) whether it differed from *"Lithium heparin"* or *"pre-heparinised dry lithium syringes"* and if so in what respects
They are the same.

(iii) state the reasons for the change in heparin use

To standardise in the hospital.

(2) Answer to Question 3(c) at p. 3:

"I have no recollection of any concerns regarding accuracy of any parameter at that time. If we had any problems with accuracy I would have dealt with it, I would have informed senior medical staff on the day that we were querying the reliability of a parameter and then contacted the service company."

(a) State whether you contacted the service company of the blood gas analyzers machines at any time in relation to:

(i) the use of heparin when added to serum samples and any effect it may have on the accuracy of the blood gas machine serum sodium measurement

I cannot remember.

(ii) the accuracy and reliability of the blood gas machines in analysing serum sodium levels.

Quality control was used daily on this equipment, records were not kept. If any parameter was out of range I would have informed the consultant on duty that day and then tried to rectify the problem (either by doing it myself of if I could not fix it call the service engineer).

(b) If so, state the nature of your contact with the service company, when you made that contact, the documents which would record the contact you made, and the outcome of your contact with that service company.

I have no recollection of any contact and would refer to the service reports.

N.B A service report dated the 2/11/95 shows that new Sodium and Potassium electrodes were changed that day. I cannot say if this was because of a fault or a routine service.

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

The DOH Hazard Notice 89/31 is not on file however two different copies of the DHSS NI equivalent 27/89/76 dated 24.10.89 are. There are also on file two different copies of another DHSS NI Hazard Notice 24/89/76 dated 13.09.89 on a similar issue regarding a batch of blood collection tubes containing incorrect quantities of lithium heparin giving rise to incorrect calcium, albumin, sodium and potassium measurements (copies enclosed).

The two copies of each of the Hazard Notices are likely to have been forwarded to me by Mr. J. Wilson and Dr. G. Black as routine distribution of such notices.

(d) If that Hazard Notice was not brought to your attention, explain the reasons why not.

(e) 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.

I would have brought this Hazard Notice to the attention of the other MTO Mr. Peter Shaw. The covering letter had been annotated that the Circular was distributed to the Chairman of the Anaesthetics Division as well as Dr. Black. This was the route that medical staff would have been advised of this Hazard Notice. (copy covering letter enclosed)

(f) State what action, if any, was taken by you as a result of that Hazard Notice and when this action was taken.

Peter Shaw and I would have then been immediately aware that when capillary samples were taken for analysis that it was necessary to ensure that the capillary tube was completely filled to give rise to reliable results.

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

(h) State whether there was a written operational protocol for the blood gas analyser machine used on 27th November 1995 at approximately 0932, 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.

I don't recall.

(i) Explain what steps were taken by RBHSC prior to 27th November 1995 to ensure that the results of the blood gas analyser machine used at 0932 in relation to Adam were comparable with those produced by a quality-controlled laboratory-based instrument.

I don't recall.

(j) 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, explain why there was not such a policy.

Quality control using a box of vials was used every day. This was purchased from the specific company for this instrument. There was no written policy, it was just done every day as part of the daily checks.

II ADDITIONAL QUERIES

(3) State the date of your retirement.

31/7/09

(4) State exactly what checks would have been carried out at the end of surgery on the Siemens Patient Monitor model 1281 to ensure that the machinery was ready for the next operation and in full working order.

All equipment in theatres was checked daily before the lists began. Should a theatre be in use first thing, then after surgery and the theatres cleaned, the daily checks on the monitor and anaesthetic machine would have been carried out and the log for the anaesthetic machine signed (unfortunately this log from that date and equipment no longer exist). The monitor (1281) when switched from off to on did an internal self check, if a fault was found the monitor would not "boot up". These monitors were put on standby between cases and only switched off at the end of the surgical list.

(5) 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.

Yes

(6) 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.

During the day we used RBHSC porters and out of hours the portering service for the RVH site.

(7) 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.

No.

(8) 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:

No.

(a) Identify the type of blood gas analyser that was 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

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

Yes it was possible. It would have been the responsibility of the anaesthetist.

(a) if a nephrologist was present in theatre at the time

I don't know.

(b) if no nephrologist was present

I don't know.

(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 for such an X-ray.

X-ray equipment was to my knowledge available at all times (I was not a radiographer)

(11) If, as the subsequent X-ray showed, the CVP line was going up the neck vessels, state what could and should have been done to address that during the course of the transplant surgery and who should have taken the responsibility to take that action.

I am sorry I am not a doctor.

(12) State the likely effect of the CVP line going up the neck vessels on the accuracy and reliability of the initial CVP reading and any relative changes to it.

I am sorry I am not a doctor.

(13) State what options were available to achieve accurate and reliable information on Adam's CVP and who should have considered and exercised those options.

The Anaesthetist would have stated if it was felt there was a problem, usually the transducer would be changed. It was very rarely but not impossible for a transducer to be faulty but I cannot remember any mention of this.

(14) 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 don't know

(15) 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 is located and how long it took to analyse the blood sample at that time.

I don't recall any other.

(16) 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 am sorry as I was a technician other than equipment I was not involved in Adams treatment.

(17) 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

(d) 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 was not aware.

(18) Describe the procedure for clinical audit at RBHSC in November 1995 and identify any relevant documents, including:

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

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

I do not know.

(19) 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.

I do not know.

(20) 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

I do not know.

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

Signed: Thomas Ryan **Dated:** 9/10/11

GA ROYAL GROUP OF HOSPITALS

Dr. Mackay
Miss Duffin
sent 28/4/
A.137

EASTERN HEALTH AND SOCIAL SERVICES BOARD

Telephone No
Belfast 321313

12/22 Linenhall Street
BELFAST
BT2 8BS

Our Ref: 111/86/2

HAZARD CIRCULAR NO 27/89/76

23 November, 1989.

Dear Sir/Madam,

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

I enclose a copy of Hazard Circular No 27/89/76.

As you will be aware, the action to be taken by you in relation to Hazard Circulars is detailed in Circular ET 1/89 issued by the Board on 17 January 1989

Yours faithfully,

for Chief Administrator

TO: All Group Administrators
Area Supplies Officer
Director of Regional Medical Physics Service
Dr McClelland, Blood Transfusion Service
Area Works Officer

NS/if

Enc.

Chairman Anaesthetics Division for
Chairman Lab Division Comm
Mr. J. J Wilson Ricu + secr
Prof Trimble of
Dr G. McClure Roth Ricu
Dr W.S. Blair Ricu
Dr. J. Johnston Ricu

LH 15

Hazard No. 27/89/76
HC (Hazard) (89) 31
(English Equivalent)

HAZARD

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
~~Works Unit~~ Estate Services Division
Stoney Road Dundonald Belfast BT16 0US
Telephone Dundonald 4535 Ext 2412 FAX 3299

26 OCT 1989

For joint action by:

CAMO of each Health & Social Services Board
CANO of each Health & Social Services Board

Please reply to The Secretary
Your reference

Our reference 19378/89

Date 24 October 1989

Dear Sir

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

1. 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.

2. General advice on the management of equipment was published in Health Equipment Information, Number 98, (NI Version), August 1986. The advice given should be followed in the management of extra-laboratory analytical equipment and systems.

3. 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.

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

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

1/INQ-AS circulated to all D.E.C's

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

7. 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.

8. 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.

9. Boards should ensure that this information is passed to all nursing homes and private hospitals in their areas.

BACKGROUND

10. 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.

11. Such clinically-misleading results are particularly likely to occur where quality control programmes are lacking and where there is no formal training of staff, nor systematic maintenance and calibration of such equipment.

ENQUIRIES

12. Photocopies of Health Equipment Information, Management of Equipment, Number 98 (NI Version) August 1986 can be obtained from General Services Branch at the above address (Ext 2412).

13. Medical enquiries concerning this Circular should be addressed to Dr R H Flett, DHSS, Medical and Allied Branch, Room 931, Dundonald House, Belfast BT4 3SF. Telephone: 650111, extension 373.

14. Nursing enquiries should be addressed to Mrs E Campbell, DHSS, Estate Services Division, Stoney Road, Dundonald, Belfast BT16 0US, extension 2304.

Yours faithfully

DR R H FLETT
Senior Medical Officer

M A HAUGHEY
Chief Nursing Officer

Circulated for information to:-
GM) of each Health & Social Services Board
CDO)
Medical Adviser)
CAO) of the Central Services Agency
Chief Supplies Officer)
Chief Admin Pharmaceutical Officers
Area Supplies Officers

HAZARD

Hazard No 24/89/76 + CAPO
HC (Hazard)(89)25
(English Equivalent)

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

Dundonald House Upper Newtownards Road Belfast BT4 3SF

Telex 74578 Telephone 0232 (Belfast) 650111 ext

Please reply to The Secretary
Your reference

Our reference

Date 13 September 1989

For Action:-

CAMOs of each Health and Social Services Board Area Supplies Officers

Dear Sir

LABORATORY SALES (UK) LTD., LITHIUM HEPARIN 5 ML BLOOD COLLECTION TUBES: INCORRECT ANTICOAGULANT LEVELS

SUMMARY

Incorrect quantities of lithium heparin anticoagulant were found to be present in 5 ml tubes supplied by Laboratory Sales (UK) Ltd. These tubes have no batch number or other means of batch identification. Advice is given on the immediate withdrawal of this product to prevent the generation of clinically misleading results.

ACTION

The following information should be brought to the attention of all who need to know or be aware of it. This will include supplies officers, pathology laboratory staff and phlebotomists.

All 5 ml Lithium Heparin Tubes supplied by Laboratory Sales (UK) Ltd (LSL) since July 1989 should be withdrawn from use and returned to the manufacturer for credit.

BACKGROUND

1. Incorrect quantities of lithium heparin have been found in LSL's 5 ml blood collection tubes; these quantities may exceed the company's specification by 160 fold. It is estimated that at least 2% of all tubes supplied are affected.

2. The anticoagulant error has resulted in a 100% increase in some calcium results and a 50% decrease in some albumin results. It may also affect sodium and potassium measurements.

3. Errors on six patients' blood tests have arisen. Fortunately repeat tests were requested and correct test results were then obtained.

ENQUIRIES

4. Technical enquiries regarding this Circular should be addressed to Dr R H Flett, DHSS, Medical and Allied Branch, Room 931, Dundonald House, Belfast, BT4 3SF (Telephone 0232/650111 Extension 373).

Yours sincerely

R. Hilary Flett

R H FLETT

Circulated for information to:-

General Manager of each Health and Social Services Board
Medical Adviser)
CAO) of the Central Services Agency
Deputy Director (HPSS Procurement)

LH 9

HAZARD

Hazard No 24/89/76 + CAMO
HC (Hazard)(89)25
(English Equivalent)

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

Dundonald House Upper Newtownards Road Belfast BT4 3SF

Telex 74578 Telephone 0232 (Belfast) 650111 ext

E.H. & S.S.B.
REF. No. 111/86/2
18 SEP 1989
Admin.

Please reply to The Secretary
Your reference

Our reference

Date 13 September 1989

For Action:-

CAMOs of each Health and Social Services Board Area Supplies Officers

To all wards + depts. 29/5/89 pat

Dear Sir

LABORATORY SALES (UK) LTD., LITHIUM HEPARIN 5 ML BLOOD COLLECTION TUBES: INCORRECT ANTICOAGULANT LEVELS

SUMMARY

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3. Errors on six patients' blood tests have arisen. Fortunately repeat tests were requested and correct test results were then obtained.

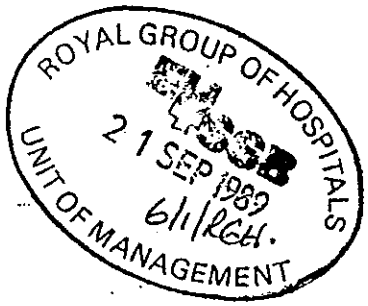
Dr. Murnaghan.
Mr. Doherty.
Mr. Rooney.
Miss Duffin.
Sent 21/9/89

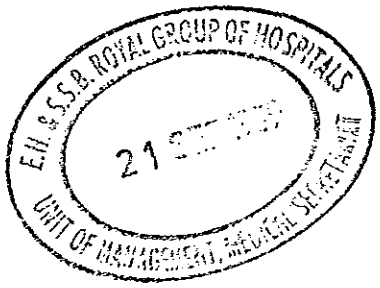
EASTERN HEALTH AND SOCIAL SERVICES BOARD

TELEPHONE NO:
BELFAST 321313

12/22 LINENHALL STREET
BELFAST
BT2 8BS

A.137





Our Ref: 111/86/2

19 September, 1989.

Dear Sir/Madam,

Hazard Circular No: 24/89/76

I enclose a copy of Hazard Circular No: 24/89/76.

As you will be aware, the action to be taken by you in relation to Hazard Circulars is detailed in Circular ET 1/89 issued by the Board on the 17 January, 1989.

Yours faithfully,

for Chief Administrator.

TO: All Group Administrators
Area Supplies Officer
Director of Regional Medical Physics Service
Dr McClelland, Blood Transfusion Service
Area Works Officer

DW/if