Witness Statement Ref. No. 110/2

NAME OF CHILD: ADAM STRAIN

Name: John James Wilson

Title: Mr.

Present position and institution:

Retired Business Manager, Baxter Healthcare Ltd. Retired since January 2010

Previous position and institution:
[As at the time of the child's death]
Chief Medical Technical Officer for Anaesthetics, Theatres & Intensive Care- Royal Group of Hospitals ("RGH").

Membership of Advisory Panels and Committees:
[Identify by date and title all of those since your Witness Statement dated 14th May 2011] None

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 14th May 2011] None

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

Ref:	Date:	
WS-110/1	14.05.2011	Witness Statement to the Inquiry
093-027-071	24.04.2006	Statement to PSNI
093-027-074a	Undated	Report on Equipment used during Untoward Incidents in the Operating Theatres, Royal Belfast Hospital Sick Children ("RBHSC").

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 QUALIFICATIONS, EXPERIENCE, TRAINING AND RESPONSIBILITIES

(1) Please provide the following information:

(a) State your qualifications as of 1995; Full C & G Certificates Radio, Television and Electronics Technicians, in Micro Electronics & Semi- Conductor Technology; Telecommunication & Electronics (Switching Principles).C &G Full Mechanics Certificate in Industrial Control & Servo Mechanisms; Digital Logic Techniques

(b) State the date you qualified as a Medical Technical Officer ("MTO"); I was in post as a Medical Physics Technician from 1970 prior to the formation of the MTO grade.

(c) Describe your career history before you were appointed Chief Medical Technical Officer for Anaesthetics, Theatres & Intensive Care ("CMTO")- RGH; I provided technical support to the Regional Intensive Care Unit from 1970. My role was ensuring all equipment was working in a satisfactory manner, providing clinical support for technical procedures (from oxygen therapy to electronic pressure monitoring and set-up of life support equipment).

(d) Describe your work commitments at the RGH from the date of your appointment to 1995; With the passage of time and not working in the Health Service since January 2000 this is difficult. It included equipment review, introduction of new clinical procedures and related equipment, assisting in research, training staff from various disciplines, providing support to the 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 cannot recall if there was a job description and I do not hold copies from that time. The functions are the same as those in 1d

(f) Describe the accountability of the CMTO - RGH at that time. Accountable to the Director of Anaesthetics, Theatres and Intensive Care Directorate

(2) Please outline in full your involvement in the case of Adam Strain, and its aftermath. I was only involved in the equipment inspection and was unaware it was in relation to Adam's death.

II. KINGS FUND ORGANISATIONAL AUDIT

(3) What knowledge do you have of the King's Fund accreditation process? None

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

(5) 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.

III. DISSEMINATION AND INSTITUTIONAL LINKS

(6) 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? This was outside my remit and I cannot answer this question.

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;

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

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

IV. INTERNAL REVIEW

(8) Did the RBHSC conduct an internal review in respect of the use of equipment before and after Adam Strain's surgery? This was outside my remit and I cannot answer this question.

V. BLOOD GAS MACHINES

(9) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the use of blood gas machines? This was outside my remit and I cannot answer this question.

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;

(10) In 1995 what did the guidance, policy or procedures associated with the use of blood gas machine say about the following matters: This was outside my remit and I cannot answer this question.

(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.

(11) In 1995 was there established within the RBHSC a committee, group or team to oversee the safe use of blood gas machines? This was outside my remit and I cannot answer this question.

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?

(12) 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: The passage of time and not working within the health service for over 12 years leaves me with no clear understanding of how these directives were implemented in the Royal Hospitals

(a) Disseminate this guidance and to whom;

(b) Monitor and record compliance with the same;

(c) Enforce compliance.

VI. LABORATORY TESTING

(13) In 1995 did the RBHSC have guidance, policy or procedures in place which governed the conduct of biochemical laboratory testing during major surgery? This was outside my remit and I cannot answer this question.

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;

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

(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?

VII. THEATRE EQUIPMENT

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

(a) The purchase; This was outside my remit and I cannot answer this question.

(b) Maintenance; and This was outside my remit and I cannot answer this question.

(c) Replacement of theatre equipment, and if so, This was outside my remit and I cannot answer this question.

(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;

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

(15) 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? This was outside my remit and I cannot answer this question.

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;

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

(16) 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; This was outside my remit and I cannot answer this question.

(b) In Adam's case, what steps were taken in relation to the guidance, policy or procedures; This was outside my remit and I cannot answer this question.

(c) Who took those steps; This was outside my remit and I cannot answer this question.

(d) What conclusions were reached? This was outside my remit and I cannot answer this question.

(17) **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?
This was outside my remit and I cannot answer this question.
If so,

(a) Explain fully how it was applied;

(b) Who applied it?

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

(18) 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? This was outside my remit and I cannot answer this question.

VIII. QUERIES ARISING OUT OF YOUR WITNESS STATEMENT (WS-110/1)

(19) *"When Dr. G.M. Murnaghan asked me to carry out the survey of the equipment I was informed of a serious matter that required the equipment in the operating theatre to be checked and a report given to him. I was to select a small team, arrange a suitable time, but was not to discuss the matter with anyone other than the team members, especially staff from RBHSC. I could arrange the time and request documentation relating to the equipment, but that was all".*

(a) Identify members of your team? Mr Brian McLaughlin, myself

(b) Why were you not permitted to discuss this matter? And especially not with staff from the RBHSC? We were made aware that it was a very sensitive matter and to only discuss it between Mr McLaughlin and myself as to how we would carry out the inspections.

(c) Did you request and receive the documentation relating to the equipment prior to your examination? No

(d) What documentation did you receive? None

(e) Why did you not appreciate that the Siemens Patient Monitor in the theatre was not the one being used at the time of Adam Strain's operation/ the untoward incident? I was not aware of the actually or type of incident. The request was to check the equipment and identify any issues discovered. I cannot be 100% certain due to the passage of time, but on examining the monitor it had only 1 pressure monitoring channel and I had expected a 2 pressure channels. It was at this point I was told the normal monitor had been sent for repair some days before. It was therefore impossible to verify its condition prior to any incident.

IX. QUERIES ARISING OUT OF YOUR *"REPORT ON EQUIPMENT USED DURING UNTOWARD INCIDENTS IN THE OPERATING THEATRES, RBHSC"* (093-027-074a)

(20) In respect of you examination of the equipment on 2nd December 1995 please state:

(a) Who asked you to make this examination? Dr. G.M. Murnaghan

(b) What were you asked to do? Check that all theatre equipment was working correctly and report any defects.

(c) Was there a request in writing, if so please provide? No

(d) In terms of your examination of *"Equipment used during Untoward Incidents"*- please state how you were expected to identify the equipment referred to; by make or if any serious defect was found to remove it from service.

(e) Were you supplied with equipment identification or serial numbers or dates of user? No

(f) Were you aware that the Coroner had asked for an independent examination of the equipment? No

(g) Were you accompanied by Dr. Fiona Gibson and, if so, for what purpose? Dr Gibson had arranged a meeting with medical staff, who, I do not know.

(h) Why was Dr. Fiona Gibson not noted as being present when you wrote the Report? She was not in theatre during the equipment inspection. She was at a separate meeting with medical staff. I do not believe she was expected to be present during the inspection, but due to the passage of time I cannot be certain of this.

(i) What steps did you take to confirm that the equipment you examined was implicated in the untoward incidents? The meeting with Dr. G.M. Murnaghan gave an indication that an incident had occurred, but at no time was I given any details of any event or events

(j) Were you investigating more than one incident? I was asked to check equipment and was not aware of the incident or if there was more than one incident. My role was to verify that the equipment was functioning correctly.

(21) In respect of the Report itself:

(a) Why is it undated? Please confirm date of the Report and the date upon which it was sent to Dr. Murnaghan? I was not aware it was undated, and with the passage of time I am unable to satisfactorily answer this question.

(b) Why did Mr. B. McLaughlin not also sign the Report? As 21 a I am unable to clarify this point due to the passage of time.

(c) Did you make any verbal or other Report to any other person, and if so please particularize? No

(d) Please state when and how you first realized that the Siemens Patient Monitor in the theatre was not the one under investigation? During the equipment checks the MTO on duty informed me that this was not the usual monitor. Their own monitor was sent for repair some days earlier. Due to the passage of time I am not sure which MTO was on duty.

(e) What records were kept in 1995 as to the condition, movement and location of equipment? I have not worked in the Health service for over 12 years and have no clear

memory of the procedures in place in the RBHSC. I did not work in RBHSC.

(f) Was a daily MTO log kept in respect of the Siemens Patient Monitor? As 21e

(g) Did the daily MTO log reveal the identity of the machine to be examined and its location? With the passage of time I cannot accurately answer this question

(h) Did you inspect the Siemens Patient Monitor that was in use during Adam's surgery on 27th November 1995? If the monitor was not in theatre on the day I would not have examined it. I was also not aware that the incident with Adam was the reason for the equipment inspection.

(i) Did you inspect the Service Report for the Siemens Patient Monitor that was in use during Adam's surgery on 27th November 1995? I have no recollection of doing so, due to the passage of time.

(j) Did you make any subsequent or additional report in respect of the Siemens Patient Monitor that was in use during Adam's surgery on 27th November 1995? I have no recollection of doing so, due to the passage of time.

(22) *"A copy of service report for the Siemens monitor is expected this week but verbal indications are that nothing untoward was discovered during its overhaul"*. Please state:

(a) Did you receive the *"service report"*? What were its findings? Please provide copy of the same. ? I have not worked in the Health service for over 12 years and with the passage of time cannot accurately answer this question.

(b) Who gave the *"verbal indications"* referred to? As 22a

(c) What was discovered during *"its overhaul"*? As 22a, but I believe it related to a problem on the display board that made for a dim display of both traces and numbers.

(23) In relation to the deficiencies identified in the Pin Index System in Lamtec anaesthetic machine, please state:

(a) Did you inspect the service records? Service records were examined at the time.

(b) Was any omission found, either on the part of the service company or the hospital? Again with the passage of time it is difficult to accurately answer this question, but I believe it covered all routine items covered by the manufacturer's service recommendations.

(c) Was any subsequent scrutiny undertaken to inspect all Pin Index equipment? If so, when, by whom and with what result? Again with the passage of time it is difficult to accurately answer this question.

(d) What steps were taken to ensure that such deficiencies could not reoccur? I did not work

in RBHSC and only prepared a report of the findings on the day. Any changes to procedures or policies were outside my remit.

(24) *"The anaesthetist using the machine is also expected to sign the log before commencing the list but this does not happen on most occasions. A reason for this omission should be requested"*. Please state:

(a) What guidelines, procedures or protocols were in place in 1995 governing the signing of the log book? The log books were a RBHSC in house design and policy decision and during the inspection it was noticed that the MTO signed the log, but the anaesthetists only occasionally completed their part. I was not made aware of any written procedures or protocols relating to the log books.

(b) What system existed to monitor compliance, and what procedures were in place to enforce compliance? Again with the passage of time it is difficult to accurately answer this question.

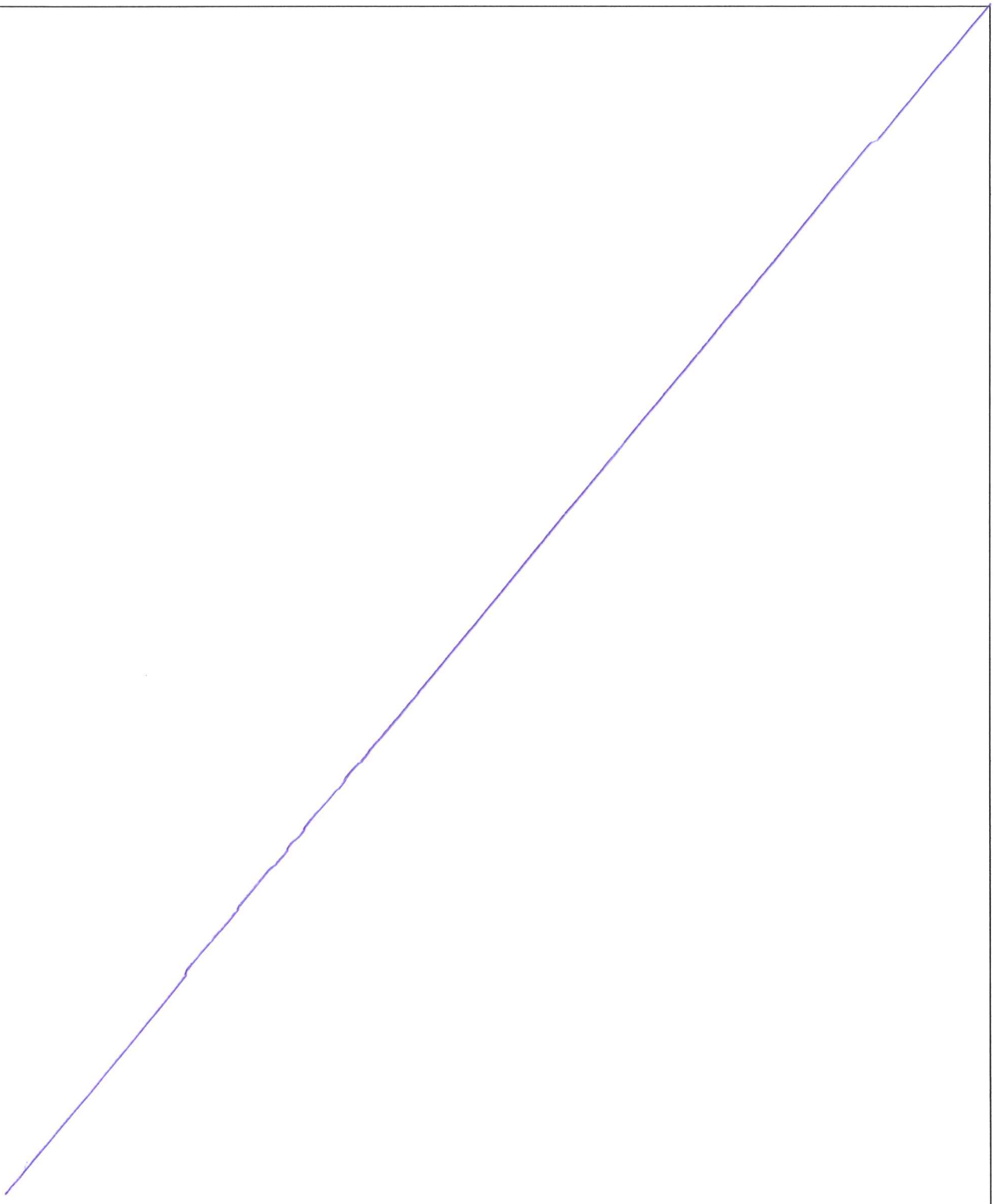
(c) Who was responsible for ensuring compliance? Again with the passage of time it is difficult to accurately answer this question, but I believe it rested with the anaesthetists.

(25) *"Finally it must be emphasized that the protocols and monitoring procedures set up within the RBHSC's theatres for more than two years, would have discovered if a reversal of cylinders had occurred"*.

(a) Please identify these *"protocols and monitoring procedures"* and provide copies of the same; ? The protocols and monitoring procedures refer to the logbook. The anaesthetic machine was fitting with an oxygen monitor that would alarm if a swap had occurred due to low oxygen concentration. I do not have copies of same.

X. GENERAL

(26) 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:** 24th April 2012