ADAM STRAIN

Report by Advisors (Part 2 – Governance)

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16th June 2012

This short report, written by the Advisors to the Inquiry, describes the main management and governance issues that impacted on Adam's care during his hospital admission in November 1995 that they think require further examination by the Inquiry during the forthcoming Oral Hearings

In addition to all the relevant clinical, nursing and administrative records, the following statements and reports were used in the generation of this document:

1. Protocol and briefs for experts
2. Witness Statements and responses to questions both in writing and at the oral hearings:
    a. Dr Taylor, consultant paediatric anaesthetist.
    b. Dr Montague, senior registrar in anaesthesia.
    c. Dr Savage, consultant paediatric nephrologist.
    d. Mr Keane, consultant urologist.
    e. Mr Brown, consultant paediatric surgeon.
    f. Dr O'Connor, consultant paediatric nephrologist.
3. Evidence provided by other witnesses at oral hearings
4. Witness statements to PSNI
5. PSNI interviews
6. Inquiry Witness statements
7. Expert reports from Stephen Ramsden
8. Expert reports from Aidan Mullen
9. Welfare of Children and Young People in Hospital – Department of Health 1991 (HMSO IBSN 0 11 321358 1)
10. Children First – A Study of Hospital Services" – Audit Commission 1993 HMSO (IBSN 011 886096 8)
11. Patient's Charter – Department of Health (1992) HMSO ISBN 0 335 157327
12. Setting Standards for Children undergoing Surgery" - Christine Hogg 1993. Action for Sick Children. ISBN 0904076
13. HSS(GHS)2/95 Patient Consent to Examination or Treatment – HPSS 6 Oct. 1995 **(Ref:306-058)**
14. Standards for Care for Paediatric Intensive Care' (1st Edition) (undated) RCN Quality Patient Care, the Dynamic Standard Setting System.
15. The Standards for Records and Record Keeping', (April 1993) United Kingdom Central Council for Nursing, Midwifery & Health Visiting **(Ref:202-002-052)**
16. National Confidential Enquiry into Perioperative Deaths 1989 **(Ref:210-003-156)** http://www.ncepod.org.uk/pdf/1989/Full%20Report%201989.pdf
17. Tertiary Services for Children & Young People: a review of the present position and future needs. British Paediatric Association September 1995 **(Ref:306-064)**
18. British Association for Paediatric Nephrology. "The provision of services in the UK for children and adolescents with renal disease". Report of a working party - BAPN, March 1995**(Ref:306-065)**
19. The role of the Medical Director, Turner S and Smidt L, British Journal of Health Care Management 1995, Vol 1, No 3
20. Accountable officers Langlands, Alan - Department of Health. NHS Executive

We consider that the main issues in relation to governance that need to be considered by the Inquiry are as follows. We have not covered those areas which were contained in the advisors report on Adam's clinical treatment[1], except where we believe there are additional issues which are relevant to the Inquiry's interest.

[1] Advisor's report on Adam Strain Part 1 – Clinical (24 March 2012)

1. Paediatric transplant surgery in Belfast in 1995

The development of paediatric transplant surgery in Belfast has been described in the transcript of Dr Savage's oral evidence to the Inquiry (17/04/2012 pages 11-21).

In addition Dr Ian Carson states that "*medical policy and strategy*" was within his job description but the viability of the transplant unit "*would be more appropriately addressed to the Paediatric Directorate, EHSSB or DHSSPS*" (WS-077/2 Para 53). The CEO and Dr Mulholland (clinical director of paediatrics at the time) were not aware of the viability of the renal unit being an issue. (WS-243/1 p14)

Matters for further consideration:

- ***Was Trust Management (at both Clinical Directorate and Corporate levels) aware of the development of paediatric transplant surgery at RBHSC? If so what action was taken to ensure that this would be of a satisfactory standard, and in particular***

  - that there was adequate infrastructure and support services in the hospital?

  - that the clinical staff involved were sufficiently trained and skilled in renal transplantation?

- ***Were the Eastern Health and Social Services Board and the Department of Health in Northern Ireland aware of the development of paediatric transplant surgery at RBHSC? If so what action was taken to ensure that this would be of a satisfactory standard? Was there any system of accreditation of such services and what monitoring was undertaken to ensure good quality outcomes? Was there an established link to a larger unit in England for advice and support where required.***

- ***Did the Trust, Health Board or the Department of Health consider the advantages or disadvantages of whether a paediatric renal service should be developed locally or whether referring children for paediatric renal transplants elsewhere might be an option? If not why not?***

2. Consent process.

Issues around consent were examined in detail in the advisors report on clinical treatment of Adam. This is summarised by the question posed below in that report, together with narrative explaining the background.

- ***Was the consent process for Adam adequate, comprehensive and at least equal to the standard expected at the time?***

There are different expert opinions as to who should have gained consent for paediatric renal transplantation in the mid 1990's. Guidance on consent is much clearer today.

Consent to Adam's surgery was obtained by Dr Savage, who had known Adam and his mother, Ms Slavin for several years. No explanation of surgical or anaesthetic procedures, risks and alternatives (including the possibility of a transfer to another hospital in the UK) is evidenced. Mr Keane, consultant transplant surgeon did not visit Adam and his mother before the operation. In addition, Ms Slavin had previously expressed a view on which surgeon she did not wish to be involved but this view was not communicated, forgotten or disregarded.

Dr Savage had previously spoken to Ms Slavin about transplantation and knew her to be concerned about the risks involved; apparently he spoke to her again on the evening of the 26th November. (**WS 002/3: 22a**) Dr Savage stated that: *"I would have expected the transplant surgeon and consultant anaesthetist to also talk with Ms Slavin." (**WS 002/3: 21a and 4h**)* In her PSNI statement, Ms Slavin stated that she did not see a consultant on the morning prior to the transplant surgery, (**093-003-005**), though Dr Taylor told the PSNI that he spoke to Ms Slavin at 0545. (**093-035-110b**). Apparently, no one from the surgical team discussed the surgery with Ms Slavin or had been available to answer her questions prior to the operation.

Messrs Rigg and Forsythe state: *"It is the role of the transplant surgeon to gain consent from a paediatric patient's parents …" (**203-004-065**)* Similarly, Dr Haynes opined in his reports that it would be normal practice for the anaesthetist to visit a child and parents prior to surgery to discuss proposed perioperative care. (**204-004-162**) In contrast, Dr Coulthard states that in 1995 it *"was relatively common for the final written consent for a child's kidney transplant to be undertaken by the consultant paediatric nephrologist." (**200-007-117**)*

Matters for further consideration:

- ***What was the normal practice in the RHBSC at the time for providing explanations of major elective surgical procedures, particularly transplants, to children and parents For example, Dr Mulholland states that, in his specialty of paediatric cardiology "[consent] was always taken by a consultant and fully explained with the aid of standard diagrams and leaflets which we designed. (WS-243/1 p7)***

- ***Whether it was reasonable that Mr Keane (and, possibly, Dr Taylor) did not speak to Ms Slavin prior to Adam's surgery.***

- ***Whether the Trust implemented the relevant consent guidance effectively including making all relevant staff aware of the guidance (including those contracted from other organisations) and monitoring practice.***

- ***To what extent should Adam's parents have been made aware of all risks associated with Adam's treatment and which clinical staff would be involved in his surgery? What evidence is there to suggest whether this would have changed the choice made by her to give consent?***

2. Communication Issues

The Advisors Clinical report[2] (Para 8, page 17) raises questions as the adequacy of communication between clinical staff and Adam's parents following Adam's surgery and the adequacy of record keeping (12, Page 19).

The advisors would also raise the issue of communication with Adam's family in the following areas;

2.1 Information in relation to the development of paediatric transplant surgery in Northern Ireland at that time.

This issue is highlighted in paragraph 1 above.

Matters for further consideration:

- ***Did the Trust or the clinical staff responsible for Adam's care, discuss referring Adam to another paediatric renal transplant centre? If not why not?***

2.2 Information given to Adam's family during and following surgery

This background is covered in the Advisor's Clinical report (Para 10, page 19).

There is a reference to Ms Slavin being kept informed by Dr O'Connor, Consultant Paediatric Nephrologist (093-003-004), during the procedure itself. In her statement (093-003-004) she outlines some information given to her whilst the surgery was underway, at first *"that things were going well",* and later *"things were taking longer than expected".* Following surgery she was told *"he (Adam) was being slow to waken".*

Ms Slavin then states

"I was then taken away to have a cup of tea and settle myself, but no one gave any indication at this point that there was anything wrong. I returned to ICU, but was not allowed in. I was then informed that there was something seriously wrong, but they could not tell me what"

In Dr Savage's statement (093-006-019), he says that *"As soon as this situation was clear I sat down with Adam's mother and the family and told them we were in a grave situation."*
Dr Savage also states that *"In the succeeding months I kept in contact with Debra strain and her parents as they struggled to cope with their tragic loss.*

Mrs Slavin states "*I spoke to the Coroner, Mr Leckey in January 1996 and he sent me Dr Armour's Report. This was the first time I heard of the condition "Dilutional Hyponatraemia" and that Adam's sodium level had dropped during surgery"*[3]

Matters for further consideration:

[2] Advisor's report on Adam Strain Part 1 – Clinical (24 March 2012)
[3] Witness statement 001, page 5, Mrs Debra Strain undated

- ***Whether Trust management provided any general guidance to staff in respect of communication with parents/relatives of children undergoing surgery.***

- ***Whether Trust management provided guidance to clinical staff in respect of communication with parents/relatives when aspects of care have not gone to plan and have resulted in harm to a patient.***

- ***Whether nursing staff on the ward, in theatres and in ITU had any written or informal policy or guidance on communication with parents during surgery or following the sudden or unexpected death of a child.***

2.3 Information given to Adam's family during and after the clinical negligence claim

A claim for possible clinical negligence was initiated by Francis Hanna and Company, on 25 April 1996, which was settled without court proceedings on 29 April 1997 (060-013-024) on the recommendation from the Trust's solicitors Brangam Bagnall & Co.

In her statement to the Inquiry,[4] Mrs Strain stated that her pursuance of a legal claim against the Trust was an attempt to *"establish the truth of what happened"*, *..."to get answers and make the hospital and doctors accountable."*
However the subsequent settlement did not in her opinion do so and failed to ensure that important lessons were learned.

On 9 May, Dr George Murnaghan (Director of Medical Administration/Director of Risk and Litigation Management) wrote to the senior consultants involved in Adam's care (Webb, Brown, Keane, Taylor and Savage 060-010-015 to 019)

"I am sure you will be pleased to be informed that this claim has been successfully concluded... subject to a confidentiality clause binding on both parties to the action. From a liability position the case could not be defended particularly in the light of information provided by one of the independent experts retained by HM Coroner at the Inquest. Additionally, it would have been unwise for the Trust to engage in litigation in a public forum, and given the tragic circumstances of death. It would not have been helpful for an opportunity to be provided to lawyers to explore any differences of opinion which might exist between professional witnesses who would have been called to give evidence.
I am grateful for your generous assistance in arriving at this successful conclusion"

There is no evidence of any communication between the Belfast Trust and the Strain family during the pursuance of the legal claim.

There is no evidence of any actions being taken as a result of the outcome of these legal proceedings (see para 5.2 below)

[4] Witness statement 001, page 6, Mrs Debra Strain undated

Matter for further consideration:

- ***Whether the lack of explanation of the circumstances of Adam's death by the Trust contributed to the pursuance of legal action by Adam's family?***

- ***Whether the Trust recognised that there was a difference of opinion between clinical staff as to the cause of Adam's death and what action was taken to explore this, and if not why not?***

- ***Whether the conclusion of the clinical negligence claim and its confidentiality clause stifle any learning opportunities for the Trust and the clinical staff.***

3. Investigation and learning following Adam's death

Dr Gaston, Clinical Director, had been involved as an auditor/surveyor in both the King's Fund Organisational Audit (KFOA) and Health Quality Service Survey processes between 1992 and 2008. He was also part of the trust steering committee for KFOA audit (WS 013/2 P7). In his statement (093-023-064) he states that there were "a number of meetings to discuss the management of the case", but there appear to be no written notes. He states that Adam's case was "very unique" at that "learning from this case was primarily in paediatrics", although in his supplementary statement (WS-013/2), he states that "it was certainly was my opinion that lessons could be learned". Dr Gaston states that he wrote a draft document on a policy for managing hyponatraemia in children in consultation with anaesthetic paediatric anaesthetists. It is unclear if and when this became a substantive policy and to whom it was circulated. He also highlighted the importance of detailed documentation of fluid management in patient's notes at an internal meeting of the anaesthetic and intensive care staff. Dr Gaston states that Dr Taylor, paediatric anaesthetist, came to speak to him about the case and "I assured him of my support and understanding of what had been a very complex and challenging anaesthetic". There are no further records of a review of the actions of clinical staff which were taken following Adam's death although Dr Gaston would have expected to receive a written report regarding Adam's death (WS 013/2 P17).

Dr George Murnaghan, Director of Medical Administration, recollects that he had the following responsibilities included in his job description (WS-015/2)

- Conduct of investigative and disciplinary processes for medical staff
- Development and implementation of an organisational wide risk management programme including the changes identified
- Co-ordination of medical audit
- Accountable to the Trust Board for the administration of complaints, legal services...

Dr Murnaghan, at the Coroner's request arranged for an independent examination of the anaesthetic equipment involved. In his statement (093-025-068b), Dr Murnaghan, states that "no steps were taken apart from the direct involvement of the clinicians in discussion with pathologists and the anaesthetic staff in attempting to clarify the cause of death and thereby assist the Coroner in his proper duties where possible..." He stated that no records or minutes of meetings were taken in the discussions between clinicians in attempting to clarify the cause of death. (WS-

015/2). His recollection was that a seminar which was to be convened to discuss "other issues identified" at the Inquest, never took place.

Dr Murnaghan assisted in publishing a draft media statement addressing the complication of hyponatraemia in patients undergoing renal transplantation. In his statement Dr Murnaghan makes it clear that he accepts the view of both anaesthetists and paediatric nephrologists that this issue was only relevant to the Royal and "It did not need to be shared elsewhere within the Trust or elsewhere outside the Trust".

Dr Carson, Medical Director, could not recall receiving a report of Adam's death and was unable to recall the details of a discussion he had had with Dr George Murnaghan, concerning the outcome of the Coroner's Inquest. He stated *"Unexpected or unexplained deaths during or following anaesthesia and surgery would be reported externally to the Coroner, and internally to Dr G. Murnaghan, Director of Medical Administration. Any issues specifically for anaesthetic staff would be a matter initially for the Anaesthetics Directorate"*.
In response to the Inquiry's question whether the RBHSC took any steps to have an internal investigation to establish whether lessons could be learned, Dr Carson responded that *"this was outside my knowledge and this would be more appropriately addressed with the Paediatric Directorate RBHSC"*

Mr William McKee, Chief Executive, stated that the Director of Medical Administration *"ensured the internal dissemination of lessons learned from inquests and appropriate action was identified to address any vulnerabilities identified"*, but he could not recall any specific vulnerabilities being reported to him concerning Adam Strain. He further stated that *"Action plans would routinely* been developed by the clinical staff at directorate level..." There is no evidence that the death of Adam Strain was discussed at Trust Board level in the year December 1995 to December 1996.

As Acting Clinical Director for Paediatrics, Dr Mulholland would have been one of the key people responsible for providing information disseminated from the CEO's office to the staff within the children's hospital. He states: "I do not know more than is contained in Dr Murnaghan's and Dr Gaston's statements." (WS-243/1 p13)

Aidan Mullen has stated that this system of devolved management to the clinical teams was relatively new and may not have been well developed. However, there is evidence that the children's directorate undertook medical audit including mortality reviews, but it is not clear that Adam's case was discussed.

Nurses who provided Adam's care and treatment were not involved in discussions or investigations into the equipment following Adam's death. There is no evidence that senior nursing staff were informed about the death of Adam or that they were involved in a review of systems and processes within the ward or theatre following Adam's death. In addition, Catherine Murphy, who provided most of Adam's care on the ward, Eleanor Boyce (nee Donaghy) and Gillian Popplestone reported that they were not aware of an investigation and were not asked for a statement at the time of Adam's death.

Matter for further consideration:

- **Whether the Trust conformed to any extant guidance on the reporting and investigation of an unexpected event such as the death of Adam?**

- **Whether it was reasonable at the time of Adam's death, and following the Inquest, for the Trust to have held an investigation into the causes of his death, and who should have been responsible for such an investigation?**

- **Whether the responsibilities for the investigation of a serious untoward incident in the Trust were clearly identified, and whether the reporting system through the organisation was satisfactory?**

- **Whether staff involved in the care of Adam were appropriately interviewed and counselled following Adam's death, and whether there were any issues of professional competence which should have been addressed?**

- **Whether the lessons learned from Adam's death and in particular, the Draft Policy on Hyponatraemia (060-014-025) was reasonable and adequate? If not, whether there should have been other lessons from Adam's case and whether these should have been more widely distributed?**

- **What was the role of the Director of Nursing in investigating serious incidents in 1995? How did she ensure that learning from incidents contributed to developing nursing practice? Was there any evidence of learning from Adam's death – how did nursing practice change as a result?**

- **Were the trust systems for self-regulation and governance clear to staff managing incidents and were there structures in place to manage quality and safety?**

4. The implementation of external guidance or advice.

At the time of Adam's death there was extant policy and guidance surrounding the care and treatment of children in hospital which could have been relevant to his treatment and care?

Examples of this guidance or advice is below

- Welfare of Children and Young People in Hospital – Department of Health 1991 (HMSO IBSN 0 11 321358 1)
- Children First – A Study of Hospital Services" – Audit Commission 1993 HMSO (IBSN 011 886096 8)
- Patient's Charter – Department of Health (1992) HMSO ISBN 0 335 157327
- Setting Standards for Children undergoing Surgery" - Christine Hogg 1993. Action for Sick Children. ISBN 0904076
- HSS(GHS)2/95 Patient Consent to Examination or Treatment – HPSS 6 Oct. 1995 **(Ref: 306-058)**
- Standards for Care for Paediatric Intensive Care' (1st Edition) (undated) RCN Quality Patient Care, the Dynamic Standard Setting System.
- The Standards for Records and Record Keeping', (April 1993) United Kingdom Central Council for Nursing, Midwifery & Health Visiting **(Ref:202-002-052)**
- National Confidential Enquiry into Perioperative Deaths 1989 **(Ref: 210-003-156)**http://www.ncepod.org.uk/pdf/1989/Full%20Report%201989.pdf

- Tertiary Services for Children & Young People: a review of the present position and future needs. British Paediatric Association September 1995 **(Ref: 306-064)**
- British Association for Paediatric Nephrology. "The provision of services in the UK for children and adolescents with renal disease". Report of a working party - BAPN, March 1995 **(Ref: 306-065)**
- The role of the Medical Director, Turner S and Smidt L, British Journal of Health Care Management 1995, Vol 1, No 3
- Accountable officers Langlands, Alan - Department of Health. NHS Executive

Mr William McKee, Chief Executive in his witness statement WS-061/2 *stated "in general, external guidance was received by staff in the Chief Executive's office and then disseminated to the relevant Clinical Director(s) and their senior management teams for action. On occasion an expert committee may have been required to consider guidance, for example the Health and Safety Committee. Clinical Directorates and expert committees would then be required to report progress back through accountability arrangements to Trust Board (or a subcommittee of Trust Board)"*

The Trust management arrangements in 1995 were also described by Mr McKee. *"The Trust's management structure at the time was based on a clinical directorate structure and each clinical directorate which included paediatrics and anaesthetics, theatres and intensive care had a clinical director that was accountable to the Chief Executive. The clinical director was typically a senior medical consultant from within the organisation who had demonstrated an interest in management and leadership skills. They were supported by a business manage and a senior nurse."*

In addition the Trust had commenced implementation of the King's Fund Organisational Accreditation (KFOA) scheme. Dr Gaston, Clinical Director, had been involved as an auditor in the KFOA since 1992. He was also part of the trust steering committee for KFOA audit (WS 013/2 P7). The KFOA standards incorporated current guidance from a number of bodies, which were updated as new guidance was introduced. Therefore, the trust was required to demonstrate how it achieved these standards. The trust was working towards accreditation and would have been reviewing processes including the management if incidents and records.

Dr Mulholland is unable to remember what steps the Trust took to disseminate external guidance. (WS-243/1p9)

Professional guidance from the United Kingdom Central Council for Nursing and Midwifery (and now the Nursing and Midwifery Council) was sent directly to every registered nurse. There was an expectation that registered nurses would read and work within this guidance. However, Catherine Murphy stated that she was not aware of this guidance (hearing transcript 27-04-2012).

Matter for further consideration:

- ***Whether the arrangements in the Trust were sufficient to ensure that guidance and advice was considered and implemented appropriately? Whether the Trust had arrangements to monitor and review the implementation of such advice?***

- ***Whether there were arrangements for monitoring adherence to professional guidance governing the practice of registered nurses and whether adherence to this professional guidance was included within job descriptions or contracts of employment.***

- ***Whether the management arrangements in the Trust were sufficient to ensure that responsibilities were clear and that accountability could be identified?***

- ***Whether the accountability and reporting arrangements contributed or not to learning from Adam's death being internal only?***

- **What role did the Director of Nursing take in the implementation of national guidance relating to children's services?**

5. The Role of the nurse within the children's hospital/trust.

The work of nursing staff in the Children's Hospital at the time of Adam's transplant would appear to be largely directed by the medical team. Catherine Murphy gave evidence that she does not remember the existence of the renal protocol (Hearing transcript 27-04-2012). In her witness statement (WS 005) she stated that frequency of measuring vital signs and the need to measure urine output was undertaken on instruction from Dr Savage or another doctor. There was a lack of clarity regarding the responsibility for monitoring and recording of Adam's dialysis.

Matters for further consideration:

- **How did the Director of Nursing monitor nursing practice on the wards across the trust including the children's hospital?**
- **What was the structure of nursing the Trust/hospital in 1995?**
- **What role did the ward and night sisters have in implementing changes in practice and directing nursing practice?**
- **How autonomous were nurses in deciding the type and frequency of observations and care? Was this largely led by the medical staff or nurses or both?**
- **What was the expected practice/local guidance for monitoring clinical care such as dialysis and fluid balance on the ward and who determined this? Has this changed since Adam's death?**

6. The experience and composition of the clinical team involved in Adam's care

In his report, Aidan Mullen has highlighted a number of issues relating to the clinical team responsible for Adam's care. The two main issues are the inexperience of the team in renal transplantation in children and the lack of time that this team had spent working together prior to Adam's surgery. Additionally, only Dr Taylor and Mr Brown were reported to be present in theatre throughout the entire surgical procedure, as surgery was undertaken at a time when staff were changing shifts.

Matters for further consideration

- ***Is there evidence that the relative inexperience and lack of time spent working together impacted on the functioning of the team?***

7. Issues explored but no longer considered relevant to Adam's death

There have been a large number of issues explored in relation to Adam's death in relation to management and governance of his case. There is one area which has been explored thoroughly as potentially related to the cause of death and this is the equipment used in theatre. Whilst there are governance issues regarding how this equipment was managed and investigated, it is not specifically relevant to the cause of Adam's death. Therefore, we do not consider there are any further issues for consideration in this area.

8. Conclusion

Whilst the advisors recognise that there may be additional issues which arise during the governance hearings in relation to Adam's case, these are the issues which we consider of most importance.