MO/176/05,

From: Siobhán McKelvey
Secondary Care Directorate

Date: 30 June 2005

1. Andrew Browne – *agreed/AB/30.6.05*
2. Secretary – agreed 30.6.05
3. Shaun Woodward

INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS: BRIEFING FOR PHONE CONVERSATIONS AND MEETINGS WITH SLAVIN AND FERGUSON FAMILIES

SUMMARY

Issue:	**You have agreed to meet with the Slavin and Ferguson families**
Timing	**Urgent.**
FOI Implications:	**This submission is fully disclosable.**
Presentational Issues:	**It is likely that the families will be in contact with the media regardless of the outcome of your meeting**
Recommendation:	**That the Minister notes the attached briefing and lines to take.**

1. BACKGROUND

1.1 Following the Minister's speech on Wednesday, the Slavin and Ferguson families have written to you with a number of queries relating to the Inquiry

into the deaths of their children. You have subsequently spoken to them by telephone.

1.2 Briefing on the background to the Inquiry has already been provided in previous submissions. This submission covers:

- The events relating to Adam Strain's death
- The Strain/Slavin family
- The events relating to Raychel Ferguson's death
- The Ferguson family
- Issues raised in the families' letter
- Minister's meeting with the Crawford family.
- Conor Mitchell

2. EVENTS RELATING TO ADAM STRAIN'S DEATH

2.1 On 28 November 1995, Adam Strain died following renal transplant surgery. Adam was a 4-year-old with a medical history of polyuric renal failure which had required numerous hospital admissions and operations. He underwent a renal transplant on 27 November 1995, at the end of which he was noted to have suffered a major cerebral event. Following brain stem tests he was pronounced dead on 28 November 1995.

2.2 Adam's death was reported to the Coroner and a Coroner's post-mortem was requested. The cause of death was determined as:

(a) Cerebral Oedema
due to
(b) Dilutional Hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy).

2.3 An Inquest was held on 18 and 21 June 1996.

2.4 Further detail on this case is attached at **ANNEX A.**

3. THE STRAIN/SLAVIN FAMILY

3.1 At the time of Adam's birth his mother Debra Slavin (nee Strain) was single and she and Adam lived with her parents. Adam's father was not involved in his upbringing and his mother is reported to have shown great dedication and commitment in her care of a child with numerous medical problems.

3.2 Following Adam's death his mother would not take any form of support or bereavement counselling. Her parents were extremely concerned about her wellbeing. Several of the nurses on the ward where Adam was treated kept in contact with her and did what they could to provide support. This informal contact was maintained until the point at which she became engaged.

3.3 Adam's mother is now married and, due to the confidentiality clause that she agreed to as part of her legal settlement, it is her husband Jay Slavin who is the spokesperson for Adam.

4. EVENTS RELATING TO RACHEL FERGUSON'S DEATH

4.1 On 10 June 2001, Raychel Ferguson died. Raychel was a 9-year-old girl, admitted to Altnagelvin Hospital on 7 June 2001 with appendicitis. She had an appendicectomy on the same day. On 8 June she vomited a number of times and at 3.00am on 9 June she developed seizures. She was transferred to the RBHSC but was pronounced dead at 12.09pm on 10 June.

4.2 A Coroner's post-mortem was conducted on 11 June 2001 which concluded that she had cerebral oedema and aspiration pneumonia. Her death was thought to be caused by: 1. Infusion of hypotonic fluids, 2. Profuse vomiting, and 3. Antidiuretic hormonal (ADH) secretion.

4.3 A Coroner's inquest was subsequently held and the verdict on 5 February 2003 concluded that Raychel's cause of death had been:

(a) Cerebral Oedema.

(b) Hyponatraemia.

4.4 Further detail on this case is attached at **ANNEX B.**

5. THE FERGUSON FAMILY

5.1 Raychel's parents are Ray and Marie Ferguson. Raychel was one of four children. She is survived by 2 elder brothers and a younger brother.

6. ISSUES RAISED IN THE FAMILIES' LETTER

6.1 "Altnagelvin Trust is still holding on to crucial documents" –

Under Schedule 8 of the Health and Social Services (NI) Order 1972 the Inquiry may "require any person...to furnish....such information relating to any matter in question at the inquiry as the person appointed to hold the inquiry may think fit, and as the person so required is able to furnish"

Line to take – This is a matter for the Chairman of the Inquiry, who has the power to require the submission of all relevant documents from any source.

6.2 "the questions over the deaths of our children are primarily for your Department" –

Line to take - We are determined to get to the truth of what happened and learn whatever lessons there are for the Department and the wider HPSS. This is why we have instituted a public inquiry. It is now for the Inquiry to investigate these matters.

6.3 "the Chief Medical Officer told us that our children's deaths were "idiosyncratic" –

This is likely to date back to the CMO's appearance on UTV's "The Issue" in March 2004, where she made comments in relation to the rarity of hyponatraemia which were taken as a contradiction of the Coroner's findings as to the cause of death. She did not say that the deaths were idiosyncratic.

Line to take – The Independent Inquiry will look in detail at all the events surrounding the death of each child and all subsequent actions taken.

6.4 Lucy's death/Sperrin Lakeland Trust are being singled out for special attention –

Line to take – The Inquiry will investigate each of the cases thoroughly. There are, of course, other issues affecting Sperrin Lakeland Trust at this time, which have led to extensive media coverage for this Trust.

6.5 Senior counsel for the families –

Each family is represented by a solicitor and junior counsel. The proposal was that they should share senior counsel. However representations were made at the preliminary hearing on 23 June that they should all have senior counsel and John O'Hara has now written to the Department requesting this. Notwithstanding the cost implications, it is likely that this will be agreed.

Line to take – This is a matter for the Chairman of the Inquiry to consider. The Department will of course give full consideration to any suggestions that he makes.

6.6 Seating plan at the Inquiry –

The families appear to feel that their seating at the Inquiry is not sufficiently prominent and does not offer a good enough view of witnesses. The matter was discussed at the recent preliminary hearing and Mr O'Hara took the view that the plan as suggested was the best available, but that he would look at any alternatives offered.

Line to take – The layout at the Inquiry is a matter for the Chairman and we will abide by his decision.

6.7 Appointment of Harvey Marcovitch as senior advisor –

Harvey Marcovitch was a consultant paediatrician in the NHS from 1977 until 2001, and an Honorary Senior Clinical Lecturer at the University of Oxford. From 1994 to 2002 he was the editor of the leading paediatric scientific journal "Archives of Disease in Childhood". He is now an associate editor of the BMJ and he sits on and chairs Fitness to Practise Panels of the General Medical Council.

The objections to his appointment are largely based on an article that he wrote six years ago in the British Medical Journal. This article was written in strong terms but was clearly related to a particular campaign – that of doctors who have exposed child abuse being hounded and the role of the media in this. Dr Marcovitch has emphasised that he distinguished that particular campaign from the vast majority of genuine concerns that members of the public have about medical treatment.

More recently Dr Marcovitch has also been quoted as saying, "those (parents) who know their rights and wanted them, in the main, didn't seem to help their child at all. All they managed to do was upset their doctors and cause their children to be over-investigated."

Line to take – The choice of appropriate expert advisors is a matter for the Chairman of the Inquiry. The Inquiry does however have a system whereby the work of all the advisors is subject to peer review.

6.8 The Department/Permanent Secretary "covered up" the deaths –

The Department was not made aware of the deaths of Adam and Lucy until long after they occurred. When CMO was notified of the death of Raychel prompt action was taken resulting in the production and dissemination of guidelines for the avoidance of hyponatraemia.

Line to take – Contrary to the allegation of a cover-up it was the Department that moved promptly, once it was made aware of Raychel's death to introduce guidelines to help prevent any recurrence and it is the Department, under Clive Gowdy's leadership, that is continuing to address the issue of reporting and follow-up of serious adverse incidents. Again it is for the Inquiry to investigate the role of the Department and all other relevant parties.

6.9 The Permanent Secretary denied the families an Inquiry –

Line to take – The decision to hold a fully independent Inquiry with wide remit and powers was taken by the then Minister, Angela Smith, on the direct advice of the Permanent Secretary.

7. MINISTER'S MEETING WITH THE CRAWFORD FAMILY

7.1 The Crawford family have been receiving a number of phone calls from the Impartial Reporter asking whether they have met with the Minister. They have refused to confirm or deny this but have made it clear that they are content for the Minister to tell the Ferguson and Strain/Slavin families that a meeting has taken place.

Line to take – The Crawford family contacted me specifically requesting a private meeting and this took place recently.

8. CONOR MITCHELL

8.1 Conor, a 15-year-old boy with significant physical disability and a history of epilepsy was admitted to Craigavon Area Hospital with a history of general malaise and vomiting. He was treated with fluids and antibiotics but his condition deteriorated, he had a number of seizures and suffered a respiratory arrest. He was transferred to the Royal Belfast Hospital for Sick Children but his condition failed to improve and he died on 12 May 2003.

8.2 The Coroner's report on Conor was ambivalent and the Inquiry has requested advice from an independent expert before deciding whether the case should be included.

8.3 Until a decision is made the Mitchell family have a right to have their privacy maintained and the case should not be discussed by name with any of the other families. This is made especially important by the fact that any information shared may possibly make its way back to the media.

8.4 The Inquiry had been considering the possibility of including a further child (not Conor) but this now appears unlikely.

Line to take – The Inquiry will consider any case it believes relevant. The Department will co-operate fully in any request for information from the Inquiry.

9. TERMS OF REFERENCE OF THE INQUIRY

9.1 The Terms of Reference of the Inquiry (**ANNEX C**) were drawn up after discussion with John O'Hara and were the subject of a submission to Angela Smith on 12 November 2004. It was acknowledged that it was essential that they were set sufficiently broadly to enable the concerns of the families and the wider public to be fully addressed so as to restore public confidence in our health care system. It was felt that in addition to the specific requirements in relation to the three deaths, the provision to "examine and report on any other relevant matters which arise" was broad enough to meet all reasonable expectations.

10. RECOMMENDATION

10.1 That the Minister notes the above briefing and lines to take, and agrees to offer to meet with the two families.

SIOBHAN MCKELVEY

Adam Strain **ANNEX A**

Date of Birth: 4/8/1991

Date of Death: 28/11/1995

Medical condition prior to admittance to hospital

Adam was born with a renal abnormality – an obstructive uropathy which resulted in polyuric renal failure. He had five ureteric reimplant operations (ending with one ureter connected to the other with only one draining into the bladder), a fundoplication for gastro-oesophageal reflux and, in October 1995, an orchidoplexy. He ate nothing by mouth and was fed via a gastrostomy button. He also received peritoneal dialysis. He was being prescribed calcium carbonate, Keflex, iron, one alpha vitamin sodium bicarbonate and erythropoietin. (E Sumner's report/Autopsy report)

Despite his health problems Adam was described as generally progressing quite well. He was on the 50th centile for height and 95th for weight

Admittance to hospital

On 26th November, 1995, he was admitted to the Royal Belfast Hospital for Sick Children at 11.30p.m. for a renal transplant operation. For accounts of the operation see attached E Sumner's medical report 27/1/1996 (**Tab C**), John Alexander's medical report (undated) (**Tab A**) and Autopsy report 29/11/1995 (**Tab M**).

The surgery, which began at approx. 7.00 am on 27th November, was noted to have been made more difficult due to the previous surgical procedures and there was considerable blood loss. Details of the fluids given to combat this are in the attached reports. A blood gas analysis carried out at 9.32 showed abnormal results including a very low sodium level of 123 mmol/l (normal 135-145). At the end of the procedure (between 11.00 and 12.00) Adam was given drugs to reverse the neuromuscular blockade but Adam did not breathe and was found to have fixed and dilated pupils. He was transferred to paediatric ICU where he was treated in an attempt to shrink the brain however a CT scan showed severe cerebral oedema with obliteration of the ventricles and the neurologists confirmed that his signs were compatible with brain stem death.

Neurologists carried out brain stem tests and life was pronounced extinct by a hospital doctor on 28th November 1995 at 9.15 am.

Analysis of treatment provided

The Coroner, John Leckey, sought reports as follows:

Dr John Alexander, Consultant Anaesthetist, BCH – **Tab A**
Edward Sumner, Consultant Paediatric Anaesthetist, GOS Hospital – Dr Sumner was asked for a report following advice from anaesthetists at the Children's hospital that Dr Alexander lacked experience in paediatric anaesthetics, which is a very specialised field – **Tab C**

Prof P J Berry, professor of Paediatric Pathology, University of Bristol – **Tab E**

Depositions were also taken from:

Mr D F Keane, Consultant Urologist, BCH, who carried out the transplant – **Tab F**
Dr M Savage, Consultant Paediatric Nephrologist, RBHSC, Adam's doctor – **Tab G**
Dr R H Taylor, RBHSC, Consultant Paed. Anaesthetist, anaesthetised Adam – **Tab H**
Constable Tester, RUC – **Tab I**
Dr Alison Armour, Pathologist, carried out the post-mortem – **Tab J**
Dr Edward Sumner – **Tab D**
Dr John Alexander – **Tab B**
Debra Strain – Adam's mother – **Tab K**

A report was also prepared by Medical Technical Officers in relation to the anaesthetic, temperature control and monitoring equipment used in the theatre – **Tab L**

The autopsy report is attached at **Tab M**

Report findings

Edward Sumner - conclusion was that, "on the balance of probabilities Adam's gross cerebral oedema was caused by the acute onset of hyponatraemia...from the excess administration of fluids containing only very small amounts of sodium (dextrose-saline and plasma)". He also mentions a number of possible exacerbating influences – see inquest findings.

John Alexander – conclusion was that, "the complex metabolic and fluid requirements of this child having major surgery led to the administration of a large volume of hypotonic (0.18%) saline which produced a dilutional hyponatraemia and subsequest cerebral oedema".

Both Anaesthetists refer to the same paper entitled "Hyponatraemia and death or permanent brain damage in healthy children" by Arieff et al which was published in the BMJ in 1992 – **Tab N**

Prof. Berry – conclusion was that, "From the material available to me I have been unable to determine an anatomical cause or underlying disease to account for this child's failure to recover from his transplant operation".

Inquest – 18 June 1996

This gave the cause of death as, "Cerebral oedema due to dilutional hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy)". The findings were that, "The onset of cerebral oedema was caused by the acute onset of hyponatraemia from the excess administration of fluids containing only very small amounts of sodium and this was exacerbated by blood loss and possibly the overnight dialysis and the obstruction of the venous drainage to the head". – **Tab O**

Outcome

The RBHSC concluded that: "From a liability position the case could not be defended particularly in the light of the information provided by one of the independent experts retained by HM Coroner at the Inquest". The case was therefore settled for [redacted] plus costs, without any admission of liability and subject to a confidentiality clause binding on both parties to the action – **Tab P**

The RBHSC also produced draft recommendations for use by paediatric anaesthetists for prevention of hyponatraemia in major paediatric surgery – **Tab Q** - it is unclear how widely these were circulated, if at all. On 15 April 2004 Dr McCarthy sent a minute to CMO which states, "I have spoken to Peter Crean regarding fluid policies at RBHSC. He does not recall any specific policy in place prior to the issue of Departmental guidance. He stressed that within the RBHSC emphasis on better fluid management followed the death of Raychel Ferguson in 2001, rather than events relating to the Lucy Crawford case."
(Further clarification about this issue was sought by Miriam McCarthy from Bob Taylor in June 05 – he said that the protocol was drawn up for fluid management during complex surgery carried out only in RBHSC and therefore was not widely distributed in the hospital or to other hospitals)

DHSSPS Action

The Department only became aware of Adam Strain's death when working on hyponatraemia guidelines following the death of Raychel Ferguson. A member of the working group heard of the case from the Coroner and informed Dr McCarthy. Dr McCarthy spoke to the Coroner by telephone on 14 December and he forwarded some of the inquest papers – received on 17 December by DHSSPS.

It is unclear whether the RBHSC informed any authorities other than the Coroner.

Raychel Ferguson

Date of Birth: 4/2/1992

Date of Death: 10/6/2001

Medical condition prior to admittance to hospital

Raychel was a previously fit and healthy child with normal development.

Admittance to hospital

At approx. 19.00 on 7 June 2001 Raychel was brought to A&E at Altnagelvin by her parents having been complaining of abdominal pain since her return from school. The diagnosis was probable appendicitis and her mother signed a consent form for her appendix to be removed.

She was admitted to a ward shortly after 22.00. The surgical SHO prescribed Intravenous Hartman's solution – a nurse pointed out that this was not in keeping with common practice on the ward and the prescription was changed to Solution 18 (0.18% saline with 4% dextrose). The fluids were in progress until Raychel went to theatre. They were recommenced when she returned to the ward following surgery.

Preoperative haematology and biochemistry was normal, notably the serum sodium was normal at 137. (Normal level is 135-145, below 128 is a hyponatraemic state, below 123 is dangerously low)

Anaesthesia was induced at approx. 11.30pm. All accounts show that anaesthesia and surgery were routine. 200 ml of Hartmann's solution was infused during the surgery. Surgery finished after midnight, Raychel was awake in recovery by 0115 and returned to the ward by 0210 on 8 June.

During the day Raychel vomited a number of times and at approx. 1730 to 1800 an anti-emetic was administered. At 2115 the nurses noted,"vomiting ++ (coffee grounds), colour flushed to pale, complaining of headache" and at 22.15 a further anti-emetic was administered. Raychel appears to have continued to vomit after this though only in small amounts.

During this time she was receiving Solution 18 at 80 ml per hour with a total input of 2220 ml in a little over 24 hours.

At approx. 3.00 on 9 June Raychel was observed to be fitting and to have been incontinent. Medical help was called and diazepam administered which was successful in stopping the seizure. Raychel's vital signs were

satisfactory but she was unresponsive. An electrolyte disorder was suspected and this was urgently checked – results showed marked abnormalities including sodium 119 at 0330 and 118 at 0430. Fluids appear to have been changed at this point to 0.9% sodium chloride and the rate reduced to 40 mls per hour. Raychel also had a petechial rash and at this stage there was still concern that she might have meningitis, therefore antibiotics were administered. Shortly after 0440 Raychel was intubated and ventilated as she was in respiratory difficulty. The consultant, who had been called at home and had given advice by phone, arrived at this point. He noted in his deposition that pupils were fixed and dilated.

Raychel was taken for a brain scan at 0530 – this showed evidence of subarachnoid haemorrhage with raised intracranial pressure - and from there to ICU at 0700. The neurosurgical unit in the RVH were contacted and at their request a second, enhanced, CT scan was arranged.

Raychel was transferred to the ICU at the RBHSC, leaving Altnagelvin at around 1110. At the time she left the expert medical report states she was hypothermic and with a negative fluid balance of one litre, she was ventilated and monitored throughout the journey. She arrived at RBHSC at 1220.

On arrival at RBHSC Raychel had no purposeful spontaneous movement and her pupils were dilated and unreactive to light. Brain stem death tests were performed at 1730 and 0945 on 10 June. Both tests confirmed brain stem death and ventilation support was discontinued at this time.

Events following Raychel's death

On 12/6/01 Dr Raymond Fulton, Medical Director of Altnagelvin set up a Critical Incident Enquiry involving all relevant clinical staff to establish the clinical facts. As a result of this six Action Points were agreed and circulated (Tab 1).

As a result of the review in Action Point 1 it was decided by Dr Nesbitt, Clinical Director for Anaesthetics, that Solution 18 should no longer be used in surgical paediatric patients in Altnagelvin.

In mid June, Dr Fulton informed the WHSSB DPH of the death. Following discussions with the DPHs of the other Boards and the CMO each DPH agreed to alert Paediatricians in their respective Board areas to the hazards of Hyponatraemia. This was done in July

Following discussions between Altnagelvin and CMO's office it was decided to set up a regional Enquiry Group - this led to the development and circulation of guidelines which aim to raise the awareness of hyponatraemia and provide clear and practical advice on prevention. The guidance was completed in Feb. 2002 and disseminated to Trusts (Tab 2).

An inquest was originally scheduled for 10 April 2002, but was postponed because the parents applied for funding for legal representation under an extra-statutory scheme established by the Lord Chancellor.

Analysis of treatment provided

The Coroner sought reports as follows:

Dr Edward Sumner, Consultant Paediatric Anaesthetist, recently retired from GOS Hospital – Dr Sumner had also given an expert opinion in the case of Adam Strain (Tab 3)

Dr John Gordon Jenkins, Senior Lecturer in Child Health, QUB, Consultant Paediatrician (Tab 4)

Depositions were taken from:

Altnagelvin staff –

Dr Vijay Gund, Anaesthetist (Grade unclear) – anaesthetised Raychel (Tab 5)
Dr Claire Jamison, Anaesthetic SHO – assisted with the anaesthetisation (Tab 6)
Mr Robert Gilliland, Consultant Surgeon – Raychel was admitted under his care though she was operated on by Mr Makar, the surgical SHO and was not seen by Mr Gilliland at any point (Tab 7)
Dr Brian McCord, Consultant Paediatrician – called after Raychel had fitted (Tab 8)
Dr Bernie Trainor, Paediatric SHO – involved in emergency treatment (Tab 9)
Dr Jeremy Johnston, Paediatric SHO – involved in emergency treatment (Tab 10)
Dr G A Nesbitt, Clinical Director – involved in emergency treatment (Tab 11)
Dr Raymond Fulton, Medical Director – investigated the death (Tab 12)
Staff Nurse Ann Noble (Tab 13)
Staff Nurse Michelea Rice (Tab 14)
Sister E Millar (Tab 15)
Staff Nurse Sandra Gilchrist (Tab 16)

Expert witnesses –

Dr Edward Sumner (Tab 17)
Dr John Gordon Jenkins (Tab 18)

Other –

Dr Peter Crean, Consultant Anaesthetist, Paediatric ICU, RBHSC – cared for Raychel post transfer (Tab 19)
Dr Brian Herron, Dept of Neuropathology, RVH – carried out the post-mortem (Tab 20)

Mrs Marie Ferguson – Raychel's mother (Tab 21)

The autopsy report is attached at Tab 22.

Report findings

Dr Sumner concluded that Raychel died from acute cerebral oedema leading to coning [the process in which intracranial pressure rises to such a degree that the base of the brain is forced down into the foramen magnum with subsequent brain death] as a result of hyponatraemia. He felt that the state of hyponatraemia was caused by a combination of inadequate electrolyte replacement in the face of severe postoperative vomiting and the water retention always seen postoperatively from inappropriate secretion of Antidiuretic Hormone (ADH).

(Stress, pain and nausea, such as that caused by surgery, can cause the body to inappropriately secrete ADH which causes water retention)

Dr Sumner stated that in his opinion Raychel should have received normal saline to replace her gastrointestinal fluid losses and that her electrolytes should have been checked when the vomiting did not settle down. He also suggested that a nasogastric tube should have been inserted to allow gastric losses to be accurately quantified.

Dr Jenkins agrees with Dr Sumner's assessment however he adds in his conclusion that the staff involved "acted in accordance with established custom and practice in the Unit at this time. Rachel's untimely death highlights the current situation whereby one sector of the medical profession can become aware of risks associated with particular disease processes or procedures through their own specialist communication channels, but where this is not more widely disseminated to colleagues in other specialties who may provide care for patients at risk from the relevant condition."

Inquest – 5/2/2003

This gave the cause of death as cerebral oedema caused by hyponatraemia. The hyponatraemia being caused by a combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and water retention resulting from the inappropriate secretion of ADH (Anti-Diuretic Hormone).