Witness Statement Ref. No. 080/1

INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Name: Miriam McCarthy

Title: Dr

Present position and department/employer:
Senior Medical Officer, Department of Health Social Services and Public Safety

Length of time in post: 7 years

Previous position and department/employer in 1995:

In 1995 I was working as an independent consultant in Minneapolis/St Paul, Minnesota, USA

Previous position and department/employer in 2000:

Senior Medical Officer
DHSSPS

Previous position and department/employer in 2001:

Senior Medical Officer
DHSSPS

Membership of Professionals Bodies:

Member of Royal College of General Practitioners MRCGP (1985)
Member of the Faculty of Public Health Medicine MFPHM (pending administrative procedures)

Particular areas of interest
[Please attach additional sheets if more space is required]

(i) How and when did you first become aware of the deaths of Adam, Lucy and Raychel?

I became aware of Raychel Ferguson's death on 14th August 2001, when Dr Paul Darragh, the then Deputy Chief Medical Officer in DHSSPS, met with me in my office and informed me of her death. He then asked me to convene a working group to produce guidance on the prevention of hyponatraemia in children.

I became aware of Adam Strain's death on 13th or 14th of December 2001 (006-056-441). During a telephone conversation with Mr John Leckey, the HM Coroner for Greater Belfast, in which we discussed the preparation of guidance on the prevention of hyponatraemia, he advised me that Adam Strain had died in 1995 and that hyponatraemia was identified as a cause of death. Mr Leckey forwarded the medical report on Adam Strain, which I received on 17th December 2001

I became aware of Lucy Crawford's death on either the 5th or 6th March 2003 (006-056-443). Mr John Leckey informed me in a telephone conversation, that Lucy Crawford, who died on 14th April 2000, might have died as a result of hyponatraemia.

(ii) Describe in detail the steps you took:
(1) To discover why the children died;
(2) Why the DHSSPS was not made aware of the deaths at an earlier stage; and
(3) To ensure that lessons would be learned for the future.

(1)The coroner's inquest papers and medical reports prepared for the coroner provided me with the detail of events surrounding the children's deaths. My role as senior medical officer did not focus on discovering why the children died. Rather, I was involved in action to prevent further cases of hyponatraemia.

(2) At the times of the deaths of Adam, Lucy and Raychel in 1995, 2000 and 2001 respectively there was no formal mechanism by which the Department was made aware of individual deaths in hospital. Notwithstanding this, the DHSSPS was informed of Raychel's death at a very early stage, when it was discussed at a meeting between Dr Campbell and the Directors of Public Health on 2nd July 2001 (075-081-323), following which Dr Campbell requested that a working group be established to produce guidance on the prevention of hyponatraemia.

(3) Following Raychel's death, action was taken to ensure that future cases of hyponatraemia would be prevented. Dr Campbell asked for a Working Group to be convened under the chairmanship of Dr Paul Darragh, then DCMO, to produce regional guidance on the prevention of hyponatraemia. Dr Darragh requested that I convene a multidisciplinary group to develop the guidance.

I convened the first meeting of the Hyponatraemia Working Group on 26 September 2001 (007-048-094) which was attended by Dr B Taylor, RBHSC, Dr D Lowry, Craigavon Area Hospital, Dr G Nesbitt, Altnagelvin Hospital, Mr G Marshall, Erne Hospital, Mr B McCallion,

RBHSC, Dr F Kennedy, NHSSB, Dr C Loughrey, BCH, Ms E McElkerney, Ulster Hospital, Dr P Crean RBHSC and Dr M Mark DHSSPS (medical secretary to the group), and myself.

The first meeting was chaired by Dr Darragh, after which I chaired a subgroup responsible for drafting the guidance. The guidance was published in March 2002 and sent to all acute Trusts (006-053-435). I drafted a short article on hyponatraemia for inclusion in the CMO Update of June 2002 (075-085-346), to raise awareness of the issue and the guidance.

Following the inquest into Lucy Crawford's death, Mr Leckey wrote to Dr Campbell (006-001-022) enclosing a set of inquest papers. Mr Leckey wrote in his covering letter 'Whilst the protocol devised by your working party has not been criticised in any way (in fact it has been praised) by any of those who gave evidence either at this inquest or the inquest into the death of Raychel Ferguson, nonetheless there may be merit in the working party examining the inquest papers in relation to the death of Lucy to see if any changes to the protocol might be required."

In response to Mr Leckey's letter, and following discussions with Dr Campbell, I wrote to all members of the Hyponatraemia Working Group, and asked them to consider the current guidance and any additions or amendments that should be made. This letter was issued on 5th July 2004 to Dr Jenkins, Dr Taylor, Dr Crean, Dr McCallion, Mr Marshall, Dr Nesbitt, Dr Kennedy, Mrs McElkerney and Dr Loughrey. Ms Patterson, nursing officer in the Department was also invited. The letter was copied to Ms Wilkinson who organised the meeting. (007-062-131).

On 8th July 2004 I met with Sir Cyril Chantler, Dr Ian Carson, and Dr Campbell to discuss the Hyponatraemia guidance and specifically to identify any amendments that Sir Cyril thought appropriate. (Hand written notes of this meeting are attached at Tab A)

In light of Sir Cyril's comments and the responses received from members of the Hyponatraemia Working Group, I convened a short meeting to facilitate discussion on any proposed amendments. A letter of invitation was issued to Dr Jenkins, Dr Taylor, Dr Crean, Dr Loughrey and Dr McAloon on 12th August 2004 (007-055-120). On 22nd September, I met with Dr Jenkins, Dr McAloon and Dr Angela Jordan (Specialist registrar in Public Health Medicine). Notes of the meeting are attached at Tab B. It was agreed that rather than amend the guidance, complementing it with a fluid care pathway would offer greater benefits. Subsequently, on 5th November 2004, Dr Campbell wrote to Dr Jarlath McAloon and invited him to convene and to chair a small multidisciplinary group to develop a care pathway for fluid management. (A copy of this letter is attached at Tab C). This group has met several times, with its final meeting anticipated to take place in September 2005.

(iii) Give details of your colleagues within the DHSSPS with whom you discussed the steps to be taken in response to the deaths of Adam, Lucy and Raychel to include the reasons why and when they were contacted by you and the outcome of your discussions.

When Dr Darragh requested that I convene a multidisciplinary group to develop guidance on the prevention of hyponatraemia I discussed with him the issue of hyponatraemia, and steps to be taken in establishing a group and timescales.

The first meeting was chaired by Dr Darragh, with whom I discussed the most appropriate action to be taken in developing the guidance and agreed that I would chair a subgroup responsible for drafting the guidance. The guidance was published in March 2002.

Throughout the time during which the guidance was being prepared I regularly discussed progress with Dr Campbell, providing verbal updates and drafts of the document as appropriate.

At the time I became aware of Adam's death, preparation of the guidance was well underway. Finalising and publishing the guidance was considered to be the most appropriate response and I recollect that this was confirmed in discussions with Dr Campbell.

When I became aware of Lucy's death in March 2003, the guidance had been issued and was in use throughout hospitals in Northern Ireland. Following discussion with Dr Campbell, in which we noted that this was a third death in which hyponatraemia was a factor, I wrote to Ms Williams, Joint Chief Executive, at the National Patient Safety Agency (NPSA) on the 14th March 2003 (006-052-434) asking if this was an issue that the NPSA would like to explore in greater detail. The NPSA responded on 11th April 2003 (006-051-433) informing me that the matter had been referred to their Assistant Director for Children's Services. Further communication was received by electronic mail from David Cousins on 22nd June 2005, advising me of the NPSA work plan in relation to hyponatraemia. A copy of this is attached. (Tab D)

(iv) Describe in detail your role in the drawing up of the Guidance on Hyponatraemia in Children, issued in 2002, to include details of colleagues both within and outside Northern Ireland with whom you consulted.

Following Raychel's death, Dr Campbell asked for a Working Group to be convened under the chairmanship of Dr Paul Darragh, then DCMO, to produce regional guidance on the prevention of hyponatraemia. Dr Darragh requested that I convene a multidisciplinary group to develop the guidance.

I convened the first meeting. Invitations were issued on 21 August 2001 (007-050-099) to: Dr B Taylor RBHSC, Dr D Lavery, Craigavon Area Hospital, Dr G Nesbitt, Altnagelvin Hospital, Mr G Marshall, Erne Hospital, Mr B McCallion, RBHSC, Dr F Kennedy, NHSSB, Dr C Loughrey, BCH, Ms E McElkerney, Ulster Hospital, Dr P Crean, RBHSC and Dr J Jenkins, Antrim Area Hospital.

The first meeting was held on 26 September 2001 (007-048-094) and attended by Dr B Taylor, RBHSC, Dr D Lowry, Craigavon Area Hospital, Dr G Nesbitt, Altnagelvin Hospital, Mr G Marshall, Erne Hospital, Mr B McCallion, RBHSC, Dr F Kennedy, NHSSB, Dr C Loughrey, BCH, Ms E McElkerney, Ulster Hospital, Dr P Crean RBHSC and Dr M Mark DHSSPS (medical secretary to the group) and myself.

The first meeting was chaired by Dr Darragh, after which I chaired a subgroup responsible for drafting the guidance.

In addition to the original members of the group Dr Maurice Savage, RBHSC was invited to participate (007-042-087). A second meeting was held on 10th October 2001,at which it was agreed that further communication would be via e-mail (007-038-072).

My role as chair of the subgroup included gathering the information needed for inclusion in the guidance, leading discussion on the proposed content of the guidance, documenting and circulating revisions to the draft guidance, and agreeing and designing the format for presentation of the material. When members of the Working Group agreed the guidance, I arranged for printing and dissemination of the guidance. The guidance was issued on 26 March 2002 (006-053-435), preceded by a CMO letter on 25 March 2002 (006-054-436), highlighting the risk of hyponatraemia and the importance of implementing the guidance to prevent further incidences of serious hyponatraemia.

In preparing the guidance I had regular telephone and e-mail communication with members of the Working Group. I also consulted with Dr Angela Bell, Ulster and Community Hospitals Trust. Drafts of the guidance were shared with other medical colleagues in the DHSSPS.

Also, during the preparation of the guidance, a draft was shared with professional colleagues attending Special Advisory Committee Surgery on 11th December 2001(075-084-338). On 14 December 2001 I contacted Dr Edward Summer, an expert witness at Raychel Ferguson's inquest hearing (007-016-032). Dr Summer responded on 17th December 2001, including comments on standard practice in Great Ormond Street hospital. (007-016-032).

Dr Bob Taylor, as a member of the Hyponatraemia Working Group, consulted paediatric colleagues in Alder Hey Hospital and at Toronto Sick Children's Hospital. Dr Taylor also contacted the Committee on Safety of Medicines, (CSM). He confirmed this in an e-mail dated 27 September (007-043-088). A follow-up letter to Dr Cheng at the CSM (007-033-060) was copied to me on 25 October (007-032-059) as was Dr Cheng's reply to Dr Taylor dated 26 November 2001 (007-017-034)

(iv) Give details of colleagues in the DHSSPS and outside with whom you consulted before preparing the briefing papers and line to take for the Minister in respect of the Department's response to the deaths of Adam, Lucy and Raychel

On 20th February 2003, following the inquest into Raychel Ferguson's death I prepared a ministerial submission, including lines to take for Des Browne, then Minister for Health, Social Services and Public Safety (006-039-389). From recollection, I did not consult with colleagues in the preparation of this briefing material.

On 6th April 2004 following the inquest into Lucy Crawford's death a ministerial submission was prepared and sent to Angela Smith, then Minister for Health Social Services and Public Safety (004-003-011). This included a copy of the inquest verdict and a copy of the Hyponatraemia Guidance. From my recollection, I consulted with Dr Campbell regarding the content of this briefing.

I prepared further ministerial briefing on 28 May 2004 (004-010-105) and 1st June 2004 (004-010-055). In preparing these briefs, I recall consulting with Dr Campbell, Dr Carson, Mr Noel McCann, Mr Colm Shannon and Mr Kevin Mulhern.

Particular areas of interest (Cont'd)

Other points you wish to make including additions to any previous Statements, Depositions and or Reports
[Please attach additional sheets if more space is required]

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

Signed: M R M Cauley **Dated:** 6th May 2005

8/7/04.

Hyponatraemia - CMO/MC/Sir Cyril.

① Arch.

Journal of Paed. - Accepted in Press
(Halliday + Gamble)

Mac Holiday -

? Hazardous. ADH ? Exists in children.
AVP levels in hyponatraemia maybe due to perceived vol. depletion - ie relative hyponatraemia.

Tonsillectomy pts - vol. depleted high AVP levels - Primed to go hyponatr

Replacement - Give isotonic sol=s.

Nitrous ox. ('can't secrete water after surgery)

Hypoglycaemia - risk.

Na. ≤ 136 → Always 9% Saline

Maintenance. - Always give physiological

Introductions

Stress ; high level of ADH = presence of norm or low Na is due to volume depletion

Replace. - physiological saline - Hartmanns Ringers.

- Restore Circulating bl. vol.

Maintenance

Never give hypotonic sol= if < 138.

(Halbertal) -

½ day of hyponatraemia - Septr. Give Cyril Chantler to be invited

Major improvements - ICU/HDU.
Major improvements staffing + grading.
Pre admission assessment clinics

22/9/04.

Hyponatraemia.

Best in general paed unit.

Anwin MD Group - Nursing/Med/Pharm

Care Pathway.

Oral fluids - need to be highlighted *

In general hypotor should not be used in Na < 138 but may be circumstances which indicated.

Maintenance R could be reduced - children ICU.

Departmental D. → D. Sharon McCluskey
Nikki Patterson.

Workshop. →

Education → MID Training Agency
Needs to be cover postgrad syllabus.

NPSA - Check what is happening →
-? Any other units guidance -

American Academy of Paediatrics
→ Pediatric Clin Practice + Guidelines. 3rc
CDC - Managing Acute Gastroenteritis

Group: - Speak Claire MDiSC

Jarlath → ~~to Clar~~
Sheevor - Rec - Nursing staff
Pharmacy.
?Junior Doc. - Paeds -

Care Pathway - Fluid Chart. | Prompts | ?Audit
Oral fluids -

Dean - Funding - Networks.
Regional Event.

From the Chief Medical Officer
Dr Henrietta Campbell CB

Department of
Health, Social Services
and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

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Stormont Estate
Belfast BT4 3SQ
Tél: [redacted]
Fax: [redacted]
Email: Henrietta.Campbell[redacted]

Your Ref:
Our Ref:
Date: 5 November 2004

Dear Dr McAloon

CARE PATHWAY FOR FLUID MANAGEMENT

I know Dr John Jenkins and yourself met recently with Dr Miriam McCarthy to discuss any necessary revisions to the guidance on the prevention of hyponatraemia in children. I understand that rather than amend the guidance you proposed the development of a care pathway for fluid management. I think this is an excellent approach and a care pathway would undoubtedly improve fluid management among children admitted to hospital.

I would appreciate if you could convene and chair a small multidisciplinary group to take this forward. Dr Angela Jordan, specialist registrar in Public Health Medicine, would like to be included in the group (she can be reached on [redacted].

On January 6th I will host a workshop on The Care of Children in Hospital. I would appreciate if you were able to give a short talk on the development of the care pathway, although I appreciate that it will be a 'work in progress'. Dr Willis will be in contact with you to discuss details.

I appreciate your commitment to this very important issue in the management of children. If you have any questions or comments please do not hesitate to contact me.

Yours sincerely

DR HENRIETTA CAMPBELL
Chief Medical Officer

c.c. Dr John Jenkins – Consultant Paediatrician, Antrim Area Hospital
Dr Miriam McCarthy
Dr Claire Willis
Dr Angela Jordan

McCarthy, Miriam

From: David Cousins [david.cousin[redacted]
Sent: 22 June 2005 15:19
To: miriam.mcCarth[redacted]
Cc: Joint Chief Executive; Linda Matthew
Subject: NPSA work on the safe use of hypotonic infusions in children

Dear Dr McCarthy,

Thank you very much for your telephone call to exchange information about work on this topic.

I can confirm that a proposal for the NPSA to undertake work on this topic during 2005-6 was fully supported by the NPSA external prioritisation group.

Our work plan is to organise an expert external reference group to develop therapeutic guidelines on fluid replacement and the use of hypotonic infusions in children. In addition we plan to use an implementation method similar to the one we used for potassium chloride concentrate injection and recommend withdrawal of hypotonic infusions from general paediatric wards that will use isotonic infusions and restrict hypotonic infusions to critical care and specialist units where children are under the direct clinical care of specialist clinicians and strict monitoring of fluid and electrolytes is undertaken.

We are very interested to receive information from the recent work that your expert group has been undertaking in Northern Ireland to assist with our work.

You kindly agreed that you would put me into contact with Dr McCloon, Chairman of the working party that will be submitting a report to the Chief Medical Officer (NI) in the next few weeks.

Thank you once again for bringing this important patient safety risk to our attention and agreeing to work collaboratively with us to make this aspect of medication practice safer.

Professor David Cousins
Head of Safe Medication Practice,
National Patient Safety Agency,
4-8 Maple Street,
London WIT 5HD
Telephone [redacted]
Mobile [redacted]
Email [redacted]

24/06/2005