Witness Statement Ref. No.	075/3

DEPARTMENTAL AND GENERAL GOVERNANCE

Name: Henrietta Campbell

Title: Dr.

Present position and institution:

Retired

Previous position and institution:

Chief Medical Officer, Department of Health, Social Services and Public Safety

Membership of Advisory Panels and Committees:
[Identify by date and title all those since your Witness Statement of 5th September 2013]

Previous Statements, Depositions and Reports:
[Identify by date and title all those since your Witness Statement of 5th September 2013]

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

Ref:	Date:	
WS-075/1 WS-075/2	07.07.05 05.09.13	Witness Statement to the Inquiry Witness Statement to the Inquiry

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.

(1) In your answer to Question 7(a) at **WS-075/2, p.7**, you stated:

"The Department set up a Standards and Guidelines unit to facilitate comment from clinical experts and policy/professional leads in NI."

In relation to the Standards and Guidelines Unit,

(a) Please state when it was set up by the Department.

(b) Please identify who was head of the Unit when it was set up.

(c) Please state to whom the Unit is/was accountable.

(d) Please state some of the areas in which the Unit has taken action since it was set up.

This unit did not fall within my remit at the Department. The Department may be able to assist with these questions.

(2) On 21st October 1994, at a meeting of the Directors of Public Health (DsPH)/DHSSs, Dr. Donaghy raised an issue regarding the fact that *"a number of publications which are issued by the CMO in Great Britain are not being issued by DsPH in Northern Ireland"* **(Ref: 320-061-010)**

(a) How would such materials or guidelines be disseminated in Northern Ireland?

There was no formal process by which they were disseminated. I would have received copies of such publications and if they appeared to be relevant to Public Health, I would send them to the Directors of Public Health.

(b) In reply to Dr. Donaghy, you stated that *"there is a list of circulars which the Medical Branch receives regularly"* and that *"this would be made available to DsPH"*. **(Ref: 320-061-011)**

(i) Please state if this occurred, and, if so, when this occurred.

I have no recollection at this stage what happened in relation to this. It was listed as an action point in the minutes so I presume something was done but I can't recall anything about it now, almost 20 years later.

(ii) What else, if anything, was done about this issue?

See 2(b)(i)

(3) On 5th December 2005, at a meeting of the Directors of Public Health (DsPH)/CMO, Dr. Briscoe informed the members that the Department was creating *"a database of contacts which*

it can access for specialist advice re: Public Health related issues in NICE Guidance". **(Ref: 320-100-004)**

(a) Please provide more details about this database, including:

(i) When it was formed

(ii) Whether it still exists

(iii) What it has done since it was formed

This hadn't been created by the time I retired. Perhaps the Department can assist.

HYPONATRAEMIA WORKING GROUP

(4) At the SAC (surgery) meeting of 12th December 2000 at which you are noted to be present:

"It was also felt that the guidance could be more explicit in general and particularly in the use of 1/5 normal saline" **(Ref: 320-121-004)**

I believe the date might be wrong. I presume this is a typographical error as the meeting referred to at that reference was on 11th December 2001. If this is wrong please do let me know.

(a) What was done as a result of this discussion?

I don't recall this discussion but I do recall that there was a debate between members of the working party about the role of 1/5 normal saline in the guidelines. The Inquiry will see evidence of that debate in file 7 in emails exchanged between members of the working party. For example, see 007-003-005, 007-008-014, 007-011-024, 007-011-027, 007-013-027, 007-016-032. There are no doubt numerous other such references. The end result was that the working party decided amongst themselves how best to draft the guidelines and produced a set of guidelines that I issued.

(b) What opposition was there to the guidance being *"more explicit in general"*?

The two sides of the debate are set out in the references above at 4(a). Some clinicians felt 1/5 normal saline should be specifically named, whilst others felt there was no evidence base for taking such a step.

SPECIALTY ADVISORY COMMITTEES

(5) In relation to the Specialty Advisory Committee (SACs):

(a) Please describe their main purpose.

The main purpose of the SACs was to provide a mechanism for obtaining resolved medical advice which could assist the Department and Ministers in developing policy. They also provided a vehicle for explaining Government policies to representatives of the medical profession.

(b) Please state when they were created.

Before my time as CMO. Probably more than 30 years ago.

(c) Please explain why they were created.

See (a) above.

(d) How did you / the Department identify those who would form the membership of the SACs? For example, were they selected, did they volunteer etc.

Each SAC had a slightly different membership. Commonly they included representatives from undergraduate and postgraduate education, the Colleges, the regional centre, each area Board, the BMA and each Director of Public Health. Some were members because of the Office they held, some such as the BMA and College were there through their own electoral processes.

(6) In your answer to question 13(b) at **WS-075/2, p.9**, you stated in relation to the statement produced by the RBHSC following the Inquest of Adam Strain (**Ref: 011-014-107a**):

"I would have expected the Department to be informed because the minister may have required to be briefed on the case. It is also the type of case I would have thought should be discussed at the SAC for Anaesthetics or Paediatrics."

(a) Please state under what circumstances individual cases should be discussed at the SACs.

Individual cases weren't normally discussed at the SACs. If a member of an SAC felt a certain individual case had implications for regional policy then they could have raised it.

(b) Please explain how clinicians are expected to make the decision whether a case is one which should be discussed at a SAC. What guidelines / protocols / training is/are in place to assist them in this decision?

It was down to the individual judgment of the clinician. There were no guidelines/protocols/training to assist them that I am aware of. The members of the SAC were generally senior members of the profession and as such would be expected to recognise issues falling within their area of expertise that might have regional policy implications.

(c) Dr. Elaine Hicks, Consultant Paediatric Neurologist, RBHSC gave evidence at the Oral Hearings (**Transcript, 7th June 2013, p.22**) where she stated in relation to SACs:

"I think many of us were not convinced that it was as effective as it might have been."

Please provide any comments that you have.

(d) Were you aware of the limitations that clinicians saw in the SACs?

Clinicians often expressed the view that their area of medicine required further resources to fund training requirements in their specialty. As against that, the Department had finite resources so everyone couldn't get what they wanted. That is one of the sort of issues that were commonly discussed at SACs. I wouldn't call it a limitation as such. That limitation (by way of example) was in the budget, not the SAC.

(7) Please state if the implications of variation in the age limits of paediatric patients were discussed in relation to the hyponatraemia guidance.

(a) Was a target age range for the application of the guidelines?

(i) If so, what was it?

(ii) If not, why not?

(b) Please state if it was recognised during:

(i) the drafting of the guidance

(ii) the distribution of the guidance

that there is a variation in the definition of a paediatric patient.

The only information I have relevant to this question is contained in the various emails etc from the working party which I understand are in file 007.

(c) Please explain the relevance for the hyponatraemia guidance of the discussion at the SAC meeting of 10th September 2002 – **Ref: 320-056-005** (discussion regarding the fact that 12 years old is too young for admission to adult ward – CMO to write to Trust CEOs & look for DHSSPS policy documents on the issue)

The two issues were discussed separately and no link was drawn between them at the meeting.

AUDIT

(8) In your letter dated 25th March 2002 (**Ref: 007-001-001**), you stated:

"The Guidance is designed to provide general advice and does not specify particular fluid choices. Fluid protocols should be developed locally to complement the Guidance and provide more specific direction to junior staff. [...]. It will be important to audit compliance with the guidance and locally developed protocols and to learn from clinical experiences."

(a) How did the Department intend to ensure that the locally developed fluid protocols would complement the Guidance?

It was a matter for the Trusts to ensure any protocols they issued would complement the Guidance.

(b) Explain what you meant by "*audit*" in this context.

The normal sort of medical and multiprofessional audit.

(c) Who was intended to "*audit compliance with the guidance*"?

(i) The Department and Trusts together

(ii) The Department alone

(iii) The Trusts alone

(iv) Other organisations?

The Trusts alone.

(d) Who was intended to "*audit compliance*" with the "*locally developed protocols*"?

(i) The Department and Trusts together

(ii) The Department alone

(iii) The Trusts alone

(iv) Other organisations?

The Trusts alone.

(9) The minutes of a meeting of the SAC Paediatrics on 10th September 2002, at which you were present, state: *"It was suggested that an audit of the [hyponatraemia] guidelines in due course would be valuable."* **(Ref: 320-056-002)**

(a) By whom was this suggested?

I do not have any recollection of who suggested this and the minutes do not specify who suggested it.

(b) What happened regarding the suggestion of auditing the guidelines?

Dr McAloon conducted an audit.

(c) When and how was it thought that would occur?

I do not have any recollection of when or how it was thought that would occur from the meeting on 10th September 2002 and the minutes don't assist. Dr McAloon did however carry out an Audit in 2003/2004.

(d) Why was a formal process not put in place for a Review at the time of issuing the 2002 guidelines?

As noted above, the Trusts were expected to audit their own compliance with the guidelines. There would have been nothing to audit for a time after the implementation of the guidelines since they would have to be operational for a period of time before they could be audited.

(10) Dr. Jarlath McAloon conducted a Regional Audit in 2003-2004 to examine adherence to the DHSSPS hyponatraemia guidance **(Ref: 007-054-114)**.

(a) Why was Dr. McAloon in particular asked to conduct the audit?

You would need to check with Dr McAloon for a definitive answer but I think he volunteered.

(b) Who instructed Dr. McAloon to carry out the review of the 2002 guidelines, or was it on his initiative following on from the 2002 SAC Paediatrics committee meeting comment?

See 10(a).

(c) By what method was it intended that Dr. McAloon would conduct the audit.

I am not aware of any particular method being prescribed. Dr McAloon is and was a senior paediatrician who would need no guidance on how to conduct an audit.

(d) What action was taken by you / the Department in relation to the results of this audit, particularly that implementation of the Guidance *"has so far been incomplete"* **(Ref: 007-054-118)?**

(11) With reference to a letter sent by you to Dr. Jarlath McAloon dated 5th November 2004 **(Ref: WS-075/1, p.24 & 25)**:

(a) What revisions were considered necessary to the Guidance in 2004?

(b) If no revisions were considered, why was the Guidance considered appropriate?

The background to this is set out in my original witness statement at 078-013-090 to 078-013-091. Some revisions had been suggested by members of the working group. For example, see 007-052-112, 007-056-125, 007-064-134, 007-065-135. Dr McAloon's audit had also been prepared by this stage. Some members of the working group had a meeting with Dr McCarthy and they agreed that it would be better not to revise the guidance but to supplement it with a care pathway.

(c) Describe what is meant by Dr. McAloon's proposal of *"a care pathway for fluid management"*.

A care pathway is a structured multidisciplinary care plan which details essential steps in the care of a patient. They often take the form of a flow chart.

(i) State if such a care pathway was developed. If so, please describe and provide details of the care pathway and its formation.

I do not know if such a pathway was developed.

(ii) Please explain why this was considered better than revising the guidelines of 2002.

The working group thought it was a better way to proceed. In the SAC paediatrics meeting on 5th October 2004 075-079-315 it was suggested that internationally, best practice was still controversial and that was an obstacle to issuing definitive protocols. I believe a care plan was suggested to try and complement the existing guidelines.

(d) Please explain how the *"small multidisciplinary group"* suggested by you was formed.

(i) State whether this entity was the same as the 'Northern Ireland Regional Paediatric Fluid Therapy Working Group'.

(ii) Please explain the purpose of the *"small multidisciplinary group"*.

(iii) Explain your role within the *"small multidisciplinary group"*.

(iv) State when it was formed.

(v) Identify its members.

(vi) Explain how you / the Department identified the clinicians who would form the membership of the *"small multidisciplinary group"*. For example, were they selected, did they volunteer etc.

(vii) State how often the Group met, and if it is still in existence. If it is not still in existence, please state when it ceased to exist.

(e) Please describe the work since 2004 of this *"small multidisciplinary group"*, including meetings and publications.

I cannot provide any assistance with 11(d) or 11(e). I was not a part of the group and I do not know anything of their work.

KNOWLEDGE OF HYPONATRAEMIA DEATHS

(12) How and when did you first become aware of the death of Conor Mitchell?

I have no contemporaneous recollection of when I became aware of the death of Conor Mitchell but from the documents it looks like Dr Sumner copied me into a letter concerning Conor's Inquest on 11 June 2004 (087-062i-247).

(a) What did you / the Department regard as the implications of Conor's death for the successful implementation of the guidelines?

Since he was not apparently nursed in a paediatric ward, I don't think I/the Department thought Conor's death had any implications with respect to the successful implementation of the guidelines. As discussed elsewhere however, there was a discussion shortly after this when a care pathway was proposed in response to the audit outcome and various other factors.

(13) Mr. John Leckey, HM Coroner, stated in his witness statement to the Inquiry that, following the Inquest of Adam Strain in 1996: **(WS-091/1, p.3)**:

"I had assumed that the RBHSC would have circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some "best practice" guidelines. Children are not always treated in a paediatric unit and, in the event of surgery, the anaesthetist may not be a paediatric anaesthetist."

(a) Would you have expected the RBHSC to have *"circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some "best practice" guidelines"?*

If "best practice" guidelines were developed by the RBHSC (the regional centre) then I would have expected those to be disseminated. I do not think I would have expected the details of the evidence given at the inquest to be circulated.

(14) In your answer to Question 11 at **WS-075/2, p.8**, you stated in relation to further deaths from hyponatraemia:

"In the course of the deliberations of the working party, I understand information was shared between members."

(a) Please explain how and from whom you *"understand"* this.

From 007-025-048 I can see that Dr Loughrey emailed Dr McCarthy mentioning the death of another child. Other than that, I am speculating that information would have been shared.

(b) Please describe what *"information was shared between members"*.

(15) In your answer to Question 12 at **WS-075/2, p.8**, you stated in relation to why the Working Party was established:

"The information I had at that time was that Raychel had died and that there had been "problems in the past" at RBHSC."

(a) To what extent were you aware of the details of the "*problems in the past*" at RBHSC?

On 26 July 2001 Stella Burnside emailed me to suggest that guidelines be considered on a regional basis (095-011-059k). I replied to that email on 27 July 2001 confirming that I would oversee the production of guidelines (email attached to my statement at file 078). At that stage I think the information I had was that Raychel had died and that the RBHSC had had some problems with Solution 18 in the past. I do not think I had any more detail than that.

(b) Were you aware at the time that there may have been more than one death from hyponatraemia in Northern Ireland, even if you were unaware of the details?

I was not aware of any other deaths from hyponatraemia at that time. I note that Dr Carson emailed me on 30th July 2001 (021-056-135) suggesting that there was a previous death in the Mid Ulster approximately 6 years ago. That email came after my decision to address this as a regional issue. You could say by virtue of that email I had been notified of another death due to dilutional hyponatraemia. The email also noted 5-6 deaths over a 10 year period of children with seizures. I never however received details of any of the deaths referred to in Dr Carson's email.

(16) What discussions did you / the Department have with:

(a) Colleagues in the DHSSPS

(b) Colleagues in other hospitals

regarding the failure to inform the Department of Adam / Claire / Lucy's deaths.

Following Lucy's inquest I know that the Permanent secretary was concerned that the Minister and Department had not been informed of her death and I recall there were a number of meetings to discuss how this should be addressed. This led ultimately to a review of governance at the Erne Hospital. I wasn't at the Department when I learned of Claire's death. I don't recall any discussions within the department in relation to the fact that Adam's death hadn't been notified to the department.

ADDITIONAL INFORMATION

(17) Provide any further points and comments that you wish to make, together with any relevant documents.

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

Signed: [signature] **Dated:** 14.10.13