Witness Statement Ref. No. 075/2

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 of those since your Witness Statement of 7th July 2005]

Up until February 2006 – See previous witness statement – those committees etc as CMO

Since February 2006 –

- *Chair of review of Breast Cancer Services in Limerick – reporting to Health Minister in ROI - circa 2008*
- *Chair of review of Confidentiality and the use of patient data for GMC – 2009*

Previous Statements, Depositions and Reports:
[Identify by date and title all those since your Witness Statement of 7th July 2005]

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

Ref:	Date:	
WS-075/2	07.07.05	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.

N.B. In answering the below questions, and where appropriate, please detail the circumstances throughout your appointment as Chief Medical Officer, including any changes that may have occurred during that period.

ROLE AS CHIEF MEDICAL OFFICER

(1) State the dates on which:

(a) You became Chief Medical Officer

January 1995

(b) You ceased to hold that position.

February 2006

(2) Describe your career history prior to becoming Chief Medical Officer.

See CV

(3) Describe your career history since ceasing to be Chief Medical Officer.

See CV

(4) Please explain the Role of Chief Medical Officer and the responsibilities the role entailed.

As Chief Medical Officer (CMO) I had responsibility for advising the Minister and the Department on matters relating to public health. These included: co-ordination of inter-departmental public health programmes; environmental health issues; European public health policy; oversight of Institute of Public Health in Ireland; health promotion policy; immunization; screening programmes; sexual health; mental health promotion; smoking, drug and alcohol misuses; communicable disease control policy; liaison with Food Safety Promotion Board and the Health Promotion Agency.

One of my responsibilities was to communicate with the public on matters relating to the protection and promotion of health. This was done through publications, media and other public appearances.

As the head of the medical service within the NI Civil Service I was responsible for the employment and management of all medical staff in the Department, in the Prison Medical Services, the Civil Service Occupational Health Services, the Employment medical service and the Medical Service to the Benefits Agency within Northern Ireland.

I also established and chaired working groups of health service professionals in developing policy advice for the Minister and the Department on various issues such as cancer services; renal dialysis; major trauma and the health services response to SARS.

I was expected to provide an effective bridge between the Minister and the medical profession. This required on the one hand bringing resolved medical advice to the Minister, and on the other hand

facilitating, influencing and persuading the medical profession to accept Government policies and to implement change. I had no role in the employment or management of HPSS doctors.

As one of the Chief Medical Officers in the UK, I sat on various committees which determine policy on national health and health service issues. For example I chaired two national committees, the National Screening Committee and the Pathology Modernisation Committee. I also chaired the UK Zoonoses Committee and the Safety of Blood Committee in rotation with the other CMOs.

As the Inquiry will appreciate from the above, the role of CMO was a varied one. The above is not intended to be an exhaustive description of my time as CMO.

(a) Please describe any change to the role during your time as Chief Medical Officer.

During my 11 years as CMO there were inevitably significant changes in the challenges facing the public health, in health service priorities and perhaps most significantly with devolution. With the arrival of devolution there was an inevitable learning curve and a move towards more locally responsive policy-making.

At the time of devolution there was a restructuring of the Departmental Board and a move towards giving the Chief Professionals a more inclusive role in policy decisions. Instead of carrying a purely advisory role in Public Health I was given an executive role with responsibility for public health policy and the management of the budget and administrative staff in the Public Health Directorate.

(5) In particular, please explain your responsibilities as Chief Medical Officer in regard to the quality of care provided to patients by hospitals, including any responsibilities to ensure that Trusts exercised their statutory duty to provide quality care.

This was not part of the role of Chief Medical Officer. Prior to the introduction of the statutory duty of quality the chain of responsibility (as I understood it) for the quality of care would have been as follows:

(i) *Doctors and other healthcare professionals were responsible for the quality of care they provided*

(ii) *The Trusts had a duty of care to their patients for the quality of care they provided*

(iii) *Any concerns about the standard of care provided by a doctor or healthcare professional could be addressed by their regulator or their employer (the Trust) or commissioning body (the Board)*

(iv) *Any concerns about the performance of a Trust could be dealt with by the Trust Board*

(v) *The Chair of the Trust was appointed by the Minister and was directly accountable to the Minister*

After the introduction of the statutory duty of quality the Trusts and Boards had a further responsibility to monitor and improve the quality of care provided to patients.

(b) Please explain how those responsibilities were fulfilled.

See above

ACCOUNTABILITY ARRANGEMENTS IN THE HPSS

(6) Mr William McKee, former Chief Executive of the Royal Group of Hospitals HSS Trust, has told the Inquiry **(Ref: transcript day 76, 17th January 2013, page 6 lines1-4)** that *"in 1993/1994 ...and subsequently for many years I was specifically not held responsible for clinical safety, clinical quality, clinical matters."* He confirmed **(Ref: transcript day 76, 17th January 2013, page 16 line 4)** that the Board of the Trust had no such responsibility either. His evidence was that the Trust only became responsible for clinical quality in January 2003 when a circular was issued by the DHSSPS advising Trusts that they now had a duty of quality**(Ref: transcript day 76, 17th January 2013, page 7 lines 13-19 and page 8 lines 1-9).**

However, Mr Hugh Mills, former Chief Executive of the Sperrin Lakeland Trust, was asked by the Chairman if the Trust reported Lucy Crawford's death to the Western Board in 2000 *"because the Trust felt that it had a responsibility for clinical care"* and replied *"Oh, certainly the Trust had a responsibility for clinical care."* **(Ref: transcript day 110, 17th June 2013, page 45 lines 18-20)**. Arising from this, please answer the following:

(a) Do you agree with Mr McKee that, prior to the issue of HSS(PPM) 10/2002 on 13th January 2003 **[Ref: 306-119-001]** and the coming into operation of the statutory duty of quality in Article 34 of the Health and Personal Social Services (Quality Improvement and Regulation) Order 2003 in April 2003, the Royal Group of Hospitals HSS Trust had no responsibility for clinical care? Or do you agree with Mr Mills that in 2000 the Sperrin Lakeland Trust did have responsibility for clinical care? Please give reasons for your answer.

My understanding of the position is more in line with Mr Mill's view, as per my answer to (5) above.

(b) What did you consider to have been the major changes brought about by Circular HSS(PPM) 10/2002 in relation to the reporting of adverse incidents?

I understand the aim of the circular was to assist HPSS bodies in implementing and developing Clinical and Social Care Governance arrangements.

(c) Who did you consider had responsibility for clinical care in Health Service hospitals in Northern Ireland prior to the issue of HSS(PM) 10/2002 and the coming into operation of Article 34?

See (5) above

(d) How did that responsibility arise? For example, did you consider it to be statutory, or by virtue of a circular or direction, or by custom and practice? Please give details of any relevant statute, circular or direction.

See (5) above

(e) To whom did you consider that those who had responsibility for clinical care in Health Service hospitals in Northern Ireland prior to 2003 were responsible?

See (5) above

(f) Describe what arrangements were in place to ensure that those responsible for clinical care in Health Service hospitals in Northern Ireland discharged their responsibilities prior to 2003.

See (5) above.

(g) If Trusts were responsible for clinical care prior to 2003, what was the purpose of the duty of quality in Article 34 and what difference did it make?

From my perspective the driving force behind Article 34 was the medical profession's desire to have a statutory duty of quality. Around that time there was a growing concern amongst members of the medical profession that there was too much emphasis on the financial and budgetary accountability of HPSS bodies. The medical profession was concerned about the possibility of this taking precedence over quality of care and hence were keen that there be a statutory duty of quality to mirror the financial accountability system.

DISSEMINATION OF INFORMATION

(7) Please explain your role and responsibilities in the dissemination of information / guidelines / policies to Trusts and Hospitals. In particular:

There is a distinction to be drawn here between public health or regional policies (which did come under my remit) and clinical guidelines (which generally speaking did not come under my remit – the Hyponatraemia guidelines being a notable exception). Insofar as the former type of policies are concerned, I was responsible for disseminating government policies to the medical profession. Examples of these would include issues like the response to the SARS outbreak or the concerns about the MMR vaccine. I understand this question to be aimed towards clinical guidelines which I will address below.

(a) How were new guidelines / practices which were developed elsewhere in the U.K. considered and adapted for use in Northern Ireland?

*Prior to the establishment of NICE (now NIHCE), the vast majority of clinical guidelines were issued by the Royal Colleges. When such guidelines are issued by the Royal Colleges, they are circulated to their members (whether they are practising in Mainland UK or Northern Ireland). For illustration, the RCOG guidelines are listed on their website at http://www.rcog.org.uk/guidelines?filter0%5B%5D=**ALL**. The RCPCH guidelines are listed on their website at http://www.rcpch.ac.uk/title-z. I believe all of the Royal Colleges publish similar guidelines relevant to their speciality.*

Since the early 1990s there has been a body called CREST in NI that was funded by the Department to allow the medical profession to develop guidelines specific to NI.

When NICE was established in England and Wales there was discussion at the Department about whether we should join them or create a body within NI to decide whether to adapt or adopt NICE guidelines. In 2005 the Departmental Board agreed to register with NICE as a commentator organisation in order to receive advance copies of documents at various stages throughout the guideline development process. The Department set up a Standards and Guidelines unit to facilitate comment from clinical experts and policy/professional leads in NI.

(b) How does new guidance find its way into medical training, at undergraduate and postgraduate level?

The medical schools set their own curricula, but the GMC have an oversight responsibility. The GMC's role is to promote high standards in medical education and training. It sets and rigorously checks standards which medical schools need to meet. The Royal Colleges supervise the further training of doctors.

(c) How were issues that required the production of guidelines / policies flagged up to you or the Department by Trusts and Hospitals?

(i) The quality of care provided to patients

(ii) Ensuring that Trusts exercised their statutory duty to provide quality care

(iii) The implementation of guidelines / practices

As mentioned in the opening answer to this paragraph, there is a distinction between public health or regional policies and clinical guidelines. I understand this question to relate to the latter. Generally clinical guidelines would have been issued by the Royal Colleges. Generally speaking therefore issues were not "flagged" to me or the department when it was felt that new guidelines were required. The more obvious route for guidelines to be brought out would be for members of a Royal College to raise the issue with their Royal College who could issue guidelines if necessary. Having said that, if concerns were raised with me, I would have done my best to assist (as I did in this case). This did not happen frequently. There was no formal process by which people would raise these issues with me or the department because the department did not generally have a role to play in setting clinical guidelines. Occasionally I would have been approached by clinicians directly, or by a SAC to advise me of a concern that may require guidelines. In those circumstances I would have referred the issue to CREST to ask if they felt guidelines were required and if so, let them draft them. In the present case I oversaw the guidelines personally because of the level of concern expressed by people at Altnagelvin.

(8) How is it decided that an issue is one which can be handled by, or is limited to, a local hospital as opposed to something that is of regional significance?

The individual who considers there is an issue that needs to be addressed must initially make a judgement on this. They could then refer the issue to their employing trust or Royal College or ask for it to be discussed in a SAC, or take other appropriate action.

(9) In your Witness Statement to the Inquiry at **Ref: WS-075/1, p.2**, you state that Dr Raymond Fulton, Medical Director of Altnagelvin Trust, telephoned you and informed you of Raychel Ferguson's death. In doing so, he mentioned that clinical staff at RBHSC had informed staff at Altnagelvin that they no longer used Solution 18 as they had encountered *"problems with it in the past."*

(a) Prior to Dr. Fulton's phone call, were you aware of this action by RBHSC? Were you aware of any *"problems"* RBHSC had encountered with it *"in the past"*?

No

(b) As Chief Medical Officer, would you have wanted the RBHSC to inform you of this?

The answer to this depends on the nature of the "problems" that RBHSC had. If there was a regional policy or public health issue arising from the problems then I would have expected to have been informed of that.

(c) Did you make any enquiries with the RBHSC about this change in policy regarding Solution 18 or regarding any "problems with it in the past"?

I left that to the working group to explore since it contained representation from RBHSC.

(10) When did you become aware of the death of Claire Roberts?

In the course of this Inquiry.

(11) What steps were taken by your staff to investigate if there were any further deaths from hyponatraemia in Northern Ireland?

None with that goal directly in mind. In the course of the deliberations of the working party I understand information was shared between members.

(12) What exactly led to the establishment of the working party which prepared the hyponatraemia guidelines? Was it only the report of Raychel's death or was there also significant information about other events?

I am not sure what is meant by "significant information about other events". If this is intended to refer to the death of Lucy Crawford, I have already addressed this at 078-013-074. The information I had at the time was that Raychel had died and that there had been "problems in the past" at RBHSC. On that basis Dr Fulton and Mrs Burnside asked for guidance to be issued. I agreed to oversee those guidelines and set up the working group.

(13) You have stated that Medical Directors of Trusts or Directors of Public Health at the Boards would share information arising out of unusual cases or adverse incidents. Was this solely at the discretion of those directors?

Yes

(a) Would you have expected the deaths of:

(i) Adam Strain

Since there was the possibility of media interest and since a statement was made publically by the Trust, I would have expected the Medical Directors and Directors of Public Health to have had some discussion about the case.

(ii) Claire Roberts

I only found out about Claire's case in the context of this Inquiry. I am not sure whether the Medical Directors or Directors of Public Health would have considered there was a need to share information about it, or whether they would have considered it to be of interest primarily to the RBHSC. Since there was no inquest initially, the Medical Directors or Directors of Public Health may not have discussed it. It is difficult for me to say whether I would have expected them to discuss it because the answer depends on their thought processes at the time.

(iii) Lucy Crawford

That would depend on the outcome of the investigation carried out by the Trust into Lucy's death. Given the fact that her cause of death was not attributed initially to fluid management the case might not have been considered by the Medical Directors or Directors of Public Health.

to have been reported to you or the Department under this informal system?

(b) Would you have expected you or the Department to have been informed of 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.

(14) Would you have expected:

(i) The death of Adam Strain

(ii) The statement produced by the RBHSC at Adam's Inquest **[Ref: 011-014-107a]**

(iii) Claire Roberts

(iv) Lucy Crawford

to have been raised at a Special Advisory Committee (particularly the SAC on Anaesthetics in relation to (ii))?

As stated above, I would have thought there would have been some discussion about Adam's inquest at one or more of the SACs. Given there was no inquest initially into Claire's death it might not have been raised at an SAC. Likewise, since Lucy's death was not attributed to fluid management initially, her case might not have been discussed at an SAC.

(15) You have told the Inquiry (**WS-075/1, page 3**) that you first became aware of the death of Lucy Crawford in March 2003. Arising from that;

(a) Please confirm whether you were made aware by the Sperrin Lakeland Trust during the period 2000-2002 of any untoward deaths occurring following treatment in the Trust's hospitals?

Not to the best of my recollection.

(b) Would you have expected the Sperrin Lakeland Trust to have made you or the Department aware of the untoward and unexplained death of a seventeen month old child following treatment at the Erne Hospital? Please give reasons for your answer.

I assume this question relates to Lucy Crawford. The minister would probably have wanted to be briefed on the case if there was likely to be any publicity surrounding the case.

(16) What do you consider to have been the main impetus behind the creation of a formal adverse incident reporting system from 2002?

This is addressed in detail in my last witness statement at 078-013-087 to 078-013-088.

(17) Why was a formal approach not adopted for adverse incident reporting prior to 2002?

The need for a formal approach was only starting to be identified in 1999/2000. Changes cannot be introduced overnight and there was a period of consultation following Best Practice Best Care in 2001. The background is set out in my last witness statement at 078-013-087 to 078-013-088.

(18) Prior to 2002, what would you have expected Trusts / Hospitals to have done (if anything) in regard to informing you when cases involving deaths due to possible medical mismanagement were involved in:

(a) Formal complaint procedures

(b) Coroner's Inquests

(c) Medical negligence actions

I would have expected the Department to be made aware of cases where there was a regional policy or public health issue, or cases where there was likely to be publicity since the minister would require to be briefed about them.

(19) Mr. Clive Gowdy, former Permanent Secretary, DHSSPS, stated in his Inquiry Witness Statement as follows:

"In December 1998, the Department commissioned Healthcare Risk Resources International consultants to undertake a survey of risk management in all HPSS organisations. The terms of reference for the survey were to determine the level of application of risk management methods and the

implementation of best risk management practices within these organisations. Incident reporting was one of the items included in the survey. [...] There was a general perception that there might have been a significant level of under-reporting of adverse incidents."

(a) Were you aware of this report and its findings? Please provide a copy of the report if you are able to do so.

I do not recall this report and do not have a copy.

(b) What was done as a result of the report's finding that *"there might have been a significant level of under-reporting of adverse incidents"*?

N/A

(20) In relation to the "CMO update":

(a) Please describe its purpose.

The CMO update was a means of engaging with the medical profession. It was intended to highlight some news-worthy items of significance to the medical profession. It was intended to be easily read, short and of broad interest.

(b) Please state when was it started.

I understand it was introduced in 1994

(c) Please explain why it was started

I understand it followed some discussion amongst the CMOs about how they might try to communicate better with the broader medical profession.

(d) Please explain who produced it and who decided its contents

It was produced by me and my staff with the final decisions on content being taken by me.

(e) Please explain what preceded it in terms of provision of information.

There was no precedent for the type of communication which the CMO update was attempting to present.

MEDIA INTERVIEWS 2003/04

(21) The Inquiry has been given several transcripts of interviews you gave as Chief Medical Officer to the media in the aftermath of Lucy and Raychel's deaths:

- 17th February 2003 - UTV **[Ref: 069A-033-078]**
- 17th March 2004 - BBC Radio Ulster Evening Extra **[Ref: 034-151-407]**
- 25th March 2004 - UTV's "The Issue"**[Ref: 006-037-375]**
- 25th May 2004 - The Impartial Reporter **[Ref: 034-142-372]**

Please read these transcripts and confirm that their contents are accurate, so far as you can recall. In addition:

They were a long time ago now but I have no reason to doubt their accuracy.

(a) Please provide a copy of the study you referred to in the Impartial Reporter interview **[Ref: 034-142-377].**

This was intended to be a reference to the Arieff article which the Inquiry has already. The figures quoted were intended as a simplified version of those quoted by Arieff at 011-011-076 under the heading "Epidemiological Findings" where he quotes 340 cases of paediatric postoperative hyponatraemia and 29 deaths per 100000 inpatient operations.

(b) Please provide copies of the e-mail correspondence you shared with Dr. Edward Sumner as referred to in the Impartial Reporter interview **[Ref: 034-142-383].**

I believe this was a reference to emails with Dr McCarthy. They are at 007-016-032.

(22) *"Of course it happens occasionally in very ill patients but we have never before seen it in a healthy child."* **[Ref: 069A-033-078]**

(a) Please identify whom you meant by *"we"*.

This is a reflection of my general reluctance to use the personal pronoun. I was not an expert in the field and had not carried out any research myself. I was referring here broadly to the medical profession in NI.

(b) Please explain what you meant by this statement.

I had not been made aware of any instances in NI prior to Raychel's death where a previously healthy child had died from iatrogenic hyponatraemia.

(23) You commented that Adam Strain's case was *"an entirely different clinical situation"* **[Ref: 069A-033-078]** to that of Raychel Ferguson.

(a) Please explain what you meant by this statement.

I understood that Raychel had been a healthy child with no concurrent medical conditions prior to her admission to hospital. I considered this to be different to Adam's case since he had a chronic condition that had required significant medical interventions in the past. Adam also died during the course of a kidney transplant which seemed like a different clinical situation to Raychel who died following a routine appenicectomy.

(24) *"It happens very rarely, but it has happened before. We didn't know that but we have now been able to put in place measures to help prevent it happening again."* **[Ref: 069A-033-079]**

(a) Please identify whom you meant by *"we"*.

See 22(a).

(25) *"What we have recognised in the Health Service in the whole of the U.K. over recent years, is that by putting information together from every quarter of the U.K., that we can learn from the rare event, the untoward events. [...] Northern Ireland [...] is too small a place to effectively learn those lessons from rare events, so therefore we need to be part of a bigger picture."***[Ref: 069A-033-079]**

(a) Please explain what has been done since June 2001 to put information together *"from every quarter of the U.K."*

I believe I was referring here to discussions in the working group chaired by Sir Liam Donaldson on clinical quality which led to the establishment of the NPSA. I was also referring broadly to the lead up to formalised adverse incident reporting which is addressed elsewhere in this statement.

(b) Please explain what you meant by your statement that *"Northern Ireland [...] is too small a place to effectively learn those lessons from rare events"* in the context of the deaths under investigation by the Inquiry.

This was intended to be a reference to the small population of NI which makes it difficult to identify rare problems (since by their nature they do not occur frequently). "Learn" was probably not the best word to use – "identify" or "recognise" would have been better.

(26) *"What we know now is that the fluids which were given to Lucy were the ones that were being used in ordinary custom and practice throughout the whole of the NHS except for one or two practitioners who'd begun to recognise this issue of hyponatraemia where the body goes through this abnormal response in just a very few cases and you being to get oedema or swelling of the brain."* **[Ref: 034-151-407]**

(a) Please explain what you meant by *"abnormal response"*.

Dr Loughrey said at 014-006-015 that "Normally administration of generous volumes of hypotonic fluids will result in a brisk diuresis, and certainly this will be noted by most healthy people who can tolerate drinking large amounts of dilute fluids without consequence".

Dr Jenkins said at 006-002-054 that 'Solution 18 has been routinely used in Paediatric medical practice for a very long time and is rarely associated with any acute electrolyte disturbances such as were seen in this tragic case. However, this is largely related to the range of conditions commonly seen by Paediatricians and cared for within the medical (as opposed to surgical) environment. By and large these are not associated with the syndrome of inappropriate secretion of antidiuretic hormone.'

This was the message I was trying to convey.

I also note that the Inquiry's expert Dr Haynes refers to Raychel having been an "extreme responder".

(27) *"On speaking with Sperrin Lakeland Trust it's quite clear that they did not realise at the time, nor would they have been expected to, that there were implications for the wider service from the case."* **[Ref: 034-151-408]**

(a) Please explain why you consider that Sperrin Lakeland Trust would not have been expected to realise that there were implications for wider service from Lucy's case.

I do not think they initially implicated hyponatraemia as a cause for Lucy's death. I was referring to the fact that they could not have realised the wider implications of hyponatraemia if they did not recognise it as a cause for Lucy's death.

(28) *"This new and emerging problem of hyponatraemia or retention of fluids in a very small number of children"* **[Ref: 034-151-408]**

(a) Please explain how the problem of hyponatraemia or retention of fluids was *"new"* and/or *"emerging"*.

I meant that it was "new and emerging" in the sense that several deaths had been attributed to the condition in recent years and it was starting to be recognised as a problem. Dr Sumner described it to the Coroner as a "Cinderella area of medicine".

(29) *"With Lucy, we saw the first test of what was a very rare occurrence, written up in the medical journals only recently"* **[Ref: 006-037-375]**

(a) Please explain what you meant by this statement. In particular, please explain what you meant by *"written up in the medical journals only recently."*

I think this was intended to be a reference to the fact that there had not been much medical literature on the subject of iatrogenic hyponatraemia in advance of Lucy's death when compared to the amount of literature which was subsequently and continues to be published. In retrospect this was probably a poor choice of words. I was trying to convey the fact that the problem was much more prominent in the medical literature in latter years.

(30) *"The rarity in these 2 events [the deaths of Lucy and Raychel] was the abnormal reaction which is seen in a very few children to the normal application..."* **[Ref: 006-037-377]**

(a) You were cut off by Mr. McKinney before finishing your sentence. Please state how you would have finished the sentence.

I cannot recall what I was going to say when I was interrupted.

(b) Please explain if you considered / consider that Lucy and Raychel received a *"normal application"* of IV fluids.

I meant "normal" only in the sense that solution 18 was widely used. I did not mean to refer to the rate or quantity infused since I would not have had the expertise to comment on that.

(31) *"In the knowledge of the evidence which has been in the medical journals over the past 4 years since Lucy's death, [the coroner's findings are correct], but in the light of what was known in the medical community throughout the whole of the U.K. in the year 2000, when poor Lucy died, there were very few people who would have known what was going wrong, apart from one or two experts who had begun to notice the very abnormal reaction in certain children."* **[Ref: 006-037-378]**

(a) What do you consider *"was known in the medical community throughout the whole of the U.K. in the year 2000"*?

See (c) below.

(b) Please explain the basis of your statement that *"there were very few people who would have known what was going wrong"*.

See (c) below.

(c) Please explain the basis of your statement *"apart from one or two experts who had begun to notice the very abnormal reaction in certain children"*.

From discussions I had with Dr Ted Sumner and Prof Cyril Chantler I understood that the problem was only recognised in specialist centres. Dr Sumner in particular was frustrated by the lack of understanding of the risks associated with hypotonic solutions. I also understood from discussions with members of the SAC paediatrics that there was a lack of awareness of the risk of fatal iatrogenic hyponatraemia within the paediatric medical community in NI.

(d) In particular, please explain what you meant by "*the very abnormal reaction in certain children*".

See 26(a) above.

(32) *"The coroner and I together, both recognise that these 2 tragic deaths [Lucy and Raychel's] brought together as a pattern, then allowed us, to put two and two together and to recognise that there were some strange but rather unique features afoot which needed to be taken into..."* **[Ref: 006-037-378]**

(a) Please explain the "*strange but rather unique features*" that you consider Lucy and Raychel's cases shared.

I cannot now recall what point I was trying to make here. I think I meant that they were strange and unique in the sense that they were both otherwise healthy children.

(b) Please explain if you recognised any pattern between the deaths of Raychel Ferguson and Adam Strain.

I am not sure whether this question means to refer to me recognising a pattern prior to the interview, at interview or subsequently. In the interview I was being asked about Lucy and Raychel's cases, not Adam's. There were similarities and differences between their cases and Adam's with the most obvious similarity being the use of Solution 18 and the most obvious difference being the context of the treatment.

(33) *"Going back to the year 2000, it would not have been unusual for a doctor or a group of experts not to have recognised what happened to Lucy. It is easier to do that in the knowledge of what has been presented to us through the medical journals in the last 4 years."* **[Ref: 006-037-379]**

(a) Please explain the basis of your statement.

This was a reference to the fact that the risk associated with hypotonic fluids was not well recognised at that time. Dr Sumner described it as a Cinderella area of medicine. The clinicians at Altnagelvin also did not clearly appreciate the risk associated with hypotonic fluids when they were treating Raychel. By the time of this interview the risk was much better appreciated.

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

The Inquiry have only invited specific responses in relation to extracts from the interviews. Other extracts are also relevant, such as:

BBC Evening Extra 18th March 2004

Audrey Carville: ... At the inquest last month into Lucy Crawford's death, the coroner John Leckey said Lucy died from poor treatment compounded by poor record keeping. You've studied the case, could her death have been prevented?

Dr Campbell: Well firstly, if Mr And Mrs Ferguson are listening, I would like to extend to them my personal heartfelt sincere sympathy to them. Based on the knowledge that we now have, **the deaths of Lucy and Raychel may indeed have been entirely preventable** and as a

parent I share with the Fergusons, I know how dreadful that conclusion is for them...[emphasis added]

UTV The Issue 25th March 2004

Fearghal McKinney: The Coroner said the Doctor gave the wrong liquid at the wrong dose, nothing to do with how the victim responded to it, that's what happened, isn't it. That's what happened to Lucy?

Dr Campbell: In retrospect, **yes.** [emphasis added]

Fearghal McKinney: The Coroner said it was the wrong dose and too much, now you are backtracking on that, do you accept the Coroner's findings?

Dr Campbell: In the knowledge of the evidence which has been in the Medical Journals over the past four years since Lucy's death, **yes** that is true... [emphasis added]

It is clear from the above extracts that I did accept that these deaths had been caused by clinical mistakes.

It is relevant however for the Inquiry to consider the context in which I was being asked to comment on these cases. I understood prior to the UTV interview that there was going to be a panel including Hugh Mills and an expert paediatrician. When I attended the interview I found I was the only person being interviewed and I was also faced with an aggressive tone of interview.

Looking back on the interviews I can see the potential for them to be misinterpreted and I regret that. I think this was in part due to differing agendas between the interviewers and me. Fearghal McKinney for example seemed to be under the misconception that I was somehow ultimately accountable for the provision of medical care in Northern Ireland. He seemed to want to make the case that I was responsible for the fact that guidelines hadn't been introduced prior to Raychel's case which could have prevented her death. I felt that was unfair. On the other hand, my main aim in attending the interviews (from a public health point of view) was to convey the rarity of this problem and the fact that guidelines had been introduced to address it. I thought that if parents became worried that IV fluids were unsafe they might not seek appropriate medical attention when their children were sick and I was concerned about the possibility of that resulting in unnecessary harm to children.

5.9.13