OPENING: DEPARTMENT (HISTORIC ISSUES)

THE ORAL HEARINGS IN THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Chairman: O'Hara J

Banbridge Court House, 30th October 2013

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I. Introduction

The Opening

1. This Inquiry is not just about the deaths in hospital of Adam Strain, Claire Roberts, Lucy Crawford, Raychel Ferguson and Conor Mitchell. Nor is it only about the role that hyponatraemia and the intravenous administration of what has become known as 'Solution No.18' played in their deaths. Although it involves all of these matters, on which a great deal of evidence has been received, arguably the 'legacy' questions which arise from all that material are:

   How should lessons be learned from the deaths of children in hospital so as to reduce the incidence of such deaths re-occurring? Who has the responsibility to ensure that those lessons are learned and that practice is changed accordingly?

2. Mr. Chairman, you explained your approach to the key issues to be investigated by the Inquiry at a Public Hearing on 3rd February 2005:[1]

   "The public needs to know that our Health Service is managed and organised in such a way that when unfortunate events happen, as they inevitably will, lessons are learned to prevent their repetition. Nobody can reasonably expect that mistakes will not occur in our Health Service. What we all should expect, however, is that steps will be taken to help to minimise the risk to the health of others in the future. [p.2] …

   Perhaps the single most important [general issue] is what procedures have been in place to ensure that information and lessons which emerge from inquests are disseminated within the hospital concerned, within the Health Service in Northern Ireland and within the Health Service throughout the United Kingdom generally." [p.10]

3. The Revised Terms of Reference require consideration of such issues at all levels from the Department (including the Chief Medical Officer) to the relevant Trusts and Boards, down to the management of the individual hospitals and right down to the specific hospital Divisions/Clinical Directorates.

4. The Inquiry has therefore investigated the reporting and management structure within the hospitals, Trusts and Area Boards, together with the dissemination of information amongst clinicians working in different hospitals and the institutional linkages between the different Trusts, Area Boards, Department, Chief Medical Officer, Coronial Service and the Medical School at Queen's University Belfast.

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1 Ref: 303-005-057

5. The Inquiry's investigation has also included the means by which the Department's 2002 Guidance on the Prevention of Hyponatraemia in Children was produced, the process by which it was introduced into hospitals and the extent to which its enforcement was audited and evaluated, together with the quality of the governance exercised by the Department in relation to the occurrence of serious adverse incidents in hospitals.

6. Up to this point in the Inquiry's investigations, each of the individual cases has been considered clinically and from the perspective of governance. The investigations have thus far been confined to the conduct of clinicians, managers and others directly involved and with the performance of the Trusts and area Boards. This section of the Inquiry's investigations will deal with Departmental involvement.

7. Given the volume of documentation available for consideration, this Opening will:

   (i) Seek to summarise the factual background and the steps taken by those involved[2]

   (ii) Set out the principal issues in relation to the Department in the context of the evidence gathered to date, the revised Terms of Reference and updated List of Issues

   (iii) Identify the main areas which the Legal Team consider require further investigation through questioning in these Oral Hearings.

II. Evidence Received

8. The Inquiry's search and request for relevant documents started in or about the beginning of 2005. Requests are guided by the Inquiry's Advisors and its Experts, as well as arising out of documents witness statements requested by the Inquiry.

9. For convenience, the source of the documents and other material received is set out in Appendix I to this Opening.

10. Mr. Chairman, you will be making findings and recommendations on the basis of all of the evidence received and not just what you receive during the Oral Hearings. You have a complete set of the documentary materials gathered by the Inquiry as part of its investigation, the contents of which do not therefore require to be summarised. Rather, I will try to indicate the key elements of the evidence that has been received in relation to the Department.

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[2] Throughout this Opening, the positions of those involved is given as it was at the relevant time, unless it is relevant to also identify their position at any other time

Expert Reports

11. In all of the cases to date, the Inquiry, with the guidance of its Advisors, has engaged Experts to address a number of specific issues. In relation to the Department, the Inquiry has retained Professor Gabriel Scally[3] (Director of WHO Collaborating Centre of Healthy Urban Environments), who previously provided a report and gave evidence in relation to Lucy Crawford's case. He has examined the Departmental issues that will be addressed during this section of the Oral Hearings.[4]

Background Papers

12. The Background Papers prepared by Experts that are of particular relevance to the Departmental issues are:

    (i) Dr. Michael Ledwith,[5] Clinical Director of Paediatrics, Northern Trust and Professor Sir Alan Craft,[6] Emeritus Professor of Child Health, Newcastle University, on the training and continuing professional development of doctors in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2009

    (ii) Professor Mary Hanratty,[7] former Vice-President of the Nursing and Midwifery Council and Professor Alan Glasper,[8] Professor of Children and Young Persons' Nursing, University of Southampton on the training and continuing professional development of nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2011

    (iii) Dr. Jean Keeling, Paediatric Pathologist, on the system of procedures for the dissemination of information gained by post-mortem examination following unexpected death of children in hospital[9]

    (iv) Dr. Bridget Dolan, Barrister at Law and Assistant Deputy Coroner, on the systems of procedures and practices in the United Kingdom for reporting and disseminating information on the outcomes or lessons to be learned from Coroner's Inquests on deaths in hospital (involving Hospitals, Trusts, Area Boards, Department of Health and Chief Medical Officer)[10]

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3 See List of Persons Ref: 337-001-001 *et seq*
4 Ref: 341-002-001 *et seq*
5 Ref: 303-046-514 *et seq*
6 Ref: 303-047-561 *et seq*
7 Ref: 303-048-571 *et seq*
8 Ref: 303-049-674 *et seq*
9 Ref: 308-020-295 *et seq*
10 Ref: 303-052-715 *et seq*

13. All of those reports have been published on the Inquiry's website. The report of Professor Scally will be published on the Inquiry's website in due course in accordance with the Inquiry Protocols and procedures.

Oral Testimony

14. Finally, there are the accumulated Transcripts of the Inquiry's Oral Hearings.[11] For the most part it will not be necessary for that oral evidence to be set out to any great extent because, Mr. Chairman, you have already had the benefit of hearing it first hand and, in many cases, of questioning the witnesses yourself. Furthermore, the transcripts of that evidence are available on the Inquiry's website.

III. Schedules Compiled by the Inquiry

15. The Inquiry has received a vast amount of information and in order to assist you and the Interested Parties, the Legal Team has compiled a number of schedules and charts as ancillary documents to distil the salient points.

List of Persons Involved in relation to the Department

16. The Legal Team has also compiled a list of all those persons involved in relation to the Department from all of the information received by the Inquiry.[12] It explains their position at the relevant time and the date on which they state they became aware of each of the children's deaths. The List of Persons also identifies those who have made statements and to whom they were provided.

Chronology of Departmental Response

17. The Legal Team has prepared a Chronology[13] detailing the key events in each of the Children's cases and, more pertinently, the response of the statutory bodies in regard to management, governance and lessons learned.

18. This document is created almost exclusively from sources regarding events that appear to be uncontroversial. However, if any particular timing or event is disputed, then it is expected that witnesses giving oral evidence will make their position clear to the Inquiry, either directly or through their legal representatives.

19. The structure of the Chronology is straightforward and follows the pattern already established in previous cases.

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11 On the Inquiry website, under heading of 'Oral Hearings- Timetable'
12 See List of Persons Ref: 337-001-001 *et seq*
13 Ref: 337-003-001 *et seq*

IV. Revised Terms of Reference

20. The Inquiry's original Terms of Reference have been revised following the removal of Lucy from the scope of the Inquiry and the addition of the cases of Claire and Conor. They may now be construed to require:

> *"an Inquiry into the events surrounding and following the deaths of Adam Strain, Claire Roberts and Raychel Ferguson, with particular reference to:*
>
> *(i) The care and treatment of Adam Strain, Claire Roberts and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case*
>
> *(ii) The circumstances of the death of Conor Mitchell in the context of the guidelines on fluid management in children*
>
> *(iii) The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of*
> *(a) Adam*
> *(b) Claire*
> *(c) Lucy (in relation to the failure to identify the correct cause of her death and the alleged Sperrin and Lakeland Trust cover up)*
> *(d) Raychel*
> *(e) Conor (in relation to the guidelines on fluid management in children)*
>
> *(iv) The communications with and explanations given to the respective families and others by the relevant authorities."*

21. It is useful to repeat again that the 'governance' issues arising out of the Inquiry's revised terms of reference are being considered at three 'levels':

> (i) Hospital management and clinical governance
>
> (ii) Corporate or trust level; and
>
> (iii) Government or departmental level within the Health and Social Care Services (HSC).

22. This final section of the Inquiry's work will focus on the Departmental level, but the governance structures and processes that existed between the Trust boards and the Department, and which have previously been considered, remain relevant.

23. The reference in the Revised Terms of Reference to investigating *"The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths"* raises important management and governance issues at a Departmental level as it

concerns the ability of the relevant bodies both to learn lessons and to act effectively on them.

V. Institutions Involved

24. The offices, bodies and organisations whose conduct falls most specifically to be investigated include:

(i) The Department of Health, Social Services and Public Safety (DHSSPS)

(ii) The Chief Medical Officer (CMO) and the Chief Nursing Officer (CNO)

(iii) School of Medicine, Dentistry and Biomedical Sciences at Queen's University Belfast, which provides undergraduate training and research facilities. The School has established Sub-Deaneries within the local Health Trusts to try and ensure greater integration between academic and clinical colleagues.

(iv) Northern Ireland Medical and Dental Training Agency (NIMDTA) and its predecessor the Northern Ireland Council for Postgraduate Medical and Dental Education. The task of both of those bodies was to ensure that doctors and dentists are effectively trained to provide patients with the highest standards of care.

(v) Medicines and Healthcare Products Regulatory Agency (MHRA) and its predecessor Medicines Control Agency, which ensures that medicines and medical devices work and are acceptably safe. The Commission on Human Medicines (CHM) is a committee of the MHRA whose duties came into being on 30th October 2005.[14] For the purposes of this Inquiry and in relation to the use of Solution No.18, those duties include advising Ministers on matters relating to human medicinal products and promoting the collection and investigation of information relating to adverse reactions for human medicines for the purpose of such advice. Prior to its formation, that function was carried out by Medicines Commission and the Committee on Safety of Medicines.

(vi) NHS National Patient Safety Agency (NPSA) which was a special health authority of the National Health Service (NHS) in England. It was created to monitor patient safety incidents, including medication and prescribing error reporting. On 1st June 2012, the key functions of the NPSA were transferred to the NHS Commissioning Board Special Health Authority.

[14] Medicines Act 1968 as amended by the Medicines (Advisory Bodies) Regulations 2005

(vii) HPSS Regulation and Quality Improvement Authority (RQIA), is Northern Ireland's independent health and social care regulator, which promotes safe practice on the use of medicines and products.

(viii) The Patient and Client Council (PCC) was established by statute[15] in April 2009 as part of the reform of Health and Social Care in Northern Ireland, replacing the Health and Social Service Councils. The overarching objective of the PCC is to provide an independent voice for patients, clients, carers and communities on health and social care issues.

VI. List of Issues in Relation to the Department

25. Some of the issues developed from the Inquiry's Revised Terms of Reference have already been addressed both in written material to the Inquiry and evidence during the Oral Hearings. As a result Mr. Chairman, during the Oral Hearings in July 2013, you explained the approach to be taken in relation to the remaining issues being investigated by the Inquiry:[16]

"Throughout the public hearings, evidence has been given which could only cause concern to anyone who has heard or followed that evidence. The evidence is of a dominant culture of keeping quiet about mistakes which were made even when those mistakes led to the deaths of children. This has been put in different ways by different witnesses. For instance, in recent weeks, Dr Ian Carson said that as recently as 2000, it was common for the NHS to advertise its successes but not its failures. Dr Crean put it more bluntly when he said, metaphorically speaking, that doctors feared they would be shot for putting their heads above the parapet.

As against that, I have been told many times that the picture has changed dramatically and for the better in the last 13 years. I have been told that clinical governance has developed to a degree which is unrecognisable. The suggestion is that there is now mandatory reporting of adverse incidents, that lessons are learned and that there is a greater willingness to report doctors to the GMC. There is also said to be more reporting of deaths to coroners. It is also clear that in the specific area of hyponatraemia, guidelines were developed, perhaps on the foot of Altnagelvin Hospital reporting Raychel's death to the Department, and that those guidelines have been reviewed and updated on foot of review by the RQIA.

It is not my function to try to re-organise the National Health Service nor am I capable of doing so. Instead, what I have to do, beyond scrutinising the specific events which have been put under the spotlight so far, is to investigate how the systems and procedures of statutory and public bodies have improved in the last decade. This will involve examining whether the culture referred to above is still prevalent. I will then

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15 Health and Social Care (Reform) Act (Northern Ireland) 2009 and The Patient and Client Council (Membership and Procedure) Regulations (Northern Ireland) 2009.

16 Ref: Transcript of the Oral Hearings on 2nd July 2013, p.157-158

recommend what might be done better and differently in future. Against that background, I have reviewed the List of Issues."

26. Mr. Chairman, you made it clear during those Oral Hearings that you considered an important issue to be the means by which the Department was able to know the extent to which the Trusts were discharging their duty to provide quality medical care.

27. In accordance with that approach, you produced a Revised List of Departmental issues dealing with 'Responsibility for Quality Care', 'Actions of doctors, nurses and Trusts', 'Chief Medical Officer and Hyponatraemia Guidelines'.[17]

28. In addition, you requested 'Position Papers' from the Department, Belfast Trust, and the Health and Social Care Board dealing with the evidence already received and the current position. The 'current position' is a matter to be addressed by a series of panel discussions to be conducted at the end of these Oral Hearings.

29. The Revised List of Departmental Issues is divided into two sections, 'historic' and 'current'.

Historic Issues

30. As you stated, Mr. Chairman, during the Oral Hearings in July:[18]

"using Conor's case as an illustration, we want to look at how the 2002 guidelines were disseminated and how their implementation was monitored and enforced. This is relevant because we've heard from time to time over the last year of evidence that there is a concern about how best to disseminate and enforce various protocols, guidelines and new sources of learning."

"I think the first issue is about who was responsible for the quality of care from the point when trusts were established in the early to mid-1990s until 2003...[T]o the extent that there were issues before 2003, I'm concerned to find out how the department actually knew what was going on in hospitals prior to that time and then, since 2003, have the trusts exercised their statutory duty to provide quality of care, who have they been answerable to and how has that reporting worked?"

31. The historic issues, in summary, are:

(i) Who had responsibility for quality of NHS hospital care from the mid-1990s until the statutory duty of care in 2003 and how was that fulfilled?

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17 Ref: 337-004-001 *et seq*

18 Ref: Transcript of the Oral Hearings, 2nd July 2013, p.162

(ii) What did the Department know about the deaths of Adam, Claire, and Lucy, and when?

(iii) What did the CMO and/or the Chief Nursing Officer and/or their senior officials know about the deaths of Adam, Claire or Lucy before 2001?

(iv) What led to the establishment of the Hyponatraemia Working Group?

(v) What led the CMO to say what she said in 2004 about the deaths of the Children?

(vi) How were the 2002 guidelines disseminated, monitored and enforced by Trusts and the Department (using Conor as an illustration and taking account of the evidence already heard e.g. from Drs. Taylor and Crean)?

(vii) What have been the respective roles and contributions in this area of the Trusts, Department, Health and Social Care Board (HSCB), Public Health Agency (PHA), Regulation and Quality Improvement Authority (RQIA), Chief Medical Officer (CMO) & Chief Nursing Officer (CNO)?

Current issues

32. There are a number of strands to this segment of the Inquiry, but in summary it is to establish how matters are currently addressed with a view to examining the scope for further improvement:

(i) Reporting and investigating adverse clinical incidents

(ii) Disseminating lessons

(iii) Reporting to the GMC/NMC/Coroner

(iv) How Trusts now exercise their statutory duty of quality

(v) The respective roles and contributions are in this area of the Trusts, Department, HSCB, PHA, RQIA, CMO & CNO

(vi) Adoption and dissemination of guidelines/practices

(vii) What more needs done to improve the service.

33. These current issues will be covered in the final week of the Oral Hearings by a series of panel discussions. This Opening will focus on the historic issues.

VII. The Department of Health, Social Services and Public Safety (DHSSPS)

34. At the outset of this section of the Inquiry, it is important to understand the relationship between the Department and its Boards and Trusts, and how that has changed over the period with which the Inquiry is concerned.

The Department

35. The powers of the Department of Health, Social Services and Public Safety derive from the Health & Personal Social Services (Northern Ireland) Order 1972 and subsequent amending legislation. Article 4 of the Order imposes on the Ministry the duty to:

    (i) Provide or secure the provision of integrated health services in NI designed to promote the physical and mental health of the people of NI through the prevention, diagnosis and treatment of illness

    (ii) Provide or secure the provision of personal social services in Northern Ireland designed to promote the social welfare of the people of Northern Ireland

    (iii) Discharge its duty as to secure the efficient coordination of health and personal social services.

36. The Departments (Northern Ireland) Order 1999 expanded the functions of the Department of Health and Social Services to include responsibility for Public Safety.

37. The duties above were in force at the time of the children's deaths. They were revoked in 2009 and replaced by a more detailed duty in Section 2 of the Health and Social Care (Reform) Act (Northern Ireland) 2009. One of the express duties on the Department under the 2009 Act is to monitor and hold to account the Regional Board, Regional Agency, RBSO and HSC Trusts in the discharge of their functions.

38. The structure of the health service in Northern Ireland upon the admissions of the Children to the Royal Belfast Hospital for Sick Children (RBHSC) and their deaths there in 1995, 1996, 2000, 2001 and 2003 respectively is as shown in 'Structure of the Health Service in Northern Ireland (pre-2007)'[19] and on the map 'Health and Personal Social Services Northern Ireland'.[20] The present structure is set out in 'Structure of the Health Service in Northern Ireland – Commissioning of Services'.[21]

[19] Ref: 303-039-505
[20] Ref: 300-001-001
[21] Ref: 303-040-506

The Boards

39. Article 16(1) of the Health & Personal Social Services (Northern Ireland) Order 1972 provides for the Ministry to establish Health and Social Services Boards for such areas as it may determine. Four Boards - Eastern, Northern, Southern and Western - were established in 1973.

40. Article 17 (1) (a) of the 1972 Order provides that Boards are to:

"exercise on behalf of the Ministry, such functions (including functions imposed under an order of any court) with respect to the administration of such health and personal social services as the Ministry may direct"

41. In 1989, the Government announced a fundamental review of the NHS which led to the publication of a White Paper 'Working for Patients'[22] which proposed major reforms. The Government's principal objective was to show real improvement for every patient. In Northern Ireland this involved:

(i) Delegating as much power and responsibility as possible to local level, including the appointment of Unit General Managers in major acute hospitals and the reorganisation of the management of the major teaching hospitals in Belfast

(ii) Engaging doctors in the management of the services and obtaining their commitment to medical audit

(iii) Encouraging a small number of hospitals to progress towards self governing status as Hospital Trusts

(iv) Encouraging larger GP practices to opt for their own budgets for buying particular services direct from hospitals

(v) Reconstituting Health and Social Services Boards as management bodies

(vi) Developing a simpler system for resource allocation which will fund Boards for the population they serve rather than the services they provide

(vii) Strengthening arrangements for the external audit of the services to ensure better value for money.

42. The delegation of responsibility for the delivery of healthcare to local level was to be achieved through the introduction of an internal market, where money would follow the patient and be directed to areas of service delivery.

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[22] Working for Patients: A Summary of the White Paper on the Government's Proposals Following its Review of the NHS - January 1989

This also introduced the concept of a 'Purchaser/Provider split', with Boards assuming the role of Service Commissioners (or Purchasers) with Trusts as Providers of services.

43. The Department policy document 'People First' (1990), introduced a division between the commissioning and provision of health and social services. The implementation of the major Community Care Reforms in 1993 established Boards as commissioners of services responsible for:

(i) Assessing the health and social care needs of their resident population

(ii) Strategic planning to meet need

(iii) The development of purchasing plans.

The Trusts

44. Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991 gave the Department the power to establish Health and Social Services Trusts, with a remit to provide local acute and community health services. Schedule 3 of the 1991 Order sets out the duties, powers and status of Trusts.

45. The Department document 'HSS Trusts: A Working Guide' (1991) states:

"A key element of the changes is the introduction of HSS Trusts. They are hospitals and other units which are run by their own Boards of Directors; are independent of Health and Social Services Board Management; and have wide-ranging freedoms not available to units which remain under Health and Social Services Board control i.e., directly managed units.

Whilst remaining fully within the health and personal social services, Trusts differ in one fundamental respect from directly managed units - they are operationally independent. Trusts have the power to make their own decisions - right or wrong!- without being subject to bureaucratic procedures, processes or pressure from higher tiers of management."

46. Trusts were created as self-governing bodies, managerially and administratively independent of Boards. Trusts became providers of healthcare in a contractual relationship with Boards as purchasers / commissioners. Trusts were also required to assess needs within their respective local areas and plan to address these in consultation with Boards.

47. The accountability of the Trusts directly to the Department will be examined later in this Opening.

The Permanent Secretary & the Departmental Board

48. The Permanent Secretary is the most senior civil servant in the Department, charged with running the Department on a day-to-day basis. The Permanent

Secretary is non-political and generally holds his position for a number of years as distinct from the changing political Secretaries of State to whom they are responsible and provide advice.

49. From 1997 to 2005, the Permanent Secretary was Mr. Clive Gowdy.[23] His predecessor was Mr. Alan Elliott.[24]

50. The Departmental Board, which was constituted of senior officials and professionals of the Department who reported to the Permanent Secretary, met on a monthly basis to discuss important matters.

51. Those who attended the monthly Board meetings included the following (positions as in 2003/04):[25]

- Permanent Secretary (who acted as Chairman)
- CMO
- Chief Nursing Officer
- Chief Pharmaceutical Officer
- Chief Dental Officer
- Deputy Secretary, Resources & Performance Management Group
- Deputy Secretary, Strategic Planning & Modernisation Group
- Deputy Secretary, Primary, Secondary & Community Care Group
- Chief Executive, Health Estates Agency
- Principal Information Officer
- Chief Inspector, Social Services Inspectorate

52. The involvement of the Departmental Board in the matters being investigated by the Inquiry will be the subject of examination during the Oral Hearings.

Department Reorganisation in 2007 & 2009

53. In June 2002, the Northern Ireland Assembly Executive launched the Review of Public Administration with a view to putting in place accountable and effective arrangements for public service delivery. The final outcome of the Review launched in 2002 was announced by the Secretary of State in November 2005. It led to a major reorganisation of health and social care to be effected in two phases.

54. The first phase was the establishment of five new integrated Health and Social Care Trusts with effect from 1st April 2007. They replaced the Trusts that had been in operation during the cases of all of the Children. The original Health and Social Services Boards remained in place until the introduction of the second phase in April 2009 which involved their replacement by the Health and Social Care Board.

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23 See List of Persons Ref: 337-001-001
24 See List of Persons Ref: 337-001-003
25 Ref: 004-018-222; Ref: 004-019-236; Ref: 004-020-238

55. In addition, seven Local Commissioning Groups (LCGs) were created in April 2007 before being reduced to five with boundaries aligned to those of the Trusts in April 2009. Prior to that re-organisation, the four Boards commissioned services from the Trusts. The functions of the LCGs are to assess and plan for health and social care needs and to deliver the care required to meet those needs.

56. The relationship between the Trusts and the LCGs between April 2007 and April 2009 and from April 2009 onwards is shown in a chart compiled by the Inquiry 'Boards, Trusts, Hospitals & Commissioning Groups (pre-April 2007 and post-April 2009)'.[26] In addition, the intermediate position which operated between 2007 and 2009 is shown on the map 'Health and Social Care, Northern Ireland: Existing Acute, Local and Mental Health or Learning Disability Facilities'.[27] The final position is shown on the map 'Health and Social Care Trust Boundaries showing location of Hospitals'.[28]

57. In broad terms, the function of those organisations, and therefore their relevance to the work of this is Inquiry, is that:

    (i) The Department of Health, Social Services and Public Safety (and its predecessor) has overall authority for health and social care services in Northern Ireland and for the allocation of government funding for that purpose. That authority includes the formulation of policy and legislation for hospitals.

    (ii) The Health and Social Care Board (and its predecessor Regional Boards) commissions the health and social care services.

    (iii) The five Trusts, of which three are particularly involved in the work of the Inquiry (and their predecessor hospital Trusts), are responsible for the provision of the health and social care services. Each Trust manages its own staff and services and controls its own budget.

    The Royal Group of Hospitals Trust has been of particular concern to the work of the Inquiry as it included the RBHSC where all the Children received their final care and treatment and ultimately died. The structure of that Trust as it was in 1995 and 1996 when Adam and Claire were admitted to the RBHSC is shown in 'Royal Group of Hospitals Trust – Organisation Structure 1995/96'.[29] The Royal Group of Hospitals and therefore the RBHSC are now within the Belfast Trust, the structure of which is shown in a chart compiled by the Inquiry

26 Ref: 303-042-509
27 Ref: 300-002-002
28 Ref: 300-078-149
29 Ref: 303-043-510

'Belfast Health & Social Care Trust: Organisation Structure (present day)'.[30]

(iv) The Hospitals within those Trusts is where health and social care services are actually delivered. The work of this Inquiry has been concerned with four of those Hospitals:

- RBHSC
- Erne Hospital
- Altnagelvin Area Hospital
- Craigavon Area Hospital

Direct Rule

58. It should be noted that, at the time of Adam's admission to the RBHSC on 26th November 1995, Northern Ireland was under a period of 'direct rule' from Westminster with the Secretary of State for Northern Ireland responsible for the Departments of the Northern Ireland government.

59. Under 'direct rule', the Northern Ireland Department of Health came under the remit of the Parliamentary Under-Secretary of State at the Northern Ireland Office. The Minister responsible for health care in Northern Ireland at the time of Adam's admission was Malcolm Moss.

60. The Belfast Agreement was signed on 10th April 1998. It entered into force on 2nd December 1999 and ushered in a period of devolution. The significance of that, so far as this Inquiry is concerned, is that it resulted in the Departments (Northern Ireland) Order 1999, which established the Department of Health Social Services and Public Safety as a 'devolved Department'. The first Minister of the Department was Bairbre de Brún.

61. Although devolution has now been continuously in place since May 2007, it was suspended on four occasions starting with 12th February 2000. The Ministers responsible for health and social care in Northern Ireland from 1994 (the year prior to Adam's death) until the present day, including through periods of direct rule, are shown in a chart 'Ministers responsible for Health and Social Care in Northern Ireland from 1994 to Present Day'[31] compiled by the Inquiry.

62. Although the Department was sometimes subject to direct rule, and sometimes subject to devolution, the underlying hierarchy (from the Permanent Secretary down) does not appear to have been directly affected. It is unclear whether direct rule permitted the introduction of UK-wide policies, practices and guidelines into Northern Ireland.

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30 Ref: 303-044-511

31 Ref: 303-041-507-8

VIII. Responsibility for Care in the DHSSPS

63. A statutory duty of quality for Trusts was imposed in 2003. It is therefore important to examine the performance and accountability of Trusts both before (and thus at the relevant time for the children's' deaths) and after the imposition of the statutory duty.

The Management Executive

64. The Management Executive was primarily established to act as the operational arm of the Department.[32] It was tasked with overseeing the establishment and performance of the Trusts and other operational Health bodies within the Department. As such, it was charged with ensuring that contemporaneous Government policies in relation to health and social care matters, such as the operation of the internal market in healthcare and the delivery of services, were properly implemented.

65. Mr. Clive Gowdy was Chief Executive of the Management Executive from January to March 1997,[33] replacing Mr. John Hunter.[34] On Mr. Gowdy's appointment as Permanent Secretary, he was replaced by Mr. Paul Simpson.[35][36]

66. The Chief Executive of the Management Executive was responsible for overseeing the implementation of government health and social care policies and delivering on the Department's statutory duty to secure the provision of health and social services.[37]

67. This broad set of responsibilities embraced a number of key issues:

(i) Development of appropriate measures and programmes

(ii) Dissemination of information and instructions

(iii) Monitoring the delivery of objectives

(iv) Interacting with the various health and social care bodies on their performance

(v) Securing and providing appropriate levels of funding

(vi) Ensuring proper stewardship of public monies

(vii) Maintaining proper lines of governance and accountability

32 Ref: WS-062/2, p.3
33 Ref: WS-062/2, p.2
34 See List of Persons Ref: 337-001-003
35 Ref: WS-084/2, p.2
36 See List of Persons Ref: 337-001-003
37 Ref: WS-062/2, p.3

(viii) Keeping Ministers informed and briefed on significant issues.

68. The Management Executive was discontinued in 2000 with the creation of the Northern Ireland Executive[38] and its functions absorbed within the traditional structure of the Department.[39]

Pre-statutory Duty of Care – Mr. Gowdy's views

69. Mr. Gowdy, the former Permanent Secretary, states in his Witness Statement to the Inquiry:

"The Trusts were ultimately responsible to the Minister for the services they provided. That responsibility was generally exercised through the Department. It was also the case that they had a responsibility to the Health and Social Services Boards who commissioned their services."[40]

70. He adds:

"It is, of course, correct to say that there was no specific statutory duty for the quality of clinical services on Trusts, their Boards or Chief Executives prior to the Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003. It might also be argued that previously the historical perception within the Health and Social Services system was that clinical matters were for the clinical professionals. However, it does not follow that Trusts or their Boards or Chief Executives had no responsibility for clinical care or clinical outcomes prior to the commencement of the Order."

71. He offers five reasons for this conclusion:

(i) Management Executive Circular METL 2/93

(ii) The decline of deference to clinicians

(iii) The increase in risk management and clinical governance

(iv) The increased interaction between hospital managers and clinicians

(v) The need to be aware of what was happening in Trusts

- ***Management Executive Circular METL 2/93***

72. Management Executive Circular METL 2/93[41] sets out "*the framework of accountability which will exist between the Management Executive (ME) and HSS Trusts in the future.*" This was an important document setting out how the relationships between the Trusts, Board and Department were to operate in

38 Ref: WS-084/2, p.2
39 Ref: WS-062/2, p.3
40 Ref: WS-062/2, p.6
41 Ref: WS-062/1, p.527

the light of the separation of the roles of purchasing and providing brought about by the Health and Personal Social Service (Northern Ireland) Order 1991. It established a tripartite framework of accountability for Trusts:

(i) To the public

(ii) To purchasers; and

(iii) To the Management Executive (i.e. the Department).

73. The Circular made clear that Trusts were accountable to the Management Executive "*for the performance of their functions, including the delivery of objectives and targets set out in the Strategic Direction and the Business Plan"* whilst the Department would retain "*ultimate legal responsibility for the functions and will wish to ensure that both Boards and trusts are discharging their responsibilities."*

74. Circular METL 2/93 states that "*the primary accountability of Trusts is for the quantity, quality, efficiency of the service they provide*." Mr. Gowdy has commented:[42]

"It is hard to see how this could be interpreted as excluding any corporate accountability or responsibility for the clinical care or clinical outcomes delivered to the patients. In fact, the raison d'être of the Trusts concerned was to deliver effective clinical care to sick or injured people and it is rather difficult to see how they might argue that they had no interest in, or responsibility for , the quality of the service they were providing."

75. The circular contains a section[43], which sets out the areas the Department will focus on in monitoring and says that:

"*While the normal lines for service delivery issues will be via purchasers, Trusts will be expected to provide any information required by the ME in support of Ministers or for Parliamentary purposes."*

76. The circular also includes *"Ground Rules for Intervention"*.[44] These state that intervention by the Management Executive in the affairs of a Trust should be exceptional but may be judged necessary in certain circumstances e.g. "*items of concern relating to patient or client care*". It is therefore unclear how the Management Executive could be apprised of such concerns, in the absence of a formal system for the reporting of serious adverse incidents.

42 Ref: WS-062/2, p.4
43 Ref: WS-062/1, p.531-2
44 Ref: WS-062/1, p.532

- ***Decline in Deference to Clinicians***

77. Mr. Gowdy states that historical deference to clinicians was "*well in retreat*"[45] by the 1990s and early 2000s, citing events such as the Beverley Allitt trial (1993), the Bristol Paediatric Cardiac Surgery Inquiry (1998-2001), the Inquiry into the Retention of Human Organs at Alder Hey (1999) and the trial of Dr. Shipman (2000). He states that these had:

"undermined much of the mystique of clinicians and had shown that greater corporate responsibility had to be exercised by Health Service organisations in relation to the quality of the clinical care provided by them."[46]

- ***Increase in Risk Management & Clinical Governance***

78. Mr. Gowdy states that, in the late 1990s and early 2000s, the issues of risk management and clinical governance were being developed and were becoming increasingly part of the systems in place within the Health and Social Services.[47] He adds:

"These were matters on which Trust Boards and Chief Executives were in the lead for their organisations and they necessarily had to involve the clinical services and the role of the clinicians."

79. The Department emphasised *"better practice"* in its Management plan for 1995/96 – 1997/98 indicating that improvements in practice necessitate a strategy for *"continuing quality improvement."*[48] This was a broad clinical governance approach requiring hospitals to *"ensure that there is a clear policy on; clinical audit as part of a programme to improve all aspects of service quality not just clinical outcomes [together with] support and evaluation of quality improvement programmes; and multi-disciplinary approaches to the development of best practice in service delivery."*[49]

- ***Increased interaction between hospital managers and clinicians***

80. Mr. Gowdy states that the Ministerial focus on the delivery of services against targets and policy objectives brought hospital managers into direct contact and negotiation with clinicians on the performance of their services.[50] He adds:

"No Trust Board or Chief Executive could afford to argue that these were purely matters for clinicians and for which they bore no responsibility."

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45 Ref: WS-062/2, p.4
46 Ref: WS-062/2, p.5
47 Ref: WS-062/2, p.5
48 Ref: 306-083-001
49 Ref: 306-083-017
50 Ref: WS-062/2, p.5

- ***Knowledge of what was happening in Trusts***

81. Finally, Mr. Gowdy argues that issues of public, media or political debate or controversy often involved the delivery or outcomes of clinical services.[51] Ministers expected the Trusts to be aware of what was happening within their organisations and to be in a position to provide briefing on the matter in question. Therefore:

"It would have been regarded as unacceptable, or indeed wholly negligent, for a Trust Chairman or Chief Executive to have pleaded ignorance on the grounds that he or she had no responsibility for the quality of the clinical care provided within his or her organisation."

Views of Other Witnesses

82. Mr. William McKee, former Chief Executive of the Royal Group of Hospitals HSS Trust, gave evidence to the Inquiry[52] that "*in 1993/1994 ... and subsequently for many years I was specifically not held responsible for clinical safety, clinical quality, clinical matters*". He confirmed that the Board of the Trust had no such responsibility either.[53] His evidence was that the Trust only became responsible for clinical quality once the statutory duty was introduced.[54]

83. 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.*"[55]

84. When Mrs. Stella Burnside, Chief Executive of the AHHSST, was asked who bore ultimate responsibility for the quality of care in that Trust in 2001, she stated: "*I did*"[56] and indicated that:

"...the manner in which the service is delivered, how much service is delivered and the quality of the outcome and experience of the patient was something that we were trying to develop clear responsibility and accountability for. The fact that the legislation did not arrive until much, much later is, you know -- whether it is a legal point or not, I don't know. But clearly a hospital's purpose is to care for patients and to have everybody working with that ethos together is a very important part of the culture of the organisation."[57]

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51 Ref: WS-062/2, p.5
52 Ref: Transcript of the Oral Hearings, 17th January 2013, p.6, lines 1-4
53 Ref: Transcript of the Oral Hearings, 17th January 2013, p.16, line 4
54 Ref: Transcript of the Oral Hearings, 17th January 2013, p.7, lines 13-19 and p.8 lines 1-9
55 Ref: Transcript of the Oral Hearings, 17th June 2013, p.45, lines 18-20
56 Ref: WS-046/2, p.8
57 Ref: Transcript of the Oral Hearings, 17th September 2013, p.10, lines 8-18

85. Of the Department witnesses who were asked by the Inquiry all, including the CMO[58] and Mr. Gowdy[59], agreed with the position taken by Mr. Mills and Mrs. Burnside.

86. Dr. Henrietta Campbell[60], the former CMO, has explained that, prior to the introduction of the statutory duty of quality, the chain of responsibility for the quality of care might be described as:[61]

(i) Doctors and other healthcare professionals were personally responsible to their patients 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 (e.g. General Medical Council in the case of doctors) 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 or the commissioning body

(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).

87. Mr. Paul Simpson[62], who was successively Deputy Chief Executive and Chief Executive of the Management Executive (HSSE) and then Deputy Secretary in the Department, says that "*The line of accountability was from the Boards to the Department. My recollection is that there were no arrangements for the HSSE and later the Department to hold formal accountability reviews with Trusts.*"[63]

88. His predecessor Mr. John Hunter[64] said something similar citing the impracticality of holding Trusts to account directly because of the number of Trusts.[65] He said the Department held Trusts to account "*primarily through the purchasers*".[66]

58 Ref: WS-075/2, p.4
59 Ref: WS-062/2, p.4
60 See List of Persons Ref: 337-001-002
61 Ref: WS-075/2, p.3
62 See List of Persons Ref: 337-001-003
63 Ref: WS-084/2, p.4
64 See List of Persons Ref: 337-001-003
65 Ref: WS-349/1, p.3
66 Ref: WS-349/1, p.5

89. Mr. John McGrath[67], who became Director of Planning Performance Management in the Department in 1999, states that his remit was to "*provide an integrated accountability system across the HPSS*"[68] and that this line of accountability was from the Department through the Boards to the Trusts. He also states that Trusts would not normally account directly to the Department, but would instead do so with the Boards.[69]

- ***Accountability Reviews***

90. Mr. McGrath adds that, by the time he left his post in January 2003, there was no programme of formal accountability meetings between the Department and the Trusts and that the principal reason for this was not to undermine the primary role of Boards in holding Trusts to account.[70] He recalls that at the time of his departure, the Department was contemplating an annual formal meeting with each Trust chaired by the Director of Planning Performance Management.

91. Mr. Clive Gowdy states that, although he has no recollection of attending such meetings[71]:

> *"Accountability reviews were conducted by the Department with the Trusts each year to scrutinise their performance across the range of their business. While these reviews did not focus specifically on issues of clinical care, they did examine the delivery of services and the achievement of outcomes and objectives."*[72]

92. Similarly, Mr. Alan Elliott refers to:

> "*annual accountability reviews through which the Minister and/or Permanent Secretary and senior officials met the Chairman and senior officers of each Board or Trust to work through an agenda of facts and questions holding the body concerned to account. These in my experience were not a routine chore, but a serious piece of business.*"[73]

93. Dr. Paddy Woods, the current Deputy Chief Medical Officer, told the Inquiry that, in 2000, formal accountability meetings took place between the Department and Sperrin Lakeland Trust twice annually, usually mid-year and end of year.[74]

94. This is in contrast to Mr. McGrath who states that, by the time he left his post in January 2003, there was no programme of formal accountability meetings

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67 See List of Persons Ref: 337-001-004
68 Ref: WS-362/1, p.5
69 Ref: WS-362/1, p.9
70 Ref: WS-362/1, p.11
71 Ref: WS-062/2, p.8
72 Ref: WS-062/1, p.5
73 Ref: WS-348/1, p.5
74 Ref: 323-001a-001

between the Department and the Trusts and that the principal reason for this was not to undermine the primary role of Boards in holding Trusts to account.[75] He recalls that at the time of his departure, the Department was contemplating an annual formal meeting with each Trust chaired by the Director of Planning Performance Management.

95. Similarly, according to Mr. David Galloway[76] *"formal review meetings with Trust Chief Executives did not commence until the autumn of 2002."*[77]

96. There would seem to have been a difference between Departmental officials as to the accountability arrangements of Trusts to the Department as appears from their statements above. This is something that will be explored further during the Oral Hearings.

The views of Professors Scally & Swainson

97. Professor Scally, in his report into Lucy's case[78], explained that there was no direct managerial accountability between Trusts and Boards in 2000. This was in line with Government policy of the 'purchaser-provider split' established in 1989. The relationship thus became a Board agreeing with a Trust both what services it required of the Trust and the sums of money to be passed to the Trust in respect of those services. A Trust was thus responsible to a Board for its fulfilment of the commitment as laid out in that agreement.

98. Professor Scally was additionally of the view that, by 2000, Trusts were accountable to the Department for the management of services (e.g. in the Erne Hospital).[79] In exercise of that accountability arrangement, Professor Scally has explained that the Trusts *"could reasonably [have been] expected to have notified the DHSSPS if they felt that the death was potentially due to inadequate treatment."*[80]

99. Professor Scally's analysis of the Trust's accountability to the Department for the management of services is not accepted by the Department. Accordingly this is a matter to be addressed at the Oral Hearings.

100. Finally in his report, Professor Scally explains the duty of the Trust to the Department:

> *"As it was to the DHSSPS that the Trust was accountable, it would have been appropriate that the death and, in particular, concerns about her treatment should have been reported to the DHSSPS.*

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75 Ref: WS-362/1, p.11
76 See List of Persons Ref: 337-001-001
77 Ref: WS-066/1, p.4
78 Ref: 251-002-002
79 Ref: 251-002-004
80 Ref: 251-002-015

There were procedures in place requiring Trusts to notify the DHSSPS of certain untoward events. In particular, there were systems in place covering events affecting patients in the care of mental health and learning disability services. It has to be noted, however, that there does not appear to have been a requirement for Trusts so to do in relation to potentially avoidable death or other instances of serious clinical failure in other clinical areas.

The replacement of the accountability of the Erne Hospital to the WHSSB with accountability of the Sperrin Lakeland Trust to the DHSSPS does not appear to have been accompanied by the enunciation of a systematic protocol for the reporting of incidents. It is however possible to argue that there is a general duty to keep the DHSSPS informed of events that have had serious consequents and which might become the subject of media attention or public controversy."[81]

101. As Professor Swainson observes:

"There was no explicit duty on the Trust to communicate a rare fatal event to the Board or to the Department, or more generally".[82]

102. He stated that there were no clear lines of communication in place for the sharing of significant events in 2001. He did expect informal communication to the extent of warning about press or other interest.

103. In Lucy's case, the officers of the former WHSSB shared Professor Scally's view that the Sperrin Lakeland Trust was arguably obliged, within the terms of the operating norms of that time, to inform the Department of serious adverse incidents. Mr. Frawley set out his view:

"I would have expected the Trust to notify the DHSSPS of an 'untoward death' such as that of Lucy Crawford because the Trust's line of accountability was to the DHSSPS."[83]

104. Dr. McConnell was asked in his second Inquiry witness statement to identify the section or the department within DHSSPS to whom Lucy's death should have been reported by the Trust. He answered:

"Following the creation of Trusts throughout Northern Ireland in the 1990s, a mechanism was developed within DHSSPS, through the Permanent Secretary's office/department, for direct managerial responsibility to be handled through the line management. Trust Chief Executives reported individually and collectively through regular meetings to a Senior Officer within the PS's department on issues within their Trusts. Any major event, such as Lucy's death, might have been considered relevant to report within that line of management."[84]

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81 Ref: 251-002-016
82 Ref: 226-002-026
83 Ref: WS-308/1, p.14
84 Ref: WS-286/2, p.4

105. Professor Scally took the view that, on being informed by the Trust of Lucy's death, there was also an onus on the Board to make the Trust aware that they should contact the Department (and, for that matter, the Coroner).[85] In addition:

"The role of 'scrutinising' the action of the Trust should fall squarely within the remit of the DHSSPS as the body to which the Trust was formally accountable."[86]

Responsibility of the Trusts to the Boards

106. As an example of what was being done at Board level, the Eastern Health & Social Services Board issued a 'Quality Standards: Commissioning Quality Care' dated August 1998 in which they laid out the essential issues for commissioners (the Board) and providers (the Trusts).

107. The essential issues for the Board were to determine the quality standards to be met, and to monitor, test and evaluate commissioning decisions. The essential issue for the Trusts meanwhile were to:

(i) Assure the Board about quality

(ii) Develop medical/nursing/clinical audit processes

(iii) Explore ways of discovering and reacting to patients' needs

(iv) Find ways of ensuring continuous improvement in the quality performance of the whole organisation.

108. The standards expected by the Board included such items as:

(i) Untoward events

(ii) Complaints procedures

(iii) Discharge planning

(iv) Paediatric services including medicine, surgery, pathology, nephrology & ICU

(v) Quality standards – general (acute) hospital services & inpatient services

(vi) Quality standards under the Northern Ireland Charter for Patients & Clients[87] (including the Eastern Board's own charter of November 1992 – 'Making Life Better').

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85 Ref: 251-002-006
86 Ref: 251-002-011
87 Ref: 317-025-001

109. In addition to the 'Quality Standards', the EHSSB also issued 'Technical Information Associated with the Commissioning Intentions Document' which provides guidance on how to deal with the EHSSB's standards and requirements. This document makes specific reference to NCEPOD:

"The Board seeks to [...] address the quality issues identified through the medical audit process including NCEPOD."

110. The publications above suggest that the Royal Group of Hospital Trust was accountable to the EHSSB for 'quality standards' in the provision of health care.

Programme for Government

111. One of the five priorities of the Northern Ireland Executive's first Programme for Government (2000) was 'Working Together for a Healthier People'. It acknowledged that that Northern Ireland had fallen behind the rest of the U.K. in the provision of healthcare, and included a commitment to put in place a framework to raise the quality of services provided to the community by the Health Service and tackle issues of poor performance.

Best Practice - Best Care (BPBC)

112. This framework was set out in 'Best Practice – Best Care' (BPBC) which was issued for consultation in April 2001.[88] BPBC proposed:[89]

(i) Setting standards to improve services and practice

(ii) Ensuring local accountability in the delivery of healthcare

(iii) Improving the monitoring and regulation of healthcare.

- ***Standards to Improve Services & Practice***

113. It was recognised that a "*more co-ordinated and structured approach*"[90] was required and that clear, consistent, evidence-based guidelines and standards would improve outcomes for patients.

114. Many guidelines were produced on a reactive basis rather than as part of a planned agenda.[91] There was no systematic approach to the identification of gaps. In addition, it noted that there was no single focus for the production and dissemination of guidelines or standards for healthcare, as they were developed by a range of bodies across Great Britain and Northern Ireland,

88 Ref: WS-068/1, p.9
89 Ref: WS-068/1, p.13
90 Ref: WS-068/1, p.25
91 Ref: WS-068/1, p.27

including CREST and RMAG, and that this was causing "*uncertainty*".[92] In England and Wales, they had reacted to this with the establishment of NICE in 1999. CREST, RMAG and NICE are mentioned in further detail later in this Opening.

115. BPBC therefore proposed a "*single, easily accessible source for producing and disseminating standards and guidelines for services*" which would also handle guidelines emanating from NICE and other standard setting bodies.

- ***Ensuring Local Accountability***

116. It was proposed to introduce *"a system of clinical and social care governance, backed by a statutory duty of quality"*[93] noting that governance arrangements are already in place to ensure *"overall probity, transparency and adherence to public service values."*

117. It also proposed a system of clinical and social care governance that:

"will bring together all the existing activity to the delivery of high quality services for example, education and research; audit; risk management and complaints management."[94]

- ***Improving Monitoring & Regulation of Services***

118. BPBC noted that there must be "*a clear line of accountability from front line delivery back to the Executive"*[95] and that when things are going wrong in the Health Service, *"people need to know what failures are identified quickly, openly investigated and put right."*[96] The latter statement is an issue, Mr. Chairman, that has been at the centre of the governance hearings during this Inquiry.

119. BPBC proposed the introduction of a new independent body – the Health and Social Services Improvement Authority (which would become the RQIA) as a means of monitoring the delivery of services.[97]

- ***The Effect of BPBC***

120. BPBC therefore initiated performance reform:[98]

(i) The implementation of a statutory duty of care

92 Ref: WS-068/1, p.28
93 Ref: WS-068/1, p.14
94 Ref: WS-068/1, p.14
95 Ref: WS-068/1, p.49
96 Ref: WS-068/1, p.52
97 Ref: WS-068/1, p.15
98 Ref: 333-129-013

(ii) The establishment of Safety, Quality & Standards Directorate within DHSSPS as a single engine for the production and dissemination of standards and guidelines

(iii) The introduction of Service Frameworks

(iv) The creation of the Guidelines and Audit Implementation Network (GAIN) as a single, regional body to facilitate regional audit and guideline development for the HSC

(v) The establishment of the RQIA

(vi) The establishment of formal links with NICE and the subsequent process of departmental endorsement of NICE guidance for use in the HSC.

121. On 24th August 2001, a letter was sent to Chief Executives of HSS Boards and Trusts regarding Priorities for Action - Monitoring and Accountability, stating that the Department would now monitor progress towards the achievement of Priorities for Action on a quarterly basis.[99]

Statutory Duty of Quality

122. In March 2002, the Departmental Board adopted a common model of risk management for the Department and all of its associated bodies, including the HPSS. The Australia/New Zealand model of risk management, which was already in use in the NHS in England, was adopted and promulgated to the HPSS through the circulars on Corporate Governance and the Statement of Internal Control (HSS (PPM) 3/2002 and AS/NZS 4360: 1999 - Risk Management (HSS (PPM) 6/2002)).[100]

123. In February 2003, the Department issued guidelines to the HPSS on the implementation of clinical and social care governance (Circular HSS (PPM) 10/2002). These stressed the importance of organisations taking corporate responsibility for performance and for providing the highest possible standard of clinical and social care. The Circular also placed an emphasis on adverse incident management.

124. Mr. Gowdy has described the changes brought about by the Order as follows:

"This circular was designed to strengthen the drive to develop solid clinical and social care governance arrangements throughout the HPSS. The onus placed on the family of HPSS organisations was to act rigorously and timeously in reviewing, enhancing and monitoring the performance of their organisation against high standards of performance in the delivery of their services.

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99 Ref: WS-066/1, p.168

100 Ref: WS-062/1, p.93

It was made clear that adverse incident management was an integral part of this process and the culture should be one of openness and honesty where poor performance, adverse events and near misses could be raised and dealt with through appropriate action.

It made clear that these matters should be shared with and, where appropriate, outwith the organisation to enable lessons to be learned but stopped short of imposing a duty of reporting such matters to the Department or other external body.

The circular did, however, introduce the monitoring of clinical and social care governance in HPSS organisations by the RQIA and gave it the role of helping organisations to tackle serious or persistent shortcomings in clinical or social care service delivery."[101]

125. The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 created the legal framework for strengthening the quality of health and social care services in Northern Ireland and extended regulation and quality improvement to a wide range of establishments and agencies. It was passed on 27th February 2003 and came into effect a month later.

126. The Order also introduced a statutory duty of quality to be placed on HSS Boards, HSS Trusts and some special agencies with regard to services they provide. Mr. Gowdy has described this as:

"a seminal development which brought the importance of quality of performance into sharp relief and joined clinical and managerial staff in the pursuit of high quality care and treatment."[102]

127. The CMO described the driving force behind Article 34 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as being:

"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."[103]

101 Ref: WS-062/2, p.5
102 Ref: WS-062/2, p.6
103 Ref: WS-075/2, p.5

Post-statutory Duty of Quality

128. The accountability arrangements across the Department as of 2005 were therefore:[104]

(i) The Department was responsible for carrying out the wishes of Ministers. Its primary functions were in relation to the formulation and implementation of policy and the allocation of resources. Apart from providing I.T. and estates services to the HPSS, the Department had no direct operational responsibilities in relation to the HPSS. The Department set the framework, priorities and targets within which the HPSS was required to operate and maintained a high-level overview of the performance of the HPSS. As appropriate, the Department issued guidance and direction to the HPSS and ensured that there were effective governance systems in place in the HPSS organisations.

(ii) The Boards acted as the planners and commissioners of health and social services for the population of their areas. The Department allocated funds to the Boards to meet the cost of providing those services and the Boards in turn provided the Trusts with funding for the commissioned and agreed services. The Boards worked in close collaboration with the Trusts on service, quality and finance issues.

(iii) The Trusts provided the services to their respective communities. They also employed the clinical and administrative staff working in the hospitals and social care facilities to deliver that service. The Trusts were directly responsible for the operation of these services and for the quality of the service delivery. A statutory duty of quality was imposed on all Trusts. Governance within Trusts was the responsibility of the Board of the Trust. Each Trust Board is made up of a Chair and Non-Executive Directors, appointed by the Minister through the public appointments process, and the Executive Directors who sat on the Board on an ex officio basis.

129. According to Mr. Gowdy, the Department had a responsibility to ensure that the whole system was delivering what Ministers wished and that the health and social care needs of the population of Northern Ireland as a whole were being addressed.[105] He states that there were a number of ways in which the system was held to account:

(i) Accountability reviews were held with all of the Health and Social Services bodies each year

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104 Ref: WS-062/1, p.12
105 Ref: WS-062/2, p.7

(ii) Chief Executives were formally designated by him as Accountable Officers and required to account to him in relation to financial matters and the use of public monies

(iii) All HSS organisations were required to provide responses to issues raised with the Minister or on matters being examined by officials

(iv) Regular meetings (2 or 3 per year) were held with all Chief Executives as a group

(v) Meetings were held with the Chairs and Boards of each of the HSS organisations each year

(vi) Departmental officials had close working contact with the various HPSS bodies on a daily basis. There were accountability reviews with HPSS bodies each year.

IX. Chief Medical Officer (CMO)

130. For the purposes of the historic issues which the Inquiry is investigating during this section of the Inquiry, the CMO during the relevant time period was Dr. Henrietta Campbell. She assumed office in January 1995 and retired in February 2006. She was replaced temporarily by Dr. Ian Carson in an acting capacity and then permanently by Dr. Michael McBride.

Role & Responsibility

131. The CMO is the head of the medical service within the Northern Ireland Civil Service. Accordingly, she 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. However, she had no role in the employment or management of HPSS doctors.

132. The CMO is responsible to the Department and the Minister for providing advice on medical issues.[106] She 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.

133. The CMO has specific responsibility for improving the health of the population in his/her role as the senior public health professional within Northern Ireland. These included:

[106] Ref: 001-031-109

- 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
- Immunisation
- 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.

134. According to Dr. Campbell, public health and regional policies came under her remit as CMO. She was therefore responsible for disseminating government policies regarding public health to the medical profession. Examples of these would include issues like the response to the SARS outbreak or the concerns about the MMR vaccine.

135. However, Dr. Campbell states that clinical guidelines did not normally come within the CMO's remit[107] and that she made a notable exception in the formulation and publication of the hyponatraemia guidelines.

136. In the case of hyponatraemia, the CMO says that she oversaw the production of the guidelines personally "*because of the level of concern expressed by people at Altnagelvin.*"[108] Dr. Miriam McCarthy[109] has said that the Hyponatraemia Guidance was drafted "*as a response to the knowledge of a single case in which there was a mortality associated with hyponatraemia*".[110]

137. In addition, she had a role to play in setting standards for the quality of medical care.[111] According to Dr. Campbell, that did not extend to rendering her responsible or accountable for the delivery of services or for the actions of individual clinicians.[112]

Specialty Advisory Committees (SACs)

138. The Specialty Advisory Committees (SACs) provided a forum for discussion with the CMO on strategic issues, service provision and workforce planning.

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107 Ref: WS-075/2, p.5
108 Ref: WS-075/2, p.6
109 See List of Persons Ref: 337-001-002
110 Ref: WS-080/2, p.4
111 Ref: 004-010-154
112 Ref: 004-010-154

139. The SACs were established by the Department to provide professional advice to the CMO. SACs in a number of specialities were established in the 1970s.

140. A report in 1981 entitled 'Medical participation and advice in the management of the Health and Personal Social Services in Northern Ireland' recommended the establishment of SAC (Paediatrics). Following the report, new SACs were introduced, including one for Paediatrics. It is likely that the SAC (Paediatrics) was established in 1983.

141. Terms of Reference for all SACs were agreed in 1992:

(i) To advise the Department through the CMO on strategic policy and planning issues

(ii) To comment on the quality of service provision with specific reference to agreed quality standards

(iii) To review the balance between local and regional service provision

(iv) To advise on specialty manpower issues on a regional basis and to attain commitment to agreed change in training grade numbers and ratios

(v) To advise on the implications for the Health Service of medical, technological and scientific advances.

142. It appears the SACs met about twice each year. The Committees were chaired by the CMO, or a member of the CMO's team of medical officers on behalf of CMO. Members were invited to contribute agenda items, and others were included by the CMO. Items were discussed and decisions about further work or advice were made at the meeting. Minutes of the meeting were distributed to each attendee.

143. SACs provided an opportunity for collective professional advice to the CMO rather than the formal decisions on most policies or procedures. All SACs were regional not hospital based.

144. Those who were members of the SAC (Paediatrics) at different times included Drs. Carson[113], McCarthy, McConnell, Crean, McAloon[114] and Professor Savage.

145. Dr. Elaine Hicks, Consultant Paediatric Neurologist, RBHSC noted during the Oral Hearings:[115] *"I think many of us were not convinced that [the SAC structure] was as effective as it might have been."*

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113 See List of Persons Ref: 337-001-002

114 See List of Persons Ref: 337-001-004

115 Ref: Transcript of the Oral Hearings, 7th June 2013, p.22

146. Dr. McCarthy has commented: "*There was a view among Departmental colleagues and SAC members that the frequency of meetings (most were annual) meant the meetings were not designed to facilitate a response to the wide range of issues arising between meetings and for · which alternative mechanisms were needed.*"[116]

147. The SAC (Paediatrics) last met in 2009. Following a review of advisory structures it was agreed that the SACs would no longer meet.

Sources of Information / Knowledge for the CMO

148. There was no formal process by which issues of performance of clinical standards could be raised with the CMO or the Department because the Department did not generally have a role to play in setting clinical guidelines. Occasionally, the CMO would have been approached by clinicians directly, or by one of the SACs to inform her of a concern that may necessitate guidelines. In those circumstances, the CMO says that she would have referred the issue to CREST to ask if they felt guidelines were required and if so, let them draft them.

149. It seems that the CMO met with Trust Medical Directors on a regular basis. These meetings were informal, and were set up to provide a channel of communication between the CMO and Trust Medical Directors.[117] They were somewhat 'ad hoc' in nature and intended to mirror the SACs. Very few papers were circulated in advance due to the absence of secretarial support.

150. The CMO also established and chaired working groups of health service professionals to develop policy advice for the Minister and the Department on a broad range of health issues. As one of the CMOs in the UK, she sat on various committees to determine policy on national health and health service issues.

151. Dr. Campbell says that, generally speaking, issues were not 'flagged' to her or the Department when it was felt that new guidelines were required.[118] However, if concerns were raised with her, she "*would have done [her] best to assist*", but that "*this did not happen frequently*".[119]

152. Another important responsibility of the CMO was communication with the public on matters relating to the protection and promotion of health. The means of doing so was through publications, the media and other public appearances. Her appearances in the media in the aftermath of Raychel and Lucy's Inquests will be examined in greater detail later in this Opening.

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116 Ref: WS-080/2, p.19
117 Ref: 021-018-037
118 Ref: WS-075/2, p.6
119 Ref: WS-075/2, p.6

153. The CMO was supported by a Senior Medical Officer, whose role was to provide support to senior officers within Medical and Allied Branch and to provide medical advice to the Minister and also to policy colleagues within the then Department of Health and Social Services.[120] Ultimately, the Senior Medical Officer was accountable to the CMO. For some areas of work, the immediate accountable officer was either a Principal Medical Officer or Deputy Chief Medical Officer. Dr. Miriam McCarthy was Senior Medical Officer from October 1998 to April 2006.

CMO Update

154. The 'CMO Update' was a newsletter provided by the CMO's Office to provide a regular communication with the medical profession on matters of importance. As the CMO described it:

> *"The CMO update was a means of engaging with the medical profession. It was intended to highlight some newsworthy items of significance to the medical profession. It was intended to be easily read, short and of broad interest."*[121]

155. It was started in 1994, following discussion amongst the CMOs about how they might try to communicate better with the broader medical profession.[122] It was produced by a Senior Medical Officer or medical officer in the Medical and Allied branch, with administrative support.[123]

156. As will be seen later, information about the Hyponatraemia Guidance was included in the CMO's Update No.21 of April 2002.[124]

Chief Nursing Officer (CNO)

157. The CNO provided an expert contribution on nursing, midwifery and health visiting matters to the Department, and like the CMO, assisted in the development, promotion and implementation of health and social policy. She was a member of Departmental Board.

158. During the relevant period being investigated by the Inquiry, the CNO was Miss Judith Hill[125] (now Professor Dame Judith Hill). Despite the fact that Ms. Elizabeth McElkerney, a Senior Paediatric Nurse, was a member of the CMO's Working Group[126], Professor Dame Hill has stated that she was unaware of the children's deaths due to hyponatraemia until February 2004, at which point she spoke to the CMO to see if there were any nursing issues

120 Ref: WS-080/2, p.3
121 Ref: WS-075/2, p.10
122 Ref: WS-075/2, p.10
123 Ref: WS-080/2, p.20
124 Ref: 075-085-346
125 See List of Persons Ref: 337-001-001
126 Ref: WS-076/2 p.5

involved.[127] The CMO told her that the main issues related to medical practice. The CNO says that she asked for a review to be undertaken of nursing education in relation to fluid management.

X. Clinical Guidelines

159. Mr. Gowdy explains that the policy for the dissemination of guidelines from the Department down to the Boards and Trusts was "*a pragmatic one*".[128] Where the Department judged that there was a need to issue direction to the HPSS, the matter would be set down in a circular letter and issued to the relevant Chief Executives, Chairs or Chief Professional Officers as appropriate. Such circulars had a fairly standard format and were given a specific reference number to identify them.

160. He adds that many of the directions and guidelines issued "*were not subject to any specific monitoring*".[129] It was assumed that the HPSS organisations concerned would act in accordance with them. Where it was considered appropriate, confirmation of action might be required and deadlines for reply might be set. It was a matter of judgement when to adopt this latter approach.

161. He states that issues requiring guidance may have emerged in various ways including:[130]

    (i) The Minister might ask for the issue of information or instruction to the HPSS bodies

    (ii) The Department might wish to set out a particular policy direction for the HPSS

    (iii) The Department might judge that guidance or direction was required to ensure appropriate or consistent action by HPSS bodies

    (iv) The Department might wish to issue information, guidance or direction to the HPSS similar to that issued to NHS bodies in England

    (v) HPSS bodies might request guidance from the Department on matters of concern to them. The HPSS bodies would do this by letter, through meetings with the Department or in more informal contact with Departmental officials.

127 Ref: WS-082/1, p.2
128 Ref: WS-062/2, p.11
129 Ref: WS-062/2, p.11
130 Ref: WS-062/2, p.11

Royal Colleges

162. Prior to the establishment of NICE, the vast majority of clinical guidelines were issued by the Royal Colleges.[131] Members of a Royal College would raise an issue with their College who could issue guidelines if necessary. When such guidelines were issued, they were circulated to their members wherever they practised.

Clinical Resource Efficiency Support Team (CREST)

163. CREST was established in 1988 under the auspices of the DHSS (Northern Ireland) Medical Advisory Structure.[132] It was funded by the Department to allow the medical profession to develop guidelines specific to Northern Ireland. Its formation was at the instigation of the medical profession because of concerns about the increasingly competitive pressures on scarce health service resources. It was felt that it was vitally important to continue to maintain the highest possible standards of quality while recognising the need to take account of economic constraints and improve the cost effectiveness of the service.[133]

164. The CREST group comprised 18 health care professionals from health and personal social services in Northern Ireland with an active interest in promoting clinical efficiency. The Chairman was the late Professor Gary Love, Emeritus Professor of Medicine at Queen's University, Belfast.

165. In pursuing its work, the medical profession in Northern Ireland was invited to suggest specific target areas and CREST then operated by commissioning small sub-groups or task forces to address agreed topics. The Convenor of CREST was Dr Glenda Mock[134], Senior Medical Officer, DHSSPS.

166. CREST had the following terms of reference:

(i) To promote clinical efficiency in the health service in Northern Ireland while ensuring that the highest possible standard of clinical practice is maintained

(ii) To identify examples of good clinical practice in Northern Ireland, throughout the United Kingdom and elsewhere

(iii) To disseminate ideas, examples of good practice in Northern Ireland and other relevant information to health care professionals in Northern Ireland

131 Ref: WS-075/2, p.6
132 Ref: 333-129-009
133 Ref: 333-129-010
134 See List of Persons Ref: 337-001-001

(iv) To consider ways of encouraging new initiatives including the commissioning of further research

(v) To evaluate on an ongoing basis what effect, if any, the group's activities and deliberations are having on the use of clinical resources in Northern Ireland.

167. By the time it was amalgamated with two other organisations to form GAIN, CREST had produced 51 pieces of guidance and associated resources for the HSC.

National Institute for Clinical Excellence (NICE)

168. NICE, now the National Institute for Health and Care Excellence, was established in 1999 as a Special Health Authority with the remit to promote clinical excellence and the effective use of resources for people using the NHS in England and Wales.

169. NICE is a Non-Departmental public body tasked with producing national guidance on the promotion of good health and the prevention and treatment of ill health, as well as developing guidance and quality standards in social care for England.[135]

170. NICE produces a range of guidance including clinical guidelines on the management of specific diseases and groups of patients. [136] NICE guidance is written for implementation in England; it does not automatically apply in Northern Ireland and requires review before endorsement for use in HSC.

171. When NICE was established in England and Wales, there was discussion within the Department about whether Northern Ireland should join them or create a body within Northern Ireland to decide whether to adapt or adopt NICE guidelines.

172. 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 Northern Ireland.

173. The Department established formal links with NICE on 11st July 2006 whereby guidance (generally Technology Appraisals and Clinical Guidelines) published by the Institute from that date, would be locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in the HSC. A new process for the endorsement, implementation, monitoring and assurance of NICE Technology Appraisals

135 Ref: 333-129-011
136 Ref: 333-129-012

and Clinical Guidelines in Northern Ireland came into effect on 28th September 2011, and is set out in circular HSC (SQSD) 04/11.

174. Relevant policy and professional staff in the Department check clinical guidance to ensure that it is applicable to the legal and policy context in Northern Ireland. When endorsed on the DHSSPS website, there are links to any caveats explaining the relevant legal and policy context in Northern Ireland. On rare occasions, a particular section or all of a piece of guidance may be excluded from endorsement because it would be illegal in Northern Ireland. It should be noted that NICE does not allow its actual guidance to be amended, for example to include the Northern Ireland legal and policy context.

175. The Department is currently reviewing the process in order to reduce bureaucracy and allow Trusts to begin implementation of NICE Guidance. If agreed, a new circular will be issued to update and replace circular HSC (SQSD) 04/11.

176. In order to support the implementation of NICE guidance, the Department funds NICE to provide a NICE Implementation Facilitator to work in Northern Ireland. The post has been filled since October 2012.

The Centre for Reviews & Dissemination (CRD)

177. The CRD is a health services research centre based at the University of York. CRD was established in January 1994, and aims to provide research-based information for evidence-based medicine. CRD analyses healthcare interventions, and disseminates the results of research to decision-makers in the NHS. CRD is funded by the UK Department of Health's NHS Research and Development Programme.

178. In February 1999, the CRD published 'Getting Evidence into Practice' which summarises the results of systematic reviews of different dissemination and implementation interventions. It is unclear to what extent the Department in Northern Ireland engaged with the CRD.

Dissemination of U.K. Guidelines in Northern Ireland

179. A number of guidelines and protocols have been mentioned on a variety of issues during the Oral Hearings, in areas such as:

- Consent
- Brain stem death tests
- Surgery (NCEPOD)
- Pathology / conduct of post-mortems.

180. It is an issue to be examined during the Oral Hearings as to what extent the Department/CMO were responsible for disseminating U.K. guidance to the

Boards/Trusts and to what extent they were aware of how such guidance was being implemented at Trust level.

181. Dr. Carson has stated that, during his time as Deputy CMO (from August 2002), where there were 'service level agreements' with national bodies e.g. NICE, NPSA, NCEPOD etc. guidance was then disseminated through the Department.[137]

182. The Inquiry previously looked at the issue of consent during Adam's case and it is a useful area on which to examine the implementation of guidelines prior to 2000.

183. In 1990 the DoH published its 'Guide to Consent for Examination or Treatment'. This states *"a patient has the right under common law to give or withhold consent prior to examination or treatment… This is one of the basic principles of healthcare."*[138] This was followed in 1991 by further guidance entitled 'Welfare of Children and Young People in Hospital'[139] which directs that hospitals *"should ensure that good practices are followed on seeking consent to the treatment of children: a guide to consent for examination and treatment, published by the NHS Management Executive in August 1990, will be of assistance here"*.[140]

184. The British Association for Paediatric Nephrology stated in 1995 that *"any unit offering care for children and young people with renal disease will be expected to implement in full the DoH guidelines 'Welfare of Children and Young People in Hospital'"*.[141] Mr. McKee did not however *"recollect this guidance being adopted by the Department of Health in Northern Ireland."*[142]

185. The NHS Management Executive issued its 'Risk Management in the NHS' Manual in December 1993. This notes *"Obtaining consent to treatment is an area almost entirely under the control of professional healthcare staff and not one in which managers are generally involved.* ***But managers have a responsibility to ensure that professionals are fully aware of their obligations and understand the legal framework in which they are operating****."*[143] (Emphasis added)

186. The 1990 Guide to Consent was amended by the 1992 NHS 'Patient Consent to Examination or Treatment' Guidelines[144] which were in turn consolidated within Northern Ireland by a handbook published on 6th October 1995 containing most of the advice previously included in the 1990 guidelines

137 Ref: WS-077/4, p.7
138 Ref: 305-002-009; Health Circular (90)22
139 Ref: 314-004-001 *et seq* & Department of Health: The Stationary Office, 1991
140 Ref: 210-003-019
141 Report of a Working Party, March 1995, The Provision of Services in the United Kingdom for Children and Adolescents with Renal Disease
142 Ref: WS-061/2, p.7
143 Ref: 211-003-008
144 Ref: 210-003-018 & Issued by the NHS Management Executive, 28th July 1992, SG (92) 32

together with the model consent forms as contained in the 1992 publication. The guidance was distributed by the Chief Executive of HPSS Northern Ireland with explicit instructions that:

"Health and Social Service Boards/HSS Trusts are asked to ensure that procedures are put in place to ensure the consent is obtained along the lines set out in the Handbook and ***introduce revised documentation (preferably based on the new model consent forms described in it) with adequate monitoring arrangements****".*[145] (Emphasis added)

187. It is noteworthy that the HPSS letter which accompanied the Patient Consent handbook on 6th October 1995 stipulated that: *"****Boards/HSS Trusts are asked to confirm by 31 December 1995 that this has been done****. Confirmation should be sent to Mr. N. Lunn, General Hospitals Policy Branch, Room 115, Dundonald House, to whom any enquiries about this circular should also be sent."*[146] (Emphasis added)

188. Whilst Mr. McKee advised that

"In general, external guidance was received by staff in the Chief Executive's officer and then disseminated to the relevant Clinical Director(s) and their senior management teams for action. On occasion, an expert committee may have been required to consider guidance, for example the Health and Safety Committee. Clinical Directorates and expert committees would then be required to report progress back through accountability arrangements to Trust Board."[147]

189. There is no evidence that the required action was taken or that any such confirmation was given. Rather the evidence of the clinicians during the Oral Hearings was that the 1995 guidance had not 'cascaded' down to them.[148] Indeed none of the clinicians were aware of any specific written guidance in relation to consent.[149]

XI. Audit

Northern Ireland Regional Audit Advisory Committee (NIRAAC)

190. NIRAAC was set up in 1989 as a sub-committee of the Northern Ireland Council for Post-Graduate Medical and Dental Education (now the Northern Ireland Medical and Dental Training Agency).[150] It organised audit of the smaller medical specialties on a regional basis in order to facilitate peer review.

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145 Ref: 305-002-003; Circular HSS (GHS) 2/95
146 Ref: 305-002-004
147 Ref: WS-061/2, p.11
148 Ref: Transcript of the Oral Hearings, 18th April 2012, p.65 line 25 to p.66 line 5
149 Ref: WS-002/3, p.11 and WS-006/3, p.22
150 Ref: 333-129-010

191. In general, a specialty with 10 consultant staff or fewer was considered a smaller specialty and there were around 25 of those specialties in the four main areas of laboratory medicine, surgery, medical specialties and dentistry at the time.

192. NIRAAC also arranged for clinicians to undertake external peer review of particular problem services in what were HSS Boards and advised on and supported the development of audit across Northern Ireland.[151] NIRAAC was chaired by Dr Tom Trinick and had a budget of £40,000 which was used to fund audit activity. Secretariat was provided by NIMDTA.

Regional Multi-professional Audit Group (RMAG)

193. RMAG was created in 1995 under the auspices of the Management Executive to encourage multi-professional audit.[152]

194. Multi-professional audit is a process in which all relevant health and social care staff review and, where necessary make changes to, the care and treatment they provide. Its primary aim is to improve the quality of care in accordance with the following Terms of Reference:

(i) To promote and co-ordinate the development of multi-professional audit in Northern Ireland

(ii) To advise the HSS Executive on all issues relating to multi-professional audit including selection of regional topics for audit

(iii) To act as an information resource and to develop a database of audit projects and examples of good practice to be shared between professions

(iv) To advise on projects which should receive regional funding

(v) To advise on education and training.

Northern Ireland Regional Review of Clinical and Social Audit – 2004

195. The Northern Ireland Regional Review of Clinical and Social Audit was tasked with issuing recommendations to the Department on future arrangements for the support of clinical and social care audit in Northern Ireland in support of the agenda set out in 'Best Practice-Best Care'. A range of interested parties were involved in the review including NIPEC, the two audit bodies (NIRAAC & RMAG), the Department and the Northern Ireland Medical and Dental Training Agency.

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151 Ref: 333-129-011

152 Ref: 333-129-011

196. The review, which was chaired by Dr. David Stewart, reported to the Department in January 2005. One of the principle findings was the need for a single regional audit focus, in place of the two current committees – RMAG and NIRAAC. The review concluded that the different roles of the audit groups were unclear and led to confusion and fragmentation of effort. It recommended that a single regional audit focus would help to ensure more effective development of clinical and social care audit in Northern Ireland.

Regulation & Quality Improvement Authority (RQIA)

197. The RQIA was created by the Health and Social Personal Services (Quality Improvement & Regulation) (Northern Ireland) Order 2003, and was established on 1st April 2005. It is a non-departmental public body of the DHSSPS and acts as the regulator of health and social care services in Northern Ireland.

198. The RQIA's two main functions are:[153]

(i) To inspect the quality of health and social services provided by HPSS bodies in Northern Ireland. These inspections address arrangements for clinical and social care governance within HPSS bodies

(ii) To regulate (register and inspect) a wide range of health and social care services delivered by HPSS bodies and by the independent sector.

199. The RQIA has a role in relation to the inspection, regulation, investigation and review of performance within Health and Social Service organisations (and by the independent sector) against five key 'quality themes', which were laid out in a follow-up document to 'Best Practice, Best Care' namely 'The Quality Standards for Health and Social Care' published in April 2005.[154]

200. The themes were as follows:[155]

- Safe and effective care
- Timely delivery of quality services
- Promoting, protecting and improving health and social well-being
- Open and effective communication
- Leadership and accountability of organisations.

201. The Quality Standards are used by RQIA in its assessment of the quality of care delivered by the Trusts and, where serious and/or persistent clinical governance problems come to light, the RQIA will have *"a key role to play"* in the investigation of such incidents.

153 Ref: 010-036-222
154 Ref: WS-068/1, p.255
155 Ref: WS-068/1, p.256

202. Finally, the Quality Standards state that health organisations should demonstrate:

(i) That national/regional standards are incorporated into specific aspects of clinical practice, and that these are audited

(ii) An effective incident reporting policy and dissemination of learning

(iii) Compliance, auditing and review of practice in accordance with Departmental guidance on the safe prescribing, supply and administration of IV fluid management.

203. According to Dr. Carson, the current chairman of the RQIA, the RQIA fulfils its responsibility to inspect by carrying out a planned programme of announced and unannounced inspections against standards set by the Department in regulations.[156]

204. The RQIA Chairman and Chief Executive have Accountability Review meetings with the Permanent Secretary twice a year. [157]

Northern Ireland Audit and Guidelines Implementation Project – 2006

205. Following the Northern Ireland Review of Clinical and Social Audit, CREST, NIRAAC and RMAG agreed by June 2006, to work together to establish a single focus for regional audit integrated with Northern Ireland clinical guidelines development.[158]

206. Accordingly, the Northern Ireland Audit and Guidelines Implementation Project was then established in July 2006, under the leadership of Dr. Mock, Principal Medical Officer, DHSSPS and with representation from CREST, the audit bodies, the Department and the RQIA.

207. The aim of the Project was to recommend future arrangements to support clinical efficiency and audit in the HPSS. Its objectives were to:

(i) Develop recommendations for an integrated structure and governance/organisational arrangements for the future development of clinical guidelines and the support of audit across the HPSS – to replace the current CREST and audit committees

(ii) Establish a framework and mechanisms to ensure that clinical and social care audit projects, guidelines development and implementation are undertaken effectively and deliver real service benefit

156 Ref: WS-077/4, p.9
157 Ref: WS-077/4, p.12
158 Ref: 333-129-018

(iii) Ensure the new group sits appropriately with Review of Public Administration structures and is linked appropriately to the DHSSPS (NICE) guidance process, RQIA and the educational bodies.

Northern Ireland Audit Office (NIAO)

208. The Comptroller and Auditor General for Northern Ireland (C&AG) is head of the Northern Ireland Audit Office (NIAO).

209. He is responsible for the external audit of central government bodies in Northern Ireland, including Northern Ireland Departments and a wide range of other public sector bodies, including health and personal social service bodies. He undertakes financial audit and value for money audit and the results of his work are reported to the Northern Ireland Assembly.

210. The C&AG works closely with the Assembly's Public Accounts Committee (PAC) which takes evidence from senior officials on his reports.

211. The NIAO reported on 'The Safety of Services Provided by Health & Social Care Trusts' in October 2012. This found:

(i) Levels of incident reporting are increasing, however these still fall short of what is expected, particularly in hospitals.

(ii) There is no incident monitoring system that collates patient safety data across the entire HSC sector.

(iii) Regional sharing of lessons learned has not been as structured or comprehensive as it could be

212. The Comptroller gave evidence before the PAC in November 2012. In their report on the Safety of Services Provided by Health & Social Care Trusts, they concluded:

"Despite the introduction of a number of safety policies and initiatives, there is no reliable evidence to show that people receiving health and social care are any safer today than they were a decade ago.

The Department still lacks a reliable means of tracking the progress of the health and social care services in improving the safety of those receiving care or in holding service providers accountable for minimising preventable harm."

213. The PAC also noted that a National Reporting and Learning System (NRLS) had been operating across England and Wales since 2003. This is a centralised database which aims to improve patient safety nationally. However, such a centralised system is not present in Northern Ireland, with a pilot scheme due in 2014.

XII. Notification of Adverse Incidents

214. An important issue to be examined during the Oral Hearings is the procedure and practice in Northern Ireland, at the time of the children's deaths, for the reporting and dissemination of information to the Department, and the medical community in general, of unexpected deaths in Hospital and outcomes from Coroners' Inquests.

215. The Allitt Inquiry into deaths and injuries on the children's ward at Grantham and Kesteven General Hospital reported in 1994 that "*there must be a quick route to ensure that serious matters [...] are reported in writing to the Chief Executive of the hospital, and in the case of directly managed units, to the District Health Authority*".

216. In May 2000, the NHS in England published a document on learning from adverse incidents in the NHS – 'An Organisation with a Memory'. Even at that time, the report acknowledged that "*there are no universally accepted criteria for identifying the occurrences or outcomes of health care that should constitute a basis for recording or reporting poor quality*".

217. The report explained the different mechanisms that can yield information on adverse incidents:

(i) Incident reporting systems (e.g. local risk reporting systems in NHS Trusts and other bodies, untoward incident schemes run in NHS regions, reporting of adverse reaction to medicines and medical devices)

(ii) Data derived as a by-product of systems designed to investigate or respond to instances of poor quality care (e.g. litigation for alleged medical negligence, the NHS complaints procedure, cases referred to the Health Services Commissioner, Coroner's cases)

(iii) Databases of on-going studies on a national basis which aim to identify poor outcomes and avoidable factors in certain specific fields of health care (in particular the confidential enquiries into perioperative death, maternal mortality, stillbirth and infant deaths, homicides and suicides by mentally ill people)

(iv) Periodic external studies and reviews (e.g. the national Value for Money studies conducted by the Audit Commission)

(v) Spontaneous reporting outside normal channels by individual members of staff (sometimes known as "whistle blowing")

(vi) Health service and public health statistics.

Formal Notification Systems

218. Despite the Allitt Report, prior to Raychel's death in 2001 there was no formal reporting requirement to the Department of untoward deaths.[159] According to Mr. Clive Gowdy, who was Permanent Secretary from 1997-2005, this was consistent with the basis on which Health and Social Services Trusts had been established in the 1990s.[160] He states that, as set out in Circular METL 2/93[161] issued to the HPSS in October 1993 by the then Management Executive (a part of the then DHSS), the Trusts were intended to operate with maximum operational freedom and autonomy.

219. There were, however, some national reporting systems for deaths in the UK. These included:

(i) the Confidential Enquiry into Maternal Deaths (deaths of women during pregnancy or within one year of childbirth)

(ii) the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) (stillbirths and infant deaths)

(iii) the Confidential Enquiry into Peri-Operative Deaths (NCEPOD) (hospital deaths within 30 days of surgery)[162]

(iv) from 1997, the Confidential Enquiry into Suicides and Homicides by People with Mental Illness (suicides within one year of contact with mental health services and homicides involving people who have been in contact with mental health services at any time). [163]

These enquiries were funded by the DHSSPS but administered by the Royal Colleges.[164]

220. The Yellow Card System operated by the UK Committee on Safety of Medicines required the reporting of all incidents relating to adverse effects of medicines. The Yellow Card System has been in place since 1964.[165] The scheme provides a system for early detection of emerging drug safety hazards and routine monitoring for all medicines in clinical use in the UK. Suspected adverse reactions are reported to the Committee on Safety of Medicines (CSM)/Medicines and Health Care Products Regulatory Agency, which are jointly responsible for running the scheme. Reporting is voluntary by doctors, dentists, Coroners, pharmacists and nurses. The death of Raychel Ferguson was reported under this system in 2001.

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159 Ref: WS-062/1, p.4
160 Ref: WS-062/1, p.3
161 Ref: WS-062/1, p.527
162 Ref: WS-062/1, p.3
163 Ref: WS-062/1, p.4
164 Ref: WS-075/1, p.13
165 Ref: WS-075/1, p.13

221. There were only two formal requirements in relation to the reporting of adverse incidents affecting patients to the Department in Northern Ireland at this time:[166]

(i) The first was in respect of adverse incidents and reactions and defective products relating to medical and non-medical equipment and supplies, food, buildings and plant, which had to be reported to the then Northern Ireland Defect and Investigation Centre in the HPSS Management Executive (Circular PEL (93)36).[167] This later became the Northern Ireland Adverse Incident Centre in November 2000.[168] There were 241 reports of adverse incidents in 2003. From 1998 to 2004, only 4 reports to the centre concerned deaths; of which two involved the use of bed rails in private nursing homes, one involved the transport of a critically ill patient and the other an accident involving a visitor falling against a glass window.[169]

(ii) The second was in relation to the notification of untoward events in psychiatric and special care hospitals, which required notification to the Department of all untoward events (unauthorised absences, accidents and sudden, unexpected or unnatural deaths) involving patients in psychiatric or special care hospitals (Circular HSS4 (CS) 1/73).[170]

222. The Department estimate that there are about 15,000 deaths each year, the majority of which occur in hospital.[171] Approximately 3,500 of all deaths each year are reported to the Coroner, of which 1,400 inquests are held.[172] The outcomes of Coroners' Inquests were not routinely notified to the Department or circulated to the HPSS[173] and there were no formal mechanisms for reporting, analysing or disseminating information from a Coroner's Inquest or untoward death. [174]

Informal Notification Systems

223. There was an informal system whereby Chief Executives and Medical and Nursing Directors in the HPSS brought significant untoward incidents, resulting in death, to the attention of the CMO.[175] In May 2004, the CMO is recorded as saying that she received just 3 to 4 reports annually of serious

166 Ref: WS-062/1, p.3
167 Ref: WS-062/1, p.13
168 Ref: 010-023-150; WS-062/1, p.4
169 Ref: 010-026-181
170 Ref: WS-062/1, p.34
171 Ref: 001-041-138 – statistics from 2004
172 Ref: 002-008-049
173 Ref: WS-062/1, p.3
174 Ref: WS-062/1, p.4
175 Ref: 010-023-150; Ref: WS-075/1, p.3

untoward incident deaths.[176] Raychel's death was reported as part of this informal system.

224. The Department internally noted in May 2004 that, as regards informal notification of adverse incidents "*frankly, the picture is not a good one*".[177] Notification was described as "*patchy*", the numbers of notifications "*small"* and "*there is no overall analysis*".

225. It was further commented that the Minister is "*somewhat vulnerable to the accusation that the Department is not aware what is going on as regards serious incidents.*" In addition, there was "*no empirical evidence to support*" the Secretary's line that "*it was usual for the CMO / Department to be notified, and Lucy Crawford was an exception*".

Implementation of a Formal Notification System

226. In December 1998, the Department commissioned Healthcare Risk Resources International consultants to undertake a survey of risk management in all HPSS organisations.[178] The terms of reference for the survey were to determine the level of application of risk management methods within these organisations. Incident reporting was one of the items included in the survey. The survey provided each of the organisations with an assessment of their position against the average performance on each of the factors covered in the survey.

227. When the consultants reported in 1999, they concluded that there was a good level of awareness of the need to develop rigorous systems for risk management and a good level of compliance with the requirements for risk management.[179] However, they noted the following:

(i) Risk Management Strategy: "*greater efforts need to be made in order to ensure that the Strategy is endorsed fully by the Board of the Trust concerned and that all managers, clinicians and other professionals are aware of its contents*" Ref: 127-004-095

(ii) Incident Reporting: "*major deficiency relates to the very limited and, therefore, probably significant under-reporting of clinical incidents and 'near misses'. A major effort is needed in almost all Trusts to improve in this area*" Ref: 127-004-096

(iii) Patient Records: "*There was a low level of compliance with this issue amongst the majority of Trusts … Accordingly, there is a real need for most Trusts to develop an explicit policy document incorporating all of the elements*

176 Ref: 010-030-188
177 Ref: 010-025-180
178 Ref: WS-062/1, p.4
179 Ref: WS-062/1, p.4

shown, and for there to be a system in place for the routine audit of compliance with the policy" Ref: 127-004-096

(iv) Supervision of junior staff: "*consultants found few examples of formal, written procedures for ensuring that clinical staff have ready access to advice and support from their seniors. This does not imply that such procedures are not in place, but these do need to be made more explicit. This is a particularly vulnerable arena in the context of clinical risk and needs more focussed attention*" Ref: 127-004-097

(v) Claims Management: "*few examples of a claims management policy*" Ref: 127-004-098

228. Throughout the UK, there was a growing recognition of the significance of these issues. In England, the CMO published a document on learning from adverse incidents in the NHS – 'An Organisation with a Memory' in May 2000, which stated:

"There is evidence that 'safety cultures', where open reporting and balanced analysis are encouraged in principle and by example, can have a positive and quantifiable impact on the performance of organisations. 'Blame cultures' on the other hand can encourage people to cover up errors for fear of retribution and act against the identification of the true causes of failure, because they focus heavily on individual actions and largely ignore the role of underlying systems. The culture of the NHS still errs too much towards the latter;

Reporting systems are vital in providing a core of sound, representative information on which to base analysis and recommendations. Experience in other sectors demonstrates the value of systematic approaches to recording and reporting adverse events and the merits of quarrying information on 'near misses' as well as events which actually result in harm. The NHS does not compare well with best practice in either of these areas."

229. This report recommended that a mandatory scheme should be introduced in the NHS in England and Wales to ensure comprehensive reporting of adverse health care events and to ensure that important lessons were implemented quickly and consistently. This was followed by the Department of Health document 'Building a Safer NHS for Patients' in April 2001.

230. In addition, two major Inquiry reports were published in England which had a significant impact on how adverse incidents were viewed. These were the Royal Liverpool Children's Inquiry Report in January 2001 and the Bristol Royal Infirmary Inquiry Report in July 2001.

231. In Northern Ireland, the Department published 'Confidence in the Future- for Patients and for Doctors' in October 2000, a consultation document dealing with the prevention, recognition and management of poor performance by

doctors. This recommended that methods of recording adverse events should be put in place to identify poor clinical performance.

232. As aforementioned, in April 2001, the Department published the consultation document 'Best Practice, Best Care', which was a major policy paper setting out proposals for improving the quality and standards within the HPSS and giving recognition to the need for more effective arrangements for monitoring adverse incidents.

233. In April 2003, the statutory duty of quality on HPSS organisations came into effect and core risk management standards were introduced as part of the establishment of controls assurance standards across the HPSS. These arrangements also emphasised the need for an adverse incident reporting system to be in operation and the Risk Management Controls Assurance Standard included a specific criterion on adverse incidents which requires "*an agreed process for reporting, managing, analysing and learning from adverse incidents*" to be in place.

234. Under the auspices of the Best Practice, Best Care Steering Group, a Safety in Health and Social Care Group (SHSCG) was established. The remit of this Group included the development of a strategic approach to the recording, reporting and investigation of adverse incidents and near misses and the promotion of good practice to minimise risk. A part of its work was to undertake an evaluation of the effectiveness of systems used to identify and manage adverse incidents and near misses.

- ***Deloitte & Touche Reports 2003/04***

235. The SHSCG commissioned a report from Deloitte & Touche to evaluate clinical and social care governance.[180] The final report from Deloitte and Touche was prepared on 19th September 2003. [181]

236. The report highlighted a lack of understanding and implementation of clinical and social care governance. This included a lack of co-ordinated risk activities including identification and management of risk, risk registers and risk audits. The report noted poor performance by the Western and Eastern Boards in areas of risk management and adverse incident management, and Altnagelvin Hospital Trust performed lowest of the Trusts evaluated, with the Royal Group of Hospitals also performing poorly.

237. Dr. Campbell stated in her Inquiry Witness Statement:

"It was clear from this baseline assessment of clinical and social care governance that there was a need within the HPSS for training, development and support if awareness and understanding of clinical and social care governance and the practical application

180 Ref: 010-037-230
181 Ref: WS-075/1, p.76

of the duty of quality imposed by the Health and Personal Social Services (Northern Ireland) Order 2003 were to be achieved."[182]

238. The report made a number of recommendations including:[183]

(i) A central database of lessons learned

(ii) Publication of Northern Ireland agreed practice guidelines

(iii) Annual summation of audit results

(iv) The establishment of links with national bodies such as the NPSA

239. The DHSSPS commissioned a further report from Deloitte to carry out a scoping exercise on adverse incidents and near miss reporting in the HPSS.[184] This report was finalised on 31st March 2004 and highlighted "*one overwhelmingly obvious finding: inconsistency of approach*"[185] between HPSS bodies in their systems to report, record and analyse adverse incidents and near misses. It noted that "*currently there is limited sharing of knowledge between the healthcare organisations and bodies within Northern Ireland*".

240. The report recommended DHSSPS facilitate consistency of approach in incident reporting and consider what formal investigations were required on a regional basis.

- ***Interim Guidance on the Reporting & Follow-up of SAIs***

241. The Department issued a circular on the reporting and follow-up on serious adverse incidents in July 2004 (HSS (PPM) 06/04).[186] This Circular defines adverse incidents and requires HPSS bodies to report serious adverse incidents to a Senior Manager within the HPSS body with responsibility for the reporting and management of adverse incidents within the organisation. If the Senior Manager considers that the incident is likely to warrant regional action to be of public concern, or to require an independent review, he is required to provide DHSSPS with a brief report within 72 hours of the incident being discovered. In response, the DHSSPS will collate information on the incidents reported to it through this mechanism and provide relevant analysis to the HPSS bodies.

242. The Department established a Clinical and Social Care Governance Support Team in 2004. The work of the team was designed to support and encourage the effective implementation of the statutory duty of quality across the HPSS.

182 Ref: WS-075/1, p.17
183 Ref: WS-075/1, p.104
184 Ref: WS-075/1, p.144
185 Ref: WS-075/1, p.147
186 Ref: WS-062/1, p.314

The team organised two Incident Investigation Workshops for the HPSS in 2005. These focused on current experience in dealing with adverse incidents.

243. In accordance with 'Best Practice, Best Care' a new HPSS Regulation and Improvement Authority was established and formally came in to existence in April 2005. Its role is to inspect and investigate the performance in HPSS organisations.

244. The SHSCG also recommended that formal links should be created with the National Patient Safety Agency (NPSA). [187]

245. The number of SAIs reported following the interim guidance is as shown in a schedule compiled by the Legal Team[188] from information provided by the HSCB.[189] It should be noted that Circular HSC (SQSD) 22/09 issued in March 2009 removed from SAI reporting certain categories of incident (suspected suicides and admissions of under-18s to adult mental health wards).

246. The current HSC Serious Adverse Incident Report Form requires those completing it to decide whether the adverse incident falls into one of five categories, one of which is "*serious injury to, or the unexpected / unexplained death of a service user*". However, this is not divided into further categories, e.g. suspected clinical mismanagement.

247. The Inquiry has sought information from DSO as to the number of SAIs related to clinical incidents, but has yet to receive this information.

- ***Safety First (2006)***

248. In 2006, the Department published 'Safety First: A Framework for Sustainable Improvement in the HPSS'. Its introduction stated that particular attention would be paid over the next few years to:

(i) Creating an informed, open and fair safety culture within the HPSS

(ii) Raising awareness of risk and promoting timely reporting of adverse incidents

(iii) Investigating serious incidents

(iv) Sharing the learning across HPSS environments

(v) Implementing change

(vi) Developing skills, knowledge and expertise

187 Ref: 010-037-230
188 Ref: 337-002-001
189 Ref: 331-003-005

(vii) Involving and communicating with the public.

249. In 2004/05, a total of 10,107 medication-related patient safety incidents were reported by staff in Northern Irish hospitals, 89% of which were 'near misses'. It defined an adverse incident widely so as to include 'near misses': *"Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation."*

250. The paper noted that, in Northern Ireland, there was no common reporting or data analysis system for adverse incidents and that therefore, neither the number of adverse incidents in health and social care environments is known nor can the number of untoward deaths be estimated. It recommended a systematic approach to data analysis and intelligence gathering from a number of sources including:

(i) Published literature for health and social care environments e.g. NICE, SCIE and NPSA

(ii) National Inquiries - e.g. Confidential Inquiries: CEMACH, NCISH, NCEPOD

(iii) Statutory and voluntary reporting systems - e.g. local medicines and devices reporting, MHRA, child protection, Mental Health Commission

(iv) Hospital and social care episode statistics

(v) Health and social care complaints

(vi) Local and national Inquiries, e.g., Lewis, Ombudsman, Hyponatraemia, Climbié, Shipman and Bristol Inquiry Reports

(vii) Regional and local audit findings

(viii) Regulation and Quality Improvement Authority (RQIA) reviews and reports

(ix) Social Services Inspectorate reports

(x) Claims and litigation findings

(xi) Coroner's findings

(xii) Death certification data.

251. The CEMACH report 'Why Children Die', published May 2008, stated that a body was to be set up to aggregate the numbers of child deaths. Such an arrangement has been present in England and Wales under the Children Act 2004. The Safeguarding Board for Northern Ireland (SBNI) was established in

2012. As part of its remit, the SBNI has a role in analysing information in relation to child deaths in Northern Ireland and cooperating with regional and national initiatives such as CEMACH.

Coroner's Inquests

252. The system of reporting to the Coroner has been dealt with in previous hearings, but at the Departmental level, it is notable that the CMO for England and Wales wrote to all doctors in 1998 regarding their duty to report, stressing "*the need for clinicians to disclose all relevant information to the Coroner to ensure a fully informed decision on the cause of death*" and emphasising that clinicians disclose information voluntarily and not only when requested to do so.[190] The Inquiry Legal Team is seeking information on whether the Northern Ireland CMO took similar action.

253. Dr. Bridget Dolan has informed the Inquiry that Rule 23(2) of the Coroner's (Practice and Procedure) Rules (Northern Ireland) 1963 gave the Coroner the power to report the circumstances of an inquest case to an appropriate authority:

"A Coroner who believes that action should be taken to prevent the occurrence of fatalities similar to that in respect of which the inquest is being held may announce at the inquest that he is reporting the matter to the person or authority who may have power to take such action and report the matter accordingly". [191]

254. An almost identical rule (Rule 42) exists in England and Wales. The Luce Review (2003) into the Coroner's system in England and Wales revealed that this power to report matters was being used in just less than 1 in 50 inquests.[192]

255. Dr. Dolan reports that, in Northern Ireland, the average number of reports issued was said to be 2.2 per Coroner in the year under study. She adds:

"Despite such reports often being construed as Coroners "recommendations" the relevant rules actually provide no power to make any recommendation or propose remedies for any danger they only give only a power to report facts. Notwithstanding this coroners frequently use the report to suggest necessary action to relevant bodies."[193]

The recipient of a report under these rules is under no duty to respond to or even acknowledge the report.

190 Ref: 303-052-731
191 Ref: 308-013-242
192 Ref: 308-013-243
193 Ref: 308-013-243

256. The Luce Review found that, according to those Coroners who had made reports, around half of their reports had led to some remedial action being taken, however in around a quarter of cases the Coroner believed the response was inadequate or that "*the recommendation had been rejected*". [194]

257. Dr. Dolan explains that a Coroner has no power to enforce action under the rules and the view of many is that the only weight the reports had was the adverse media publicity either when the report was made or when the media later asked question about what had been done in response.[195]

258. Dr. Dolan was informed that the Northern Ireland Coroners Service does not currently hold central figures for Rule 23 referrals, each Coroner being aware only of their own Rule 23 reports. This is essentially the same as the position in England and Wales before the amendments to the equivalent rule in 2008. Since then, a summary of the Rule 43 reports in England and Wales is compiled every year.[196]

Clinical Negligence Database

259. On 5th July 2002, NIAO published a report 'Compensation Payments for Clinical Negligence' which stated in relation to 'risk management':

> *"It is disappointing that action in response to the survey [A survey of Risk Management in the HPSS Organisations] has been delayed, given the high expectations of the Department … A permissive approach to the implementation of good risk management has not brought the results that are required. We would, therefore, expect the Department to be able to provide positive assistance of substantial progress in risk management within HPSS bodies, by 2003 at the latest."*[197]

> *"Providers suggested that the existence of clinical incident reporting systems was no guarantee that all appropriate incidents were reported. Also, the current arrangements had no provision for reports to be reported to a central body"*[198]

260. The report recommended the creation and regular update of a central database for clinical negligence. Mr. Andrew Hamilton, Director of Financial Management published Department Circular HSS(F) 20/2002 in September 2002, which noted the recent NIAO report and stated that a small working group would be established with the objective of delivering an interim regional database.[199]

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194 Ref: 308-013-243
195 Ref: 308-013-243
196 Ref: 308-013-246
197 Ref: 127-004-081
198 Ref: 127-004-083
199 Ref: 317-037-005

261. A Department memo in July 2005 noted the setup of a database but also that there had been "*concerns raised about the quality and accuracy of this data*"[200]. The memo went on to review the current position as to clinical negligence and noted that Northern Ireland has no centralised approach to claims management, with the Department playing no active role in the management of claims and litigation cases, as claims management is devolved to Boards and Trusts.

262. The memo noted the difference in the system for management of clinical negligence claims in England and Wales, where centralised information systems and 'risk pooling' arrangements are "*well-established*". In 1995, the NHS Litigation Authority was established to ensure that claims were managed consistently and manage the financial consequences of such claims. There is no equivalent organisation in Northern Ireland.

Complaints

263. The Northern Ireland Health and Personal Social Services Charter for Patients and Clients (March 1992) set out the Government's commitment to the provision of quality services and indicated the rights and guarantees which were being introduced in relation to those services.[201] The Charter also advised of the arrangements to be made by Boards and Trusts to deal with complaints.

264. These arrangements required all HPSS organisations to have clear procedures for dealing with complaints. In particular, they were required to publicise the name, address and telephone number of the senior officer responsible for handling complaints and to make the necessary information available to all patients and clients. The complaint would be conducted in full by the complaints officer, who would provide the complainant with a written report explaining what went wrong and describing the action being taken.

265. If the complainant was still dissatisfied, there was scope for the matter to be raised sequentially with the Chairman or General Manager of the Board and with the Chief Executive of the Management Executive in the Department. There was also scope for the complaint to be raised at any stage with the Commissioner for Complaints. There were also special arrangements for dealing with complaints about the clinical judgement of hospital medical and nursing staff.

266. In March 1995, the Department published 'Acting on Complaints',[202] setting out the HPSS response to the 1994 Wilson report, 'Being Heard'. This was the product of a review committee chaired by Professor Alan Wilson which had

200 Ref: 330-108-006
201 Ref: 306-085-001 *et seq*
202 Ref: WS-062/1, p.345

been established to review how NHS complaints were dealt with in the light of criticism regarding outdated procedures. It recommended a common local system throughout the NHS and, although it concerned the NHS, it did embrace the HPSS in Northern Ireland.

267. Following on from those two publications, in March 1996 the Department published its guidance, 'Complaints – Listening Acting Improving'. This was to complement the Directions and Regulations being introduced to provide a mandatory statutory framework for the complaints procedure.[203]

268. Directions were issued under the HPSS Complaints Procedures Directions (Northern Ireland) 1996, The Miscellaneous Complaints Procedures Directions (Northern Ireland) 1996 and HPSS (Special Agencies) Complaints Procedures Directions (Northern Ireland) 1996. However, the guidance was intended only as 'broad advice' and the Department expected the Trusts and Boards to design and operate their complaints procedure *"within the spirit of the Guidance, while adhering to the legal requirements of the appropriate Directions and Regulations"*.[204]

269. Further guidance on complaints was published by the Department in April 2000, 'Guidance on Handling HPSS Complaints: Hospital and Community Health and Social Services'. In 2002, as part of a wider quality agenda, the Department initiated a review of the HPSS Complaints Procedure. A Regional Complaints Review Group was set up to consider the issues emerging from the UK national evaluation of complaints and to draft a framework of proposals to improve the HPSS complaints procedure.

270. As the Group undertook its work, it had to take account of some major emerging issues, including the Shipman Inquiry, the proposals for reorganisation within the Review of Public Administration and the establishment of the HPSS Regulation and Improvement Authority.

- ***Complaints by Doctors***

271. In February 1996, Circular HSS(GEN1) 1196 was issued with a document 'Guidance for Staff on Relations with the Public and the Media'. It was designed to encourage a climate of openness and dialogue within the HPSS so that staff could freely express their concerns to their managers as a means of contributing to the improvement of services.

272. In October 1999, the Public Interest Disclosure (Northern Ireland) Order 1998 came into effect. Circular HSS(GEN1) 112000 was issued to the HPSS to draw attention to the provisions of this legislation. These so-called 'whistle blowing' arrangements provided for staff to be able to raise concerns about

[203] Ref: WS-062/1, p.351
[204] Ref: WS-062/1, p.356

health and social care matters in a responsible way without fear of victimisation and required all HPSS organisations to have local policies and procedures in place to give effect to these arrangements.

- ***Complaints against Doctors***

273. In relation to concerns about the performance of doctors, the role of the General Medical Council (GMC) provides for complaints about a doctor's competence or fitness to practise to be referred to the Fitness to Practise Committee. The HPSS arrangements for dealing with complaints set out in the 1995 document 'Acting on Complaints' provide principles which, while primarily focused on complaints by patients and clients, are equally applicable to complaints and concerns from healthcare professionals.

274. In 1994, Sir Kenneth Calman, then CMO in England, chaired a group to review the guidance and procedures relating to complaints and concerns underperforming doctors. The final report of this group 'Maintaining Medical Excellence: Review of Guidance on Doctors' Performance' was issued to the HPSS in August 1995 by the CMO Dr. Campbell, with a covering letter underlining the professional responsibility of individual clinicians in the monitoring of standards.[205]

275. In November 1995, the GMC were given new powers to deal with doctors' performance. The Medical (Professional Performance) Act 1995 enabled the GMC to introduce new professional performance procedures and extended the GMC's existing powers to impose interim suspension or interim conditions pending a full hearing of a competence or conduct case. These new procedures came into effect in 1997.

276. Following the response from the profession to 'Maintaining Medical Excellence', the CMO in England asked representatives of the medical profession and NHS employers to suggest how the report's recommendations might be utilised. The group's conclusions were circulated to the HPSS by the Northern Ireland CMO under cover of a letter, HSS(MD) 3/97 in January 1997 asking that the agreed arrangements be put into effect in Northern Ireland.

277. In October 1998, the Government announced that it would be reviewing the suspension procedures for hospital and community medical and dental staff. The CMO in England issued a consultation paper in November 1999, 'Supporting Doctors, Protecting Patients' setting out a wide range of new proposals to assist with the prevention, early recognition and improved management of poor clinical performance of doctors. To address similar issues in Northern Ireland a Working Group was established in March 2000, which included Dr. Ian Carson (Royal Group of Hospital Trust), Mrs. Stella Burnside (Altnagelvin Hospitals Health and Social Services Trust) and Dr.

[205] Ref: WS-062/1, p.480

John Jenkins (QUB and United Hospitals Trust), together with John McGrath and Dr. Paddy Woods from the Department. As a result of their work, the Department issued the consultation document 'Confidence in the Future - for Patients and for Doctors' in October 2000.[206]

278. Measures designed to address the prevention, detection and management of underperformance by doctors were published in May 2002. In addition, new arrangements to support clinical and social care governance came into effect on 1st April 2003 following publication of the policy document 'Best Practice, Best Care'. A service level agreement was also entered into with the National Clinical Assessment Service in England, extending its services of advice, support and assessment of clinical competence to Northern Ireland.

- ***Northern Ireland Commissioner for Complaints***

279. The Northern Ireland Commissioner for Complaints, also known as the Northern Ireland Ombudsman has jurisdiction for complaints in health and social care matters under the Commissioner for Complaints (Northern Ireland) Order 1996. His jurisdiction, which included complaints of maladministration about Health and Social Care Trusts, was extended in 1997[207] to include matters of complaint which related to 'the merits of a decision taken in consequence of the exercise of clinical judgement'.

280. As a result of this extension of jurisdiction, the Commissioner for Complaints was empowered to investigate complaints about the care and treatment of patients arising from the actions of General Health Service Providers, (these include General Practitioners, Dentists, and Pharmacists) as well as Independent Providers of Health Services, (e.g. Nursing Homes).

281. Where an individual is dissatisfied with the outcome of their complaint to a Trust or other HSC body, having been investigated and responded to under the HSC complaints procedure, they are advised of their right to forward their complaint to the Commissioner.

282. The purpose of the Commissioner's office is to investigate complaints of maladministration. The service provided by his Office is intended to be independent, free and confidential.

283. Article 9(3)(b) of the 1996 Order prevents the Commissioner from investigating any matter in which the person aggrieved has or had a remedy in law. This bar is not absolute, however, as a residual discretion is afforded to the Commissioner by virtue of Article (4)(a) which enables the Commissioner to investigate, where he is satisfied that, in the particular circumstances, it is not reasonable to expect the complainant to resort or have

206 Ref: 321-004fi-001 *et seq*

207 The Commissioner for Complaints (Northern Ireland) Order 1996 as amended by Article 7(10) of the Commissioner for Complaints (Amendment) (Northern Ireland) Order 1997

resorted to the legal remedy. The circumstances in which such discretion may be used include where the complainant may not have the financial resources to fund court proceedings.

284. The Commissioner's approach to deciding those complaints involving clinical treatment of a patient recognises that, in theory, every complainant could potentially have a legal remedy. The Commissioner, therefore, considers carefully the remedy being sought by the complainant in respect of their complaint.

285. Often the complainant simply seeks an explanation of what happened and, where failures in care or treatment have been identified, an assurance that this will not happen again. In many instances, a complainant seeks only an apology. These are responses unobtainable by legal action.

286. Although his evidence gathering powers are equivalent to those of a High Court judge, the Commissioner's investigations are conducted in private and are inquisitorial in nature. The standard which is adjudged is one of 'maladministration'. This is not defined in the legislation in order that the discretion afforded to the Commissioner for Complaints in determining whether maladministration has occurred is unfettered.

287. The Commissioner's approach is to assess whether the actions of a health professional are fair and reasonable. This is not the same as a finding by a Court that a duty of care has been breached.

288. Where maladministration is found to have caused an 'injustice' to an individual, the Commissioner can recommend a remedy which may include a change in practice or service improvement. Therefore, the outcomes of the Commissioner's investigations may result in learning for the HSC sector.

289. The Commissioner has the discretion to recommend a wide range of remedies. These can include a fuller explanation of events leading to the injustice suffered by the complainant, an apology, service improvement recommendations or, in appropriate cases, financial redress.

290. Given the extent of the Commissioner's jurisdiction in the HSC sector, he enjoys a unique and valuable insight into the experiences of individuals who may have been failed by the sector. Significantly, the Commissioner also has an express power to disclose information to any person or body where he considers that information should be disclosed in the interests of the health and safety of 'any person'. For example, this power of disclosure enables the Commissioner for Complaints to refer a concern about a particular doctor to the GMC, or to refer an institution to the RQIA where regulations or procedures, on the face of it, appear to have been breached.

291. To assist with this important mechanism for sharing information in the interests of patient safety, the Commissioner is currently finalising a protocol with the RQIA.

XIII. Statistics & Coding

Background

292. Iris Robinson (then MP for Strangford) asked Angela Smith (the then Secretary of State for Northern Ireland and responsible for setting up the Inquiry) the following parliamentary question on 25th January 2005:

"To ask the Secretary of State for Northern Ireland how many dilutional hyponatraemia-related deaths occurred in the Province in each of the last 20 years"[208]

293. The answer was provided on 27th January 2005 by a table showing 6 deaths where the primary cause of death was 'hyponatraemia'/'fluid overload' and 55 deaths where an associated or secondary cause of death was 'hyponatraemia'/ 'fluid overload'.[209] It also led you Mr. Chairman to write to the Department seeking the number of deaths in Northern Ireland in the last 25 years in which hyponatraemia had been identified as a primary or secondary cause.

294. During the Public Hearing on 3rd February 2005 on the Inquiry's Procedures, the Chairman announced:

"Another issue which we want to address is what is the frequency of death as a result of hyponatraemia in Northern Ireland. Our understanding from figures which we have received recently from the Department is that in the last 20 years, there have been eight deaths which have been registered as directly attributable to hyponatraemia; but that there have been 55 deaths registered with hyponatraemia as a secondary or contributory factor and 16 of those deaths were registered in 2002 and 2003. We want to inquire whether this is in keeping with equivalent figures for the rest of the United Kingdom; we want to inquire whether this is in keeping with other European countries; and whether it is or is not equivalent to other countries, ***is there any extent to which such deaths are avoidable***."[210] (Emphasis added)

N.I. Deaths from Hyponatraemia compared to Europe

295. The Inquiry sent out letters of request to a number of European countries in the following terms:

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208 Ref: 073-019-092
209 Ref: 073-019-093
210 Ref: 303-005-066

"The Department of Health in Northern Ireland has already provided statistical data on the number of deaths here over the past 20 years where (a) the primary cause of death was hyponatraemia or fluid overload and (b) the an associated/secondary cause of death was hyponatraemia or fluid overload.

I am in the process of establishing the incidence of deaths linked to hyponatraemia and any general patterns here, and across the UK. It would greatly assist my understanding if I could have comparative data for […]

I would appreciate if you could possibly provide the following data for each of the last 25 years, by gender and age group (under 16 years and adult);

deaths where the primary cause of death was 'hyponatraemia' or 'fluid overload' including:

ICD-10 E87.1 (hypo-osmolality and hyponatraemia)

ICD-10 E87.7 (fluid overload);

deaths where an associated/secondary cause of death was 'hyponatraemia' of 'fluid overload' including:

ICD-9 276.1 (hypo-osmolality and hyponatraemia

ICD-9 276 (fluid overload fluid retention)"

296. Responses were received from all the countries concerned, namely:

- Denmark
- England and Wales
- France
- Germany
- Netherlands
- Republic of Ireland
- Scotland
- Sweden
- Switzerland.

297. The information was passed to the Northern Ireland Statistical and Research Agency (NISRA) to compare mortality statistics relating to hyponatraemia/ fluid overload in Northern Ireland with those in other European countries and provide a preliminary analysis.

298. NISRA reported in June 2005.[211] The Report advised caution in the interpretation of the crude annualised death rates for deaths due to hyponatraemia/fluid overload. Nevertheless, it suggested that the crude mortality rates indicated that Northern Ireland was within the range of other

[211] Ref: 308-016-272

European countries for those aged 15 years and over. The Report advised even greater caution in the interpretation of the figures for the death rates of those aged less than 14 years given the very small number of registered deaths in Northern Ireland (i.e. 4). Notwithstanding that, the Report stated that the initial analysis indicated a higher rate of child mortality in Northern Ireland than in the European countries concerned in the survey.

299. Further information and analysis was recommended:

"22. In addition information would need to be gathered on the following issues:

- *although not easily quantified most countries have experienced an increase in the number of conditions recorded on the death certificate.* ***It would be important to know when different versions of ICD/automated coding were used****. These issues would need to be considered more fully in any more detailed analysis;*

- *the number of ICD codes allowed for in the death registration system in each country (e.g. in Northern Ireland a maximum of five ICD codes have been used up until 2003);*

- *in their response to the inquiry the Swiss Statistical Office questioned the particular ICD codes used. In particular they questioned whether ICD10 codes Y63.0, Y63.1, Y65.1 and T80.0 should also be included. These codes are related to complications of medical treatment and are not included in the analysis noted here. It is noted that* ***no cases have been coded to these causes in Northern Ireland in the period of analysis, since 1984****. This issue should be addressed in any more detailed analysis;*

- ***data from a wider selection of European countries*** *(or indeed in other developed countries) would also be beneficial; and*

- *the comments noted by Statistics Netherlands would need to be considered further by medical experts - research would be required on the likelihood of doctors recording hyponatraemia on death certificates and other related issues*

23. To assist the Inquiry attached, as Annex B, is an outline of the additional data that would be required to develop the analysis shown above further. ***This additional data would enable the calculation of age and gender standardised mortality ratios for hyponatraemia related death and would thus ensure that any differences due to population age and gender structures were not distorting the statistics*** *presented. In addition it would be beneficial to discuss and further document the issues raised with the countries that responded to the initial request for information from the Inquiry.*

24. However, it is important to note that the initial results presented in this paper coupled with comments from the countries that responded to the Inquiry

suggest that further analysis of hyponatraemia related death should be concentrated on children. Given the relatively small number of cases, a case study approach using more detailed hospital information on hyponatraemia related deaths of children rather than death certificate information may be more informative. ***This would require gathering information from hospital records of those children whose death was hyponatraemia related. This information could then be used to identify the circumstances that caused the death*** *and, if possible, using this information to make comparisons."*[212] (Emphasis added)

300. Following the completion of the PSNI investigation into the children's deaths, the Inquiry asked NISRA to update the statistical information it had previously provided. A letter from the Inquiry dated 16th June 2009 was sent to all those that had previously responded seeking statistics from 2004 to date. All except Denmark provided the updated statistics sought.

301. NISRA's updated Report was produced in April 2010 stating its purpose as being not just to provide an update but also to deal with issues relating to the analysis of hyponatraemia mortality statistics.[213] The caveats in the previous Report were reiterated but, once again, the Report indicated that the crude annualised death rates for those aged under 14 years from hyponatraemia/fluid overload showed a higher rate of mortality in Northern Ireland than in the selected European countries. However, the Report pointed to the following anomalies/inconsistencies in the data:

"24. When processing the European data some inconsistencies were discovered.

- *The data from the Republic of Ireland and Germany only included cases where the underlying cause of death and not the secondary cause was hyponatraemia/fluid overload therefore we have omitted these countries from the analysis.*

- *The figures provided for more recent years for France seem very large in comparison to data provided for the original paper. Indeed there is discrepancy between the data in the original data supply in 2005 and the most recent data files for the years which overlap (1993-1999). Further investigation into the reason for these differences would be necessary to ensure the data is accurate and therefore data provided for France within with paper should be treated with caution.*

25. A further issue is the standard of reporting of cause of death. Evidence from health officials suggest that relatively junior hospital doctors tend to fill out death certificates and there is limited training on this for new doctors. This could affect the quality of the statistics presented. All parts of the United Kingdom are considering further safeguards on death certification. These

212 Ref: 308-016-276
213 Ref: 308-017-279

changes should include improved training or re-training for doctors in this important public health resource."[214]

302. Again, the Report concluded by recommending further analysis by the 'case study' approach in view of the relatively small numbers involved:

*"This information could then be used to identify the circumstances that caused the death and, if possible, using this information to make comparisons and guidance on best practice." (*Emphasis added)

303. No further statistical work has been carried out and therefore the anomalies identified in the data remain in respect of Germany, the Republic of Ireland and France.

NISRA 2011 Report

304. The Inquiry has made periodic requests for 'death data' from the Department of Health, Government Records Office (GRO) and NISRA in respect of:

(i) Deaths where the primary cause of death was 'hyponatraemia' or 'fluid overload' including: ICD-10 E87.1 (hypo-osmolality and hyponatraemia), ICD-10 E87.7 (fluid overload)

(ii) Deaths where an associated/secondary cause of death was 'hyponatraemia' of 'fluid overload' including: ICD-9 276.1 (hypo-osmolality and hyponatraemia, ICD-9 276 (fluid overload fluid retention).

305. The Inquiry has also sought details from NISRA as to deaths of children with an underlying cause of death of 'cerebral oedema' using ICD-10 G93.6 and ICD-9 348.5. In addition, the Inquiry made requests for 'hospital data' from the Directorate of Legal Services and of the various Trusts for:

(i) Details of any serious adverse incidents/near miss records involving children in which fluid management and/or hyponatraemia are concerned

(ii) Deaths recorded using the codes ICD-9 276.1 (hypo-osmolality and hyponatraemia, ICD-9 276 (fluid overload fluid retention) and ICD-10 E87.1 (hypo-osmolality and hyponatraemia), ICD-10 E87.7 (fluid overload).

306. On 10th February 2011 NISRA provided the Inquiry with an update on its 2010 information, namely that:

[214] Ref: 308-017-284

"Between the 1st January 2008 and 30th September 2010 (which is the last quarter's data available) there have been no deaths to children (aged under 16 years) registered where hyponatraemia or fluid overload was the underlying cause of death or a contributory cause of death."[215]

307. On 18th February 2011, NISRA provided information in relation to the request for deaths of children with an underlying cause of death of 'cerebral oedema':

"Since 1995 there have been 2 deaths registered [where] the deceased was a child with an underlying cause of death of cerebral oedema (348.5 or G93.6). The first death was registered in 1995 but the year of death was 1993 and the second child died and was registered in 2006.

Deaths data is only available and coded for registrations up until the end of September 2010."

308. The Directorate of Legal Services and the various Trusts were unable to provide information in respect of deaths by the requested ICD coding. To date no information was furnished in relation to serious adverse incidents involving children in which fluid management and/or hyponatraemia are concerned.

Inquiry Background Papers on Statistics & Coding

309. The Inquiry engaged Dr. David Marshall, Senior Principal Statistician in NISRA, to provide a Background Paper on the comparison of statistics of child hospital deaths in Northern Ireland from hyponatraemia or fluid overload with such deaths in the rest of the United Kingdom and Western Europe over the period 1979 to 2008. The salient points of this Paper are:

(i) There were 111 deaths registered in Northern Ireland between 1979 and 2008 where hyponatraemia or fluid overload was recorded as a cause of death. Of these 13 were coded as the underlying cause of death (none of which were children). For the remaining 98 deaths, hyponatraemia/fluid overload was recorded as a secondary cause of death and 5 of these deaths were to children aged less than 15 years

(ii) Initial analysis indicates a higher rate of child mortality in Northern Ireland than in selected other European countries, where hyponatraemia/ fluid overload is a factor in the cause of death

(iii) However, this analysis should be treated with caution due to: (a) the small number of registered deaths in Northern Ireland, (b) the fact the numbers are based on death certificate coding which can vary greatly from country-to-country and (c) the knowledge and awareness of a condition can also vary from country-to-country.

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215 Ref: 308-018-287

310. The difficulties in statistical comparison resulting from coding variations were referred to by the Chairman at the Progress Hearing on 9th March 2011:

> *"In particular, one issue of concern which emerges is that there is a coding system for deaths, and a potential problem is the accuracy and reliability of the coding system. Unless the coding system is accurate and reliable it doesn't give you, whether in hyponatraemia or any other area, a truly accurate report on the incidence of various conditions such as hyponatraemia."[p.8]*[216]

311. That is an issue which affects not only inter-country comparisons but intra-Northern Ireland comparisons both between Trusts and over time. Dr. Jean Keeling, Paediatric Pathologist, provided a Background Paper[217] on the systems and procedures for the dissemination of information gained by post-mortem examination following unexpected deaths of children in hospital. Some of the key points from her Background Paper are:

(i) Apart from the issuing of a Death Certificate, there is no standard practice in the UK for disseminating the information regarding an unexpected death in a hospital to other hospitals and bodies

(ii) Likewise, there is no common practice for internal analysis of deaths by hospitals, though many hospitals have meetings in which recent deaths are discussed

(iii) Coding is performed by clerks in hospitals based on information received from doctors. The likeliest source of error in coding is from the doctors involved, rather than the coders. Inaccurate coding could affect Government-generated statistics but is unlikely to affect analyses such as the National Confidential Enquiry into Perioperative Deaths (NCEPOD), where information is obtained on direct enquiry from the consultants concerned

(iv) There are no formal practices governing the dissemination of information from Coroner's Inquests to hospitals, Trusts and educational establishments.

312. An audit report of clinical coding in the Belfast Health and Social Trust published in August 2011 showed that 27.4% of episodes audited involved coding errors. In the RBHSC, this figure was 10.9%, closer to the English national average of 10%.

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216 Ref: 303-009-198

217 Ref: 303-053-754

XIV. Medical & Nursing Education

313. Mr. Chairman, you stated at the Progress Hearing on 23rd June 2005 that:[218]

"We will also be looking at the education and training and at the continuing education and training of nurses and doctors [p.15]" [219]

314. The early concerns over the content of education and training in relation to fluid management and the incidence of paediatric death in Northern Ireland from hyponatraemia were addressed through commissioning 'Background Papers' from experts, which are published on the Inquiry's website.

315. Mr. Chairman, you explained the purpose of doing so in relation to education and training during the Public Hearing on 9th March 2011:

"The reason for commissioning these papers and then circulating them is that we wanted to obtain a picture of the extent to which nurses and doctors have been taught about hyponatraemia and related issues over the last 30 or so years. The picture, as you will see when you receive the reports, the picture which emerges is a bit patchy, but we wanted to do that because it helps to set a background against which witnesses can be questioned at the Oral Hearings about the extent to which they were aware of hyponatraemia and what training they had received." [p.][220]

316. According to Mr. Gowdy in his Inquiry Witness Statement, the Department had no role in determining the content of the training provided to medical and nursing staff.[221] In addition, the universities are responsible for the content of courses and the Royal Colleges who are responsible for the training of junior doctors. The General Medical Council is responsible under the Medical Act 1983 for monitoring the content and quality of the medical education provided by Medical Schools across the UK.

317. The Inquiry engaged Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust[222] and Professor Sir Alan Craft, Emeritus Professor of Child Health, Newcastle University[223] to provide a Background Paper on the training and continuing professional development of doctors in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2009. The following points emerge from that work:

(i) Until recently, teaching was at the discretion of individual lecturers and tutors. Solution No.18 was a commonly recommended fluid in paediatrics. Hyponatraemia and Syndrome of Inappropriate Anti Diuretic Hormone were understood but regarded as uncommon. There

218 Ref: 303-006-116
219 Ref: 303-006-130
220 Ref: 303-009-198
221 Ref: WS-062/1, p.3
222 Ref: 303-046-514
223 Ref: 303-047-561

was no agreed protocol for the management of children on intravenous fluids. There were no recommendations for regular electrolyte testing.

(ii) More recently, teaching systems have become more accountable. Curricula have specific requirements for the teaching of the management of intravenous fluids in paediatrics. Medical students at Queen's University, Belfast, for example are taught the prevention of hyponatraemia in adults based on the Clinical Resource Efficiency Support Team (CREST) guidelines. Alert No. 22 is specifically referred to in relation to the use of Solution No. 18. There are also guidelines for the management of children on intravenous fluids.

318. Professor Mary Hanratty, former Vice-President of the Nursing and Midwifery Council[224] and Professor Alan Glasper, Professor of Children and Young Person's Nursing, University of Southampton[225] were engaged by the Inquiry to provide a Background Paper on the training and continuing professional development of nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2011. The main points in which may be summarised as:

(i) Maintaining fluid balance was often part of pre and post-registration nurse education programmes, but hyponatraemia itself was rarely specifically mentioned

(ii) On the whole, there was little attention paid to the Department of Health Guidance on the Management of Hyponatraemia that was circulated in 2002

(iii) This led to the RQIA assessment in 2008 finding that changes in practice were patchy

(iv) Every Trust has since revised and updated the prescription, administration instructions and fluid intake and output documents reflecting the efforts to prevent the development of hyponatraemia in children.

319. Dr. John Jenkins brought the subject of fluid management to the attention of the GMC education committee in 2004.[226]

320. Prior to the publication of Alert No.22, Dr. Henrietta Campbell, the CMO wrote on 8th July 2004 to Dr. Jack McCluggage, who was the Postgraduate Dean of Medicine at Queen's University, Belfast at the time, to request that he consider *"training in Fluid Administration"* a priority.[227] Dr. McCluggage

224 Ref: 303-048-571
225 Ref: 303-049-674
226 Ref: 007-063-132
227 Ref: 075-007-017

forwarded that request on to Senior Trainers within Paediatrics and other Medical Specialities on 20th July 2004.[228]

321. Professor Maurice Savage appears to have replied to the CMO to explain the current state of fluid administration education in July 2004:

"The topic is taught and highlighted at several junctures throughout the undergraduate curriculum. The modern curriculum links physiology and clinical practice very early in the course. Again, in the 3rd year Nephrology attachment, this is a specific topic addressed by experts in the field. In the 4th year, it is a core component of the Paediatric course, and we have a specific session in the final year in preparation for PRHO practice in relation to prescribing fluids."[229]

322. He added that he had "*no doubt*" that Dr. McCluggage would make fluid administration a "*key component*" of pre-registration house officer (PRHO) training.

323. Dr. McCluggage remained the Postgraduate Dean until October 2004 when he was succeeded by Dr. Terry McMurray who wrote on 14th June 2005 to all Directors of speciality training committees, all Postgraduate Clinical Tutors, all Education Co-ordinators and to the Director of Postgraduate General Practice Education requesting evidence about training being delivered, and how it had changed.[230] Dr. McMurray then wrote on 21st May 2008 to all the Heads and Deputy Heads of the Schools of many of the key areas of practice including all Foundation Doctors specifically referring to the fact that the *"development of Hyponatraemia in previously well children undergoing surgery or with mild illness may not be well recognised by clinicians"*.[231] He enclosed the 'Regional Paediatric Central Fluid Therapy Chart' developed by the Department of Health as well as a 'Workforce Competence Statement' developed by the National Patients' Safety Agency to assist in 'implementing and embedding the training'. Dr. McMurray stressed *"It is very important that training in this area is addressed by your speciality and I would be grateful if you can inform me as soon as possible how you mean to address this issue"*.

324. On 20th June 2008, the Associate Dean for Foundation Training contacted all Foundation Doctors and their educational supervisors, to advise them that completion of the BMJ e-learning module on Hyponatraemia was mandatory and that proof would be required of completion of the module within four weeks of them starting their F1 post.[232]

325. The teaching and training of medical students and student nurses in Northern Ireland on fluid management (with particular regard to hyponatraemia),

228 Ref: 303-054-766
229 Ref: 006-041-400
230 Ref: 303-055-767
231 Ref: 303-056-768
232 Ref: 303-057-774

record keeping and drug prescribing/administration and the communications, if any, between the Department, University and Trusts in relation to training about guidance on fluid management and hyponatraemia are issues to be investigated during the Oral Hearings.

XV. Professor Scally's Views on Departmental Knowledge

326. In his report for the Inquiry, Professor Scally addresses the central question of 'How did the Department know what was going on in hospitals prior to 2003 in terms of the quality of care?' He puts that question in context by observing that there is little evidence in the available documentation to indicate that there was a firm expectation that either Health and Social Services Boards or Trusts would be subject to any systematic monitoring of the quality of care provided to patients or in respect of their handling of adverse clinical events.

327. He refers to the 'Management Executive Circular METL 2/93'[233], which is relied upon by Mr. Gowdy as part of his reason for stating that *"it does not follow that Trusts or their Boards or Chief Executives had no responsibility for clinical care or clinical outcomes prior to the commencement of the Order"*[234] and notes that it was a key Department document relating to the accountability framework for Trusts. However, Professor Scally advises that it does not display any interest in patient care issues and they are not included in the five key items listed in relation to monitoring the performance of Trusts and he observes that it is not necessarily apparent how information about such problems in patient care would reach the Department. That assessment by Professor Scally of 'Management Executive Circular METL 2/93' is regarded as incorrect by the Department and is a matter that will be addressed in the course of the Oral Hearings.

328. Professor Scally identifies two main types of mechanisms generating information for the Department[235]:

(i) Mechanisms to be regarded as integral parts of a functioning healthcare system:

- Information from routine clinical audit mechanisms at a local, area and Northern Ireland level, together with that from participation in UK wide audits, such as the National Confidential Enquiry into Peri–Operative Deaths (NCEPOD)
- Routine collection, analysis and distribution of data from systems to report incidents of note within healthcare settings

233 Ref: 341-002-003
234 Ref: WS-062/2, p.4
235 Ref: 341-002-002

- Committees providing clinical advice to the Department such as the Central Medical Advisory Committee (CMAC) and the COM's Special Advisory Committees (SACs)
- Routine meetings between the Department and organisational or professional leaders, such as the Directors of Public Health
- The outcomes of settlements, whether reached before or after the commencement of litigation

(ii) Other means by which information might be obtained[236]:

- Matters raised by elected members of councils or assemblies
- Letters and other communications directly to the Department from members of the public
- Organisations representing patients, clients and carers - such as the four Health and Social Services Councils

329. He goes on to analyse the principal sources of information for the Department, pointing out their deficiencies. Tellingly, although he considers it to be perfectly clear that both Health and Social Services Boards and Trusts were accountable to the Department, he is of the view that there does not appear to have been a generalised understanding that the Department might have an interest in the occurrence of these deaths. He regards it as not surprising that the Children's deaths from hyponatraemia did not come to the attention of the department in a systematic fashion, given the substantial deficiencies outlined above in the systems within the health service in Northern Ireland in relation to quality of care. Indeed he characterises what happened in place of organised systems as a series of unstructured communications taking place outside any recognised protocols and heavily reliant upon interpersonal relationships. In those circumstances he also regards it as unsurprising that such communications did not necessarily engender action.[237]

330. Professor Scally concludes that there was no effective system in place in Northern Ireland prior to 2003 and that no significant efforts have been made at any stage to develop comprehensive and effective notification systems.[238] He refers to the difference in the level of engagement of the Department in Northern Ireland on issues of quality as compared to the emphasis being given to them at an equivalent level in England, which difference he regards as significant.

331. The Department disagrees with Professor Scally's view as to the extent of efforts made to develop appropriate notification systems. Furthermore, it does not accept the conclusions he reaches from a comparison between the

236 Ref: 341-002-003
237 Ref: 341-002-019
238 Ref: 341-002-006

developments in Northern Ireland and those in the rest of the UK. In particular, the Department relies upon the Report of Sir Liam Donaldson, 'Organisation with a Memory', for a portrayal of what it regards as the frailties of the system in England at that time. These are matters to be explored during the Oral Hearings.

332. Whilst Professor Scally recognises that there is some evidence of good practice and of local attempts to introduce the principles of clinical governance, he nonetheless points to a very clear leadership role for the Department in Northern Ireland and concludes that there would appear to have been a failure to provide the necessary impetus to achieve progress at anything other than a very slow pace indeed. The Department does not accept that any flaws which there may have been in the system in Northern Ireland were dues to failings in leadership. This is a matter to be addressed at the Oral Hearings.

333. Subject to any evidence to the contrary, he considers the responsibility for such a failure in leadership to rest predominantly with the professional leadership in the Department at this time.

XVI. Departmental Knowledge of Children's Deaths

334. During the course of the Oral Hearings, the Inquiry has investigated the extent to which the risks of 'hyponatraemia' and the matters addressed in the Hyponatraemia Guidelines issued by the Department in 2002 were, or could reasonably have been expected to be have been, known to clinicians in Northern Ireland at the time of the treatment and deaths of Adam, Claire, Lucy and Raychel in 1995, 1996, 2000 and 2001 respectively.

335. Mr. Gowdy would "*certainly*"[239] have expected the Trusts to have informed the Department of all of the deaths the Inquiry has been investigating. His predecessor Mr. Alan Elliott would have expected the Department to be informed of cases involving deaths due to possible medical mismanagement arising from complaints, Inquests and legal action. [240]

336. Although Witnesses have stated that the Department was not aware of the deaths of Adam, Claire and Lucy prior to Raychel's death in June 2001, it is important to investigate whether the Department could have known, or could have been informed, about their deaths prior to this time, and when it became aware of the other cases after June 2001.

337. In particular, the Inquiry will investigate the knowledge of those in the Working Group. The Inquiry has received comparatively little information

[239] Ref: WS-062/2, p.10
[240] Ref: WS-348/1, p.7

detailing the Working Group research. This matter will be pursued during the Oral Hearings.

Adam Strain

- ***Adam's Inquest and the Statement made on behalf of the Trust***

338. As you are aware Mr. Chairman, at Adam's Inquest on 21st June 1996, Dr. Taylor produced a draft Statement to the Coroner on behalf of the RGHT, which has became known as the 'C5' statement. Dr. George Murnaghan, the Director of Medical Administration, and the Trust's solicitor, George Brangam of Brangam, Bagnall & Co, were instrumental in the provision of that statement, which reads as follows:

"In the light of the rare circumstances encountered in the Adam Strain case, and having regard to the information contained in the paper by Arieff et al (BMJ 1992) and additionally having regard to information which has recently come to notice that perhaps there may have been nine other cases in the United Kingdom involving hyponatraemia which led to death in patients undergoing renal transplantation, the Royal Hospitals Trust wish to make it known that:

In future, all patients undergoing major paediatric surgery who have a potential for electrolyte imbalance will be carefully monitored according to their clinical needs, and where necessary, intensive monitoring of their electrolyte values will be undertaken. Furthermore, the now known complications of hyponatraemia in some of these cases will continue to be assessed in each patient, and all anaesthetic staff will be made aware of these particular phenomena and advised to act appropriately.

The Trust will continue to use its best endeavours to ensure that operating theatres are afforded access to full laboratory facilities to achieve timely receipt of reports on full blood picture and electrolyte values thereby assisting rapid anaesthetic intervention when indicated."

339. According to Dr. Murnaghan he was under the erroneous impression that the Coroner would circulate the statement.[241]

340. Mr Chairman, you have heard and read evidence that other hospitals and the Department were unaware of the publication of this statement by the RGHT.

341. The CMO has stated that she would have expected the Medical Directors and Directors of Public Health to have had some discussion about the case, due to the possibility of media interest and since a statement was made publicly by the Trust.[242] In addition, she would have expected the Department to be informed because the minister may have required to be briefed on the case. It

241 Transcript of the Oral Hearings, 25th February 2012, pages 186-187
242 Ref: WS-075/2, p.8

is also the type of case she would have thought should be discussed at the SAC for Anaesthetics or Paediatrics.[243]

342. In addition, Mr. Gowdy has stated that the 'C5' statement" was "*of such general application as to be of interest and significance to other hospitals likely to be treating young patients*."[244] In the circumstances in which this statement was made, he would therefore have expected it to have been "*at least copied*" to the Department and, "*ideally*", to have been the subject of some prior discussion with the CMO because of the regional implications and the desirability of wider dissemination.

343. The medical negligence action concerning Adam's death was being "*managed*" by Dr. Murnaghan. It would appear that there was not a sufficient concern "*that clinical practice or performance was impaired*" to justify reporting Adam's death to the DHSSPSNI[245] despite the content of Dr. Sumner's Report and the clear finding of H.M. Coroner. No further investigation was considered after the Inquest excepting only that Dr. Murnaghan and Dr. Carson considered it appropriate to consider convening a seminar involving Drs. Mulholland, Gaston, Savage, O'Connor, Taylor, Hicks and Mr. Keane[246] to address the "*other issues identified*"[247] at the Inquest. Although some urgency was indicated, the seminar did not take place. Dr. Murnaghan's evidence was that he had gone on holiday and then been unwell: "*I regret to this day that I totally forgot about this important issue … and all I can do is say 'hands up … I'm sorry'*".[248]

344. This is an issue to be considered during the Oral Hearings as to whether those in the Department should have been aware, or should have been made aware, of the circumstances of Adam's death, and the statement made by the RGHT.

- ***Post June 2001***

345. Dr. Taylor sent copies of his 23rd October 2001 letter to the Medicines Control Agency, in which he stated that he was aware of "*at least two other deaths attributable to the use of 0.18NaCl/4% glucose*"[249], to the Coroner on 24th October 2001[250] and to Dr. McCarthy on 25th October 2001.[251]

346. In subsequent correspondence with the Coroner dated 1st November 2001, Dr. Taylor mentioned Adam Strain's death: "*As you will remember I also had a child's death related to this type of fluid.*"

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243 Ref: WS-075/2, p.8
244 Ref: WS-062/2, p.10
245 Ref: WS-061-1 p.2
246 Ref: 059-001-001
247 Ref: 059-001-001
248 Ref: 059-036-070. Transcript of the Oral Hearings, 25th June 2012, p.209
249 Ref: 012-071e-412
250 Ref: 012-071d-411
251 Ref: 007-032-059

347. On 30th November 2001, Dr. Loughrey, Chemical Pathologist, e-mailed Dr. Miriam McCarthy to enquire whether she was aware of *"the death of a four year child in what sound like very similar circumstances in Northern Ireland in 1996"*. She stated that she had been speaking to the Coroner about the case. The CMO cannot recall whether or not Dr. McCarthy brought this e-mail to her attention at the time.[252]

348. The same day, the Coroner wrote to Dr. Brian Herron, the Neuropathologist charged with Raychel's post-mortem, on 30th November 2001, stating:

> *"You may be aware that in 1996 I held an inquest into the death of a four year old child called Adam Strain – for your information I am enclosing two copies of the post mortem report... The reason I am sending these to you is to enable me to discover whether there are any parallels between the death of Adam Strain and Raychel Ferguson."*[253]

He also enclosed two copies of Dr. Sumner's Report on Adam Strain to enable Dr. Herron to pass one to Dr. Loughrey. At that time, Dr. Loughrey was serving on the CMO's Working Group into the Prevention of Hyponatraemia. Accordingly, copies of the Adam Strain post-mortem Report and Dr. Sumner's Report on that death could have been available for the purpose of the deliberations of that Group.

349. Mrs. Therese Brown subsequently made a note on 4th December 2001 of a telephone conversation with H.M. Coroner in which she was informed of the Inquest into the death from hyponatraemia of a child who can only have been Adam Strain.[254]

350. Dr. McCarthy discussed the deaths of both Adam and Raychel with H.M. Coroner in a telephone conversation dated 13th/14th December 2001.[255] The Coroner forwarded Dr. Sumner's report from Adam's Inquest and the autopsy report on 17th December 2001.[256] Dr. McCarthy passed a copy of the report to the CMO, although she is unsure of the precise date.[257]

351. On 1st May 2002, Dr. Nesbitt wrote to the CMO:

> *"I am interested to know if any... guidance was issued by the Department of Health following the death of a child in the RBHSC which occurred some five years ago and whose death the Belfast Coroner investigated. I was unaware of the case and am somewhat at a loss to explain why. I would be grateful if you could furnish me with*

252 Ref: WS-075/1, p.2
253 Ref: 012-060e-308
254 Ref: WS-322/1, p.18 (17v) & 022-070-170 & 022-100-312
255 Ref: 006-056-440
256 Ref: 006-003-253
257 Ref: WS-075/1, p.3

any details of that particular case for I believe that questions will be asked as to why we did not learn from what appears to have been a similar event."[258]

352. The CMO responded by assuring Dr. Nesbitt that:

"This Department was not made aware of the case at the time either by the RVH or the Coroner. We only became aware of that particular case when we began the work of developing guidelines following the death at Altnagelvin."[259]

353. This letter was copied to H.M. Coroner who wrote to the CMO on 7th November 2002[260] stating that he did not formally notify the Department under the provisions of Rule 23(2) of the Coroner's Rules 1963, but that his "*clear understanding*" was that changes would be made in relation to the future management of cases like that of Adam Strain. He explained that he did not therefore see a need for formal action at the time. He also assumed that there existed some mechanism for dissemination of Dr. Sumner's opinions but accepted that "*this is not the case*."

354. The Coroner added that if the CMO felt that he should make formal reports to the Department on a more regular basis, he would "*certainly consider that*". He also asked her to advise him of "*a mechanism in existence*" for advising the medical profession of the outcome of inquests and the opinions of independent expert called to give evidence. The CMO replied accepting his request to discuss how the health service and the Coroner's Office could work together to improve the management of risk.[261]

355. Dr. Taylor later made a "*detailed examination*"[262] of the issues surrounding Adam's case, and it was reported to the Department by the RGHT in September 2004 that "*there were no new learning points, and therefore no need to disseminate any information*." It is unclear whether this refers to at the time of Adam's death / Inquest in 1995/96, or at the time of examination and writing in 2004.

Claire Roberts

356. UTV broadcast its documentary 'When Hospitals Kill' on 21st October 2004. The investigative focus was on the role hyponatraemia played in the deaths of Lucy Crawford, Adam Strain and Raychel Ferguson and whether there was cause to suspect a 'cover-up'. The programme was the product of many months work and had involved contact and correspondence with the RBHSC.

258 Ref: 006-045-427
259 Ref: 006-002-117
260 Ref: 006-015-311
261 Ref: 006-014-309
262 Ref: 023-045-105

357. Claire's parents watched the programme, seeing it as "*virtually a mirror image*" of Claire's case. They contacted the RBHSC and had two meetings with medical staff. The Coroner was informed and met Mr. and Mrs. Roberts on 7th January 2005.

358. Mr. Roberts wrote to you, Mr. Chairman, on 17th January 2005 to suggest that you might consider adding Claire's case to the work of the Inquiry. You then wrote to Mr. Gowdy, the Permanent Secretary, on 27th January 2005[263] about her case and it was subsequently added to the Inquiry.

359. The Trust formally reported Claire's death to the Department's Quality & Performance Improvement Unit as a Serious Adverse Incident (SAI) on 28th March 2006[264] under the arrangements outlined in the Interim Guidance HSS (PPM) 06/04.[265] Dr. McBride, then Medical Director of the RBHSC, e-mailed Dr. Ian Carson, the Deputy CMO on the same day to inform him of the formal notification.[266]

Lucy Crawford

360. No one within the Department admits knowing about Lucy Crawford's case and death until March 2003.

361. Dr. McConnell has stated that it was his understanding, gained from information provided to the WHSSB by Mr. Fee and Mr. Mills, that the Trust had reported Lucy's death to the DHSSPS ("*they were already in discussion with the DHSSPS*"[267]).

362. In particular, Dr. McConnell has stated that his belief is that Mr. Mills had communicated the death of Lucy to senior DHSSPS in the course of a telephone call[268] but when pressed for further details of whom Mr. Mills spoke to in the Department and what was discussed, Dr. McConnell is unable to answer and he has indicated that it would be better for Mr. Mills to address these issues.

363. Mr. Frawley has stated that he has no knowledge of the Trust submitting a report in relation to Lucy's death (or its findings) to the DHSSPS.[269]

364. Moreover, none of the Trust's senior management team admits reporting Lucy's death to the DHSSPS, and Mr. Mills specifically denies that the Trust's review into Lucy's death was ever brought to the Department's attention. He

263 Ref: 322-041-001
264 Ref: 322-070-003
265 Ref: 322-070-001
266 Ref: 322-070-005
267 Ref: WS-286/1, p.7
268 Ref: WS-286/2, p.4
269 Ref: WS-308/1, p.21

did not consider reporting the review to the Department and he states that others did not suggest to him that he should do so.[270]

365. After Raychel's Inquest, the Western Health & Social Services Council attended a meeting with the AHHSST on 19th February 2003 so that it might *"learn of the Altnagelvin Trust perspective on the death of Raychel Ferguson."*[271] Mr. Stanley Millar, Chief Officer of the WHSSC, having attended the meeting and reflected upon it for a week, wrote to the Coroner on 27th February 2003 about the case of Lucy Crawford:

"Following the Raychel Ferguson Inquest I, with other members of the WHSSC, received a briefing on the events which led up to Raychel's death. I was struck by the similarities in the two tragedies... I am left with two questions which you may be able to answer. (1) Are there direct parallels in the events leading up to the death of both girls? (2) Would an Inquest in 2000/2001 have led to the recommendations from the Raychel Ferguson Inquest being shared at an earlier date and a consequent saving of her life?"[272]

366. The Coroner asked Dr. Crean to have a look at Lucy's medical records and compare her case with Raychel's. He gave the opinion that the issues regarding Lucy "*are not as clear cut*"[273] as those concerning Raychel, although he had "*concerns*" about her management at the Erne Hospital. The Coroner therefore copied Mr. Millar's letter to the CMO[274] and Dr. Sumner[275] on 3rd March 2003, asking the latter for a report. He followed this up with a phone call to Dr. McCarthy on 5th/6th March.[276]

367. The CMO states that she was unaware of Lucy's death until she was contacted by the Coroner.[277]

368. H.M. Coroner also arranged a meeting with Dr. McCarthy, amongst others, on 5th June 2003 at the State Pathologist's Department to discuss his concerns that all hyponatraemia deaths were not being identified.

369. Mr. Clive Gowdy, Permanent Secretary of the DHSSPS, has stated that he did not become aware of Lucy's death until a Departmental Board meeting on 27th February 2004.[278] At the meeting, Mr. Gowdy stated that Trusts needed to be reminded of the importance of alerting the Department to cases such as Lucy Crawford.[279] Mr. Hill said during the meeting that Noel McCann, Director,

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270 Ref: WS-293/1, p.6
271 Ref: 014-016-028
272 Ref: 006-012-297
273 Ref: 006-011-295
274 Ref: 006-010-294
275 Ref: 006-011-295
276 Ref: 006-056-440 & 443
277 Ref: WS-075/1, p.3
278 Ref: WS-062/1, p.2
279 Ref: 004-019-236

Planning & Performance Management, would arrange for the distribution of a Notification letter to be followed by more detailed guidance from the Department. It may be that Circular HSS (PPM 06/04) 'Reporting and Follow-Up on Serious Adverse Incidents: Interim Guidance', distributed on 7th July 2004,[280] was the "Notification letter" mentioned by Mr. Hill at the Departmental Board meeting.

Conor Mitchell

370. H.M. Coroner contacted Dr. Miriam McCarthy on 13th May 2003 to let her know of Conor Mitchell's death, and that this may have been another death from hyponatraemia. Dr. McCarthy e-mailed the CMO and Dr. Carson, the Deputy CMO, that afternoon to inform them.

XVII. Litigation

371. The impact upon the Children's families of the Trusts' delay in acknowledging fault and apologising has been a consistent feature of their evidence and the submissions made on their behalf by their respective legal teams. It may be Mr. Chairman that this is a matter that can be considered by the relevant officials in the forthcoming Oral Hearings and Panel Discussion.

372. Summarised below are the events as they relate to each of the Children. The relevant dates and extracts from the documents indicating the Trusts' positions are set out in a Schedule of Trusts' Admissions of Liability' compiled by the Legal Team. [281]

Belfast Trust

373. During the end of the last stage of the Oral Hearings, on 18th September 2013, Counsel for the Belfast Trust made the following statement:

"I think it's important that the families be made aware that at the outset of any panel discussion it is the intention of the chief executive to apologise to the families for the shortcomings in the management of the Belfast Trust, both in relation to the clinical management of the patients concerned and in relation to any shortcomings in governance which have been uncovered by this Inquiry and, finally, in relation to the conduct of the litigation in relation to the case of Strain and in relation to any other case where the way in which the case has been managed has added to the distress of the families. I think, Mr. Chairman, it's important that the families are aware that this development will not be in response to what you've said, but has already been decided upon as the appropriate response to the evidence that has been given during this inquiry."[282]

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280 Ref: WS-065/1, p.9
281 Ref: 337-004-001
282 Ref: Transcript of the Oral Hearings, 18th September 2013, p.148

374. This statement came in the light of the evidence given during the Oral Hearings, and what had happened in the litigation of the children's cases. It can be seen as applying to all of the cases under consideration by the Inquiry, given that all of the children were admitted or transferred to the RBHSC. It was not immediately clear why the families should wait until the onset of any panel discussion before they received such an apology.

375. In Adam's case against the Belfast Trust, proceedings were commenced by way of Letter of Claim dated 25th April 1996.[283] After the Inquest, the Trust's Solicitor Mr. George Brangam expressed his views in a letter dated 19th March 1997 to Dr. Murnaghan:

"I believe from a liability point of view, this case cannot be defended and this is based largely upon the information given by one of the Independent Experts retained by H.M. Coroner at the Inquest."[284]

376. The case was settled on 29th April 1997 on undisclosed terms, without any admission of liability on the part of the Trust and subject to a confidentiality clause.[285] The Inquiry has heard evidence of how the lack of admission of liability and the imposition of the confidentiality clause caused distress to the Strain family.[286]

377. After settlement of the claim, Dr. Murnaghan wrote to the key clinicians involved in Adam's case to advise them of settlement. He stated:

"Additionally it would have been unwise for the Trust to engage in litigation, in a public forum, and given the tragic circumstances of the death. It would not have been helpful for an opportunity to be provided to lawyers to explore any differences of opinion which might exist between various professional witnesses who would have been called to give evidence."[287]

378. It was not until 17th October 2013 that the Trust provided Adam's mother with a full admission of liability and apology. It was preceded by a question to Dr. Robert Taylor at the conclusion of his evidence in Raychel's case as to whether he thought *"Adam's mother should have received an acknowledgement of responsibility, liability, for Adam's death"*.[288] Subsequently Mr. Chairman you wrote to the Trust asking whether it might consider taking a similar line in Adam's case as Altnagelvin had recently taken in Raychel's case in which there had been an admission of liability and an apology. The Trust responded positively during the Oral Hearings on 17th October 2013:

283 Ref: 060-022-042
284 Ref: 060-016-031
285 Ref: 060-013-024
286 Ref: WS-001/2, p.16
287 Ref: 060-010-018
288 Ref: Transcript of the Oral Hearings, 18th September 2013, p.146

"Obviously, Mr Chairman, a formal response will have to be written to you, but I can indicate at this stage that the Belfast Trust accept that there were shortcomings in the fluid management in the case of Adam Strain. It is public record that proceedings were previously initiated by the relatives of Adam Strain in relation to his death. That claim was settled on terms endorsed, with no admission of liability and a confidentiality clause. The confidentiality clause was subsequently waived by the trust. In response to your letter, the trust will be writing to the family and that response will contain a full admission of liability and an apology and an expression of sympathy."[289]

379. In the case of Claire, there was no suggestion to her parents by the Belfast Trust that there was anything untoward in her death. Her parents received a letter in March 1997 from Dr. Webb offering his condolences and telling them about the outcome of the hospital brain-only autopsy that had been carried out. The letter informed them that there was evidence of a low grade infection suggestive of a viral cause.[290] Nearly 7 years later Claire's parents contacted RBHSC after they had seen the UTV documentary 'When Hospitals Kill', which dealt with the fatal administration of solution 18. That led to a review of Claire's notes and a meeting with Claire's parents during which they were told that *"the Trust wants to be completely open about this case"*.[291] That was followed by a letter to them from Dr. McBride dated 17th December 2004: *"our medical case note review has suggested that there may have been a care management problem in relation to hyponatraemia and that this may have significantly contributed to Claire's deterioration and death"*[292]

380. However, notwithstanding the outcome of the Inquest, the Trust did not admit its liability for Claire's death to her parents. This is despite the fact that Mr. Walby acknowledged during his evidence at the Oral Hearings on 11th December 2012 that: *"I had it in my mind at the end of the Inquest that we had not handled it well and should the Roberts bring a clinical negligence claim, the Trust would be settling it"*.[293] He went on to explain that he would have settled the case simply on the failure to carry out a blood test the morning after Claire's admission. [294]

381. Despite that view by the then Associate Medical Director, Litigation Department, it took sixteen years after Claire's death for the Trust to provide her parents with the open admission of liability and apology which they sought. However, that did not happen until considerably after the Oral Hearings into Claire's case, which concluded on 17th January 2013 and after the service of a Letter of Claim on 26th September 2013. The Trust's response was a letter on 16th October 2013 stating: *"the Trust acknowledges that there were*

289 Ref: Transcript of the Oral Hearings, 17th October 2013, p.2-3
290 Ref: 090-001-001
291 Ref: 089-002-002
292 Ref: 089-005-011
293 Ref: Transcript of the Oral Hearings, 11th December 2012, p.168
294 Ref: Transcript of the Oral Hearings, 11th December 2012, p.170

shortcomings in the management of [Claire] and the Trust does not wish to in any way add to the distress of [Claire's parents]". It went on to state: "*We, therefore, formally concede liability*". There was no apology but that was provided during the Oral Hearings on 17th October 2013,[295] during which the "*full and frank admission of liability on behalf of the Belfast Trust in relation to the death of Claire*" was reiterated and the Trust's senior counsel went on to say: "*I would wish to offer an apology, a sincere apology, to the family on behalf of the Trust for the shortcomings in the management of Claire*".

Sperrin & Lakeland Trust

382. In Lucy's case, a Letter of Claim was sent to the Sperrin Lakeland Trust on 27th April 2001, following that her parents had received from Mr. Mills dated 30th March 2001 in which he stated:

> "*the outcome of our review has not suggested that the care provided to Lucy was inadequate or of poor quality. As you are aware, the Trust engaged an independent consultant, from another Trust, to review Lucy's case notes and to advise us on this very question*".[296]

383. During the period of legal action, Lucy's parents made an attempt to find out what happened with Lucy's care. Mrs. Crawford contacted Dr. Holmes, Consultant Anaesthetist. His report of this conversation to Mrs. Kelly contains the statement: "*Mrs. Crawford states firmly that in taking recourse to legal help, they are not seeking financial compensation. They just want 'an explanation and an apology*".[297]

384. Approximately five days before the case was listed to be heard, the Trust declared on 10th December 2003, that it 'would not be contesting the issue of liability'. The Trust accepted liability on 10th December 2003 and the litigation was eventually settled.

385. However, it was not until a month after the Inquest in relation to the circumstances of Lucy's death, which concluded on 19th February 2004, that Mr. Mills wrote to Lucy's parents to apologise for the Trust's failure to provide adequate care for their daughter:

> "*I am writing on behalf of the Trust to indicate our regret and apologies for the failings in our service at the time of Lucy's death in April 2000. These failings, not fully identified in or original review became evident later in the process following another reported death in Northern Ireland. At that time we sought, through your legal representatives, to reach settlement on the legal proceedings.*"[298]

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295 Ref: Transcript of the Oral Hearings, 17th October 2013, p.4
296 Ref: 047-004-004
297 Ref: 033-056-169
298 Ref: 067h-004-006

386. On 23rd February 2004, Mr. Fee, Director of Acute Hospital Services, Sperrin Lakeland Trust, produced a list of *"Issues for Consideration"* arising out of Lucy's Inquest.[299] Key issues identified included:

(i) The inappropriate use of Solution No.18

(ii) The inappropriate volume of fluid management

(iii) The failure to have a properly completed prescription

(iv) The communication difficulties and confusion amongst staff

(v) The poor record keeping including the accuracy of the fluid balance recording

(vi) The level of observation during the infusion period and

(vii) The inconsistency between the decisions taken by the Trust as reflected in the letter of 30th March 2001 and the later settlement of litigation.

Altnagelvin Trust

387. Litigation in Raychel's case was started by a Letter of Claim of 1st May 2003 which made it *"clear from our clients' instructions that the death of their daughter was occasioned by the negligence, breach of duty and/or breach of statutory duty... in or about the provision of medical treatment."*[300]

388. The Altnagelvin Trust's denial of liability was comprehensive. The DLS wrote to the solicitors for Raychel's parents to emphasise that the AHHSST does:

"not accept that it, or its staff, were negligent or that, if there was any failure to apply appropriate standards, that the failure caused or contributed to the death of Raychel Ferguson and therefore liability is denied."[301]

389. Indeed, following the broadcast of UTV's Insight programme in 2004 the Altnagelvin Trust moved swiftly to produce a public statement on 15th June 2004, with advice from the DLS solicitor[302] and with which the CMO was *"content"*,[303] to recite all that had been done following Raychel's death and to state: *"The Trust believes that it acted professionally and honestly following Raychel's death."*[304] Nevertheless, and in view of the establishment of the Inquiry, the solicitors for Raychel's parents wrote on 3rd June 2005 to the DLS

299 Ref: 067k-012-024
300 Ref: 024-001-001
301 Ref: Transcript of the Oral Hearings, 1st February 2013, p.113 on
302 Ref: 023-017-027
303 Ref: 023-022-049
304 Ref: 023-007-011

enquiring whether liability was being disputed. The response was unequivocal:

"We would however make it clear that the Trust do not accept that it or its staff were negligent or that if there was any failure to apply appropriate standards that the failure caused or contributed to the death of Raychel Ferguson and therefore liability is denied".[305]

390. It was not until 30th August 2013 that the Altnagelvin Trust announced its admission of liability. It is not clear why it had not been able to do so sooner, bearing in mind the extent of the investigation into Raychel's treatment carried out by the Inquiry, which culminated in the Oral Hearings on clinical issues that had concluded 26th March 2013, and the start of the Oral Hearings on governance issues on 27th August 2013 in which the attitude to the litigation was queried.

391. Nevertheless, that statement that was made during the Oral Hearings on 30th August 2013 was comprehensive, leaving no doubt as to the position of the Altnagelvin Trust:

"The Trust, having taken into account the evidence heard during this inquiry, including independent expert evidence and the interim comments of the Chairman, formally admits liability. The Trust apologises unreservedly for Raychel's death and regrets any further hurt or distress that the delay in admitting liability has caused the family".[306]

Craigavon Area Hospital Trust

392. Turning now to Conor, the Inquest into his death was concluded on 9th June 2004. Shortly after that, on 21st July 2004, Mr. Templeton wrote to Conor's grandmother stating that: *"I consider that all matters relating to Conor's death and treatment were fully and openly discussed during the Inquest process"* and *"I want you and your family to know that as Chief Executive, I wish to do all I can to re establish your confidence in the Trust and its staff"*.[307]

393. Conor's grandmother took issue with that, saying that there had been *"no answers as to why it was allowed to happen"*[308] and subsequently asserting that "*someday there will have to be admitted that Conor received sub-standard care*".[309] In the interim, a Letter of Claim was issued.

394. There was no acknowledgement by the Craigavon Area Hospital Trust that there had been any failings in the implementation of the CMO's 2002 Guidelines or any consideration of the possible implications for Conor's care

305 Ref: 326-002-001
306 Ref: Transcript of the Oral Hearings, 30th August 2013, p.1
307 Ref: 329-022-021
308 Ref: 329-022-022
309 Ref: 329-022-026

of such a failure. Mr. Templeton responded on 16th December 2004 to the correspondence from Conor's grandmother by advising that the matter was now in the hands of the solicitors but, nonetheless stating:

"I am satisfied that the Trust and all of the staff involved in Conor's treatment and care have acted properly in their clinical activities and in an honest and open manner during our enquiries".[310]

395. In 2008, it was announced that Conor's case would be included into the Inquiry's work primarily to assess compliance with the 2002 Guidelines. It is not clear whether that prompted any review of his case from that perspective or any reconsideration of the Trust's statements to Conor's family.

396. Subsequently the NMC carried out a fitness to practise hearing into the care and treatment given to Conor by Nurse Bullas. The Panel *"found Joanna and Judith Mitchell to be credible and consistent witnesses and accepts their evidence in this respect [seizures] in its entirety"*.[311] It concluded that Nurse Bullas should not bear sole responsibility as she was lacking in experience, having not yet completed her preceptorship, and she was given insufficient or no support with briefings being inadequate. The Panel went on to refer to systematic deficiencies at the Trust.[312] The Trust took issue with the finding of systematic deficiencies, considering that the issue lay outside the scope of such a hearing. Again it is not clear whether the Trust nonetheless took the opportunity see those comments in the light of the issues being investigated by the Inquiry and to reflect on the extent to which it might have failed to comply with the 2002 Guidelines and if so the significance of any such failure.

397. The Oral Hearings in relation to Conor were opened on 16th October 2013. On the following day, 17th October 2013, the Trust sent a letter to Conor's mother admitting its liability for the failure to comply with the 2002 Guidelines and apologised, which was read out during the hearing that day:

"The Southern Health and Social Care Trust, which includes the legacy Craigavon Area Hospital Trust, (The Trust) accepts that the DHSSPS 2002 Guidelines on the Prevention of Hyponatraemia in Children were applicable to Conor Mitchell.

The Trust accepts that for various reasons which will be the subject of this Inquiry, the directions of the Chief Medical Officer as contained in these Guidelines and accompanying correspondence were not properly implemented in the Medical Assessment Unit or Emergency Department of Craigavon Area Hospital at this time, and that staff in those areas were not made aware of or trained by the legacy Trust in the implementation of these guidelines. We would contrast that situation with the Southern Trust's response to the DHSSPS 2007 Guidelines.

310 Ref: 329-022-028
311 Ref: 303-025-346
312 Ref: 303-025-349

The Trust accepts that throughout his course of management in Craigavon Area Hospital in 2003, it was the Trust's responsibility to ensure the Clinicians and Nurses who were looking after Conor Mitchell had the Guidelines at the fore front of their minds when treating him and the Trust accepts that these Clinicians and Nurses should have had this guidance available to them when treating Conor.

Although there is nothing to indicate that the failure to comply with the Guidelines resulted in Conor's death, the Trust fully acknowledges its liability for the failures and shortcoming that occurred in the implementation of the DHSSPS 2002 Guidelines on the Prevention of Hyponatraemia in Children both generally and specifically in relation to Conor's care. The Trust apologises to Conor's family for the failings referred to above and again offers our sincere sympathies to Conor's family."[313]

398. The Trust has since followed that up with a letter about seizures acknowledging its failings in that regard in relation to communication with Conor's family and apologising for those failings.

XVIII. CMO Media Response

399. The CMO was involved a number of interviews with the press in 2003 and 2004. Some of the comments that she made left her subject to criticism from, amongst others, the families of Raychel and Adam who publicly called for her resignation in December 2004.[314]

400. Dr. McCarthy recalls that it would have been normal practice for Dr. Campbell to discuss with her and other colleagues the relevant issues prior to any media interview and to cover specific key messages and how they were best articulated for the particular audience.[315] She also recalls that the issues involved in the hyponatraemia cases were discussed with Dr. Campbell before her media interviews, though she cannot recall any details.

Interview with UTV – 17th February 2003

401. In the aftermath of Raychel's Inquest, the CMO accepted an invitation for an interview from Mr. Trevor Birney, Editor of Current Affairs at UTV. Mr. Birney interviewed her on 17th February 2003.

402. The CMO expressed her concern about Raychel's death and her wish for lessons to be learnt so that nothing like it could happen again.[316] She mentioned the difficulty for the service to learn from such "*very rare*" events, and that the Department would have to work with the rest of the U.K. to look

313 Ref: Transcript of the Oral Hearings, 17th October 2013, p.6-7
314 Ref: 073-037-162
315 Ref: WS-080/2, p.21
316 Ref: 069A-033-078

for patterns of untoward events, as Northern Ireland was "*too small of a place to learn of itself*". The CMO has since explained:

"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."[317]

403. When asked about Adam Strain's death, the CMO stated that, over the last 10 years in Northern Ireland, she was "*not aware of any case of hyponatraemia in a normal, healthy child.*" She has since explained that she was only aware of the deaths of Adam and Raychel at this time (in particular, she was unaware of Lucy's death).

404. She stated that Adam's case involved an "*entirely different clinical situation*".[318] She has since explained that she considered Adam to have:

"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 appendicectomy."[319]

In this sense, she did not consider Adam to be a "*normal, healthy child*" due to his renal problems. Dr. McCarthy agrees with this assessment.[320]

405. The CMO mentioned that the Inquest system in Northern Ireland was "*another way of bringing into the open issues which are of concern*" and that "*it is one that I feel that people should have been using properly*".[321]

406. Some of the CMO's comments were included in a UTV Insight broadcast on 27th February 2003 entitled *"Vital Signs"* which concentrated on Raychel's treatment and death, and which, although he was not named, also mentioned Adam's death.[322]

Interview with BBC Radio Ulster Evening Extra – 18th March 2004

407. A year later, in the aftermath of Lucy's Inquest, the CMO gave two interviews to the BBC on 18th March 2004. The first broadcast was a live radio interview with Ms. Audrey Carville.[323]

317 Ref: WS-075/2, p.12
318 Ref: 069A-033-079
319 Ref: WS-075/2, p.11
320 Ref: WS-080/2, p.21
321 Ref: 069A-033-084
322 Ref: 068a-005-015
323 Ref: 004-010-166

408. The CMO began by expressing her sympathies to the Ferguson family.[324] She deemed Lucy and Raychel's deaths as "*entirely preventable*" and mentioned the importance of lessons to be learned, including communications with parents.

409. In relation to Lucy's case, the CMO stated that the fluids given to her were those 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.*" She stated that the body "*goes through this abnormal response in just a very few cases*".[325]

410. She has later explained that "*abnormal response*" was a reference to the fact that healthy people are able to remove excess fluid through urination, and to respond otherwise (for example, by SIADH) was "*abnormal*".[326] As shall be seen in a later section of this Opening, the use of this term was the subject of a complaint by the Ferguson family to the General Medical Council.

411. Dr. McCarthy has stated that, whilst she agreed that such cases were rare, she could not agree with the use of the term "*abnormal reaction*" as used by the CMO.[327] She states that increased ADH secretion (as in SIADH) is a physiological response to stress, such as infection or surgery, and could therefore be considered as a child's "*anticipated*",[328] rather than "*abnormal*" response to such stress, although she states that this is a "*complex area*", in which she is not an expert, and it was a "*challenging*" task for the CMO to translate for the purposes of the audience.

412. The CMO went on to add in the interview that Sperrin Lakeland Trust did not realise at the time, "*nor would they have been expected to*", that there were implications for the wider service from that case. She has explained to the Inquiry that she "*does not think that Sperrin Lakeland Trust initially implicated hyponatraemia as a cause for Lucy's death*"[329] and so "*they could not have realised the wider implications of hyponatraemia if they did not recognise it as a cause for Lucy's death.*" She said that "*with the benefit of hindsight*" had they begun gathering evidence, Raychel's death might never have occurred.

413. She stated that H.M. Coroner put the 2 deaths together and began to realise that there might be a pattern which alerted the Department to "*this new and emerging problem of hyponatraemia [...] in a very small number of children*." She has explained to the Inquiry[330] that she meant that, because several deaths had been attributed to the condition in recent years, it was starting to be

324 Ref: 004-010-166
325 Ref: 004-010-167
326 Ref: WS-075/2, p.12
327 Ref: WS-080/2, p.22
328 Ref: WS-080/2, p.23
329 Ref: WS-075/2, p.12
330 Ref: WS-075/2, p.13

recognised as a problem and that Dr. Sumner had described it to the Coroner as a "*Cinderella area of medicine*". Dr. McCarthy has commented that, whilst the risks of hyponatraemia could be said to be "*new*", hyponatraemia as a response to low sodium fluids or SIADH as a response to surgery were "*unlikely to be new*".[331]

414. Finally, the CMO added that she hoped that the guidelines in place, with careful monitoring and implementation would reduce the risk markedly, and that the guidance had been shared with the rest of the U.K.[332]

Interview with BBC Newsline – 18th March 2004

415. The second broadcast interview with the CMO on 18th March 2004 was a pre-recorded television interview with Mr. Julian O'Neill of BBC Newsline.[333]

416. The CMO repeated her assertion that Lucy's death was "*entirely preventable*"[334] and that, had there been an earlier inquest into her death, Raychel's death might never have happened. In addition, she stated that H.M. Coroner had agreed that he will draw to the Department's attention "*very early*" on those deaths about which he has concern.[335]

417. The latter comment caused H.M. Coroner to write to the CMO on 22nd March 2004.[336] He stated that inquests "*should not be seen as the means of disseminating medical knowledge.*"[337] He also reminded the CMO that Dr. Sumner, when giving evidence at the Inquests of Adam, Raychel and Lucy, had been "*at pains*" to state that his views on fluid management of children did not constitute 'new' knowledge. The Coroner also suggested that there may be merit in developing a protocol addressing what the relationship should be between the Department and Coroners.

Interview with UTV's 'The Issue' – 25th March 2004

418. The CMO agreed to an interview with UTV's 'The Issue', which took place on 25th March 2004[338]. The programme was to be broadcast that night[339], but the programme was pre-recorded that morning. The interviewer was Mr. Fearghal McKinney.

419. The CMO began the interview by stating how tragic Lucy and Raychel's deaths had been and how she and the Health Service deeply regretted the

331 Ref: WS-080/2, p.23
332 Ref: 004-101-168
333 Ref: 004-101-163
334 Ref: 004-101-164
335 Ref: 004-101-165
336 Ref: 006-004-281
337 Ref: 006-004-282
338 Ref: 006-037-375
339 Ref: 006-004-281

death of any child, and that lessons had to be learned.[340] In regard to Lucy's death, the CMO characterised it as "*a very rare occurrence, written up in the medical journals only recently.*" She added:

"*At that time in the year 2000, the fluids being used in every paediatric unit in Northern Ireland, and in most paediatric units throughout the UK, were the fluids that were being given to Lucy. What we know now is that from a few cases written up in the medical journals, in some children, a very few children.*"[341]

420. In addition, she said that:

"*The rarity in these 2 events was the abnormal reaction which is seen in a very few children to the normal application...*[342]

"*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*"[343]

"*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.*"[344]

421. The CMO accepted that they had no system within the Health Service at that time for the reporting of all deaths of children.[345]

422. The CMO and her staff were unhappy with the conduct of the interview and complained to UTV[346], terming the interview "*extremely aggressive and bullying*", "*deeply insulting*" and "*misogynistic*"[347].

423. Mr. Alan Bremner, Director of Television, UTV, strenuously denied these allegations in a letter to Mr. Clive Gowdy, the Permanent Secretary, DHSSPS dated 8th April 2004.[348] He accused the CMO of being "*evasive*" in answering Mr. McKinney's questions.[349] In addition, he stated that the CMO was rehearsing the argument that Lucy and Raychel's deaths were due to an idiosyncratic physiological response to the fluids, which he said "*completely contradicts the Coroner's findings which said nothing about physiology or an unpredictable and abnormal reaction*". There had not been a "*normal application of fluids.*"

340 Ref: 006-037-375
341 Ref: 006-037-376
342 Ref: 006-037-376
343 Ref: 006-037-377
344 Ref: 006-037-378
345 Ref: 006-037-377
346 Ref: 001-001-002 & 003
347 Ref: 001-001-002
348 Ref: 006-034-366
349 Ref: 006-034-367

424. Dr. Dewi Evans was interviewed by UTV and, was asked to comment on the CMO's statement that *"The rarity in these 2 events was the abnormal reaction which is seen in a very few children to the normal application ...*

Reporter: *Is this statement right or wrong?*

Dr. Evans: *Oh this statement is wrong.*

Reporter: *Would it therefore worry you that it was made by the CMO for Northern Ireland?*

Dr. Evans: *Well, yes it would. Clearly the CMO may not be a practising clinician and may have no experience of children's medicine at all. But it is incorrect."*[350]

425. The CMO has since explained to the Inquiry[351] that, by "*normal application of fluids*", she meant "*normal*" only in the sense that Solution No.18 was widely used. She did not mean to refer to the rate or quantity infused since she "*would not have had the expertise to comment that*".

426. In addition, Mr. Bremner had spoken again to Dr. Sumner following the broadcast and he had rejected the CMO's claim that "*very few people*" would have understood the cause of the children's deaths as articles on hyponatraemia were first published in the 1980s in the BMJ, and that the outcomes of fluid maladministration would been understood long before 2000.

427. In her witness statement to the Inquiry, the CMO stated:

"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 Northern Ireland."[352]

428. Mr. Bremner also mentioned a telephone conversation between him and Mr. Gowdy which took place on 26th March in which he recorded Mr. Gowdy expressing "*legitimate concerns*"[353] about the CMO not being told about untoward events and that there were "*procedural shortcomings*" in the communications about untoward events between some Trusts and/or Boards and the Department.

350 Ref: 068-006-040
351 Ref: WS-075/2, p.13
352 Ref: WS-075/2, p.13
353 Ref: 006-034-366

429. In response, Mr. Gowdy wrote to Mr. Bremner on 13th May 2004 denying that the CMO was evasive or lacking in veracity and rejecting the suggestion that there was a contradiction between the CMO's comments and the Coroner's findings.[354]

'Platform' Article in the Irish News – 21st May 2004

430. The editor of the Impartial Reporter newspaper, Mr. Denzil McDaniel, had a 'Platform' article published in the Irish News on Wednesday 19th May 2004. This article referred to the CMO's statements in her interview with UTV as "*nonsense*" as "*it is clear from the medical experts that there was nothing idiosyncratic about Lucy that made her susceptible*."

431. The CMO responded by providing her own article to the Irish News, which was published on Friday 21st May 2004 in which she reiterated her sympathies for Lucy's family and her acceptance of the Coroner's findings. She added:

"Lucy died from a medical condition called hyponatraemia, rightly recognised by the Coroner as being brought about by the fluids used in her treatment. It is important to note that the fluids used in the treatment of Lucy have been in common use for more than 30 years in all paediatric units across the globe and have saved many lives. However, it is now known that in some instances these fluids may put some children at risk of the potentially fatal condition called hyponatraemia. Unfortunately, this condition was not widely recognised amongst health professionals across the UK at the time of Lucy's death."[355]

432. The CMO stated that she was made aware of Lucy's death in June 2001, but this was the subject of a correction the following day, when it was amended to March 2003.[356]

Interview with the Impartial Reporter – 25th May 2004

433. Mr. McDaniel sought, and obtained, permission for an interview with the CMO which took place on 25th May 2004. The CMO erroneously stated in the interview that the Department was made aware of Raychel's case by the Royal who realised there was a problem of a regional nature. The CMO also stated:

"*There's still I think a hard search to find how people [could] recognise early those children that might be at risk of responding in this dangerous way developing [hyponatraemia] which may go on to be fatal*."

434. Furthermore she stated:

354 Ref: 001-041-137
355 Ref: 004-010-154
356 Ref: 004-010-155

"Maybe it was because of some genetic makeup of Lucy, we don't know that yet, we don't know what makes certain youngsters at risk."[357]

435. The CMO also referred to the fact that "*the fluids we're talking that Lucy got were in general use*"[358] and that a study that she received from Dr. McCarthy stated that one in 300 children receiving those fluids would develop hyponatraemia and one in 3,000 children receiving those fluids would go on to have a fatal reaction, which she categorised as a "*very small risk*".

436. She has later explained to the Inquiry[359] that her figures were a simplified version of those quoted by Arieff in his 1992 article[360]. It should be noted that Arieff's statistics were in the context of the development of hyponatraemia in paediatric postoperative patients. She conceded that the management of Lucy's fluids was "*inadequate*" and could have been "*much, much better*".[361]

Interview between Dr. Jenkins and UTV – 7th June 2004

437. Dr. Jenkins agreed to an interview with Mr. Birney of UTV on 7th June 2004.[362] He was asked about some of the CMO's comments and the debate regarding whether some of the deaths were due to idiosyncratic or physiological reasons.

438. He responded by saying that it was "*complicated*" and it was not simply "*black or white*".[363] He explained that "*different children, indeed different adults, will respond to a particular set of circumstances in different ways*". By way of example, he stated that he had seen children with very severe hyponatraemia suffer no complications, whilst other children in similar circumstances have.[364] He agreed that some children would therefore have an "*abnormal*" response, but did not want to use the word "*idiosyncratic*".

439. Dr. Jenkins stated that the Working Group was set up when it was recognised that <u>both</u> Raychel and Lucy had died.[365] Indeed, he stated that it was Dr. Taylor who had approached the CMO with the link between Raychel and Lucy's deaths.[366] He later corrected this, saying he had been confused as to the timings of when he found out about the deaths, and that in fact they did not know about Lucy's death at the time of the Working Group meetings, so she could not have been mentioned.[367]

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357 Ref: 069A-035-095
358 Ref: 069A-035-093
359 Ref: WS-075/2, p.11
360 Ref: 011-011-076
361 Ref: 069A-035-094
362 Ref: 069A-056-179
363 Ref: 069A-056-179
364 Ref: 069A-056-180
365 Ref: 069A-056-181
366 Ref: 069A-056-182
367 Ref: 074-016-071

GMC Complaint against the CMO by the Ferguson family

440. Mr. and Mrs. Ferguson made a formal complaint to the GMC on 6th November 2004[368] in respect of a number of clinicians and officials including the CMO.

441. The Fergusons' complaint concerned what they regarded as a failure of those doctors to reveal the truth in the investigations into Lucy's death. They believed that the death of their daughter Raychel "*could have been avoided if Lucy Crawford's death had been properly and independently investigated in 2000*".They accused the CMO of attempting to "*cast blame on the Coroner for not knowing the extent of the problem of dilutional hyponatraemia sooner*".[369]

442. The specific allegations made against the CMO were that:[370]

(i) She knew, or should have known, that Lucy and Raychel's deaths were caused because they were given the wrong type and volume of fluid, not because their reactions were "*abnormal*"[371]

(ii) She knew, or should have known, that Lucy's Inquest was delayed because information had been withheld from the Coroner inappropriately

(iii) She knew, or should have known, that clinical mistakes rather than any abnormal reactions were responsible for Lucy and Raychel's deaths

(iv) Her comments in media interviews were a misrepresentation of the facts and not in the interests of the wider medical community in Northern Ireland.

443. The CMO responded to the allegations through her solicitors.[372] She stated that she did not, in any interview, suggest directly, nor wish to imply, that the Coroner was responsible for the delay in holding Lucy's inquest.[373] She also stated that she was "*completely clear in both interviews that both deaths were preventable, and hence she clearly accepted by implication that they were caused by clinical mistakes*."[374]

444. She stated that her other comments were made in the context of her role as CMO and were intended to reassure parents who were worried about the potential dangers of hyponatraemia.[375] She also stated that she does not hold

368 Ref: 068-013-022
369 Ref: 068-013-022
370 Ref: 104-013-036
371 Ref: 004-010-168
372 Ref: 104-026-514
373 Ref: 104-026-515
374 Ref: 104-026-519
375 Ref: 104-026-520

herself out to be an expert in fluid management and has never sought to do so, but her view was (and remained) that the deaths of Lucy and Raychel could have been prevented if they had received appropriate care.[376]

445. The CMO added that she deeply regretted causing the Ferguson family further upset and distress by her comments, but "*there was no intention on her part to mislead or misrepresent the facts.*"[377] In response, Mr. Desmond Doherty, solicitor to Raychel's parents, wrote to the GMC to state:

"*Dr. Campbell, before going on television and dealing with the media at large, should have made sure that she knew exactly what she was talking about so as not to cause any further offence and distress to our clients.*"[378]

On behalf of the Fergusons, he described her actions as "*reckless*", an allegation expressly denied by the CMO.

446. In their decision, the GMC Fitness to Practise Directorate decided that, in relation to the "*abnormal reaction*" comment, that the CMO's comments were "*misleading*"[379] in that they "*appeared to contradict*" the coroner's conclusions that Lucy had been given the wrong type and volume of fluid. They added that her interviews were "*ambiguous*" and "*open to misinterpretation*", and that she had handled them "*inappropriately*".[380] However, they were not satisfied that there was any evidence that she was aware of the true circumstances of Lucy's death prior to March 2003, or that she was engaged in a deliberate cover-up.

447. The GMC was not satisfied that her failures were sufficiently serious for there to be a realistic prospect of establishing that the CMO's fitness to practise was impaired to a degree justifying action on her registration, nor to warrant a formal warning. However, they did invite her to "*reflect on this decision and the concerns expressed by the complainant*s".[381] The case was therefore closed on 27th May 2010 with no further action.

The CMO's Reaction to the Media Response

448. In a recent witness statement to the Inquiry, the CMO was asked about a number of statements she made in 2003 and 2004. She wanted to make clear that she did accept that the deaths had been caused by clinical mistakes. In addition, she made the following statement:

"*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*

376 Ref: 104-026-521
377 Ref: 104-026-522
378 Ref: 104-014-039
379 Ref: 104-022-446
380 Ref: 104-022-447
381 Ref: 104-022-447

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."[382]

XIX. Response to Raychel Ferguson's Death in June 2001

449. On 18th June 2001, Dr. Raymond Fulton, of Altnagelvin Hospital, disclosed the circumstances of Raychel's death to a regular meeting of Medical Directors[383] chaired by Dr. Ian Carson on behalf of the CMO.[384]

450. Dr. Kelly, of the Erne Hospital, recalls telling Dr. Fulton about Lucy Crawford's death before the meeting and further that other Medical Directors present were aware of *"previous problems."*[385] Dr. Fulton later told the Coroner at Raychel's Inquest that *"there were several anaesthetists present, some of whom said that they had heard of similar situations though it was not clear if there had been fatalities."* It is equally unclear whether there was any discussion of the *"several deaths involving No. 18 Solution"*[386] which Dr. Fulton had understood, from Dr. Nesbitt's letter of 14th June 2001, to have occurred in Northern Ireland.[387]

451. At the meeting, Dr. Fulton suggested that there should be regional guidance and that he considered that Solution No.18 was hazardous when used in post-operative children.[388] The CMO was informed of Raychel's death by Dr. Ian Carson shortly after the meeting.

452. Four days later, Dr. Fulton telephoned the CMO to inform her of the circumstances of Raychel's death[389] and further that the RBHSC had stopped using Solution No.18 because of *"problems with it in the past."*[390] The CMO states that she would have expected to have been previously informed as to the discontinuance of Solution No.18, had there been a public health issue.[391]

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382 Ref: WS-075/2, p.15
383 Ref: 095-011-054
384 Ref: 012-039-179
385 Ref: WS-290/1, p.24
386 Ref: 022-102-317
387 Ref: Transcript of the Oral Hearings, 4th September 2013, p.76 line 12
388 Ref: 095-011-054
389 Ref: 012-039-180
390 Ref: WS-075/1, p.2
391 Ref: WS-075/2, p.7

Nevertheless, she does not appear to have specifically responded to this information.

453. Dr. Fulton suggested that she should publicise the dangers of hyponatraemia when using low saline solutions in surgical children and urged the need for regional guidelines. Dr. Campbell suggested that the CMO suggested that CREST might be involved in the development of guidance.

454. No formal written report of Raychel Ferguson's death was made to the Department. There was no formal requirement to do so. Professor Swainson considers it:

"regrettable that there was not a clear framework from the Department that would have ensured that serious clinical incidents were reported by Trusts and disseminated to the other Trusts. Wide sharing of serious incidents can stimulate quicker and national efforts to reduce harm."[392]

455. On 26th June 2001, Dr. Robert Taylor advised a meeting of the Sick Child Liaison Group that work was to take place on *"agreed guidelines from the Department of Health on this subject."*[393] He made this announcement in the presence of Dr. McCarthy, Senior Medical Officer of the Department. It is unclear how and when the decision to issue guidelines was taken or how Dr. Taylor became privy to such information so early.

456. Dr. McConnell, Director of Public Health at the WHSSB, referred Raychel's death to the next meeting of the Directors of Public Health on 2nd July 2001 in the presence of both the Chief and Deputy Chief Medical Officers.[394] It was agreed that guidelines should be issued to all units. However, no further steps appear to have been taken by the Department at that stage.

457. Mrs. Stella Burnside, Chief Executive of Altnagelvin Trust, e-mailed the CMO on 26th July 2001 to emphasise that she was:

"concerned to ensure that an overview of the research evidence is being undertaken. I believe that this is a regional, as opposed to a local hospital issue, and would emphasise the need for a critical review of evidence. I would be extremely grateful if you would ensure that the whole of the medical fraternity learned of the shared lesson. I await to hear further from you."[395]

458. The CMO responded that she had not taken any action as the Directors of Public Health had told her that they would "*take this in hand at local level.*"[396] However, she decided that she would now "*take steps to personally oversee this in line with your suggestions.*"

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392 Ref: 226-002-010
393 Ref: WS-008/1, p.15
394 Ref: 075-081-323
395 Ref: 006-002-249
396 Ref: WS-075/1, p.22

459. She sought advice, on 27th July 2001, from Dr. Ian Carson as to whether there was *"anyone at RBHSC who could put together a short paper on this."*[397] He responded that he would ask Dr. Taylor *"to consider drafting advice and guidance suitable for dissemination throughout the HPSS."*[398]

460. Dr. Carson e-mailed Dr. Taylor's paper, entitled 'Hyponatraemia in Children'[399] to the CMO on 30th July 2001.[400] He copied Drs. Fulton and Taylor into this correspondence and commented:

> *"The problem today of 'dilutional hyponatraemia' is well recognised (See reference to BMJ Editorial). The anaesthetists in RBHSC would have approximately one referral from within the hospital per month. There was also a previous death approx. six years ago in a child from the Mid Ulster. Bob Taylor thinks that there have been 5-6 deaths over a 10 year period of children with seizures..."*

Neither Dr. Carson[401], nor anyone else at the Department, took any steps to investigate this information or make any enquiries about the deaths to which they had been referred.

461. Dr. McCarthy stated that Dr. Taylor's briefing was *"very helpful"*[402] in informing the Department as to the key issues with regard to hyponatraemia.

Formation of the Working Group

462. The CMO directed her Deputy, Dr. Paul Darragh[403], to assemble a Working Group to consider hyponatraemia in children and make recommendations on fluid balance.[404] To that end, Dr. Darragh met with Dr. McCarthy, on 14th August 2001, and asked her to convene the Working Group.[405]

463. Dr. McCarthy recalls that in determining the membership of the Working Group *"clinicians from relevant specialty areas were identified giving due account to appropriate geographic distribution."*[406] It is unclear who made this identification, but individuals were then 'sounded out' and those who agreed to participate received a formal letter of invitation from Dr. Darragh, dated 21st August 2001, which expressed the hope that *"we could achieve a broad measure of agreement on how to proceed and... we would only need one or two meetings to achieve a consensus."*[407]

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397 Ref: WS-330/1, p.10
398 Ref: WS-330/1, p.10
399 Ref: 043-101-223
400 Ref: 021-056-135
401 Ref: WS-331/1, p.4
402 Ref: WS-080/2, p.6
403 See List of Persons Ref: 337-001-001
404 Ref: 075-082-329
405 Ref: WS-080/1, p.2
406 Ref: WS-080/2, p.6
407 Ref: 007-050-099

464. Apart from Drs. Darragh, Mark[408] and McCarthy of the Department, those invited to take part were:

(i) Dr. Robert Taylor, RBHSC, who brought knowledge of Adam's case to the Group. Whilst he cannot now recall, it would appear that he also examined Claire Roberts in PICU[409] and may possibly have chaired the RBHSC mortality meeting which discussed Lucy's death[410]

(ii) Dr. Darrell Lowry, Craigavon Area Hospital, was a Consultant Anaesthetist who had worked at RBHSC. After learning of Raychel's death from Dr. Nesbitt in June 2001, he was prompted to develop guidelines at Craigavon Hospital to prevent a similar occurrence

(iii) Dr. Geoff Nesbitt, Altnagelvin Hospital, may be taken as having been selected by reason of his involvement in Raychel's case and his interest in the use of Solution No.18 in general paediatric therapy

(iv) Mr. G. Marshall was a Surgeon from the Erne Hospital where Lucy had been treated

(v) Mr. William McCallion, RBHSC, provided the input of a Paediatric Surgeon (he also had incidental knowledge of Adam Strain, having operated on him some years prior to his death)

(vi) Dr. Clodagh Loughrey, Belfast City Hospital, was a Chemical Pathologist who had furnished the Coroner with an expert opinion as to the cause of hyponatraemia in Raychel's case

(vii) Dr. Peter Crean, also of the RBHSC, was a Consultant Paediatric Anaesthetist who had treated both Lucy and Raychel, and was conversant with the fluid issues arising in Adam's case. Notwithstanding his non-engagement with Claire's case, his name appears as her Consultant on her Case Note Discharge Summary[411]

(viii) Dr. John Jenkins, of Antrim Area Hospital, was a Consultant Paediatrician and Senior Lecturer in Child Health (QUB) who had a special interest in fluid and electrolyte balance; he also provided the Sperrin Lakeland Trust with an expert report on the management of Lucy's case on 7th March 2002

(ix) Dr. Fiona Kennedy, Northern Health and Social Services Board, had an interest in public health issues

408 See List of Persons Ref: 337-001-001
409 Ref: WS-157/1, p.2
410 Ref: 061-038-123
411 Ref: 090-009-011

(x) Ms. Elizabeth McElkerney, Ulster Hospital, was a Nurse Manager most probably selected for her nursing perspective.

465. In preparation for the first meeting of the Working Group, Dr. Taylor prepared a PowerPoint Presentation on *"Hyponatraemia in Children"* which he sent to Dr. Darragh on 18th September 2001.[412] Dr. McCarthy also read and noted the content of the presentation.[413] Whilst Dr. Taylor did not make this presentation, Dr. McCarthy recalls that the *"issues contained in the presentation were discussed at meeting of the Working Group and subsequent meeting of the sub-Group."*[414]

466. The presentation incorporated Dr. Taylor's detailed figures of the 'Incidence of Hyponatraemia at RBHSC' which omitted the deaths of Adam Strain, Claire Roberts and Lucy Crawford. Dr. Taylor has since stated that these figures were based on incomplete data. Nonetheless, he quite expected Dr. Darragh to share the content of this presentation with the Working Group.[415]

Meetings of the Working Group

467. The Working Group held its first meeting on 26th September 2001.[416] The meeting was chaired by Dr. Darragh. Minutes were taken by Dr. Mark.[417]

468. It would appear from the minutes that Dr. Taylor took a leading role at the meeting. He informed the meeting as to the background, the "*incidence of cases seen in RBHSC"* and those patients particularly at risk of hyponatraemia. He stated that this was "*a problem that has been present for many years.*" Dr. Taylor proposed a number of recommendations to prevent hyponatraemia.

469. A general discussion followed in which it was agreed that simple new guidelines were required, that audit of such guidelines was to be encouraged and that a small group would undertake the drafting of guidelines and audit protocol.

470. Dr. Jenkins was unable to attend. The Group expressed the need for paediatric input which it deemed essential.

471. Dr. Darragh has noted:

> *"given Dr. Taylor's presentation at the Working Group there were clearly likely to be other cases emerging, but the important step of producing guidelines was the appropriate step to be taken at regional level at that time."*[418]

412 Ref: 007-051-100
413 Ref: WS-080/2, p.7 (14c)
414 Ref: WS-080/2, p.7 (14d)
415 Ref: Transcript of the Oral Hearings, 18th September 2013, p.98 line 22
416 Ref: 007-048-094
417 Ref: 073-020-098
418 Ref: WS-076/2, p.12

472. It is clear that Raychel's death, which was the catalyst for the Working Group, was discussed.[419] Dr. Nesbitt remembers that *"Raychel was mentioned at the meeting because I kept on and on about it."*[420] He has also said *"I used every opportunity to talk about that case. This was a 'burning issue' for me..."*[421]

473. Dr. McCarthy has stated:

> *"I recall Dr. Taylor highlighting one death, that of Raychel Ferguson. I also recall Dr. Taylor advising attendees of the increased identification of cases of hyponatraemia in the RBHSC, including 2 cases resulting in fatality."*[422]

474. Dr. Taylor remembers that, in order:

> *"to assist in the work of the Northern Ireland Working Group on Hyponatraemia in Children"- "I did discuss the hyponatraemia deaths with other colleagues. I cannot recall what information was discussed. At this time in 2001 we were aware of Lucy and Raychel's deaths."*[423]

475. Whilst it is clear that the individual cases which concern this Inquiry were known to individual group members, the extent to which information was shared and examined within the Working Group is unknown.

476. When taxed about whether the Working Group considered the deaths of Adam Strain, Lucy Crawford or Claire Roberts the official line from the Department in 2004 was:

> *"the CMO's Working Group was established to prepare guidance on the prevention of hyponatraemia and not to consider the case of any specific child or children. At the time the Working Group was established, the CMO was not aware of Lucy Crawford's death."*[424]

477. Evidence given by Drs. Jenkins, Crean, Nesbitt and Taylor has been to the effect that the Working Group did not collectively consider the deaths of Adam Strain, Claire Roberts or Lucy Crawford, notwithstanding that individual members might have been able to. Dr. Taylor has said that in a Working Group:

> *"there is a real need to progress the guidelines, and if you hold them back by... if there is an argument that develops and somebody says 'that is not true, that patient didn't die of that cause' or 'that patient did die' it distracts the team, and as I said the*

419 Ref: 001-078-270
420 Ref: Transcript of the Oral Hearings, 3rd September 2013, p.161 line 8
421 Ref: WS-035/2, p.33 (45a)
422 Ref: WS-080/2, p.13
423 Ref: WS-157/2, p.3
424 Ref: 009-014-022

composition of the team was directed towards developing a guideline, not to go over a death that might have already been subject to a Coroner's Inquest."[425]

478. Dr. Jenkins was of the view that *"an essential part of that process [was] for guidance to be tested against individual cases that took place. And certainly I regarded it as my responsibility to test the guidance against the knowledge that I had."*[426] Dr. Crean thought that *"we probably were all drawing on our own expertise with children we had managed."*[427]

479. However, Dr. Jenkins entertained no expectation that a member of the Working Group who had information in relation to individual cases would mention it by e-mail so that the Guidelines might be tested against it.[428] He thought *"it would have been easier, for doctors to have shared that type of information in a face-to-face meeting other than in e-mails."*[429]

480. On 30th November 2001 Dr. Loughrey wrote to Dr. Miriam McCarthy to enquire whether she was:

"aware of the death of a four year child in what sound like very similar circumstances in Northern Ireland in 1996? I was speaking to the Coroner about it today he is to send me a copy of his report in that case. Let me know if you'd be interested in seeing it. Perhaps you are already aware of it."[430]

481. Professor Swainson has expressed the view that it is logical that the known individual cases of hyponatraemia deaths would likely have been examined by the Group because

"I don't think you can divorce the context in which you are doing the work from the work itself. And I still think you'd want to test the assumptions and the conclusions you are coming to against your experience of those cases."[431]

Medicines Control Agency contact by Dr. Taylor

482. *At the meeting of the Hyponatraemia Working Group on* 26th September 2001, Dr. Taylor undertook to report Raychel's case to the Medicines Control Agency (MCA). In preparation, he had already completed the 'Yellow Card' form.[432] In subsequent correspondence with the MCA dated 23rd October 2001, he requested that it consider issuing a hazard notice in respect of Solution No.18 fluid.[433] He also informed it that he was:

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425 Ref: Transcript of the Oral Hearings, 18th September 2013, p.128 line 5
426 Ref: Transcript of the Oral Hearings, 10th September 2013, p.27 line 8
427 Ref: Transcript of the Oral Hearings, 11th September 2013, p.90 line 9
428 Ref: Transcript of the Oral Hearings, 10th September 2013, p.71 line 15
429 Ref: Transcript of the Oral Hearings, 10th September 2013, p.32 line 11
430 Ref: 007-025-048
431 Ref: Transcript of the Oral Hearings, 19th September 2013, p.127 line 15
432 Ref: WS-008/1, p.18
433 Ref: 007-043-088

"*conducting an audit of all infants and children admitted to the PICU with hyponatraemia. My initial results indicate at least two other deaths attributed to the use of 0.18NACL/4% glucose.*"[434]

483. This correspondence was circulated amongst some Working Group members, namely Drs. Jenkins, McCarthy and Nesbitt. Whether this prompted any inquiry as to the detail of the "*other deaths*" is unknown.

484. The MCA considered Dr. Taylor's request and wrote on 26th November 2001[435] stating that it had been considered by the Working Group on Paediatric Medicines, a sub-group of the Committee on Safety of Medicines. They decided that although hyponatraemia is a risk in children during the use of 4% dextrose/0.18% saline, "*electrolyte imbalance is a risk with the use of all IV solutions.*" It noted that careful monitoring of children after surgery was "*crucial*" and in particular, care should be taken not to overload patients with intravenous fluids if they are oliguric as part of the normal response to surgery. It advised that there should be no amendments to product information.[436]

485. Dr. Taylor forwarded a copy of the correspondence to Dr. McCarthy on 30th November 2001.[437] The debate as to whether to prohibit Solution No.18 and/or recommend specific intravenous fluids became a major theme in the deliberations of the Working Group and subsequent professional re-assessments.

Production of the Guidance

486. Dr. McCarthy was delegated to assemble a sub-committee of the Group to undertake the drafting of the guidelines. Notwithstanding Dr. Taylor's experience and continued contributions and suggestions, he was not included in the sub-committee. Dr. Nesbitt was also not included.

487. Drs. Jenkins, Crean and McCarthy did however meet on 10th October 2001 along with Dr. Jarlath McAloon, Consultant Paediatrician, who like Dr. Lowry, had been quick to grasp the necessity of clinical protocol to govern the use of hypotonic fluids in children.[438]

488. He was co-opted to ensure the presence of a second paediatrician on the Working Group. His understanding was that Dr. McCarthy chairing on behalf of DHSSPS:

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434 Ref: 012-071e-412
435 Ref: 007-017-034
436 Ref: 064-010-038
437 Ref: 006-055-439
438 Ref: WS-080/2, p.8

"*wanted to take away suggestions, shape them into a format on which to base further discussion, and to conduct e-mail correspondence with a larger drafting group and produce the DHSSPS guidance this way.*"[439]

489. The sub-committee decided to proceed by way of e-mail communication as a *"virtual group"* with all the limitations to interaction and communication that that must necessarily have entailed. As Dr. McAloon records *"my responses were channelled through Dr. McCarthy's office and I am not aware of who saw them."*[440]

490. The criteria for inclusion in the sub-committee are unknown. Professor Maurice Savage, Professor of Paediatrics and President of the Ulster Paediatric Society, wrote to Dr. Darragh on 1st October 2001 *"concerned that someone in my position only hears about such a Group 'on the grapevine'... and trusting that the document you prepare will have wide consultation."*[441] He was subsequently consulted, as was Dr. Bell of the Ulster Hospital.

491. On 1st October 2001, Dr. Darragh chaired a meeting of the SAC (Anaesthetics). He referred to draft guidance in respect of prevention of hyponatraemia in children and asked for comments to be sent to Dr McCarthy.[442] Dr. Taylor consulted paediatric colleagues in Alder Hey Hospital and at Toronto Sick Children's Hospital and reported to Dr. McCarthy on 3rd October 2001.[443]

492. The Working Group moved swiftly and Dr. McCarthy was able to refer draft guidance papers to a meeting of the SAC (Paediatrics) on 30th October 2001[444], a meeting of the Directors of Public Health/DHSSPS on 5th November 2001[445], and a meeting of CREST on 8th November 2001.[446] At the Directors of Public Health meeting, it was noted that the guidelines had already gained the support of the SAC (Anaesthetics) and (Paediatrics).[447]

493. However, the draft did not address Dr. Nesbitt's position that Solution No.18 was the significant hazard factor in children's post-operative hyponatraemia. Accordingly Dr. Fulton was prompted to write to the Chief Executive of the AHHSST, Mrs Burnside, on 14th November 2001 that:

"You may have received a copy of the enclosed correspondence about intravenous fluids in children together with the draft Guidelines. I have told Dr. Nesbitt that I think the 'choice of fluid' section is totally inadequate considering the gravity of our

439 Ref: WS-363/1, p.8 (16f)
440 Ref: WS-363/1, p.8 (17)
441 Ref: 007-042-087
442 Ref: 075-080-322
443 Ref: 007-041-082
444 Ref: 075-076-287
445 Ref: 075-083-333
446 Ref: 076-066-210
447 Ref: 075-083-333

local experience. As Geoff says it is a 'fudge' and fails to address the use of No.18 Solution. I firmly advised Geoff to challenge this section."[448]

494. Dr. McCarthy sent a "*final draft*" of the guidelines to the Group members on 7th November 2001.[449] Dr. Taylor responded by terming it an "*excellent guide for generic use of fluids in children with careful monitoring and use of available expertise.*" Dr. Loughrey however was "*disappointed*" that they were not actively discouraging the use of hypotonic fluids for replacement since she believed that this was "*a major (if not the major) factor in the demise of the child in Altnagelvin.*" She conceded that there were "*clearly others who do not agree with me."*

495. Dr. McCarthy subsequently sought the views and advice of Dr. Sumner on the level of detail in the draft guidelines and on recommendations for specific fluid choices.[450] Dr. Sumner replied on 17th December 2001 to advise that:

"Post-operatively fluid should be restricted for the first 24-48 hours because of inappropriate ADH associated with surgical stress. At GOS we give 2ml per kg per hr of 4% (10% for newborns) dextrose/.18% saline for the first 24 hours BUT replace colloid losses with the appropriate colloid and intestinal losses with an equal volume of normal saline with 10mmol potassium in 500ml."[451]

Dr. Sumner's view may be interpreted as signifying that the use of Solution No.18 is appropriate, so long as it was used in the manner he described.

496. Dr. McCarthy e-mailed the Working Group on 20th December 2001 to inform that, following meetings of the SAC (Surgery) and Medical Directors, and the feedback received, she had decided to make some reference to Solution No.18 in the guidelines.

497. Dr. Crean replied the same day to note his concern that advice as to specific IV fluids had been added to the guidance despite the fact that "*there is not really any evidence to suggest that one solution is more or less harmful than another."* He cited the continued use of Solution No.18 by Dr. Sumner at Great Ormond Street as an example.

498. In contrast, Dr. Loughrey replied to say that she felt so strongly about a reference to the risk associated with the use of Solution No.18 for replacement fluid purposes that, if it was not included, she would want her name disassociated from the guidelines.[452]

499. Dr. McCarthy, in her e-mail to the Working Group on 10th January 2002, stated:

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448 Ref: 021-055-134
449 Ref: WS-035/2, p.346
450 Ref: 012-062-314
451 Ref: 007-016-032
452 Ref: 007-013-027

"There is not a sound evidence base to suggest that [Solution No.18] carries an intrinsic risk in itself. When CSM commented recently they emphasised the risk of hyponatraemia with any fluid and did not feel it appropriate to amend product information."[453]

500. She therefore suggested deleting the explicit reference to Solution No.18 in the Guidance. In reply, Dr. Nesbitt stated that he was "*disappointed*"[454] that Solution No.18 was not to be mentioned specifically in the guidance, questioning "*what evidence do you need exactly?*" and stating that Solution No.18 "*is as close to free water as you can get.*" He ended his e-mail with the statement that "*you can be sure that [Solution No.18] will remain highlighted as a risk in any protocol produced by Altnagelvin Hospital.*"

501. Throughout the preparation of the guidance, Dr. McCarthy regularly discussed progress with the CMO, providing verbal updates and drafts of the document as appropriate.[455] The guidelines were discussed prior to publication at a meeting of the Directors of Public Health and DHSSPS on 25th February 2002.

502. In addition, CREST set up a sub-group to draft guidance for the 'Management of Hyponatraemia in the Adult Patient.' It held its initial meeting on 27th February 2002, in the presence of Dr. McCarthy.[456] It was hoped to produce guidance by the end of June 2002. The minutes of the CREST meeting for 9th May 2002 record *"a worrying scenario which came to light during deliberations, was that medical students were no longer taught about pharmacology and nurses were taught very little about fluid balance"* noting *"whilst these issues needed to be addressed [they] were outside the remit of the Group."*[457]

Publication of the Guidance in 2002

503. The Department published its 'Guidance on the Prevention of Hyponatraemia in Children' in March 2002. The CMO wrote a general letter to all interested parties on 25th March 2002 to accompany publication in which she advised that:

"The Guidance is designed to provide general advice and does not specify particular fluid choices. Fluid protocols should be developed locally to compliment 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."[458]

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453 Ref: 007-008-014
454 Ref: 007-003-005
455 Ref: WS-080/1, p.4
456 Ref: 075-073-076
457 Ref: 075-067-223
458 Ref: 021-064c-328

504. Dr. Campbell has told the Inquiry that "*it was a matter for the Trusts to ensure any protocol they issued would complement the Guidance*".[459]

505. The Hyponatraemia Guidelines warn that: "*Any child on IV fluids or oral rehydration is potentially at risk of hyponatraemia*".[460] The guidance was produced in the form of an A2-sized wall chart which was issued on 26th March 2002. It highlights particular risk areas including those associated with post-operative patients, bronchiolitis and vomiting. It addresses:

(i) Baseline assessments, specifically referring to urine and electrolytes

(ii) Fluid requirements for both maintenance and replacement

(iii) Choice of fluid

(iv) Monitoring of the child's clinical state, fluid balance (input and output) and biochemistry

(v) Seeking advice from the RBHSC if necessary.

506. The Guidelines omit any explicit reference to Solution No.18.[461] Dr. Taylor later commented in a letter to the Coroner on 23rd February 2003[462] that several members of the Working Party were "*not happy*"[463] that Solution No.18 should be '*banned*', while others, like him, were "*adamant*" that the fluid should be "*named and shamed*."

507. Likewise, the Guidelines fail to define the age range of the children undergoing the very treatment the Guidelines sought to direct. This issue was not seemingly considered by the Working Group, sub-group or those committees whose views were canvassed. However, it was expressly covered by the subsequent NPSA 'Alert 22' Guidance and has relevance when children are admitted to an adult ward.

508. The SAC (Paediatrics) had, on 8th November 1994, voiced concern that a lack of standard practice in relation to the age limits for admission onto an adult ward "*often caused problems.*"[464] The matter was left for further consideration.[465] The SAC (Paediatrics) raised no issue with the draft Guidelines when presented to it for comment.

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459 Ref: WS-075/3, p.5
460 Ref: 006-054-438
461 Ref: 006-054-438
462 Ref: 064-006-033
463 Ref: 064-006-034
464 Ref: 320-049-012
465 Ref: 320-056-005; 10th September 2002

509. Dr. McCarthy states that the Working Group ceased to exist after the publication of the guidance.[466] It did not seemingly produce the *"audit protocol"* agreed at its first meeting, nor did it offer guidance on how fluid protocols might be developed locally.

510. Information about the Guidance was included in the CMO's Update No.21 of April 2002, a newsletter sent out regularly by the CMO's Office[467], and subsequently in an article published in the Ulster Medical Journal in November 2003 by Drs. Jenkins, Taylor and McCarthy.[468]

XX. Regional Audit of Guideline Compliance & Other Developments

511. As the CMO emphasised when introducing the Guidelines:

> *"It will be important to audit compliance with the Guidance and locally developed protocols and to learn from clinical experiences."*[469]

512. Activity was undertaken locally in 2002 to develop protocols designed to meet the needs of individual hospitals. The necessity to audit compliance with the Guidelines became increasingly clear. The suggestion to do so came from Dr. Jarlath McAloon and was raised at the SAC (Paediatrics) meeting on 10th September 2002 (attended by, amongst others, the CMO and Drs. Carson, McCarthy, McConnell and Crean):

> "*It was suggested that an audit of the guidelines in due course would be valuable. CMO asked member to suggest names and contact details of possible SpRs in either paediatrics or anaesthetics who would be interested in taking this forward."*[470]

513. As Dr. McAloon explains:

> "*the Guidelines had been in place for just over one year which seemed a reasonable length of time to allow for induction to be working."*[471]

514. After the Inquest into Raychel Ferguson's death, the Coroner wrote to the CMO on 11th February 2003[472] to inform her that Dr. Sumner had "*expressed praise*" for the 2002 Guidance and had commented that in this regard "*Northern Ireland was ahead of the rest of the U.K.*" Both the Coroner and Dr. Sumner believed the 2002 Guidance ought to be drawn to the attention of the CMOs for England & Wales, Scotland and the Republic of Ireland.

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466 Ref: WS-080/2, p.6
467 Ref: 075-085-346
468 Ref: 007-083-198
469 Ref: 012-064c-329
470 Ref: 075-077-295
471 Ref: WS-363/1, p.10 (28a)
472 Ref: 006-002-156

515. The Coroner further asked the CMO to consider the evidence of Drs. Fulton and Nesbitt, both of whom had expressed the view that the Guidance was not prescriptive enough and should apply to all patients – not just children.

516. He added that the issue of the dissemination of medical information was discussed at the Inquest and that the view expressed by a number of the medical witnesses was that "*journal articles alone do not provide the solution*"[473] as "*for whatever reason, they may not be read*". That being so, it was "*felt*" that the Department might have a responsibility in this area. The Coroner asked the CMO to consider the implications of Raychel's Inquest for the training of both doctors and nurses and welcomed the CMO's views.

517. The CMO promptly acted upon the Coroner's suggestion and raised the issue of hyponatraemia at her next meeting with the Chief Medical Officers of the UK. It was suggested to her that the matter might best be pursued through the NPSA because there was then no guidance on hyponatraemia elsewhere in the UK.

518. To that end, Dr. McCarthy subsequently wrote to the NPSA on 14th March 2003 to ask whether hyponatraemia might *"be an issue which the National Patient Safety Agency would like to explore in greater detail."*[474] The NPSA responded to acknowledge that "*the matter is one which the NPSA would like to explore in further detail as there is the potential to influence practice to prevent this type of incident happening again"*[475] and indicated that it would consider inclusion of the issue in its future 'plan of work.'

519. A number of events occurred in early 2003 which must have further focused Departmental attention on the issue of hyponatraemia in children and healthcare governance. Raychel's Inquest in February 2003 was followed by the enactment of the HPSS (Quality Improvement and Regulation) (Northern Ireland) Order 2003, the referral of Lucy Crawford's death to the Coroner in March 2003, the death of Conor Mitchell in May 2003, and the broadcast of a television documentary on the subject.[476]

520. Altnagelvin Hospital had meanwhile been motivated, between January and May 2003, to conduct its own "*Audit of Documentation of Fluid Requirements and Fluid Balance on Children following Surgery*" as against the Department's Guidelines.[477] It noted improvement but incomplete compliance, indicating *"93% children received maintenance fluids in line with DoH guidelines (2002)."*[478]

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473 Ref: 006-002-157
474 Ref: 006-052-434
475 Ref: 006-051-433
476 Ref: 006-050-432
477 Ref: WS-046/2, p.132
478 Ref: 321-078b-007

521. CREST, having endorsed the Department's Guidelines, issued its own guidance on the 'Management of Hyponatraemia in Adults' in June 2003. The Guidance was accompanied by a wall chart which noted children amongst those patients deemed at risk from hyponatraemia.[479]

522. At the CMO's request, Dr. McAloon took the lead in conducting a regional audit of the Hyponatraemia Guidelines. All units treating children in Northern Ireland took part. Identical audit exercises were repeated in all units during the same *"time window"* in June 2003 and January 2004.[480] The audit interrogated adherence to the standards of the Guidelines by reference to 8 questions, namely:

(i) Was the child's weight recorded?

(ii) Was the calculation for maintenance I.V. fluid volume consistent with the Guidance?

(iii) Was the composition of I.V. used appropriate?

(iv) Were maintenance and replacement fluids prescribed separately?

(v) Was fluid balance assessed at least every 12 hours?

(vi) Was U&E checked at least once per 24 hours?

(vii) Was the oral fluid intake considered in the most recent I.V. fluid prescription?

(viii) What oral fluids were used during this period?

523. At the SAC (Paediatrics) meeting on 7th October 2003: *"Members were advised that an audit [of hyponatraemia] was in progress. Results should be available over the next 6 months."*[481]

524. Following the Inquest into Lucy Crawford's death, the Coroner wrote to the CMO on 23rd February 2004[482] to ask if there was merit in the Working Party examining the Inquest papers with a view to possible Guideline amendment. The Coroner added that the 2002 Guidance had not been criticised in any way (in fact it had been praised) at both Raychel and Lucy's Inquests. He additionally raised concerns regarding the levels of understanding amongst nurses of fluid balance.

525. A short time after the Coroner's letter, and perhaps in response, the CMO wrote to the Chief Executives of all Trusts on 4th March 2004 asking for

479 Ref: 338-002-006
480 Ref: 007-092-235
481 Ref: 075-078-303
482 Ref: 006-001-022

confirmation that both the 2002 Guidelines for paediatric patients and the CREST Guidance for the Management of Hyponatraemia in Adults had been incorporated into clinical practice in their Trust and that implementation had been monitored. Most Trusts responded promptly and in the affirmative. However, in November 2004, Dr. McCarthy was forced to write to the Trusts which had not replied.[483] The RGHT did not respond until 16th December 2004.[484]

526. Dr. McCarthy wrote to the members of the Working Group on 5th July 2004, to advise that the CMO was reviewing the 'Guidance on the Prevention of Hyponatraemia in Children', and wished to revise it in light of the most recent evidence.[485] She asked members to suggest amendments in the light of clinical experience and relevant audit. Responses were received from Drs. Crean, Jenkins, Kennedy, Taylor and Ms. McElkerney.

527. The CMO also contacted Professor Sir Cyril Chantler, Chairman of Great Ormond Street Hospital for Sick Children, asking that he provide an external expert assessment of the Guidelines[486] and *"to quality assure the guidance in light of the findings of the Inquest into Lucy's death."*[487] Sir Cyril offered opinion[488] and met with the CMO, Dr. Ian Carson and Dr. McCarthy on 8th July 2004. The question as to whether explicit guidance should be given as to the intravenous fluid to be prescribed in the presence of low serum sodium levels was discussed.[489]

528. Additionally the CMO wrote to Dr. Jack McCluggage, Postgraduate Dean, on 8th July 2004 to stress that having *"developed guidelines for fluid maintenance and replacement which should form the basis of a training programme"* she *"would be pleased if [he] would ask the training committees to consider this a priority area."*[490] She also wrote to Professor Savage, as Director of Undergraduate education, QUB Medical School, to emphasise the necessity *"for better training and education in this area"* and to ask him to *"consider how this might be taken forward."*[491]

529. After Conor's Inquest in June 2004, Dr. Sumner, who had appeared as an expert for the Coroner, wrote to Dr. Jenkins on 11th June 2004.[492] He copied his letter to the Coroner and Dr. Campbell. In this correspondence, he expressed his disquiet about fluid management in Conor's case which he

483 Ref: 073-041-172
484 Ref: 073-030-136
485 Ref: 007-062-131
486 Ref: 075-040-138
487 Ref: 001-015-062
488 Ref: 006-044-410
489 Ref: WS-075/1, p.20
490 Ref: 075-007-017
491 Ref: WS-075/1, p.30
492 Ref: 006-043-405

described as "*suboptimal*."[493] Dr. Sumner went on to say that it was his impression "*that the basics of fluid management are neither well understood, nor properly carried out*." [494]

530. Dr. Jenkins spoke to Dr. Campbell before replying to Dr. Sumner's correspondence on 28th June 2004.[495] In his reply, he noted the steps that had been taken in Northern Ireland to improve the practice of fluid management, including the regional audit of the implementation of the Guidelines. He recognised, however, that further work needed to be undertaken to bring further improvement to this area.

2004 Audit Findings

531. Dr. McAloon's Regional audit findings were formally reported to the CMO on 2nd August 2004.[496] In summary, the paper concluded:

"*The evidence from this Regional audit is that implementation has so far been incomplete. This could, but does not necessarily, indicate that there is inadequate guideline awareness due to failure of training programmes and/or failure of units to provide direction to junior staff.*"[497]

532. The authors of the Audit Report suggested that units, if they had not done so already, should organise a review by nursing, pharmacy and medical staff, to address difficulties and identify possible solutions.[498] Relevant issues for discussion and action included:[499]

(i) Appending a simplified fluid maintenance calculation formula on prescription sheets

(ii) Providing descriptors for hydration/dehydration status on fluid prescription sheets

(iii) Redesign of prescription sheets to facilitate separate prescriptions when only one IV line is in situ

(iv) The facility to indicate required infusion finish times

(v) Provision of action boxes on fluid balance sheets to trigger clinical and biochemical reassessments

(vi) Developing a consensus on the appropriate use of oral hypotonic fluids

493 Ref: 006-043-405
494 Ref: 006-043-406
495 Ref: 007-063-132
496 Ref: 007-092-234
497 Ref: 007-092-238
498 Ref: 007-092-239
499 Ref: 320-126-098

(vii) Providing oral fluid management information and advice for carers

(viii) Effective nursing and medical handovers of management plans for all children on IV fluids

(ix) Standardisation of redrafted/new documentation.

533. Furthermore, the Report recommended that *"the original guidelines Working Group, as part of its process of guidance review"*[500] might ensure that:

(i) Redrafted or new documentation should be standardised in all Trusts, and

(ii) A consensus be developed on the appropriate use of hypotonic oral fluids.

534. The audit was later published in the Ulster Medical Journal - 'A Study of Current Fluid Prescribing Practice and Measures to Prevent Hyponatraemia in Northern Ireland's Paediatric Departments'.

535. Dr. McAloon outlined the findings of the audit at the SAC (Paediatrics) Meeting of 5th October 2004 which was attended by the CMO, and:[501]

"acknowledged that, internationally, best practice is still controversial and preparation of definitive protocols is not yet possible. Until then it is essential that all clinicians in Northern Ireland caring for children in receipt of fluid therapy know of the associated risks and are aware of the regional best practice guidance and that paediatric departments initiate a process of regular monitoring of guideline adherence as part of their multidisciplinary audit and clinical governance programme."[502]

536. The outcome and lessons of the audit were widely shared. The CMO recalls that:

"Dr. McAloon also presented the Audit results at a workshop on 6th January 2005 on the Clinical Care of Children which I chaired. There were over 100 participants at the workshop with representatives from the various disciplines and Trusts involved in delivering children's services throughout Northern Ireland. One of the issues covered at the workshop was Hyponatraemia. Dr. McAloon presented the audit findings on the use of the guidelines and highlighted that these were not being fully implemented across all Trusts." [503]

537. Thereafter, and in the words of the CMO:[504]

500 Ref: 007-092-239
501 Ref: 075-079-311
502 Ref: 075-079-315
503 Ref: WS-075/1, p.11
504 Ref: WS-075/1, p.20

"in light of Sir Cyril Chantler's comments, the responses received from members of the Working Group, and the audit findings submitted by Dr. McAloon, I requested that a meeting should be held to facilitate a discussion on any proposed amendments. Dr. McCarthy arranged this, issuing a letter of invitation to Dr. Jenkins, Dr. Taylor, Dr. Crean, Dr. Loughrey and Dr. McAloon on 12th August 2004"[505]

Fluid Therapy Regional Working Group

538. The meeting took place on 22nd September 2004. Dr. McAloon suggested that, rather than amend the existing Guidelines, the Working Group should develop a care pathway for fluid management. The CMO and others in the Department were, at this time, much interested in the broadcast of the UTV documentary *"When Hospitals Kill"* on 21st October 2004.

539. It was not therefore until 5th November 2004 that the CMO wrote to Dr. McAloon to agree with his proposal for a "*care pathway for fluid management."*[506]

540. Accordingly, the Fluid Therapy Regional Working Group was established, under the chairmanship of Dr. McAloon. It *"concluded that attempting to create a complete integrated care pathway was likely to introduce complexity... it was agreed"*[507] – *"to produce a short, user-friendly safe prescribing tool, complementary to the DHSSPSNI Regional Guidance on Prescribed Fluids and hyponatraemia"* and *"To incorporate potential lessons/learning points from local inquests and audit."*[508]

541. The Group held its initial meeting on 26th January 2005,[509] doubtless conscious of the newly established Inquiry into Hyponatraemia-related Deaths. The objectives included:

(i) A review of evidence (and leading centre practice) for appropriate IV fluid solutions and amounts and associated recommendations

(ii) Drafting prescription and fluid balance sheets to complement the current guidelines

(iii) A review of the literature on use of oral/naso-gastric fluid therapy and drafting recommendations, including advice to nursing & medical staff and carers

(iv) An investigation and report on any learning points from local fluid therapy associated mortality

505 Ref: 007-055-120
506 Ref: 320-126-125
507 Ref: WS-363/1, p.12 (dii)
508 Ref: 320-126-038
509 Ref: 320-126-122

(v) Making proposals for how the education in fluid therapy for medical students and surgical and medical doctors in training could be improved.

542. It is noteworthy that, at a further meeting on 27th April 2005[510], Dr. Angela Jordan, Specialist Registrar in Public Health Medicine and member of the Group found it useful to present an analysis of "*key learning points*"[511] deriving from the Inquest evidence of "*the three deaths*" (presumably Adam, Raychel and Lucy) namely:[512]

(i) Knowledge and awareness

- Awareness of hyponatraemia, its causes and consequences amongst medical and nursing staff
- Awareness amongst medical and nursing staff of the possibility of SIADH post operatively
- The type of fluid used for replacement
- The type and amount of fluid used for resuscitation

(ii) Recording

- Keeping good medical records
- Clear records as to how the degree of dehydration is determined
- Clear records of how the fluid requirement is calculated
- Recording clearly the type, volume and rate of IV fluids
- Clear and complete recording of all inputs and outputs on fluid balance charts

(iii) Monitoring

- Regulation of the rate of the infusion
- Regular observations whilst on IV fluids
- Regular monitoring of electrolytes
- Regular readjustment of IV fluids required after careful monitoring and re-evaluation.

510 Ref: 320-126-114
511 Ref: 320-126-124
512 Ref: 320-126-097

543. In introducing this information, she said, "*I am hoping to share this with the Group so they can take the points into consideration when developing the care pathway.*"[513]

544. The Group agreed that 'awareness of hyponatraemia among medical nursing staff' was outside its remit.

545. By the end of 28th April 2005, the group had produced a "*summary of relevant information on the prevention of hyponatraemia in association with IV fluid administration and draft recommendations for IV fluids in children in various settings.*"[514] New draft documents were produced to record IV fluid prescriptions and fluid intake and output. The group also produced a draft information sheet to advise parents as to the correct use of oral rehydration and a sheet to record this on the ward.

546. The regional Working Group held its final meeting to consider the fluid care pathway on 22nd June 2005. It issued an Interim Report in October 2005[515] and provided an algorithm for Parenteral Fluid Therapy for children over 3 months old, and a fluid prescription sheet, incorporating assessment, calculation and reassessment.

547. Guidelines were produced and sent to the Department in 2006. The then acting CMO, Dr. Ian Carson, issued the new guideline on 21st April 2006 as the 'Parenteral Fluid Therapy Protocol.'

XXI. National Patient Safety Agency

548. The National Patient Safety Agency (NPSA) was a special health authority of the National Health Service (NHS) in England created in June 2001. It was created to monitor patient safety incidents, including medication and prescribing error reporting, in the NHS.

549. Since 1st April 2005, it has also overseen safety aspects of hospital design and cleanliness, as well as food (transferred from NHS Estates). Its remit now includes safety in medical research, through the Central Office for Research Ethics Committees (COREC). It runs the National Clinical Assessment Service that deals with concerns about the performance of individual doctors and dentists. Finally, it also manages the contracts with the three confidential enquiries (NCEPOD, CEMACH and CISH). This responsibility was transferred from the National Institute for Health and Clinical Excellence (NICE).

513 Ref: 320-126-123
514 Ref: 320-126-118
515 Ref: 320-126-038

550. As well as making sure that incidents are reported in the first place, the NPSA is "*aiming to promote an open and fair culture in hospitals and across the health service, encouraging doctors and other staff to report incidents and 'near misses'*." In various publications, it has encouraged the creation of a "no-blame culture" to encourage staff to report incidents without fear of personal reprimand and know that by sharing their experiences others will be able to learn lessons and improve patient safety. The NPSA collects and analyses information from staff and patients via a national reporting and learning system, as well as from other sources. If there is a trend of incidents, it may issue reports, recommendations and guidance to avoid repetition.

551. On 1st June 2012, the key functions of the NPSA were transferred to the NHS Commissioning Board Special Health Authority.

Contact with the Department

552. On the same day as the Paediatric Fluid Management Regional Working Group met for the last time, Professor Cousins, Head of Safe Medication Practice, NPSA, wrote to Dr. McCarthy to confirm that the NPSA would proceed to formally examine the use of isotonic infusions in children by means of an expert external reference group which would develop therapeutic guidelines on fluid replacement and the use of hypotonic infusions in children – *"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."*[516]

553. The NPSA proceeded to set up a National Group to look at hypotonic fluids.[517] Its plan was to meet three times before December 2005 and then issue findings before 1st April 2006. By January 2006, it had prepared a draft of its Patient Safety Alert.[518]

554. Dr. McAloon informs that:

> *"Mr. Victor Boston (retired Paediatric Surgeon RBHSC), Drs. Miriam McCarthy, Clodagh Loughrey, John Jenkins and myself were members of the External Reference Group convened in October 2005 that contributed to a programme of workshops, meetings, and e-mail correspondence to advise the NPSA on safer practice recommendations that were then taken forward to a wider stakeholder consultation and eventually the publication of NPSA Safety 'Alert 22'."*[519]

555. The timeliness of the NPSA work to produce the Patient Safety Alert received emphasis from the survey conducted by Dr. Way, of the Department of Anaesthesia, Southampton University Hospital, of the prescription of post-

516 Ref: WS-080/1, p.15
517 Ref: 320-059-004
518 Ref: 320-126-001
519 Ref: WS-363/1, p.13 (31a)

operative intravenous fluid by paediatric anaesthetists in England. Published in the British Journal of Anaesthesia in July 2006, it revealed that over 75% of anaesthetists prescribed hypotonic dextrose saline solutions in the postoperative period. The authors concluded that national guidance was required.

Alert No.22

556. Subsequently, on 28th March 2007, the NPSA issued its 'Alert No.22'- *"to reduce the risk of hyponatraemia when administering intravenous infusions to children"* (i.e. 1 month to 16 years old).[520] It noted that *"since 2000 there have been 4 child deaths (and one near miss) following neurological injury from hospital-acquired hyponatraemia."* It recommended implementation by 30th September 2007. Helpfully the Alert appended a *"suggested template for local development of intravenous fluid guidelines."*[521]

557. In consequence of 'Alert No.22', Dr. Michael McBride (then Chief Medical Officer for Northern Ireland), Dr. Norman Morrow (Chief Pharmaceutical Officer for Northern Ireland) and Mr. Martin Bradley (Chief Nursing Officer for Northern Ireland) wrote a joint letter to the Chief Executives of HSC Trusts (Circular HSC (SQS) 20/2007) on 27th April 2007, to inform them that:[522]

"HSC organisations are required to implement the actions identified in the Alert by 30 September 2007. Independent sector providers which administer intravenous fluids to children will also wish to ensure that the actions specified in the alert are implemented in their organisations within the same time scale."

558. The letter further stated that:

"It should be noted that one of the actions in the NPSA Alert is for each NHS organisation to produce and disseminate local clinical guidelines for the fluid management of paediatric patients based on the suggested NPSA guidelines template. As the Northern Ireland Regional Paediatric Fluid Therapy Working Group and the NI Medicines Governance Team were part of the NPSA external reference group, the Department has asked both of these groups to work collaboratively to produce an intravenous fluid clinical guideline in accordance with NPSA guidance, by 31 July 2007. This will then be disseminated to each HSC Trust for local implementation and monitoring."[523]

559. The letter most specifically indicated that:

"HSC Trust Chief Executives are responsible for implementation of NPSA Alert 22. All Trusts should:

520 Ref: 303-026-350
521 Ref: 303-026-360
522 Ref: 303-028-367
523 Ref: 303-028-368

a. Develop an action plan and ensure that action is underway by 2 July 2007
b. Complete actions by 30 September 2007
c. Return the audit template by 31st October 2007."[524]

560. Helpfully a number of attachments were enclosed to support implementation of the Alert. These included:

(i) A guideline template to assist with the production of local clinical guidelines

(ii) A prescription template providing ideas on how local prescriptions for intravenous fluids could be improved

(iii) An e-learning module for clinical staff prescribing paediatric infusion therapy

(iv) A practice competence statement for the prescription and monitoring of intravenous infusions

(v) An audit checklist to assist the annual audit process and ensure that the recommendations were implemented

(vi) A patient briefing.[525]

561. The actions identified included the:

(i) Removal of 'Solution No.18' from stock and general use in areas where children receive treatment

(ii) Production and dissemination of clinical guidelines for the fluid management of paediatric patients

(iii) Provision of adequate training and supervision for all staff involved in the prescription, administration and monitoring of intravenous infusions for children

(iv) Reinforcement of safer practice by reviewing and improving the design of existing intravenous fluid prescriptions and fluid balance charts for children

(v) Promotion of reporting of hospital acquired hyponatraemia incidents

(vi) Implementation of an audit programme to ensure NPSA recommendations were adhered to.

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524 Ref: 303-028-368
525 Ref: 303-028-368

562. 'Alert No.22' therefore went further than the Northern Ireland Guidelines or the Parenteral Fluid Therapy Protocol had done, in that it recommended the removal of 'Solution No.18' from stock and from use in areas where children receive treatment.

563. The Commission on Human Medicines (CHM) has since reviewed all data as to the benefits and risks of intravenous hypotonic saline (0.18% saline/4% glucose infusion solution) when used in children. As a result, it published a further Alert in October 2012 (Drug Safety Update Oct 2012 vol 6, issue 3: A1).

Guidance issued by the Department

564. The CMO asked that Northern Ireland Regional Paediatric Fluid Therapy Working Group, chaired by Dr. McAloon, look at local guidance, consider whether it required update in light of the NPSA guidance, and to produce the necessary IV Fluid Clinical Guideline in accordance with the NPSA guidance.

565. The new recommendations were duly localised by the Fluid Therapy Working Group as a wall chart to be placed in all areas where children received treatment in hospitals and the September 2007 version was sent out as an addendum to circular HSC (SQS) 20/2007 on 16th October 2007 - 'Parenteral Fluid Therapy (1 month – 16 years): Initial Management Guidelines.'[526] Subsequently poster-size wall charts were printed and forwarded to HSC Trusts in March 2008.

566. In 2010, the title of the wall chart was amended to "*Parenteral Fluid Therapy for Children & Young Persons (aged over 4 weeks & under 16 years)*"[527] to clarify age limits as an adjunct to the publication by GAIN of its own guidance on Hyponatraemia in Adults (i.e. those on or after 16th birthday).

567. In 2013, as a result of the findings of the GAIN audit of IV fluid use in hospitalised children, and in the light of technological advances in glucose testing, the wall chart was amended again. The charts were re-printed and re-issued to Trusts, but due to an error in the title, the chart had to be further re-issued in July 2013. It was accompanied by template prescription and fluid balance charts and a training package, as has become standard. The Department have since requested GAIN to design an audit to measure compliance with this wall chart.

526 Ref: 303-059-817
527 Ref: 303-060-818

XXII. RQIA Reviews

2008 Review

568. In 2007, the RQIA was asked to conduct an independent review of, and compliance with, 'Alert No.22.'[528] All aspects were to be scrutinised including the dissemination of the clinical guidelines and wall chart throughout HSC Trusts and independent hospitals. It was hoped that such a review would provide the Minister with assurance, both as to healthcare response and patient safety in respect of hyponatraemia.

569. The RQIA Review Team submitted its 'Summary Report following Validation Visits to Trusts and Independent Hospitals throughout Northern Ireland'[529] to the Minister in April 2008. Thereafter, the RQIA provided its full Report on 'Reducing the risk of Hyponatraemia when Administering Intravenous Fluids to Children' in September 2008.[530] It was noted that all the Health and Social Care Trusts and independent hospitals visited had undertaken considerable work to reduce the risks of hyponatraemia. Evidence was found of a commitment to achieve full compliance with the recommendations of 'Alert No.22' and to disseminate the Paediatric Parenteral Fluid Therapy clinical guidelines and wall charts.

570. However, concern was sounded as to:

(i) The necessity of ensuring that the Guidance was consistently applied in adult wards where children receive treatment

(ii) The continued presence of Solution No.18 in stock and on site

(iii) The provision of fluid management training for non-paediatric staff caring for older children on adult wards because it was deemed poor across all organisations visited by the review team

(iv) The lack of evidence of a reporting culture for incidents relating to intravenous fluids and hyponatraemia.

571. The RQIA Report made 16 recommendations. These focused upon:

(i) The availability of No. 18 Solution

(ii) The need for continued work on the dissemination of clinical guidelines

(iii) The requirement to display only the most recent version of the fluid therapy wall chart

528 Ref: WS-077/4, p.14
529 Ref: 303-058-771
530 Ref: 303-030-376

(iv) Training and assessment of staff in the administration of IV infusion to children

(v) The treatment of older children on adult wards

(vi) Incident reporting

(vii) The need for a regional audit tool.

572. As Jim Livingstone, Director of Safety, Quality and Standards, indicated to the RQIA on 18th September 2008 the *"RQIA review is... particularly welcome and highlights a number of issues that need to be addressed to ensure that all Trusts are adhering to NPSA guidelines."*[531] However, he noted *"that the review does not cover all hospitals. We need to be able to assure ourselves about the implementation of NPSA safety 'Alert 22' at all hospitals."*[532] Further, he identified the review finding of *"a general culture of under-reporting"* as being *"particularly worrying."*[533]

573. In February 2009, the Department wrote to the Chief Executives of all HSC Trusts requiring confirmation not only of implementation of 'Alert 22' but all 16 recommendations made by RQIA on or before 30th April 2009.

2010 Follow-up Review

574. The RQIA Review Team conducted a follow-up review and published its second report in May 2010 - 'Report of actions taken by HSC Trusts and Independent Hospitals to implement Recommendations made in the Report: Reducing the Risk of Hyponatraemia when Administering Intravenous Fluids to Children' (RQIA, June 2008)'.[534] They found that Solution No.18 had now been completely removed from all clinical areas where children were being treated.

575. The Review Team concluded that Trusts and independent healthcare facilities in Northern Ireland have good operational control of the administration of intravenous fluids to children and compliance with NPSA 'Alert 22' had been substantially achieved.

576. In addition, they found that members of staff were aware of the Clinical Guidelines and that nursing staff had received training in paediatric fluid administration. There was, however, some concern that generic adult fluid balance charts were still being used for some paediatric patients on adult wards. This concern reflects the context in which Conor received treatment in

531 Ref: 330-045-001
532 Ref: 330-045-002
533 Ref: 330-045-003
534 Ref: 303-031-415

Craigavon Area Hospital in May 2003. The Review Team made 8 further recommendations focusing upon:

(i) The complete removal of No.18 Solution

(ii) The development of a competency assessment tool on the administration of intravenous fluids

(iii) The development of a strategy to ensure that there be collaborative clinical management between paediatric and adult clinicians for the administration of intravenous fluids to children in adult wards

(iv) Training and assessment of staff in the administration of intravenous infusion to children

(v) Dissemination of learning from adverse incidents.

2012 Review

577. As a result of these reviews and their consideration of the arrangements in place when managing IV infusions for children in adult wards, the RQIA carried out a further review in December 2012 entitled "Baseline Assessment of the Care of Children under 18 admitted to Adult Wards in Northern Ireland".[535]

578. The review team found that there is no standardisation of the age limits across hospitals up to which children are admitted to paediatric wards, and it was recommended that there is a regionally agreed age up to which admission to paediatric wards would be the normal practice.

XXIII. Subsequent Developments

Development of Fluid Balance Charts for Regional Use – 2011–present

579. In March 2012, Dr. Julian Johnston of the Belfast HSC Trust advised the Department of on-going work between Trusts to develop uniform fluid prescription and balance chart (one variant for adults and one for children) for use on a regional basis. To that end, a group had been convened to design, test and implement such charts in June 2011.

580. It was hoped that such a standardised chart would achieve:

(i) Safety in fluid prescribing and administration

(ii) A reduction in the incidence of Hyponatraemia

[535] Ref: WS-077/4, p.13

(iii) Safer prescribing for the young person in an adult ward

(iv) Safer transfer of patients between Trusts

(v) Simpler, easier and better training of doctors and nurses throughout Northern Ireland in fluid prescription practice

(vi) Potential cost savings because there will be 2 charts instead of the 13+ presently in use.

581. Dr. Johnston requested that a regional pilot of the charts be facilitated, a training package developed and funding provided to cover the costs of printing the charts.

582. On 1st August 2013, the CMO and CNO issued a circular to the HSC (HSS (MD) 30/2013) publishing and endorsing the use of the charts and requesting that Chief Executives make resources available to train staff.[536]

Guidelines and Audit Implementation Network (GAIN)

583. The Guidelines and Audit Implementation Network (GAIN), was formally established as a partnership body of the Department in 2007. It works closely with the Department's Standards and Guidelines Quality Unit, which was also established in 2007. It receives programme funding of around £400,000 per annum to conduct regional audits and produce local guidelines for the HSC where no national guidance exists. Since its inception in 2007, GAIN has completed 21 guidelines and 42 audits.

584. GAIN aims to support the achievement of high quality health and social care by:

(i) The development and dissemination of best practice clinical and social care guidance where important gaps have been identified

(ii) Audit to assure implementation of guidance

(iii) The provision of relevant training.

GAIN Audits 2008 & 2011

585. In February 2008, GAIN received an application to fund an audit of IV fluid use in hospitalised children against the 2007 'Parenteral Fluid Therapy- Initial Management Guidelines.' The proposal was submitted by Dr. Mike Smith, Consultant Paediatrician at Antrim Area Hospital and approved in July 2008.

536 Ref: 329-020a-221

586. The audit focused on children hospitalised with appendicitis and bronchiolitis (conditions that can pose increased risk of hyponatraemia). There were delays completing the audit due to illness and pressures of clinical work.

587. When an initial but incomplete report was eventually received in the Department in August 2011, it was decided to commission a further 'snapshot audit' of compliance with the revised wall-chart guidance. The purpose of the audit was to assess the situation using up-to-date data and to evaluate the position for children admitted with any condition requiring IV fluid not only those with appendicitis or bronchiolitis. In accordance with the wall chart guidance, the audit excluded children cared for in specialist settings such as Intensive Care Units and those with liver, renal or cardiac diseases.

588. As a response to the initial GAIN audit and the 'snapshot audit', the CMO has requested that a new audit be designed by GAIN to encompass a sufficiently large sample of children within the scope of the guidance to enable detailed analysis.

589. The scope of the audit has yet to be determined, but it is anticipated that it will examine the correct prescription of fluids and use of fluid balance charts in those adult settings where children may receive treatment. The design of the new prescription and fluid balance charts will also be examined.

590. This intended rolling audit is to commence soon, but no sooner than 4 weeks after regional prescription and fluid balance charts have been introduced in all Trusts. There are to be interim reports after 3 and 6 months' data collection as well as a full report at the end of the audit period. If any significant failures should emerge, they are to be highlighted to the Trusts and remedial action taken urgently.

NICE Guidelines

591. NICE issued guidance on 'Vomiting Due to Gastroenteritis in Children Under 5' in April 2009. In accordance with practice, the Department reviewed the guidance to ensure that it met the conditions for endorsement in Northern Ireland. The guidance was endorsed on 12th February 2010 subject to the caveat that *"Where this guidance refers to the management of IV fluids, clinicians should apply the guidance in the wall chart on Parenteral Fluid Therapy for Children and Young Persons aged Over 4 Weeks and Under 16 Years."* When the guidance was reviewed by NICE in 2012, it was not thought necessary to make any amendments.

Development of NICE Guidance on IV Fluid Use in Children – September 2011-present

592. By September 2011, the Department had fully embraced the process of endorsement, implementation and monitoring of NICE clinical guidelines. The CMOs of the UK then decided at their September 2011 meeting that it

was Dr. McBride who should write to the Chief Executive of NICE, Sir Andrew Dillon, to request that it consider developing UK guidance on IV fluid therapy for children. He wrote on 20th September 2011 and followed it up with a letter to Professor Sir Bruce Keogh, NHS Medical Director and co-chair of the National Quality Board, to draw the request to his attention.

593. On 29th December 2011, Professor Sir Bruce Keogh advised the CMO that the topic of IV fluids in children would be referred to NICE.

594. The process of developing the NICE guideline continues and it is expected to issue guidance by November 2015. Dr. Peter Crean chairs the Working Group. This will provide uniform best practice guidance throughout the UK.

Appendix I – Evidence Received By the Inquiry

595. Following the establishment of the Inquiry on 1st November 2004[537], requests for information and evidence were sent out to a number of bodies including, in relation to the Department:

(i) Department of Health, Social Services and Public Safety

(ii) The Belfast Health and Social Care Trust

(iii) Health and Social Care Board

Documents and Other Material

596. The call for documents has been ongoing since the establishment of the Inquiry and it is continuing. The search for relevant documents has and is being informed by guidance from the Inquiry's Advisors, from its Experts and from the responses to requests for witness statements.

597. The material received to date in relation to the DHSSPS includes:

(i) DHSSPS Correspondence[538]

(ii) Papers held by UTV[539]

(iii) DHSSPS Additional Correspondence[540]

(iv) Brangam Bagnall Papers[541]

(v) DHSSPS, CMO Group, Medical Advisory Structures[542]

(vi) Departmental Solicitors Office Correspondence[543]

(vii) Departmental Solicitors Office Updated Departmental Papers[544]

(viii) Position Paper prepared by the Health and Social Services Board[545]

(ix) Position Paper prepared by the Belfast Trust[546]

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537 Ref: 008-032-093
538 Ref: Files 1-10
539 Ref: File 69
540 Ref: Files 73-75
541 Ref: Files 125-138
542 Ref: File 320
543 Ref: File 323
544 Ref: File 330
545 Ref: File 331
546 Ref: File 332

(x) Position paper prepared by the DHSSPS[547]

(xi) Health and Social Services Board Papers[548]

(xii) Health and Social Services Trust Papers[549]

(xiii) DHSSPS Additional Documents 2006-2013

Publications

598. The Legal Team has added to its bibliography any publications referred to by its Advisors, Experts and Witnesses. It is available on the Inquiry website and is updated as further authorities are cited.

Expert Reports & Background Papers

599. These are referred to in detail above in Section II of the Opening.

Witness Statements

600. The Legal Team requested and received a large number of witness statements and supplemental witness statements from persons involved in relation to the Department. The Legal Team has been informed in that task by:

(i) The Inquiry's Advisors

(ii) Previous statements made, whether through Depositions to the Coroner, statements taken by the PSNI or witness statements to the Inquiry

(iii) Statements from others and in some cases the evidence of others during the Oral Hearings

(iv) Subsequent documents received from the DLS and a variety of other sources

(v) Reports from the Inquiry's Experts.

601. The Legal Team has compiled a list of all those involved in the Department from all of the information received by the Inquiry.[550] It explains their position then and now, and whether they have provided a statement and, if so, for whom. Importantly, it also indicates the witnesses that it is proposed to call to give evidence during the Oral Hearings.

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547 Ref: File 333
548 Ref: File 335
549 Ref: File 336
550 Ref: 337-001-001