EXPERT BRIEF FOR GABRIEL SCALLY

DEPARTMENTAL ISSUES (HISTORIC)

Introduction

1. This briefing paper sets out the background to the Departmental issues being investigated by the Inquiry. It concludes by identifying the discrete issues which you are asked to address in a report for the Inquiry.

2. The children's cases which are the subject of this Inquiry are:

(a) Adam Strain

Adam was born on 4th August 1991. He died on 28th November 1995 in the Royal Belfast Hospital for Sick Children ("RBHSC") following kidney transplant surgery the previous day. The Inquest into Adam's death began on 18th June 1996. The Inquest Verdict identified cerebral oedema as the cause of his death with dilutional hyponatraemia as a contributory factor.

(b) Claire Roberts

Claire Roberts was born on 10th January 1987. She was admitted to the RBHSC on 21st October 1996 with a history of malaise, vomiting and drowsiness and she died on 23rd October 1996. Her death certificate recorded the cause of her death as cerebral oedema and status epilepticus. That certification was subsequently successfully challenged after the UTV television documentary referred to below.

The Inquest into Claire's death was carried out nearly 10 years after her death on 4th May 2006. The Inquest Verdict found the cause of her death to be cerebral oedema with hyponatraemia as a contributory factor.

(c) Lucy Crawford

Lucy was born on 5th November 1998. She was admitted to the Erne Hospital, Enniskillen on 12th April 2000 with a recent history of drowsiness and vomiting. She was transferred to the RBHSC on 13th April 2000 and she died on 14th April 2000. Her death certificate recorded the cause of her death as cerebral oedema due to or as a consequence of dehydration and gastroenteritis. That certification was later successfully challenged.

The Inquest into Lucy's death began on 17th February 2004. The Inquest Verdict found the cause of her death to be cerebral oedema acute dilutional hyponatraemia, excess dilute fluid and gastroenteritis as contributory factors.

(d) Raychel Ferguson

Raychel Ferguson was born on 4th February 1992. She was admitted to the Altnagelvin Area Hospital on 7th June 2001 with suspected appendicitis. An appendectomy was performed on 8th June 2001. She was transferred to the Royal on 9th June 2001 where brain stem tests were shown to be negative and she was pronounced dead on 10th June 2001.

The Inquest into her death was conducted on 5th February 2003. The Inquest Verdict found the cause of Raychel's death to be cerebral oedema with acute dilutional hyponatraemia as a contributory factor. It also made findings that the hyponatraemia was caused by a combination of inadequate electrolyte replacement following severe post-operative vomiting and water retention resulting from the secretion of anti-diuretic hormone (ADH).

(e) Conor Mitchell

Conor Mitchell was born on 12th October 1987 with cerebral palsy. His mother brought him to the Accident and Emergency Department of Craigavon Hospital on 8th May 2003 with signs of dehydration and for observation. He was admitted to the medical ward of that hospital where he suffered a seizure later that day. He was transferred to the RBHSC on 9th May 2003 where brain stem tests were shown to be negative and he was pronounced dead on 12th May 2003.

The Inquest into Conor's death was conducted on 9th June 2004. Despite the Inquest, the precise cause of Conor's death remains unclear.

The clinical diagnosis of Dr. Janice Bothwell (Paediatric Consultant) at the RBHSC was brainstem dysfunction with Cerebral Oedema related to viral illness, over-rehydration/inappropriate fluid management and status epilepticus causing hypoxia. Dr. Brian Herron, Consultant Neuropathologist, performed the autopsy. He was unsure what 'sparked off' the seizure activity and the extent to which it contributed to the swelling of Conor's brain but he

considered that there was evidence of major hypernatraemia and that this occurred after brainstem death and therefore probably played no part in the cause of the brain swelling. He concluded that the ultimate cause of death was Cerebral Oedema. The Coroner's expert, Dr. Edward Sumner, commented in his report of November 2003 that Conor died of the acute effects of cerebral swelling which caused coning and brainstem death but he remained uncertain why. He noted that the volume of intravenous fluids was not excessive and the type appropriate but queried the initial rate of administration. That query was raised in his correspondence shortly after the Inquest Verdict. In that correspondence, Dr. Sumner described the fluid management regime for Conor as 'sub-optimal'.

The Inquest Verdict stated the cause of death to be brainstem failure with cerebral oedema, hypoxia, ischemia, seizures and infarction and cerebral palsy as contributing factors.

3. The impetus for this Inquiry was a UTV Live 'Insight' documentary 'When Hospitals Kill' which was shown on 21st October 2004. The documentary primarily focused on the death of Lucy Crawford.

4. The programme makers identified what they considered to have been significant shortcomings of personnel at the Erne Hospital. In effect, the programme alleged a 'cover-up' and it criticised the hospital, the Trust and the Chief Medical Officer. The programme also referred to the deaths of Adam and Raychel in which hyponatraemia had similarly played a part. At that time, no connection had been made with the deaths of Claire and Conor. That was to happen later at the instigation of their families.

Terms of Reference

5. The Inquiry's original Terms of Reference have been revised following the removal of Lucy (for reasons personal to her family) 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."*

6. The reference in the Revised Terms of Reference to investigating the "*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 and poses significant questions about the ability of the relevant bodies to learn lessons and to act upon them.

7. There is a considerable volume of documentation available for consideration relating to the Inquiry's investigation into those Departmental issues, which is summarised in this Brief.

Institutions involved

8. The bodies and organisations whose conduct falls most specifically to be investigated in relation to the issues raised by the Inquiry's Terms of Reference include:

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

(b) The Chief Medical Officer

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

9. The structure of the health service in Northern Ireland at the admissions of the Children to the 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)'[1] and on the map 'Health and Personal Social Services Northern Ireland'.[2] The present structure is as shown in 'Structure of the Health Service in Northern Ireland – Commissioning of Services'.[3]

10. 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.

11. Under 'direct rule', the Northern Ireland Department of Health was 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.

12. 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. Devolution was suspended on four occasions starting with 12th February 2000.

13. 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'[4] compiled by the Inquiry.

14. The DHSSPSNI set out its proposals for new clinical governance arrangements in its 'Best Practice – Best Care' Consultation paper in April 2001. It suggested *"a system of clinical and social care governance, backed by a statutory duty of quality"* noting that *"governance arrangements are already in place to ensure overall probity, transparency and adherence to public service values."* It 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*

---

1 'Structure of the Health Service in Northern Ireland (pre-2007)' - Ref: 303-039-505
2 'Health and Personal Social Services Northern Ireland' – Ref: 300-001-001
3 'Structure of the Health Service in Northern Ireland – Commissioning of Services' - Ref: 303-040-506
4 'Ministers responsible for Health and Social Care in Northern Ireland from 1994 to Present Day' - Ref: 303-041-507 and 508

example, education and research; audit; risk management and complaints management."[5]

15. The HPSS had emphasised *"better practice"* in its Management plan for 1995/96 – 1997/98 indicating that improvements in practice necessitate a strategy for *"continuing quality improvement."*[6] 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."*[7]

16. When finally, the 'Clinical and Social Care Governance' Circular HSS (PPM)10/2002 was effected, it did not introduce a completely new system but rather drew upon the existing clinical governance structures and approaches, to consolidate them and create organisations within which the final accountability for clinical governance and quality rested with the Chief Executive.[8] This responsibility was accorded the weight of statutory duty of care by Article 34 of The HPSS (Quality Improvement and Regulation) Northern Ireland Order 2003.[9]

17. In June 2002, the Northern Ireland Assembly Executive launched the Review of Public Administration with a view to putting in place modern, accountable and effective arrangements for public service delivery.

18. The final outcome of the review was announced by the Secretary of State in November 2005. It led to a major reorganisation of health and social care, which was to take place in two phases.

19. 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.

20. In addition, seven Local Commissioning Groups (LCGs) were created in April 2007 pursuant to the HSC (Reform) Act (NI) 2009 before being

---

5 Ref: WS-068/1 p.14
6 Ref: 306-083-001
7 Ref: 306-083-017
8 Ref: 306-119-001
9 Ref: www.legislation.gov.uk

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 current and emerging health and social care needs and to secure the delivery of health and social care to meet those needs.

21. The position as regards 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)'.[10] 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'.[11] Whilst the final position is shown on the map 'Health and Social Care Trust Boundaries showing location of Hospitals'.[12]

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

    (a) 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 to allocate government funding for that purpose. That authority includes the formulation of policy and legislation for hospitals.

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

    (c) 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

---

10 'Boards, Trusts, Hospitals & Commissioning Groups (pre-April 2007 and post-April 2009)' - Ref: 303-042-509

11 'Health and Social Care, Northern Ireland: Existing Acute, Local and Mental Health or Learning Disability Facilities' - Ref: 300-002-002

12 'Health and Social Care Trust Boundaries showing location of Hospitals' – Ref: 300-078-149

Adam and Claire were admitted to the RBHSC is shown in 'Royal Group of Hospitals Trust – Organisation Structure 1995/96'.[13] 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 'Belfast Health & Social Care Trust: Organisation Structure (present day)'.[14]

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

(i) RBHSC;

(ii) Belfast City Hospital;

(iii) Erne Hospital;

(iv) Altnagelvin Area Hospital;

(v) Craigavon Area Hospital.

Hyponatraemia Guidelines

23. An important aspect of the work of the Inquiry is the impact of the 'Guidance on the Prevention of Hyponatraemia in Children' which the Department issued in 2002 well before the Inquiry was established.

24. It is possible that the need for such guidance was raised at a meeting on 18th June 2001 of Medical Directors, within days of Raychel's death. In any event, a working party was quickly established under Dr Paul Darragh, then the Deputy CMO. Its work led to guidance being drafted, circulated for consultation purposes, finalised and published by 25th March 2002.

25. The Hyponatraemia Guidance starts with the warning that: "Every child on IV fluids or oral rehydration is potentially at risk of hyponatraemia". It highlights the particular risks of the condition including those associated with post-operative patients, bronchiolitis and with vomiting. It addresses:

(a) Baseline assessment, specifically referring to urine and electrolytes

---

13 'Royal Group of Hospitals Trust – Organisation Structure 1995/96' - Ref: 303-043-510

14 'Belfast Health & Social Care Trust: Organisation Structure (present day)' - Ref: 303-044-511

(b) Fluid requirements for both maintenance and replacement

(c) Choice of fluids

(d) Monitoring of the child's clinical state, fluid balance (input and output) and biochemistry

(e) Seeking advice

26. The 'audit' on the implementation of the Hyponatraemia Guidelines was the subject of a review by Dr. Jarlath McAloon and Dr. Raj Kottyal (respectively Consultant Paediatrician and Senior House Officer at the Antrim Hospital) published in the Ulster Medical Journal 'A Study of Current Fluid Prescribing Practice and Measures to Prevent Hyponatraemia in Northern Ireland's Paediatric Departments'. In summary, the paper concluded that the *"evidence suggests that implementation has so far been incomplete"* and it highlights *"problem areas"*.[15]

27. A meeting was held in 2004 to discuss proposed amendments to the 2002 Guidance.[16] Following this meeting, the Chief Medical Officer wrote to Dr. McAloon on 5th November to agree with his proposal that a care pathway for fluid management be developed.[17]

28. 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, Lucy and Raychel in 1995, 2000 and 2001 respectively.

29. In addition, the Inquiry has investigated the circumstances giving rise to the formulation of the Hyponatraemia Guidance, its implementation, monitoring, auditing and evaluation.

Alert No.22

30. On 28th March 2007, the NHS National Patient Safety Agency (NPSA) issued its Alert No.22 for 1 month to 16 year olds[18] recommending the

---

15 Ulster Med J 2005; 74(2) 93-97 – Ref: 303-027-362
16 Ref: 007-055-124
17 Ref: 320-126-125
18 NPSA Alert No.22 of 28th March 2007 – Ref: 303-026-350

taking of action by 30th September 2007 to *"to minimise the risk of hyponatraemia in children"*.

31. That action by the NPSA was the culmination of a process that had been instigated as far back as 25th September 2001 by Dr. Taylor who reported to its predecessor organisation, Medicines Control Agency through the 'yellow card scheme', a suspected adverse drug reaction in respect of intravenous Solution 0.18%/4% glucose and the death of Raychel on 10th June 2001.[19] It was welcomed by the Medicines Control Agency as *"an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of medicines"*.[20]

32. The progress of the investigation is summarised by Dr. Katherine Cheng of the Medicines Control Agency in her letter to Dr. Taylor of 26th November 2001.[21] The Working Group on Paediatric Medicines (the Working Group) conducted a review of 4% dextrose/0.18% saline and considered that although hyponatraemia is a risk to children during the use of 4% dextrose/0.18% saline, electrolyte imbalance is a risk with the use of all intravenous solutions.

33. The Working Group noted at its meeting on 21st November 2001 that careful monitoring of children after surgery is crucial and in particular, care should be taken not to overload patients with intravenous fluids if they were oliguric as part of the normal response to surgery. However, the Working Group considered that the issue of hyponatraemia related more to clinical practice rather than to medicines regulation and advised that there should be no changes to product information.

34. In 2006, Way and others published in the British Journal of Anaesthesia the results of a survey that had been carried out to assess the practice of postoperative intravenous fluid prescription by paediatric anaesthetists. The results showed, amongst other things, that 75.2 percent of anaesthetists prescribed hypotonic dextrose saline solutions in the post operative period. The authors suggested that national guidance was required. Ultimately, Alert No.22 was issued.

35. Following on from the issue of Alert No.22, on 27th April 2007 Dr. Michael McBride (then Chief Medical Officer for Northern Ireland), Dr. Norman Morrow (Chief Pharmaceutical Officer for Northern Ireland) and Martin

---

19 Suspected Adverse Drug Reactions Yellow Card Ref: WS-008/1 p.17-18
20 Letter from Medicines Control Agency to Dr. Robert Taylor dated 1st October 2001 Ref: WS-008/1 p.16
21 Letter from Dr Katharine Cheng to Dr. Robert Taylor dated 26th November 2001 Ref: 064-010-038

Bradley (Chief Nursing Officer for Northern Ireland) sent a joint letter to the Chief Executives of HSC Trusts informing them that:[22]

"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."

36. The actions identified included:

    (a) Removal of 'Solution No.18' from stock and general use in areas that treat children;

    (b) Production and dissemination of clinical guidelines for the fluid management of paediatric patients;

    (c) Provision of adequate training and supervision for all staff involved in the prescribing, administering and monitoring of intravenous infusions for children;

    (d) Reinforcement of safer practice by reviewing and improving the design of existing intravenous fluid prescriptions and fluid balance charts for children

    (e) Promotion of the reporting of hospital acquired hyponatraemia incidents via local risk management reporting systems;

    (f) Implementation of an audit programme to ensure NPSA recommendations are adhered to.

37. Alert No.22 therefore went further than the Hyponatraemia Guidance in that it recommended the removal of 'Solution No.18' from stock and general use in areas that treat children.

38. The Commission on Human Medicines (CHM) reviewed all data on 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)

39. The implementation required by Alert No.22 is to be found in the guidance published by the Department in September 2007, 'Parenteral

---

[22] Joint letter of 27th April 2007 – Ref: 303-028-367

Fluid Therapy (1 month – 16 years): Initial Management Guideline'.[23] The title of that guidance was amended and the guidance re-issued in February 2010 to, 'Parenteral Fluid Therapy for Children & Young Persons (aged over 4 weeks & under 16 years): Initial Management Guideline.'[24] That guidance is more comprehensive in respect of the management of fluid therapy that that provided in the Hyponatraemia Guidelines. The introduction of that guidance into hospitals in Northern Ireland and the effectiveness of the systems in place for monitoring compliance with them are matters being investigated by the Inquiry.

40. Prior to the publication of Alert No.22, Dr. Henrietta Campbell, the Chief Medical Officer 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.[25] Dr. McCluggage forwarded that request on to Senior Trainers within Paediatrics and other Medical Specialities on 20th July 2004.[26]

41. 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.[27] 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"*.[28] 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"*.

---

23 Department's September 2007 Guidance - Ref: 303-059-817
24 Department's amended Guidance issued in February 2010 - Ref: 303-060-818
25 Letter dated 8th July 2004 from the CMO to Dr. Jack McCluggage – Ref: 075-007-017
26 Dr. McCluggage's letter of 20th July 2004 – Ref: 303-054-766
27 Dr. McMurray's letter of 14th June 2005 – Ref: 303-055-767
28 Dr. McMurray's letter of 21st May 2008 – Ref: 303-056-768

42. On 30th 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.[29]

43. The communications, if any, between the Department, University and Trusts in relation to training about guidance on fluid management and hyponatraemia is something that is being investigated by the Inquiry.

RQIA

44. The RQIA was established by the Health and Social Personal Services (Quality Improvement & Regulation) (Northern Ireland) Order 2003. It has a role in relation to the inspection, regulation, investigation and review of performance within Health and Social Service organisations against five 'quality themes':

    (a) Corporate leadership and accountability;

    (b) Safe and effective care;

    (c) Accessible, flexible and responsive services;

    (d) Promoting, protecting and improving health and social well-being;

    (e) Effective communication and information.

45. The RQIA was asked to carry out an independent review to provide assurance to the Minister with regards to implementation of recommended actions outlined within the NPSA Alert No.22. In addition, the dissemination of the clinical guidelines and wall chart throughout HSC Trusts and independent hospitals was also reviewed.

46. The RQIA review Team reported in April 2008, 'Summary Report following Validation Visits to Trusts and Independent Hospitals throughout Northern Ireland'.[30] Thereafter the RQIA provided its full Report on 'Reducing the risk of Hyponatraemia when Administering

---

29 Email of 20th June 2008 from Dr. Terry McMurray forwarding an email from the Foundation Programme dated 2nd June 2008 - Ref: 303-057-769 and 770

30 RQIA 'Summary Report following Validation Visits to Trusts and Independent Hospitals throughout Northern Ireland' dated April 2008 – Ref: 303-058-771

Intravenous Fluids to Children' dated September 2008.[31] It was acknowledged in those Reports that all the Health and Social Care Trusts and independent hospitals that had been visited had undertaken considerable work to reduce the risks of hyponatraemia when administering intravenous fluids to children. Evidence was also found in all the areas visited of a commitment to achieve full compliance with the recommendations made in the NPSA Patient Safety Alert No.22 and to disseminate the Paediatric Parenteral Fluid Therapy clinical guidelines and wall charts.

47. However, some concern was expressed as to:

(a) The need to ensure that measures are consistently applied in adult wards where children are treated;

(b) The continued presence of Solution No.18 in stock on site;

(c) That the provision of fluid management training for non-paediatric staff caring for older children on adult wards was poor across all organisations visited by the review team;

(d) That there was little evidence of a reporting culture for incidents relating to intravenous fluids and hyponatraemia.

48. The RQIA review team published a follow-up 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)'.[32] They found that Solution No.18 had been completely removed from all clinical areas where children were treated.

49. In addition, they found that members of staff were aware of the Clinical Guidelines and that nursing staff had attended training in paediatric fluid administration. There was some concern that generic adult fluid balance charts were still being used for some paediatric patients rather than dedicated paediatric equivalents and over the continuing risk associated with the administration of intravenous fluids to children on adult wards and clinical areas. That latter issue, which is referred to at page 15 of the

---

31 RQIA Report on 'Reducing the risk of hyponatraemia when administering intravenous fluids to children' dated September 2008 – Ref: 303-030-376

32 RQIA 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)' dated May 2010 – Ref 303-031-415

May 2010 Report was a matter of concern in Conor's case when in May 2003 he was treated in an adult unit at Craigavon Area Hospital.

50. The extent to which the NPSA Alert No.22 has been implemented in Northern Ireland, and the response to the reports of the RQIA, are issues being considered by the Inquiry.

Subsequent developments

51. The National Institute for Health and Care Excellence is currently working on guidelines in the area of 'Intravenous Fluid Therapy in Children'. Dr. Peter Crean, who is a senior Consultant Paediatric Anaesthetist at the RBHSC and directly involved in the care of Lucy and Raychel in PICU, is the Chairman of the Working Party. The Inquiry will investigate the role of Northern Ireland in the subsequent development of the guidelines.

Departmental Issues

52. The Chairman explained his approach to the key issues to be investigated by the Inquiry at a Public Hearing on 3rd February 2005:[33]

> *"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 one [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]*

53. The Revised Terms of Reference require a 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.

54. The Inquiry has therefore investigated the reporting and management structure within the hospitals, Trusts and Area Boards, together with the

---

[33] Transcript of the Public Hearing on 3rd February 2005 – Ref: 303-005-055

dissemination of information amongst clinicians 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.

55. The Inquiry's investigation has also included the means by which the Department's 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.

56. Up to this point in the Inquiry, each of the individual cases been heard from the perspective of clinical and governance investigations. The Inquiry will shortly hear evidence in the case of Conor Mitchell which is being investigated in relation to the extent and quality of compliance with the 2002 Hyponatraemia Guidelines only. The investigations have thus far been confined to the clinicians, nurses, managers and individuals involved, and those institutions up to Trust and area Board level. Those at the next hierarchical level have been reserved for consideration at this section of the Inquiry's investigation – namely Departmental level governance.

57. The Inquiry has compiled a chronology to summarise the events and lessons learned in relation to this aspect of its work: 'Chronology of the Response of the Department and Statutory Bodies: Governance and Lessons Learned', which is being updated to reflect the results of the investigation into the governance issues arising out of each of the children's cases.

58. Many of the areas of governance have already been touched upon in the evidence which has been given to the Inquiry, both in writing and in the public hearings in Banbridge. In light of this, the Chairman recently explained the approach that would be taken in regard to the remaining issues to be investigated by the Inquiry:

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

59. The revised List of Issues in relation to Departmental governance is divided into two sections, historic and current.

Historic Issues

60. The historic issues are in summary:

(a) 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?

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

(c) 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?

(d) What led to the establishment of the hyponatraemia working party?

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

(f) 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)?

(g) 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)?

61. Conor's case is being dealt with in a separate Oral Hearing immediately prior to that dealing with Departmental issues.

62. As the Chairman stated during the Oral Hearings in July:[34]

And [...], 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?"

Current issues

63. There are a number of strands to this, but in summary it is to establish how matters are dealt with now in 2013 with a view to examining the scope for further improvement:

(a) Reporting and investigating adverse clinical incidents;

(b) Disseminating lessons;

(c) Reporting to the GMC/NMC/coroner;

(d) How trusts now exercise their statutory duty of quality;

---

[34] Transcript of the Oral Hearings on 2nd July 2013, p.161-163

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

(f) Adoption and dissemination of guidelines/practices;

(g) What more needs doing to improve the service

Queries relating to the historic issues

64. The first issue is one under the heading of "Responsibility of Quality of Care", namely;

(i) 'How did the Department know what was going on in hospitals prior to 2003 in terms of the quality of care?'

65. This includes the following sub-issues:

(a) Which of the deaths should have come to the attention of the CMO and the Department?

(b) If the Department should have known about the deaths of Adam, Clare or Lucy what system should have been in place from the perspective of the Department (including the CMO and senior officials) to ensure that it did know?

(c) How did the means of the Department's knowledge or lack of knowledge compare with the rest of the U.K. at the relevant times which were 1995, 1996 and 2000?

(d) What have been the respective contributions of the Trusts, Department, HSCB, PHA, RQIA, CMO and CNO in this area?

66. The second and third issues are under the heading of "Actions of Doctors, Nurses and Trusts", namely:

(ii) 'Has there been an increase in reports of serious adverse incidents (SAIs) and other adverse clinical incidents within the Trust?'

(iii) 'How effectively were such incidents reviewed? How are they now? To what extent do they now involve families? How were the findings disseminated? How are they now?'

67. We wish you to comment on the three issues above and ask that you commence work on the first issue whilst we endeavour to obtain outstanding information that is relevant to the second and third issues.

68. The Inquiry is currently seeking additional information from the Department in regard to the latter two issues, which it will forward to you as soon as it is received and paginated.

Conclusion

69. Your assistance in compliance with the Inquiry's requirements should be provided in the form of a fully referenced Expert's Report. Your Report, and any supplemental or addendum Reports, will be made public.

70. The Role of Expert to the Inquiry is set out in 'Protocol No.4: Experts', a copy of which is attached.

71. It is of fundamental importance to the Inquiry that it receives a clear and focussed report on the matters raised in this Brief. Your report may form the basis for additional witness statement requests which the Inquiry may address to those who had responsibility for the departmental governance issues associated with the children's cases. Moreover, you are liable to be questioned in relation to the contents of your report at the Oral Hearings of the Inquiry. If any issue which has been raised with you falls outside of your area of expertise, you should explicitly say so within the body of your report.

72. If any of the issues raised in this Brief cannot be addressed in a comprehensive fashion at this stage for whatever reason, please explain the position and identify what it is that you require in order for you to furnish a final opinion.

73. The Inquiry has a large volume of materials available to it in relation to all of the cases which have been investigated by it, much of which is available on the Inquiry website at www.ihrdni.org. We have provided you with only the most relevant documents from the large volume of documentary material which is available to the Inquiry. You will note that some of the documents provided to you have been heavily redacted to exclude irrelevant material.

74. An Appendix of the material provided to you is included with this Brief. If you believe that you require any additional class of documents, the Inquiry will be happy to take steps to source those for you, where they exist.

APPENDIX

Documents

We attach the following documents to provide a context and information for the preparation of your Report:

1. Protocol No.4: Experts

2. Revised List of Issues – Departmental Governance

3. Chronology of the Response of the Department and Statutory Bodies: Governance and Lessons Learned'

4. Governance Reports produced by the experts in each of the individual cases:

   (a) Adam – Professor Mullan

   (b) Claire – Dr. MacFaul

   (c) Lucy – Dr. MacFaul & your own report

   (d) Raychel – Dr. Swainson

5. Governance Reports prepared by the Inquiry's Advisors for each of the individual cases

6. Transcripts of the evidence received during the Inquiry Oral Hearings:

   (a) Dr. William McKee (Adam - 17th Jan 2013)

   (b) Dr. Ian Carson (Adam – 15th & 16th Jan 2013, Lucy – 11th & 26th June 2013, Raychel – 30th September 2013)

   (c) Dr. Michael McBride (Claire - 17th Dec 2012)

   (d) Dr. Raymond Fulton (Raychel – 4th September 2013)

   (e) Dr. Geoff Nesbitt (Raychel – 3rd September 2013)

   (f) Mrs. Stella Burnside (Raychel – 17th September 2013)

   (g) Dr. William McConnell (Lucy - 19th June 2013)

   (h) Dr. James Kelly (Lucy – 12th/13th June 2013)

(i) Mr. Hugh Mills (Lucy - 17th June 2013)

7. Inquiry Witness Statements:

(a) Mr. Clive Gowdy

(b) Dr. Henrietta Campbell

(c) Judith Hill

(d) Noel McCann

(e) David Galloway

(f) Dr. Paul Darragh

(g) Dr. Ian Carson

(h) Dr. Norman Morrow

(i) Dr. Miriam McCarthy

(j) Paul Simpson

(k) Margaret Mark

The following information/documents have been requested from the Department and the Trusts, and will be provided to you as possible:

8. The Department:

(a) SAI data from 2005 to the present day for each Trust broken down to reflect the proportion of clinical SAIs

(b) Policies on SAIs and clinical incidents including near misses

(c) Information on the environment around reporting of colleagues (touched upon by the PAC also)

9. The Trusts:

(a) Who in the Trust structure, in relation to clinical incidents, deals with:

(i) Litigation

(ii) Complaints

(iii) Incident reporting

(b) To whom do they report the results and what happens

10. In the recent 'Report on the Safety of Services Provided by Health and Social Care Trust' Public Account Committee report, serious adverse incident (SAI) figures are included for each Trust for the period 1st April 2012 to 31st March 2013. The Inquiry has therefore requested from the Department:

(a) SAI data from 2005 to the present day for each Trust broken down to reflect the proportion of clinical SAIs

(b) Policies on SAIs and clinical incidents including near misses

(c) Information on the environment around reporting of colleagues (touched upon by the PAC also)

11. In addition, the Inquiry has requested the following information from the Trusts:

(a) Who in the Trust structure, in relation to clinical incidents, deals with:

(i) Litigation

(ii) Complaints

(iii) Incident reporting

(b) To whom do they report the results and what then happens.

As can be seen above, there is outstanding material that may hamper your progress on all the issues. The Inquiry Team would therefore suggest you begin by preparing the first issue, allowing you to move onto the subsequent two issues once the Inquiry has received the relevant material.