

# INTRODUCTION

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## Preamble

- 1.1 In June 2001 nine year old Raychel Ferguson was admitted to the Altnagelvin Area Hospital in Derry. She underwent routine surgery but did not recover as expected. She vomited repeatedly and her condition deteriorated. Her parents voiced concern. Within 48 hours of admission Raychel had suffered brain death. Mr and Mrs Ferguson were not satisfied with the explanation they were given for her death.
- 1.2 In February 2003 the Coroner at Raychel's inquest found that her death had been caused by hyponatraemia brought about by an intravenous ('IV') fluid therapy which had given her inadequate sodium replacement in the context of vomiting and water retention. Reference was also made at the inquest to the death of another child in Northern Ireland from hyponatraemia, that of Adam Strain.
- 1.3 Mr and Mrs Ferguson were determined to question why their daughter had died. They were not alone. Investigative journalists at Ulster Television ('UTV') also questioned her death and broadcast a documentary in February 2003 drawing attention to hyponatraemia and the clinical failings in Raychel's case.<sup>1</sup>
- 1.4 At the same time, and in response to the inquest, the Chief Officer of the Western Health and Social Services Council ('WHSSC') drew the Coroner's attention to the death in 2000 of a child called Lucy Crawford because her case had similarities to Raychel's. He asked whether an inquest into Lucy's death might not have saved Raychel.<sup>2</sup>
- 1.5 The UTV team then added Lucy's case to their investigation and, in October 2004, broadcast a further documentary entitled 'When Hospitals Kill' which examined the deaths of Raychel, Adam and Lucy.<sup>3</sup> It claimed that all had died from hyponatraemia because all had been given too much of the wrong type of fluid. The programme raised concerns about a failure to learn

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<sup>1</sup> UTV 'Insight' 27-02-03 'Vital Signs'

<sup>2</sup> 006-012-297

<sup>3</sup> UTV 'Insight' 21-10-04 'When Hospitals Kill'. UTV also treated the issue in 'The Issue' 25-03-04.

lessons and the possibility that there had been a deliberate 'cover-up'. It criticised clinicians, Trusts and the Chief Medical Officer.

- 1.6 The programme provoked considerable media interest and public disquiet. Concern was widespread and Ms Angela Smith MP, then Minister with responsibility for Health in Northern Ireland, was obliged to take action. In November 2004 she announced that *"in pursuance of the powers conferred by Article 54 and Schedule 8 of the Health and Personal Social Services (Northern Ireland) Order 1972, the Department of Health, Social Services and Public Safety hereby appoints Mr John O'Hara QC to hold an Inquiry into the events surrounding and following the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson."*<sup>4</sup>
- 1.7 The Minister emphasised that it is *"of the highest importance that the general public has confidence in the quality and standards of care provided by our health and social services."* The Department of Health, Social Services and Public Safety for Northern Ireland ('the Department'), recognising that public confidence in the Health Service had been undermined, granted the Inquiry broad terms of reference so as to permit the concerns of families and public alike to be addressed.
- 1.8 The terms of reference required inquiry into:
- (i) The care and treatment of Adam Strain, Lucy Crawford and Raychel Ferguson, with particular reference to the management of fluid balance and the choice and administration of intravenous fluids in each case.
  - (ii) The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson.

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<sup>4</sup> 303-034-460

- (iii) The information and explanations given to the respective families and others by the relevant authorities.

Additionally, discretion was granted me to examine and report on any other matter I should think relevant and to make such recommendations to the Department as I should think fit.

- 1.9 The UTV documentary was also watched by the parents of Claire Roberts who had died in the Royal Belfast Hospital for Sick Children ('RBHSC') or ('the Children's Hospital') in 1996. Her death had not been reported to the Coroner and her parents had never really understood why she had died. When Mr and Mrs Roberts watched the programme they immediately recognised similarities with their own daughter's case and were prompted to ask questions. Subsequent investigation and inquest revealed that hyponatraemia had played a part in her death too. I added Claire's case to those I had been originally tasked to investigate because hyponatraemia was implicated and she had died in the same hospital as Adam. In addition to my obvious concern about the treatment Claire had received, I was troubled by the failure to report her death to the Coroner in 1996 and about what was revealed at her inquest 10 years later.
- 1.10 In May 2008, and for private reasons, Mr and Mrs Crawford requested that the Minister withdraw Lucy's case from the scope of my Inquiry. This request was respected and the terms of reference revised. However, concern was then raised that had the circumstances of Lucy's death been made known at the time of her death and had appropriate lessons been learnt, then the deficient therapy given Raychel 14 months later might have been avoided and her life spared. Accordingly it was urged upon me that examination of what happened after Lucy's death was integral to the Inquiry into Raychel's case and should therefore be pursued.
- 1.11 I found this persuasive, and having issued a consultation paper on the issue in 2009 and received extensive response, I decided in February 2010 that the terms of reference both permitted and required investigation into what

had transpired after Lucy's death.<sup>5</sup> Accordingly, I directed that that part of her case be examined by the Inquiry.

- 1.12 In the course of conducting this Inquiry, 4 other deaths were brought to my attention. I considered them in detail and having satisfied myself that hyponatraemia was not implicated, determined that they required no further investigation. Notwithstanding, it cannot be assumed that there were no other child deaths in Northern Ireland from hospital related hyponatraemia during the period under scrutiny.
- 1.13 In examining the issues it also became necessary to determine whether the Department's 'Guidance on the Prevention of Hyponatraemia in Children,' issued in 2002, was being followed in Northern Ireland's hospitals. The death in 2003 of 15 year old Conor Mitchell in Craigavon Area Hospital was not a death from hyponatraemia but it was a case in which concerns were raised about whether the Departmental guidance had been followed properly, or at all. I directed that his case be examined in order to scrutinise an actual implementation of the hyponatraemia guidance and to ascertain whether concrete change in practice had resulted.
- 1.14 I think it important to acknowledge the role played by informed investigative journalism in revealing the extent of the hospital mismanagement in these sad cases. But for the UTV documentary, the close public scrutiny of this Inquiry would not have happened and Mr and Mrs Roberts might never have learnt what really happened to Claire. Whilst the process of inquiry has been long and costly and the amount of information gathered considerable, it is to be recognised that the essential issues as identified by the initial UTV investigation remain as they were. This Inquiry found a Health Service that had been largely self-regulating and unmonitored. In such circumstances the value of independent and inquiring journalism cannot be overstated.

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<sup>5</sup> 303-037-466

## **Process**

### ***Inquiry procedures***

- 1.15 Upon appointment I directed the following protocols to govern procedures, namely:
- (i) General Procedure.
  - (ii) Oral Hearing.
  - (iii) Interested Parties.
  - (iv) Documents.
  - (v) Witnesses.
  - (vi) Experts.
  - (vii) Costs.
  - (viii) Disclosure.
  - (ix) Consultation with, and questioning of, Witnesses.

These protocols were amended from time to time as was necessary and are to be found on the Inquiry website at [www.ihrdni.org](http://www.ihrdni.org)

### ***Counsel***

- 1.16 Counsel were appointed to assist in identifying and investigating relevant issues, the analysis of evidence and the examination of witnesses at public hearings. Legal advices were sought from counsel and received. These duties were performed with great distinction by counsel to the Inquiry, Ms Monye Anyadike-Danes QC and her juniors, Martin Wolfe QC, Jill Comerton, David John Reid, James Anderson and John Stewart.

### ***Solicitors***

- 1.17 An immense debt of gratitude is owed Anne Dillon, Solicitor to the Inquiry. With patience and expertise she assisted and guided at every turn. She was preceded in this role with no less distinction by Fiona Chamberlain. The Inquiry also received the assistance of Brian McLoughlin, Htaik Win, Brian Cullen, Caroline Martin and Clare McGivern. To them I extend my gratitude.

### ***The Secretariat***

- 1.18 The Secretary to the Inquiry, Mrs Bernie Conlon, together with her deputies Ms Denise Devlin and Miss Leanne Ross rose to the formidable challenge of creating and managing the structures and office of the Inquiry. They were assisted by a dedicated and hard-working team. Their administration was one of great professionalism and the tasks performed by them, with efficiency and good grace, were beyond number. I particularly wish to place on record my admiration for the caring and sensitive support given intuitively by them to many of the witnesses to the Inquiry. Given the stresses and sensitivities involved this cannot have been easy and was of considerable assistance to all.

### ***Conflict of Interests***

- 1.19 All who worked for the Inquiry were required to and did sign a 'Declaration of Interests' for the purposes of confirming the credentials of independence underpinning the Inquiry.

### ***Documentation***

- 1.20 The Inquiry, having been established pursuant to the Health and Personal Social Services (Northern Ireland) Order 1972, enjoyed broad powers to compel the production of documents.
- 1.21 A very considerable volume of documentary evidence was received and collated. Documents were filed in an electronic management system, with

each page given a 9 figure identifying number, comprising a file number (first 3 figures), the document number (second 3 figures) and page number (final 3 figures). These are available on the website. Irrelevant and protected information was redacted. Documents and materials which were subject to legal privilege or which failed to satisfy the tests of relevance or fairness were excluded from consideration and do not appear on the Inquiry website.

- 1.22 In order to marshal and present aspects of the very extensive information gathered, a number of tables, schedules, charts and chronologies was compiled for summary and reference. These too may be found on the website.
- 1.23 The Inquiry website is the archive for documents released by the Inquiry. It includes transcripts of public hearings, openings, witness statements, exhibits, expert reports, medical notes and records, charts, schedules, briefing papers, memoranda and other relevant materials. This record amounts to more than 113,000 pages and 12,650 documents. All documents comprising the Inquiry record will be deposited with the Public Record Office for Northern Ireland and access to the website will be maintained within the Record Office web archive. Accordingly, it is unnecessary to append specific documents to this Report.

#### ***Expert witnesses, advisors and peer reviewers***

- 1.24 Respected specialists were retained by the Inquiry to advise and report on relevant aspects of clinical care as well as hospital management and governance. Many of these experts gave evidence at the public hearings. Their invaluable contribution is gratefully acknowledged. In addition, a number of expert background briefing papers were commissioned advising on matters ranging from fluid management training for nurses (1975-2009)



to post-mortem practice, coronial process and statistics. They are to be found on the Inquiry website.<sup>6</sup>

- 1.25 I wish to acknowledge the guidance of the team of expert advisors who assisted the work of the Inquiry. To Dr Harvey Marcovitch in paediatrics, the late Dr Peter Booker in paediatric anaesthetics, Ms Carol Williams in nursing and Ms Mary Whitty and Mr Grenville Kershaw in health service governance and management, I owe a debt of gratitude. Independent of the Health Service in Northern Ireland the advisors submitted their assessment of matters to be considered at the public hearings. Their reports are to be found on the Inquiry website.
- 1.26 The work of the advisors was in turn ‘peer reviewed’ by leading international experts Dr Desmond Bohn (paediatric anaesthesia) and Dr Sharon Kinney (paediatric intensive care nursing). Their signal contribution is to be recognised.
- 1.27 Additionally, I received expert assistance in finalising my draft recommendations from Professor Gabriel Scally (Professor of Public Health and Planning and one time Regional Director of Public Health, NHS England 1996 – 2012) and Dr Tracey Cooper (Chief Executive for Public Health, Wales and former Chief Executive of the Health Information and Quality Authority, Ireland). They advised as to whether my draft recommendations were realistic and achievable and, where appropriate, suggested refinement.

### ***Witnesses and Interested Parties***

- 1.28 In accord with convention, the Inquiry sought and received an undertaking from the Director of the Public Prosecution Service that the evidence of witnesses would not be used in criminal proceedings against them.<sup>7</sup> This was done to encourage co-operation.

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<sup>6</sup> [http://www.ihrdni.org/background\\_papers.htm](http://www.ihrdni.org/background_papers.htm)

<sup>7</sup> 370-048-001

- 1.29 Evidence was sought initially from potential witnesses by way of detailed questionnaires known as witness statement requests. Supplementary witness statements were then sought to clarify and particularise. The Inquiry received 538 individual witness statements but some were of lesser importance than others and not all witnesses were asked to give oral testimony. A list of all who provided evidence to the Inquiry may be found at Appendices 4 and 5.
- 1.30 I designated family members and key witnesses ‘interested parties’ in accordance with protocol. Doctors, nurses, managers and healthcare professionals were named in this way together with the Department, HSC Trusts and others. Interested parties became entitled to legal representation at the public hearing, were allowed to make submissions, suggest lines of questioning and on occasion to question witnesses. A full list of those accorded interested party status is provided at Appendix 6

### ***List of Issues***

- 1.31 These reflected the terms of reference as revised and the evidence as received. They were subject to comment and suggestion from interested parties and are to be found on the Inquiry website.

## **Background**

### ***Hyponatraemia***

- 1.32 The shared fate of Adam, Claire, Lucy and Raychel was to suffer hyponatraemia, a condition in which the concentration of sodium in the blood falls below safe levels. It can result from excessive sodium losses, caused for example by vomiting, or can arise in a number of different ways. One variant is dilutional hyponatraemia in which excess fluid in the system reduces sodium levels by dilution. The less sodium in the excess fluid, the greater the dilution. Excess fluid can be introduced by excessive intravenous infusion or can result from excess water retention, or a combination of both.

1.33 Children can react to illness or surgical stress with a recognised Syndrome of Inappropriate Anti-Diuretic Hormone secretion ('SIADH') which inhibits urine production and causes water retention. The resultant increase in the amount of water in the blood leads to dilution of its sodium concentration. This can become problematic if the sodium level is already low. Thus, for example, if sodium rich fluids lost through vomiting are replaced by sodium light fluids (such as an intravenous low saline solution) in the presence of anti-diuretic hormone activity, the inevitable result will be a lowering by dilution of already lowered sodium levels and ultimately a dilutional hyponatraemia. If left untreated, the fall in the sodium concentration will induce cerebral oedema causing raised intracranial pressure, respiratory arrest, coma and potential brain-stem death. The symptoms of hyponatraemia are often lethargy, headaches, nausea and vomiting. The severity of the symptoms relates to the rate at which the sodium level falls. A diagnosis is made easily by assessing the serum sodium levels. Accordingly, safe IV fluid management of a child with sodium losses cannot be assured without testing the sodium levels and understanding the fluid balance. Because such a patient is the subject of active fluid therapy, dilutional hyponatraemia should not happen in a hospital. It is a preventable hospital illness.

### ***Solution No. 18***

1.34 In each of the cases examined in this Report (excepting only Conor) the patient was given intravenous infusion of a fluid known as Solution No.18, so called because it contains only 0.18% sodium chloride. This is deemed a low saline or hypotonic solution because it contains only about 1/5 of the sodium and chloride found in blood. Because it is so low in sodium it cannot replace sodium lost through vomiting or diarrhoea and can, if administered excessively or too quickly, create a dilutional effect on sodium levels resulting in hyponatraemia. It is not dangerous of itself, but can become so if given inappropriately in the presence of established sodium losses or SIADH.

- 1.35 The risks of using low sodium solutions such as Solution No.18 and the dangers of dilutional hyponatraemia were understood from the early 1990s. In a leading paper published in the British Medical Journal ('BMJ') in 1992,<sup>8</sup> Professors Arieff, Ayus and Fraser concluded that "*symptomatic hyponatraemia can best be prevented by not infusing hypotonic fluids to hospitalised children unless there is a clear cut indication for their use.*"<sup>9</sup> Notwithstanding and despite similar subsequent warnings in the medical literature, it is clear that even at the time of Raychel's death, Solution No.18 remained the standard IV solution for general use with children.
- 1.36 In consequence of Raychel's death, Dr Henrietta Campbell<sup>10</sup> the Chief Medical Officer ('CMO'),<sup>11</sup> directed that the Department issue Guidance on the Prevention of Hyponatraemia in Children.<sup>12</sup> This was published in March 2002 specifically warning that "*hyponatraemia may occur in any child receiving any IV fluids... vigilance is needed for all children receiving fluids.*" It gave clear advice for the regular monitoring of fluid balance, the regular evaluation of sodium levels and the accurate calculation of IV fluid requirements. Fluids were specifically to be prescribed as maintenance fluids to meet anticipated fluid requirements or as replacement fluids to replace fluids and sodium actually lost. This was a most valuable guideline and the first of its kind in the UK. The work of providing guidance was thereafter undertaken by the National Patient Safety Agency ('NPSA').<sup>13</sup> By 2010 the Regulation and Quality Improvement Authority ('RQIA') was able to report that Solution No.18 had been removed from all clinical areas where children might receive treatment.<sup>14</sup>

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<sup>8</sup> 070-005-018

<sup>9</sup> 070-005-018

<sup>10</sup> 337-001-002

<sup>11</sup> 338-001-001

<sup>12</sup> 007-003-004

<sup>13</sup> 303-026-350

<sup>14</sup> 303-031-435

## The Children

### *Adam Strain*

1.37 Adam was born on 4<sup>th</sup> August 1991 and died on 28<sup>th</sup> November 1995 at the RBHSC having undergone renal transplant surgery. He was born with kidney abnormality and, having suffered multiple problems, was placed on the transplant register and admitted for kidney transplant on 26<sup>th</sup> November 1995. He did not survive surgery. As with the other cases being examined he received intravenous infusion of Solution No.18. His death was scrutinised at inquest and found to have been caused by cerebral oedema brought about by the acute onset of hyponatraemia suffered in consequence of an excess administration of fluids containing only very small amounts of sodium. There may also have been other factors combining with this underlying cause. The consultant anaesthetist responsible for the management of Adam's fluids refused to accept that Adam had suffered dilutional hyponatraemia.<sup>15</sup>

1.38 In the course of Adam's inquest, draft 'Recommendations for the Prevention and Management of Hyponatraemia arising during Paediatric Surgery'<sup>16</sup> were submitted by the RBHSC paediatric anaesthetists in order to reassure the Coroner as to the future management of such cases. These recommendations specifically referenced Professor Arieff's paper on hyponatraemia and indicated that all anaesthetic staff would be made aware of the complications of hyponatraemia. The recommendations were not however circulated, and the opportunity to familiarise clinicians in the RBHSC and elsewhere with the risk to children of dilutional hyponatraemia in the context of IV infusion of hypotonic solution was lost.

### *Claire Roberts*

1.39 Four months after the inquest into Adam's death Claire Roberts was also admitted to the RBHSC. She was nine years old and had a past history of

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<sup>15</sup> 093-038-238

<sup>16</sup> 060-018-036

convulsions in early childhood. On 21<sup>st</sup> October 1996 she was referred by her GP to the RBHSC with symptoms of vomiting, malaise and drowsiness. In light of her medical history it was thought that she could be suffering seizures. She was admitted and placed on an IV infusion of Solution No.18. Her blood tests revealed slightly lower than normal sodium levels but her sodium was not then reassessed over the next 24 hours despite the fact that she was receiving a continuous infusion of Solution No.18. Her condition did not improve, her consciousness reduced and the doctors did not know what was wrong with her. No further tests were performed. She was then given too much of an anti-convulsant medication, her levels of consciousness declined further and early in the morning of 23<sup>rd</sup> October she suffered respiratory arrest and was transferred to the Paediatric Intensive Care Unit ('PICU') where she died. Her death was not reported to the Coroner and only a partial autopsy was performed. A death certificate was issued citing cerebral oedema and status epilepticus as the cause of her death. Mr and Mrs Roberts were led to believe that Claire may have suffered encephalitis.

- 1.40 Eight years later, having watched the UTV programme about the deaths of Adam, Lucy and Raychel and recognising similarities with Claire's case, Mr and Mrs Roberts contacted the RBHSC. They queried the management of her fluids and asked whether hyponatraemia might not have played a part in her death. Only then was the Coroner notified. He conducted an inquest in May 2006 and found that hyponatraemia due to SIADH had contributed to the cerebral oedema which caused her death. He also found an indeterminate contribution from meningo-encephalitis and status epilepticus.

### ***Lucy Crawford***

- 1.41 Lucy was born on 5<sup>th</sup> November 1998 and admitted to the Erne Hospital on 12<sup>th</sup> April 2000 with a history of drowsiness and vomiting. The vomiting may have caused dehydration and she was assessed an appropriate candidate for IV fluid replacement. Blood tests revealed normal sodium levels and an

IV infusion of Solution No.18 was commenced. However, she was given an excessive volume of Solution No.18 at an excessive rate. In the early hours of 13<sup>th</sup> April she suffered a seizure. Her serum sodium levels had fallen significantly since admission. She was transferred to PICU in the RBHSC where she was pronounced dead the following day. Her death was not formally notified to the Coroner. A hospital post-mortem was performed and a death certificate issued citing cerebral oedema due to dehydration and gastroenteritis as the cause of death. Lucy's parents were concerned with the treatment she had received at the Erne Hospital and did not feel that the cause of her death had been adequately explained to them.

- 1.42 The Erne hospital conducted a review of her case and sought the opinion of Dr Murray Quinn, Consultant Paediatrician of the Altnagelvin Area Hospital. He concluded that the cause of Lucy's seizure and cerebral oedema could not be determined with confidence but that her fluid therapy had been acceptable. There the matter would have rested but for the concern of Mr Stanley Millar,<sup>17</sup> Chief Officer of the WHSSC, who referred her death to the Coroner. The subsequent verdict at inquest was that Lucy's death was caused by cerebral oedema due to acute dilutional hyponatraemia in the context of gastroenteritis. In terms, the Coroner found that the cerebral oedema had not been due to dehydration but rather to excessive rehydration with Solution No.18. Revised terms of reference restricted the Inquiry to an investigation of what had happened after Lucy's death and specifically to the failure to correctly identify the cause of her death.

### ***Raychel Ferguson***

- 1.43 Raychel was born on 4<sup>th</sup> February 1992 and enjoyed a childhood of excellent health. She was admitted to Altnagelvin Area Hospital on the evening of 7<sup>th</sup> June 2001 with pain on urination, stomach ache and nausea. She underwent an uneventful appendectomy that night. On admission her sodium levels had been normal and she was placed on an IV infusion of

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<sup>17</sup> 325-002-011

Solution No.18 which was re-commenced after surgery. The rate of fluid administration was marginally more than it should have been. Raychel vomited repeatedly over the course of the following day and her parents expressed concern. Notwithstanding that her condition deteriorated, her sodium levels were not reassessed, her fluid balance was not monitored and her IV infusion continued until she suffered a collapse in the early hours of 9<sup>th</sup> June. Her sodium levels were then found to be exceptionally low. She had acute hyponatraemia and was transferred to PICU at RBHSC where she was pronounced dead the next day. Raychel's parents did not feel they were given a satisfactory explanation. Her death was notified to the Coroner who found at inquest that she had died from cerebral oedema caused by hyponatraemia which had been caused in turn by a combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and water retention resulting from anti-diuretic hormone activity.

- 1.44 After Raychel's death Altnagelvin reviewed her case and having identified shortcomings in clinical care, set about addressing them. It also took steps to draw the risks attaching to the infusion of Solution No.18 and hyponatraemia to the attention of the CMO and a wider medical audience. This prompted the Department to prepare its Guidance for the Prevention of Hyponatraemia in Children.

### ***Conor Mitchell***

- 1.45 Conor was born on 12<sup>th</sup> October 1987 with spastic tetraplegia, cerebral palsy and mild epilepsy. He was admitted onto an adult medical ward at the Craigavon Area Hospital ('CAH') on 8<sup>th</sup> May 2003 with a history of vomiting and malaise. He was given IV fluids but unlike the other children, received an isotonic solution rather than Solution No.18. Nonetheless, his condition deteriorated and his family expressed concern. He suffered two seizures in the evening and was transferred to PICU at the RBHSC the following day. He was pronounced dead on 12<sup>th</sup> May. His family were concerned about the care he had received. The Coroner commissioned expert opinion and conducted an inquest but the precise cause of Conor's



death remained unclear. There was cerebral oedema but no obvious cause. Notwithstanding that the Coroner considered the fluid management to have been acceptable, concerns were raised about whether the Department's hyponatraemia guidance had been followed properly, or at all, and whether the fluid therapy administered was appropriate.

- 1.46 It was a matter of particular interest to this Inquiry to determine whether the guidance introduced in consequence of Raychel's death was being followed. Accordingly, I directed investigation into the way in which the guidance had been issued by the Department and the means by which it had been implemented and enforced. Conor's case was selected for scrutiny so as to permit inquiry into how the hyponatraemia guidance had been introduced at CAH, whether Conor's treatment had been informed by it and whether any changes to practice or procedure had resulted. The terms of reference were accordingly amended so as to permit inquiry into *"the circumstances of the death of Conor Mitchell in the context of the guidelines on fluid management in children."*

### **The Department**

- 1.47 One of the fundamental questions for this Inquiry was whether lessons could and should have been learned from the 'adverse incidents' described. Whilst clinicians and hospitals were obliged to investigate such incidents it was also necessary to consider whether responsibility for collecting information about such matters extended to the Department. It was necessary to understand the Departmental procedures for assuring delivery of safe healthcare and the extent to which information about healthcare problems, and specifically the deaths of Adam, Claire, Lucy and Raychel, became known to the statutory authorities, and what was done in response.
- 1.48 Having so closely examined all that had gone wrong it became equally necessary to determine whether it had been put right and to assess what the relevant statutory bodies had done to remedy matters in the years

following the period under review. I was interested to know, for example, if updated systems could be bypassed in a culture which concealed error.

1.49 Accordingly, and when examining the present Health Service and in exploring what might be achieved for the future, I considered that a different approach to information gathering was required of the Inquiry. In order that views could be more readily aired and ideas for improvement exchanged, I directed a forum for opinion and discussion with representatives from the Department, the Belfast Health & Social Care Trust ('BHSCT'), the Health and Social Care Board ('HSCB'), Action against Medical Accidents ('AvMA'), the Patient and Client Council ('PCC'), Regulation and Quality Improvement Authority ('RQIA') and others. Participants were not subject to criticism and it was hoped debate would emerge from the evidence already received, the agenda for discussion and my own questions. Parties were asked for up-to-date information and position papers about the current processes for ensuring the provision of satisfactory healthcare. In particular, submissions were invited in respect of my more significant concerns including the handling of complaints, the notification and investigation of Serious Adverse Incidents ('SAIs'), the involvement of families and the introduction of a legally enforceable duty of candour. The responses and position papers received were circulated amongst the interested parties and are to be found on the Inquiry website.<sup>18</sup>

1.50 Identification of relevant lessons for the future is necessarily dependent upon an understanding of the systems as they are today. The Inquiry has sought relevant up-to-date information and has attempted to note the changes which have occurred in the years since the deaths examined. Given the pace of reform and procedural change in the years since, this has been no easy task. This Report is not to be understood as intending a comprehensive and up-to-the-minute account of the current position.

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<sup>18</sup> <http://www.ihrdni.org/supp-eviden-additional-papers.htm>

## Hearings

- 1.51 The public hearings were conducted over the course of 148 days at The Courthouse, Banbridge, County Down, from February 2012 to November 2013. In all, 179 witnesses gave evidence. Full transcripts of the hearings extending to over 32,000 pages may be found on the website, together with the written closing submissions of 37 of the interested parties.
- 1.52 In relation to all the cases under consideration (excepting Lucy) evidence was heard and examined in respect of both clinical and governance issues. Hearings were conducted on that basis and in that order. There was occasional and inevitable overlap between clinical and governance evidence. Senior Counsel to the Inquiry opened each stage with a full background statement identifying the facts and issues as then understood. These openings are to be found on the website. It was not the function of counsel to advance any particular case but to test the evidence and assist the process of the Inquiry.
- 1.53 All hearings were conducted openly and in public, save for one issue considered in private session in accordance with the requirements of the European Convention on Human Rights and two separate and specific orders of the High Court.<sup>19</sup> This was done in an attempt to identify the possible whereabouts of the consultant responsible for Claire's care while protecting the privacy of other patients then receiving treatment within the RHBC.
- 1.54 All witnesses were advised as to the general subject matter of questioning in advance. They were questioned by Inquiry counsel. On occasion I permitted the legal representatives of interested parties to pose questions when there was a reasonable basis so to do.
- 1.55 Salmon letters<sup>20</sup> were sent in confidence to those witnesses thought most likely to be criticised, so as to place them on notice. This is done in the

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<sup>19</sup> [http://www.ihrdni.org/high\\_court\\_orders.htm](http://www.ihrdni.org/high_court_orders.htm) *O'Hara v BHSC* [2012] NIQ 575

<sup>20</sup> Letters of 'warning' compliant with the 'Salmon principles' set out in The Royal Commission on Tribunals of Inquiry Report, 1966.

interests of fairness. I directed such letters be sent to a number of individuals and organisations in accordance with the procedure for hearings.

- 1.56 Those who assisted the Inquiry and re-lived their experiences in public, did so with dignity and patience. The Inquiry is indebted to them for their invaluable assistance. In particular and in this regard I acknowledge the courage of family members and pay tribute to them.
- 1.57 The Inquiry also heard from a wide range of clinicians, healthcare professionals and independent expert witnesses. The experience of giving evidence in public was no doubt stressful for many and the Inquiry is grateful.

## **Evidence**

- 1.58 The Public Inquiry process is investigative and inquisitorial and seeks to determine what has happened in order to better identify what may be learned. Accordingly, I have found myself in a very different position to a judge sitting in a court of law. In identifying what has gone wrong I have inevitably criticised some individuals and organisations, but my findings are not binding and are not determinative of liability.
- 1.59 This has not been an investigation into allegations of criminal wrongdoing. It has been an investigation into deficiencies in clinical performance and shortcomings in governance control and response. Accordingly, I did not think it correct to adopt the criminal standard of proof when making a finding of fact. I considered the civil standard of proof found on the balance of probabilities to be appropriate. Were it otherwise, my findings would be limited in number by the more onerous criminal burden of proof and would suffer a consequent reduction in scope to identify lessons. The drawing of lessons is the most important task of this Inquiry.
- 1.60 In applying the balance of probabilities as the standard of proof, I have borne in mind the concepts of 'common sense' and 'inherent improbability'

when reaching a finding of fact. In addition and for the avoidance of doubt, where I permit myself comment expressing suspicion or concern, it is because I think it relevant. It is not a finding of fact. I have striven at all times to be fair.

- 1.61 I have, of course, assessed the acts and omissions of all involved against contemporaneous expectations and standards and not against those of today. Where there was no consensus as to those standards I have taken that into account. I have not assumed that a written record is proof of its content any more than I have assumed that the absence of record means that something did not happen.
- 1.62 Passage of time and memory degraded some of the evidence. Given the absence of full investigation at the time of the deaths and the time since lapsed, this was a relevant consideration. Nonetheless, I was surprised at how little some witnesses found themselves able to recall.
- 1.63 I am conscious that the individuals who are criticised were not able to defend themselves as they might in adversarial proceedings and were circumscribed in their right to make representations. I am also aware that individuals who are criticised may attract adverse publicity affecting both reputation and career. Therefore where critical comment is made of an individual, it must be assessed in the context of the limitations of the process.

## **Costs**

- 1.64 Inquiry costs are as set out at Appendix 10.

## **Report**

- 1.65 This Report deals in turn with the deaths of Adam and Claire, the events that post-dated Lucy's death, Raychel's case and the fluid management and organisational issues presented by Conor's treatment.

- 1.66 The role and involvement of the Department in these specific cases and in general is dealt with in a separate chapter as is my assessment of the progress and current involvement of the Department and Health Service.
- 1.67 In general, and unless otherwise stated, I have accepted the evidence as recited. Whilst I have had regard to all the evidence and to the submissions made, I have not referenced it all in the Report or made fully reasoned decisions for each and every issue of fact because to do so would unduly extend the Report. Footnoted references are given for fact or quotation or otherwise to explain. Where significant dispute has arisen as to fact, I have given a fuller reasoning for my conclusion. It is important when considering my treatment of the facts as well as my comments, criticisms and conclusions, to read them in context, just as the Report itself must be read in its entirety.
- 1.68 The Report does in large measure deal with all those issues appearing in the list of issues. However, some matters once thought germane, were found on examination to have less relevance to the overall view, in which circumstances they do not always find detailed reference in the Report. It has been inevitable that some material and evidence will be referred to in more than one chapter. Whilst repetition has been kept to a minimum, in some contexts it has been permitted in aid of clarity.
- 1.69 I acknowledge the assistance of counsel to the Inquiry in the assessment of the evidence and its significance. However, the conclusions of the Report are mine and mine alone.

## **Recommendations**

- 1.70 I set out my recommendations to strengthen and improve practice and systems in the hope that the failings found, cannot easily be repeated. The recommendations are presented in Chapter 9 of this Report. It is for the Department of Health to take them forward. Many will doubtless require significant detailed consideration to enable implementation. I expect the Department to indicate not only which of my recommendations it accepts

but also to make clear how and when implementation is to be achieved. Further and subsequent reports should then be made detailing progress towards implementation with a final published confirmation of same.

## Delay

- 1.71 I accept there has been delay in the presentation of my Report. This is regrettable but has been due to a number of factors starting with the suspension of all work from October 2005 - May 2008 to allow a police investigation into the deaths of Adam, Lucy and Raychel. A detailed revision of the terms of reference, in consultation with all concerned, then followed. The scope of the terms of reference (both original and revised) required an ambitiously broad and time consuming range of investigation. Analysis of differing expert opinion in complex areas of hyper-specialism was particularly demanding. Differences of opinion required that not only the evidence and the clinical basis for conclusion be tested, but also underlying expert assumptions.
- 1.72 The scope of the Inquiry's work broadened to examine the deaths (in various respects) of five children over a period of eight years. The work of the Department and the Chief Medical Officer together with clinicians and administrators from the following came within the remit of the Inquiry's investigation:
- (i) Royal Belfast Hospital for Sick Children.
  - (ii) Royal Group of Hospitals Trust (now Belfast Health & Social Care Trust).
  - (iii) Eastern Health & Social Services Board (now Regional Health & Social Care Board).
  - (iv) Erne Hospital.
  - (v) Sperrin Lakeland Trust (now Western Health & Social Care Trust).
  - (vi) Altnagelvin Area Hospital.

- (vii) Altnagelvin Hospital Trust (now Western Health & Social Care Trust).
- (viii) Western Health & Social Services Board (now Regional Health & Social Care Board).
- (ix) Craigavon Area Hospital.
- (x) Craigavon Area Hospitals Group Trust (now Southern Health & Social Care Trust).
- (xi) Southern Health & Social Services Board (now Regional Health & Social Care Board).

1.73 In addition, there were other investigations into the circumstances of the children's deaths, namely at inquest and by the Police Service of Northern Ireland ('PSNI'). The General Medical Council ('GMC') also investigated the conduct of a number of doctors involved with the cases of Lucy and Raychel and the Nursing and Midwifery Council likewise considered complaints relating to nursing care in two of the cases. The detail and documentation thereby generated was all potentially relevant and was analysed in full. Where appropriate it was shared.

1.74 Apart from the very real difficulties experienced in gathering the evidence, investigating and analysing testimony, I found the writing of this report exceptionally time consuming. This was due to the mass and complexity of detail together with the nature and nuance of the evidence. I recognise that it has been delayed and regret that it has taken so long. I offer my sincere apologies for any additional distress which this has caused.

## **Conclusion**

1.75 It is the task of an Inquiry to focus specifically on what has gone wrong, not on what has gone right and such close focus can act as a distorting lens. It is to be stressed that critical comment of an individual does not necessarily imply that the same individual has not otherwise made much positive contribution to healthcare or that the pressures of modern clinical practice



have been taken for granted. It is recognised that untoward clinical incidents can cause terrible suffering, not only for patients and their families but also to the clinical professions.

- 1.76 The purpose of identifying underperformance is to highlight acts or omissions, attitudes or assumptions to be avoided in the future. Whilst it is proper that individuals be accountable, it is also better to learn than to punish. To place undue emphasis on blame is to encourage the cycle of defensiveness, concealment, indifference to learning and further harm. There is much for all who work in the Health Service to reflect upon and learn from in the sad narratives of this Report. In addition, I recognise that others, including Her Majesty's Coroners, may draw insight and instruction from what has been revealed.
- 1.77 However, in each of the cases examined, deficiencies in practice and system did become apparent and in most cases the shortcomings were evident from the outset. Accordingly, I was surprised at how difficult it was to persuade some witnesses to be open and frank with the work of the Inquiry. All too often, concessions and admissions were extracted only with disproportionate time and effort. The reticence of some clinicians and healthcare professionals to concede error or identify the underperformance of colleagues was frustrating and depressing, most especially for the families of the dead children.
- 1.78 This remained largely the case until 30<sup>th</sup> August 2013 when Altnagelvin fully and publically accepted its responsibility for the death of Raychel Ferguson. Twelve years had passed since her death and ten years since the start of litigation.<sup>21</sup> Altnagelvin's concession, whilst belated, was correct and was to be followed by the Belfast and Southern Trusts in October 2013 when they accepted full responsibility for the deaths of Adam and Claire and the failings revealed in Conor's case.<sup>22</sup> They proffered formal apology for all the hurt caused by the acts and omissions of the Trusts. This was a

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<sup>21</sup> T-30-08-13 p.1

<sup>22</sup> T-17-10-13 p.2 *et seq*

welcome and partial vindication of the work of the Inquiry but was achieved at considerable cost to all.

- 1.79 It should not have been so. Health service guidance for 25 years and more has repeatedly recommended transparency and openness in the interests of the patient. This has proved inadequate to the problem which is why this Report must recommend a statutory duty of candour in Northern Ireland.