THE DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY FOR NORTHERN IRELAND

Contents

Introduction

7.1 What happened immediately after Raychel's death illustrates what can be achieved when such a death is reported promptly. The Department responded quickly and decisively to analyse and issue guidelines. However the deaths of Adam, Claire and Lucy were not formally reported to the Department and it remained seemingly unaware of them at the time. So why did the Department fail to ensure that it was notified about such serious adverse incidents?

Expert reports

7.2 The Inquiry was guided by the reports of:

(i) Professor Gabriel Scally[1] (Professor of Public Health and Planning, Director of WHO Collaborating Centre for Healthy Urban Environments, University of the West of England) who examined the responsibilities and accountabilities of HSC Trusts, Health Boards and the DHSSPS in Northern Ireland.[2]

(ii) Professor Charles Swainson[3] (onetime Consultant Renal Physician and Medical Director, Lothian NHS Board, Edinburgh) who considered the issues of governance arising from Raychel Ferguson's case.[4]

(iii) Professor Aiden Mullan[5] (former acting Chief Executive Officer and Director of Nursing and Clinical Governance, North Tees & Hartlepool NHS Trust) who provided advices on governance matters relating to Adam Strain.[6]

7.3 The Inquiry was also assisted by expert background papers received from:

---

1 337-001-005
2 341-002-001 & 341-003-001
3 328-001-006
4 226-002-001
5 306-081-008
6 210-003-001

(i) Dr Jan Keeling[7] (Paediatric Pathologist) on systems and procedures for disseminating information derived from post-mortem examinations.[8]

(ii) Dr Bridget Dolan[9] (Barrister and Assistant Deputy Coroner) on UK practice and procedure on the dissemination of information from inquests.[10]

Schedules compiled by the Inquiry

7.4 In an attempt to summarise all the information received, the following schedules were compiled:

(i) List of persons involved.[11]

(ii) Chronology.[12]

(iii) Structure of the Health Service in Northern Ireland (pre-2007).[13]

(iv) HSC Trust areas in Northern Ireland.[14]

(v) Commissioning structure for HSC services in Northern Ireland.[15]

(vi) Membership of Chief Medical Officer's Working Group on Hyponatraemia.[16]

7 306-081-010
8 308-020-295
9 306-081-010
10 303-052-715
11 337-001-001
12 337-003-001
13 303-039-505
14 300-001-001
15 303-040-506
16 328-003-001

Department's responsibility for clinical services

7.5 At the time of the children's deaths, as now, the Department and the Minister bore ultimate responsibility and accountability for the healthcare provided to patients in Trust hospitals.[17]

7.6 Article 16(1) of the Health & Personal Social Services (Northern Ireland) Order 1972[18] created 4 Health and Social Services Boards, namely the Northern, Southern, Eastern and Western. The Department made provision for and oversaw the Health Service through those four regional Boards. Subsequent re-structuring was undertaken, broadly following that in the rest of the UK, to re-constitute the Boards as commissioning bodies, responsible for assessing local requirements and purchasing healthcare and social services from the hospitals, which re-emerged as Trusts.

7.7 Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991[19] created the new Health and Social Services Trusts to provide the health services. The Chair of each Trust was appointed by the Minister and was directly accountable to the Minister.[20] The Trusts were established as 'autonomous self-governing' bodies, independent of the Boards but with 'arms-length' accountability to the Department.

7.8 The Department described this re-ordering in 'HSS Trusts: A Working Guide,' 1991 noting that "*A key element of the changes is the introduction of HSS Trusts. They are hospitals and other units which are run by their own Boards of Directors; are independent of Health and Social Services Board Management; … Trusts differ in one fundamental respect from directly managed units – they are operationally independent...*"

7.9 The understanding at the time was that, whilst standards of clinical care remained primarily the responsibility of consultants within the Trusts,[21] the

17 333-001-003 & 306-083-003
18 https://www.legislation.gov.uk/nisi/1972/1265/contents
19 http://www.legislation.gov.uk/nisi/1991/194/contents/made
20 Mr Hunter T-04-11-13 p.50 line 2
21 WS-348-1 p.3

Trusts were accountable to the Boards and the Department retained a leadership role in respect of the whole Health Service.[22]

7.10 The Department was responsible for articulating the directions of its Minister and the Permanent Secretary was accountable for the management and organisation of the Department. He was supported by the Departmental Board which included a Chief Medical Officer ('CMO'), a Chief Nursing Officer ('CNO') and his most senior officials. The Department formulated and implemented policy, allocated resources and established the context and objectives for the Health and Personal Social Services ('HPSS').

7.11 The CMO led the medical service within the Civil Service and was responsible for advising the Minister and the Department on matters relating to public health. The CMO from 1995-2006 was Dr Henrietta Campbell.[23] It was envisaged that she would provide a link between the Minister and the medical profession.[24] Ultimate responsibility for the Department lay with the Permanent Secretary.

7.12 The Department did not assume general operational responsibility in relation to the HPSS but did on occasion issue guidance and instruction for HSS Trusts. The Department created a Management Executive to oversee performance of the HSS Trusts.[25] One of the main objectives of the Management Executive was to ensure that standards were raised and quality improved in accordance with Departmental policy.[26] Until 2000 it was responsible for the communication of Departmental policy and instruction to the Trusts.

7.13 The relationship of accountability between the Management Executive and the Trusts was set out in an 'Accountability Framework for Trusts' (1993).[27] It indicated that whilst the "*primary accountability of Trusts is for the*

22 Mr Elliott T-05-11-13 p.70 line 16
23 337-001-002
24 WS-075-2 p.2
25 WS-062-2 p.3
26 WS-002-2 p.3
27 323-001a-002 - Circular METL 2/93

quantity, quality, efficiency of the service they provide"[28] (and this lay to the Boards) the Department was to retain "*ultimate legal responsibility for the functions and will wish to ensure that both Boards and Trusts are discharging their responsibilities.*"[29] In broad terms, the Department planned to appraise itself of patient care issues and hold the Trusts to account through their relationship with the Boards.[30] This was to be "*a light touch*" approach.[31] However, the Management Executive retained a degree of direct management accountability in relation to the Trusts[32] and reserved the right, in certain and exceptional circumstances (including those relating to patient care), to intervene in the affairs of a Trust.[33] In short, the Department was responsible for holding the whole system to account.[34]

7.14 However, in respect of the specifics of Departmental monitoring of the performance of the Trusts, Professor Scally noted that the 'Accountability Framework' did not indicate any particular focus on patient care issues.[35] The question therefore arose as to how the Department ensured that the Trusts discharged their responsibilities in respect of the quality of healthcare and in particular why it did not know about the hospital related deaths from hyponatraemia in the very hospitals for which it was responsible? Accordingly, Professor Scally examined the question of how the Department knew what was going on in hospitals prior to 2003 in terms of the quality of care.[36]

Serious Adverse Incident reporting to Department

7.15 Professor Scally advised that there was no requirement during the period under review for Boards or Trusts to notify the Department about "*potentially avoidable deaths or other instances of serious clinical failure.*"[37]

---

28 323-001a-003
29 323-001a-003
30 Mr Simpson T-08-11-13 p.6 line 20 & WS-349-1 p.5
31 WS-084-2 p.4
32 306-083-003
33 WS-348-1 p.14
34 WS-348-1 p.4 & WS-308-1 p.11
35 341-002-002
36 341-002-002
37 341-002-004

Whilst there had hitherto been formal requests that hospitals report untoward incidents to their Board,[38] he noted that the "*changes in accountability that took place with the creation of Trusts altered the position whereby the Boards had been responsible for occurrences within their directly managed units. It appears that once hospitals became Trusts they ceased to report serious untoward incidents to the Boards.*"[39]

7.16 Even though Trust lines of accountability remained initially to the Boards, there would appear to have been no attempt at that time to develop alternative replacement notification systems. Further and importantly, given that the Boards no longer received reports, no requirement was introduced to ensure reporting to the Department.[40] This was a vulnerability and not without consequence.

7.17 Professor Swainson considered it: "*regrettable in hindsight that there was not a clear framework that would have ensured that serious clinical incidents were reported by Trusts and disseminated to the other Trusts. Wide sharing of serious incidents can stimulate quicker and national efforts to reduce harm.*"[41]

7.18 This omission is to be seen in a context where functioning systems already existed to notify the Department of adverse incidents relating to equipment, supplies,[42] food, buildings and plant[43] or affecting patients[44] in psychiatric or special care hospitals.[45] The Department was part funding[46] a number of national reporting systems for deaths including National Confidential Enquiry into Perioperative Deaths ('NCEPOD')[47] and systematically receiving reports of maternal deaths, stillbirths and deaths in infancy for

38 341-002-005
39 341-002-005
40 341-002-006
41 226-002-010
42 WS-062-1 p.13 & 210-003-1132
43 WS-062-1 p.13.
44 WS-062-1 p.3
45 WS-062-1 p.34
46 WS-075-1 p.13 & p.32
47 WS-062-1 p.3

inclusion in the UK Confidential Enquiry into Stillbirths and Deaths in Infancy.[48]

7.19 However, the absence of any formal reporting requirements to the Department was, in the view of Mr Clive Gowdy (Permanent Secretary in the Department 1997-2005)[49] consistent with the intention that Trusts should operate with maximum freedom and autonomy.[50] Notwithstanding external developments, including the disturbing 1994 Report into the Deaths of Children in the Grantham and Kesteven General Hospital (the Beverley Allitt inquiry), which stressed that "*reports of serious untoward incidents to District and Regional Health Authorities should be made in writing and through a single channel which is known to all involved,*"[51] nothing substantive was done.

7.20 By comparison, Regional Directors of the National Health Service Executive in England were directed in 1995 to establish notification systems for serious untoward incidents.[52] The English regions, all of which were significantly larger than Northern Ireland, proceeded to put systems, albeit imperfect, into place. Within Northern Ireland, and notwithstanding that the Management Executive "*received a constant flow of documentation, particularly from England, in respect of initiatives that were being taken there,*"[53] the then Permanent Secretary Mr Alan Elliott[54] indicated that "*it didn't occur to anyone to say that there should be a system.*"[55] Mr John Hunter,[56] Chief Executive of the HPSS Management Executive, was unable to advance any explanation as to why this was so.[57]

---

48 WS-075-1 p.13
49 337-001-001 & 323-027e-003
50 WS-062-1 p.3
51 341-002-007 & Mr Elliott T-05-11-13 p.21 line 14
52 341-003-009
53 Mr Hunter T-04-11-13 p.10 line 20 & p.27 line 5. Documentation included the 'Risk Management in the NHS' manual (1994) (211-003-001) recommending a comprehensive incident reporting system as the foundation of a good tracking system. This was forwarded by the Management Executive to the RGHT (Dr Carson T-16-01-13 p.4 to 5).
54 337-001-003
55 Mr Elliott T-05-11-13 p.66 line 19
56 337-001-003
57 Mr Hunter T-04-11-13 p.31 line 19

7.21 In 1998 the Department commissioned the consultants 'Healthcare Risk Resources International' to survey risk management in the HPSS.[58] Mr Gowdy recalled that it reported '*a general perception that there might have been a significant level of under-reporting of adverse incidents.*'[59] In the light of such intelligence, the Department could not safely assume that it would be informed of potentially serious patient care issues. Notwithstanding, it made no policy change and gave no direction for adverse incident reporting.

7.22 In 2000 the Department of Health ('DoH') in London published 'An Organisation with a Memory' specifically recommending more comprehensive systems for reporting and analysis of adverse events.[60] The Department did not follow suit but did publish for consultation 'Confidence in the Future' in relation to the problem of poor medical performance.[61] It recommended, amongst other things, Serious Adverse Incidents ('SAI's') recording as an aid to the identification of the under-performing doctor. Additionally, the Department published for consultation 'Best Practice, Best Care' in 2001 noting in particular the necessity for "*a clear line of accountability from front line delivery back to the Executive*"[62] and the requirement to monitor adverse events. Formal reporting requirements were not however introduced until 2004.[63]

7.23 In the absence of a formal system, informal channels of communication were used. Trust Chief Executives and Clinical Directors could bring significant untoward clinical incidents to the attention of the CMO at any time.[64] Indeed, Raychel's death was reported in just such a way. It was in this context that Mr Gowdy said that he "*would certainly have expected the*

---

58 338-006-107

59 WS-062-1 p.4 –*"The major deficiency relates to the very limited and therefore probably significant under-reporting of clinical incidents and near misses."*

60 Professor Scally noted that the NHS 1995 Regional serious untoward incident reporting scheme had informed the recommendations of 'An Organisation with a Memory'. (341-003-004).

61 333-184-001

62 WS-068-1 p.49

63 WS-062-1 p.321 - Circular HSS (PPM) 06/04. Professor Mullan pointed out that 'An Organisation with a Memory' referred to Department of Health guidance for untoward incident reporting in England issued in 1955, which was still current in 2000.(210-003-038).

64 010-023-150 & WS-075-1 p.3

Trusts to have informed the Department of all of them."[65] Moreover he "*assumed that the informal system was working effectively because* [he] *was being told of serious things*"[66] estimating that he had been informed of approximately two deaths during his eight years as Permanent Secretary.[67] Upon reflection he recognised that he had been "*lulled into a false sense of security by the fact that* [he] *was getting reports about serious incidents from some of the Chief Executives and chairs.*"[68] Both Mr Paul Simpson,[69] former Chief Executive of HSS Executive,[70] and Mr Gowdy accepted with hindsight that it was not an effective system.[71]

7.24 Dr Campbell acknowledged that the informal mechanisms of adverse incident reporting "*were found to be totally inadequate and recognised by myself as such in 1999.*"[72] She fairly conceded that she could not "*defend the fact that it took until 2004 to put a proper system in place.*"[73] As Mr Gowdy observed "*you don't know what you don't know, so you need to have a system to find out.*"[74] The Department did not know, did not have a system and did not find out.

7.25 While Trusts and Boards were clearly accountable to the Department and the Department had a clear role in overseeing the functioning of the Health Service, Professor Scally nonetheless believed that the Trusts did not generally understand that the Department might have had an interest in the occurrence of these deaths.[75] It was not made clear. He concluded "*that there was no effective system in place in Northern Ireland prior to 2003 and …no significant efforts had been made at any stage to develop comprehensive and effective notification systems. This would appear to be borne out by a briefing for the Minister prepared within the Department in*

65 WS-062-2 p.10
66 Mr Gowdy T-06-11-13 p.100 line 2
67 Mr Gowdy T-06-11-13 p.96 line 19
68 Mr Gowdy T-06-11-13 p.96 line 8
69 337-001-003
70 Mr Simpson T-08-11-13 p.14 line 19
71 Mr Gowdy T-06-11-13 p.112 line 17
72 Dr Campbell T-07-11-13 p.62 line 3
73 Dr Campbell T-07-11-13 p.74 line 4
74 Mr Gowdy T-06-11-13 p.111 line 2
75 341-002-018 & Dr Jenkins T-10-09-13 p.73 line 25

2004. The opening sentence reads: 'There is no unified reporting of untoward incidents in the HPSS to the Department.'[76] Indeed it was noted within the Department at that time that reporting of adverse incidents was "*patchy*" and the Minister was thought to be "*somewhat vulnerable to the accusation that the Department is not aware what is going on as regards serious incidents.*"[77]

7.26 I consider that in the circumstances it should have been obvious to the Permanent Secretary Mr Gowdy, his predecessor Mr Alan Elliott,[78] the Chief Executive of the Management Executive, the CMO and the other senior Departmental officials, that untoward clinical events were not being routinely reported to the Department. I do not understand how they could have thought otherwise. Professor Scally characterised the approach to adverse incident reporting as "*fragmented and incoherent*"[79] and the evidence confirmed that. In such circumstances it was foreseeable that hospital related child deaths might not be brought to the Department's attention. The Department appeared to proceed on the basis of 'hear no evil, see no evil'.

Other channels of information

7.27 It has to be recognised that even had a structured system of SAI reporting been in place, there is no absolute certainty that the deaths of Adam, Claire or Lucy would have been formally notified to the Department.

7.28 There were however other means whereby the Department might have hoped to gain some information about what was happening in Trust hospitals and to learn whether things were going wrong. Mr Elliott expected that the Department would have been informed of those deaths where

76 341-002-006
77 010-025-180
78 Permanent Secretary 1987-1997
79 341-002-006

medical mismanagement was implicated, through complaints, inquests and legal action.[80] There were also other sources of information.

Complaints

7.29 The Department was clearly interested in complaints as part of its wider interest in Risk Management, not least because they could inform as to the nature of those risks. In 1992 the Government published 'The Citizen's Charter for Patients and Clients'[81] setting out the standards of treatment to be expected from the HPSS and indicating what to do if those standards were not met. The section entitled 'If Things Go Wrong' outlined a patient complaints procedure and indicated that final referral lay to the Chief Executive of the HPSS Management Executive.[82]

7.30 In 1995-1996 the Department published the HPSS Complaints Procedure[83] and followed it up with further 'Guidance on Handling HPSS Complaints.'[84] It reviewed the HPSS Complaints Procedure in 2002 and established a Regional Complaints Review Group.

7.31 Whilst Mr Crawford did attempt to invoke the HPSS Complaints Procedure in relation to Lucy, the system was not engaged in the cases of Adam, Claire or Raychel. Accordingly, and although the complaints procedure represented an important part of the Department's 'quality agenda', it was not always used and could not therefore have been relied upon to alert the Department to particular issues of patient safety.

Inquests

7.32 Dr Campbell expressed the view that the inquest system in Northern Ireland was "*another way of bringing into the open issues which are of concern*" and "*is one that I feel that people should have been using properly.*"[85]

---

80 WS-348-1 p.7
81 306-085-001
82 306-085-014
83 126-004-001
84 333-294-001
85 069a-033-084

However there was no formal mechanism to inform the Department about Coroner's findings in healthcare related inquests.[86] Nor were patient safety matters arising from inquests routinely notified to the Department or circulated to the HPSS.

7.33 This lack of procedure became evident at Adam's inquest. The Royal Group of Hospitals Trust ('RGHT') 'recommendations' which Mr Gowdy considered "*of such general application as to be of interest and significance to other hospitals likely to be treating young patients*"[87] and which he expected to be "*at least copied*" to the Department and "*ideally*" to have been the subject of prior discussion with the CMO, were not seen by the Department at all. There was no mechanism for communication, which was why, as the Coroner was later obliged to point out to Dr Campbell "*an inquest should not be seen as the means of disseminating medical knowledge.*"[88]

7.34 That inquests were not used to gather or share information is to be regretted. Their value as a resource for learning was very clearly demonstrated in April 2005[89] by Dr Angela Jordan, Specialist Registrar in Public Health Medicine, when she presented an analysis of the "*key learning points*" deriving from the evidence given at the inquests of Adam, Raychel and Lucy.[90]

Litigation

7.35 During the period under review claims administration was managed by individual Trusts and Boards. There was no centralised approach and the Department played no active role in the management of litigation or claims. The detail and outcome of individual cases was not collated by the Department and the potential for monitoring HPSS failings not exploited. Whilst the Department did issue a HPSS Protocol on Claims Handling[91] this

86 WS-062-1 p.4
87 WS-062-1 p.10
88 006-004-282
89 320-126-114
90 320-126-124
91 317-039-001 - Circular HSS (F) 20/98

did not stimulate much more than a "*few examples of a claims management policy.*"[92] In 2002 the Northern Ireland Audit Office ('NIAO') published an assessment of the medical negligence system and expressed surprise at the absence of central collection of data.[93] When rather later, attempts were made to collect the information offered, difficulties were encountered and a Departmental memo of July 2005 records concern about "*the quality and accuracy of this data.*"[94] This did not therefore constitute a reliable channel of information.

Meetings

7.36 The Department held formal accountability reviews with the Boards[95] but not with the Trusts.[96] The CMO did however meet Trust Medical Directors on a regular basis[97] and there were other less formal discussions with Board and Trust officers.[98] Routine meetings were also held with organisational, educational and professional leaders including Directors of Public Health and representatives of the Health and Social Care Councils.[99] Dr Campbell described this as "*a fairly well trampled pathway in that the Directors of Public Health quite often brought issues to me of concern, not just of serious clinical incidents …*"[100] The CNO used a 'Nurse Leaders Network' to communicate directly with senior nurses.[101]

7.37 Individual committees provided direct clinical advice to the Department.[102] They included the Central Medical Advisory Committee (CMAC)[103] and the CMO's Special Advisory Committees (SACs).[104] Their meetings mixed formal and informal business but did provide a useful means whereby

92 127-004-098
93 341-002-009
94 330-108-006.
95 WS-084-2 p.6 & WS-066/1 p.63
96 WS-362-1 p.10-11
97 021-018-037
98 WS-348-1 p.5 & Mr Hunter T-04-11-13 p.89
99 WS-361-1 p.8
100 Dr Campbell T-07-11-13 p.54 line 20
101 WS-082-2 p.13
102 320-104-009
103 Mr Hunter T-04-11-13 p.36 line 2
104 Mr Hunter T-04-11-13 p.19 line 7 & 320-110-001

clinical information could pass from Trusts to Department.[105] However, they were unstructured and had no secretarial support. It was in the context of such a meeting that the initial report of Raychel's death was made.[106] Notwithstanding that the meeting enabled effective reporting in that case, the arrangement of committees and meetings failed to convey any hint to the Department of the other deaths from hyponatraemia.

Audit

7.38 The routine collection and systematic analysis of data by audit reveals incidents of note and is an invaluable source of information. The 1989 NCEPOD Report, which was part-funded by the Department, stressed the importance of information systems and audit for clinical quality assurance.[107] The Department recognised clinical audit as an integral part of a functioning healthcare system and emphasised the importance of clinical audit programmes in its Management Plans from 1995/96.[108] The Management Executive sought to encourage multi-professional audit.[109] However, in practice audit took a very long time to become established[110] and Professor Scally noted the absence of a generalised culture of participation in structured systems of clinical audit.[111] Indeed, the evidence repeatedly revealed deficiencies in the systems of audit as implemented and little indication that the Department was receiving regular audit analysis.[112]

Other

7.39 The Department also received information directly from members of the public, elected representatives and special interest groups. The CMO was lobbied by practitioners in relation to specific issues[113] and the Department

105 320-018-001 & Mr Elliott T-05-11-13 p.14 line 7
106 Dr Fulton T-04-09-13 p.87 line 18
107 210-003-012
108 306-083-001
109 333-129-011
110 320-067-007
111 341-002-016
112 320-067-007
113 WS-076-2 p.13

sought to be attentive to media coverage and public debate.[114] There were also diverse Health Service statistics and confidential reports from whistle-blowers.[115] However useful, these were random conduits of information.

Risk Management, Clinical Governance and the Statutory Duty of Quality

7.40 The absence of any reliable system whereby the Department might learn of catastrophic clinical mismanagement reflected the broader reality that care quality was not being adequately monitored in the hospitals themselves. Professor Scally observed that there is little "*to indicate that there was a firm expectation that either Health and Social Services Boards or Trusts would be subject to any systematic monitoring of the quality of care provided to patients or in respect of their handling of adverse clinical events.*"[116]

7.41 The HPSS 'Charter for Patients and Clients' published in 1992 contained the personal pledge of the Minister for Health and Social Services "*to all citizens that services in Northern Ireland will continue to match the very best available in the rest of the United Kingdom.*" [117] During the 1990s and early 2000s the Department did act to promote risk management controls and clinical governance. In so doing it almost always followed, at some remove, the lead of the DoH in London. For example, the DoH published 'Working for Patients' in 1989 to introduce a comprehensive system of medical audit[118] and in Northern Ireland, the HPSS Management Executive published its plans for audit in the Management Plan for 1995/6–1997/8.[119]

7.42 In 1997 the DoH published 'The New NHS – Modern and Dependable' introducing clinical governance to the rest of the UK. Within Northern Ireland, and notwithstanding the findings of 'Healthcare Risk Resources International'[120] the Department did not move to introduce a system of

114 Mr Gowdy T-06-11-13 p.104 line 13
115 403-019-001
116 341-002-003
117 306-085-003 & Mr Hunter T-04-11-13 p.22 line 20
118 210-003-012
119 306-083-001
120 WS-062-1 p.4

clinical governance in Northern Ireland until 2001 when it published 'Best Practice, Best Care' for consultation. Whilst it did not then give any particulars, it did propose "*a system of clinical and social care governance, backed by a statutory duty of quality*…"[121]

7.43 In 2002 a NIAO report[122] noted the limited progress actually achieved in the implementation of risk management[123] and indicated that "*We would therefore expect the department to be able to provide positive assurance of substantial progress in risk management within HPSS bodies by 2003 at the latest.*"[124] The Department sent out a circular requiring HPSS organisations to adopt the model of risk management used in Australia and New Zealand.[125]

7.44 Early in 2003 the Department published 'Clinical and Social Care Governance: Guidelines for implementation.'[126] The Northern Ireland guidelines for clinical governance emerged some four years after their NHS counterpart.

7.45 In addition HPSS organisations became subject to the statutory duty of quality in April 2003. The introduction of the statutory duty was to allow Mr William McKee,[127] former Chief Executive of the RGHT to claim that as Chief Executive of a Trust Hospital he bore no responsibility for the quality of care in his hospital prior to the enactment of the statutory duty. He said that "*in 1993/1994… and subsequently for many years I was specifically not held responsible for clinical safety, clinical quality, clinical matters.*"[128] He maintained furthermore that the Board of the Trust had no such responsibility either[129] and that the Trust only became responsible for clinical quality when the statutory duty was enacted.[130]

---

121 WS-068- p.14
122 338-006-062
123 Mr Gowdy T-06-11-13 p.48 line 1
124 338-006-091
125 WS-075-1 p.56
126 306-119-001
127 306-081-006
128 Mr McKee T-17-01-13 p.6 lines 1-4
129 Mr McKee T-17-01-13 p.16 line 4
130 Mr McKee T-17-01-13 p.7 line 13

7.46 Mr Gowdy was however most firmly of the view that both the Chief Executive and the Trusts were responsible for clinical care and clinical outcomes before the 2003 Order. He observed that "*the raison d'être of the Trusts concerned was to deliver effective clinical care to sick or injured people and it is rather difficult to see how they might argue that they had no interest in, or responsibility for, the quality of the service they were providing.*"[131] He understood the legislation to formalise the existing position as set out by the Accountability Framework, namely that *'the primary accountability of Trusts is with the quantity, quality, efficiency of the service they provide'*.

7.47 As Senior Counsel for the Department put it "*we simply don't accept that any person or anybody involved in the Health service can walk away and say 'I have no responsibility'*."[132] I consider that self-evidently correct.

7.48 The introduction of clinical governance in Northern Ireland required an understanding of the arrangements already in place. To that end Deloitte & Touche were commissioned to evaluate existing clinical and social care governance.[133] Its report in 2003 identified a lack of both understanding and implementation of clinical and social care governance and noted in particular a lack of co-ordinated activity in relation to risk, risk registers and risk audits.[134] Mr Gowdy acknowledged that the report "*certainly would have suggested that we didn't know enough about how they were progressing*…"[135] The consultants indicated that the position in Northern Ireland was comparable to that pertaining in England a few years before.

7.49 Whilst Professor Scally did recognise some positive and timely Trust activity in relation to the introduction of clinical governance, he nonetheless singled out the Department's very clear leadership role and identified a departmental failure to provide the necessary impetus to progress clinical governance at anything other than a very slow pace. He observed that by

131 WS-062-2 p.4
132 David McMillen QC T-04-11-13 p.77 line 10
133 WS-075-1 p.76
134 WS-075-1 p.100
135 Mr Gowdy T-06-11-13 p.79 line 4

2003 "*there was a significant gap between the progress in Northern Ireland and that achieved in England and Scotland*" and argued that '*given the size of the province it would be a reasonable assumption that it would have been possible, if the will and competence had existed, to put in place within a short period of time a comprehensive clinical governance structure.*"[136]

7.50 Mr Hunter acknowledged that the responsibility for "*driving those changes rested with the Department from the Minister down.*"[137] Dr Campbell accepted "*it as a corporate responsibility across the Department*"[138] and Mr Paul Simpson (from 1997 Chief Executive HSS Executive and Deputy Secretary HPSS Management Group) conceded that leadership within the Department could have been better.[139]

7.51 Mr Gowdy maintained that "*there was no lack of will, there was no lack of direction. There was a very clear desire to move this agenda forward and, unfortunately, it didn't happen and I find that disappointing.*"[140] The Department contended that comparisons with progress in England and Scotland were misleading and that there was no proper evidence base for such an exercise. It was suggested that because the Department was responsible for social care in addition to healthcare, that the extra responsibility made comparison inappropriate[141] and furthermore, it advised that the alternation of direct rule with devolution in the 1990s and 2000s, had hindered progress.[142]

7.52 Whilst I accept these broad distinctions and recognise constant financial constraint,[143] I do not accept that circumstances in Northern Ireland should have unduly delayed the implementation of systems to improve the quality of care, still less the introduction of reporting procedures whereby the Department might have learned what was happening in the hospitals for

136 341-002-023
137 Mr Hunter T-04-11-13 p.92 line 25
138 Dr Campbell T-07-11-13 p.12 line 9
139 Mr Simpson T-08-11-13 p.24 line 12
140 Mr Gowdy T-06-11-13 p.83 line 15
141 Mr Gowdy T-06-11-13 p.82 line 1
142 Mr Gowdy T-06-11-13 p.48 line 1 & Dr Campbell T-07-11-13 p.21 line 18
143 Mr Gowdy T-06-11-13 p.72 line 20 & Mr Simpson T-08-11-13 p.18 line 22

which it was responsible.[144] I do not suggest that the Department should have introduced comprehensive SAI reporting in the mid-1990s, but do consider that the absence of any reliable means of learning about hospital related child deaths indicates a serious failure on the part of the Department.[145]

Quality of Care

7.53 Departmental engagement with issues of quality of care appeared to lack constancy in terms of focus. Whilst the Department did, for example, issue important guidance in relation to standards and quality of healthcare, it did not maintain proper checks to ensure that its guidance was being heeded. Notwithstanding that the Department would request confirmation of compliance in respect of its more important guidance, Mr Gowdy indicated that many of the directions and guidelines issued "*were not subject to any specific monitoring*."[146] The Department proceeded on the assumption that HPSS organisations would comply.

7.54 Such an assumption was unwise because the evidence disclosed failures to comply with Departmental guidance. Guidelines for Consent were issued on 6th October 1995 with explicit instruction that "*Health and Social Service Boards/HSS Trusts are asked to ensure that procedures are put in place to ensure the consent is obtained along the lines set out in the Handbook…*"[147] and that "*Boards/HSS Trusts …confirm by 31 December 1995 that this has been done.*"[148] In this instance Mr Gowdy "*expected that it would have been followed up and followed up fairly quickly*,"[149] However, this specific direction was ignored by RGHT and almost five years passed before this important[150] guidance was adopted at RBHSC.[151] The Department did not know because it had failed to follow-up either confirmation or

144 Mr Hunter T-04-11-13 p.31 line 19 & Dr Campbell T-07-11-13 p.30 line 19
145 Professor Dame Judith Hill T-04-11-13 p.140 line 24
146 WS-062-2 p.11
147 305-002-003
148 305-002-004
149 Mr Gowdy T-06-11-13 p.131 line 25
150 Mr Hunter T-04-11-13 p.102 line 17
151 210-003-022

implementation. Overall it was apparent that the Department did not accord particular priority to the quality of care in the Health Service.

7.55 Those charged with leadership within the Department were aware of the importance of quality of care and the DoH commitment to introduce clinical governance. To achieve such slow progress on such key government patient care policies indicates failure in Departmental leadership. The failure was corporate and so too is the responsibility.

Professor Scally's Conclusion

7.56 Overall, and in answer to the primary question, Professor Scally concluded that the "*Department had no effective means of knowing what was going on in hospitals prior to 2003 in terms of quality of care*" given the absence of:

"*a. a culture of universal participation in a structured system of clinical audit,*

b. a broad based system of surveillance and analysis of serious untoward incidents/adverse events,

c. quality of care as a major focus for the Department and its professional advisory systems, and

d. the timely implementation of clinical governance from 1998 onwards…"[152]

Accordingly he did not find it surprising "*that the series of deaths from hyponatraemia did not come to the attention of the department in a systematic fashion.*"[153]

Knowledge of the deaths

7.57 Whether by systematic means or otherwise, the deaths of all the children should have been reported. Mr Gowdy indicated that he would "*certainly*"

[152] 341-002-019
[153] 341-002-019

have expected the Department to have been informed of them all[154] and Mr Colm Donaghy, Chief Executive of the Belfast Health and Social Care Trust, on behalf of the former RGHT, apologised for the lack of communication with the Department.[155]

7.58 However, as the evidence unfolded, and despite Departmental denials, it became necessary to consider whether the Department might not in fact have known about the deaths of Adam, Claire and Lucy prior to Raychel's death in 2001.

Adam Strain

7.59 Just as Adam's death was not formally reported within the RGHT, it was not formally reported to the Department. The findings at inquest were not shared and there was no other obvious communication of information. The CMO stated that the "*Department was not made aware of the case at the time by either the RVH or the Coroner. We only became aware of that particular case when we began the work of developing guidelines following the death at Altnagelvin.*"[156] However, this assertion came to be questioned.

7.60 During Adam Strain's inquest on 21st June 1996 the RGHT provided the Coroner with draft 'Recommendations for the Prevention and Management of Hyponatraemia arising during Paediatric Surgery.'[157] They were drafted by Dr Joseph Gaston,[158] approved by Dr Peter Crean[159] and signed by Dr Robert Taylor.[160] Notwithstanding that they purported to indicate how such cases might be managed in the future,[161] they were not circulated among other clinicians or submitted to the Department. Mr Gowdy observed that the references to hyponatraemia in the recommendations "*was of such general application as to be of interest and significance to other*

154 WS-062-2 p.10
155 Mr Donaghy T-12-11-13 p.6 line 13
156 006-002-117
157 060-018-036
158 306-081-003, 060-018-035 & WS-013-2 p.4
159 303-001-007 & 060-014-025
160 303-001-003 & 011-014-107a
161 122-044-048

hospitals"[162] and that he would have expected a copy to be sent to the Department because of the regional implication.

7.61 The CMO herself believed that had they been brought to her attention she would have regarded them as an appropriate matter for consideration by her Specialty Advisory Committees for Anaesthetics and Paediatrics.[163] In this connection it is to be noted that Drs Gaston, Crean and Taylor had all been one-time members of these committees[164] and Dr Crean accepted that the case for guidelines on fluid management and hyponatraemia would have been an appropriate matter for discussion.[165]

7.62 I do not however consider it likely, given their earlier disinclination to share their recommendations, that they notified the Department's SACs about Adam. The committees were not well suited for the purposes of such communication. Dr Miriam McCarthy[166] indicated the "*view among Departmental colleagues and SAC members was that the frequency of meetings (most were annual) meant the meetings were not designed to facilitate a response to the wide range of issues arising between meetings and for which alternative mechanisms were needed.*"[167]

7.63 It also became apparent that Dr Gaston had involved the senior hospital anaesthetist, Dr Samuel Morrell Lyons,[168] in the aftermath of Adam's death.[169] He was, amongst other things, Chairman of the Central Medical Advisory Committee of the Department.[170] Whilst this could speculatively be interpreted as some form of indirect 'reporting' to the Department, I do not believe that to have been the case. Dr Lyons had very little engagement with the facts of the case[171] and there is nothing to suggest that he understood matters much beyond what Dr George Murnaghan[172] and Dr

162 WS-062-2 p.10
163 WS-075-2 p.8 & 320-110-001
164 075-076-287
165 Dr Crean T-11-09-13 p.12 line 22
166 337-001-002
167 WS-080-2 p.19
168 306-081-006
169 Dr Gaston T-19-06-12 p.2 line 8
170 306-081-006 & 093-024-066
171 093-024-067
172 306-081-005

Gaston were telling him and there is no reason to suppose that they told him more than they told anyone else in a position of governance. I do not consider that the Department was thereby informed about Adam's case.

Claire Roberts

7.64 Claire's death was not formally reported to the Department until 28th March 2006[173] when the Trust reported it as a SAI pursuant to interim guidance HSS (PPM) 06/04.[174] Notwithstanding that the report could and should have been made in 2004, her case had already come within the scope of this Inquiry and the Department was therefore on notice. This was however another example of RGHT failure to follow guidance and Departmental failure to check that its requirements were being met.

Lucy Crawford

7.65 There is no evidence that Lucy's death was reported at the time to the Department. In February 2003 Mr Stanley Millar[175] Chief Officer of the WHSSC notified the Coroner of Lucy's death.[176] The Coroner copied Mr Millar's letter to the CMO on 3rd March.[177] The Department therefore maintained that it did not become aware of Lucy's case until March 2003.

7.66 However, Dr Campbell wrote an article about Lucy's death for the 'Irish News' on 21st May 2004 in which she stated that "*In fact, the Coroner referred Lucy's case to me as long ago as June 2001*…"[178] Whilst she quickly corrected this to read 'March 2003',[179] it nonetheless gave rise to suspicion that the Department was in possession of information earlier than claimed and at a date before the death had been properly explained to Lucy's parents.

---

173 322-070-003
174 322-070-001
175 325-002-011
176 013-056-320
177 006-010-294
178 004-010-154 – Dr Campbell made a similar assertion in an interview with UTV on 25-03-04 (006-037-376).
179 004-010-155

7.67 Relevant in this context was the suggestion by Dr William McConnell[180] that Mr Hugh Mills[181] had telephoned the Department about Lucy.[182] Mr Mills was very clear that he had not[183] and Dr McConnell could provide no further detail. Notwithstanding that Mr Thomas Frawley[184] of the WHSSB "*would have expected the Trust to notify the DHSSPS of an 'untoward death' such as that of Lucy Crawford*"[185] he did not believe that the Trust had reported Lucy's death to the Department.[186] There is no evidence that any other member of the Sperrin Lakeland Trust's senior management reported Lucy's death and Mr Mills confirmed that the Trust's review of the case was not drawn to the Department's attention either.

7.68 It is difficult therefore to conclude that the Department was aware of either the facts or import of Lucy's case before it was drawn to the Dr Campbell's attention by the Coroner and the Coroner could not have done so before he himself was informed in February 2003. The fact that Dr Campbell had always been clear that it was the Coroner who informed her about Lucy and this had always been capable of corroboration, suggests to me that her statements were simply confused as to dates. She is unlikely to have known about Lucy in 2001.

Chief Medical Officer's Working Group on Hyponatraemia

7.69 In 2001, Dr Ian Carson,[187] Medical Director of RGHT, was also serving as Special Advisor to the CMO.[188] It was in this capacity that he was informed on 18th June 2001 that Raychel had died of hyponatraemia and that her death was linked to fluid management with low saline solution.[189] He brought the matter to the immediate attention of Dr Campbell and

180 325-002-009
181 325-002-008
182 WS-286-2p.4
183 WS-293-3 p.3
184 325-002-010
185 WS-308-1 p.14
186 WS-308-1 p.21
187 306-081-004
188 WS-077-3 p.1
189 012-039-179

suggested that in the circumstances, it might be appropriate to provide regional guidance.

7.70 On 27th July 2001 Dr Campbell sought background information and asked if there was "*anyone at RBHSC who could put together a short paper on this?*"[190] Dr Taylor was asked[191] and his paper entitled 'Hyponatraemia in Children'[192] was e-mailed by Dr Carson to the CMO on 30th July 2001 with the observation that "*The problem today of 'dilutional hyponatraemia' is well recognised (See reference to BMJ Editorial). The anaesthetists in RBHSC would have approximately one referral from within the hospital per month. There was also a previous death approx. six years ago in a child from the Mid Ulster. Bob Taylor thinks that there have been 5-6 deaths over a 10 year period of children with seizures...*"[193]

7.71 Dr Campbell was assisted within the Department by Senior Medical Officer Dr McCarthy.[194] She considered Dr Taylor's briefing and thought it "*very helpful*"[195] but did not attempt to learn any more about the deaths referred to. Nor does it seem that Dr Campbell[196] or Dr Carson,[197] or anyone else in the Department asked any questions about the alarming numbers of deaths from dilutional hyponatraemia thus brought to their attention.

7.72 Dr Carson interpreted the deaths to have occurred in the UK, not least because "*if there'd been five or six deaths over a ten year period in the Royal Belfast Hospital for Sick Children, I would have known about it.*"[198] Taking account of the deaths now known and another referenced by Dr Taylor, it is possible that there were five deaths within ten years in RBHSC. [199] Notwithstanding, I fully accept that Dr Carson did not know about those deaths. In any event, the Department had clearly been informed that the

190 WS-330-1 p.10
191 WS-330-1 p.10
192 043-101-223
193 021-056-135
194 WS-080-2 p.3
195 WS-080-2 p.7
196 Dr Campbell T-07-11-13 p.115 line 3
197 WS-331-1 p.4 & Dr Carson T-30-08-13 p.98 line 7
198 Dr Carson T-30-08-13 p.96 line 23
199 Dr Carson T-30-08-13 p.98 line 11 *et seq*

problem of dilutional hyponatraemia was implicated in more than a single death in Northern Ireland.

7.73 Dr Campbell then gave direction that a Working Group should develop and provide guidelines for safe paediatric fluid management and the avoidance of hyponatraemia.[200] On 14th August 2001 the task of co-ordinating production of the guidelines was delegated to Dr McCarthy.[201] It was, she indicated, "*a task and finish group established only to develop guidance on the prevention of hyponatraemia.*"[202]

7.74 The Working Group assembled on 26th September 2001[203] and included a number of clinicians, familiar not only with hyponatraemia but also with some of the other deaths concerning this Inquiry, including Claire and Lucy.[204] The question therefore arose as to whether their work within a Departmental group placed the Department on notice of the other deaths known to them. Of particular interest was whether group members discussed amongst themselves the deaths known to them. If they did, they might have been sharing information about the deaths of Claire and Lucy within a Departmental context which had not been disclosed to their grieving families or the Coroner and which would not be disclosed for some considerable time to come.

7.75 Of particular interest was the involvement of Drs Taylor, Nesbitt,[205] Crean, Jenkins[206] and Loughrey.[207] Dr Taylor was more than fully aware of Adam's case and had examined Claire in PICU.[208] As Paediatric Audit Co-ordinator he may possibly have learned of Lucy's death.[209] Dr Crean treated both Lucy[210] and Raychel[211] and was aware of the fluid issues in Adam's case.[212]

200 075-082-329
201 WS-080-1 p.2 & WS-075-1 p.6
202 WS-080-2 p.5
203 007-048-094
204 328-003-001
205 328-003-001
206 328-003-001
207 328-003-001
208 WS-157-1 p.2
209 061-038-123
210 013-021-071
211 012-032-159
212 060-014-025

His name appears as Claire's Consultant in her Discharge Summary.[213] Dr Nesbitt not only knew about Raychel's case but had advised his Medical Director on 14th June 2001 of "*… several deaths involving No.18 Solution.*"[214] Dr Loughrey was the Chemical Pathologist who advised the Coroner about the cause of hyponatraemia in Raychel's case and Dr Jenkins was known for his particular interest in fluid and electrolyte management and was to be asked in February 2002 to provide expert opinion in Lucy's case.[215] Mr G Marshall FRCS was also included. He was from the Erne Hospital where Lucy had been treated.

7.76 When asked whether the Working Group considered the deaths of Adam, Claire or Lucy, the Department maintained that "*the CMO's Hyponatraemia Working Group was set up to develop guidance on the prevention of hyponatraemia and not to consider the case of any specific child.*"[216]

7.77 Professor Swainson nonetheless considered that it would have been logical for the group to consider those deaths specifically known by group members to be due to hyponatraemia because he did not "*think you can divorce the context in which you are doing the work from the work itself. And I still think you'd want to test the assumptions and the conclusions you are coming to against your experience of those cases.*"[217]

7.78 Further suspicion arose because Dr Jenkins told UTV that the Working Group had been set up after it was recognised that both Raychel and Lucy had died with hyponatraemia.[218] Dr Jenkins corrected himself, explaining that he had become confused as to when he had found out about the deaths and that he had not in fact known about Lucy's death at the time of his contribution to the Working Group.[219]

---

213 090-009-011
214 022-102-317
215 Dr Jenkins T-10-09-13 p.25 line 5
216 009-014-022
217 Professor Swainson T-19-09-13 p.127 line 15
218 069a-056-181
219 074-016-071 & Dr Jenkins T-10-09-13 p.19 line 18

7.79 In preparation for the first meeting of the group, Dr Taylor prepared a presentation on "*Hyponatraemia in Children*"[220] which he sent to the Department on 18th September 2001.[221] Dr McCarthy noted the content of the presentation.[222] It placed hyponatraemia in the context of the administration of excessive maintenance fluids[223] and incorporated detailed information on the 'Incidence of Hyponatraemia at RBHSC.' Remarkably it omitted the deaths of Adam, Claire and Lucy. In the event, his presentation was not given, perhaps because, as Dr Taylor explained, his figures were based on incomplete data.[224]

7.80 The Deputy CMO Dr Paul Darragh[225] chaired the first meeting of the Working Group on 26th September 2001.[226] Dr Taylor described those patients most at risk and advised that it was "*a problem that has been present for many years.*"[227] Dr McCarthy recalled "*Dr Taylor advising attendees of the increased identification of cases of hyponatraemia in the RBHSC, including 2 cases resulting in fatality.*"[228]

7.81 Dr Taylor undertook to report Raychel's case to the Medicines Control Agency (MCA).[229] He wrote to the MCA on 23rd October that he was: "*conducting an audit of all infants and children admitted to the PICU with hyponatraemia. My initial results indicate at least two **other** deaths attributed to the use of 0.18NACL/4% glucose*"[230] (emphasis added). This correspondence was then shared with Drs Jenkins, Nesbitt and McCarthy[231] and may thus have been the origin of Dr Jenkins' belief that the working group had been set up after the deaths of two children in Northern Ireland. If so, his confusion is then more readily understood.

220 007-051-101
221 007-051-100
222 WS-080-2 p.7
223 007-051-106
224 Dr Taylor T-11-12-12 p.151 line 8
225 337-001-002
226 007-048-094
227 Dr Taylor T-18-09-13 p38 line 10
228 WS-080-2 p.13
229 WS-008-1p.18
230 012-071e-412 nb emphasis added
231 007-032-059

7.82 Within the Department the correspondence "*would have been noted and filed.*"[232] Throughout work on the guidelines, Dr McCarthy regularly discussed progress with Dr Campbell, providing her with updates and drafts as appropriate.[233]

7.83 It is clear that Raychel's death was discussed[234] and whilst discussion of broader incidence may have been vague, it is also clear that the group knew that it was addressing a problem that extended beyond Raychel's death alone.[235] It is in this context that it might be thought to have been natural for individual members to discuss the overall incidence of deaths and compare and contrast the rather different cases of Adam and Raychel, and possibly also Claire and Lucy, to better understand the issues arising. Even Dr Campbell agreed that it "*would be unnatural for them not to put that into the pot.*"[236] As Dr Darragh put it "*all doctors always talk about their individual experiences.*"[237]

7.84 In the event, Dr Darragh noted that "*given Dr Taylor's presentation …there were clearly likely to be other cases emerging but the important step of producing guidelines was the appropriate step to be taking at regional level at that time.*"[238] Accordingly, it was agreed that simple guidelines were required and that in order to move quickly, a small sub-group would undertake the drafting of the guidelines together with an audit protocol.

7.85 Notwithstanding Dr Taylor's contribution, he was not included in the drafting sub-group. Instead, Drs McCarthy, Jenkins and Crean met on 10th October 2001 with Dr Jarlath McAloon[239] who was co-opted for additional paediatric perspective. The sub-group decided to proceed by way of e-mail communication as a "*virtual group*"[240] in order "*to facilitate more rapid*

232 Dr McCarthy T-31-10-13 p.46 line 14
233 WS-080-1 p.4
234 001-078-270
235 Dr McCarthy T-31-10-13 p.12 line 17
236 Dr Campbell T-07-11-13 p.117 line 2
237 Dr Darragh T-30-10-13 p.158 line 17
238 WS-076-2 p.12
239 337-001-004
240 WS-080-2 p.9

progress in developing the guidance."[241] This limited the scope for group discussion and indeed subsequent communication does not appear to have been general. As Dr McAloon recalled his "*responses were channelled through Dr McCarthy's office and I am not aware of who saw them.*"[242]

7.86 Dr McAloon considered that his role "*was to provide comments from the perspective of a general paediatrician who would be expected to implement the guidance once produced*"[243] and recalled "*the initial face-to-face brainstorming meeting to help identify key components needing to be addressed in the guideline.*"[244] Notwithstanding that Dr Jenkins "*regarded it as* [his] *responsibility to test the guidance against the knowledge that* [he] *had*"[245] he did not expect others in the group to mention individual cases or test the draft against such cases.[246] He acknowledged that "*it would have been easier, for doctors to have shared that type of information in a face-to-face meeting other than in e-mails.*"[247] The focus, he said "*was on the guidelines, not on any individual case.*"[248] The guidance was intended for the generalist junior doctor and not the specialist[249] and accordingly the drafting group concentrated on the key general principles to be applied to all children receiving IV fluids.

7.87 Dr Crean thought that "*we probably were all drawing on our own expertise with children we had managed.*"[250] It is to be noted that apart from Dr Crean, no other member of the drafting sub-group had managed any of the children known to have died. Notwithstanding that Dr Crean could have drawn on his own expertise, there is no indication that he shared his knowledge in respect of individual cases. Indeed, the evidence of Drs Jenkins,[251]

241 WS-082-2 p.9
242 WS-363-1 p.8
243 WS-363-1 p.8
244 WS-363-1 p.9
245 Dr Jenkins T-10-09-13 p.27 line 8
246 Dr Jenkins T-10-09-13 p.71 line 15
247 Dr Jenkins T-10-09-13 p.32 line 11
248 Dr Jenkins T-10-09-13 p.72 line 7
249 Dr McCarthy T-31-10-13 p.34 line 22
250 Dr Crean - T-11-09-13 p.90 line 9
251 Dr Jenkins T-10-09-13 p.71 line 15

Crean,[252] Nesbitt[253] and Taylor[254] agreed that the Working Group did not at any time discuss or consider the deaths of Adam, Claire or Lucy.

7.88 This does seem odd, not least because there were some within the group who were interested in other cases. On 30th November 2001 Dr Loughrey e-mailed Dr McCarthy to enquire whether she was aware of "*the death of a four year child in what sound like very similar circumstances in Northern Ireland in 1996.*"[255] Dr McCarthy then discussed the cases of Adam and Raychel with the Coroner[256] and received copies of Adam's autopsy report and Dr Edward Sumner's[257] report which were relayed to Dr Campbell.[258] There is however no reference to either Claire or Lucy in any of the extended threads of e-mail correspondence seen by this Inquiry.

7.89 Dr McCarthy circulated a "*final draft*" of the guidelines to the group on 7th November.[259] Dr Loughrey expressed disappointment that it did not positively discourage the use of hypotonic fluids because she believed this was "*a major (if not the major) factor in the demise of the child in Altnagelvin*"[260] Dr Crean did not agree, arguing that advice on specific IV fluids should not be given when "*there is not really any evidence to suggest that one solution is more or less harmful than another.*"[261] Dr Loughrey countered that she felt so strongly about referencing the risk associated with Solution No.18, that if it was not included, she would wish to be disassociated from the guidelines.[262] This was an issue that was discussed in detail[263] and given the genuine disagreement it would seem to have presented an obvious opportunity to test the draft guidelines against known cases. Indeed, Dr McCarthy recognised that "*the patient's illness, condition, age, post-op status and serum sodium all play a role in dictating*

252 WS-038-3 p.8
253 Dr Nesbitt T-03-09-13 p.124 line 14
254 Dr Taylor T-18-09-13 p.130 line 15
255 007-025-048
256 006-056-440
257 303-001-010
258 WS-075-1 p.3
259 WS-035-2 p.347
260 007-025-048
261 007-014-029
262 007-013-027
263 WS-080/2 p.11

the choice of fluid."[264] Whilst Dr Darragh conceded that this would have been both useful and obvious, it was seemingly not done.[265] In this context, I consider it very likely that had the known deaths been referred to, then some reference would appear in at least one of the multiple threads of e-mail correspondence. However there is no such reference.

7.90 Dr McCarthy said that "*information on previous deaths was absolutely not shared in that group. When I now see what people knew, it is a surprise to me that that wasn't, but that is the reality.*"[266] Indeed she said she found it "*inexplicable more than anything*".[267]

7.91 On the evidence before me I cannot therefore be persuaded that the Department can be fixed with notice of the deaths of Claire or Lucy in this context. A combination of urgency to complete the guidelines, the distancing effect of individual communication by e-mail, the obscuring effect of Dr Taylor's purported 'Incidence of Hyponatraemia at RBHSC', Dr Crean's silence and the busy professional lives of all concerned probably inhibited the sort of exchanges that might have been thought obvious. The absence of any evidence to the contrary supports this conclusion.

7.92 The Department issued its 'Guidance on the Prevention of Hyponatraemia in Children' in March 2002. Dr Campbell published it with her direction that "*Fluid protocols should be developed locally to compliment the Guidance and provide more specific direction to junior staff... It will be important to audit compliance with the Guidance and locally developed protocols and to learn from clinical experiences.*"[268] The Working Group ceased to exist on publication[269] and did not produce the "*audit protocol*" agreed at its first meeting. Nor did it offer any guidance as to how fluid protocols might be developed locally. Dr McCarthy thought that they "*would probably follow*

264 012-062-314
265 Dr Darragh T-30-10-13 p.180 line 25
266 Dr McCarthy T-31-10-13 p25 line 17
267 Dr McCarthy T-31-10-13 p.75 line 21
268 007-001-001
269 WS-080-2 p.6

up in due course…"[270] They did not and with hindsight that is a matter for regret.

7.93 Notwithstanding, it is to be recognised that the CMO's guidelines placed Northern Ireland, in the view of Dr Sumner, "*ahead of the rest of the UK.*"[271] This was achieved with speed and efficiency. It was a significant achievement and properly worthy of praise because, as Professor Swainson observed, the guidelines "*have improved considerably the quality of care across the province and reduced the risk of Hyponatraemia.*"[272]

Chief Medical Officer

7.94 Unfortunately, and undermining her important work in publishing the guidelines, Dr Campbell gave a series of extraordinary interviews to the media in the aftermath of the inquests into the deaths of Raychel and Lucy. Rather than communicating in order to inform and reassure, she made statements which so inflamed the suspicion and distrust of Mr and Mrs Ferguson and Mr & Mrs Slavin that they called for her resignation in December 2004.[273] Such was Mr & Mrs Ferguson's disquiet at what she had said that they asserted that she was engaged in a cover-up and referred her conduct to the GMC.[274]

7.95 Transcripts of two BBC and two UTV interviews, together with another given to a journalist,[275] reveal carelessness as to facts and an inappropriate defensiveness about clinical treatment. Whilst they mislead and are troubling in their lack of professionalism, they do not constitute a cover-up. In this regard it is to be emphasised that Dr Campbell made clear her view that "*the deaths of Lucy and Raychel may indeed have been entirely preventable,*"[276] that "*if we'd had an early inquest into Lucy's death, then it*

---

270 Dr McCarthy T-31-10-13 p.79 line 13
271 006-002-156
272 226-002-006
273 073-037-162
274 068-013-022
275 To: Trevor Birney of UTV 17-02-03 (069A-033 078),To: Audrey Carville of BBC Radio Ulster Evening Extra 18-03-04 (034-151-407),To: Julian O'Neill of BBC Newsline 18-03-04 (023-020-044),To: Fearghal McKinney of UTV 'The Issue' 25-03-04 (006-037-375),To: Denzil McDaniel of 'The Impartial Reporter'25-05-04 034-142-372.
276 034-151-407

might have been that the death of Raychel might never have happened,"[277] that "*anybody reading those* [Coroner's] *reports would say and agree with the coroner that the management of the fluids could have been much much better and that it was inadequate.*"[278]

7.96 In addition she stated on the record that "*It's quite clear that there was no process for the reporting of Lucy's death to me, nor indeed the outcome of any investigation,*"[279] "*I absolutely agree that if we had in place a system for the reporting of all …untoward deaths, that we could have begun to learn lessons earlier*"[280] and "*Our role as the Department is development of strategy and policy and a strategy and policy on proper investigation is what we need to do.*"[281]

7.97 However and at the same time she repeatedly misinformed her interviewers and the public. She appeared intent on distancing the Health Service from responsibility and understating the known risks of hyponatraemia so as appear an apologist for much that had happened. That she repeatedly allowed herself to be exposed in this way for interview was an error of judgement and what she said is a cause for concern.

7.98 Amongst other things she claimed:

(i) "*…when untoward and rare events happen we need to find a way of learning from them. Now they only happen every 5 or every 10 years.*"[282] This can only have been invented. Not only was there no reliable system to inform her of such events, but an internal Departmental e-mail from the following year records Dr Campbell as estimating the "*numbers of serious untoward incident deaths reported to her…about 3-4 annually*"[283]

277 023-020-045
278 034-142-378
279 034-142-387
280 006-037-379
281 034-142-393
282 069A-033-078
283 010-030-188

(ii) That Adam "*was an entirely different clinical situation*"[284] to Raychel – "*From what I know of the clinical details the case 7 years ago was of a child who was already very ill…I think it is important to recognise that in this case here we had a normal healthy child so therefore something had to be looked at…they needed to consider what measures needed to be put into place in order to prevent that happening again.*"[285]The suggestions that Adam was a victim of his pre-existing condition and not blatant clinical error, that he was not sufficiently normal or that his case was less deserving of investigation in order to prevent recurrence are erroneous and insulting.

(iii) "*with Lucy we saw the first case of what was a very rare occurrence written up in the medical journals only recently…*"[286] Dr Campbell was fully aware of the earlier case of Adam, had been briefed with Professor Alan Arieff's paper published 12 years before and had been advised by Dr Carson of the previous incidence of death.

(iv) Speaking of Lucy and Raychel she said "*The rarity in this event and you do have to return to the medicine, the physiology behind these 2 events… was the abnormal reaction which is seen in a very few children to the normal application…*"[287] Asked to comment on this assertion, Dr Dewi Evans[288] indicated that the statement was wrong and it would worry him that it was made by the CMO for Northern Ireland.[289]

(v) "*What we now know is, that the fluids which were given to Lucy were the ones that were being used in ordinary custom and practice throughout the whole of the National Health Service except for one or two practitioners who'd begun to recognise this issue of*

---

284 069A-033-079
285 069A-033-079
286 006-037-375
287 006-037-377
288 325-002-013
289 'When Hospitals Kill'-UTV-'Insight'- 21-10-04

hyponatraemia where the body goes through this abnormal response in just a very few cases and you begin to get oedema or swelling of the brain. Now in retrospect, and knowing all the evidence that has been published since Lucy's case and over the last four years, we now know that that condition exists, that it can happen, albeit in a very few patients…"[290] Dr Campbell appeared to reject the Coroner's findings at inquest. Lucy's death resulted from clinical error not abnormal response. It was disingenuous of her to suggest that the excessive fluids given Lucy were standard because she was more than fully aware of the distinction between type and volume of fluid. It was misleading to assert that only one or two practitioners were alert to the issue, given that she knew Professor Arieff's paper had been published in the British Medical Journal.[291] Further and in any event it was quite wrong to characterise hyponatraemia as an abnormal response and dishonest to suggest that the condition was not known to exist in 2000.

(vi) That this was not inadvertent error is clear from the CMO's repeated assertions that the mismanaged fluid therapy was somehow normal and the risks negligible "*…the fluids that we are talking about, that Lucy got, were in general use and …one in 300 of children who were getting those fluids would develop hyponatraemia…and ten percent of those would go on to have a fatal reaction.*"[292]

(vii) When asked whether an investigation or inquest should not have been held earlier in Lucy's case she said that "*the coroner did not feel at that time that an inquest was required…*"[293] Later the same day she said that "*on looking back at the issues, I think if we'd had an early inquest into Lucy's death, then it might have been that the death of Raychel might never have happened…What the coroner*

---

290 034-151-407

291 In this regard it is informative to note that the connection between fluid mismanagement and dilutional hyponatraemia was made very quickly in each of the cases of Adam, Claire, Lucy and Raychel. Furthermore, in the cases of Claire and Lucy the diagnosis was made by doctors who had not yet attained consultant status.

292 034-142-377

293 034-151-408

has now agreed is that he will draw to our attention very early on those deaths about which he has concern."[294] This suggested that the lack of a timely inquest was the responsibility of the Coroner rather than of the clinicians themselves and furthermore carried the implication that, but for the Coroner's decision, Raychel might have lived. The Coroner immediately wrote to her and protested that "*in the interview you gave on BBC television you mentioned that the death of Raychel Ferguson could have been prevented if the full circumstances of the death of Lucy Crawford had been known sooner and you mentioned the desirability of there having been an earlier inquest into Lucy's death. I believe the papers I have provided you with explain what happened when Lucy's death was reported to my office and why a coroner's post-mortem examination was not then ordered.*"[295] Further and by way of additional information he added "*When he gave evidence in the inquests in to the deaths of Adam Strain, Raychel Ferguson and Lucy Crawford, Dr Sumner was at pains to state that his views on fluid management of children did not constitute 'new' medical knowledge.*"[296]

7.99 Dr Campbell has since indicated her deep regret for what she said and for causing the Ferguson family additional distress. She said that "*on reflection I realise -- I realised much after the interviews -- that some of the things that I said could have been misunderstood in terms of what I was trying to say. They were very poorly crafted.*"[297] She accepted that she "*was ill-prepared*"[298] and took "*full responsibility for saying things in a way which could have been misinterpreted. That was never my intention and it has cast a shadow over my life since.*"[299]

7.100 Dr Campbell's approach bore many of the same characteristics as marred those meetings arranged by clinicians with Mr and Mrs Ferguson and Mr

294 034-151-408 & 023-020-045
295 006-004-282
296 006-004-282
297 Dr Campbell T-07-11-13 p.165-166
298 Dr Campbell T-07-11-13 p.167 line 19
299 Dr Campbell T-07-11-13 p.168 line 2

and Mrs Roberts. Defensiveness continued even after mismanagement had been revealed and when inaccuracy and evasion could only exacerbate suspicion. Whilst such failures in communication may be ascribed to lack of preparation and a desire to deflect criticism, it must be stated that in my view they also proceed from arrogance and complacency. The CMO's public statements were a further manifestation of a culture which has revealed itself to this inquiry at every level of the Health Service.