GOVERNANCE OPENING: ADAM STRAIN

THE ORAL HEARINGS IN THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Chairman: John O'Hara QC

Banbridge Court House, 18th June 2012

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I. Introduction

1. Mr. Chairman, it is now the duty of the Inquiry to consider the wider implications of Adam's death; to understand the organisation and systems in place at the Royal Belfast Hospital for Sick Children (the "Children's Hospital") at that time, in order that the central question troubling so many people may be addressed, namely: What lessons could or should have been learned from the unexpected death of Adam Strain and how should those lessons have been shared to improve the healthcare given to children and possibly to avoid the loss of further life?

2. The evidence you have heard so far has been concerned with the clinical detail surrounding Adam's care, surgery and death. Now the evidence will deal with the systems and mechanisms underpinning the delivery of those medical services and for responding to paediatric deaths in hospital. This part of the investigation has loosely been referred to as 'governance'.

3. So far as is possible, the practices which were in place and/or which should have been in place to ensure the provision of high quality acute care to sick children will be identified. In particular, we will use the evidence on the 'clinical' issues, especially that received during the Oral Hearings, as a means of examining the extent to which appropriate systems and mechanisms were in place and in operation. The response of the Healthcare Service to Adam's death will also be addressed - from the doctors to the Hospital and to the Healthcare Trust. In due course we will consider the response to the deaths of all the Children of the Boards and on up to the Department of Health, Social Services and Public Safety ("DHSSPSNI") itself.

II. Evidence Received

4. As with the Opening for the Oral Hearings on clinical issues, this Opening will also seek to set out the information that has so far been received by the Inquiry on governance issues. To assist in appreciating the key events, the Legal Team has compiled a 'Chronology of Hospital Management and Governance',[1] which is divided into three Schedules:

   (i) Schedule 1: Position as at Adam's admission on 27th November 1995 – which shows the Protocols, Guidance, Circulars and Practices in force together with particularly relevant papers and publications

[1] Ref: 306-080-001-042

(ii) Schedule 2: From Adam's death on 28th November 1995 to the Inquest Verdict on 21st June 1996 – showing the events that particularly relate to Adam's case as well as other developments that relate to governance

(iii) Schedule 3: From the Inquest Verdict on 21st June 1996 to November 1998 – which shows events in relation to Adam together with other governance developments

5. During the Clinical Opening on 16th April 2012[2], it was explained that following the establishment of the Inquiry on 1st November 2004[3], requests for information and evidence were sent out to a number of bodies in relation to Adam's case.

Documents

6. The call for documents has been ongoing since the resumption of the Inquiry's work in 2008 and is continuing. While much of this documentation will have been considered at the Oral Hearing into clinical issues, it will now be relevant to set out those documents that have significance for this Oral Hearing into governance issues.

7. To date the Inquiry has received a vast amount of material in relation to the governance issues arising in Adam's case, including:

(i) Documents held by the Coroner (Depositions from the Inquest into Adam's death and Reports commissioned by the Coroner) including those from[4]:

- Ms. Debra Strain[5]
- Dr. Alison Armour[6] (Pathologist, Institute of State Pathology, who was asked to provide a Report of Autopsy)
- Mr. Patrick Keane[7] (Consultant Urologist, Belfast City Hospital and the surgeon in Adam's case)
- Dr. Robert Taylor[8] (Consultant Paediatric Anaesthetist, Children's Hospital and the anaesthetist in Adam's case)
- Dr. Maurice Savage[9] (Consultant Paediatric Nephrologist, Children's Hospital and Adam's nephrologist)[10]

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2 Ref: 'Opening Statement- Adam Strain, Clinical by Senior Counsel to the Inquiry' on the Inquiry website, under heading of 'Latest News'

3 Ref: 008-032-093

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

5 Deposition Ref: 011-009-025

6 Deposition Ref: 011-010-030; Report of Autopsy Ref: 011-010-034

7 Deposition Ref: 011-013-093

8 Deposition Ref: 011-014-096

9 Deposition Ref: 011-015-109

(ii) Documents held by Adam's family[11]

(iii) Documents from the investigations of the Police Service of Northern Ireland ("PSNI")[12], including statements from witnesses[13] and the reports of experts[14]

(iv) Correspondence from the Directorate of Legal Service ("DLS") providing responses to the Inquiry's requests for information[15]

(v) Documents from other bodies and organisations such as:

- The National Health Service ("NHS")
- National Patient Safety Agency
- Estate Services Directorate
- Royal College of Physicians
- Royal College of Nursing
- DHSSPSNI
- Belfast Health and Social Care Trust
- Northern Ireland Medical and Dental Training Agency

8. The Inquiry has been referred to numerous publications and papers by its Advisors, Experts and Witnesses. The Legal Team has carried out its own research and it has added all of those publications and papers to the bibliography for Adam's case that to date has largely comprised clinical material. The bibliography is available on the Inquiry website[16] and is up dated as further material is cited.

Background Papers

9. In the Clinical Opening, I referred to the commissioning of Background Papers by Experts to provide a context for the consideration of the evidence. Of particular relevance to the investigation into the governance issues involved in Adam's case are the Background Papers of:

(i) Dr. Michael Ledwith, Clinical Director of Paediatrics, Northern Trust[17] and Professor Sir Alan Craft, Emeritus Professor of Child

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10 Appointed Professor of Paediatrics, Queen's University Belfast, June 1990; hereinafter referred to as "Professor Savage"
11 Contained at Ref: 070-001-001 to 070-024-293
12 Ref: 094-001-001 to 094-254-1215
13 Ref: 093-001-001 to 093-040-002
14 In particular that of Mr. Koffman – Ref: 094-007-027
15 Contained at Ref: 301 (see all)
16 Ref: 'Articles Index' under heading 'Key Inquiry Documents'.
17 '*A Review of the Teaching of Fluid Balance and Sodium Management in Northern Ireland and the Republic of Ireland 1975 to 2009'* (Dr. Michael Ledwith) – Ref: 303-046-514

Health, Newcastle University Education[18] on the training and continuing professional development of doctors in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2009

(ii) Dr. Jean Keeling, Paediatric Pathologist, on the system of procedures for the dissemination of information gained by post-mortem examination following unexpected death of children in hospital[19]

(iii) Ms. Bridget Dolan, Barrister at Law and Assistant Deputy Coroner,[20] on the systems of procedures and practices in the United Kingdom for reporting and disseminating information on the outcomes or lessons to be learned from Coroner's Inquests on deaths in hospital (involving Hospitals, Trusts, Area Boards, Department of Health ("DoH") and Chief Medical Officer)

(iv) Professor Mary Hanratty, former Vice-President of the Nursing and Midwifery Council[21] and Professor Alan Glasper, Professor of Children and Young Person's Nursing, University of Southampton[22] on the training and continuing professional development of nurses in Northern Ireland, the rest of the United Kingdom and the Republic of Ireland over the period 1975 to 2011

Expert Reports

10. The Inquiry has also engaged Experts to provide Reports on a number of specific issues, including:

(i) Professor Aidan Mullan RGN, DMS, MBA who has provided a detailed analysis and overview of the clinical governance issues arising from Adam's case[23]

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18 '*A Review of the teaching of fluid balance and sodium management in Northern Ireland and the Republic of Ireland 1975 to 2009'* (Professor Sir Alan Craft) – Ref: 303-047-561

19 Paper to the Inquiry into Hyponatraemia-Related Deaths: '*Dissemination of information gained by post-mortem examination following unexpected death of children in hospital'* (Dr Jean Keeling)- Ref: 308-020-295

20 '*Report to the Inquiry into Hyponatraemia-Related Deaths'* (Dr. Bridget Dolan) – Ref: 303-052-715

21 '*Chronology of Nurse Education in Northern Ireland - Comparisons with UK mainland and Republic of Ireland - 1975 to date'* (Professor Mary Bridget Hanratty) – Ref: 303-048-571

22 '*A Selective Triangulation of a Range of Evidence Sources Submitted to Explain the Chronology Of Nurse Education in Northern Ireland and England with Reference to the Teaching of Record Keeping and the Care Of Children Receiving Intravenous Infusions - 1975 to date'* (Dr Edward Alan Glasper) – Ref: 303-049-674

23 Report to the Inquiry into Hyponatraemia-Related Deaths (Professor Aidan Mullan) – Ref: 210-003-003

(ii) Mr. Stephen Ramsden, who has provided a report on the hospital management and governance issues arising from Adam's case[24], along with a supplementary report on NHS Management & Governance[25]

(iii) Dr. Simon Haynes, who has provided reports on the anaesthetic issues but has also commented on the requirements for an adequate paediatric renal transplant service[26]

(iv) Professor John Forsythe and Mr. Keith Rigg, who have provided joint reports that address certain aspects of the paediatric renal transplant service provided by the Children's Hospital in 1995, including the implications of the relatively low numbers of transplants being carried out on young children[27]

(v) Ms. Sally Ramsay who has provided a number of reports on the nursing care at the Children's Hospital, in particular that given to Adam in November 1995[28]

Witness statements

11. In addition to the Depositions that the Inquiry received from the Inquest[29] and the Statements from the PSNI investigation,[30] the Legal Team also requested and received a large number of Witness Statements and Supplemental Witness Statements from a variety of persons involved to varying degrees in Adam's case. The Legal Team has been guided in that task by:

(i) The Inquiry's Advisors

(ii) Medical notes and records and other contemporaneous material

(iii) Previous statements made, whether through Depositions to the Coroner, Statements taken by the PSNI or Witness Statements to the Inquiry

(iv) Statements from others and in some cases the evidence of others during the Oral Hearings

(v) Subsequent documents received from the DLS and a variety of other sources

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24 Expert Witness Report on Hospital Management & Governance – Ref: 211-003-001

25 Report of Expert on NHS Management & Governance, Supplementary (Mr. Stephen Ramsden) – Ref: 211-005-001

26 Ref: 204-002; 204-004; 204-006; 204-008; 204-013 & 204-014

27 Ref: 203-002; 203-004; 203-006; 203-008 and 203-009

28 Ref: 202-002, 202-004, 202-006, 202-007 and 202-009

29 Ref: 011-001-001 *et seq*

30 Ref: 093-001-001 *et seq*

(vi) Reports from the Inquiry's Experts

12. The Legal Team has compiled a list of all those involved in the governance aspect of Adam's case from all of the information received by the Inquiry.[31] It explains their position then and now, briefly summarises their role in Adam's case, and whether they have provided a statement and if so for whom. Additionally it also indicates the Witnesses that it is proposed to call to give evidence during the Oral Hearings.

13. As with the evidence of the Witnesses on clinical issues, it is entirely possible for the evidence provided in a Witness Statement to be sufficient on any given issue, particularly where it is not contradicted by another Witness or information from any other source or where it is clear from an Expert Report that further probing of the Witness would not be useful. Should the evidence in a Witness Statement be regarded as sufficient, then it will stand in lieu of oral evidence from that Witness. The Inquiry Witness Statement, PSNI Statement or Deposition, as the case may be, of those who are not being called will be tendered as an unchallenged account.

14. In due course and as was done with the Witnesses in clinical issues, the Legal Team will compile a Schedule of all those whose evidence it is tendering to you in that way. It will be a matter for you Mr. Chairman whether you nonetheless wish the Witness to be called.

Oral Testimony

15. Finally, there are the accumulated Transcripts of the Inquiry's Oral Hearings on the 'clinical' issues.[32] For the most part it will not be necessary for that oral evidence to be set out in any detail since Mr. Chairman you have had the benefit of hearing it first hand and in many cases questioning the Witnesses yourself.

16. Some of that oral evidence bears on governance. Of particular relevance to the governance issues arising in Adam's case is the evidence that was given by:

(i) Professor Savage[33] and Dr. O'Connor[34]

(ii) Dr. Taylor[35]

(iii) Mr. Keane[36] and Mr. Brown[37]

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31 Ref: 306-081-001-010
32 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable'
33 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (17th & 18th April 2012)
34 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (25th April 2012)
35 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (19th & 20th April 2012)

(iv) Dr. Haynes[38]

(v) Professor Forsythe and Mr. Rigg[39]

(vi) Dr. Coulthard[40]

(vii) Mr. Koffman[41]

III. Revised Terms of Reference in relation to Adam

17. As you are aware, and as I said in the Clinical Opening, the Terms of Reference in relation to Adam's case remain unchanged from the original Terms, namely:

> *"In pursuance of the powers conferred on it by Article 54 and Schedule 8 to 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 and Raychel Ferguson, with particular reference to:*
>
> (i) *The care and treatment of Adam Strain and Raychel Ferguson, especially in relation to the management of fluid balance and the choice and administration of intravenous fluids in each case.*
>
> (ii) *The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain and Raychel Ferguson.*
>
> (iii) *The communications with and explanations given to the respective families and others by the relevant authorities."*[42]

18. It is clear that these Terms necessitate an investigation into the governance issues surrounding Adam's case. In addition, the investigation into the case of Claire Roberts requires an investigation into the aftermath of Adam's death and whether it could or should have had any impact on Claire's subsequent care and treatment, which was also at the Children's Hospital and within five months of his Inquest.

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36 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (23rd, 24th & 26th April 2012)
37 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (1st May 2012)
38 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (2nd & 3rd May 2012)
39 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (4th May 2012)
40 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (8th & 9th May 2012)
41 Ref: On the Inquiry website, under heading of 'Oral Hearings- Timetable' (16th May 2012)
42 Ref: 021-010-024

IV. List of Governance Issues

19. The issues raised by the Terms of Reference are reflected in the Inquiry's List of Issues. The List of Issues is a working document that is updated and revised as appropriate. The current List of Issues was published by the Inquiry on 14th February 2012.[43] The governance issues surrounding Adam's case fall into the following areas:

    (i) Investigation into the relevant governance issues which arise out of the care and treatment that Adam Strain received at the Children's Hospital prior to and after 26th November 1995

    (ii) The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the death of Adam Strain

    (iii) Investigation into the quality of the information on Adam provided to and received from Adam's next of kin from when the possibility of placing of Adam on the renal transplant list arose in 1994 until the announcement of the Inquiry in 2004

    (iv) Procedures, protocols and/or practices governing paediatric renal transplant surgery at the Children's Hospital, their adequacy and whether they were followed

    (v) Investigation into the experience of the transplant team including surgeons, anaesthetists and nurses

    (vi) Investigation into the extent to which the care and treatment provided to Adam and his family was consistent with guidance provided by the DHSSPSNI and other professional bodies at the time

    (vii) Investigation into the teaching/training in Northern Ireland on fluid management (in particular hyponatraemia) and record keeping that was provided in the 20 years immediately prior to Adam's death (i.e. 1975 - 1995) to medical students and student nurses as part of their qualification and to doctors and nurses as part of their induction, training and continuous professional development

    (viii) Investigation into the procedures and practices that existed in Northern Ireland at the time of Adam's death for the reporting and dissemination of information to the DHSSPSNI and the

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[43] Ref: Revised List of Issues - Inquiry into Hyponatraemia-related Deaths website, under 'Key Inquiry Documents'.

medical community in general, of unexpected deaths in Hospital and outcomes of Coroners' Inquests

(ix) Investigation into the information that was actually provided to the DHSSPSNI and the medical community in general about Adam's death in 1995 and the lessons that emerged from the Coroners' Inquest into it in 1996

(x) Investigation into what action was taken by the hospital or DHSSPSNI following the communication on 25th April 1996 of a medical negligence claim the settlement on the 29th April 1997 of the subsequent action

V. The Concept of 'Governance'

20. Mr. Chairman, as these Oral Hearings are now concerned with the 'governance' issues arising out of Adam's care, surgery and subsequent death, it is important therefore that I describe what is meant by 'governance' in that context.

21. Governance as a term comprises both 'clinical' and 'corporate' governance.[44]

22. The particular term 'clinical governance' was used in a government White Paper on health, 'The New NHS Modern and Dependable' (DoH 1997) and became a point of reference for what it encompassed:[45]

*"3.6 Locally there will be … a new system of **clinical governance** in NHS Trusts and primary care to ensure that clinical standards are met, and that processes are in place to ensure continuous improvement, backed by a new statutory duty for quality in NHS Trusts*

6.4 In the new NHS: …

- *clinical governance arrangements will be developed in every NHS Trust to guarantee an emphasis on quality …*
- *public confidence will be rebuilt through openness, improved governance and public commitment to the values and aims of the NHS*

6.12 Professional and statutory bodies have a vital role in setting and promoting standards, but shifting the focus towards quality will also require practitioners to accept responsibility for developing and maintaining

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44 Ref: 210-003-009 & 210-003-010

45 Ref: 210-003-006 & Department of Health, Dec. 1997. London: The Stationary Office as ISBN 0 10 1380720

standards within their local NHS organisations. For this reason the Government will require every NHS Trust to embrace the concept of 'clinical governance' so that quality is at the core, both of their responsibilities as organisations and of each of their staff as individual professionals." (Emphasis added)

23. Whilst that paper was published on 8th December 1997, the concept of 'governance' was nonetheless already well known and many of the principles underlying clinical governance were already in place, as is recognised in the paper itself:

6.15 These arrangements should build on and strengthen the existing systems of professional self-regulation and the principles of corporate governance, but offer a framework for extending this more systematically into the local clinical community.[46]

(Emphasis added)

24. However, it was the DoH 1999 publication 'A First Class Service: Quality in the new NHS'[47] that is thought to have provided an actual definition of the term 'clinical governance': "*The system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish*".[48]

25. Broadly speaking and as explained by Professor Aidan Mullan in his Report to the Inquiry dated 29th February 2012, 'clinical' governance is concerned with the guidance and performance of medical professionals and with the management of the hospitals in which they work. 'Corporate' governance is concerned with the organisations and systems at the higher Trust, Board and Departmental levels.

26. More particularly and for the purposes of the investigation into the governance issues arising in Adam's case, 'clinical' governance will be used to refer to the system by which the health and social care organisations are rendered accountable for safeguarding, monitoring and improving the quality of care and services provided. This covers the reporting lines from the medical professionals to the Medical Directorate and ensures that management provides the leadership, procedures and systems that the organisation requires in order to deliver and maintain the standards for which it is accountable.

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46 Ref: 210-003-007

47 Ref: 210-003-007 & Department of Health, Feb 1999 HSC 1999/033

48 Ref: Department of Health, Feb 1999 HSC 1999/033

27. As explained by Professor Mullan in his Report,[49] in 1995 a level of governance would have been achieved by individual medical practitioners following professional college guidelines and other national standards in order to provide best practice and to keep up to date with developments and research. However, what is at issue here is the development of systems and procedures to achieve governance at the level of the organisation.

28. Governance could have been achieved at the organisational level through the monitoring of cases, reviewing of outcomes and by identifying deficiencies through clinical audit. The purpose of that would be to identify risks to patients and establish formal procedures to report and investigate adverse incidents, complaints and litigation. Achievements could have been measured through set objectives assisted by the development of information systems that, in 1995, might have included medical case notes.[50] The extent to which those objectives were met could in turn have allowed for more strategic management in order to plan and develop future services and facilities, as well to ensure that the hospital and Trust complied with statutory regulation and best practice guidelines. [51]

29. Of particular significance to Adam's case is that element of governance which is concerned with adverse or untoward incident reporting. Professor Mullan refers in his Report to the publication by the DoH of 'An Organisation with a Memory' in June 2000,[52] which states: *"Formal Department of Health guidance on untoward incident reporting was first issued in 1955.*[53] *Somewhat surprisingly, this guidance is still current."*[54] Professor Mullan continues: *"The 1955 guidance serves to provide insight into what was and still is expected from organisations such as the Royal Group of Hospitals Trust at a fairly basic level, when an adverse incident occurs ... 'a brief report should be prepared by the Secretary of the Board of Governors or Hospital Management Committee as soon as possible after any occurrence of the kind in question'"*.[55]

30. Incident reporting was also addressed in subsequent guidance and *"in the recommendations of major independent incident inquiries"*,[56] which, according to Professor Mullan, should have informed the development of the Trust's Serious Adverse Incident reporting policies and

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49 Ref: 210-003-014

50 See the Inquiry Witness Statement of Dr. Carson, in which he states that: *"Some Clinical Directorates may have included case note reviews as part of their audit programme, but there was no regular trust-wide systematic review of case notes."* – Ref: WS-077-2 p.8

51 Ref: 210-003-009

52 Ref: 210-003-038

53 H.M.(55)66: *National Health Service- Reporting of Accidents in Hospitals, Ministry of Health, July 1955*

54 Ref: 210-003-038

55 Ref: 210-003-038

56 Ref: 210-003-038

procedures in the period leading up to Adam's death in 1995, including:

(i) 'Risk Management in the NHS Manual' (1993) which set out the requirements that a procedure should be devised and implemented covering the action to be taken by line managers in the event of an incident involving actual or potential loss, injury or damage, that all such incidents be reported immediately, and that a designated individual should be responsible for initiating further communication or enquiries and ensuring that appropriate action is taken[57]

(ii) 'EL (94)16 Report of the Independent Inquiry relating to deaths and injuries on the Children's ward at Grantham and Kesteven General Hospital during the period February to April 1991' (the "Allitt Inquiry")[58] which stated that *"there must be a quick route to ensure that serious matters ... are reported in writing to the Chief Executive of the hospital ... All District Health Authorities and NHS Trust Boards should take steps immediately to ensure such arrangements are in place"*.[59]

31. This part of the investigation in Adam's case has sought to identify and explain the professional self-regulation and governance arrangements which were in place or should have been in place in the Children's Hospital in November 1995. [60]

32. However, to understand the framework that was in place then to support the provision of healthcare, it is necessary to appreciate the corporate 'architecture' of the Health Service. For it is the structure of management and clinical functions which defines the 'chain of responsibility' and the 'lines of accountability'.

VI. Organisational Context

33. When Adam was admitted to the Children's Hospital on 26th November 1995 that hospital did not stand alone as an independent, self-regulating organisation. Rather the Children's Hospital, the Royal Group of Hospitals of which it formed a part, their Trust and the Board within which that Trust was located can all be viewed as an accountable, 'corporate whole'.

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57 Ref: 210-003-038 & *Risk Management in the NHS,* NHS Executive 1993 reissued 1996. Department of Health London.
58 Ref: 210-003-038 & NHS Executive 1994.
59 Ref: 210-003-038
60 Ref: 210-003-011

34. In 1993 the Royal Group of Hospitals, including therefore the Children's Hospital, all became part of an integrated Health and Social Care Trust known as the Royal Group of Hospitals Trust ("Trust"), which was established by the DHSSPSNI, under the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust (Establishment) Order (Northern Ireland) 1992. The functions of the Trust included the owning and management of the *"hospital accommodation and services at the Royal Group of Hospitals and Dental Hospital including the management of the teaching and research facilities associated with these hospitals and the support services related thereto"* all pursuant to the Health and Personal Social Services (Northern Ireland) Order 1991.

35. Professor Mullan describes this in his Report: *"the establishment order required the creation of a Trust Board with a Chairman, Non-Executive Directors, a Chief Executive and Executive Directors, very similar to that previously seen in private companies"*.[61] In that *"the Non-Executive Directors will have been appointed to provide independent expertise; represent patient, carer and public interests"* and to *"provide reassurance that proper standards of governance and probity were being observed."*[62] It should be noted that the Health and Personal Social Services (Northern Ireland) Order 1991 provided that one of the non-executive directors be appointed from Queen's University Belfast, as the Trust was regarded as having a significant teaching commitment. The implications of this will be considered later in this Opening.

36. The picture therefore that emerges is of the hospitals being held accountable by the Trust, in accordance with proper governance standards. To understand what these 'governance standards' were in 1995, it is necessary to refer to the 'Code of Conduct and Accountability',[63] which sets out the following specific expectations for the Trust Board:

    (i) To be collectively responsible for adding value to the organisation, for promoting the success of the organisation by directing and supervising the organisations affairs

    (ii) To provide active leadership of the organisation within a framework of prudent and effective controls which enable risk to be assessed and managed

    (iii) To set the organisation's strategic aims, ensure that the necessary financial and human resources are in place for the

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61 Ref: 210-003-007

62 Ref: 210-003-007

63 Ref: 210-003-009 & 'Codes of Conduct and Accountability' – Circular HSS (PDD) 8/1994, Department of Health and Social Services

organisation to meet its objectives, and review management performance

(iv) Set the organisations values and standards and ensure that its obligations to patients, the local community and the Secretary of State are understood and met.[64]

37. The Trust Board of Directors would in turn have been held accountable by the Eastern Health and Social Services Board ("EHSSB") which commissioned health services from the Trust. In order for it to fulfil the obligations placed upon it by the EHSSB, the Trust Board of Directors should have had to maintain an effective system of internal control over its finances and financial management systems and provide suitable evidence that it had such systems of internal control in place.

38. As I described in the General Opening, that institutional structure changed in two phases. The first was in April 2007 when five new integrated Health and Social Care Trusts were established replacing those that were in existence during Adam's case and those of the other children, Claire, Lucy, Raychel and Conor. The second phase was in April 2009 when five Local Commissioning Groups were established with boundaries aligned to those of the new Health and Social Care Trusts.

39. As a visual aid to understanding, a Corporate Organisational Chart was compiled by the Inquiry Legal Team.[65] This diagram sets out the organisational structure of the Trust as it was in 1995/96. As can be seen there is a hierarchical structure of Executive Directors. Mr. William McKee, Chief Executive, was the principal Accountable Officer on behalf of the organisation. With him the Director of Finance, Mr. Norman Bennett, the Director of Nursing & Patient Services, Miss Elizabeth Duffin, and the Medical Director, Mr. Ian Carson. Professor Mullan comments that: "*it is reasonable to say that their statutory positions on the Trust Board were [there] to provide professional clinical advice and clinical leadership to the organisation.*"[66] By way of contrast, the Legal Team has also compiled a Corporate Organisational Chart showing the current structure of the successor Trust, Belfast Health and Social Care Trust.[67]

40. It is important to note that the responsibility of the Trust Board of Directors was based on providing effective clinical services, and this

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64 Ref: 210-003-009. See 'Structure of NHS in Northern Ireland (pre-2007)' at Ref: 303-039-505. See also: 'Boards, Trusts, Hospitals & Commissioning Groups (pre-April 2007 and post-April 2009)' - Ref: 303-042-509. See too the maps at Ref: 300-001-001 and Ref: 300-002-002 for the boundaries of the area Boards and the Local Commissioning Groups.

65 Ref: 303-043-510

66 Ref: 210-003-008

67 Ref: 303-044-511

necessitated the development of a clinically based management structure. The result was:

"… the devolution of decision-making to the front line clinical staff, given leadership by the Chief Executive and empowered and supported by a clinical board. It involved giving doctors, nurses, therapists and others direct responsibility for making decisions regarding not only patient treatment and care but also day to day running, planning and the development of their service".[68]

41. The concept of clinically based management was first introduced into most NHS Trusts during the early 1990s with staff and clinicians delegated full authority to make and carry out decisions and to assume accountability for them. Together with this came an expectation that they act corporately to efficiently and effectively fulfil the needs of patients. Professor Mullan describes the move: *"at the time, this change was seen by many as not just another reorganisation of health service management, but rather a revolution in health management."*[69]

42. Despite what has been described as a 'revolution in health management', it seems that it was not thought necessary to provide clear written guidance as to what the new management roles entailed. So although Dr. Carson, who was the Medical Director at the time of Adam's transplant surgery, interpreted his *"principle role"* as Medical Director as being: *"to provide medical leadership within the Trust; at the corporate level to advise the Chief Executive and the Board of the on all medical policy and strategy matters; and to deputise for the Chief Executive in his absence"*,[70] none of that is to be found in any 'job description'. Indeed the DLS has informed the Inquiry that: *"the Royal Group of Hospitals Trust had been created a self governing Trust under the chairmanship of Sir George Quigley on devolvement from direct administration by the Eastern Health & Social Services Board on 1st April 1993. The posts of Clinical Directors, Unit General Manager and Unit Clinician were rolled over into their new nominated positions without creation of new posts requiring Job Descriptions. The Trust therefore does not hold Job Descriptions pertaining to the posts in 1995. The Trust has consulted with the postholders at the time and they have confirmed that they were not issued with Job Descriptions."*[71]

43. Nevertheless, we can now begin to see the treatment of Adam in November 1995 against a backdrop of accountable structures: the EHSSB imposing obligations of systematic internal control upon the Trust; the Trust Board of Directors assuming those obligations through

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68 Ref: 210-003-008
69 Ref: 210-003-008
70 Ref: WS-077-2 p.3
71 Ref: 305-030-001

its executive and non-executive directors; the Chief Executive and executive Directors performing their duty to provide professional clinical advice and leadership to the staff and clinicians; the staff and clinicians being delegated responsibility for patient treatment and the development of the service.

44. In addition it appears from the Annual Reports of the Royal Group of Hospitals Trust of around that time, 1993/1994 and 1995/1996, that the management structure included a 'Hospital Council'. The minutes of that Council which have been provided to the Inquiry[72] show that it was chaired by Mr. McKee and its membership included Drs. Murnaghan, Carson, Gaston, Mulholland, Mr. Hood and Miss Duffin, who were all heads of Directorates. It is not clear how the Hospital Council was integrated into the organisational structure and what, if any, role it had in the delivery of health care to patients that was of an appropriate standard.

Directorates

45. To appreciate the manner in which governance standards were applied in practice, it is necessary to proceed further along the Organisational Chart and consider the clinical divisions, or Directorates, which were established within the Royal Group of Hospitals Trust in 1995.

46. The Trust, in line with many other NHS Trusts throughout the UK, established a series of Directorates which were "*small units of management encompassing the range of services relating to a speciality or group of specialities.*"[73] As can be seen each Directorate was led by a medical consultant, or Clinical Lead, who was accountable to Dr. Ian Carson as Medical Director, and who in turn had the responsibility of communicating information to their colleagues.[74]

47. According to Mr. William McKee,[75] who was then Chief Executive of the Royal Group of Hospitals Health and Social Services Trust, the Clinical lead was supported by a business manager and a senior nurse. Together, they should have provided the organisation with assurances that corporate systems of clinical and non-clinical controls were in place. In 1995 the Clinical Leads in the relevant Directorates were:

(i) Dr. Joseph Gaston: Anaesthetics, Theatre & Intensive Care

(ii) Dr. Connor Mulholland: Cardiology (substantive)
Paediatric (acting)

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72 Ref: 305-117-002 *et seq*
73 Ref: 210-003-008
74 Ref: 305-117-070
75 Ref: WS-061-2 p.7

(iii) Mr. John Hood: Surgical (Royal only)

(iv) Miss Elizabeth Duffin: Nursing & Patient Services

48. As regards the Surgical Lead, it should be noted that Mr. Hood states in his Inquiry Witness Statement: "*my remit did not extend beyond the Royal Victoria Hospital. The Royal Belfast Hospital for Sick Children had a directorate of its own and from memory at that time I believe the Clinical Director was Mr. Stephen Brown who was a paediatric surgeon.*"[76] Mr. Brown lists in his curriculum vitae that he was Clinical Director in Paediatrics for the Royal Group of Hospitals Trust up to April 1995 but does not show what happened thereafter.[77] The Inquiry sought clarification of the position from DLS who has advised that: "*There was no paediatric surgical lead in the RBHSC in 1995/96, in the sense of a formal appointment with a job description.*"[78]

49. The response from DLS may have confused matters in that the issue is not whether there was a 'Paediatric Surgical Lead', whether formal or otherwise. Rather, it is whether the Paediatric Directorate acted as a Directorate for the Children's Hospital embracing all paediatric care including paediatric renal transplants. More importantly, what is not presently clear and will therefore be a matter to be addressed during the Oral Hearings, is precisely where within the overall management structure lay the management of the Children's Hospital and, more particularly, the paediatric renal transplant service. This matter will be pursued during the Oral Hearings.

50. In addition to those Clinical Leads, there were also 'administrative Directorates' and Dr. George Murnaghan was the Director of Medical Administration.

51. The Trust's Annual Report on Health and Safety 1998/99, which although post-dates Adam's death by a period of years and deals specifically with health and safety matters nevertheless provides a reflection of how such a management structure might have operated in 1995:[79]

"While the Chief Executive remains accountable for the effective management of Health and Safety/ Risk Management and compliance with legislation, responsibility cascades down through the line management structure to Directors, Directorate Managers and Heads of Department, who are in turn

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76 Ref: WS-246-1 p.2
77 Ref: 306-028-003
78 Ref: 305-150-001
79 See Professor Mullan who is of the view that the same principals should have applied to all aspects of internal control within the Trust in 1995 - Ref: 210-003-009

supported by their Directorate and Departmental Health and Safety Committees".[80]

Paediatric Renal Transplant Service

52. A paediatric programme of renal transplants was started in 1980 at the Belfast City Hospital ("BCH") which already had an established adult renal transplant programme. Subsequently, a decision was made to carry out renal transplants in relation to young children at the Children's Hospital, namely those under the age of 14 years and especially those under 5 years. The first renal transplant involving a child of less than 5 years old took place at the Children's Hospital in 1990.

53. It would seem that Professor Savage, then the sole Consultant Paediatric Nephrologist, was the driving force behind the move to the Children's Hospital: *"as we gradually developed the service I worked with the adult nephrologists and the adult transplant surgeons and initially we would have transplanted older children and we could manage them in an adult unit. But of course, an adult unit isn't ideal for children and as we gained the skill to dialyse and transplant smaller and smaller children, it became obvious we should be taking those children into the environment of a children's hospital with all the other ancillary provision there."*[81] Nevertheless, from the disaggregated figures provided by DLS it is clear that as at 1995 and up until 1999, the BCH was still carrying out renal transplants on children who were younger than 14 years old, whilst the Children's Hospital was carrying out and continues to carry out transplants on children who are older than 14 years old.[82]

54. Although the BCH, which is in a different Trust to the Children's Hospital, is the recognised renal transplant centre for Northern Ireland[83] it would appear that the Royal Group of Hospitals Trust assumed control over the paediatric renal transplant programme being carried out at the Children's Hospital.

55. Nevertheless, it is unclear what planning went into the decisions to extend the paediatric renal transplant programme to children under 5 years and to have those transplants carried out at the Children's Hospital. It is also unclear whether the development was left to Professor Savage, who was eager to ensure that such a service was made available in Northern Ireland, or whether it required the sanction

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80 Ref: 210-003-009

81 Ref: Transcript of Oral Evidence of Professor Savage, 17th April 2012 p.12, lines 1-10

82 Ref: 301-120-655

83 See the list of specialist centres on the website of NHS Blood and Transplant (NHSBT), which is the Special Health Authority in the NHS with responsibility for optimising the supply of blood, organs, and tissues and raising the quality, effectiveness and efficiency of blood and transplant services – www.organdonation.nhs/ukt/about_transplants/transplant_units

of management, whether a Clinical Lead, the Medical Director or even higher.

56. The relative lack of experience of both the BCH and the Children's Hospital in carrying out renal transplants on children of Adam's age is evident from the statistical data maintained by NHS Blood and Transplant ("NHSBT") and was acknowledged in evidence by Professor Savage.[84] Indeed, until 1990 there were no renal transplants involving children under 5 years old and were no such transplants for the 2 years prior to Adam's case.[85] Then two were carried out in 1995 prior to Adam's surgery, one of which was on 17th November 1995. All the surgeons came from BCH, although there was no dedicated paediatric renal transplant surgeon, and none of them had been involved in more than four such procedures.[86]

57. Complex cases were not carried out in Belfast and Mr. Keane acknowledged in his evidence at the Oral Hearings that in 1995 he would not have carried out a paediatric transplant that required an aortic graft and, for that reason, he would not have carried out a paediatric transplant from a living donor. Indeed, there had not been a paediatric transplant in Belfast involving a living donor, despite the fact that the evidence given at the Oral Hearings was that it was recognised at that time to offer considerable benefits in terms of planning and graft survival.[87]

58. The British Association for Paediatric Nephrology produced a Working Party Report in March 1995 entitled 'The Provision of Services in the UK for Children and Adolescents with Renal Disease'.[88] This provided a commentary on existing and recommended practice in paediatric nephrology and transplantation. It recommended that in order to accumulate and maintain expertise, a population base of three million was the minimum to sustain a comprehensive paediatric renal service although four million was deemed ideal. It was recognised that exceptions were necessary on geographical grounds in Wales and Northern Ireland.[89] The Report detailed the renal transplant activity by region across the UK in 1992. It records that of the 102 transplants

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84 Ref: Transcript of Oral Evidence of Professor Savage, 17th April 2012 p.15, lines 12-24

85 UK paediatric kidney only transplants (deceased and living) at dedicated paediatric units, by transplant year, transplant unit and age group – Ref: 300-021-033. See also the paper by Dr. Mayes and Professor Savage, 'Paediatric renal transplantation in Northern Ireland (1984-1998)', The Ulster Medical Journal, Vol.69, No.2, pp.90-96

86 Ref: 094-013j-080. It should be noted that in some of those cases 2 or surgeons might have been involved, whilst not all of the surgeons were involved as Consultants – for example Mr. Keane did not become a Consultant until 1994, the year before Adam's surgery

87 Ref: Transcript of Oral Evidence of Professor Forsythe and Mr. Rigg, 3rd May 2012 p.172, lines 11-13

88 Ref: 306-065-001

89 The population of Northern Ireland in 1995 was approximately 1.6 million and is now approximately 1.8 million: 'Population and Migration Estimates Northern Ireland (2010) – Statistical Report', NISRA, 2011.

performed only 15 were performed on children aged less than 5 years of age. The Report concluded that no UK unit was performing a large number of transplants on young children at that time. It also noted, as was the case with the paediatric renal transplant services provided at the Children's Hospital at the time of Adam's transplant surgery, that "*with few exceptions, the transplant and paediatric renal services in the UK are located on different sites*" and "*strongly urge[d] the development of arrangements for children to be transplanted within the familiar surroundings of the paediatric renal unit, to facilitate continuity of care by the same multi-disciplinary team*".[90]

59. Subsequently, in September 1995, the British Paediatric Association ("BPA") published a report entitled 'Tertiary Services for Children & Young People',[91] which reviewed the current and future needs for tertiary services for young people in the UK and provided: "*A guide for the purchase, provision and planning of specialist services for sick children*". The report referred to the development of specialist services within paediatrics that were nonetheless mainly being provided by "*general paediatricians, adult specialists or a combination of both*" and that the "*Results of treatment for some children and babies with life threatening diseases were poor, with high levels of morbidity and mortality. This led to a view that certain treatments, such as organ transplant, should not be offered to children.*"[92] The Report went on to point out that in Northern Ireland (and Wales), specialist services such as paediatric renal transplants were not formally recognised or funded through regional or super-regional funding and in consequence, some aspects of the service were poorly developed.

60. The concern over insufficient cases and its implications for maintaining the necessary expertise to carry out specialist services such as paediatric renal transplants was not new. In particular, Belfast reliance at the time on cadaveric transplants meant that the necessary expertise and resource infrastructure needed to be in place "*around the clock*".[93]

61. Professor Savage contends in his Inquiry Witness Statement[94] that some of the points being made in the BAPN Report were already recognised and, for example, the appointment of Dr. O'Connor commencing as a second Consultant Paediatric Nephrologist on 1st November 1995 was a direct response to the view in the Report that each centre should have three consultants with there being an urgent

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90 Summary of Recommendations p.1 – Ref: 306-065-005-6

91 Ref: 306-064-001 *et seq*

92 Ref: 306-064-004

93 See Dr. Mayers & Professor Savage, 'Paediatric renal transplantation in Northern Ireland', The Ulster Medical Journal, Viol.69, No.2, pp.90-96, November 2000, at p.93 which refers to 8 offers having to be declined up to 1998 for 'lack of resources' meaning either the lack of a post-operative intensive-care bed or that "*key consultant nephrology or surgical staff were not available*".

94 Ref: WS-002-3, pgs.3 and 4

need to increase the posts in Belfast from one to two.[95] However, what is not clear is:

(i) Whether prior to Adam's transplant surgery the Trust had any processes and procedures whereby the analysis and/or recommendations in such reports was considered and, if appropriate, acted upon with the outcome being either evaluated or monitored. If so, what they were and who they made was responsible for implementing them

(ii) Alternatively, whether the response to such reports was left to the discretion of Professor Savage

62. It is not the function of this Inquiry to investigate the operation of the paediatric renal transplant programme, which has been subject to independent review, the most recent of which having been carried out in 2011 and recording: *"We heard that transplants on small children tended to be carried out by one surgeon. He would travel across to the Royal Victoria [site] and either try to arrange to bring his own surgical assistant with him or the paediatric nephrologists would endeavour to get an assistant from the Children's Hospital. At times it sounded quite difficult to get such assistance which is very regrettable in a very difficult and important operation."*[96] The recommendations for paediatric renal transplantation include: *"It is unlikely that new transplant surgical appointments will have much expertise in performing such transplants in small children. Sadly it is hard to see how the renal transplant service for children can be put onto a robust footing for the future. It would appear unacceptable to rely on one surgeon performing the renal transplant operation in small children. Therefore consideration may wish to be given as to whether such a service could be run in one venue for the whole of the island of Ireland."*[97]

63. However, what is of interest is the system that the Trust had established prior to Adam's surgery in relation to the paediatric renal transplant service being delivered by the Children's Hospital. Of particular interest are those who were charged with the responsibility to monitor its performance and investigate and report on adverse incidents in relation to its operations. Also, of interest is the consideration that was given to the support services that would be required to sustain a properly functioning and safe service.

64. The Inquiry has been advised that access to a suitably equipped biochemistry laboratory and adequate portering or other arrangements for transporting blood samples for testing is an important support

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95 Ref: 306-065-017
96 Ref: 301-115-640
97 Ref: 301-115-641

service for any transplant programme.[98] However, whilst there was a laboratory adjacent to the operating theatres in the Children's Hospital the DLS have advised the Inquiry that it was not available outside the hours of 09:00 to 17:00.[99] Accordingly, samples for biochemical testing outside those hours, such as electrolyte testing in Adam's case when he was first brought into the operating theatre at about 07:00 and for the first part of his transplant surgery, would need to be taken by porter to the main laboratory on the Royal Victoria site. The timeliness of the response was therefore dependent upon the proximity and sufficiency of porters at any given time. However, the extent to which any of that was considered prior to the transfer to the Children's Hospital of the paediatric renal transplants involving the very young is unclear.

VII. Internal Control

65. At the time of Adam's transplant surgery the Mission Statement of the Royal Hospitals, and therefore of the Children's Hospital,[100] was to:

"provide the highest quality cost effective health care as an outstanding acute general hospital and tertiary referral centre, through exceptional service to our patients, staff and community in an environment of education, teaching and research."

In order to achieve that purpose, one of the stated aims was to:

"• provide training and education for health care professionals in association with the Queen's University, the University of Ulster …
• promote and support scientific and clinical research and foster an ethos of inquiry and innovation and make cost-effective use of all resources"

66. The principle clinical governance issue in relation to Adam's case is the internal control established and exercised by the Trust to deliver on those objectives and on its health care obligations generally.

Medical and Clinical Audits

67. The mechanisms by which standards of care could be upheld and improved were recognised long before Adam's death. One of the principal methods employed to maintain and raise standards was a medical audit programme entailing a critical examination and review of the quality of care and practice. This could allow deficiencies and mistakes to be identified and thus lessons to be drawn and shared.

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98 Ref: 204-002-022
99 Ref: 301-018-331
100 Ref: WS-061-2 p.26

68. As far back as 1989, the DoH published its White Paper 'Working for Patients'[101] and 'Working for Patients: Medical Audit Working Paper 6'[102] to set out plans for a comprehensive system of medical audit. The basic principles of medical audit were that:

(i) Every doctor should participate in regular, systematic medical audit

(ii) The system should be medically led, with a local medical audit advisory committee chaired by a senior clinician

(iii) The overall form of audit should be agreed locally between the profession and management, which itself would need to know that an effective system of medical audit was in place and that the work of each medical team be reviewed at regular and frequent intervals

(iv) The results of medical audit in respect of individual patients and doctors must remain confidential at all times. However, the general results need to be made available to local management so that they may be able to satisfy themselves that appropriate remedial action is taken where audit results reveal problems

(v) Where necessary management must be able to initiate an independent audit. This may take the form of external peer review or a joint professional and managerial appraisal of a particular service

69. It is worth noting that Dr. Taylor's experience and evidence is that: "*Clinical audit came in really around that time, 1992, when I was co-opted or asked to sit on that committee [Audit Sub-Committee of the Anaesthetics, Theatre & Intensive Care Directorate]. A clinical audit – and I think it was initially called medical audit – was coming in as a method of doctors undertaking reviews of their outcomes with certain patients, with certain treatments*".[103] It seems that Dr. Taylor served on that Sub-Committee for the period 1992 to 1996.[104] It is also worth noting that the 1995 employment contract of Dr. James McKaigue, who was a Consultant Paediatric Anaesthetist at the time of Adam's transplant surgery, included a requirement that he participate in "*medical audit*".[105]

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101 Ref: 210-003-012 & Department of Health. London: HMSO (Cm 555)

102 Ref: 210-003-012 & Department of Health. London: HMSO, 1989

103 Ref: Transcript of Oral Evidence of Dr. Taylor, 19th April 2012 p.8, lines 16 *et seq*

104 See Dr. Taylor's curriculum vitae – Ref: 306-019-011

105 Ref: WS-129-1, 39. See also the employment contract of Mr. Keane at BCH, from a different Trust but the same Eastern Heath and Social Service Board, which required him to "*participate in medical/clinical audit*" (Ref: 301-033-379) and "*in monthly audit meetings*" (Ref: 301-033-385)

70. Nevertheless, Mr. McKee has been unable to provide any further information or detail about the *"organisational framework for medical audit."*[106]

71. Nevertheless as an overall tool to effect change, 'medical audit' came to be regarded as having its limitations as they were generally uni-disciplinary with the aim of making improvements in the quality of medical care in that particular discipline. As the use of audits was developed to apply to the multi-disciplinary or inter-disciplinary delivery of care, it came to be referred to as 'clinical' audit seen as a: *"professionally-led initiative which seeks to improve the quality and outcome of patient care through clinicians examining their practices and results and modifying practice where indicated. Although audit has been undertaken by some clinicians for many years it has only been accepted as an essential part of professional practice and central support made available in the last few years."*[107]

72. Professor Mullan explains in his Report that at the same time as the emphasis on audit as a quality-improvement tool increased, central government provided 'ring-fenced' money to support local audit committees and the involvement of the clinicians.[108] He concludes that it might:

> *"… therefore be reasonable to expect that a robust programme of clinical audit should have been well established in the Trust in 1995, some six years after the publication of 'Working for Patients'. The Trust should have established a Clinical Audit Committee, chaired by a senior clinician, with representation from each of the clinical Directorates, which would have been responsible for developing an annual clinical audit programme. However, the Inquiry has been informed (Ref: 305-009) that the Trust did not have an Annual Clinical Audit programme in 1993/94 or 1994/95. If this was in fact the case, the implications are that the Trust Board, and in particular Chief Executive, as Accountable Officer, had no recognisable system for quality assuring the safe provision of clinical care within his organisation".*[109] (Emphasis added)

73. Mr. McKee has referred the Inquiry[110] to the Royal Hospitals' Annual Report for 1st April 1993 to 31st March 1994 and to page 33 on 'Medical Audit'.[111] That Annual Report asserts that: *"The Royal Hospitals Trust has developed an effective organisational framework for medical audit which supports and encourages changes in clinical practice as a natural part of*

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106 Ref: WS-061-2 p.9
107 Ref: *Promoting Clinical Effectiveness: A Framework for Action in and through the NHS*, NHS Executive, Department of Health, 1996
108 Paragraph 2.34 at Ref: 210-003-013
109 Ref: 210-003-013
110 Ref: WS-061-2 p.9
111 Ref: WS-061-2 p.58

organisation-wide quality assurance."[112] It goes on to explain under its 'goals':

"Since the establishment of medical audit under the direction of the Hospitals' Audit Co-ordinator, a number of developments have been achieved. Directorate Audit Co-ordinators have been appointed and meet as a committee bi-monthly to discuss, plan and monitor medical audit activity. More recently, and in recognition of the extending role of audit, the committee now includes a senior nursing representative and two general practitioners."[113]

74. The Report then expands upon what is referred to as a *"rolling programme of audit"* in which Directorates participate:

"Meetings take place monthly and are attended by consultants, junior staff and senior medical students. The meetings format includes sessions on case note review, discussion and presentation of audit projects, discussion of guide-lines and protocols, and medical education.

More recently there has been a move toward multi-disciplinary audit (clinical audit) with a number of Directorates having taken the lead with meetings being attended by other inter-disciplinary teams. Completed audit projects have involved clinical and nursing staff with planned projects to include the whole care team.

The Medical Audit Department provides a technical and administrative medical audit service for all the Hospitals in the Trust."[114] (Emphasis added)

75. The Northern Ireland Health and Personal Social Services Management Executive stressed the need for programmes of audit in its Management Plan for 1995/1996 - 1997/8,[115] which includes reference to *"Better Practice"* and states:

"Providers need to continue to focus on improvement in standards of practice. The service they provide should also continue to achieve the best possible outcomes for patients and clients within the available resources, which necessitates a strategy aimed at sustaining a process of continuing quality improvement. Specifically, units should ensure that there is a clear policy on:

- *Clinical audit as part of a programme to improve all aspects of service quality, not just clinical outcomes*
- *Support and evaluation of quality improvement programmes*

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112 Ref: WS-061-2 p.58
113 Ref: WS-061-2 p.58
114 Ref: WS-061-2 p.58
115 Ref: 306-083-001 *et seq*

- *Multi-disciplinary approaches to the development of best practice in service delivery".*[116]

76. The Trust's Board Meeting Minutes for 24th November 1995 record an agreement *"that Dr. Carson should ensure that audit projects are expanded to look at outcomes as they are the key element of making a success of clinical audit."*[117] (Emphasis added)

77. Despite that emphasis on clinical audit, Dr. Carson who was the Medical Director in 1995, seems to sound a different note, stating in his Inquiry Witness Statement that: *"what was recognised generally was that very limited resources were available to support clinical audit in HSS Trusts. In the Royal Hospitals, the Audit Department had at the most 5 or 6 trained audit assistants to work across all 12 clinical directorates."*[118] (Emphasis added)

78. An implication is that the clinical audit programme was not then considered to be wholly adequate. The extent to which the members of the Trust Board of Directors were fulfilling their obligations and whether the Chief Executive could properly be assured that the systems for internal control were effective is a matter to be investigated during the Oral Hearings.

Role of the Individual Clinician

79. The medical profession also provided an impetus for the development of clinical audit. In 1995, the advice to the profession was clear. The General Medical Council ("GMC") circulated 'Good Medical Practice, Guidelines for Doctors'[119] recommending that all doctors: *"must work with colleagues to monitor and improve the quality of health care. In particular, you should take part in regular and systematic clinical audit."*[120] Furthermore, 'The Guidelines to Clinical Audit in Surgical Practice'[121] issued in June 1995 by The Royal College of Surgeons in England outline the underlying principles of clinical audit and the basic components of a surgical audit programme. The 'Clinical Audit and Quality of Practice in Anaesthesia'[122] circular issued in June 1994 by The Royal College of Anaesthetists similarly provides guidance for participation in clinical audit.

80. The extent to which it would have been reasonable to expect the clinicians involved in Adam's care to have participated in a clinical

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116 Ref: 306-083-017
117 Ref: 'Minutes of Royal Hospitals Trust, Board of Directors Meeting, 5th December 1995, page 6'
118 Ref: WS-077-2 p.8
119 Ref: 210-003-013 & Published by the General Medical Council, Oct. 1995
120 Ref: 210-003-013
121 Ref: 210-003-014 & Royal College of Surgeons of England, Jun. 1995
122 Ref: 210-003-014 & Royal College of Anaesthetists, Jun. 1994

audit to include his case as recommended by the GMC and the Royal Colleges, will be pursued during the Oral Hearings.

81. The Inquiry has been informed that the Paediatric Directorate did hold regular Medical Audit Meetings in 1995.[123] It may be that a proper consideration of Adam's case would have required a multi-disciplinary or multi-Directorate approach involving the Anaesthetists or the Anaesthetic, Theatre & Intensive Care Directorate. It is unclear the extent to which such Medical Audit Meetings occurred in 1995. In any event, the practice at that time in such Medical Audit Meetings seems to have been though not to minute or record any discussion of mortality cases. Certainly, no evidence has been provided to the Inquiry of any discussion of Adam's case at such a meeting. Nor has any evidence been provided to the Inquiry to indicate that information was given to the Trust Board of Directors on Adam's case so as to enable it to be satisfied that the problems that had been arisen in it had been appropriately addressed.

82. Professor Mullan is of the view that it would have been a task for the respective Clinical Leads in each clinical Directorate to ensure that Directorate audit programmes were developed. It is to be remembered *"that within the clinically-based management structure operating at the time"*[124] the Chief Executive looked to the medical/nursing directors who in turn would have looked to and held the Clinical Directors responsible for implementing the guidance.

Monitoring Clinical Performance

83. It is worth noting that the minutes of the Paediatric Directorate Medical Audit meeting for 15th March 1995 record a discussion relating to emergency surgery.[125] The minutes of that meeting refer to the 'The Report of the Confidential Inquiry into Perioperative Deaths 1989',[126] which is largely concerned with the deaths of children aged ten years and under. Amongst other things the Report recommended:

(i) That information systems, particularly clinical information systems in the NHS, should be considerably improved to provide accurate and timely information for audit and clinical quality assurance and that all consultants should assist in achieving this improvement

(ii) Local audit meetings are essential to good clinical practice and all consultants should participate

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123 Ref: 305-011-572
124 Ref: 210-003-042
125 Ref: 210-003-014
126 Ref: 210-003-012

(iii) Surgeons and Anaesthetists should not undertake occasional paediatric practice. The outcome of surgery and anaesthesia in children is related to the experience of the clinician involved

(iv) Consultants who take the responsibility for the care of children must keep up to date and competent in the management of children

(v) Given that children operated on at night are more likely to have complications, there should be a designated 09:00 to 17:00 emergency operating theatre

84. Therefore, it would appear clear that the Paediatric Directorate was fully aware of the available advices in relation to audit meetings as part of good clinical practice.

85. Nevertheless, it has proved difficult to obtain relevant corporate documentation in relation to how, or indeed if, the Trust Board of Directors adhered to the requirement for effective systems of internal control so as to assess and manage risk in 1995. The Inquiry has not been provided with any evidence that in 1995 the Trust had and operated a systematic method of monitoring the clinical performance of medical staff or of the hospitals. There seems to have been no external review to identify good or poor performance. The clinicians appear to have had no one to satisfy but themselves that the service they provided was of appropriate quality. As Dr. Gaston recalls in his Inquiry Witness Statement *"There was no policy in place"* for the appraisal of anaesthetic staff after an unexpected death."[127] Mr. McKee states, *"there was no system of appraisal or process of assessing and developing the competence of doctors outside of the GMC."*[128] Indeed Dr. Carson has informed the Inquiry that: *"I am not aware of any system or systematic checklist whereby the Trust would have assured itself that clinical directors/ directorates had disseminated guidance, policy or procedures, yet alone compliance by individual clinicians. A system of directorate 'accountability reviews' was introduced much later (late 1990's/ 2000) as 'performance management' was developed within the Trust"*.[129]

86. Despite the views of Dr. Gaston and Dr. Carson, Professor Mullan thinks it unlikely that the Trust did not have some system for internal control given the corporate management structure established for it,[130]

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127 Ref: WS-013-2 p.7
128 Ref: WS-061-2 p.17
129 Ref: WS-077-2 p.12
130 See article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991

its functions[131] and the continuing requirement to comply with the 'Code of Conduct and Accountability'.[132]

87. Support for Professor Mullan's view may be found in a letter dated 27th July 1994 sent by the Divisional Director, Mr. McConkey, of the Estate Services Directorate at Management Executive to the Chief Executives of the Health and Social Services Board and the Health and Social Services Trusts, to update them on 'Reporting Adverse Incidents and Reactions, & Defective Products Relating to Medical and Non-Medical Equipment & Supplies, Food, Buildings & Plant, and Medicinal Products'.[133] The letter specifically draws attention to the responsibility of Chief Executives for "*ensuring prompt reporting of adverse incidents and reactions.*" It also states that: "*Adverse drug reactions to medicinal products should be reported to the Medicines Control Agency on specifically designed yellow cards*"[134] and concludes that: "*It is essential that ALL those who work in Health and Personal Social Services including those in the Private Sector are aware of the procedures for reporting occurrences, accidents, incidents and defects*".[135] (Emphasis added) Indeed the Trust had responsibility on occasions to report incidents to the EHSSB. Mr. McKee points out: "*that Circular ET 5/90 required "all Unit General Managers to ensure that appropriate reporting mechanisms were in place to ensure that the EHSSB received prompt notification of 'untoward incidents'*".[136]

88. Whether and if so how the Trust monitored clinical performance in 1995 will be addressed during the Oral Hearings, as will their adequacy.

Risk Management

89. According to the NHS Management Executive Manual (1993), "*risk management is generally thought of as a four-phase cycle*" of "*risk identification, risk analysis, risk control and risk funding.*"[137] The Inquiry has obtained the Trust's Annual Reports on Health and Safety covering the years 1995 to 2011.[138] These reveal some aspects of the Trust's internal control mechanisms in 1995. The first Health & Safety Report provided for the Trust Board covers the period 1995/96. The introduction of the Report states:

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131 See as provided by article 3 of the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust (Establishment) Order (Northern Ireland) 1992

132 Ref: 210-003-007

133 Ref: 210-003-1132

134 That is the system that Dr. Robert Taylor subsequently used to notify Solution No.18 in Raychel's case in 2001, Ref: WS-008-1 p.9. See also a description of the system at Annex F, Ref: 210-003-1132

135 Ref: 210-003-1134

136 Ref: WS-061-1 p.2

137 Department of Health, December 1993 10M

138 Ref: 305-007-182 *et seq*

"This report covers the year April 1995 – March 1996. It deals with all aspects of health and safety risk management and should form the basis for monitoring the Trust's performance in future years. It is the first report presented to the Trust and has been made possible by significant advances in the collection, storage and analysis of information on accidents, untoward incidents and personal injury claims. The Directorates of Occupational Health Services and Medical Administration have developed new computer systems to facilitate the process and are cooperating in the use of available information for more effective risk management".[139]

90. With reference to the management of risk, the Report states, "*effective risk management requires that all untoward incidents are reported, irrespective of whether injury or loss occurred.*"[140] Advice, for example, was available in 1995 as to how to examine medical equipment after incidents and for defect. The 'Risk Management in the NHS Manual' (1993) offered the following guidance on investigating incidents: *"when the designated staff member receives incident forms and scans them, he or she will decide what further information is needed and what action needs to be taken. Witness reports may be needed, photographs may need to be taken, defective equipment may need to be removed from use and steps taken to prevent a recurrence. It is important that any allegedly defective equipment or other item is preserved together with its maintenance records, evidence of purchase."*[141] Additional instruction on investigation was provided by the letter of 27th July 1994 issued by the Estates Services Directorate[142] which advises HSS Boards, HSS Trusts and Agencies about accidents and defects in medical equipment. At Annex G, it even provides a sample Advice Incident Report Form. Dr. Gaston concedes in his Inquiry Witness Statement that he was *"aware of PEL(93)(36) since the information was widely publicised at the time"*.[143]

91. Therefore, in 1995, and at least in the context of Health and Safety, the importance of information analysis and performance assessment was clearly acknowledged by the Trust. This is reflected by the statement appearing at page 10 of the Report *"In November 1995 a fatality was recorded of a patient within the medical directorate. A full internal investigation has been carried out together with investigation by the RUC and the Health & Safety Inspectorate."*[144]

92. It is now understood that the patient referred to died in the Royal Victoria Hospital having fallen from a fire escape.[145] The death occurred in the same month as Adam's but, unlike Adam's, was the

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139 Ref: 305-007-189
140 Ref: 305-007-191
141 Ref: 211-003-019
142 Ref: 210-003-033
143 Ref: WS-013-2 p.5
144 Ref: 305-007-193
145 Ref: 305-115

subject of a full internal investigation. That investigation was driven by Health & Safety and Risk Management considerations, which was thought a necessary part of the system for internal control.

93. Exactly what happened in terms of any review of Adam's death as part of the system for internal control will be investigated during the Oral Hearings.

The King's Fund Organisation Audit (KFOA)

94. The same Health & Safety Reports for 1995/96 and 1996/97 suggest that the Trust had embarked on an approach seeking systematic and continuous quality improvement. It had made application in 1995 for accreditation by the King's Fund Organisational Audit ("KFOA"). This involved adopting a systematic programme identified by KFOA for the implementation of professional guidance and best practice within hospitals.

95. Professor Mullan states that accreditation was defined by KFOA itself as *"The external evaluation of an organisation against an agreed set of standards and criteria."*[146] KFOA standards were based on the proposition that *"the capacity to provide high quality acute care depended on the underlying systems and processes of the organisation. These systems should have been developed, implemented, monitored and reviewed by the organisation and form an integral part of its quality programme."*[147] KFOA provided a framework of standards which enabled organisations to assess their systems, processes and effectiveness by ensuring that outcomes were considered and acted upon. This systematic assessment of the organisation was designed to facilitate change within the organisation.

96. Mr. Ramsden has highlighted through his Report of 22nd July 2011[148] and Appendix 1 to it,[149] the extracts from the King's Fund Organisational Audit 1994 that he considers to be of especial relevance to the governance aspects of Adam's case, including:

    (i) Patients' Rights: *"given a clear explanation of their medical condition … including risks and alternatives, before agreeing on the course of action to be taken"*[150]

    (ii) Children: *"written policies and procedures to guide staff in obtaining the informed consent … from the parent"*[151]

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146 Ref: 210-003-010
147 Ref: 210-003-010 to 011
148 Ref: 211-003-001 *et seq*
149 Ref: 211-003-024 *et seq*
150 Ref: 211-003-024
151 Ref: 211-003-025

(iii) Corporate Management: *"records are kept of complaints, accidents, errors and incidents and include details of the action taken"*[152]

(iv) Health Record Service: *"health records committee … with responsibility for … analysing the content of the health record on a systematic basis … Health records staff are involved in hospital/Trust evaluation activities … reviewing health records to determine compliance with established standards"*[153]

(v) Core Standards for Clinical Services[154]

(vi) Medical Service[155]

(vii) Operating Theatres Service/Anaesthetic Service[156]

(viii) Pathology Service: *"evidence that quality indicators are reviewed on a service wide basis [for] – number of requests – frequency of loss of results – turn around times for results"*[157]

(ix) Specialist Care Services (i.e. ITU, ICU, PICU)[158]

(x) Health Record Content[159]

97. It would seem that Mr. William McKee, Chief Executive, regarded gaining KFOA accreditation for the Trust as important, as he was personally *"responsible for the Kings Fund Organisation Audit applications"*[160] albeit he delegated the management of the application to the Director of Nursing, Miss Elizabeth Duffin.[161] It is recorded in the minutes of the Trust's Formal Hospital Council meeting on 20th November 1995 that she and Dr. Gaston felt that the KFOA survey had been positive and a lot had been gained from the process. Miss Duffin referred to the observation of the KFOA surveyors: *"that the Hospital Council works very well as a corporate body but that firm links were needed at operational level to ensure that financial performance, activity and quality etc. are being achieved."*[162]

98. It is noteworthy that from 1992 to 2008 Dr. Gaston acted as a surveyor on behalf of the KFOA and thereafter its successor Health Quality

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152 Ref: 211-003-025
153 Ref: 211-003-026
154 Ref: 211-003-026
155 Ref: 211-003-026
156 Ref: 211-003-027
157 Ref: 211-003-028
158 Ref: 211-003-028
159 Ref: 211-003-029
160 Ref: 305-008-560
161 Ref: WS-061-2 p.8
162 Ref: 305-117-010

Service.[163] His potential contribution to systems of internal control will be a matter to be considered during the Oral Hearings.

99. It is also worth noting though that none of the 'key' Consultant clinicians who were involved in Adam's case appear to have had any knowledge of the Trust's engagement with the KFOA programme.[164] However, Dr. Mulholland, who was the acting Medical Director for Paediatrics, acknowledges changes in practice occurring as a result of the KFOA engagement, which he regarded as being in the main: "*related to precision in drug prescription and clinical note taking, in particular documenting what was said to the parents of children.*"[165] Furthermore, Dr. Carson, Medical Director, while unable to recall the outcome of the KFOA process, states, "*it would have contributed in some way to the improvement of risk management arrangements.*"[166]

100. The very fact that an application was made to KFOA, would suggest that there was a move towards improving systems of risk management at clinical directorate as well as corporate level, and that there was an interest in monitoring and reviewing the hospital's services and care.

101. The 1995/96 Annual Health & Safety Report to the Trust Board (Section 7) does however record that: "*This audit included criticism of aspects of health and safety management. The criticism is reflected in the Kings Fund criteria for which further action is required in order that we may obtain full accreditation ... In acknowledgement of the recommendations received, the medical director is leading a review of risk management arrangements within the Trust ... The Trust had already recognised a need to 'close the loop' in risk management, ensuring that policies and procedures for health and safety are effectively implemented at directorate level. This requires mechanisms for communication, audit and monitoring and a commitment to training.*"[167] (Emphasis added)

102. In a letter to the Inquiry dated 17th August 2011, the DLS has confirmed that the Trust achieved accreditation in 1997,[168] following the award of provisional accreditation in 1995/1996.[169] However, "*the documentation associated with this cannot be traced.*"[170] Accordingly, the detailed comments of the KFOA surveyors are not known, in particular

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163 Ref: WS-013-2 p.7

164 See the Inquiry Witness Statements of Professor Savage (Ref: WS-002-3 p.54), Dr. O'Connor (Ref: WS-014-3 p.17), Dr. Taylor (Ref: WS-008-3 p.41), Mr. Brown (Ref: WS-007-3 p.7-8) and Mr. Keane (Ref: WS-006-3 p.26)

165 Ref: WS-243-1 p.5. He goes on to state in his Inquiry Witness Statement that: "*engaging in the King's Fund Organisational Audit process was the main stimulus to improving record keeping*" – Ref: WS-243-1 p.8

166 Ref: WS-077-2 p.6

167 Ref: 305-007-196

168 Ref: 305-001-001

169 Ref: WS-061-2 p.121

170 Ref: 305-038-001

surrounding the award of provisional accreditation only. Nor is it properly known the means by which the Trust responded to those comments so as to achieve full accreditation eventually.

103. Nevertheless, it would seem from the Trust's Annual Health and Safety Report that was not until 1999-2000 that *"health and safety was fully integrated into a risk management system that includes clinical risk management."*[171]

104. The significance of the Trust only achieving KFOA accreditation and only establishing a fully integrated risk management system that incorporated clinical risk after the period of Adam's admission, treatment and death, are matters that will be pursued at the Oral Hearings.

VIII. Education and Training

105. A further issue for investigation has been that of education and training. There are two elements to this. One is whether the teaching and training that was being given to medical students was adequately preparing them for a case such as Adam's. The other is the extent to which the lessons learned from actual cases were used to inform medical education and training. To assist in this investigation the Inquiry briefed Dr. Michael Ledwith.

Standard & Scope

106. The GMC has a statutory duty, pursuant to the Medical Act 1983 to set and maintain the standards for medical education, and ensure that medical schools meet these criteria and outcomes *"through a process of regular visits to each medical school as part of the Quality Assurance of Basic Medical Education process."*[172]

107. Dr. Ledwith describes the educational context that existed before 1996 as being *"largely didactic"*[173] and states, *"educators would have broad awareness of topics likely to feature in examinations but the curriculum was not codified."*[174] However, he acknowledges that he has unable to *"obtain copies of curricula from before the mid nineties … for any medical school on the island of Ireland."*[175]

108. It seems that environment changed significantly with the introduction of the GMC's document 'Tomorrow's Doctors' in 1993. Based upon this

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171 Ref: 305-039-001
172 Ref: 303-046-522 & School Guidance; Preparing for the QABME process GMC document
173 Ref: 303-046-518
174 Ref: 303-046-518
175 Ref: 303-046-518

document, new curricula began to be formulated and introduced. In his commentary on Dr. Ledwith's Report, Professor Sir Alan Craft (Emeritus Professor of Child Health, Newcastle University, England) describes how: *"Until the production of the first version of 'Tomorrow's Doctors' in 1993 there was little, if any, central prescription from the GMC as to what should be in individual medical schools curricula"*.[176]

109. Dr. Ledwith states that there was *"no mechanism to ensure uniformity"*[177] in undergraduate teaching in Northern Ireland before 1996, and a picture is presented of an environment where a thorough knowledge of a particular field was ensured only by *"the random nature of topics which may have arisen in final examinations."*[178] Professor Craft agrees and states with particular reference to the undergraduate teaching of fluid management that *"there was no prescription as to what teaching there should be about fluid management and even less so for this in children. It was left to individual schools to decide what to include in their teaching and detailed instruction in fluid balance was not expected. Fluid management was not usually a part of the assessment process either during the course or at the end."*[179] Professor Craft then comments: *"Since the publication of 'Tomorrows Doctors' there has been a gradual move to a much more structured programme, with principles defined by the GMC and detailed implementation left to the individual schools"*.[180]

110. It is recognised that one of the basic factors which prompted the GMC to revise its guidance was the *"recognition of the fact that their previous stance of expecting medical students to have a comprehensive knowledge of medicine was no longer tenable."*[181] In addition to this, Professor Craft observes *"Prior to the late 1990's I would not expect a comprehensive knowledge of fluid management or of hyponatraemia, in particular, to be taught to UK medical students. Even now, in 2011, there is no mandate from the GMC that a detailed knowledge of fluid balance in children should be taught or the knowledge of it assessed."*[182]

111. As regards postgraduate medical education prior to Adam's transplant surgery, this was accredited through the Royal Colleges. The Inquiry has been advised by the Northern Ireland Medical & Dental Training Agency that at that time: *"curricula were variable or undefined; there was no recognised assessment process to mark when accredited training had been achieved; the duration of training varied between specialties and indeed, was generally not well defined … Essentially the system was inefficient, training was hit and miss … There was little by way of quality assurance and*

176 Ref: 303-047-562
177 Ref: 303-046-518
178 Ref: 303-046-518
179 Ref: 303-047-563
180 Ref: 303-047-563
181 Ref: 303-047-563
182 Ref: 303-047-564

evaluation of the professional examinations revealed little evidence of fitness for purpose".[183]

112. The publication of the Calman Report of 1993[184] marked a seminal moment in postgraduate medical education. It is regarded as a fundamental principle that specialist education was part of an overall continuum of medical education which extends from entry into medical school until retirement from medical practice. However whilst it recognised the GMC as being ultimately responsible for standards of medical practice and general oversight of all medical education, it called for improved liaison between the Medical Royal Colleges, Faculties and Postgraduate Deans as well as the NHS management: *"as both NHS management and Postgraduate Deans have legitimate interest in the development of structured training"*.[185] Amongst its recommendations were that the medical Royal Colleges and Faculties should set standards in medical education and that greater cooperation between bodies was required, arguing that NHS management and Postgraduate Deans had a legitimate interest in training.

113. The response to the Calman Report was a Consultation Paper published in April 1995,[186] leading to the European Specialist Medical Qualifications Order of 1995[187] and the establishment of the Specialist Training Authority of the medical Royal Colleges in 1996. The structured changes that were introduced included the Royal Colleges proposing standards with the Postgraduate Deans being responsible for implementing them.

114. Dr. Ledwith concludes in his Report *"since 1996 in Northern Ireland and elsewhere in the United Kingdom the teaching of medical students has become progressively more formalised with medical schools following more clearly delineated curricula."*[188] The clinicians who were involved in Adam's care and treatment following his admission on 26th November 1995 would therefore all have received their medical education and training under a much less structured and consistent system.

Fluid Balance & Sodium Management

115. The Inquiry received information from the Faculty of Medicine and Health Sciences, the Queen's University Belfast and the School of

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183 Ref: INQ-0066-09 p.2

184 HMSO (1993) 'Hospital Doctors: Training for the Future'; Report of the Working Group on Specialist Medical Training

185 Ref: Postgraduate Medical Education and Training Board (July 2009) 'Development of the Regulation of Postgraduate Medical Education and Training'; PMETB

186 Department of Health (1995) Hospital Doctor: Training for the Future. Proposals for Implementing Legislation 'The Specialist Medical Order'

187 SI 1995 no.3208 The European Specialist Medical Qualifications Order 1995

188 Ref: 303-046-522

Medicine, Dentistry and Biochemical Sciences, the Queen's University Belfast, dealing with the teaching of fluid management and hyponatraemia for the period from about 1975.[189] In addition, Dr. Ledwith was particularly asked to consider the medical teaching and training on 'Fluid Balance and Sodium Management in Northern Ireland and the Republic of Ireland from 1975 to 2009'.[190] His Report for the Inquiry provided a review of education, teaching and training from an undergraduate level through to the appointment of doctors into specific consultant posts within Northern Ireland, together with their continuing medical education.

116. The Legal Team compiled a 'Comparative Table of Education and Training of the Doctors',[191] relating to the specific clinicians involved in Adam's case. That schedule, which was opened to you Mr. Chairman during the Oral Hearing into clinical matters, details the information that the clinicians themselves provided[192] as to their own knowledge of fluid management, hyponatraemia and proper record keeping from teaching and/or training:

    (i) At undergraduate level

    (ii) At postgraduate level

    (iii) During their hospital induction

    (iv) During Continued Professional Development (CPD) training

    (v) In their experience as clinicians/nurses

117. When Dr. Taylor was asked to describe in detail his own education and training, he states that he holds no records of training in fluid management at either undergraduate, postgraduate or hospital induction level.[193] Professor Savage, when asked the same, states that it would be *"virtually impossible"* for him to provide an answer with regards to undergraduate study, but in respect of postgraduate level he confirms that he *"would have received teaching and undertaken study in the management of fluid balance and prescription, particularly for children, as all of my postgraduate study except for one year, was in Medical Paediatrics"*.[194] It is relevant to note that that he further states *"there were generally no formal induction programmes"* in operation at the time of his induction.[195]

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189 Ref: INQ-0062-09
190 Ref: 303-046-514
191 Ref: 306-005-028
192 It should be noted that the Legal Team is not in a position to verify the details provided by the clinicians that have been incorporated into the Table
193 Ref: 306-005-037 & WS-008-2 p.46
194 Ref: 306-005-033 & WS-002-2 p.28
195 Ref: 306-005-033 & WS-002-2 p.28

Mr. Patrick Keane refers to *"practical experience in wards"* at undergraduate level and *"in paediatric surgery in Galway which was part of the adult workload"* at postgraduate stage.[196] He goes on to state that his position as Lead Clinician in Urology (1995-2003) and Programme Director in Urology for 7 years ensured that he was *"responsible for the post graduate education of all trainees in Northern Ireland. Hyponatraemia is a very common problem in urology and its diagnosis and management were dealt with on multiple occasions and it is a continuing and important part of the urology curriculum."*[197]

118. For many doctors the initial guidance as to which fluids to prescribe would seem to come from experienced nurses on the ward. Dr. Ledwith states: *"the importance of this aspect of the training of junior doctors should not be underestimated."*[198] He proceeds to describe an environment in which *"some wards may have had specific guidelines as to which fluids to use and when but in most cases the doctor would be free to prescribe fluids as he or she saw fit. Further confusion could sometimes be introduced by the fact that different consultants might have had different personal stipulations concerning fluids. Fluid management would change according to which consultant was on call on a particular night"*.[199]

119. Dr. Taylor states that he was aware of the Arieff article at the time of Adam's transplant surgery[200] whilst Dr. Montague concedes that he was not.[201] Nevertheless, Dr. Taylor went on to misunderstand completely the development of dilutional hyponatraemia in Adam, as explained by Dr. Coulthard during his evidence at the Oral Hearings[202] and as conceded by Dr. Taylor.[203] Furthermore, Dr. Taylor appears to have completely misunderstood Adam's polyuric condition and its implications for his fluid management. He planned Adam's fluids on the basis that his fluid requirement for maintenance was a minimum of 200mls per hour[204] and claimed during his PSNI interview under caution that it was not possible to calculate Adam's maximum hourly urine output and likened him to *"a hole in the bucket, I had to get that bucket filled up … And keep it full"*.[205]

120. In summary, Dr. Ledwith reaches the following conclusions in respect of education and training in and around 1995:

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196 Ref: 306-005-035 & WS-006-02 p.15
197 Ref: 306-005-035 & WS-006-02 p.15
198 Ref: 303-046-527
199 Ref: 303-046-527-528
200 Ref: 011-014-108
201 Ref: Transcript of Oral Evidence of Dr. Montague, 11th May 2012 p.158, line 7
202 Ref: Transcript of Oral Evidence of Dr. Coulthard, 9th May 2012 p.98, lines 4-6
203 Ref: Transcript of Oral Evidence of Dr. Taylor, 19th April 2012 p.40, lines 3-8
204 Ref: WS-008-1 p.4
205 Ref: 093-038-195 and Ref: 093-038-241

(i) It was not the general practice for undergraduate or postgraduate curricula to include specifics of intravenous fluid management in children

(ii) There was little or no specific teaching concerning hyponatraemic encephalopathy

(iii) Junior doctors being asked to manage children post-operatively would rely on knowledge gained on adult surgical wards during their pre-registration year and on advice from experienced nurses[206]

121. Nevertheless, Dr. Haynes' evidence at the Oral Hearings was that the type of error Dr. Taylor made in his calculations of Adam's fluid management requirements was absolutely basic. He emphasised that by going on to explain the principles underlying those calculations from a chapter in a textbook that he used to help his son with his GCSE biology exam.[207]

Continuing Professional Development

122. Dr. Ledwith observes that maintaining, until very recently, awareness of advances and changes in clinical practice was seen as the personal responsibility of each consultant.[208] He also states "*there was no formalised mechanism for ensuring that any individual consultant was practising up-to-date medicine*"[209] and that there was no external body ensuring "*consultants would keep themselves up to date with changes or advances in clinical practice.*"[210]

123. However, changes in how consultants work within the NHS, including a new contract for consultants, were introduced in 1994 which, along with an appraisal system set up by the various Royal Colleges in the early 1990s, "*combined to dramatically increase the pressure on [the] consultant to keep up to date with changes in practice.*"[211]

124. It is unclear but a matter to be further investigated is the extent to which such a system is able to cater adequately for the Consultant who is unaware of his error and therefore does not appreciate the extent to which further training may be necessary. It will be appreciated Mr. Chairman that Dr. Taylor steadfastly defended his arguments on the implications of Adam's chronic renal failure and polyuria for both the fluid plan he calculated for Adam's transplant surgery and the fluids

206 Ref: 303-046-538
207 Ref: Transcript of Oral Evidence of Dr. Haynes, 2nd May 2012 p.18, lines 13-21
208 Ref: 303-046-532
209 Ref: 303-046-532
210 Ref: 303-046-532
211 Ref: 303-046-533

he actually administered during it. Indeed, in an undated note to the Trust's solicitors Dr. Taylor stated *"After the transplanted kidney failed to function I was very concerned that despite my best calculations and estimate of the losses I had not given sufficient fluid!"*[212]

125. The Inquiry has yet to be provided with any evidence that at the time of Adam's transplant surgery the Trust had established a system for systematically monitoring the competence of any clinician. Nor has the Inquiry been provided with evidence to show that at that time the Trust had a system by which it might be satisfied that the clinicians involved in the paediatric renal transplant programme being carried out at the Children's Hospital were competent for the task. These are matters to be taken up during the Oral Hearings.

Integrating Lessons Learned

126. As can be seen from their respective contracts of employment and curriculum vitae as at 1995 the lead members of Adam's transplant team, Professor Savage,[213] Dr. Taylor[214] and Mr. Keane,[215] all had teaching duties at the Queen's University Belfast.[216] Indeed, prior to 1995, Professor Savage was a member of the Faculty of Medicine Education Committee which had responsibility for course design, development and quality assurance and then in 1995 he became its Chairman.[217] He states in his curriculum vitae:

"In the early 1990's, the University was becoming aware that the current undergraduate course needed to be completely redesigned with the introduction of new teaching and learning methods, and with the integration of scientific and clinical aspects of medical education following the publication of 'Tomorrow's Doctors' by the General Medical Council ... I played a key role in laying the ground work for the massive change involved in re-organising teaching away from a traditional clinical department based model to an integrated scientific and clinical model, system-based in the early years and introducing early clinical skills acquisition and contact."[218]

(Emphasis added)

127. The Inquiry has been advised by Professor Mullan that the Trust and the University are likely to have had a joint forum for the management

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212 Ref: 059-004-007
213 Ref: 306-018-002 and Ref: 301-033-365
214 Ref: 306-019-010 and Ref: 301-033-372
215 Ref: 306-023-001 and Ref: 301-033-378
216 Such duties were not confined to them since Dr. McKaigue, who was at the time a Consultant Paediatric Anaesthetist, was also required by his 1995 terms and conditions of employment to assist the Faculty of Medicine, the Queen's University Belfast with teaching – Ref: WS-129-1, 29
217 Ref: 306-018-008
218 Ref: 306-018-008

of their relationship in respect of the provision of medical education and training but that ultimately the quality of the teaching by the clinicians at the University would be a matter for the Deanery.

128. Professor Patrick Johnston, current Dean, School of Medicine, Dentistry & Biomedical Sciences at the Queen's University Belfast, has sought to assist the Inquiry explaining something of the structure in operation at the time[219] by providing a Witness Statement[220] and a number of specimen documents. It would seem from the material he has provided that at the relevant time the University had (and has) overall responsibility for medical education including up to the year immediately after graduation, which was known in the 1990s as the 'Pre-Registration year'.

129. The clinicians at the Trust formed an integral part of the delivery of that medical education,[221] which was facilitated by the Supplement for Teaching and Research to fund the additional cost to the Trust of providing medical and dental teaching in clinical settings.[222] Although the Inquiry has not been provided with any cooperation agreement governing the University, Trust and Department that was current in 1995, Professor Johnston has provided a 'Framework of Agreement for Joint Working between Queen's University, Belfast Health & Social Care Trust and the Department of Health Social Services and Public Safety'[223] that might be indicative. He has also provided a pro forma 'Service Agreement' between the Faculty and the Trust for the Trust's provision of teaching facilities.[224]

130. The actual delivery of the services provided by the Trust would seem from the 1995 Report of the Visit to the Queen's University of Belfast Faculty of Medicine by the GMC[225] to have been organised on the University's side through a Pre-Registration Committee, which included the Dean of Medicine, Post-Graduate Dean and the Professors of Medicine and Surgery. The functions of the Pre-Registration Committee included the approval of participating hospitals, the

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219 Albeit that in 1995 he was neither employed by the Queen's University Belfast nor working in Northern Ireland

220 Ref: WS-256-1

221 The joint (Trust-Queen's University Belfast) clinical academics have contracts relating to their 'joint role and duties' - Ref: WS-256/1 p.11

222 See the Department's 'Review and Modernisation of Supplement for Undergraduate Medical and Dental Education (SUMDE)', 2009

223 Ref: WS-256-1 p.326

224 Ref: WS-256-1 p.321

225 Report of the Visit to Queen's University of Belfast Faculty of Medicine, members of GMC Education Committee, 27-28 November 1995 – Ref: WS-256-1 p.52

monitoring of attachments[226] and the appointment of clinicians as educational supervisors.

131. On the Trust's side, the services appear to have been managed through an Educational Supervisors' Sub-Committee, which reported to the Pre-Registration Committee.

132. The precise structure in 1995 is a matter that will be pursued during the Oral Hearings.

133. Professor Mullan has advised the Inquiry that it is likely that the Directorates within the Trust established committees in relation to education and training. Indeed Dr. Taylor was on the Education Sub-Committee of the Anaesthetics, Theatre and Intensive Care Directorate for 1992-1994 and 1995–1997.[227]

134. The likely effect of Dr. Taylor's views on his fluid administration and the cause of Adam's death on the use of that case as a teaching tool, as Dr. Montague has done, is a matter that will be considered during the Oral Hearings.

135. The scope for integrating the lessons learned from clinical practice into teaching may well have been a matter determined by the curricula and the Deanery. However, Dr. Montague, who is now Consultant in Paediatric Anaesthesia and Intensive Care at Our Lady's Children's Hospital in Dublin, has indicated in his evidence during the Oral Hearings what may have been possible in relation to Adam's case: *"I teach about hyponatraemia [both doctors and nurses about perioperative fluid management in children[228]] and I talk about Adam every time I teach about it"*.[229]

136. Professor Johnston refers in his Inquiry Witness Statement to there being no formal system for ensuring that any issues arising out of a serious untoward/adverse incident in a hospital were reported with a view to including any lessons learned into the curriculum.[230] However, he refers to their being *"very close working relationships between paediatricians in the RBHSC, and Joint Appointment clinical academics (QUB RBHSC), all of whom also had NHS responsibilities.*[231] *It would be*

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226 The Student Guide for 1995-1996 includes Musgrave Ward at the Children's Hospital as one such attachment for paediatrics. See too Altnagelvin Area Hospital, the Erne Hospital and Craigavon Area Hospital – Ref: WS-256-1 p.19

227 Ref: 306-019-011

228 Ref: 306-031-004

229 Ref: Transcript of Oral Evidence of Dr. Montague, 11th May 2012 p.155, lines 9-10

230 Ref: WS-256-1 p.12

231 See too the information provided on this issue by Professor Rod Hay, formerly Dean of Faculty of Medicine and Health Science, in a letter to the Inquiry dated 7th July 2005 – Ref: 306-075-001

inappropriate for information on such incidents to be passed on to undergraduates until proper and full investigations had been completed."[232]

137. The extent to which clinical experience and learning gained from Adam's case found its way into teaching is something that will be explored during the Oral Hearings, as are the processes and structures through which this might have been made possible. The integration of clinical experience and 'lessons learned' into medical teaching and training is also a general issue that will be explored in the successive cases of Claire, Lucy, Raychel and Conor as well examining the current position.

138. It will be recalled Mr. Chairman that Dr. Haynes expressed his concern during the Oral Hearings over Dr. Taylor's teaching role having made the errors that he did in his fluid management of Adam *"and not apparently being able to appreciate, recognise or acknowledge that so sort of errors had been made for so long"*.[233]

139. The Inquiry has received no evidence that the concerns that Dr. Taylor's colleagues had about his fluid management of Adam during the transplant surgery, especially any implications they felt it had for his knowledge of end-stage renal failure and the appropriate fluid management for anaesthesia in such circumstances, was raised in relation to his teaching or drawn to the attention of the Deanery. Those are also matters that will also be pursued during the course of the Oral Hearings.

IX. Information and Consent

140. The giving and gaining of a valid consent by a patient before treatment is more than a legal requirement or a matter of courtesy. It is also a right incorporated into the 1992 Northern Ireland HPSS 'Charter for Patients and Clients'[234] which was introduced as *"part of a comprehensive programme to improve the quality of services."*[235]

141. The foreword to the Charter dated March 1992 from the Minister for Health and Social Services, states: *"As the Minister responsible for the health and personal social services in Northern Ireland, this Charter is my personal pledge to all citizens that services in Northern Ireland will continue to match the very best available in the rest of the United Kingdom."*[236] The Charter declares the patient's right to *"be given clear information about*

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232 Ref: WS-256-1 p.12
233 Ref: Transcript of Oral Evidence of Dr. Haynes, 2nd May 2012 p.29, lines 6-14
234 Ref:306-085-001 *et seq*
235 Ref:306-085-003
236 Ref:306-085-003

any treatment or care proposed including any risks and any alternatives, and to have your own wishes taken into account as far as possible" and "*to be kept informed about your progress"*, and further that "*relations and friends are also entitled to be informed"*.[237] This right, which in Adam's case transferred to his mother because of his age, was reflected in the codes of professional conduct of healthcare professionals in the UK, was contained in the British Medical Association ("BMA") Guidance to Doctors and enshrined in law.

142. However, a patient's right to sufficient information to give informed consent was established in law long before the Charter. Indeed the importance of proper and valid consent was regarded as so important that in 1990 the DoH published its 'Guide to Consent for Examination or Treatment'. This states "*a patient has the right under common law to give or withhold consent prior to examination or treatment… This is one of the basic principles of healthcare."*[238] It further states "*patients are entitled to receive sufficient information in a way that they can understand about the proposed treatments, the possible alternatives and any substantial risks, so that they can make a balanced judgment. Patients must be allowed to decide whether they will agree to the treatment, and they may refuse treatment or withdraw consent to treatment at any time."*[239]

143. The guidance also deals with the concept of choice of treatment: "*where a choice of treatment might reasonably be offered the health professional may always advise the patient of his/her recommendations together with reasons for selecting a particular course of action. Enough information must normally be given to ensure that they understand the nature, consequences and any substantial risks of the treatment proposed so that they are able to take a decision based on that information."*[240] And further: "*written consent should be obtained for any procedure or treatment carrying any substantial risk or substantial side effect … written consent should always be obtained for general anaesthesia, surgery, certain forms of drug therapy ..."*[241]

144. The main purpose of written consent is described as "*to provide documentary evidence that an explanation of the proposed procedure or treatment was given and that consent was sought and obtained. Where written consent is obtained it should be incorporated into the notes"*[242] The guide proceeds to emphasise the importance of discussing treatment with the multi-disciplinary team and other doctors. These discussions, it is stated, should also be documented in the clinical case notes.[243]

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237 Ref:306-085-004
238 Ref: 210-003-017; Health Circular (90)22
239 Ref: 210-003-017
240 Ref: 210-003-017
241 Ref: 210-003-018
242 Ref: 210-003-018
243 Ref: 210-003-018

145. Then in 1991 the DoH issued further guidance entitled 'Welfare of Children and Young People in Hospital'[244] which directs that hospitals *"should ensure that good practices are followed on seeking consent to the treatment of children: a guide to consent for examination and treatment, published by the NHS Management Executive in August 1990, will be of assistance here"*.[245] The British Association for Paediatric Nephrology stated in 1995 that *"any unit offering care for children and young people with renal disease will be expected to implement in full the DoH guidelines 'Welfare of Children and Young People in Hospital'"*.[246] Mr. McKee does not however *"recollect this guidance being adopted by the Department of Health in Northern Ireland."*[247]

146. The NHS Management Executive issued its 'Risk Management in the NHS' Manual in December 1993. This notes *"Obtaining consent to treatment is an area almost entirely under the control of professional healthcare staff and not one in which managers are generally involved. But managers have a responsibility to ensure that professionals are fully aware of their obligations and understand the legal framework in which they are operating."*[248] (Emphasis added)

147. The 1990 Guide to Consent was amended by the 1992 NHS 'Patient Consent to Examination or Treatment' Guidelines[249] which were in turn consolidated within Northern Ireland by a handbook published on 6th October 1995 containing most of the advice previously included in the 1990 guidelines together with the model consent forms as contained in the 1992 publication. The guidance was distributed by the Chief Executive of HPSS Northern Ireland with explicit instructions that: *"Health and Social Service Boards/HSS Trusts are asked to ensure that procedures are put in place to ensure the consent is obtained along the lines set out in the Handbook and introduce revised documentation (preferably based on the new model consent forms described in it) with adequate monitoring arrangements"*.[250] (Emphasis added)

148. There is no documentary evidence that the Trust had any policy in 1995 to ensure that new guidance was distributed to clinicians or that it was implemented or that any checks were made to ensure that new guidelines and practices were in place and working. It is noteworthy that the HPSS letter which accompanied the Patient Consent handbook on 6th October 1995 stipulated that: *"Boards/HSS Trusts are asked to confirm by 31 December 1995 that this has been done. Confirmation should be*

244 Ref: 210-003-019 & Department of Health: The Stationary Office, 1991
245 Ref: 210-003-019
246 Report of a Working Party, March 1995, The Provision of Services in the United Kingdom for Children and Adolescents with Renal Disease
247 Ref:WS-061-2 p.7
248 Ref: 211-003-008
249 Ref: 210-003-018 & Issued by the NHS Management Executive, 28th July 1992, SG (92) 32
250 Ref: 305-002-003; Circular HSS (GHS) 2/95

sent to Mr. N. Lunn, General Hospitals Policy Branch, Room 115, Dundonald House, to whom any enquiries about this circular should also be sent."[251] (Emphasis added)

149. Whilst Mr. McKee is unable to assist in understanding how the patient consent handbook was distributed and put to use; he is able to advise that *"In general, external guidance was received by staff in the Chief Executive's officer and then disseminated to the relevant Clinical Director(s) and their senior management teams for action. On occasion, an expert committee may have been required to consider guidance, for example the Health and Safety Committee. Clinical Directorates and expert committees would then be required to report progress back through accountability arrangements to Trust Board."*[252]

150. There is no evidence that the required action was taken or that any such confirmation was given. Rather the evidence of the clinicians during the Oral Hearings was that the 1995 guidance had not 'cascaded' down to them.[253] Indeed none of the clinicians were aware of any specific written guidance in relation to consent.[254]

151. Accordingly, there is doubt as to the efficiency of whatever systems of internal control the Trust had in place in 1995 for ensuring that clinical and non-clinical policies, guidelines and regulations were implemented. Ironically, there appears to have been no relevant guidance issued to hospitals at that time as to how to determine whether guidelines were being complied with and for enforcing them if necessary. The Trust engagement with KFOA may have provided an important to the implementation of policy, guidelines and regulations.

152. In November 1998, which is of course, a few years after Adam's death, the British Transplant Society, following wide consultation amongst its members, members of the Renal Association and the Royal Colleges of Surgeons and Pathologists, compiled a document titled 'Towards Standards for Organ and Tissue Transplantation in the United Kingdom' as representing the best of current or the most desirable practice. This contains a section discussing "*Consent for transplantation*" at paragraph 2.2.1.5 which states:

"All patients should receive a full explanation of the risks and benefits of the proposed transplant. Discussion of all the common complications, any additional risk factors for the particular recipient, and any potentially serious complications (even if they are relatively rare) should take place and should be documented."

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251 Ref: 305-002-004
252 Ref: WS-061-2 p.11
253 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.65 line 25 to p.66 line 5
254 Ref: WS-002-3 p.11 and WS-006-3 p. 22

Process of Consent in Adam's Case

153. In terms of how Adam's mother gave her consent to Adam's surgery, it is relevant to note that she has stated that *"the only complication that was discussed with me was that of rejection."*[255] She confirms that this risk was explained to her by Professor Savage. Although, Professor Savage recalls matters differently, asserting in his Inquiry Witness Statements and in his evidence at the Oral Hearings that it is likely that he discussed a number of additional matters with her, including:[256]

(i) The suitability of the kidney in terms of tissue match and the age of the donor

(ii) The process of going to theatre

(iii) The potential length of time in theatre

(iv) Details of the anaesthetic and analgesia to be provided

(v) The likelihood of success of transplant

(vi) The names of the Transplant Surgeon and the Consultant Anaesthetist, and that there was likely to be Paediatric Consultant Surgeon[257]

(vii) The possibility of rejection[258]

(viii) The risk of blood loss during surgery[259]

(ix) The need for a change in his overnight feeds and for IV fluids[260]

154. Apart from the signed consent form[261] no additional information is recorded, certainly none of the information referred to by Professor Savage. Indeed, he states *"I was unable to identify in Adam's notes any records of discussions which I had with Ms. Slavin in relation to obtaining consent nor in relation to the detail of the transplant surgery."*[262] He goes on to state: *"It was not my habit at that time to make such detailed notes, but would now be standard practice. Modern consent forms now require the list of potential complications be discussed. This was not so in 1995"*.[263] Professor

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255 Ref: WS-001-2 p.5
256 Ref: WS-002-3 p.5
257 Ref: WS-002-3 p.5. Note that Professor Savage apologised at the Oral Hearings for not informing Adam's mother beforehand that Mr. Brown would be the Consultant Paediatric Surgeon - Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.128 lines 6-11
258 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.33 lines 4-6
259 Ref: WS-002-2 p.12
260 Ref: WS-002-2 p.12
261 Ref: 058-039-185
262 Ref: WS-002-3 p.11
263 Ref: WS-002-3 p.11

Savage in his evidence given in relation to the 1995 Consent Guidance Handbook said that he *"had not seen that document, to the best of my knowledge in November 1995."*[264] It is to be noted that the modern consent forms were current from 1992 NHS Guidance although seemingly not actually adopted by Children's Hospital until 2000.[265]

155. The option of carrying out the transplant at an alternative hospital to the RBHSC was not raised. Professor Savage states: *"as there was only one venue for transplant surgery in Northern Ireland for a child of Adam's age, I did not offer Ms. Slavin any other venue for the transplant"*[266] and further recalls: *"I did not consider arranging for a paediatric renal transplant surgeon to be involved. There is no specific paediatric renal transplant surgeon in Northern Ireland and as in many other units at the time and indeed now, this type of surgery, which is extremely specialised, is carried out by transplant surgeons who generally have an adult background"*.[267] There was no discussion with Adam's family as to the best hospital to undertake the transplant surgery.

156. Other issues which might properly have been discussed in order to inform the consent process in accordance with guidance were:

(i) The choice of using a live donor rather than a cadaveric donor. Adam's mother states *"I asked if I could donate but as a single parent this was not allowed, apart from that there was no other discussion on a living donor."*[268]

(ii) The information that might have been obtained from multi-disciplinary team meetings, in particular from the involvement of a surgeon and anaesthetist.[269]

(iii) Adam's mother was not informed before the transplant that the team included the surgeon Mr. Brown. Adam's mother states *"I was unhappy about Mr. Brown due to a previous procedure"*[270] and *"I had no idea that Mr. Brown was going to be present; this would have been an issue for me because I had quite clearly stated in the past that I did not want Mr. Brown to be involved in any surgery with Adam because previous experience had left me with no faith in him"*.[271] Professor Savage accepted in his oral evidence that he had *"no reason ever not to believe what Debra Strain [Ms. Slavin] says. She*

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264 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.66, line 1
265 Ref: 306-084-001 et seq
266 Ref: WS-002-3 p.11
267 Ref: WS-002-3 p.11
268 Ref: WS-001-02 p.5
269 Mr. Keane and Dr. Taylor both confirmed that there was no involvement of a multi-disciplinary team in planning and informing Adam's mother prior to her giving consent, which was taken by Professor Savage - the Paediatric Nephrologist alone - Ref: WS-006-3 p.20 and Ref: WS-008-3 p.5
270 Ref: 011-009-027
271 Ref: WS-001-1 p.2

obviously did have an antagonism to Mr. Brown … but that was not something that I probably took into account that evening or indeed thought about."[272] It is perhaps worth noting that the 1993/1994 Annual Report of the Royal Hospitals included under "*Charter for Patients and Clients*" a commitment that "*Patients and their families shall be entitled to be told the name and status of each person involved in their care."*[273]

(iv) No information seems to have been given Adam's mother as to the relevant experience or inexperience of the surgical team.

157. What the guidance in operation at the time of Adam's transplant surgery for obtaining consent actually was and whether it was followed are matters to be explored during the Oral Hearings, as is the extent to which it represented 'common practice' in 1995.

Post-consent Communication

158. Communication between the medical professionals and Adam's mother did not of course end with the taking of consent. She states that Dr. O'Connor gave her information during and after surgery[274] as did Professor Savage.[275] There is no evidence however that any surgeon explained to her what might have happened to Adam during surgery. As Professor Savage observed in his oral evidence, "*it would have been good if one of the surgeons had come and spoken to them, but they didn't."*[276] "*The practice*" Dr. Taylor says he "*was taught was to go and see patients afterwards, so that one could be aware of benefits and complications of one's own practice."*[277]

159. Adam's mother states[278] that she was told that something had gone "*drastically wrong*" but that no one gave her an indication why. She states that Dr Taylor told her this was a '*one-in-a-million thing'*. In his evidence at the Oral Hearings Dr Taylor '*wholeheartedly*' apologised for what he now considers was a "*really quite silly statement*" of "*meaningless statistics*". [279]

160. Professor Savage did maintain contact and speak with Adam's mother[280] but only agreed to discuss the medical opinions with her "*provided Dr. Murnaghan was happy and there were no medico-legal reasons*

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272 Ref: Transcript of Oral Evidence of Professor Savage, 17th April 2012 p.169, line 23, and p.170, line 21
273 Ref: WS-061-2 p.42
274 Ref: 093-003-004
275 Ref: 093-006-019
276 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.158, line 11
277 Ref: Transcript of Oral Evidence of Dr. Taylor, 20th April 2012 p.135, line 1
278 Ref: WS-001-1 p.2-3
279 Ref: Transcript of Oral Evidence of Dr. Taylor, 20th April 2012 p.136, lines 4-6
280 Ref: 093-006-019

to suggest otherwise."[281] There is no evidence of any formal communication with or further information being given to Adam's family by the Trust.

161. It is a matter to be considered at the Oral Hearing whether Adam's mother was given sufficiently full information immediately after the operation, and subsequently.

X. Keeping and Management of Medical Records

162. Records and data of all sorts are an invaluable resource because of the information they contain. High quality information is the foundation which allows high quality, evidence based healthcare to be provided. Information has most value when it is accurate, comprehensive, up to date and accessible. It is necessary for clinical and other types of audit and review and research; for the support of the proper administration of the systems delivering the healthcare itself and to form the evidence that the systems are indeed effective.

Guidance on Record-keeping

163. The Royal College of Surgeons of England published its 'Guidelines for Clinicians on Medical Records and Notes' in 1990 (and revised the same in 1994).[282] These describe clearly the record keeping and monitoring which would have been expected from a hospital such as the Children's Hospital in relation to the preparation for and steps taken during surgery. The DoH 1993 'Risk Management in the NHS' Manual addresses the importance of medical records[283] and records generally, including their role in risk management through 'tracking, trending, monitoring and projection'. Thus, at the time of Adam's surgery, relevant and up to date guidance was available with regard to record keeping.

164. The UK Central Council for Nursing (UKCC)[284] published its standards for records and record keeping in April 1993.[285] In the context of nursing this document described the purpose of medical records as to provide:

    (i) Accurate, current, comprehensive and concise information concerning the condition and care of the patient and associated observations

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281 Ref: 011-033-165
282 Ref: 210-003-026
283 See p.23 and chapter 25 at p.99 *et seq*
284 This was the predecessor to the Nursing & Midwifery Council
285 Ref: 202-002-052

(ii) A record of any problems arising and the action taken in response to them

(iii) Evidence of care required, intervention by professional practitioners and patient or client responses, including a record of any factors (physical, psychological or social) that appear to affect the patient

(iv) Record the chronology of events and the reasons for any decisions made; to support standard setting, quality assessment and audit

(v) Provide a base line record against which improvement or deterioration could be judged

165. It seems that the UKCC found it necessary to prepare this statement as to standards because substantial evidence had led it to believe that inadequate and inappropriate record keeping concerning the care of patients had given rise to impairment of continuity of care, discontinuity of communication between staff, the creation of risk of medication or other treatment being duplicated or omitted, a failure to focus attention on early signs of deviation from the norm and a failure to place on record significant observations and conclusions. It summarised the principles underpinning both records and record keeping:

"*The following principles must apply:*

(i) *The record is directed primarily to serving the interests of the patient or client to whom it relates and enabling the provision of care, the prevention of disease and the promotion of health*

(ii) *The record demonstrates the accurate chronology of events and all significant consultations, assessment, observations, decisions, interventions and outcomes*

(iii) *The record and the activity of record keeping is an integral and essential part of care and not a distraction from its provision*

(iv) *The record is clear and unambiguous*

(v) *The record contains entries recording facts and observations written, at the time of, or soon after, the events described*

(vi) *The record provides a safe and effective means of communication between members of the healthcare team and supports continuity of care*

(vii) *The record demonstrates that the practitioner's duty of care has been fulfilled*

(viii) *The record is constructed and completed in such a manner as to facilitate the monitoring of standards, audit, quality assurance and the investigation of complaints"*[286]

(Emphasis added)

166. Notwithstanding, the Inquiry has been informed: "*the RGHT had no policy or guidance in 1995 to inform clinicians of the standard of note and record making which was expected in preparation for and during the conduct of major paediatric surgery*".[287]

167. In 1995, the Audit Commission published 'Setting the Records Straight, a study of Hospital Health Records'.[288] This report observed that "*information about the clinical care of hospital patients is recorded in their health records or case notes. Accurate and comprehensive recording of information and accessibility to this information is essential for effective patient care and continuity of care between different health professionals. Case notes are also important for teaching, research and clinical audit, as well as being a source of managerial, financial and statistical data for the NHS. It is expected that they will play a key part in demonstrating clinical governance standards.*"[289] The Report identified a number of problems including lack of order, inadequacies in record keeping, the low status accorded records departments and the poor facilities for the storage of the records themselves. The report made several recommendations for records managers and Trusts and in particular, it suggested that Trust-wide health records policies be set, in conjunction with the establishment of health records committees, to monitor performance against the policies.[290]

Record-keeping and the Trust

168. There is little evidence to suggest that the Trust had followed this advice or had established a dedicated health records committee by 1995. In reviewing the available material Professor Mullan is critical in his Report to the Inquiry and states "*as a very minimum it would be reasonable to expect the Trust to have established a Medical Records Committee with accountability for ensuring compliance with guidance for record keeping in 1995. Representation from each Clinical Team plus medical records staff and senior management would have been the norm in 1995. This*

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286 Ref: 202-002-052
287 Ref: 305-123-001
288 Ref: 210-003-025
289 Ref: 210-003-025-6
290 Ref: 210-003-026

Committee would ultimately be accountable to the Chief Executive."[291] Compliance with guidelines could thus have been monitored along the established lines of accountability.

169. Mr. William McKee claims in his Inquiry Witness Statement that the Audit Commission Report did not apply to Northern Ireland.[292] Indeed Dr. Carson states in his Inquiry Witness Statement that: *"Awareness of Audit Commission or publications from professional bodies would have been for information only, and would have required direction by the DHSSPS."*[293]

170. Notwithstanding Mr. McKee's claim that the Audit Commission Report did not apply to Northern Ireland, it would nevertheless seem to be the case that some of the Report's recommendations have been considered by the Trust as Mr. McKee also states that: "*by 1995/96 a multi disciplinary medical records committee undertaking benchmarking of patient records service against cross channel teaching hospitals"*[294] was in place. Even so Mr. Williams, (the current Co-Director of Information Services, Belfast Health and Social Care Trust) states in his Inquiry Witness Statement that: *"in 1995-1996 there was no comprehensive governance framework for the management of records with H&SC Trusts. The circulars HS (31/83) and NIHA (75/76) did not relate to general corporate records; examples would include application for KFOA accreditation, anaesthetic and nursing rotas."*[295]

171. A number of issues arise in respect of the records relating to Adam's case. Some of these would not be matters of concern had an investigation into Adam's death been undertaken at the time. Others have already been explored by the Inquiry in its investigation into Adam's clinical matters. Whilst it is recognised that the sheer length of time since Adam's transplant surgery and death has undoubtedly complicated any analysis of the adequacy of the record-keeping, nonetheless the following are noteworthy from a governance perspective:

    (i) Whilst there is a signed consent form,[296] there is no record of the discussions that Professor Savage claims to have had with Adam's mother following his admission on 26th November 1995.[297]

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291 Ref: 210-003-029
292 Ref: WS-061-2 p.14
293 Ref: WS-077-2 p.11
294 Ref: WS-061-2 p.10
295 Ref: WS-251-1 p.5
296 Ref: 058-039-185
297 This is conceded by Professor Savage who acknowledges in his Inquiry Witness Statement that he subsequently changed his practice to record such discussions (Ref: WS-002-3 p.11d(ii)). However, it is not clear the extent to which that was prompted by Adam's case or by other factors such as the involvement of KFOA.

(ii) The medical care plan,[298] compiled by Professor Savage does not contain all the relevant instructions for Adam's pre and intra-operative medical care, as laid down by the Children's Hospital's 1990 'Protocol for Renal Transplant'.[299] The entry is signed but not timed by Professor Savage. It contains nothing relating to Mr. Keane's or Dr. Taylor's plans for surgical or anaesthetic management.

(iii) The Experts have commented both in their Reports and their evidence during the Oral Hearings on what they regard as deficiencies in record keeping:

- Failure to detail the pre-operative discussions held in relation to consent or pre-operative history[300]
- Failure to record Adam's weight properly, which is a significant factor in terms of fluid management[301]
- Failure to record the peritoneal dialysis for 26th and 27th November 1995 properly. There was no prescription sheet equivalent to the one for his peritoneal dialysis in PICU and there is doubt over whether the Children's Hospital retained its own records of paediatric peritoneal dialysis independent of those kept by the families[302]
- Failure to record the nature of the 'clear fluid' detailed in Adam's medical notes and records for 26th November 1995 properly.[303] A failure also to properly record the administration of the IV fluids administration,[304] as neither the prescription written up by Dr. Jacqueline Cartmill nor the notes that she made for 26th November 1995 recorded when the IV fluids were to start. Also Staff Nurse Murphy appears

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298 Ref: 059-006-011

299 Ref: WS-002-2 p.52

300 It was conceded by Professor Savage that subsequently his practice was to record such discussions

301 The 'Patient Information Form' fails to complete any entry for weight - Ref: 057-007-008. Also Adam's weight is variously recorded in his medical notes and records for 26th and 27th November 1995 as 20kg – Ref: Anaesthetic Record – Ref: 058-003-007; 20.2kg - Fluid Balance and IV Prescription Sheet - Ref: 057-010-013. See too: Nursing Admission Sheet – Ref: 057-013-018, weight chart – Ref: 057-12-016, Parenteral Drugs Prescription Sheet – Ref: 057-021-033, Treatment Form – Ref: 058-036-145, and the entry by Dr. O'Neill in Adam's medical notes and records at 22:30 – Ref: 058-035-131; and 21kg - entry by Professor Savage in Adam's medical notes and records following the cross-matching at about 01:00 – Ref: 058-035-133); "*the weight of 21kg is an approximate weight used simply to make a calculation of surface area*" (WS-002-2 p.12)

302 Ref: 057-015-021. Note this was criticised by Dr. Coulthard in his evidence during the Oral Hearings - Transcript of Oral Evidence of Dr. Coulthard, 8th May 2012 p.71, lines 15-23

303 Ref: 057-010-013

304 Nevertheless Professor Savage's evidence was that he remained in the Children's Hospital and available to respond to queries until about 02:00 on 27th November 1995 - Ref: WS-002-2 p.13

inexplicably to have erroneously recorded the re-insertion at 05:00 of the cannula that had tissued at about 01:30[305]

- Failure to record Adam's urine output both prior to and during his surgery[306]

(iv) There are discrepancies relating to the chest x-ray that was ordered by Dr. O'Neill[307] as part of the Children's Hospital's 1990 Renal Transplant Protocol[308] and the laboratory results for Adam's serum sodium on 26th November 1995

- DLS has informed the Inquiry that the failure to complete the form and the absence of a radiology report indicates that an x-ray was not carried out.[309] However, the completed checklist and records in Adam's notes and records[310] and Professor Savage's evidence during the Oral Hearings indicates the contrary.[311]

- Dr. O'Neill has recorded Adam's electrolyte results from a blood sample taken at or about 21:30, which shows his serum sodium to be within normal parameters at 139mmol/L.[312] However, there is no corresponding laboratory report. Whereas, in October 2011 the DLS provided the Inquiry with a previously misplaced[313] serum sodium result of 133mmol/L dated 27th November 1995 from a blood sample taken on 26th November 1995 for which there is no reference in Adam's notes and records to that result.[314]

(v) There does not appear to be a reliable record as to which operating theatre was used for Adam's surgery.[315]

- The sole record of the operating theatre is the Swab Count, which records: "*Theatre II.*"[316]

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305 Ref: 057-014-019
306 Ref: Transcript of Oral Evidence of Dr. Haynes of 2nd May 2012 p.119 lines 4-22 & Mr. Koffman of 16th May 2012 p.59 lines 21-23
307 Ref: 057-019-028-9
308 Ref: WS-02-2 p.52
309 Ref: 301-118-650
310 Ref: 057-019-028-9 and Ref: 058-035-133
311 Ref: Transcript of Oral Evidence of Professor Savage of 17th April 2012 p.59 lines 19-24
312 Ref: 058-035-144
313 Ref: 301-081-540
314 It is noteworthy that Dr. O'Neill was unable to explain why that was the case nor when and why the sample had been taken and sent for testing - Ref: Transcript of Oral Evidence of Dr. O'Neill of 15th May 2012 p.42 lines 1-24
315 Ref: 301-135-001
316 Ref: 058-007-021

- The position of the operating theatre was confirmed on a floor plan[317] by DLS in a letter to the Inquiry dated 24th August 2010.[318] However, during the course of the Oral Hearings on clinical issues some doubt emerged from the evidence of Mr Brown[319], Dr Montague[320] and a number of nurse witnesses[321], as to whether the operating theatre identified to the Inquiry and/or whether theatre II was the correct one.

(vi) There is now no record to identify all those who had been present in the operating theatre, despite such a catastrophic outcome:

- Dr. Taylor's evidence has always been that he had an assistant anaesthetist for the duration of Adam's transplant surgery, namely Dr. Montague and a trainee Anaesthetist whose name he does not recall. The DLS informed the Inquiry that special arrangements would need to be made for such a replacement. Dr. Montague's evidence at the Oral Hearings was that he did not make any such arrangements. Furthermore, the evidence of Dr. Hill at the Oral Hearings has called into question whether Dr. Montague was replaced.[322] Despite extensive efforts by the Inquiry and the DLS, no record of that trainee has been found.

- Dr. Taylor's evidence is also that there was an Anaesthetic Nurse and that there would have been an Auxiliary Nurse from time to time in the operating theatre to assist. Again, despite extensive efforts by the Inquiry and the DLS no record of that Anaesthetic Nurse or Auxiliary Nurse has been found.

- Despite evidence during the Oral Hearings from Staff Nurses Conway (who helped with setting up), Popplestone (who acted as scrub nurse) and Mathewson (who acted as circulating nurse or runner), it has not proved possible to identify the person who made the entries for blood loss results before those recorded by Staff Nurse Mathewson.

(vii) The Anaesthetic record may not provide a full record of Adam's anaesthetic treatment and care on 27th November 1995:

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317 Ref: 300-005-005

318 Ref: 301-015-063

319 Ref: Transcript of Oral Evidence of Mr Brown of 1st May 2012 p.57 lines 15-19

320 Ref: Transcript of Oral Evidence of Dr Montague of 11th May 2012 p.80 lines 16-25

321 Ref: Transcript of Oral Evidence of Patricia Conway of 30th April 2012 p.41 lines 11-16, Gillian Popplestone of 30th April 2012 p.63 lines 13-20 and Margaret Mathewson of 30th April 2012 p.107 line 21 to p.108 line 9

322 Transcript of Oral Evidence of Dr. Hill, 15th May 2012 p.76, line 6 *et seq*

- Parts of the 'Pre-Operative Record' have not been completed. Whilst it includes for a pre-operative assessment, it would seem from Dr. Taylor's evidence during the Oral Hearings that he might not have carried out a physical examination of Adam until he was anaesthetised.[323] Dr. Taylor acknowledged that he should have seen both Adam and his mother before the surgery[324] and his failure to do so was criticised by Dr. Haynes during the Oral Hearings. [325]

- There is no record of the dopamine that Dr. Taylor administered to Adam as *"low-dose dopamine infusion … commenced near start of the case"* and *"two small boluses of dopamine"* administered during it at about 10:00.[326] Dr. Taylor has conceded in his Inquiry Witness Statement that he should have recorded it. [327]

- There appears to be no record in the Anaesthetic Record of the immunosuppressant methylprednisolone that was prescribed by Drs. Savage[328] and O'Connor[329] being administered to Adam.[330]

- There is no entry under 'Anaesthetic Comments' for the difficulties experienced with getting in a CVP line[331] or in getting an accurate CVP value. Whilst Dr. Taylor signed the compressed trace of the CVP readings, there is no indication of any 'artefacts' or other concerns in respect of the accuracy of the values recorded.[332] The serum sodium result of 123mmol/L is not recorded.[333] Additionally the *"Anaesthetic*

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323 Ref: Transcript of Oral Evidence of Dr. Taylor of 19th April 2012 p.117 lines 7-11. Dr. Taylor also acknowledged that he should have seen both Adam and his mother before the surgery (Transcript of Oral Evidence of Dr. Taylor of 19th April 2012 p.121 lines 1-20) and his failure to do so was criticised by Dr. Haynes during the Oral Hearings (Ref: Transcript of Oral Evidence of Dr. Haynes of 2nd May 2012 p.61 lines 1-6)

324 Ref: Transcript of Oral Evidence of Dr. Taylor of 19th April 2012 p.121 lines 1-20

325 Ref: Transcript of Oral Evidence of Dr. Haynes of 2nd May 2012 p.61 lines 1-6

326 Ref: 011-014-097

327 Ref: WS-008-8 p.5

328 Ref: 058-035-133

329 Ref: 058-005-012

330 Ref: 058-035-133

331 Indeed Dr. Taylor did not record any such difficulty with insertion even though he failed to insert a line into the left subclavian following three attempts, failed in one attempt into the left internal jugular, and ultimately successfully inserted into the right subclavian, Ref:011-014-099

332 The 'Recommendations for Standards of Monitoring during Anaesthesia and Recovery' (revised 1994) make it clear that: *"monitoring artefacts [should be] identified clearly"* on the attached print out– Ref: WS-129-1 p.53

333 The evidence of Drs. Taylor and Savage is that the printout of that result would have attached to the Anaesthetic Record in the Operating Theatre. Nevertheless, Dr. O'Connor's evidence during the Oral Hearing was that the printout that is now attached to the Anaesthetic Record was not attached when she looked at the notes on 27th November 1995 after Adam's surgery - Ref: Transcript of Oral Evidence of Dr. O'Connor of 25th April 2012 p.180 lines 9-25. The 'Recommendations for Standards

Time" is not completed. Furthermore, the post-operative assessment, including "*Awake," "Rousable"* or "*Unconscious"* is not completed at all.[334]

(viii) Section II of the Kidney Donor Information Form,[335] which is to be completed by the recipient surgeon was in fact completed by the transplant coordinator Ms. Eleanor Donaghy and, in the light of the evidence received during the Oral Hearings, leaves unclear the anastomoses time.[336]

(ix) Mr. Keane's record of the transplant surgery[337] does not disclose that Mr. Brown closed the wound, which has left some uncertainty as to who closed the wound or what layers were closed by whom:

- Mr. Keane's letter dated 11th December 1995,[338] which formed the basis of his Deposition to the Coroner, and the Deposition itself[339] do not refer to Mr. Brown's involvement. Also, Mr. Brown's 'Medical Report' for the Coroner dated 20th December 1995[340] does not make any reference either him closing the wound or to Mr. Keane leaving early.

- Mr. Keane subsequently claimed in his Inquiry Witness Statement that he was called to an emergency at the BCH and Mr. Brown closed the wound.[341] Mr. Brown states in his PSNI Statement that both he and Mr. Keane were present throughout the operation and that he has no recollection of Mr. Keane leaving him to close the wound.[342]

(x) Mr. Keane's record of the transplant surgery has been criticised as lacking detail:[343]

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of Monitoring during Anaesthesia and Recovery' (revised 1994) make it clear that: *"The use of printers connected directly to monitoring devices is particularly helpful … The print-out must be attached securely to handwritten records"* – Ref: WS-129-1 p.53

334 Ref: 058-003-006

335 Ref: 058-009-027

336 Ref: The evidence from Professor Forsythe & Mr. Rigg and from Mr. Koffman during the Oral Hearings was that the time that Mr. Keane would have spent engaged in 'bench work' on the donor kidney would not have been considered as part of 'warm ischaemic time' - Ref: Transcript of Oral Evidence of Professor Forsythe & Mr. Rigg of 14th May 2012 p.166 lines 1-25 & Ref: Transcript of Oral Evidence of Mr Koffman of 16th May 2012 p.89 lines 8-25

337 Ref: 058-035-134

338 Ref: 011-026-127

339 Ref: 011-013-093

340 Ref: 059-060-146

341 Ref: WS-006-1 p.3

342 Ref: 093-011-032

343 Ref: 210-003-027

- Professor Forsythe and Mr. Rigg who make reference to: (a) no confirmation that this was an extra-peritoneal approach, (b) if it was no detail of whether the peritoneum had been breached, (c) more detail or a diagram as to the artery position on the patch, (d) no comment on the perfusion of the kidney after vascular clamps had been removed, [344] (e) no post-operative management plan,[345]

- Mr. Koffman who further refers to: (a) no time recorded for the beginning and end of anastomoses, (b) no record of the cold ischaemic time[346]

- Professor Mullan states in his report to the Inquiry that a record of the operation should have been made following surgery detailing, by accurate description, difficulties or complications encountered with immediate post-operative instructions and the surgeon's signature

172. Guidelines for record keeping were available in 1995 from a number of sources, including the DoH, Royal Colleges and Professional Regulatory Bodies. It is perhaps noteworthy that these shortcomings were seemingly not considered by Dr. Murnaghan when he emphasised to the Inquiry *"the importance, value and relevance of good record keeping as exemplified by the case notes for Adam Strain."*[347]

173. The extent to which the Trust properly implemented guidance on record-keeping or whether it allowed the doctors and nurses to, effectively, regulate the standard of their own record keeping will be addressed during the Oral Hearings. So too will the issue of whether a proper investigation into Adam's death could and should have identified and addressed any of the record-keeping issues that have been criticised by the Inquiry's Experts.

XI. Retention & Destruction of Records

174. Some documents generated in 1995 by Adam's case and relevant to this Inquiry have not survived. Some have been discarded and others have proved untraceable. For example, documents including staff rotas and minutes of some Paediatric Directorate Clinical Audit Committee meetings have been destroyed.

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344 Ref: 203-004-077-8 & Transcript of Oral Evidence of Mr Koffman of 16th May 2012 p.105 lines 1-9

345 Ref: 203-004-077-8

346 Ref: Transcript of Oral Evidence of Mr Koffman of 16th May 2012 p.101 & 105 lines 1-10 & 1-9 respectively

347 Ref: 093-025-068c

175. Whilst the Trust initially maintained that *"nursing duty rotas 26.11.95 to 28.11.95 have been destroyed in accordance with hospital policy"*;[348] the Inquiry has now been informed that:

> *"Prior to March 2008 no formal policy in relation to records management existed ... Prior to December 2004 there was no specific guidance on destruction/retention of records other than medical records and social care records. The retention of all other papers such as minutes, rosters etc. would have been subject to whatever local practice was at the time and it is likely that storage issues would have been a major factor in determining what documents would have been retained. You will note that previous correspondence as regards document retention/destruction prior to 2004 makes reference to 'Trust Policy' or 'Hospital Policy' and this may have lead to some confusion. I understand that perhaps reference to a "Practice" rather than "Policy" would have been more appropriate."*[349]

Guidance on Preservation of Records

176. It would however appear that the preservation and storage of health records has long been the subject of guidance. Mr. Noel Williams, the current Co-Director Information Services at the Trust, states in his Inquiry Witness Statement that all hospitals in 1995 would have been subject to two departmental circulars:[350]

(i) NIHA (75/62) – Preservation and destruction of hospital service records

(ii) HSS (31/83) – Retention and disposal of hospital records (for possible use in litigation)

177. The 1962 circular distinguished between those that were not to be destroyed and those that may with suggested periods for the length of their retention. Included in the category of documents that were not to be destroyed were documents: *"which are or might be relevant to legal proceedings which have been begun or to a pending claim or other matter which could result in legal proceedings"*[351] and *"Minute books of Hospital Committees and sub-committees."*[352] The category of documents that may be destroyed included *"medical records and allied documents in hospitals"*, which were to be retained for six years after the conclusion of treatment or three years after a patient's death in hospital.

178. The 1983 circular amended the 1962 circular in that it recommended new minimum periods of retention for personal health records to take

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348 Ref: 301-047-413
349 Ref:305-035-001
350 Ref: WS-251-1 p.3
351 Ref: WS-251-1 p.10
352 Ref: WS-251-1 p.12

account of Limitation (Northern Ireland) Order and the Congenital Disabilities (Civil Liability) Act 1976. It provided minimum periods for the retention of records relating to children and young people as: *"until the patient's 25th birthday or 8 years after the last entry, if longer."*[353] In cases where the child died the minimum period of retention was 8 years after the death.

179. The 1983 circular also required the Boards to be asked to observe the minimum periods and to bring the advice to the attention of all staff concerned.[354] According to his Inquiry Witness Statement Mr. Williams is not able to comment on how the circulars were disseminated within the Children's Hospital. However, Dr. Carson states in his Inquiry Witness Statement that: *"DHSSPS Circulars were received in the Office of the Chief Executive, and then forwarded to clinical directorates for action/implementation."*[355] As to these circulars in particular, Dr. Connor Mulholland who was the acting Clinical Director for Paediatrics at the time of Adam's transplant surgery, states in his Inquiry Witness Statement that in 1995 the: *"Medico legal advice was that records should be kept until three years after the patient reached their 18th birthday"*.[356] The source of Dr. Mulholland's information is unclear. In addition, he does not refer to the position where a child dies and so it is also unclear the extent to which he was aware of its possible effect on the period of retention.

180. The dissemination of the guidance in those circulars is therefore an issue to be addressed during the Oral Hearings as is the extent to which dissemination and compliance was monitored.[357]

Retention of Records relating to Adam's Case

181. In the case of Adam who died on 28th November 1995, the guidance in circular HSS (083) 1/83 would have made the minimum period for the retention of documents relating to him up until 27th November 2004, which was after the Minister's announcement on 1st November 2004 that the Inquiry had been established on the basis that: *"I regard it as very important that the general public should have confidence in the health service and in the standards of performance of all who work in it"*.[358] It was also after the Minister's release on 18th November 2004 of the Terms of Reference for the Inquiry, which referred to: *"The Terms of Reference I*

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353 Ref: WS-251-1 p.28
354 Ref: WS-251-1 p.25
355 Ref: WS-077-2 p.9
356 Ref: WS-234-1 p.8
357 It should be noted that Dr. Carson states in his Inquiry Witness Statement that he was not aware of any system or systematic checklist for ensuring the dissemination of guidance and that: *"A system of directorate 'accountability reviews' was introduced much later (late 1990s/2000) as 'performance management' was developed by the Trust"* – Ref: WS-077-2 p.12
358 Ref: Ministerial Statement dated 1st November 2004 on Inquiry Website, 2004 Ministerial Statements

have set for the Inquiry and the powers available to it are wide-ranging and should ensure that the Inquiry deals with all the issues of concern." [359]

182. An issue to be explored during the Oral Hearings is the extent to which consideration should have been given to retaining all the records relating to Adam's case with the result that they would have been available to the Inquiry. If so, where and by whom that should have been discussed and decided.

183. The UKCC 'Standards for Records and Record Keeping' 1993, which would have been applicable to Adam's case, direct at paragraph 27 that:

"It is essential that members of the professions must be involved in local discussions to determine policies concerning the retention or disposal of all or any part of records which they or their colleagues make. Such policies must be determined with recognition of any aspects of law affecting the duration of retention and make explicit the period for which specific categories of records are to be retained. Any documents which form part of the chronological clinical care record should be retained."[360]

184. The Inquiry has sought access to relevant minutes of Clinical Audit Committee meetings in relation to Adam but has been informed: *"In relation to the Trust Board's Sub Committee dealing with issues relating to quality of patient's care, a search of the registry office in the Royal Victoria Hospital has taken place and there are no minutes on file for the Audit Committee for the period preceding 1999. These minutes were held within the Finance Department during the time in question and from an accounting perspective, as the professional code stipulates retaining papers for a seven year period these minutes would not have been retained."*[361]

185. No explanation has been given as to why records relating to the quality of patients' care should have been consigned to the safekeeping of the Finance Department or subjected to retention from an *"accounting perspective."*

186. There would appear to be no evidence that a designated records officer was appointed, that local guidelines were prepared or that any policy was devised whether in consultation with health professionals or otherwise.

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359 Ref: Ministerial Statement dated 18th November 2004 on Inquiry Website, 2004 Ministerial Statements

360 Ref: 202-002-052

361 Ref: 305-018-001

XII. Medical Services & Equipment

187. The critical importance of accurate and reliable medical services and equipment to surgery has been emphasised already in the evidence relating to clinical matters. It is vital that sophisticated equipment be properly checked and maintained and used correctly by trained operators. To that end, a body of published guidance and procedure was available by 1995 to inform the governance issues to be examined in respect of equipment, services and reliability.

Blood Gas Analyser

188. In February 1994, the Association of Anaesthetists of Great Britain and Ireland published its report on 'Anaesthetic Related Equipment, Purchase, Maintenance and Replacement'.[362] It emphasised *"Studies of mortality associated with anaesthesia are not new, but the introduction of medical audit has shifted the focus of attention towards precipitating factors which lead to injury and death. The vast majority of critical incidents occurring during anaesthesia have been shown to be due to human error but up to twenty per cent may be caused by equipment failure"*[363]

189. Dr. Taylor was of the view that he could not, in all the circumstances of Adam's surgery, have relied upon the blood gas analyser ("BGA") to *"accurately analyse sodium levels."*[364] This is because he appreciated that these sodium readings were less accurate when the anti-coagulant heparin was present. The issue of potentially inaccurate BGA readings was considered so serious that it generated much published guidance. As early as 1989, the DHSSNI issued a Hazard Notice warning about the use of BGAs.[365] Thereafter a joint working party of the Association of Clinical Biochemists and The Royal College of Pathologists reported to provide the relevant guidance applicable from September 1993, known simply as 'Guidelines for Implementation of Near-Patient testing'.[366] It identifies the clinical governance issues relating to the setting up and management of near patient as opposed to laboratory testing. In particular it emphasises the need for:

(i) Training, updating and monitoring of all staff involved in near-patient testing

(ii) Quality issues including through accreditation by external bodies together with appropriate quality control procedures

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362 Ref: 210-003-031 & Published by the Association of Anaesthetists of Great Britain and Ireland, Feb 1994

363 Ref: 210-003-031

364 Ref: 011-014-108 & 093-035-100

365 Ref: WS-125-3 & WS-106-1; Hazard Notice 24/89/76

366 Ref: 210-003-031 & Joint Working Party of the Association of Clinical Biochemists & Royal College of Pathologists. ACB, London. Sept 1993

(iii) Need for standard operating procedures for regular reviews and updates

190. The Inquiry has been informed that there are no records of those who were trained or authorised to use the BGAs.[367] There is no indication as to the policy denoting who might be trained or authorised to use the BGA. Nor does there appear to be any evidence of written advices being given on the accuracy of the results provided the BGAs and therefore the extent to which they could be relied upon.

191. The 'Guidelines for Implementation of Near-Patient testing' made reference to the previously published 'Management of Medical Equipment and Devices'[368] which gave the following advice with regard to the subject:

(i) Each directorate should nominate one consultant with responsibility for equipment management and liaison with the manager of technical servicing

(ii) Anaesthetic equipment used in some locations may have a shared use. An inventory should be kept and management responsibilities clearly defined for equipment for which the Anaesthetic Department is responsible

(iii) The nominated consultant must be aware of current legislation in the UK and Ireland. There are also relevant European directives being developed

(iv) A planned preventative maintenance programme is essential. Quality issues must be monitored

(v) There should be a Department policy for equipment breakdown

(vi) A planned replacement programme which defines equipment life and disposal procedures should be agreed

(vii) Purchase of new equipment involves wide consultation and technical advice is essential to ensure practicality and cost effectiveness

(viii) An acceptance procedure and training programme should be a part of safety protocol

192. Professor Mullan thought it: *"reasonable therefore to expect that the Trust should have established a Trust-wide Group to oversee the procurement and*

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367 Ref: 301-018-331

368 Ref: 210-003-034; HEI 98 (Revised January 1991)

safe use of all such devices in accordance with the 1993 guidance. A lead professional should have been appointed to both chair the Group and take lead responsibility for ensuring compliance with the guidelines which covered all aspects of maintenance, risk assessment, quality assurance and control, reliability testing and appropriate training and selection of appropriate personnel eligible to use the device. Again it is reasonable to expect that the Group would be accountable to the Trust Board."[369]

193. The Inquiry has not been provided with any evidence that the Trust had put in place such control assurance mechanisms and this is a matter that will be raised during the Oral Hearings.

Laboratory Testing

194. A related issue has arisen as to the time it would have taken for electrolyte blood test results to have been provided to the operating theatre by the laboratory in the event of an unreliable blood gas machine result. The statement approved by Dr, Murnaghan at the Time of Adam's Inquest and signed by Dr. Taylor, carries the implication that the laboratory was too slow to produce analysis results for the operating theatres: *"The Trust will continue to use its best endeavours to ensure that operating theatres are afforded access to full laboratory facilities to achieve timely receipt of reports on full blood picture and electrolyte values thereby assisting rapid anaesthetic intervention when indicated"*.[370]

195. Professor Savage suggested a response time of less than an hour for an urgent blood test[371] ventured to suggest a response time of 1 hour,[372] whilst Dr. Taylor's estimates range from 30 minutes to 3 hours.[373] The April 1995 final report of the Systems Option Review of the Trust's Laboratory Rationalisation Project suggests that the norm for turnaround times for urgent biochemical results in 1995 was within 2 hours.[374]

196. The Inquiry has been informed that: *"the length of time to obtain an electrolyte result from theatres was variable and depended on several factors involving portering, time of day, week-end and holidays and the laboratory workload. In 1995, it was usually obtained within 1-2 hours on a week day 9-5. In 1995 out-of-hours blood tests in Clinical Biochemistry were available and done by an 'on call' MLSO. At that time not all MLSOs are thought to have stayed on-site for the whole evening; some may have gone home to have their evening meal or to have supper to await further calls by telephone. In 1995 the Paediatric Clinical Biochemistry Lab was still open 9am to 5pm in RBHSC*

369 Ref: 210-003-032
370 Ref: 011-014-107a
371 Ref: WS-002-3, p.44
372 Ref: 059-003-005
373 Ref: 093-035-101 & Ref: WS-008-3 p.37
374 Ref: 305-005-145 p.8 Table 1

but after 5pm the requests would have been analysed in the main RVH laboratory in the Kelvin Building. All out of hours requests were made by arrangement (telephone), all results were phoned back to source. A hard copy result would not have been printed until the next day. Ward based look- up systems were not available in 1995. The turnaround time for urgent samples at the Paediatric Laboratory (RBHSC) should have been no more than 40 minutes for routine tests (such as U&E). If the sample had to be portered to the main laboratory then turn around time would depend on when a porter was available but certainly should have been less than 90 minutes and probably less than 60 minutes."[375]

197. In his Oral evidence given to the Inquiry on 19th April 2012, Dr. Taylor suggests that the issue of portering was a variable one that could either expedite or prolong the turnaround of urgent blood specimens depending on the proximity of the porter.[376] Dr. Taylor took the view that it was *"not a lab factor... a blood sampling factor, it's the factor of portering"*.[377]

198. Despite the position of the DLS on the Paediatric Clinical Biochemistry Laboratory, both Dr. Taylor and Professor Savage gave evidence at the Oral Hearings to the effect that it was no longer in operation at the time of Adam's transplant surgery. Indeed Dr. Taylor stated: *"at some stage the biochemistry element of that lab [the Children's Hospital] stopped and moved to the main lab for issues to do with quality control."*[378] He also gave evidence on the limited portering service available at weekends and before 09:00: *"... only one porter was available on a Sunday night until 8/9am. So to get one porter for the whole Royal site, not just the Children's ... I think that is the factor that could prolong it. It's not a lab factor... it's the factor of the portering"*.[379]

199. The Inquiry has not been provided with any evidence on either the steps taken in respect of 'turnaround time' or the forum in which such an issue would be discussed and action decided. It is worth noting that there was available guidance in managing 'turnaround times'. Since 1992, the Clinical Pathology Accreditation (UK) Limited ("CPA") published recommendations and has applied international standards to evaluate laboratory performance. Specifically relation to response times, they have suggested that laboratories: "*should, in consultation with users, establish turnaround times for each examination, that reflect clinical needs and have a mechanism for monitoring non-conformities and recording remedial or corrective action*".[380]

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375 Ref: 301-018-331
376 Ref: Transcript of Oral Evidence of Dr. Taylor of 19th April 2012 p.41 lines 12-16
377 Ref: Transcript of Oral Evidence of Dr. Taylor of 19th April 2012 p.41 lines 20-22
378 Ref: Transcript of Oral Evidence of Dr. Taylor, 20th April 2012 p.43, lines 7-9
379 Ref: Transcript of Oral Evidence of Dr. Taylor, 20th April 2012 p.41, lines 15-22
380 Ref: 210-003-033

200. In Adam's case there is no evidence that any attempt was made to establish acceptable response times whether by agreement, in consultation or otherwise.

201. With regards to the critical issue of laboratory response to surgical need, there seems to have been an absence of internal control over the systems then in operation. The Trust had no quality assurance mechanism by which it could be reassured that the system was working and effective. In terms of clinical governance the Inquiry has been informed: "*that the laboratories have advised that they are not aware of any protocols or guidelines in 1995 on the Royal Group of Hospitals site, and specifically in relation to the Department of Clinical Biochemistry, surrounding the conduct of laboratory testing and the production of biochemical results during major surgery, nor of any protocols or guideline on the Royal Group of Hospitals site for the use of near-patient testing analysers in 1995*".[381]

XIII. Conduct of the Autopsy

202. The involvement of Dr. Armour in the post-mortem examination of Adam and the manner in which she carried out the Autopsy and prepared her Report has already been considered from a 'clinical' perspective. However, the issue of whether a thorough and accurate post-mortem investigation was carried out into Adam's death has continued importance, particularly when the matter is considered from a 'governance' perspective.

203. To assist in this respect the Inquiry has sought advice from Professor Sebastian Lucas (Professor of Clinical Histopathology and a Consultant Histopathologist to Guys and St Thomas' Hospitals Trust, London)[382] who provided a Preliminary Report to the Inquiry on 1st April 2012,[383] and Dr. Waney Squier (Consultant and Clinical Lecturer, Department of Neuropathology, John Radcliffe Hospital, Oxford), who has also provided a number of Reports to the Inquiry.[384] The issues that have been identified, and which will be matters to be pursued at the Oral Hearing into governance, include:

    (i) Whether there was any guidance in place at the time regarding the requisite experience of forensic pathologists and the mechanisms for involving line managers / more senior colleagues in respect of unusual findings.

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381 Ref: 305-127
382 Ref: 209-001-001
383 Ref: 209-001-005
384 Ref: 206-002 & 206-004 & 206-010

(ii) Whether there was any guidance in relation to photographing the external appearance of Adam's body, the neck structures and sending any sample of the 'ligature' for testing and dating.

(iii) Whether there existed protocols or procedures which could or should have guided Dr. Armour regarding the manner in which she engaged with and sought the opinions of Drs. Mirakhur, O'Hara and Bharucha, including whether those communications should have been recorded. If there were such protocols and procedures, then the extent to which Dr. Armour complied with them.

(iv) Whether the Autopsy should have been carried out on the Royal Group of Hospital site, the same site on which Adam's transplant surgery was carried out and where he died

(v) Whether there was any requirement for a pathological examination of organs being removed for donation and the circumstances in which they should be retained and not released for donation is a matter which will be pursued in the Oral Hearings

Guidance on Autopsies & Autopsy Reports

204. In 1993 the Royal College of Pathologists, of which Dr. Armour was then a member,[385] published 'Guidelines for Post Mortem Reports' in August 1993. The College envisaged them as serving as guidance: *"for all hospital, Coroner's and Fiscal post mortems other than Home Office cases."*[386] The guidance, which is not mandatory, covers the details that should be provided in a Post Mortem report including:

(i) History

(ii) External examination

(iii) Internal examination

(iv) Histology and other investigations

(v) Commentary, conclusions and cause of death

(vi) Minimum guidelines for post mortem investigation in post neonatal infant deaths

(vii) Neuropathology

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385 Dr. Armour became a Fellow of the Royal College of Pathologists in 2002 – Ref: 306-071-001

386 Ref: 306-072-002

205. The extent of which Dr. Armour's Report on Autopsy complied with those guidelines will be explored during the Oral Hearings.

206. Dr. Squier refers to the Report of a Working Group of the Royal College of Pathologists on Guidelines on Autopsy Practice that were published in September 2002[387] and to the Code of Practice and Performance Standards for Forensic Pathologists that were published in November 2004 by the Home Office and the Royal College of Pathologists.[388] Although both these publications post-date the Autopsy carried out by Dr. Armour and her Report on Autopsy, they nonetheless provide insight into the conduct of Autopsies and appropriate standards.

207. In his Report to the Inquiry[389], Professor Lucas makes reference to the 2006 National Confidential Enquiry into Patient Outcome and Death (NCEPOD), and the publication of its Report into the coronial system 'The Coroner's Autopsy: Do We Deserve Better?'.[390] Professor Jack Crane (State Pathologist and Professor of Forensic Medicine) was a member of the expert advisory group for the study. The basis for this study was to determine how well autopsy reports were written, and implicitly how well autopsies being carried out. It examined one month (in 2005) of coronial autopsies across the UK, and while this review post-dated Adam's death by a span of ten years, it is relevant to note that the following conclusions were reached:

    (i) One quarter of autopsy reports (and autopsies) were performed badly

    (ii) In one fifth of cases the review panel did not agree with the stated cause of death

    (iii) There was poor communication between coroners and pathologists at the time of autopsy

    (iv) Paediatric autopsies were performed better that adult autopsies- reflecting increasing specialisation in practice

    (v) There was little or no consistent approach taken by all the coroners.[391]

208. Professor Lucas speaks of a *"huge variation in practice quality"*[392] and attributes this in part to: "*The indifference (until very recently) of the higher*

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387 Ref: 206-004-070
388 Ref: 206-004-038
389 Ref: 209-001-006
390 Can be downloaded at http://www.ncepod.org.uk/2006.htm
391 Ref: 209-001-007
392 Ref: 209-001-007

medical regulatory bodies to what happens during coronial autopsies, since – by definition – they are outwith the National Health Service. They are done as a private contract between coroner and medical practitioner, and are not covered by NHS rules, guidelines and protocols."[393] It is further noted that the Royal College of Pathologists is a professional standards body, not a disciplinary body, and therefore whilst it has produced Guidelines on Autopsy Practice in 2002 (and specific updates thereafter), they are only guidelines and not mandatory performance standards.[394] However, medically qualified pathologists like Dr. Armour are regulated by the GMC.[395]

209. Professor Lucas concludes in respect of coronial autopsy practice, that: "*there is no governance, no standard of quality demanded by coroners, no obligatory linkage with feedback of autopsy findings with pre-mortem clinical practice, and no agreed level of investigations for particular scenarios of death*".[396] The extent to which that was the case for the State Pathologist's Department in Northern Ireland at the time of Adam's Autopsy and the production of Dr. Armour's Report on Autopsy is a matter to be explored during the Oral Hearings. In that context, it should be noted that the Northern Ireland Office published in January 2003 'The Way Forward', a consultation document on the State Pathologist's Department,[397] which was followed a 'Review of the State Pathologist's Department in Northern Ireland' which was published in June 2005 by Criminal Justice Inspection Northern Ireland.[398] Whilst they both post date the Autopsy Dr. Armour carried out on Adam and her Report on Autopsy, they nonetheless assist with an understanding of the system within which Dr. Armour operated in 1995.

XIV. Inquest into Adam's Death

210. Adam's Inquest opened on 18th June 1996 before Mr. John Leckey, H.M. Coroner. Evidence was heard from a number of witnesses and experts including Adam's mother,[399] Dr. Armour,[400] Dr. Sumner,[401] Dr. Alexander[402] and Mr. Keane[403] before being adjourned to 21st June 1996 when evidence was heard from Dr. Taylor[404] and Professor Savage.[405]

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393 Ref: 209-001-008
394 Ref: 209-001-008
395 Review of the Regulation of Public Health Professionals, DoH, Nov. 2010 (Section 5)
396 Ref: 209-001-009
397 Ref: 306-074-001 *et seq*
398 Ref: 306-073-001 *et seq*
399 Ref: 011-009-025
400 Ref: 011-010-030
401 Ref: 011-011-042
402 Ref: 011-012-079
403 Ref: 011-013-093
404 Ref: 011-014-096
405 Ref: 011-015-109

The Verdict on Inquest that was issued later that day gave the cause of Adam's death as: *"I(A) Cerebral Oedema due to (B) Dilutional hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy)"*.[406] The Coroner made a further finding that faithfully reflected Dr. Sumner's own summary[407] of the case including *"the onset of cerebral oedema was caused by the acute onset of hyponatraemia from the excess administration of fluids containing only very small amounts of sodium."*[408]

211. Of particular interest from a governance perspective is the question of whether there existed any policies or procedures to ensure that lessons and information learned from the Inquest were disseminated within the Trust hospitals and within the Health Service in Northern Ireland.

212. Mr. William McKee, in his Witness Statement to the Inquiry dated 25th June 2005, states: *"it is my understanding that the expert clinical opinion at the time was that the complication of hyponatraemia had occurred during specialised renal transplant surgery in a child with renal failure. I am not personally aware of wider dissemination of lessons learned from this Inquest to the wider Health Service in Northern Ireland and elsewhere in the United Kingdom or that this was identified to be required at this time."*[409]

213. However, Mr. McKee's reference to what might have been required at the time does not accord with the recollection of the Coroner which was that there was a discussion with Dr. Sumner whilst he was in the witness box during the Inquest as to how his views *"could be disseminated amongst the medical profession in Northern Ireland."*[410]

214. Mr. McKee further notes: *"prior to July 2004 there was no formal mechanism or requirement within Northern Ireland to report lessons learned from inquest. There was no mandatory requirement or formal mechanism for Trusts to report the death of a patient to the DHSSPSNI unless there was a concern that clinical practice or performance was impaired or likely to result in disciplinary action or referral to the General Medical Council"*.[411]

215. Notwithstanding that a medical negligence action was already being *"managed"* by Dr. Murnaghan, it would not appear that there was a sufficient concern *"that clinical practice or performance was impaired"* to justify reporting Adam's death to the DHSSPSNI[412] despite the content of Dr. Sumner's Report and the clear finding of H.M. Coroner. No further investigation was considered after the Inquest excepting only

406 Ref: 011-016-114
407 Ref: 011-011-063
408 Ref: 011-011-063
409 Ref: WS-061-1 p.2
410 Ref: WS-091-1 p.2
411 Ref: WS-061-1 p.2
412 Ref: WS-061-1 p.2

that Dr. Murnaghan and Dr. Carson considered it appropriate to consider convening a seminar involving Drs. Mulholland, Gaston, Savage, O'Connor, Taylor, Hicks and Mr. Keane[413] to address the "*other issues identified*"[414] at the Inquest. Although some urgency was indicated, the idea was nonetheless abandoned.[415]

216. Mr. McKee informed this Inquiry that "*until 1999 the Director of Medical Administration ensured the internal dissemination of lessons learnt from Inquests.*"[416] There is little evidence that this was done or that adequate thought was given to external dissemination. The Coroner remarked on what he felt could have been done after the Inquest: "*I had assumed that the Royal Belfast Hospital for Sick Children would have circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some 'best practice' guidelines. Children are not always treated in a paediatric unit and, in the event of surgery, the anaesthetist may not be a paediatric anaesthetist.*"[417]

217. Indeed it is relevant to note that Dr. Bridget Dolan has informed the Inquiry that Rule 23(2) of the Coroner's (Practice and Procedure) Rules (Northern Ireland) 1963 gave the Coroner the power to report the circumstances of an inquest case to an appropriate authority: "*A Coroner who believes that action should be taken to prevent the occurrence of fatalities similar to that in respect of which the inquest is being held may announce at the inquest that he is reporting the matter to the person or authority who may have power to take such action and report the matter accordingly*".[418]

218. It will be an issue to be considered at the Oral Hearings whether the draft statement that was provided to the Coroner contributed to him not issuing a Rule 23(2) Report. So too will be the issue of whether the fact that the Coroner did not issue such a Rule 23(2) report contributed to the lack of dissemination, in particular to hospitals outside the Trust, of the learning on dilutional hyponatraemia from Adam's case.

219. Professor Mullan expresses the opinion that:

> "*… it may have been prudent for the clinical leads engaged with the Coroner's Inquest to alert the Chief Executive of the findings of the Inquest. The Chief Executive may then have seen the value of commissioning an internal*

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413 Ref: 059-001-001

414 Ref: 059-001-001

415 Ref: 059-036-070. N.B. In his letter to Dr. Murnaghan, Mr. Keane refers to a regional meeting which seems to have taken place at which the blood loss in Adam's operation seems to have been discussed.

416 Ref: WS-061-1 p.2

417 Ref: WS-091-1 p.3. It is also worth noting that Dr. Armour published an article about Adam's case in the Journal of Clinical Pathology, May 1997, Vol.50, number 5 p.444

418 '*Report to the Inquiry into Hyponatraemia-Related Deaths*' (Dr. Bridget Dolan) – Ref: 303-052-715

investigation into the facts surrounding Adam's unexpected death in order to learn any lessons and to prevent a similar occurrence in the future. The most obvious lead clinician to act as SRO [Senior Responsible Officer] would have been Dr. Carson, the Medical Director. If such an investigation had been commissioned by the Chief Executive, the subsequent report and action plan could then have been presented to the Trust Board to enable them to fulfil their obligation to 'provide active leadership of the organisation within a framework of prudent and effective controls which enable risk to be assessed and managed'".[419]

220. However, Professor Savage has assured the Inquiry that: *"the finding at Adam Strain's inquest and the identification of the potential risk of hypotonic fluids became a significant issue for discussion within the Northern Ireland paediatric community, resulting in the setting up of the Northern Ireland Regional Paediatric Fluid Therapy Working Group in 2001".*[420]

221. The extent to which that happened and the means by which it did are matters to be addressed at the Oral Hearings.

XV. Medical Negligence Litigation

222. Prior to the Inquest hearing Adam's mother commenced legal proceedings against the Trust by way of solicitor's Letter of Claim dated 25th April 1996.[421]

223. Dr. Murnaghan the Director of Medical Administration directed the response of the Trust as *"Case Manager for the Trust."*[422] Dr. Murnaghan appears to have been the individual within the Trust charged with handling risk and claims management. George Brangam, solicitor, of Bagnall Brangam & Co was retained by Dr. Murnaghan to advise and represent the Trust. Dr. Murnaghan sought additional reports from the clinicians involved.[423] However, they would not appear to have amounted to the *"full and thorough investigation of the events"* that is envisaged by Section 5.45 of the Trust's Complaints Procedure.[424]

224. Indeed, there is no indication that additional evidence was gathered apart from the statements intended for the Coroner. A statement was not taken from Dr. O'Connor notwithstanding that she expected that her view might have been sought given that she had replaced Professor Savage as Adam's nephrologist during the transplant surgery and was in the operating theatre to discuss the high level of the CVP values

419 Ref: 210-003-024
420 Ref: WS-002-3 p.47
421 Ref: 060-022-042
422 Ref: 060-023-047
423 Ref: 060-022-041
424 Ref: WS-062-1 p.367

with Dr. Taylor. None of the nurses, including those that were in the operating theatre during the transplant surgery appear to have been interviewed. Similarly, no statement was taken from Dr. Montague despite the fact that he was present at the beginning of the procedure and when significant amount of fluids were administered to Adam in a relatively short space of time. Furthermore, there is no evidence of any particular action having been taken by the Trust as a result of Adam's mother commencing litigation. In addition, no explanation or apology was given to Adam's mother as contemplated by the Complaints Procedure.[425]

225. After the Inquest George Brangam suggested a meeting with Dr. Murnaghan to *"discuss the way in which the Trust intends to meet"*[426] the challenge of litigation. He expressed his views in a letter dated 19th March 1997 to Dr. Murnaghan:

"I believe from a liability point of view, this case cannot be defended and this is based largely upon the information given by one of the Independent Experts retained by HM Coroner at the Inquest."[427]

226. There is no evidence that the suggested meeting took place, or if it did, that it was documented. No further evidence was gathered after the Inquest.

227. Adam's mother then decided to end the litigation process by settling the case on 29th April 1997 on undisclosed terms, without any admission of liability on the part of the Trust and subject to a confidentiality clause.[428] The terms of settlement appear to have been drafted and proposed by Mr. George Brangam, solicitor on behalf of the Trust.[429] It is a question for the Inquiry as to whether confidentiality clauses governing the Trust as well as Adam's mother might act so as to suppress discussion and restrict learning opportunities.

228. After settlement of the claim Dr. Murnaghan wrote to the key clinicians involved in Adam's case as 'Director of Risk and Litigation Management' rather than 'Director of Medical Administration' to advise them of settlement. It will be a matter to be explored during the Oral Hearings when Dr. Murnaghan acquired that title and its significance if any for his conduct in relation to Adam's case. Dr. Murnaghan's communication to the key clinicians included:

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425 Ref: WS-062-1 p.351
426 Ref: 060-020-039
427 Ref: 060-016-031
428 Ref: 060-013-024
429 Ref: 060-016-032

"Additionally it would have been unwise for the Trust to engage in litigation, in a public forum, and given the tragic circumstances of the death. It would not have been helpful for an opportunity to be provided to lawyers to explore any differences of opinion which might exist between various professional witnesses who would have been called to give evidence."[430]

229. It will be a matter to be explored during the Oral whether these comments suggest that public reputation and an avoidance of debate were more important to Dr. Murnaghan than open discussion and a better understanding of the differing medical opinions expressed as to an unexpected child death.

230. Just as there would appear to be no evidence of any action having been taken as a result of the commencement of these legal proceedings so too there is no evidence of any action being taken as a result of the conclusion of these proceedings, save only and that by possible coincidence, May 1997 saw the publication of Dr. Alison Armour's article in the Journal of Clinical Pathology,[431] and in addition the publication of 'Paediatric Medical Guideline'[432] with contributions from Doctors O'Connor, Savage, Webb, Hicks et al.

Aspects of Case Management

231. Mr. Ramsden refers in his Report of 6th October 2011, to the scope for an internal investigation in 1995 by the Trust in relation to Adam's case. He explains that there was no: *"formal Serious Untoward Incident Reporting System incorporating the use of Root Cause Analysis and there was no Regional or national Reporting System"*.[433] He observes that the consequences were that:

"the lessons learned from Adam's death were left to local discretion and the individual judgment of the responsible officer, in this case Mr. George Murnaghan."[434]

232. The apparent emergence of Dr. Murnaghan in 1997 to act simultaneously as both 'Director of Medical Administration' and 'Director of Risk and Litigation Management' is noteworthy. Whereas the Chief Executive Mr. McKee maintained in his statement to the Inquiry that: *"Until 1999 the Director of Medical Administration ensured the internal dissemination of lessons learned from inquests and appropriate action was identified to address any vulnerabilities"*,[435] it could appear that the same individual as 'Director of Risk and Litigation Management'

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430 Ref: 060-010-018
431 Ref: May 1997, Vol.50, number 5 p.444
432 Ref: 301-138-001
433 Ref: 211-005-017, para.41
434 Ref: 211-005-017, para.43
435 Ref: WS-061-1 p.2

might have been conversely motivated to restrict the dissemination of information in respect of vulnerabilities, in the interests of litigation management.

233. Dr. Murnaghan's role encompassed liaison with the Coroner[436] and the gathering of evidence for the Inquest. It also entailed the strategic response to and management of any medical negligence claim that might arise after the Inquest. Dr. Murnaghan's failure to explore the issues in the case openly may be contrasted with that evinced by Dr. Armour in her letter of 8th December 1995 to the State Pathologist, Professor Crane. *"I have been dealing with the case of Adam STRAIN. I am willing to attend any meeting about this case, including a meeting with clinicians, administrative staff, HM. Coroner and whoever else wishes to attend. As I was the pathologist who carried out the Autopsy I feel my opinion on the case is relevant to such a meeting and as such the case could be discussed in full."*[437]

234. The Inquiry has not been provided with any evidence that such a meeting was convened. It is noteworthy that Dr. Armour copies her letter to the Coroner, Dr. Murnaghan, BMA and to her professional indemnity insurers the Medical Protection Society. Her reasons for doing so are unclear and will be a matter for consideration at the Oral Hearings.

235. On 7th February 1996 Dr. Murnaghan sent a fax to Dr. Armour, the covering communication of which stated: *"I have spoken on the telephone with Bob Taylor and obtained his permission to share the attached with you on the understanding that the contents are for your personal information and as a background briefing, in order to assist in coming to your conclusions in this difficult matter"*.[438] The *"attached"* to which Dr. Murnaghan refers is a note sent to him by Dr. Taylor on 2nd February 1996 pointing out *"several major problems"*[439] with the evidence of Drs. Sumner and Alexander and asserting that both experts had: *"failed to comprehend the physiological differences in this case and have used dubious scientific argument in an attempt to explain cerebral oedema"*.[440] The reasons why Dr. Murnaghan considered it appropriate to provide Dr. Taylor's dissenting view that dilutional hyponatraemia could not have been the cause of Adam's death as a means of assisting Dr. Armour to come to her conclusions, rather than convening a meeting, is a matter to be explored during the Oral Hearings.

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436 Ref: 011-025-125 & Ref: 093-025-068
437 Ref: 011-023-123
438 Ref: 059-052-107
439 Ref: 059-053-108
440 Ref: 059-053-108

236. It is a question for you Mr. Chairman as to whether a tension existed in 1995/1996 as and between the necessity to proactively investigate Adam's case, to openly discuss it and share learning from it and the dictates of litigation management which would have reacted to shield the Trust from criticism and restrict the opportunities for those who might have sought to challenge it.

XVI. Aftermath Assessment: Investigation and Dissemination

Investigation

237. The earliest assessment of the cause of Adam's death appears to have been that carried out by Dr. O'Connor at the conclusion of the transplant surgery when she *"was called back to theatre when the fixed, dilated pupils were apparent."*[441] She *"certainly formed a view that he had cerebral oedema,"*[442] and *"a significant positive fluid balance."*[443] She proceeded to telephone Professor Savage who, in his own words: *"rapidly went to the intensive care unit and reviewed the situation, with her, and it was clear that he did seem to have had, I think, with a rapid calculation we thought he had had 1,500ml of fluid more in that out on a rough calculation, so at that stage with a low sodium and subsequently with a lower sodium coming back from the laboratory, I think Dr. O'Connor and I felt that there was a situation where his fluid balance was excessive on the positive side. He had a lot of fifth normal saline and we felt that he had probably got cerebral oedema and coned."*[444] Subsequently Professor Savage attended the post-mortem *"probably just to make sure that the conclusions we had reached were correct."*[445]

238. It would seem that some of the discussions between Professor Savage and Dr. O'Connor concerned a continuation of the process of revising the existing 1990 Renal Transplant Protocol. That process had already started before Adam's transplant surgery, influenced by the 1995 Bristol Protocol and others available at that time. However, Adam's death would have afforded them the opportunity to consider any new Protocol from the perspective of intra-operative fluid management which was the particular feature of his case. It is not clear the extent to which that was done. However, the result of their deliberations was that no further use was made of the 1990 Children's Transplant Protocol after Adam's death and a new, 1996, Protocol was produced dated September 1996. Dr. O'Connor describes the process of change in her Inquiry Witness Statement:

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441 Ref: Transcript of Oral Evidence of Dr. O'Connor, 25th April 2012 p.112, line 19
442 Ref: Transcript of Oral Evidence of Dr. O'Connor, 25th April 2012 p.114, line 21
443 Ref: Transcript of Oral Evidence of Dr. O'Connor, 25th April 2012 p.115, line 21
444 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.151, line 6
445 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.156, line 19

"These 1996 guidelines were influenced by lessons learned by Adam's case with regard to hyponatraemia ... 'The guideline of 1996 is much longer and more detailed than the 1990 guideline (9 pages instead of 4). There is a longer section on preoperative planning including instructions about preoperative fluids and the necessity to check electrolytes before theatre if fluids have been given. The instruction to "D/W consultant if NA < 133 repeat U/E at time of going to theatre" was included in the protocol as a direct consequence of Adam's hyponatraemia and tragic death. This advice was to ensure that the consultant was aware of any hyponatraemia prior to transplant. The drugs used for immunosuppression are different in the 1996 protocol… The 1996 protocol gives instructions to check arterial blood gases and electrolyte two hourly in theatre and also to use only normal saline, plasma or blood to raise the CVP to 8-10mmHg prior to removal of vascular clamps. The 1990 protocol instructs the use of blood, PPF or N/2 Saline to ensure a good intra vascular volume as determined by reference to BP and CVP levels. The 1996 protocol recommends the use of 0.45 per cent saline, 2.5 per cent dextrose as urine and in sensible loss replacement (300ml/m2/day) and makes no mention of the use of 0.18 per cent saline, 4 per cent dextrose … The 1996 protocol also includes a pre operative theatre checklist which requests pre operative blood results and calculates peri-operative drug doses and a nursing checklist which records some preoperative measurements and administration of drugs".[446]

239. Mr. Koffman discussed in his evidence during the Oral Hearing the response that might have been made to Adam's death in terms of Protocol changes. He referred to a death in his hospital of a patient about 5 or 6 years ago due to hyponatraemia and following renal transplantation, stating:

"The reason I'm bringing that up is because what we did immediately is to have a review of what happened. We got an external specialist to come and look at what we did and we made changes in the protocol based on that."[447]

240. Mr. Koffman then went on to explain what a revision to the Protocol should have focussed on in the light of Adam's case, namely: *"we would really need to look at the protocols and how we managed the intraoperative fluid balance in the child because most of the protocols, including ours, don't lay down clearly what is given during the operation"*. He also said: "*We need to carefully look at that and make strong recommendations for a protocol that governs what fluids are allowed to be given during the operation and what are absolutely forbidden"* and he concluded with: *"I don't think that the protocol did govern that intraoperative management"*.[448] In fact the 1996 Transplant Protocol, refers only to: "*Use N. saline, plasma, or blood (as*

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446 Ref: WS-014-2 p.22

447 Ref: Transcript of Oral Evidence of Mr. Koffman, 16th May 2012 p.146, lines 21 *et seq*

448 Ref: Transcript of Oral Evidence of Mr. Koffman, 16th May 2012 p.149, lines 6 *et seq*

appropriate) to raise CVP to 8-10mmm mmHg prior to removal of vascular clamps".[449]

241. It is not clear whether either Professor Savage or Dr. O'Connor considered a review involving an external specialist, or an independent Consultant Paediatric Anaesthetist.[450] That issue, together with the whole process of revising the Protocol and the extent to which they were left to carry that out in an independent manner, are matters that will be considered during the Oral Hearings.

242. Professor Savage and Dr. O'Connor are not the only clinicians who were involved in Adam's case that formed an early view of the reasons for his death. Mr. Keane maintains that he spoke with Professor Savage at that time and *"communicated my view that confirmed that I was seriously worried about what had happened in terms of the fluid management of a child that was under my surgical care at the transplant operation."*[451]

243. The reason why that information and the assessment they made was not openly communicated or used to inform Adam's mother or the Coroner will be considered during the Oral Hearings. Ultimately, it will be a matter for you Mr. Chairman: was it, as Mr. Keane felt *"that the state should decide without me chirping up in the background saying: 'actually it was the anaesthetist, actually it was the anaesthetist'"*.[452] Or was it a matter of self-interest or culture?

244. Mr. Keane stated during the Oral Hearing on the clinical issues that notwithstanding he had formed an early opinion as to the inappropriate administration of fluids in Adam's case, he did not draw this to the attention of Adam's mother or mention it in his early letter and statements or tell the Coroner about it. He told you Mr. Chairman: *"the point was, from my perspective, as I looked at where I was, I had an issue, I had a serious concern about what was going on. But I thought it would be wrong of me because I was actually the surgeon involved to, if you like, try to influence something. I wanted an independent somebody to look and declare the cause of death. That was my thinking. Now, I understand that as you look back on it now, you say, 'how could you feel that way?' But you see, the Bristol governance thing came in six or seven years later. I was naïve, scared, didn't know"*.[453]

245. The nature of that 'Doctor's Dilemma'[454] is a matter to be explored during the Oral Hearings: Was Mr. Keane caught between, on the one

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449 Ref: WS-002-1 p.6

450 The 1996 Bristol Protocol would appear to have involved Consultant in Anaesthesia and Intensive Care – Ref: WS-002-2 p.68

451 Ref: Transcript of Oral Evidence of Mr. Keane, 23rd April 2012 p.31, line 14

452 Ref: Transcript of Oral Evidence of Mr. Keane, 23rd April 2012 p.73, line 22

453 Ref: Transcript of Oral Evidence of Mr. Keane, 18th April 2012 p.171, line 12

454 George Bernard Shaw

hand, not informing on a colleague for reasons of loyalty embedded in the culture of the system and, on the other, properly assisting in the Coroner's Inquiry and the medical issues arising in a manner consistent with professional probity and patient interest?

246. Dr. Haynes, Dr. Coulthard, Professor Forsythe, Mr. Rigg and Mr. Koffman all expressed their concern during the Oral Hearings that there was no investigation into Dr. Taylor's conduct but that he was allowed to continue on in his practice without any assessment of his clinical competence on fluid management in the context of end-stage renal failure, including being involved in subsequent paediatric renal transplants.

247. Had the mishandling of Adam's fluid management been communicated to a Clinical Director in the immediate aftermath of surgery then Dr. Haynes' evidence during the Oral Hearings was that the first thing the Clinical Director should have done was: "*to ask to have a discussion within a very short time frame with the individual where the perceived problem is*".[455] If then the Clinical Director was: "*still unhappy that the person whose practice was being challenged… and that then was a real problem, and that that person's perception of their own practice was unchanged, they felt they'd done nothing wrong, they were going to continue doing exactly the same again, at that point in time you have to take the matter further with a degree of urgency … "we're talking days, the Medical Director of the Trust would be hearing [from me] and [in many ways] it would be passed up to the Medical Director to take further, which would make the thing an awful lot more formal and may involve bringing in outside agencies to look at events*".[456] He then agreed "*absolutely*" with the proposition from you Mr. Chairman that: "*You can't allow that person to continue until you are reassured that this would not happen again*".[457]

248. Dr. Haynes went on to expand on the duty of the Clinical Director:[458] "*if the Clinical Director in 1995 was made aware of a problem that he thought was significant and he couldn't deal with it himself, he was responsible to the Medical Director who in turn was responsible to the Board.*"[459] Dr. Coulthard, a Consultant Paediatric Nephrologist, who like Professor Savage had started up a paediatric renal transplant service,[460] took a similar view to Dr. Haynes and added that if he could not obtain resolution to the matter he would have "*taken that to the GMC without any doubt.*"[461]The evidence of Professor Forsythe and Mr. Rigg,[462] both

455 Ref: Transcript of Oral Evidence of Dr. Haynes, 3rd May 2012 p.127, line 17
456 Ref: Transcript of Oral Evidence of Dr. Haynes, 3rd May 2012 p.128
457 Ref: Transcript of Oral Evidence of Dr. Haynes, 3rd May 2012 p.129, line 8
458 A position that he had himself held from 2000 -2006 – Ref: 306-032-001
459 Ref: Transcript of Oral Evidence of Dr. Haynes, 2nd May 2012 p.9, line 10
460 Ref: Transcript of Oral Evidence of Dr. Coulthard, 8th May 2012 p.5, line 14
461 Ref: Transcript of Oral Evidence of Dr. Coulthard, 9th May 2012 p.60, line 16
462 Ref: Transcript of Oral Evidence of Professor Forsythe and Mr. Rigg, 4th May 2012, pgs. 208-210

of whom had been Clinical Directors,[463] was also broadly in agreement with that of Dr. Haynes. Mr. Rigg in particular thought the process of review should at least have involved the Consultant Nephrologist and the Consultant Surgeon. They both considered that if others did not initiate such a process then the Consultant Surgeon ought to have done so and they agreed with you Mr. Chairman that it was: *"not an occasion to stand on ceremony."*[464]

249. Mr. Koffman, also a Clinical Director,[465] responded to the suggestion of a culture in 1995 of doctors not reporting doctors to the GMC: *"I think that it's fairly simple. If the coroner's verdict was that this was an avoidable hyponatraemic death, it has to be accepted by the team. If you do not accept that, you cannot be part of that team. So I would immediately say he could do no transplant work. But the problem with hyponatraemic illness is that it could relate to any operation; it's not just specific to transplantation. So that is why there is a wider connotation. That is why a clinician not accepting a coroner's verdict would not be acceptable."*[466]

250. Mr. Ramsden summarises: *"Despite the lack of formal Risk Management knowledge and any formal requirement for Serious Untoward Incident reporting or Root Cause Analysis in place in 1995 I would have expected a more formal approach to the lessons learned to be taken by RBHSC. I have seen no formal report from RBHSC summarising the incident, the lessons learned and an Action Plan for implementing improvement. In view of the seriousness of this case I would have expected to see a Report created by RBHSC in 1995, summarising all this … Certainly such a Report should then have commented on whether any broader lessons on fluid management and the prevention of hyponatraemia were needed."*[467]

251. However, Dr. Carson, who was the Medical Director at the relevant time, informs the Inquiry in his Witness Statement that *"unexpected or unexplained deaths following anaesthesia and surgery would be reported externally to H.M. Coroner and internally to Dr. G. Murnaghan in his capacity as Director of Administration"*[468] but *"were not formally reported to the Medical Director as routine."*[469] Mr. McKee advises *"that investigations into the unexpected death of Adam Strain "would have been led by the Director of Medical Administration in collaboration with the Directorate"*.[470]

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463 Professor Forsythe was Clinical Director for Renal Transplants from 2004 to 2009 and is now Lead Clinician in Scotland for Organ Donation & Transplantation - Ref: 306-034-002. Mr. Rigg was Clinical Director for General Surgery from 1996 to 2007 and is now Director of Transplantation - Ref: 306-038-003

464 Ref: Transcript of Oral Evidence of Professor Forsythe and Mr. Rigg, 4th May 2012, pgs. 209-210

465 Mr. Koffman is currently Clinical Director of Abdominal Medicine and Surgery and is also Deputy Medical Director - Ref: 306-053-001

466 Ref: Transcript of Oral Evidence of Mr. Koffman, 16th May 2012, pgs. 153-154

467 Ref: 211-005-018

468 Ref: WS-077-2 p.6

469 Ref: WS-077-2 p.21

470 Ref: WS-061-2 p.10

252. The wisdom of such a reporting structure, which would appear to exclude the Medical Director who was charged with the duty to advise the Board of the Trust on medical policy and strategy, will be explored during the Oral Hearings.

253. The Clinical Director for the Directorate of Anaesthetics, Theatre and Intensive Care, Dr. Joe Gaston states in his Inquiry Witness Statement that he would have expected to receive a written report into Adam's death in 1995 but *"cannot confirm this."*[471] There is no evidence that any written report was provided for the Clinical Directors or anyone else.

254. Whilst there would not seem to have been any formal or statutory obligation on the part of the Trust to investigate Adam's death, it is relevant that the DoH and the HPSS guidelines both stressed the need for audit. The GMC directed audit.[472] The Health & Safety policy was predicated upon a concept of investigation and the Trust's involvement with KFOA suggests a systematic approach to compliance with guidelines. Yet his death seems not to have been formally investigated.

255. Indeed it would seem that an initial response of the Director of Medical Administration Dr. Murnaghan and Dr. Gaston was to arrange for Dr. Fiona Gibson (Consultant Anaesthetist) to: *"visit the theatres in the Children's Hospital with Messrs. Wilson and McLaughlin to review the processes and equipment used in these theatres"*[473] and to meet Dr. Taylor to *"discuss three patients [one of whom was Adam] whose post-mortem examinations had been brought to the attention of the Coroner"*.[474] There would appear to have been no attempt to establish at the outset an investigating team that could have provided guidance on:

(i) The appropriate scope for such an investigation given Adam's transplant surgery and the circumstances of his death

(ii) How the investigation into issues might most usefully be carried out so as to identify its cause, the lessons that might be learned from and action that should be taken in the light of it

256. Such a team might have included the Director of Nursing so as to assess whether there were any 'nursing issues' to be addressed. Her inclusion could have identified the issues raised in the Reports of the Inquiry's Expert Ms. Ramsay, which could then have been addressed in the interests of future patients.

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471 Ref: WS-013-2 p.17
472 Ref: 210-003-014
473 Ref: 093-026-069
474 Ref: 059-069-162

257. Rather the 'investigation' appears to have focused on the anaesthetic procedures and equipment. Messrs. Wilson and McLaughlin both claim in their Inquiry Witness Statements that Dr. Gibson was not present when they carried out their inspection of the equipment.[475] According to Mr. Wilson: *"She was at a separate meeting with medical staff."*[476] Dr. Gibson concludes in her Report on Adam's case that: *"a very carefully thought out and well monitored anaesthetic was delivered with great care to fluid management"*.[477] She was working on the basis of Adam's normal urine output being *"100mls per hour"*, whereas Dr. Taylor's evidence and a reason for the errors that he has acknowledged in his fluid management of Adam was that his: *"fluid plan had been based on [his] incorrect assumption of [Adam's] 200ml per hour urine output")*.[478] Her overall findings were: *"the protocols for monitoring, anaesthetic setup and drug administration in this area are among the best on the Royal Hospitals site and I can see no reason to link these very sad cases into any pattern."*[479]

258. The DLS has informed the Inquiry in correspondence dated 21st July 2011 that the protocols referred to by Dr. Gibson did not exist.[480] Furthermore, the DLS has advised the Inquiry that: *"consultant anaesthetists who were working in the RBHSC in November 1995 do not know of any practice for monitoring, anaesthetic set-up and drug administration in operation at that time"*.[481] Nevertheless, Dr. McKaigue has provided with his Inquiry Witness Statement, 'A Revised Anaesthetic Record Set' dated March 1996, which gives *"suggestions as to reasonable content"* for anaesthetic records.[482] Unfortunately, Dr. Gibson cannot attend to give evidence at the Oral Hearings to clarify what she meant in her Report.[483]

259. Notwithstanding, Dr. Gibson's very positive Report, the Anaesthetic Record does not record Adam's total urine output,[484] it does not record the CVP values,[485] and mis-records the immunosuppressant as prednisolone. Dr. Taylor concedes in his Inquiry Witness Statement of

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475 Ref: WS-110-2 p.8 and Ref: WS-109-2 p.8 respectively

476 Ref: WS-110-2 p.8

477 Ref: 059-069-162

478 Ref: Transcript of Oral Evidence of Dr. Taylor, 19th April 2012 p.26, lines 5-6, on the Inquiry website under Oral Hearings, Timetable. See also Dr. Taylor's PSNI Statement under caution of 17th October 2006 at for example Ref: 093-038-227 and Ref: 093-038-233

479 Ref: 059-069-162

480 Ref: 305-014-604

481 Ref: 305-004-134

482 Ref: WS-129-1, pgs.42-43. It is perhaps worth noting that included in those 'suggestions' is: (i) all anaesthetists named, (ii) doses, concentrations and volume; (iii) urine output; (iv) limb position; and (v) untoward events – *"pre, per or post-operative"* and *"context, cause and effect"*

483 Ref: 305-013-599

484 Ref: 058-003-008

485 Ref: 058-003-005. However, there is a compressed printout of the CVP values during surgery, which may have been attached to Adam's notes. See: Ref: 058-008-023

22nd May 2012 that he did not record either the low dose dopamine infusion that he administered to Adam near the start of the surgery or the two small boluses of dopamine that he administered to Adam at about 10:00.[486]

260. Dr. Gibson's Report was sent to Dr. Murnaghan on 4th December 1995 in the *"hope this is suitable for your purposes"*[487] but it was addressed to *"Whom It May Concern"*.[488] It was then re-sent on the 11th December 1995 with Dr. Gibson's renewed expression of hope that *"it is appropriate."*[489] It is unclear what those references to 'purposes' and 'appropriate' were intended to mean or who else saw Dr. Gibson's Report.

261. The extent to which Dr. Gibson's examination amounted to an appropriate investigation into the processes and equipment used in the operating theatres at the Children's Hospital is a matter that will be pursued during the Oral Hearings.

262. There is a further dimension to the examination of the processes and equipment carried out by Dr. Gibson in that the Coroner wrote to Dr. Murnaghan on 31st November 1995 asking for statements from the clinicians involved in Adam's surgery and suggesting: *"that it would be useful to have a statement from the technician responsible for the equipment in the theatre confirming that it was functioning properly. The statement should cover the frequency of checks and whether such checks were carried out both before and after surgery in this instance."*[490] There is no evidence that Dr. Murnaghan sought such a statement.

263. On the 8th December 1995 the Coroner: *"spoke to Dr. Murnaghan and said that it appeared imperative that the equipment was now independently examined."*[491] There is no evidence that Dr. Murnaghan sought such an independent examination. Instead, he had requested a report from Messrs. John Wilson and Brian McLaughlin, both of whom were employed by the Trust as Medical Technical Officers. Dr. Gaston states in his Inquiry Witness Statement that: *"neither Dr. Gibson, Mr. Wilson or Mr. McLaughlin worked in the RBHSC"* and therefore he *"would have considered them independent."*[492]

264. The Reports that Dr. Murnaghan obtained from Dr. Gibson and from Messrs. Wilson and McLaughlin[493] failed to examine the relevant

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486 Ref: WS-008-8 p.5
487 Ref: 059-069-161 & 093-026-070a
488 Ref: 059-069-162
489 Ref: 059-065-151
490 Ref: 059-073-166
491 Ref: 011-025-125
492 Ref: WS-013-2 p.5
493 Ref: 011-028-147

equipment, which had been removed earlier for repair and was in the department 'under test'.[494] Mr. McLaughlin states in his Inquiry Witness Statement that after the checks had been carried out on the equipment Mr. Tommy Ryan, who was the Chief MTO at the Children's Hospital told them that the monitor had recently sent for repair.[495] It is possible that the significance of that for Adam's case was not appreciated by either Mr. Wilson or Mr. McLaughlin as they claim not to have been informed of the purpose of their investigation of the equipment and instructed not to discuss it with anyone.[496] Although Dr. Murnaghan states in his Inquiry Witness Statement[497] that he provided the Chief Technical Officer in the ATICS Directorate with the letter that he had received from the Coroner dated 30th November 1995[498] – it is not clear whether that is a reference to Mr. Ryan or to Mr. Wilson.[499]

265. The possibility that the anaesthetic equipment that had been used in Adam's surgery was not the equipment that had been examined can be deduced from the Report of Messrs. Wilson and McLaughlin[500] and was in fact picked by up Detective Sergeant William Cross during the course of the PSNI investigation.[501] However, it seems that it was either not noted or not followed up by Dr. Murnaghan. Nor apparently was it noted by Dr. Gibson.

266. It should be further noted that Dr. Murnaghan's letter of 5th December 1995 to the clinicians involved refers to:

> *"… the Coroner has spoken to me recently on several occasions about this very unfortunate clinical outcome and has now written requesting that I obtain for him 'as soon as possible statements from the clinicians involved'. Additionally he has 1. Requested a detailed statement from the anaesthetic technical staff about the equipment used during the surgery and anaesthesia. This has been arranged. 2. Referred the matter to the Health and Safety Inspectorate for a review of our anaesthetic systems. This will be facilitated through this office"*.[502]

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494 Ref: 094-210-999

495 Ref: WS-109-1 p.2

496 See: Mr. McLaughlin's Inquiry Witness Statement - Ref: WS-109-2 p.8. See too: Mr. Wilson's PSNI Statement – Ref: 093-027-071 and his Inquiry Witness Statements – Ref: WS-110-1 p.2 and WS-110-2 p.7

497 Ref: WS-015-2 p.3

498 Ref: 011-019-118

499 See: The Inquiry Witness Statement of Mr. McLaughlin who refers to Mr. Ryan as *"Chief MTO RBHSC"* – Ref: WS-109-1 p.2 and the Inquiry Witness Statement of Mr. Wilson who describes his position at the time as being *"Chief Medical Technical Officer for Anaesthetics, Theatres & Intensive Care – Royal Group of Hospitals "* – Ref: WS-110-2 p.1

500 See: *"This monitor is currently out for repair – a new display screen is being fitted and a loan monitor is in use"* – Ref: 011-004-012

501 See letter dated 10th April 2006 from Detective Sergeant William Cross to Dr. Walby – Ref: 094-210-997

502 Ref: 059-072-165

267. It would seem that the Report of Messrs. Wilson and McLaughlin which had already been requested by Dr. Murnaghan and was therefore 'in train', was intended to satisfy the Coroner's request for *"a detailed statement from the anaesthetic technical staff about the equipment used during the surgery and anaesthesia"*, since no statement was requested from Mr. Peter Shaw, who was the Medical Technical Officer ("MTO") during Adam's surgery, nor was any statement sought from either Mr. Wilson or Mr. McLaughlin.[503]

268. There is no evidence that the Health and Safety Inspectorate became involved or that any statement was ever obtained about the equipment actually used during the surgery for anaesthesia. Furthermore, Dr. Taylor has conceded: *"I did not do anything in terms of clinical audit as it was a Coroner's case."*[504]

269. During the course of their examination of the anaesthetic equipment, Messrs. Wilson and Mr. McLaughlin noted that the log was not always signed by the anaesthetist. They observed in their report that: *"The anaesthetist using the machine is also expected to sign the log before commencing the list but this does not happen on most occasions. A reason for this omission should be requested."*[505] Dr. Taylor counters in his Inquiry Witness Statement that: *"it was not practice for the anaesthetists to sign the anaesthetic machine log"*[506] as *"routine checks were not recorded."*[507]

270. Whatever the procedure followed by Messrs. Wilson and McLaughlin in carrying out their inspection and providing the requested Report, it seems that no action was taken by Dr. Murnaghan in respect of either it or the Report of Dr. Gibson. A reading of the two Reports taken together, should have:

    (i) Made it clear that the appropriate equipment had not been examined and tested as the Siemens monitor was *"out for repair"*[508]

    (ii) Dr. Gibson was not therefore in a position to state as she did in her Report that on the basis of the checks carried out by Messrs. Wilson and McLaughlin, they had *"found nothing at fault <u>in relation to the cases</u> in question [save for a pin indexing problem]"*[509] (Emphasis added)

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503 The first statements made by Messrs. Wilson and McLaughlin were those that they made for the PSNI – Ref: 093-027-071 and Ref: 093-028-075 respectively

504 Ref: WS-008-03 p.43

505 Ref: 011-004-014 & Ref: 011-028-147

506 Ref: WS-008-3 p.20

507 Ref: WS-008-2 p.30

508 Ref: 059-068-157

509 Ref: 011-005-017

(iii) Highlighted the fact that Dr. Gibson had relied upon and praised unidentified *"Protocols for monitoring, anaesthetic set-up and drug administration"*[510]

(iv) Required consideration to be given to what further should be done in the circumstances

(v) Called into question the extent to which he was in a position to claim: *"this examination observed [that] the equipment was 'found to be in satisfactory condition'"*[511]

(vi) Called into question the extent to which the Trust was in a position to reach any conclusions about the role of the anaesthetic equipment in the first two cases, given that fluid overload had been associated with the third case, which was Adam's

271. The conduct of the investigation of the equipment, the extent to which it complied with 1995 guidance and the appropriateness of the response to the Reports of Dr. Gibson and Messrs. Wilson and McLaughlin are all matters to be addressed during the Oral Hearings.

272. HM Coroner for Greater Belfast, Mr. Leckey, was heavily engaged in the early formal state response to Adam's death after it was reported to him by Professor Savage.[512] He liaised with Dr. Murnaghan, directed that statements be taken from clinicians and technical staff, commissioned an expert anaesthetic report from Dr. Alexander,[513] directed that the anaesthetic equipment should be examined and maintained communication with Dr. Armour. On 11th December 1995 he met with Dr. Murnaghan and two senior anaesthetists; Dr. Gaston (Clinical Director of ATICS) and Dr. Lyons (President of the Association of Anaesthetists of Great Britain and Ireland and Chairman of the Central Medical Advisory Committee of the Department of Health).[514] Thereafter the Coroner wrote to Dr. Armour to inform *"they made the point that their considered view is that the death had nothing to do with anaesthetics,"*[515] and *"that it would be most important to obtain a paediatric anaesthetic opinion."*[516] Accordingly, the Coroner approached Dr. Sumner for an opinion. Dr. Lyons confirmed to the PSNI that he had *"no recollection of being involved in any formal review or interviews of any of the doctors involved in the care of Adam Strain."*[517]

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510 Ref: 011-005-017
511 Ref: 093-025-068b
512 Ref:011-025-125
513 Ref:059-073-166
514 Ref:093-024-066
515 Ref:011-027-128
516 Ref: 011-027-128
517 Ref:093-024-067

273. The 'internal control systems' in the Trust do not seem to have led to any further investigation into the cause of Adam's death taking place before the Inquest, as Dr. Murnaghan states: *"no steps were taken apart from the direct involving [sic] of the clinicians in discussion with pathologists and the anaesthetic technical staff in attempting to clarify the cause of death, and thereby to assist the Coroner in his proper duties where possible until the Inquest was held on 18th and 21st June 1996"*.[518] These discussions were neither recorded nor monitored[519] and did not involve Dr. O'Connor who has given evidence that she was not even asked to record her recollection of events until this Inquiry made such a request.[520] Given her evidence to you Mr. Chairman as to her observations of Adam in PICU and her assessment of his condition, his significant positive fluid balance and his sodium values,[521] the extent to which this may have been an opportunity missed will be explored during the Oral Hearings.

274. The extent to which the Trust could reasonably have undertaken an investigation into Adam's death prior to his Inquest is a matter to be investigated during the Oral Hearings. So too is the issue of how that investigation should have been carried out, who should have been involved in it, what it might have revealed and what could have resulted from it.

275. The opportunity to investigate Adam's death and the surrounding issues was not of course confined to the period of its immediate aftermath. There could have been an investigation when Adam's family embarked on medical negligence litigation in April 1996. In those circumstances, the HPSS had issued clear advice in its 1996 Complaints Procedure Guide for such circumstances: *"In all prima facie cases of negligence, or where a complainant has indicated that they propose to start legal proceedings, the principles of good claims management and risk management should be applied. There should be a full and thorough investigation of the events. In any case where the Trust/ Board accepts that there has been negligence, a speedy settlement should be sought."*[522] However, it would seem that no such investigation was undertaken by the Trust.

276. The Coroner's Inquest presented a somewhat later and different opportunity for investigation. The Trust had not instituted an internal investigation into Adam's care and his death by the time the Coroner produced his Verdict on Inquest. It had no report of its own to guide its response and therefore could only use the findings of the Inquest to inform any necessary action to be taken. Nevertheless, the Trust could

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518 Ref: 093-025-068b
519 Ref: WS-015-2 p.3
520 Ref: Transcript of Oral Evidence of Dr. O'Connor, 25th April 2012 p.76, line 25
521 Ref: Transcript of Oral Evidence of Dr. O'Connor, 25th April 2012 p.114-115
522 Ref: WS-062-1 p.367

have commenced an investigation into the lessons to be learned from those findings and what action should be taken in the light of them.

277. However, it seems that opportunity was not taken even though Dr. Carson is recorded in the Minutes of the Royal Hospitals' Formal Hospital Council meeting on 29th April 1996[523] as having: *"briefed members on some progress which has been made on risk management issues. He drew attention to a workshop which has been scheduled for September on medical negligence issues which would address matters such as communication of information to patients and how to reduce the Trust's level of liability."*[524]

278. Dr. Murnaghan was of the view, following the Inquest, that: *"other issues [had been] identified which relate to structure and process of paed. renal transplant services"*.[525] It seems that he discussed them with Dr. Carson and they agreed that they *"should deal with this as a RM [Risk Management] issue & arrange a seminar"*[526] involving Drs. Mulholland, Gaston, Savage, O'Connor, Taylor, and Elaine Hicks (Consultant Paediatric Neurologist), together with Mr. Keane.[527] It is not known whether the seminar relates in any way to the workshop referred to by Dr. Carson at the meeting of the Hospital Council. No records have been made available to the Inquiry.

279. In any event, urgency was indicated by Dr. Murnaghan who felt it necessary *"in order to deal with the matters arising while still fresh in colleagues' minds and to determine if anything more required to be done."* However, the seminar *"did not take place."* Dr. Murnaghan recalls *"that attempts were made to convene the seminar but as it was then towards the end of June many of then [sic] proposed attendees had holiday arrangements and were unable to provide suitable dates. I went on holiday and following this had a period of sick leave and on my return, the proposed seminar, unfortunately, did not take place."*[528] No evidence has been provided to the Inquiry that such a seminar ever took place.

280. The risk management issues and the reasons why both Dr. Murnaghan and Dr. Carson thought a seminar to be an appropriate way of dealing with them will be addressed during the Oral Hearings. So too will be the question of how those risk management issues were ultimately addressed.

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523 This was just after the Coroner sent Dr. Armour's Report on Autopsy to Dr. Murnaghan on 22nd April 1996 – Ref: 011-062-197

524 Ref: 305-117-037

525 Ref: 059-001-001

526 Ref: 059-001-001

527 Ref: 059-001-001

528 Ref: WS-015-2 p.20

281. It is a significant feature of the opinions expressed at the Inquest as to the cause of Adam's death that Dr. Taylor was alone in dissenting, insisting that Adam's polyuric condition meant that he could not develop dilutional hyponatraemia and therefore it could not have been the cause of his death. His evidence was a continuation of the arguments that he had made from the outset and can be seen set out in a letter sent to Dr. Murnaghan on 2nd February 1996 commenting on the report of Dr. Sumner,[529] and in his Deposition to the Coroner.[530] He continued to advance and develop those arguments in his PSNI interview under caution on 17th October 2006 and maintained them until he provided an unsolicited Witness Statement for the Inquiry dated 1st February 2012.[531] It was Dr. Taylor alone who had *"difficulty in accepting the finding"* of the Inquest according to Professor Savage.[532]

282. Nevertheless, no further investigation seems to have been instituted by the Trust to achieve a fuller understanding of Adam's case, the differences of opinion and the real lessons that were to be learned from it. Whether an investigation would have provided an opportunity for all those involved in Adam's transplant care to deal frankly with their differences in the interests of the renal paediatric transplant programme and future patients is something that will be explored during the Oral Hearings.

283. The extent to which the Trust's failure to fully investigate Adam's death meant that opportunities for learning and improvement were missed will also be considered during the Oral Hearings.

284. It will be recalled that during the course of the Oral Hearing the Experts explained some of the differences in 1995 between the practices in other paediatric renal transplant centres and the Children's Hospital. An example is to be found in the use of multi-disciplinary teams once the child is placed on the transfer list. The use of such teams was included in the recommendations of the March 1995 report by the British Association for Paediatric Nephrology Working Party, 'The Provision of Services in the UK for Children and Adolescents with Renal Disease':[533] *"a high quality paediatric renal service must be family-orientated and delivered by a multi-disciplinary team which includes specialist nurse, psychiatrist/ psychologist, dietician, social worker, school teacher and play worker, in addition to medical and surgical staff"*.[534] Nevertheless, it did not happen before Adam's transplant surgery and during the Oral Hearings Professor Savage expressed 'regret' that multi-disciplinary

529 Ref: 059-053-108
530 Ref: 011-014-108
531 Ref: WS-008-6 p.3-4
532 Ref: Transcript of Oral Evidence of Professor Savage, 18th April 2012 p.171, line 12
533 Ref: 306-065-001
534 Ref: 306-065-005

meetings did not occur at that time. A fuller investigation of Adam's death and the surrounding issues might have provided timely guidance on the forum where discussions on such developments might in the future be conducted.

285. It will be a matter for you Mr. Chairman to determine what a timely internal investigation into Adam's death might have revealed, what could have resulted from it and just how important were any of the missed opportunities.

Dissemination

286. Professor Mullan is of the view that this lack of corporate incident reporting and a formalised approach to investigation in 1995 suggests that there was also a lack of formal approach to:

(i) Assessing and developing the competence of the staff involved in Adam's treatment.

(ii) The internal dissemination of lessons learned both before and after the Inquest.

(iii) The external dissemination of lessons learned both before and after the Inquest[535]

287. Dissemination is to a certain extent dependent upon investigation. The investigations that were carried out and what they produced may be summarised as:

(i) In the first instance there seem to have been discussions of Adam's case in a paediatric audit. These went unrecorded and it is not clear the information that they produced. However, such discussions in and of themselves might be considered a means of dissemination lessons learned.

(ii) There was also an investigation into the anaesthetic systems and equipment by Dr. Gibson and into the equipment by Messrs. Wilson and McLaughlin. The resulting reports were of little value. Dr. Gibson's report whilst positive referred to protocols which cannot be identified. Whereas that of Messrs. Wilson and McLaughlin reported on the wrong Siemens monitor.

(iii) There was also discussion of Adam's case amongst the Consultant Anaesthetists who then produced 'draft recommendations' in conjunction with Dr. Murnaghan. Those recommendations were so closely connected with the

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[535] Ref: 210-003-039

production of a statement for the Coroner and to be released to the press that it is considered as part of 'dissemination'.

(iv) The case was discussed by Professor Savage and Dr. O'Connor, who continued the process of revising the 1990 renal transplant Protocol that it seems they had started prior to Adam's transplant surgery. It seems that the 1990 Protocol was not used after Adam's transplant surgery. Rather the 1995 Bristol Protocol was used until the production of the 1996 Children's Hospital Protocol. How the 1996 Protocol was disseminated, the extent to which nurses and junior doctors were sufficiently alerted to the changes, the means by which that happened and the extent to which adherence to it was adequately monitored will be explored during the Oral Hearings.

288. The governance issues that arise out of those investigations in relation to dissemination, concern what was done with the information gained and/or the reports received and what, if any, guidance there was in relation to dissemination.

289. The production of the *"Draft" "recommendations for the prevention and management of hyponatraemia arising during paediatric surgery"*[536] provides an insight into how the Trust went about the identification and dissemination of 'lessons learned'. These recommendations were drafted by Dr. Gaston[537], endorsed by his fellow consultant paediatric anaesthetists Drs. Taylor and McKaigue,[538] *"in conjunction with"*[539] Dr. Murnaghan, and then subsequently approved by Dr. Crean.[540] The precise purpose of the Draft agreed by Drs. Gaston, Taylor, McKaigue and Crean is not clear. Dr. Gaston claims in his Inquiry Witness Statement that he was asked to prepare it by Dr. Murnaghan at the request of the Coroner.[541] Dr. Crean appears to agree, stating in his Inquiry Witness Statement that the primary purpose of drafting it: *"was to be produced for Adam's Inquest."*[542]

290. Subsequently, DLS has informed the Inquiry that the recommendations: *"may be considered substantive in that they were drawn up by the only anaesthetists in Northern Ireland who were performing such work."*[543] According to Dr. Murnaghan's Inquiry Witness Statement it was the intention that: *"all paediatric anaesthetic staff within the Trust would be made aware of the particular phenomenon associated with electrolyte*

536 Ref: 060-018-036
537 Ref: 060-018-035 and Ref: WS-013-2 p.4
538 Ref: 060-014-025 and Ref: 093-023-065b
539 Ref: 093-025-068b
540 Ref: 060-014-025
541 Ref: WS-013-2 p.4
542 Ref: WS-130-1 p.16
543 Ref: AD-0154-10, 24th November 2010

imbalance, the need for careful monitoring and in particular the monitoring of their electrolyte balance".[544]

291. These recommendations were not distributed to anaesthetists in hospitals other than the Children's Hospital apparently on the grounds that: "*surgery such as Adam's would only have taken place in RBHSC*"[545] or, as indicated by the DLS only the Children's Hospital carried out "*major paediatric surgery*".[546] They were also not distributed to paediatricians.

292. As an apparently separate exercise, the draft document produced by Drs. Gaston, Taylor, McKaigue and Crean was used as a basis for the preparation of a 'press release', which according to the DLS was worked on by the Trust's management and its solicitors. It was faxed by Brangam Bagnall & Co on 21st June 1996 to Dr. Murnaghan[547] and provided to the Coroner as part of Dr. Taylor's Deposition.[548] It was also apparently forwarded to the Trust's Director of Corporate Affairs and Public Relations Department on 21st June 1996: "*in anticipation of media interest at the conclusion of the Inquest*"[549] and subsequently published in the Belfast Telegraph[550] and the Irish News.[551] The 'press release' provided to the Coroner and released to the press asserts that: "*all anaesthetic staff will be made aware of these particular phenomena and advised to act appropriately.*"[552]

293. The purpose, utility and application of the "*Draft*" recommendations given the restricted publication and the extent to which they reflect the findings and relevance of the medical literature cited, will be a matter to be pursued at the Oral Hearing.

294. The recommendations and press release were both specifically stated to be made in "*the light of*" Adam Strain's case and having regard to the information contained in the paper by Arieff et al (BMJ) 1992.[553] Both were made in respect of only those patients undergoing major paediatric surgery. The Arieff paper alone was cited by both Dr. Armour and Dr. Sumner at the Inquest as the medical literature supporting the conclusion that Adam's cerebral oedema was caused by hyponatraemia from the excess administration of fluid containing small quantities of sodium. The Arieff paper is fully entitled 'Hyponatraemia and Death or Permanent Brain Damage in Healthy

544 Ref: WS-015-1 p.2
545 Ref: WS-130-1 p.16
546 Ref: AD-0154-10, 24th November 2010
547 Ref: 059-008-025
548 Ref: 011-014-107a
549 Ref: 301-008-046, 24th November 2010 and Ref: WS-015-2 p.19
550 Ref: 070-016-073
551 Ref: 070-016-070
552 Ref: 059-008-025
553 Ref: 011-011-074

Children'. Dr. Taylor accepted in his evidence at the Oral Hearings that the Arieff paper had *"wider significance in terms of alerting the profession to the potential risks of dilutional hyponatraemia."*[554]

295. Furthermore, none of the 16 hyponatraemia-affected children who formed the basis of the 'Arieff study' underwent renal transplantation, or even major paediatric surgery. Rather they were hospitalised by minor fevers, tonsillitis, appendicitis, broken elbows and other non-critical conditions. It may be significant in that regard to note that in 1995 and subsequently surgery such as paediatric tonsillectomies and appendectomies took place in hospitals other than the Children's Hospital. The 1999 Report of a Working Group on Paediatric Surgical Services in Northern Ireland identified specialist paediatric surgery taking place at the Children's Hospital and the Ulster Hospital in Dundonald and general paediatric surgery as taking place in hospitals in each of the four Boards. However, of particular interest to the Inquiry are those associated with the other Children, namely the Erne Hospital, Altnagelvin Area Hospital, and Craigavon Area Hospital.[555]

296. All 16 of the children in the Arieff study died or suffered permanent brain damage resulting from hyponatraemia. Symptoms upon hospital admission were not known for three of the patients, but of the remaining 13-11 had progressive lethargy, weakness and emesis, and 12 had headache. Arieff concludes his paper by stating *"headache, nausea, emesis, weakness and lethargy are consistent symptoms of hyponatraemia in children"* and *"when a paediatric patient receiving hypotonic fluids begins to have headache, emesis, nausea or lethargy the serum sodium concentration must be measured. Although these symptoms are somewhat non-specific, the diagnosis is easily established at minimal cost and with virtually no risk to the patient by evaluating plasma electrolyte values."*

297. It is to be recalled that Claire was admitted to the Children's Hospital four months later as a healthy child with symptoms on admission of nausea, emesis, tiredness and lethargy.[556] It will also be appreciated that Lucy was admitted to the Erne Hospital in 2000 with a history of drowsiness, lethargy and floppiness and with a suspected urinary tract infection.[557] Raychel was admitted to Altnagelvin Area Hospital in 2001 and underwent an appendectomy.[558] Whilst Conor was admitted to the Craigavon Area Hospital as drowsy, pale and unresponsive.[559]

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554 Ref: Transcript of Oral Evidence of Dr. Taylor, 20th April 2012 p.139, line 8
555 Ref: 306-079-013-4
556 Ref: 090-011-013
557 Referral letter – Ref: 027-009-020
558 Ref: 020-006-010-12
559 Ref: 088-002-020 and Ref: 088-002-021

298. Despite the failure of the Trust to communicate 'lessons learned' from Adam's death and Inquest in any systematic way, it is the case that some of those involved subsequently published papers in relation to it and may have discussed it further afield.

299. In May 1997, an article by Dr. Armour about Adam's case was published in the Journal of Clinical Pathology.[560] She has said that *"the object of the article was to ensure that this would not happen again. However, I am aware that the Journal is read mainly by pathologists."*[561] Later, an article by Professor Savage and Dr. Mayes titled 'Paediatric renal transplantation in Northern Ireland (1984-1998)' was published in the Ulster Medical Journal.[562] It makes passing reference to the occurrence of two deaths in the early postoperative period one from *"fluid overload,"* which was a reference to Adam, and the other from acute respiratory distress syndrome.

300. Then two articles contributed to by Dr. Taylor were published in 2003 and 2004 respectively. The first is co-written with Dr. Miriam McCarthy[563] and Dr. John Jenkins,[564] titled 'Prevention of hyponatraemia in children receiving fluid therapy' and is published in the Ulster Medical Journal.[565] The other is co-written with Dr. Jenkins and is published in the Archives of Disease in Childhood.[566] Both articles refer to 'at least two children in Northern Ireland having died in recent years as a result of severe hyponatraemia', which is defined in the articles as serum sodium of less than 130mmol/L. Neither article specifically mentions Adam's case or his death, and it will be a matter to be addressed during the Oral Hearings the extent to which they were able to assist in the dissemination of the particular lessons learned from Adam's case and Inquest.

301. In addition, Professor Savage asserts in his Inquiry Witness Statement that he used his professional network to advise his colleagues as to the events surrounding Adam's death: *"As a result of [Adam's death] I discussed his case with many colleagues in the UK and indeed possibly further afield at Nephrology meetings."*[567]

302. The possible implications of the Trust's failure to disseminate the recommendations from Adam's case to clinicians other than anaesthetists at the Children's Hospital and to other hospitals with

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560 Ref: May 1997, Vol.50, number 5 p.444
561 Ref: 210-003-040
562 Ref: The Ulster Medical Journal, Volume 69, No.2, pp.90-96, November 2000
563 At the time she was Senior Medical Officer
564 At the time Senior Lecture in Child Health at the Queens University Belfast and a Consultant Paediatrician at Antrim Area Hospital
565 Ref: The Ulster Medical Journal, Volume 72, No.2, pp. 69-72, November 2003
566 Ref: Arch Dis child 2004, vol.89 (1): 93
567 Ref: WS-002-2 p.26

paediatric patients, whether or not surgical cases, are matters that are being investigated.

303. Mr. Ramsden states in his Report to the Inquiry that: *"key clinicians like Dr. Taylor did not accept the view that Adam suffered from [dilutional] hyponatraemia and this will have influenced the scope of lessons learned"*.[568]

304. Indeed Dr. Peter Crean (Consultation Paediatric Anaesthetist at the Children's Hospital and Member of the Northern Ireland Working Group on Hyponatraemia in Children 2001-2002) has indicated his agreement with the view that: *"it would have been easier to use Adam Strain's case history as a vehicle for learning had there been agreement as to the role dilutional hyponatraemia played in Adam's death"*.[569] Dr. Taylor states in his Inquiry Witness Statement that *"We knew that a complete understanding of the reasons for his death would be essential before asking others to change their medical practice."*[570]

305. Dr. Taylor's understanding as to the reasons for Adam's death did not change for many years and nor does he appear to have asked others to change their medical practice. In terms of lessons learned and information disseminated the content of an email from Ms. Christine Stewart, Press and Public Relations Officer, Royal Hospitals Trust is instructive. It is dated 20th September 2004 and relates to her meeting with Consultant Anaesthetist Dr. Taylor: *"I've just spoken with Dr. Bob Taylor, Consultant Anaesthetist in PICU, who was involved in the management of Adam Strain and gave evidence at the Inquest. Following a detailed examination of the issues surrounding patient AS there were no new learning points, and therefore no need to disseminate any information."*[571]

306. The effect of Dr. Taylor's dissenting opinion together with his continued insistence on the validity of his position, despite the Coroner's Verdict, will be considered during the Oral Hearings, particularly with a view to examining the extent to which it might have caused some colleagues to refrain from further enquiry, debate and the identification of lessons through loyalty to Dr. Taylor.

307. Finally, Mr. Chairman, the Oral Hearings will be used to address the fundamental investigation and dissemination issues of:

    (i) What were the obligations, at that time, to report what was known or suspected?

    (ii) What were the proper responses of the system to Adam's death?

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568 Ref: 211-005-018, para.43
569 Ref: WS-013-1 p.14
570 Ref: WS-008-1 p.8
571 Ref: 023-045-105