Witness Statement Ref. No. 077/3

NAME OF CHILD: ADAM STRAIN & CLAIRE ROBERTS

Name: Ian Carson

Title: Dr.

Present position and institution:

Retired
Non-Executive Chairman, Regulation and Quality Improvement Authority (RQIA)

Previous position and institution: Medical Director, Royal Belfast Group of Hospitals

[As at the time of the child's death]

Membership of Advisory Panels and Committees:
[Identify by date and title all of those between January 2000 – October 2012]

Special Advisor to DHSSPS on Clinical Governance (part-time secondment from Oct 1999 to July 2002).
Nothing outside my role as Deputy CMO up to my retirement in April 2006, and my appointment as Chairman, RQIA (June 2006 to present date).

Previous Statements, Depositions and Reports:
[Identify by date and title all those made in relation to the child's death]

Witness Statement 077/1
Witness Statement 077/2
Witness Statement 270/1
Witness Statement 306/1

OFFICIAL USE:
List of previous statements, depositions and reports:

Ref:	**Date:**	

Issues relating to 'Governance'

1. Development of 'self-governing Trusts'.

1.1 The history of NHS reform has been one of constant change, and it remains so to this day. Healthcare professionals, doctors in particular, who had previously exercised considerable influence and power, became increasingly irritated and frustrated with the introduction of continually changing systems and structures. To such an extent that many had become disinterested at best, or totally disengaged at worst. The 1980s saw the introduction of modern management processes (*General Management*) in the NHS to replace the previous system of consensus management, and the Thatcher Government commissioned the Griffiths Report of 1983. This recommended the appointment of general managers in the NHS with whom responsibility should lie. The report also recommended that clinicians be better involved in management with a move to a system based on medical leadership and accountability, rather than one of medical representation.

1.2 Financial pressures continued to place strain on the NHS. In 1987, the government announced a further review of the NHS, and in 1989, the white paper *Working for Patients* was produced. These outlined the introduction of what was termed the "internal market", which was to shape the structure and organisation of health services for most of the next decade.

1.3 The principles of these reforms were adopted by the DHSSPS within Northern Ireland. In the late 80s, while still under the direct management of the former EHSSB, the Royal Hospitals had embarked on what was known as the ‘Resource Management Initiative’. This led to the development of the Clinical Directorate model of management, and ultimately the proposal to establish a ‘self-governing Trust’.

1.4 Following a ‘shadow year’, the Royal Group of Hospitals & Dental Hospital HSS Trust was established as a legal entity with effect from 1 April 1993. As well as the introduction of the local equivalent of the ‘purchaser / provider’ split, we saw the introduction of GP Fund-holding. Attitudes of doctors to the new arrangements were very mixed. Some doctors were enthusiastic and anticipated better opportunities for the ‘clinical voice’ to be heard, and to influence proceedings. Others were quite vehemently opposed. This posed a significant ‘culture’ and management challenge - many doctors saw 'management' as fundamentally being part of the problem. Doctors have been criticised by their peers of moving to ‘the dark side’, if they reduce their clinical commitments and take on greater managerial and leadership roles.

1.5 The Clinical Directorate model of management in the Royal Trust was much ‘bolder’ that that established in other Trusts in Northern Ireland, certainly initially. There was a clearly delegated financial and general management function with accountability and reporting directly to the Chief Executive. Wider governance arrangements were much less clear – the business model, and the challenge of financial survival dominated the focus in the early years of the Trust.

1.6 Within this new model of management, clinical leadership was new for most Clinical Directors and Medical Directors. Training and development was limited, as was the time available to undertake the task. The role was generally undertaken on top of busy clinical commitments. Most first-wave Medical Directors had little administrative support, had wide ranging responsibilities, but little in the way of infrastructure to deliver those responsibilities.

1.7 Arrangements for 'governance' were heavily dependent on 'good medical practice' and professional self-regulation. Considerable reliance was placed on established 'conventions' and traditional practice, rather than frameworks, structures and processes.

1.8 Despite all of this, the model of medical management in the Royal Trust was probably the most advanced in NI, we associated with and learnt from similar large teaching hospitals in Leeds, Manchester, and Birmingham. I spent a considerable amount of time trying to develop the role of clinicians in management in my links nationally with the British Association of Medical Managers (BAMM) and the Association of Trust Medical Directors (ATMD), and locally with the Beeches Management Training Centre.

2. The 'modernisation agenda' in Northern Ireland.

2.1 Progress on health service reform in NI was sluggish in comparison to England, right from the Thatcher Government era up to 2003 - 2006.
Health & Social Services in NI have been organised differently from the rest of the UK for many years.

2.2 We have an integrated health and social service (not so in England). The importance of this is in relation to the development of 'governance reforms' - in England the focus was on 'clinical governance'. Social services in NI, always considered to be the 'Cinderella service', often overlooked and under- resourced compared to the acute sector, did not wish to be separated in a policy sense from developments in governance issues. So, in NI we eventually in 2003 had the emergence of *'clinical and social care governance'*. During 'direct rule' Northern Ireland Office Ministers in my opinion were reluctant to enforce health service reforms, as this was in due course going to be a devolved matter. We have subsequently seen the emergence of four different models of health and social care provision in England, Wales, Scotland and Northern Ireland.

2.3 Structurally we had HSS Trusts (providers of services), HSS Boards (commissioners of services) and the DHSSPS (responsible for policy, funding, and 'performance management'). In England there were NHS Trusts (providing services), NHS Regional Health and later NHS Strategic Health Authorities (responsible for commissioning, service planning, but also for performance management) and the DoH (responsible for policy and funding).

2.4 English Circulars / Guidance had no remit in NI, unless adopted by the DHSSPS, although that did not prevent 'forward looking' Trusts from taking proactive steps in the absence of definitive guidance from the DHSSPS. Prior to devolution, traditionally NHS guidance was adapted for use in NI, but frequently that lagged behind (sometimes quite significantly) before it was introduced locally.

2.5 The 'internal market' with a purchaser/provider split, although it didn't operate in the way that was originally envisaged, with poorly performing organisations being outstripped by more successful organisations, did result in considerable competition between Trusts within Belfast and NI as a whole.

2.6 The focus in the 1995/96 HPSS Management Plan was on:

- Completing the separation of purchaser and provider organisations.
- Further development of GP Fund holding.
- Targets on prescribing and reducing the drugs bill.
- Improving efficiency (3% p.a).
- Targets for improving health and well being (heart disease & cancer).
- The development of the Charter for Patients and Clients.
- The DHSSPS was to establish a Clinical Standards Group to evaluate and disseminate information about clinical effectiveness. To assist purchasers in the contracting process.
- Addressing health inequalities.
- Value for Money (VFM) initiatives.
- Explore opportunities to secure private sector funding under the Private Finance Initiative.
- Reducing hospital ‘length of stay’ & increasing use of ‘day cases’.
- Reducing the overall requirement for acute beds.
- Reducing management costs.
- Stricter financial control & monitoring.

- Stewardship of public funds and accountability.

2.7 Trusts invested a lot of management time on organisational development, the achievement of such things as Kings Fund Accreditation, Charter Marks, Investors in People, EFQM etc., etc. Many clinicians viewed these achievements with scepticism, considered them to be a distraction, and didn't necessarily agree that they resulted in improvements in patient care.

3. Governance instruments

3.1 Further to the comments in 1.7 above, there were several components of what we now know as Clinical Governance, or Clinical & Social Care Governance in NI, in place prior to the establishment of the statutory Duty of Quality in 2003. They may not have been as analytical or inquisitorial as more recent application of even the same component, and the development and introduction of newer methods of scrutiny and assurance. They did serve a useful function, they were not full proof, and they did provide a vehicle for learning.

3.2 Morbidity & Mortality meetings:

Historically these were usually associated with obstetric practice, surgical disciplines and anaesthetics/ICU services. Medical colleagues usually focused their activities in the 'physicians meeting', clinical pathology conferences or multi-specialist 'grand rounds'. These were regular (usually monthly, but sometimes weekly) activities associated with a teaching hospital, such as the Royal, and what marked it out as being different to smaller local hospitals. These meetings were sometimes led by the Professor, or other senior members of the University Department, or by the Clinical Tutor, or by consultants with responsibility for education. Consultants and junior doctors from other hospitals often attended these meetings, sometimes presenting 'interesting cases'. These meetings were the sorts of activities that Medical Royal Colleges looked for during their training inspections.

Given the number of deaths that occurred in hospitals, particularly in regional centres such as the Royal with its role as major trauma facility, it would have been

difficult to ensure that every death was considered. The absence of any documentation in relation to these meetings was not solely about issues of ‘confidentiality’, or protecting the reputation of doctors during ‘robust’ discussion, it was more often due to the fact that there was unlikely to be someone present with medical secretarial skills to record a transcript of the issues discussed.

In the 1990s, the Trust also participated in the national confidential enquiries, such as the National Confidential Enquiry into Perioperative Deaths (NCEPOD), the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI), and the Confidential Enquiry into Maternal Deaths (CEMD) – again these, by definition were confidential, and participation by individual clinicians was voluntary.

3.3 Medical Audit:

In 1989, the White Paper, *Working for patients*, saw the first move in the UK to standardise audit as part of professional healthcare. The paper defined medical audit (as it was called then) as "the systematic critical analysis of the quality of medical care including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient."

In general terms it was an opportunity for doctors to 'reflect' on their practice, to look at such things as 'outcomes', rates of complications or infection rates etc. It also provided an opportunity to look at the processes that underpinned the delivery of care, how to improve efficiency, increase turnover, reduce waiting lists or waiting times, to look at factors that contributed to 'bed-blocking etc.

Some doctors viewed medical audit as being 'unscientific', lacking critical appraisal, statistically unreliable, and in general terms somewhat ‘soft’. Many preferred to push forward advances in medical science through clinical research, which they considered to be much more 'sound', and which enhanced their CVs, and their professional reputation regionally, nationally and internationally.

Medical audit was certainly not a rigorous investigative analysis of individual cases, as it has been portrayed to a significant extent during this Inquiry. It certainly did not cover every untoward event that took place in every unit across the hospital trust. Having said that some doctors considered audit to be unscientific, the process of audit

does employ certain methodologies and techniques which a limited number of trained audit staff were able to use to assist clinical staff in audit activities. The Royal Trust had a team of somewhere between 4-6 audit assistants working across all 12 Directorates. Their ability to deliver a comprehensive service was very limited, there were no additional resources to develop the service, and in fact the audit department was always vulnerable to efficiency savings and budget reductions, as Dr Murnaghan can attest to. As a consequence, not every consultant was active in audit, and it was only in the late 90s that we wrote it into job descriptions and it became a contractual commitment to be involved. Contracts still do not stipulate how much audit an individual doctor needs to undertake, or what subjects or issues should be audited.

In the mid-90s, as Medical Director, all I was required to ensure was that there was a credible audit programme in place in the Trust, and that each Directorate had a clinical audit lead. The Trust did produce Annual Audit Reports, and had an audit strategy in place. Audit activity was also undertaken at area Board level, at Regional level, within the Postgraduate Deanery (NICPGMDE) and in some specialties, at national level (e.g. National Sentinel Stroke Audit; Association of Thoracic & Cardiovascular Surgeons; Intensive care ICNARC). To participate in some of national audits required clinicians to seek additional funding to support these activities. This widespread activity, while good, was quite disparate and not always known to the Trust, it was uncoordinated and did not always reflect Trust audit or other priorities.

The National Institute for Health and Clinical Excellence (NICE), whose remit did not extend to NI until 2006, published the paper *Principles for Best Practice in Clinical Audit* in 2002 and defined clinical audit as *"a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery."* 'Explicit standards' for care were in many cases not widely available, and where they did exist (e.g. Royal College, or specialist association) there was not always agreement that they applied locally.

3.4 Clinical / Multi-professional Audit:

In the mid-90s there was a move away from uni-professional (or medical) audit to clinical or multi-professional audit, i.e., doctors, nurses and other clinical professions. For those doctors already not engaged, this was potentially a further disincentive. It is recognised that a culture of 'clinical freedom' has long existed, and there was resistance to the use of “cook book” medicine through the use of guidelines / protocols / care pathways / national frameworks.

Things didn't change until participation in audit became a requirement in such activities as appraisal and revalidation. It has also become increasingly difficult for clinical staff to obtain funding for clinical research - they need to be linked to 'recognised research groupings', subject to more rigorous research ethics and research governance requirements; interest and involvement in audit has increased as a consequence.

Even with the growing acceptance by clinicians and other progress in regard to audit, it cannot provide the analytical scrutiny of every individual incident or untoward event that takes place in a hospital as complex as the Royal Trust in the 1990s, or in the much larger Belfast Trust today.

3.5 Complaints Management:

Complaints against the Trust, its services, and its employees were the responsibility of the Chief Executive. The Director of Nursing and her staff managed the process on his behalf, including the initial investigation of the complaint. Contact would have been through the Clinical Directorate in the first instance. If the complaint was related in any way to the behaviour or performance of a doctor, then Dr Murnaghan, as Director of Medical Administration, or myself, as Medical Director would have been informed and involved where necessary. If required, and again where a doctor was involved, I would have facilitated local resolution with the complainant or family members.

If the complaint was upheld, and disciplinary procedures or professional performance procedures were considered necessary or appropriate, then the matter

would have been escalated for the Director of Human Resources and myself, as Medical Director to consider the next steps.

3.6 Health & Safety / Risk Management:

The NHS Management Executive manual '*Risk Management in the NHS'* was launched in England in 1993. The HPSS Management Executive circulated it to the HPSS shortly after that. I do not recall how the Management Executive expected it to be taken forward. Certainly I do not recall any reference in the Management Executive Plan 1995/96 requiring Trusts to achieve a definitive outcome. While it was an excellent publication outlining "a structured approach to a complex subject", it was more in the form of an educational handbook for information and use within the HPSS. It did provide a useful framework within which the Royal Hospitals Trust could develop an approach to risk management, and it was used as such.

One of the main reasons that the Royal Hospitals Trust decided to undertake the Kings Fund Organisational Audit was to try and improve local systems.

In the early to mid 90s, the emphasis was largely on financial risk, the exposure to loss through failure to comply with Health & Safety legislation, improving absenteeism the through effective occupational health services, and the safeguarding of our employees to hazards of infection (Hep B, Hep C, HIV etc).

3.7 Incident Reporting:

Incident reporting was quite rudimentary initially through the use of the nursing Ward Incident Book; it improved with the use of the IR1 reporting forms, the appointment of a Trust Health & Safety manager, and subsequently a Trust Clinical Risk manager. It is well documented, that apart from the reporting of adverse reactions to drugs (the "Yellow Card" scheme), and possibly the reporting of adverse incidents involving medical devices, doctors were very poor at reporting incidents or adverse events. The culture of reporting, although not perfect, was much better up the 'nursing line'. In the 1990's and possibly into 2000, it was generally accepted that despite improvements in processes and the prevailing culture, there was still significant under-reporting in the NHS; minor and relatively trivial events were more likely to be reported

than more significant events; as reporting increased the analysis of events became very time consuming, and the ability to assimilate and disseminate lessons even within an organisation became very difficult. This led to a major initiative in England following the publication of '*An Organisation with a memory"* in 2000, and the government's response in 2001 *"Building a safer NHS for patients"* and the establishment of the National Patient Safety Agency. Again, unfortunately, this did not have a remit in Northern Ireland.

In the 'competitive' environment that existed in the 90's Trusts were most unlikely to share learning with other organisations; the four Health Boards and the DHSSPS were generally considered to be the mechanism whereby lessons where disseminated, generally through a Departmental Circular or guidance note.

3.8 Clinical Negligence & Litigation:

Clinical negligence cases are an obvious source of learning, however, in my view it has historically exerted a somewhat negative influence. Over the past 11 years in Northern Ireland it has triggered two reports from the NI Audit Office. The first report published in 2002, indicated that over the 10 years prior to the publishing of the report (and covering the time period that the Inquiry is considering) the cost to the health service in NI was in excess of £55 million in settlement of claims, and a further £121 million of potential liability against outstanding liability. This also does not take into account the continuing cost to the health service in continuing to care for seriously injured patients as a result of medical accident.

Trusts seek to defend their resources, their staff and their reputation when cases proceed to litigation. The adversarial and inquisitorial nature of a High Court case with the associated potential media publicity is usually a very damaging and difficult process for staff to be exposed to. It is also apparent that the same mistakes recur with considerable frequency, so the learning and its dissemination to a wider health service audience that should take place, is obviously not.

In England, the NHS Litigation Authority (NHS LA) was established in 1995 as a Special Health Authority. It provides indemnity cover for legal claims against the NHS

in England, and assists the NHS with risk management, the sharing of lessons from claims and provides other legal and professional services for its members.

The Clinical Negligence Scheme for Trusts (CNST) operated by the NHS LA handles all clinical negligence claims against member NHS bodies. Although membership of the scheme is voluntary, all NHS Trusts (including Foundation Trusts) and Primary Care Trusts (PCTs) in England currently belong to the scheme. The costs of the scheme are met by membership contributions. Individual Trust contribution levels are influenced by a range of factors, including the type of trust, the specialties it provides and the number of "whole time equivalent" clinical staff it employs. Discounts are available to those trusts that achieve the relevant CNST risk management standards, and to those with a good claims history. This is a considerable incentive for organisations to learn from incident and to improve.

3.9 Apart from learning from clinical negligence, and reducing the frequency and costs of claims, there should be greater emphasis on finding alternative means of finding resolution for patients and their families. Following the publication in 2003 of the Department of Health in England consultation document *'Making Amends – Proposals for reforming the approach to clinical negligence in the NHS',* it is disappointing that there has been so little progress in the search for other methods of redress.

3.10 Another key document providing guidance to the NHS in England was the publication by the National Patient Safety Agency (NPSA) in 2004 (relaunched in 2009), of *'Being Open: communicating patient safety incidents with patients, their families and carers'*.

3.11 It is also noteworthy that in February 2011, the House of Lords rejected a proposed amendment to the Health and Social Care Bill calling for a *'Statutory Duty of Candour'*. The Government now seem to be pushing ahead with a *'Contractual Duty of Candour'* in the NHS Standard Contract in 2013/14. While the Government is currently of the opinion that a contractual duty is probably the most effective mechanism for

requiring openness, this decision may be influenced by the findings of the Mid-Staffordshire Inquiry.

4. Junior staffing

4.1 Many areas of the Trust were overstretched when it came to 'out of hours' cover, not just Children's. A&E departments were particularly troublesome and high risk. Cover for surgical wards were also difficult, particularly when the on-call surgical team had to leave the ward to operate in theatre, and especially so if more than one theatre had to be opened to deal with multiple injuries.

4.2 There were particular issues in relation to 'regional funding' of children's services. When the budgets were devolved to the Paediatric Directorate, I think there were significant shortfalls. It was difficult to differentiate how much of the costs were attributable to regional services, EHSSB provision, acute hospital or community services.

Regional services were negotiated/contracted and funded on behalf of the 4 HSS Boards by the Regional Medical Services Consortium (RMSC). The Northern, Western and Southern Boards were not always willing to contribute to funding in Belfast, as they were building up paediatric services in Antrim, Altnagelvin or Craigavon; and within the EHSSB the Royal was competing with the Ulster for paediatric resources.

The Children's Services strategy document (1996) prepared by the Trust in conjunction with the Paediatric Directorate was intended, among other things, to address some of these funding and staffing issues.

4.3 The New Deal, agreed in 1991 by representatives of the medical profession, NHS Management and the government, was a package of measures designed to improve the conditions under which Junior Doctors work. One of the key features is to place limits on the number of hours of work. By 31 December 1996, the maximum contracted hours for each type of working pattern worked by junior doctors was agreed as:

- 72 hours a week for on call rotas

- 64 hours a week for partial shifts
- 56 hours a week for full shifts.

The EU Working Time Directive while relatively easy to apply in certain work spheres to ensure 'health and safety', it was extremely difficult to introduce throughout the NHS; and it continues to be a major bone of contention in two main areas: (i) the provision of safe and effective care throughout a 24 hour period and a seven day working week, and (ii) the implications for the quality and duration of postgraduate medical training.

Many Trusts had great difficulty with implementation of the New Deal. It had significant implications for the way in which services were configured and delivered. 'Inappropriate tasks' undertaken by doctors were to be transferred to clerical staff; some 'less skilled' duties could be transferred to nursing or other non-medical staff e.g. venesection; and there were proposals to increase the numbers of non-training / career grade medical staff. All of these had huge implications for funding, and additional resources were not readily available. The New Deal was further refined in 1999 in terms of shift patterns and rest requirements along with a new pay structure for doctors.

A Northern Ireland Task Force was established by the DHSSPS to address the significant and real challenge facing Trusts. Problems were evident across the whole system, both in the smaller local hospitals, and in the larger teaching hospitals. The Northern Ireland Improving Junior Doctors' Working Lives Implementation Support Group (ISG) was established in August 2001, to facilitate the implementation of the New Deal for Junior Doctors and move towards the European Working Time Directive, which was to apply to junior doctors from August 2004. The ISG played an advisory role and worked with Trusts, Boards and the Department to improve local compliance levels throughout HPSS.

4.4 Medical workforce planning was the responsibility of the DHSSPS. In particular, junior doctor training numbers had to be closely linked to the training needs of the HPSS in Northern Ireland. If too many doctors were trained, and there was not a correlation with the number of available consultant posts, then doctors sought consultant posts outside Northern Ireland – a significant professional and economic loss. This was a delicate balancing act, and Trusts had great difficulty at times filling

consultant vacancies in certain specialties. Recruitment from outside the UK became increasingly difficult, both into training posts and to service posts.

The DHSSPS ultimately was the source of funding for all medical posts; this was channelled through the four Health & Social Service Boards, and then included in the contract funding arrangements. As a consequence service development was at times frustratingly slow.

4.5 Similar barriers were encountered when it came to resourcing capital projects, whether that was in relation to building projects, intensive care facilities, operating theatres, day-patient units, computer systems and medical equipment (including CT scanners, MRI scanners, laboratory instrumentation, critical care monitoring equipment and ventilators. The one-off procurement cost of the equipment was the easy part, it was much more difficult to secure the ongoing revenue consequences. New equipment often required additional trained staff to run it and maintain it. There were also difficulties when equipment, or on occasions when healthcare staff, had been funded through charitable donations. The purchasers were reluctant to pick up the financial consequences when donated funding ceased.

5. Training Inspections

5.1 All Medical Royal Colleges, including the Royal College of Paediatrics & Child Health as far as the RBHSC was concerned, conducted regular training visits/inspections. The Northern Ireland Council for Postgraduate Medical & Dental Education (NICPMDE) coordinated these visits/inspections. They were usually conducted on a regional basis ("the Deanery") and organised through the office of the Postgraduate Dean. The Dean (who also acted as Chief Executive), and the Council, was responsible and accountable for the oversight of all postgraduate medical and dental training in Northern Ireland. The accountability line was primarily to the DHSSPS, but in addition, the Dean and Council liaised with and reported to the 'UK competent authorities' at a national level responsible for accreditation of training. In 1995 this would have been the Specialist Training Authority (STA) for specialist medical

training, and the Joint Committee on Postgraduate Training for General Practice (JCPTGP) doctors entering general practice.

The visits certainly looked at staffing issues and well as the provision of training opportunities, including educational meetings, clinical audit, and supervision. In the 80s and early 90s College reports/findings were returned to the NICPMDE, the Postgraduate Dean, the Regional Adviser and the College Tutor, often with recommendations to increase training posts, or demands to increase consultant numbers (but they did not provide funding!). If Trusts were unable to meet the College recommendations, then the ultimate sanction was to withdraw training recognition if the staffing balance could not be achieved, or the educational support/benefit was not evident.

Health service planners at that time were reluctant to be seen to withdrawing or threatening local services. So it was not uncommon to find junior posts being sustained in non-viable training units providing mainly a service role, rather than being centralised into larger units for teaching and training purposes. In the later 90s, feedback was often given directly to 'senior management', at the end of the visitation.

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: Dr Ian W. Carson **Dated:** 9th January 2013