

## EXPERT REPORT

### GOVERNANCE ISSUES: RAYCHEL FERGUSON

My name is Professor Charles Patrick Swainson. I am a retired (2010) consultant renal physician and medical director previously employed by the Lothian NHS Board, Edinburgh, UK. I was responsible for clinical governance and risk management, research and development, medical staffing, appraisal, performance and contracts, clinical service strategy, information and technology and pharmacy services.

The Inquiry has asked for guidance and opinion in relation to the following governance issues arising from Raychel's case.

#### General Queries

*The governance context of the case of Raychel Ferguson, and whether Altnagelwin, the Royal Belfast Hospital for Sick Children and their respective Trusts complied with the governance standards which might have been expected at the time;*

1. Clinical Governance was introduced in the UK in 1998<sup>1</sup> as a "formal framework through which NHS organisations became accountable for continuous improvement in the quality of services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish". Clinical governance requires organisation wide systems to support high quality clinical care through policies, procedures and behaviours. Clinical Governance developed in each of the 4 countries of the UK differently. In Scotland, a new special Health board was created (Quality Improvement Scotland) which published governance standards in 1999 and began a series of 3-4 year cycles of monitoring and assurance against those standards of NHS Trusts. Reports were published.
2. Clinical governance has been part of the professional codes of conduct of doctors, nurses and midwives and other regulated healthcare professionals for many years predating these events although not specifically named as such. For example the General Medical Council issued, to every registered doctor in the UK, *Good Medical Practice* as a guide to the standards of practice that doctors were expected to adhere to, and which would form the basis of any investigation as to their fitness to practice in the event of serious or persistent failures to follow them. In 2000, these standards included <sup>2</sup>:

- a. "keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed;
  - b. You must work with colleagues to monitor and maintain the quality of the care you provide and maintain a high awareness of patient safety. In particular, you must take part in regular and systematic medical and clinical audit, recording data honestly. Where necessary you must respond to the results of audit to improve your practice...
  - c. Take part in confidential enquiries and adverse event recognition and reporting to help reduce risk to patients.
  - d. If a patient under your care has suffered harm, through misadventure or for any other reason, you should act immediately to put matters right, if that is possible. You must explain fully and promptly to the patient what has happened and the likely long and short term effects. When appropriate you should offer an apology. If the patient is an adult who lacks capacity, the explanation should be given to a person with responsibility for the patient, or the patient's partner, close relative or a friend who has been involved in the care of the patient, unless you have reason to believe the patient would have objected to the disclosure. In the case of children the situation should be explained honestly to those with parental responsibility and to the child, if the child has the maturity to understand the issues.
  - e. If a child under your care has died you must explain, to the best of your knowledge, the reasons for, and the circumstances of, the death to those with parental responsibility..."
3. In 2001, there was no statutory accountability for the quality of care to patients treated by an NHS Trust in Northern Ireland; I understand a statutory duty was not established until 2003 although I have not read the relevant legislation. However any organisation providing health services had a duty of care in law and operated effectively in a governance framework. For example, a Trust could be sued for negligence in respect of the actions of its professional employees; a strong framework of financial accountability for revenue and capital expenditure was in place; and Trusts were expected to implement guidance from Government. Trusts had few sources of information about the quality of care, and there was no clear reporting framework. Trusts would know about the number of claims made against them; in Scotland, a risk share scheme was in place that reported annually to the government and to Trusts on the costs of settled claims and estimates for future claims, broken down by specialty. I understand similar arrangements existed in the other countries of the UK.
  4. In 2001, there were a number of documents describing the governance framework in which Trusts in Northern Ireland were expected to operate.

The Northern Ireland Health and Personal Social Services Charter for Patients and Clients, published in 1992, sets out the standards of care and treatment to be expected <sup>3</sup>. This includes the **right** “to be kept informed about your progress”, and the **expectation** that “you should:

- a. Be told the name of the consultant responsible for your care and treatment, and
  - b. The **right** to a named nurse.”
5. *Confidence in the Future* was published in Northern Ireland for consultation in 2000 and indicated a new approach to the detection and management of doctors’ clinical performance using a new system of annual appraisal. The Chief Executive of Altnagelvin Trust was a member of the Working Party that drew up these new arrangements.
  6. Altnagelvin Trust had governance policies in place. One was a policy for the Handling of Complaints (published in 1996, and revised 1998, 2002 and 2005), the purpose of which was to ensure that staff learn lessons and improve the quality of care <sup>4</sup>. The procedure was to embody the principles in the Wilson Report (not seen) which included responsiveness and accountability.
  7. Trusts were issued with guidance on the handling of medical negligence claims in 1998 and later e.g. HSS (F) 20/1998 and HSS (F) 20/2002 which are relevant here in the context of how clinical claims should be handled. Altnagelvin Trust published a policy for handling claims <sup>5</sup> (this is undated but refers to the relevant circulars up to 2007) which gives also a broad overview of the Trust’s Risk Management philosophy and which claims to reflect the Departmental guidance referred to above. Para 2.3 states the Trust “is committed to a safe, open and learning culture that encourages staff to report...adverse events/incidents...and (para2.4) an environment of openness that encourages parties to resolve disputes, reduce delays... and reduce the requirements for litigation.” Further in para 6.1 the “Trust encourages staff to offer apologies and/or explanation as soon as an adverse outcome is discovered.”
  8. The Trust Clinical Risk Policy<sup>6</sup> in October 1997 “aims to reduce the recurrence of preventable adverse effects, minimise injury to patients, facilitate where necessary swift resolution of claims (and) improve the quality of care for patients. Clinical Incident Reporting acts as an *early warning* of impending clinical negligence claims....we want to encourage a culture of honesty and openness where mistakes... are identified quickly and dealt with in a positive and responsive way.” In a revision published in 2000 <sup>7</sup>, the revised policy has dropped the previous 3<sup>rd</sup> aim “to facilitate where necessary the swift resolution of claims” and provides no explanation for this change.

9. The Trust Policy for the Control and Administration of Medicines<sup>8</sup> requires at para 3.1 that **“nursing staff must not administer drugs...to patients which have not been authorised by a doctor.** This authorisation must be in the form of a written prescription.” An exception is allowed only for orders in an emergency and given by telephone.
10. The proposed strategy for the Implementation of Clinical Governance in 1998<sup>9</sup> states at 001: “Central to the change in culture and thinking should be the acknowledgement and dissemination of existing good practice both within and outside the organisation.” It goes on at 003: “The Trust plans to measure the outcomes of care through more rigorous Clinical Audit. The process... must include an action plan to address deficits in care and a timetable for the re-audit to take place...Issues identified through clinical incidents and litigation will provide a focus for audit topics.” Further, in 003 “The Trust will continue to seek the views of patients through...complaints procedures, patient surveys” and “The Hosquip programme will continue to provide the focus for further quality development in response to issues arising from these channels.”
11. The first published report of the new Altnagelvin Trust Health and Social Care Governance Committee<sup>10</sup> in 2003 “provides information on our progress along our clinical governance journey over the past year.” The report discusses strategy, structures, policies, audit and other activities, clinical negligence claims, risk management, education and training, user involvement and a quality action plan. There is no mention of this case or the profound changes in quality of services that happened as a result.
12. In my view the Altnagelvin Trust fell short of some of these published standards expected of public bodies and failed to implement at times its own policies and procedures. The 1992 charter<sup>3</sup> was not implemented (the Fergusons did not know their child was under the care of a consultant; no named nurse); the record of the September 2001 meeting with the Ferguson family appears to fail to follow Department advice on openness and its own Clinical Risk policy with respect to avoiding litigation<sup>5,6</sup>; and the report of the Governance Committee displays little published Board level acknowledgement of the seriousness of Raychel’s death and the consequences for the family and the Trust.
13. I have not been provided with any governance material from the RBHSC and cannot make any direct comment.

*The responsibilities and accountabilities of the employees of the Trusts from the Chief Executive down;*

14. The chief executive was responsible and accountable to the Board of the Trust. The chief executive was responsible for the operational governance of the organisation within the framework operating in 2001. This would include that the 1992 Charter for Patients and Clients<sup>3</sup> was implemented and monitored, and that the Trust policies were developed, implemented and monitored in line with guidance issued by the Department, as well as financial accountabilities. The rights and expectations of Mr and Mrs Ferguson within the Northern Ireland Health and Personal Social Services Charter for Patients and Clients, published in 1992<sup>3</sup>, were not met and were deficient in respect of not knowing who the consultant was in charge of their daughter's care, nor having a named nurse. The named nurse concept had been difficult to implement across the UK. The concept of a named nurse for a whole episode of care may have resulted in better communication with the parents; even on a single shift, a nurse with responsibility for a child could have resulted in earlier recognition of the child's deteriorating clinical state.
15. The accountabilities of chief executives were limited in 2001. They were usually required to be the Accounting Officer; that is accountable to the Department, as well as the Board, for the resources provided by Government and how those resources were applied. They would be accountable for other Government targets such as waiting times, and chief executives would have information on these aspects of governance readily available and would be expected to manage them. Chief executives would not have been expected to be responsible for the quality of care; this was viewed, until 1998<sup>1</sup>, as the responsibility of the professionals involved. Chief executives would have been informed and involved in limited circumstances. As examples, the death of a child with the attendant publicity and media attention; reckless or dangerous behaviour of a member of staff; the referral of a staff member to a professional or regulatory body; the care or treatment of a VIP with likely media interest or any clinical incident that would have consequences for the organisation. Chief executives would depend on other directors giving them the information in a timely fashion.
16. The medical director, Dr Fulton, was responsible for medical clinical audit and professional standards. He organised promptly a critical incident review. The notes indicate appropriate actions<sup>11</sup> for the immediate few weeks, in particular taking action to discover the cause(s) of the hyponatraemia and to seek alternative solutions in practice elsewhere, and agree practical actions to avoid causing and/or failing to detect hyponatraemia. The actions of Dr Fulton and Dr Nesbitt at this time are consistent with Trust policies and commendable for their speed and

decisiveness. It is clear that the doctors and nurses present at that meeting suspected that the use of Solution 18 after an operation and failure to check electrolytes while on intravenous fluids; these were discussed openly with the family in September<sup>12</sup>. Failings in the accurate recording of fluids administered and to measure urine and vomit output properly that were important factors do not appear to have been discussed, nor was any recognition that the worsening of Raychel's condition during the evening of 8 June was due to factors other than normal post-operative recovery.

17. Within 1 month, Dr Fulton, with the CMO Dr Henrietta Campbell and others, supported by the chief executive, had agreed and organised a review of the fluids to be used in children. This resulted in the regional review and new guidelines in 2002 sent to every hospital treating children in Northern Ireland. This was a significant and highly commendable set of actions which have improved considerably the quality of care across the province and reduced the risk of hyponatraemia occurring and not being recognised; none of this work in progress, and acknowledgement of the critical role of Solution 18 was discussed with the family at the meeting in September 2001.
18. Mr Gilliland, Dr Nesbitt and the other consultants were accountable to their patients for the care given by them and by doctors in training assigned to work with them; they were accountable to the General Medical Council to maintain the standards set out in *Good Medical Practice*; and accountable to their employer for discharging clinical and administrative duties as governed by their contract of employment.

*The nature of the responsibility (if any) of the Chief Executive for the quality of healthcare delivered in 2001 (prior to the introduction of statutory responsibility in 2003);*

19. The chief executive did not appear to have statutory accountability for the quality of care prior to 2003. However the chief executive was accountable to the Board for the overall delivery of care, for the implementation of Department guidance on aspects of care, a general duty of care on behalf of the organisation, and a duty to ensure that regulated employees were in good standing with their regulator(s), and acted within the law.

*Whether there were failings in the regulatory systems of internal control and quality assurance at Altnagelvin and if so what they were;*

20. There were weaknesses in the controls assurance framework, but these would be unlikely to be unique to the Altnagelvin Trust, prior to the introduction of formal clinical governance in 2002-3. For example I have seen no evidence of the learning or actions from clinical audit in the

paediatric wards prior to the fluid audit in 2004. There is no evidence provided of learning or actions from the Hosquip programme about patient complaints, and it is unclear how the Trust ensured that the general surgeons remained competent and up to date in children's surgery. I have seen no evidence of morbidity and mortality meetings in the surgical directorate and in particular after the death of Raychel Ferguson. There does not appear to be a system for considering and acting upon external reports such as the UK NCEPOD reports<sup>16</sup> or the Review of Paediatric Surgical Services in Northern Ireland<sup>17</sup>.

21. This sad case illustrates James Reason's Swiss cheese theory of how adverse events can occur<sup>18</sup>. It is a breakdown of controls that could prevent a bad outcome. For example, if Mr Makar had called Mr Gilliland, the operation may not have taken place. If the practice of prescribing fluids had been the clear responsibility of the team looking after the patient, then Hartmann's or half strength saline may have been prescribed and at a lower rate of administration; if Mr Gilliland had done a brief ward round, the instructions to the nurses on oral fluids may have been better given. If the surgical junior trainees were more available to the ward, Raychel may have been reviewed again in the later afternoon of 8 June; if she had been reviewed, electrolyte tests may have been taken that would show the developing hyponatraemia. At many points in this chain of events, I can find either latent conditions or active errors that demonstrate weak internal controls.

*Raychel's transfer to the Royal Belfast Hospital for Sick Children;*

22. The request to transfer to the RBHSC at 9 am on 9 June was reasonable<sup>14</sup>. Dr Nesbitt realised that they were dealing with a seriously ill child with possible meningitis or encephalitis and a suspected brain haemorrhage, as well as profound hyponatraemia. Dr McCord had initiated active treatment immediately with antibiotics given at 5 am; the significance of the low plasma sodium was appreciated at Altnagelvin by Dr McCord around 5.30am and he started appropriate treatment with normal saline at 2/3rds the maintenance rate. A note made at 6.15 am by Dr B McCord describes "tonic posturing -? decerebrate...→dilated fixed pupils...pupils unreactive/unresponsive"; this clinical description is of severe and probable irreversible brain damage.
23. Dr Nesbitt discussed the case with a neurosurgeon at RBHSC and stated that transfer was requested by the neurosurgeon (as an operation was contemplated after the first CT scan). After the second CT brain scan it was clear that there was no sub-dural collection and a subarachnoid haemorrhage was described as small. It is unclear whether the reasons for transfer were reviewed by the doctors at RBHSC, once they knew that the scans (available to them through the image link) suggested no operation

would be likely and the main diagnosis was cerebral oedema with a clinical picture of irreversible brain damage.

24. However the 2 hour period from agreeing the transfer at 9 am to the actual journey at about 11 am raises a number of concerns. It is clear that Dr Nesbitt believed that Raychel should go to RBHSC based on his discussion with the neurosurgeon. The consultants at RBHSC had decided at some point after the second scan at about 8.30am that no active surgery was likely to be useful; she was to be stabilised in the PICU prior to brain stem testing. This was done about 5 hours after Raychel arrived and was settled in the paediatric ICU and when the plasma sodium had returned to normal. Had the diagnosis been discussed by the PICU consultants with Dr Nesbitt, a transfer for a hopeless case could have been avoided, and the parents could have been better prepared. On the other hand, there was no proper paediatric ICU at Altnagelvin and likely no experience of confirming brain stem death in a child.
25. The final interpretation at Altnagelvin of the second CT scan was not made until 12.30 on 11 June, after Dr Morrison had reviewed the CT scans with Dr McKinstry; cerebral oedema was their conclusion and not subarachnoid haemorrhage.

*The way in which the Trust(s) managed their interaction with the Fergusons after Raychel's death (to include the sharing of information relating to the cause of death);*

26. Altnagelvin Trust appeared to follow its own policies and procedures and Departmental guidance. The chief executive was present at the meeting with Mr and Mrs Ferguson in September 2001<sup>11</sup> and had written quickly after the incident to Mr and Mrs Ferguson inviting them to contact her office for a meeting. The notes suggest that the matters discussed were determined by the questions asked by the family; there was no attempt by the chief executive, nurses or doctors to create "an environment of openness that encourages parties to resolve disputes, reduce delays... and reduce the requirements for litigation"<sup>5,6</sup>, nor one that "encourages staff to offer apologies and/or explanation as soon as an adverse outcome is discovered". I understand that the chief executive did express condolence and sympathy to Mr and Mrs Ferguson. Mr and Mrs Ferguson appear not to have been aware of the explanation for the hyponatraemia, nor the devastating consequences, and the Trust's role in causing that.
27. On the other hand, Dr Nesbitt's witness statement (WS-035/2) p22-24 makes clear that he believes that he gave a full explanation of events including the role of Solution 18 and the hyponatraemia. The nursing staff said that the vomiting was not of concern; there appears to be a difference here with the expert witnesses.



28. Mrs Burnside in her witness statement (WS-046/2) p27 says that there was no pre-meeting with staff, and staff were free to answer the family's questions how they wished. Indeed she said that staff should be kind, compassionate and honest. She observed further that "Mrs Ferguson was stunned and alone.....and was not sufficiently robust to be engaged with the process at this time". This may explain why the staff recollections of this meeting and Mrs Ferguson's recollection are different.

*The way in which the Trust(s) managed and approached the Inquest, to include the process of taking witness statements and the sharing of reports; the apparent failure of Altnagelvin Hospital Trust to supply Mr. and Mrs. Ferguson or HM Coroner with a copy of Dr. Warde's report or to refer to the initial reports of Dr. Jenkins and his reference in them to the need for further information in respect of vomiting and the conduct of the nurses;*

29. It is hard to discern a chronology for the Trust's actions and to understand the reasons for delays in holding an Inquest. This was partly because of the time to get agreed witness statements from Trust staff, for the time to get expert reports for the coroner. Dr Warde's report reinforces what others were concerned about; that hyponatraemia caused brain swelling that led to Raychel's death and that the combination of vomiting and too much hypotonic fluid led to severe hyponatraemia. This could have been shared with the family GP and the family and should have been shared with the Coroner. It would not be common practice to share with the family that once litigation had been started. It is not clear to me that the Coroner would have behaved any differently as I don't know when Dr Warde's report was commissioned and delivered; the Coroner engaged Dr Sumner early on.

30. At the meeting with the Western Health and Social Service Council in February 2003 (023-004), Mrs Burnside accepted that the death (of Raychel) was avoidable.

*The apparent failure of the Royal Belfast Hospital for Sick Children to alert Altnagelvin to their discontinuance of Solution 18 prior to the date of Raychel's death.*

31. RBHSC was an independent organisation and with no obligation to report changes in clinical practice to other paediatricians in Northern Ireland or elsewhere. There was a clinical debate at the time about the type of solutions administered to children in different clinical circumstances, and therefore clinical teams would be expected to review their own practice (clinical audit, morbidity and mortality reviews) and make changes as they saw fit. RBHSC had no duty to share changes in thinking or practice, but I

would have thought there was a professional obligation to share significant changes in practice with other colleagues in the province particularly if the change is driven by an adverse event; after all it is the only specialist paediatric centre in NI. There may have been opportunities with specialist groups (e.g. anaesthetists or surgeons) in a professional meeting to share changes in practice, especially where changes were driven by adverse events or complications of care. RBHSC is in a unique position to gather information on rare adverse events because all cases would be referred or discussed with their consultants.

32. It is regrettable in hindsight that there was not a clear framework that would have ensured that serious clinical incidents were reported by Trusts and disseminated to the other Trusts. Wide sharing of serious incidents can stimulate quicker and national efforts to reduce harm. In Scotland at that time, medical directors were encouraged by the CMO to report serious incidents that could have wider application elsewhere to him, and to disseminate to other Trusts. It is regrettable in hindsight that Dr Nesbitt found out about another case of fatal hyponatraemia 5 years earlier in a child linked to the use of Solution 18 only while investigating the role of Solution 18 in other hospitals in the province (022-091-298) and that, according to his witness statement (WS-035-1), the Department indicated that they did not know of this case.

*The apparent failure of the Royal Belfast Hospital for Sick Children to communicate to Altnagelvin its assessment of the cause of Raychel's cerebral oedema and death (other than a reference by Altnagelvin Chief Executive that a PICU nurse had told a nurse at Altnagelvin that Raychel had received the 'wrong fluids');*

33. I have been provided with the full clinical notes from the RBHSC, but I have not seen a formal discharge summary from RBHSC to the Altnagelvin Hospital following Raychel's death. A discharge summary to the general practitioner and to the referring hospital would be expected practice and in this case, I would expect a full analysis of the cause(s) of the cerebral oedema and the role of acute hyponatraemia in that. The evidence that Altnagelvin Trust heard only through an informal conversation between nurses is surprising and disturbing.

*The performance assessment of clinicians involved in the care of Raychel;*

34. It is unsatisfactory that there was no clear expectation that the surgical SHO, Mr Makar, should discuss every surgical admission with the consultant on call, Mr Gilliland. Although Mr Makar had sufficient paediatric surgical skill to remove an appendix in a child, as an SHO he would not be expected to make independent decisions about operating. It was for the consultant surgeons to make clear the boundaries of clinical decisions for their SHOs and it is not clear to me that those boundaries

were recognised or discussed. Following the death of a child, there should be an urgent peer review and the events reviewed in the context of multi-disciplinary clinical audit. The 1999 Confidential Enquiry into Perioperative Deaths makes these points very clear<sup>16</sup>; I would expect all surgeons to be familiar with the recommendations and to act on them, or document clearly their reasons for not following them.

35. Dr Fulton should have been familiar with this report and should have ensured that the recommendations were followed, or gained formal support from the chief executive and the Board for alternative arrangements. That is the heart of good clinical governance; several aspects are deficient here. On the other hand it is apparent from Dr Nesbitt's witness statement<sup>15</sup> that Mr P Reilly was appointed with the requisite additional paediatric surgical experience recommended.
36. Mr Gilliland is analysed by the expert reports and there is no clear view on whether he acted differently from other surgeons looking after children in a non-specialist service. It is surprising to me that there was no consultant surgeon involvement at all in her care, especially after an operation no matter how straightforward, and in view of the NCEPOD recommendations. However it is evident that Mr Gilliland had no time to visit the paediatric wards after a night on call as he was expected to be operating or doing clinics.

*The standard and experience levels of junior doctors and nurses involved in the care and treatment of Raychel;*

37. The clinical experience and prior training of the doctors in training and nurses were satisfactory, and unlikely to be different from the majority of district hospitals looking after children with common illnesses. Doctors in the SHO grade can be experienced from work elsewhere (e.g. Mr Makar), or fairly inexperienced because they have been qualified only 2 years and this is their first post in paediatrics (e.g. Dr Curran) (312-008). It is for the supervising consultants to assess their capabilities and to delegate duties according to that assessment. The Trust should expect systems to ensure that the consultants are delegating work appropriately to doctors in training.

*The standard of communication between clinicians;*

38. Communication is a key aspect of these events. Communication is casual and mostly verbal. Key clinical notes and observations are scanty, incomplete or inaccurate as evidenced in the expert reports<sup>13</sup>. It is not until

there is an impending disaster that the clinical medical and nursing notes become more complete, timely and accurate (File 020).

39. There was insufficient communication between the nurses and surgical staff. The nurses were aware presumably of the general pattern of recovery of children following an uncomplicated anaesthetic and appendicectomy. They did not appear to recognise any difference between Raychel and the majority of similar children; it is surprising that they did not call the surgical staff to alert them that Raychel was vomiting for longer than usual, and that her general condition after 2pm on 8 June was getting worse rather than better. On the other hand, Dr Zafar expected that Raychel would be drinking oral fluids normally during that day and that the intravenous fluids would stop; however he gave no instruction to the nurses to call him if the expected pattern of recovery did not happen. The nurses refer to the difficulty in contacting junior surgeons on call (WS-049/4 p9); they are in theatre or on duties elsewhere, and more responsibility is expected of the nurses than is usual.
40. The nurses appear to be concerned to stop the vomiting by asking the junior doctors to prescribe drugs to stop vomiting, without considering whether there might be a reason other than the operation. Either this was the usual pattern at Altnagelvin (all children vomit all day after straightforward operations); or this was worse than most other children (most would be drinking and feeling better during the following afternoon). In the first case, this could indicate a serious problem in clinical practice of anaesthesia and/or surgery in children; in the second case, this indicates a lack of nursing experience and/or a failure to act when the child was ill and not following the expected course.

*The system of education, training, mentoring and continuing professional education and development in operation at the time;*

41. I do not have expertise in this. However, the undergraduate education and training experience of the junior anaesthetists, surgeons and paediatric staff appears to provide an adequate basic knowledge and background to guide the prescription of fluids in children. The extent to which the postgraduate knowledge of the consultants made them aware of the potential problems of fluids such as Solution 18 varies from a clear awareness in some to confessed ignorance in others. Yet the higher training given to surgeons includes detailed training on fluid management and complications.

*Staffing levels, workload, resourcing and recruitment;*

42. I have not been provided with sufficient material for detailed comment. However the nursing resource on the children's ward seems satisfactory and the occupancy typical of children's wards.
43. The medical cover appears satisfactory in that there were sufficient staff for the rotas, and a fairly typical staffing pattern and levels of experience typical of district general hospitals. However the lack of consultant involvement in this case raises concerns about the capacity of consultants to supervise the care of children undergoing emergency surgery. Mr Gilliland did not do a post-take ward round because he had duties elsewhere, and there did not seem any expectation that a consultant surgeon would see all post-operative cases every day. The Trust should have been aware of these gaps in clinical care, but these were not addressed until after the tragic death of Raychel.

*The use of clinical protocols*

44. The expert witnesses have commented on these. I would not have expected a detailed protocol for the routine post-operative care of a child, nor a detailed protocol for fluid management. However I would have expected clearer responses from witnesses about the responsibilities of different staff members, and lines of communication. However Dr Nesbitt's letter to Mr Paul Bateson (021-057) hints that achieving a consensus agreement with surgeons for the use of post-operative fluids in children was not easy, and that any system of clinical governance was at a very early stage.

*The role of the Risk Management Co-ordinator in investigation, review, complaints procedures, litigation, Inquest and liaison with this Inquiry;*

45. The role is appropriate. The role is typical in many NHS organisations where an administrative post in risk management or clinical governance will act as the coordinator in reviews, litigation, inquests and Inquiries. Post holders are often senior nurses who are familiar with procedures and with the staff, so are well placed to get documents, meetings and administration organised.

*Ethos, culture, experience and leadership.*

46. My overall impression of this Trust is neutral. There appears to be engaged leadership by the chief executive and medical director in the general management of the Trust. There is a public absence of engagement by the Trust Board, although I have not seen their papers or minutes at the relevant period in 2001 or later. The Board had asked for an update in 2003 (022-003) but this was cursory and gives no clue as to the detail explored by the Board prior to 2003. I am surprised that this was provided by the risk

management co-ordinator but I have not seen any other papers showing the involvement of the Board. I would have expected the medical director to be briefing and updating the Board. Mrs Burnside refers in her witness statement (WS-046/2) to informing the chairman and the Board, and the Western Health and Social Care Board general manager, but none of this is recorded. This potential lack of corporate leadership is reflected in the defensive position adopted by the Trust once the Fergusons initiated a legal action.

47. The prevailing culture is one of misplaced confidence (see Swiss cheese theory above). There is no indication whether the recommendations of the NCEPOD report were considered – they were not all followed. The 1999 report on paediatric surgery in Northern Ireland (306-079) recommended that district hospitals should have a designated general paediatric surgeon who would assume a leadership role locally; there were to be provisions for audit, sufficient operating experience, and continuing education. I have seen no mention of these apart from the appointment of Mr Reilly. Again the NCEPOD report of 1989 (12 years previously) report states that trainees should not operate without consultation with the consultant; clearly that did not happen in this case. Altnagelvin was able to meet the other volume and frequency standards in the 1999 review<sup>16</sup>.

## Specific Questions

*Whether adequate guidance was provided on medical care including communication between clinicians and specifically:*

*Is there any evidence of systems being in place at Altnagelvin for the development of ward protocols (in respect of the management of post-surgical cases on ward 6) and for monitoring, evaluating and revising any such protocols or ward practices that may have developed? What systems ought to have been in place having regard to the standards of 2001?*

48. I think the clue here is in the apparent confusion over responsibilities for aspects of care. Dr Gund (095-13-63) thought that nurses would ask medical paediatric staff to prescribe fluids and was unclear about the role of the surgeons in the ward. Dr Gund understood his own responsibility to prescribe fluids for the operation and the immediate period in recovery until Raychel arrived back in ward 6. Surgeon and anaesthetic staff wished to use Hartmann's solution post-operatively, but deferred to the nurse led use of Solution 18 (220-002-003). Although Raychel was the responsibility of the surgical team, the nurses called members of the (medical) paediatric service to give medication and did not contact the surgical team when the (cursory) management plan agreed at the morning ward round with Dr Zafar was not going as expected. Systems for the clear lines of communication when plans

do not go as expected are notable by their absence, and are below the standards expected in 2001.

*What guidance might have applied to junior surgical and anaesthetic staff in respect of the conduct of 'out of hours' surgery e.g. was it advisable to contact and/or confer with senior members or their respective teams before proceeding to carry out such surgery? How should the Trust have ensured compliance with any such guidance?*

49. The experts have given a clear view. Dr Haynes (220-002-003) is clear that the consultant surgeon and anaesthetist should have been informed about Raychel so that a discussion about her best management could be agreed. Dr Gund was an experienced junior anaesthetist (220-003-003); even so local anaesthetic protocol was that two doctors should be present (Dr Jamieson) at the induction of anaesthesia. This fulfils also the requirement in the Altnagelvin policy (321-004fe) that the prescribing of drugs to a child should be checked by a second practitioner. Dr Jamieson is clear that it was normal practice to let the on-call consultant (anaesthetist) be aware of a child on the emergency (operating) list (WS024-002-006).
50. Mr Makar is an experienced children's surgeon also (220-003-004). It may be that Mr Gilliland and other surgeons had assessed his competence to make decisions and operate on children and did not require him to inform the consultant on call of every case; there is no evidence of this.
51. The Trust could not ensure compliance; it would be up to the consultants, clinical directors and medical director to ensure that these professional arrangements were in place.

*Whether the Trust ought to have implemented NCEPOD guidance or similar standards prior to June 2001, and if so, how ought that guidance have been applied in the circumstances of Raychel's case?*

52. The Trust should have had clear systems for ensuring compliance with relevant national UK professional guidance. Clinical audit was established firmly by 2001 and doctors would be expected to review their practice and service organisation against NCEPOD reports and guidance. The Trust medical director should have ensured that the report was considered and acted upon, and in many Trusts this would have been reported to the Board, or at least the Clinical Governance or Risk Committee, in 2001. Reasons for not implementing a NCEPOD report recommendation would need to be agreed by the medical director and signed off by the Board.
53. In the case of Raychel, there should have been clear lines of communication agreed between consultants and their junior trainees in respect of emergency operations in children. Consultation might have avoided operation. The

centralisation of children's services might have been considered and rejected by the Trust Board for practical reasons.

*Whether the Trust ought to have had guidance in place to:*

*Regulate the allocation of responsibility for the prescription of pre and post operative intravenous fluids?*

*Determine the type and amount of intravenous fluids to be prescribed pre and post operatively?*

54. This was not a matter for the Trust as an organisation in 2001. However the consultant surgeons should have been clear with the nurses and the junior doctors on who was responsible for prescribing fluids to post-operative children, and what fluids to prescribe.

*Regulate the monitoring and recording of fluid balance, electrolyte testing and observations, and for evaluating the continued appropriateness of a fluid regime?*

*Monitor post-operative vomiting?*

*Enable the nursing team to determine whether it was necessary to notify a surgical team about changes in a patient's condition?*

55. These are medical and nursing professional matters. The regular testing of electrolytes, monitoring of fluid balance and evaluating a fluid regime are the responsibility of the senior medical staff; these may be delegated to junior doctors (see *Good Medical Practice*) but remain the responsibility of the consultant surgeons. The practice of medical audit is intended to check that such arrangements are appropriate and working towards the intended outcomes. The doctors should be clear with nurses about the circumstances that they should be called about a change in a patient. The nurses have their own professional responsibilities too and would be expected to make their own professional judgements in respect of vomiting or any other change. The monitoring of fluid losses is a nursing responsibility on an hour to hour basis, but the doctors should make their own assessment when they attend a patient.

*Ensure that the staff treating Raychel were familiar with any ward protocols or practices (reportedly) in place concerning fluid management, and whether any such protocols or practices were adequate?*

56. The senior nurse, Sr Millar, would be responsible for ensuring that the ward nurses were up to the task of looking after the patients under their care. The ward sister would ensure that nurses followed any agreed protocols; as I have said there was a deficiency in the understanding and supervision of fluid management, and the expert reports give opinions on this point.



*Assist junior surgeons in determining whether it was necessary to notify a senior colleague about changes in a patient's condition?*

57. The published standards from NCEPOD<sup>16</sup> make it clear that children should not undergo emergency operation without discussing the case with the consultant on call. It is not clear whether the Trust enforced or monitored this standard.

*Whether the systems that operated to regulate fluid management in Raychel's case were adequate?*

58. The systems to regulate fluid management were deficient. Although the evidence from the junior surgeons and anaesthetists is that an isotonic fluid at a lower rate was appropriate for a child post-operatively, they deferred to custom and practice in the paediatric ward. Too much weight was given to the ward practice of using Solution 18, a fluid which may be suitable for many medical paediatric patients. There was a medical professional debate about the use of solutions, an area where the ward nurses would have neither knowledge nor experience. In such circumstances the doctors should be responsible for fluid prescription, led by the consultants, and with clear delegation to their junior staff.

*What responsibilities ought to have been delegated to an on-call Consultant Surgeon at the time of Raychel's admission to the Altnagelvin Hospital?*

*What ought to have been the responsibilities of the Consultant Surgeon under whom Raychel was admitted, and should he have been informed of the admission, the reasons for it and significant developments?*

59. The on call consultant would be expected to be available to take calls from junior doctors and give advice. They should know about cases admitted under their care, either at night, or the following day. It is a matter of professional judgement whether the consultant reviews every patient on admission. Following publication of the NCEPOD report I would expect all decisions about emergency surgery to be made by the consultant and I would have expected consultants to review patients the following morning.

60. I remain concerned about the developments the following day in this case. Dr Zafar expected an uncomplicated recovery so that Raychel was expected to be drinking well enough during that day for the intravenous fluids to be discontinued. He did not leave precise instructions for that and did not alter the excessive amount of hypotonic fluid being administered. This left the nursing staff with the responsibility of managing the increase in oral fluids and deciding whether the post-operative course was satisfactory. I do not understand the reasons for not letting Dr Zafar know that Raychel was vomiting still at 3pm; either prolonged vomiting was common at Altnagelvin or the nurses failed to properly record the amount and failed to recognise the problem.

*What arrangements ought to have been in place for the purposes of:*

*Allocating responsibilities within the surgical team in respect of Raychel's care and treatment, and whether there was sufficient clarity in terms of identifying who was responsible for Raychel's post-operative care and ensuring continuity of her care?*

*Supervising junior members of the surgical team (such as Drs. Deolin and Curran), and for making available to them advice to assist them in their approach to Raychel's care, and whether the arrangements that were in place were adequate?*

*Enabling junior members of the surgical team to notify their senior colleagues about changes in Raychel's condition, and whether the systems that operated were adequate?*

*Enabling junior members of the surgical team to seek advice/input from other medical specialties in relation to Raychel's condition?*

*Enabling the nursing team to notify surgical staff about any concerns they might have had in relation to Raychel's condition, and whether the systems that operated were adequate?*

61. The system that appears to have been in operation in 2001 is one that was common in district general hospitals without paediatric specialist surgeons. Adult surgeons, with some training in paediatric surgery, accepted the care of uncomplicated paediatric surgical illness and conditions as being within their general competence and the competence of their trainees. Complications of emergency surgery in uncomplicated illness (like appendicitis) are rare; complicated cases would be referred to the RBHSC. Consultants would delegate out of hours and in hours routine care of children to their junior trainees. It seems clear from the nurses that the consultant in charge was the on-call consultant and that the routine care of a child post-appendicectomy was the surgical trainee who conducted a routine ward round the following morning, prior to joining the consultant in the other activities of the day. This would be a theatre, outpatient, or specialist adult session which was scheduled to start at the time of the ward round; this is acknowledged by Dr Fulton, as arrangements to give surgeons time to conduct a paediatric ward round after a night on call featured in the later action plan .
62. The prescription of fluids post-operatively was clearly the responsibility of the surgical team, but in practice was managed by the nurses. Dr Zafar appears to have anticipated that Raychel would be drinking adequately later that day. Dr Scott-Jupp gives an excellent description of the clinical issues and behaviours (222-004-007,-019 et seq), and Dr Haynes gives similar insights into Mr Gilliland's role (220-003-005/6).

63. Junior trainees work alongside the consultants and have to manage situations on the wards because the consultants are working elsewhere. Trainees are encouraged usually to contact their consultant in a difficult or unusual situation. Trainees would not call a consultant from a different specialty, but would consult freely with another trainee.
64. The nurses had a clear understanding of the consultant in charge and the junior trainees that were available by bleep; however they may have had a realistic understanding that the surgical trainees could not return to the ward easily during the day (Therese Brown WS-323/1 p146), and that the medical paediatric trainees were more readily accessible.
65. In Raychel's case, the instructions given verbally by Dr Zafar were vague as he expected Raychel to be recovering during the day, taking fluids orally and that the intravenous fluids would be stopped; it appears that he expected the nurses to manage this change, and it appears also that the nurses accepted that. In retrospect, it may appear surprising that the nurses did not call the surgical trainee on call during the afternoon of 8 June; more likely they did not recognise what was happening because of inexperience of this type of complication

*What was the purpose of a ward round and how and by whom should it have been carried out in Raychel's case, also considering the seniority and specialism of those who should have carried it out, the information that should have been provided to those who carried it out, and the timing of it? Should there have been a "handover" in Raychel's case between medical teams and if so when and how should it have taken place?*

66. The ward round is the handover and communication between patients/parents, doctors, nurses and other relevant members of the staff looking after a patient. It should be carried out by the consultant typically 2-3 times weekly and at other times by trainees. A post-take word round was led commonly by a consultant (as described by expert reports) and a note would be made of the findings in respect of the patient and the care for that day. Formal medical team handovers were not common in 2001, and have become more common now.

*Was the programme of education and training provided at Altnagelvin to pre-registration and other junior doctors in relation to fluid management and post-surgical vomiting adequate by the standards of 2001 and what if any mechanism should have been in place to ensure that those trainees were achieving a satisfactory standard?*

67. I believe the education and training programme at Altnagelvin was adequate and the knowledge of the trainees was satisfactory.

*What steps ought to have been taken by the nursing team when contact with a doctor could not be established using the "bleeper" system, and what arrangements ought the*

*hospital to have had in place to provide for a situation where the “bleeper” could not be answered by the doctor?*

68. The nurses would react according to their assessment of the severity of the situation. In this case they contacted the medical trainees available on the ward to manage the prolonged vomiting. Other systems in use might have included calling the consultant directly or another member of the team.

*What was the purpose of “handovers” between nursing teams, and how should the handover of care in Raychel’s case have been managed, having particular regard to the information that should have been exchanged especially when the night shift came on duty on the 8<sup>th</sup> June 2001?*

69. Nursing matters are outside my area of expertise.

*What information should have been communicated between Altnagelvin Hospital and the Royal Belfast Hospital for Sick Children prior to, upon her transfer to the Paediatric Intensive Care Unit and after her death, and the identity of those who should have been involved in those exchanges?*

70. The communication prior to transfer was between consultants and that was good practice. All the relevant information was provided by Altnagelvin. I expected the RBHSC to have provided a more detailed discharge summary (063-004 is all I have seen) to Altnagelvin and the family general practitioner, not only to be clear about the outcome and cause of her death, but to communicate any concerns about her earlier care (if appropriate).

*Please comment, from a governance perspective, on the adequacy (or otherwise) of the medical and nursing notes and records with reference to contemporaneous guidance and expectation and the means available to ensure quality and completeness.*

71. Medical and nursing notes in the record are the fundamental means of recording the condition, assessment, communication and response to treatment of a patient. They are very important as a legal record and so that any other health professional can read easily the story of an evolving episode of illness, and understand what has happened and why, and what they can contribute next. Records should be full, comprehensive, and legible. Guidance available to doctors was *Good Medical Practice* and Altnagelvin had a policy in place since 1996, revised in 1998 (WS-323/1 p144). There is no evidence provided that this policy was audited.

72. Medical records are essential for effective and useful national or local clinical audit and for the review of morbidity and mortality that was common in surgical units in 2001. It was unusual for Trusts to monitor the content of medical records in 2001; this might happen in cases where the Trust was investigating a complaint, contributing to a Coroner’s inquest, or defending

litigation where deficiencies in the notes might be brought to the attention of those involved.

73. Raychel's records are not comprehensive, but reflect the reality of routine care at that time. The observations criticised by the expert reports, such as lack of detail of the vomiting, reflects in my view a lack of concern; no complication was expected, vomiting was common after operations, it was expected to settle especially after medication. The notes are excellent after 3 am on 9 June where all clinical findings, tests, assessments and care are detailed well.

*Whether communication with the Ferguson family was appropriate at both Altnagelvin and the Royal Belfast Hospital for Sick Children, given the nature of Raychel's condition and her care needs, including whether the information given to the family was adequate during or in relation to:*

- a. The diagnosis of appendicitis;*
- b. The taking of consent for the appendicectomy, including whether abnormal urine tests should have been discussed;*
- c. Care plans, treatment and prognosis at the time of admission and throughout the course of her treatment in Altnagelvin Hospital in the period from 7<sup>th</sup> June to the 9<sup>th</sup> June 2001, particularly at the times when Raychel was examined by nursing and medical staff;*
- d. The vomiting experienced by Raychel during the course of the 8<sup>th</sup> June 2001, the cause of that vomiting, its significance, severity and duration, together with comment as to how parental expression of concern about Raychel's condition should have been managed;*
- e. Her seizure/collapse;*
- f. The decision to transfer Raychel to the Paediatric Intensive Care Unit ('PICU') of the Royal Belfast Hospital for Sick Children and the purpose of the transfer, particularly the possibility of surgical intervention there;*
- g. The period of admission in PICU (at the Royal Belfast Hospital for Sick Children) and at the time of her death;*
- h. The reasons for Raychel's deterioration and the cause of her death, and in particular the reasons and explanation (in the light of the information gleaned by the Critical Incident Review Investigation) given to the Ferguson family during the meeting convened by the Chief Executive of the Altnagelvin Trust on the 3<sup>rd</sup> September 2001;*

74. The general importance of good communication between health professionals and parents for doctors is given in *Good Medical Practice*. It requires doctors to answer questions honestly and to give patients the information they want. Dr Makar and Dr Zafar met this standard in their limited contact with Mr and Mrs Ferguson. The diagnosis and consent for operation were not unreasonable. The urine tests would not be discussed routinely with patients but were important in assessing the likelihood of appendicitis compared with an alternative diagnosis. The expert reports do not appear to be all in agreement on this point.
75. I am not clear about the nurses' standard of communication with Mr and Mrs Ferguson during the 8 June. The differing accounts of Raychel's condition during the 8 June suggest that communication was not strong and that the parents' concerns about her progress during the afternoon and evening of 8 June were not listened to or were dismissed. For example, in the September meeting with the family, Mrs Ferguson and Mrs Doherty were clearly very concerned about the continued and perhaps worsening vomiting and the developing headache. This is a central feature in this case.
76. I do not agree with Mr Foster (223-002-043) that the surgical team/consultant needed to be present after the fit and subsequent treatment to discuss with the Ferguson family. Dr McCord was in charge and communicating well, and no surgical expertise was required. I do agree that the surgical team, in particular Mr Gilliland, should have attended the meeting with the family in September 2001. I also disagree with Mr Gilliland (Transcript of the Oral Hearings 14<sup>th</sup> March 2013 p.196-201). The responsible consultant should have met the family prior to leaving Altnagelvin if possible. It was good practice in 2001 for responsible consultants to meet with families after a death or serious adverse event. After all, these are rare.

*Having regard to the importance of risk management and of any obligation to learn lessons from adverse incidents, whether the procedures adopted by the Altnagelvin Trust after Raychel's death were adequate, with particular reference to the Critical Incident Review undertaken at the Altnagelvin Hospital, including:*

- a. *The adequacy or otherwise of the Review undertaken at the Altnagelvin Hospital including the scope of the Review, the manner in which it was conducted, the personnel who participated in it, the methodology adopted, the expert analysis relied upon, the method of recording/minuting contributions and statements, the overall independence thereof, the sufficiency of the Action Plan, the examination of the broader systems and context of any failings, shortcomings or deficiencies, the absence of a written report, and the provision of 'follow-up' to evaluate compliance with the Action Plan;*
- b. *Whether the Review should have been informed by any discussion with the clinicians at Royal Belfast Hospital for Sick Children;*

- c. *The extent to which Raychel's parents might have been involved in the Review process and informed as to its findings;*
- d. *Whether all of the issues of concern which might have been identified arising out of Raychel's case were in fact identified, or whether additional issues of concern should have been identified and dealt with;*
- e. *In addition to the Critical Incident Review which was carried out, whether any other form of inquiry or investigation was necessary in order to comply with applicable guidance or good practice, including whether a formal audit was required, and whether steps ought to have been taken to address the conduct or the competence of staff;*

77. Critical review has been a central component of clinical governance, and of previous risk management, since 1994/5. Critical reviews did not become subject to regulatory requirements until 2003 in England and about the same time in Scotland when the system became part of the new clinical governance standards. I do not know what steps were taken in Northern Ireland but I doubt if arrangements were earlier. In 2001, critical reviews were part of the risk management and controls assurance framework for Trusts.

78. The critical review initiated by Dr Fulton was sound. It was important to conduct this quickly so that events were fresh, and thus not possible to have everyone concerned attend, but there were sufficient people present to begin the process. The initial review agreed actions with individuals to prevent a similar event. The actions concentrated on immediate inquiry such as the type of fluid given post-operatively, the accurate recording of fluids, urine and vomit, the regular measurement of blood electrolytes while a child was on intravenous fluids, and the prompt information to junior doctors.

79. Drs Nesbitt and Fulton moved swiftly to inform colleagues in other Trusts and the CMO; urged a national review of Solution 18; shared information informally; and worked with colleagues to change to safer practice (although local resistance was noted 026-014-028).

80. I have not seen the papers from any further Critical Incident Review involving the medical director until some follow up notes referring to a meeting 10 months later on 9/04/02 (026-002-002). A critical review would typically meet again after a few weeks to check that the agreed actions had been completed and to begin the task of determining what went wrong. Incidents do not have single, proximate causes but rather a number of causal factors that came into play at the same time to cause the incident. The examination of these is important (root cause analysis). In this case this would include communication between consultant and trainee on the emergency admission and proposed operation; the switching of fluids from the theatre/recovery suite to different fluids on the ward; the responsibilities of nurses to change fluids; the calculation of fluids required; the post-take

ward round and review by a consultant; the recognition of vomiting; communication with parents and other aspects. Root cause analysis was a common methodology in Trusts in 2001, and does not appear to have been carried out. Reports would be compiled by the risk management coordinator and shared with the medical and nursing directors (who would chair such a review) and the chief executive. A report would be discussed with a Board committee together with plans to prevent recurrence. I have seen no evidence of this process.

*Whether appropriate steps were taken to disseminate relevant information arising out of the death of Raychel in order to:*

*Advise staff in Altnagelvin/Royal Belfast Hospital for Sick Children as to the issues of concern which had been identified as arising from Raychel's treatment and death, and the lessons to be learned from her case;*

81. The health system in Northern Ireland moved swiftly to identify hyponatraemia as a rare but serious risk. The approach taken to research and draft guidelines for the use of fluids in children was correct. However this was driven by Dr Nesbitt and from his own investigations; when he spoke to colleagues in Tyrone and RBHSC, they had changed their use of Solution 18 because of the previous adverse event.

*Assess and develop the competence of staff involved in Raychel's treatment at Altnagelvin, and other staff members who were likely to encounter similar circumstances in the course of their work;*

82. There is a central difficulty in maintaining competence in both adult and children's surgery for surgeons, anaesthetists and nursing staff. Care is satisfactory for common conditions that follow an expected uncomplicated course to recovery. The Regional Paediatric Surgical Services review found that the number of children's procedures was satisfactory, and that there was a dedicated children's ward. The nursing staff had significant paediatric experience. However when events do not go according to plan, staff not fully experienced in uncommon aspects of children's care will struggle to recognise and deal with the situation so that the likelihood of a poor outcome is greater than in a specialist children's hospital. The Trust would have to show that the training and competences of all the staff looking after children with a surgical condition was fully up to date and similar to that expected of the same staff looking after adults.

*Inform HM Coroner;*

83. RBHSC informed the coroner as part of the procedures following the death of Raychel at RBHSC, and the post mortem examination was described as a 'coroners PM' (063-004-009).



*Communicate outcomes and lessons learned externally (i.e. to the wider Northern Ireland health community);*

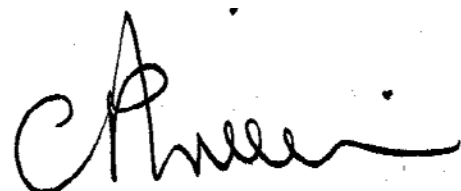
84. The steps taken by the Trust, by Dr Nesbitt, and by the CMO Dr Campbell have ensured that the use of Solution 18 was examined thoroughly, that 0.9% saline or an equivalent isotonic fluid was recommended to be given to children post-operatively, and that electrolytes were to be checked daily in children on intravenous fluids. The dangers of hyponatraemia were highlighted by the Regional Guideline Group. However the underlying problem of adult surgeons providing part-time children's surgery, and the risks that that entails, were not explored or considered in the documents I have seen.

*Provide information to Trust management, the Western Health and Social Services Board and the Department of Health and Social Services and Public Safety and/or medical community;*

85. There was no explicit duty on the Trust to communicate a rare fatal event to the Western Health and Social Services Board or to the Department of Health and Social Services, or more generally. However, I would expect informal communication to the extent of warning about press or other interest, and Mrs Burnside appears to have done this. No clear lines of communication for the sharing of significant events were in place in 2001. Policies and guidance were not in common use in the United Kingdom and did not gain momentum until the National Patient Safety Agency was established with a duty to collect and share adverse events and harm in 2003. However, Drs Nesbitt and Fulton shared the outcome and learning of this tragic case quickly, with both professional colleagues and the Department, so that action was taken quickly across the province to prevent a similar event.
86. National Confidential Enquiries should be informed of perioperative and other deaths in relation to their purposes. Altnagelvin participated in the NCEPOD Enquiry and I assume that Raychel's death would be reported when next asked to do so. The NCEPOD would send a form to the surgeon and anaesthetist for completion giving details of the case. NCEPOD would add this information to the database and report on findings across the UK later. Cases are submitted anonymously.
87. Nowadays, the clinical governance climate is very different. Systems are in place to share serious adverse events across all four countries of the UK, and within NI there is now a system of informing the Department, which will circulate the information as needed. Policies and procedures for recording all adverse events or critical incidents are widespread, as are means of learning from these.

## CONCLUSION

88. My overall conclusion is that Raychel died from a rare complication after a straightforward operation. The governance or risk assurance controls were weak with significant latent conditions in the Trust that allowed errors to happen, and compounded by significant errors by members of staff. No one person or group of persons can be blamed for the tragedy; in a sense the Trust and all individuals involved bear responsibility. Had all best practice actions been taken by the Trust and individuals prior to 2001, perhaps the outcome may have been different. The actions taken by individuals, led by Dr Fulton and supported by the Trust, and driven nationally by the CMO, ensured that accurate and considered fluid management of ill children is better now than in 2001.

A handwritten signature in black ink, appearing to read 'C Swainson', with a large initial 'C' and a long horizontal flourish at the end.

Professor C P Swainson

20 August 2013

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1. A First Class Service. Quality in the new NHS; 1998 DoH.
2. *Good Medical Practice* 2001. General Medical Council (314-014-006 *et seq*)
3. *A Charter for Patients and Clients* 1992. The Northern Ireland Health and Personal Social Services.(317-025-004 *et seq*)
4. 321-004fb
5. 321-004fc
6. 321-004fd
7. 321-004ff and 321-004gp
8. 321-004fe
9. 321-004fg
10. 321-004gr
11. 022-108
12. 022-84
13. 020 Clinical notes
14. 020-015-025 and WS-032/1 p3
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16. Report of the Confidential Enquiry into Perioperative Deaths. Extremes of Age. 1999. (220-002-049)
17. Paediatric Surgical Services in Northern Ireland. DHSS 1999. 306-079
18. Reason, James (2000-03-18). "[Human error: models and management](#)". *British Medical Journal* **320** (7237): 768–770.

## Statement of Truth

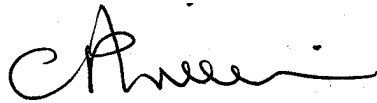
I understand that my duty as an expert is to provide evidence for the benefit of the Inquiry and not for any individual party or parties, on the matters within my expertise. I believe that I have complied with that duty and confirm that I will continue to do so.

I confirm that I have made clear which facts and matters referred to in my report(s) are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which I refer, having studied all the relevant documents supplied to me.

I confirm that I have no conflict of interest of any kind, other than any disclosed in my report(s). I do not consider that any interest that I have disclosed affects my suitability as an expert witness on any issue on which I have given evidence. I undertake to advise the Inquiry if there is any change in circumstances that affects the above. I have no personal interest in supporting any particular point of view.

I understand that I may be called to give evidence.

Signed:

A handwritten signature in black ink, appearing to read "Ameen". The signature is written in a cursive style with a large initial 'A' and a long horizontal stroke at the end.

Date: 18 August 2013

## CURRICULUM VITAE

NAME: CHARLES PATRICK SWAINSON

NATIONALITY: [REDACTED]

DATE AND PLACE OF BIRTH: [REDACTED].

<u>DEGREE ETC:</u>	MB, ChB. University of Edinburgh	1971
	MRCP (UK)	1974
	FRCPE	1985
	Fellow of the Faculty of Public Health	2002
	Fellow <i>ad hominem</i> Royal College of Surgeons	2007

### **PRESENT POST**

EHealth Clinical lead, Scottish Govt	2011-
Medical Director and vice-chair, SACDA	2009-

### **CAREER SUMMARY**

I retired from the NHS in 2010. I was appointed as part-time ehealth clinical lead to the Scottish government in 2011. I have reviewed the arrangements for the introduction of new medicines by NHS Boards for the Govt. I am the vice-chair of the Scottish Advisory Committee on Distinction Awards.

I returned to Edinburgh in 1986 after 5 years in New Zealand and Australia as a Senior Lecturer in Renal Medicine. I worked as a full-time NHS consultant, with a part-time Senior Lecturer appointment from the University of Edinburgh in recognition of my research, until 1996. I was elected Chairman of the RIE Physicians Committee in 1991 and played an influential role in the 1990 NHS reforms, developing clinical directorates and preparing for Trust status. I was the first clinical director for Medicine from 1992. I became Medical Director for the Royal Infirmary of Edinburgh NHS Trust in 1996, and reduced my clinical and teaching commitments. I was appointed Medical Director for the Lothian University Hospitals NHS Trust in April 1999. I was acting Chief Executive from April-July 1999, and again in 2002. I was appointed Medical Director to the NHS Board in 2003.

I have maintained a limited clinical commitment in renal transplantation, and a clinical research portfolio. I have undertaken GCP training in 1992 and 1999. I was a Director of Studies for the University of Edinburgh from 1986 - 2006.

## **RECENT EXPERIENCE AND ACHIEVEMENTS**

Consultant Physician, Department of Renal Medicine, Royal Infirmary, and Honorary Senior Lecturer, Department of Medical and Surgical Sciences, University of Edinburgh 1986- 2010

NHS Board medical director 2003 - 2010

## **NHS BOARD**

My major work was as Medical Director to the NHS Board. I provided medical leadership and advice to the Board. I developed strategic direction for the Board and obtained the commitment of consultants and general manager colleagues to service changes and development. I have worked closely with the Chief Executive and executive directors on the development of clinical strategies for the Board, which has gained the support of clinicians. I developed, in partnership with colleagues, and implemented systems and policies, which bring change and high quality to clinical services. I led the work to implement the new consultant contract across NHS Lothian, taking advantage of single system working and a common approach to difficult issues.

I have developed benchmarking of clinical services with other Trusts in the U.K, and internationally. I brought a strong external focus and intelligence to the local NHS based on extensive personal and professional networks.

I had the executive lead for clinical governance (shared with the Nursing Director) and for risk management. I wrote the healthcare governance and risk management strategies that were approved by the Board in 2005 and 2008. I have established a context for risk management and arrangements for implementation and quality assurance, including a revised controls assurance process, the development and active use of risk registers using the Australia/New Zealand standards, and an event reporting system. I have ensured that there are effective systems for guideline development and implementation and for the promotion of research and evidence based medicine.

I have established a research governance framework and reporting, and systems of approval and monitoring. I have worked with the Head of College of Medicine and Veterinary Medicine to establish a joint R&D administration, ACCORD, located in the Queens Medical Research Institute on the same campus as the Royal Infirmary of Edinburgh. I led for the Board on development of the new relationship in Scotland with Wyeth, a leading American pharmaceuticals company; I sat on the Translational Medical Research Initiative Board, established to provide oversight on the research collaboration and to develop further translational programmes. In 2008, I put particular effort into working with University colleagues and Scottish Enterprise to convince the Cabinet Secretaries for Finance and Health to support further infrastructure development and coordination so as to maximise Scotland's strengths in clinical research and translational benefit. I played a lead role with the chief executive in implementing the NHS strategy and initiatives to develop the BioQuarter, together with the University of Edinburgh, Scottish Enterprise, Alexandria Estates and City of Edinburgh Council.

I have gained considerable experience in briefing Scottish Executive colleagues and Ministers, and also acted as the public spokesman for the Board, not only on clinical care. I

have appeared several times in front of committees of the Scottish Parliament. I have extensive experience of working with the national and local media. I deliver 8-12 invited talks each year.

I played a leading role in the development of the new Royal Infirmary in Edinburgh (1994-2001), as a replacement for the older Royal Infirmary and associated hospitals. I played an active role in the development of the medical brief and in setting up the structures and processes, involving over 80 clinical staff that developed the detailed plans and operational policies. I have acted as the public spokesman for the former and current Trusts during the public debate and criticism of these plans. I led the Commissioning Executive Group within the Trust, which had overall responsibility for ensuring the successful transformation of clinical services and commissioning the new buildings at Little France and at the Western General Hospital. I had experience of briefing the Scottish Executive Health Department, the media and the Minister of Health throughout this project.

I had the executive lead in the Trust, and now at the Board for eHealth and information technology. I directed the investment and monitored the contract with a major IT supplier. I negotiated termination of this contract because of failure to deliver key milestones and negotiated a replacement contract with an alternative supplier. I have delivered compliance with the CHI target across acute hospitals and in the community. I am committed to the development of an electronic patient record and have a number of projects running to deliver that by 2012.

I have led the clinical effectiveness programmes, developing multidisciplinary quality improvement teams, and the implementation of evidence based healthcare using SIGN and other guidelines, and clinical benchmarking with other teaching Trusts across the U.K. I have used international benchmarking for clinical services with colleagues in Melbourne, Australia and Kaiser-Permanente, an HMO in southern California, USA, and now with McKinsey and number of other international partners.

I directed innovative, research-based surveys of patient experiences, which have shaped future service improvements. I directed the development of consultant appraisal from pilot study (1995) to Trust wide implementation (in April 2000), including joint appraisal with University colleagues.

I have built effective relationships with medical Royal Colleges, local Universities, the Postgraduate Dean, other Health Boards, locality GPs, and the new Community Health Partnerships, and the local Departments of Social Work. As an example, I have worked with the three local universities to develop a "Health Challenge Series" of public lectures and debate to be launched in the autumn of 2009. I have worked closely with the Medical Directors of other local Boards, and the Director of Public Health, to plan and implement clinical changes and shifts of resources from the acute sector to primary care and the community.

In 2003, I established the pan Lothian project to reshape acute services, before handing this over to the acute Trust Chief Executive. This resulted in the Board document *Improving Care Investing in Change*, which was consulted on successfully, approved by the Board, and is in implementation. This involved large numbers of face-to-face meetings with doctors, other members of staff and public, media briefings and meetings with MSP's and MPs to gain consensus and support.

I led the strategy to develop Hospital at Night teams in all acute hospitals, achieved in October 2006.

## REGIONAL

I established a regional Forum for medical directors and directors of public health in 2000. The southeast Scotland Postgraduate Dean and University of Edinburgh associate dean's attend also. This regional forum has been effective in developing a regional network for child and adolescent mental health services, learning disabilities and radiology. It has enabled a regional approach to be taken for *Modernising Medical Careers*.

I agreed to lead the elective work stream within the regional Action on Modern Acute Care , which will report during 2007. I established and chair a Regional Additional Cost of Teaching Group providing oversight on the allocation of resources and quality assurance for undergraduate medical teaching across five Health Boards.

## NATIONAL

I was a member of the Quality Assurance subgroup of the Acute Services Review (1997-8) and later of the working group that established the Clinical Standards Board for Scotland. I contributed to a CSBS working group seeking to establish generic clinical service standards, and I have been a regular assessor of those standards. I wrote a road map for the CMO that led directly to the creation of NHS Quality Improvement Scotland. I continue as chair of the Scottish Patient Safety Programme Steering Group for NHS QIS.

I was chairman of the CRAG Implementation subgroup established to improve the implementation of clinical effectiveness work in Scotland, and a member of CRAG and the CRAG Clinical Effectiveness Strategy group under Professor Sir David Carter. Since 2007, I have been the chair of the Scottish Patient Safety Programme steering group. This ambitious programme aims to reduce hospital mortality by 15% and recordable adverse events by 30% across all health board areas in Scotland.

I was a member of the Health Department Clinical Governance working group and played an influential role in the way that clinical governance was developed nationally (1998-). I have given many presentations to the Clinical Governance support network meetings. I chair the Better Blood Transfusion project for Scotland which is driving down the use of blood and improving the education and training of staff to improve safety.

I was a founding member and vice chairman of the Scottish Association of Trust Medical Directors, and a member of the new Telemedicine Forum to promote this work in Scotland. I chair the Scottish Centre for Tele-Health executive group, a special agency established to develop telehealth further across Scotland.

I was a member of the Review of the Public Health Function in Scotland (1999) and the Review of GP Out of Hours Services (1998). I was a member of the Review of Management Arrangements in the NHS in Scotland and supported the policy and thinking on the community health partnerships and single system working. I was subsequently appointed to the Community Health Partnership Development Group and have continued to work to establish these new organisations as credible drivers of change. I have particularly emphasised the importance of linking clinical teams within CHPs, and linking clinical teams



across the health board area. I was a member of the National Advisory Group on Service Change, chaired by Professor David Kerr from Oxford, and played a prominent role in the public meetings and front-line fora with staff. I led on the Elective Care subgroup. The SEHD response to this report, *Delivering for Health*, endorsed all main principles and the report and has generated a number of work streams for implementation. I am involved as a member of the Outcomes Design Authority (to generate credible, patient centred and measurable outcomes for health and social care in communities), and a member of the Shifting the Balance of Care Group developing implementation ideas and outcomes to drive the shift of care from hospitals to community and primary care settings.

I have also given presentations on Clinical Governance and clinical effectiveness to former NHS Regional Office colleagues in England, and have run workshops on these topics and on clinical directorates for many Trusts in England and Scotland. I have worked with a number of English trusts on clinical management models, and on clinical governance and collaborative working across Trusts. I have organised joint UK-Scotland initiatives in clinical governance. I am particularly interested and support the development of managed clinical networks and have given a number of presentations on this topic to the NHS in England.

I served for 2 years as a Board member of the UK Association of Trust Medical Directors (1997-9) and remain an active member of the British Association of Medical Managers. I joined the BAMB Fit to Lead development programme for medical managers, and achieved fellowship status in 2006. I was awarded the BAMB Distinguished Fellow award in 2006. I am a member of the UK Medical Professional Leaders Council co-ordinated by BAMB. I have maintained close collaboration with colleagues in England particularly on the development of Responsible Officers and the new regulations that will support revalidation for all doctors. I lead the quality and accreditation group within BAMB that supports the Fit to Lead Programme, a programme which will lead to the accreditation of medical managers.

I hosted a visit by the Western Australian Minister for Health, and was invited to speak at the American Physician Executive conference in 1999. I accompanied the CMO on a brief tour of North America in 2004 to visit the Veterans Administration and an HMO in California, as part of the work of the Advisory Group. I have continued to host and be involved in visits from both UK and foreign visitors to the new Royal Infirmary of Edinburgh.

## PROFESSIONAL

I have maintained a regular contribution to other aspects of professional work. I examine regularly in the clinical PACES examinations for the Royal College of Physicians of Edinburgh, and was a member of the Council of the College for three years. I continue as the local investigator for a MRC sponsored multicentre RCT in chronic renal disease. I was a founding Editor for a new Cochrane Review group in Renal Diseases 1996-99, and was one of six international editors until 2004.

I am a member of the Health Foundation Quality Advisory Group, and the Higher Education Funding Councils UK Healthcare Education Advisory Committee.

CHAPTERS IN BOOKS: 5

## PERSONAL DEVELOPMENT

I have been performance managed by chief executives since 1996. Personal development plans have been agreed and delivered. These have included participation in an international learning set around acute hospitals with public health, medical director and chief executive colleagues from Denmark, England and Australia for 6 years. John Clark from the University of Birmingham Health Services Management Centre facilitated this. We completed two years of twice yearly innovative programmes supported by the Harvard School of Design, in Boston, USA, in which we provided the UK NHS health economies with the opportunity to visit innovative health care delivery systems in Massachusetts, and parallel seminars targeted at exploring how new models could be developed in the UK. The NHS Institute for Innovation and Improvement has taken this programme over.

I have regularly used Myers Briggs and Belbin tools to understand others and mine preferred styles of working and leadership. I have regularly participated in external 360° appraisal; feedback from the most recent last year was very positive. My general areas of development and learning from structured feedback is that I have strengths in communication, strategic development, achieving results, and managing the external world; there is room to develop further support of people, and early involvement in consultation.

## OTHER ACTIVITIES

My major recreational activities are mountaineering and skiing in winter and golf in the summer. I enjoy classical music, the theatre and wine tasting. I was a member of the Lothian Region Children's Panel for nine years, and chairman 1992-94. I am president of the Scottish Wine Society.

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DH007: NHS MEDICAL DIRECTOR

DR CHARLES SWAINSON: STATEMENT OF SUITABILITY

I am an experienced and able Medical Director with 8 years in a large multisite acute teaching Trust and 3 years in an NHS board leading primary care and community services as well as acute hospitals.

I have personally led clinical engagement in service reform and transformation to achieve substantial improvements in efficiency necessary to achieve the building and occupation of a new PFI acute teaching hospital, at that time the largest PFI procurement in the NHS. I have personally developed the vision and led to the planning for shifting the balance of care locally from acute hospitals to community provision by agreeing a reduction of new outpatients of 20% and of emergency medical inpatients by 25% over the next three years.

I created a Clinical Board to bring together acute and primary care/community clinical directors in order to motivate and inspire them to agree and drive change, including hard choices about investments.

I have used benchmarking with CHKS and Dr Foster, and more recently with Civil Eyes Research and the Association of UK Teaching Hospitals, to seek best practice and drive efficiency in lengths of stay and consultant productivity. Hospitals in NHS Lothian are currently in the top quartile of efficiency measures across the UK.

I have developed clinical directors and associate medical directors building their confidence and capability and ensuring that they work effectively with managers and with senior nurses. I have personally coached and mentored clinical directors in Lothian and outside. I have actively planned for the succession of key clinical directors, and for succession to my own post. I am currently an accredited mentor with the Scottish Leadership Foundation and mentoring two nonmedical senior academic staff. Working with successive chief executives and HR directors, I have ensured programmes of development for clinical directors which have been highly valued in direct feedback. I have written a rationale and plan for further investment in clinical leadership and sustained programmes of development in NHS Scotland for the Chief Medical Officer. I am an active contributor to the Medical Professional Leaders Council and have worked with John Clark as a member of his reference group to encourage a programme of core competencies and development for clinical leaders. I am currently leading the work stream for the Postgraduate Medical Education and Training Board on the generic competencies that will be required for trained doctors in the future.

I have built effective working relationships with medical royal colleges and which resulted in my being awarded Fellowship *ad hominem* by the Royal College of Surgeons Edinburgh.

In my current role I have engaged with psychiatrists, GPs and doctors working in specialist drug and alcohol services to consider new models of care and different ways of working. I have drawn on networks of contacts, published literature, service models of work elsewhere and other data to examine changes in working practice and to persuade doctors in very different specialties other than my own of the need to change. I have strong influencing and negotiating skills that enable me to have convinced other doctors not only of the need for change but the direction of that change and then support to achieve it. Waiting times in

these key mental health specialties are now falling, and local clinical directors are more confident in job planning and appraisal than even a year ago.

I am skilled at translating government policy into health service action. My work in Scotland can demonstrate that. I have kept abreast of broad developments in England such as Payment by Results and would be confident that I could rapidly assimilate policy and the implications of service delivery. However there would be a steep learning curve in moving to England. I am an active member of BAMM and support Fit to Lead by tutoring applicants 5-6 times/y. I have used BAMM to develop a range of contacts in the NHS in England and to keep up with policy at the annual conference.

In the past two years I have learned certain aspects of medical workforce planning. I regularly work with HR colleagues to develop broad workforce plans for this NHS board that includes projected forecasting of consultant numbers. I personally ensured that this NHS board met its commitments to the Scottish government to increase consultant numbers 2003-2006, and achieved that by selective increase in certain specialties to improve capacity and meet waiting times targets.

I am proud of my record in introducing and developing clinical governance and risk management. The systems I have put in place which now enable a degree of monitoring of the safety of clinical services have demonstrated that patient safety must become the focus of future attention. The experience of the Health Foundation initiative with the Institute of Health Improvement, Boston in working with NHS boards in Scotland and England has demonstrated the success of a focused and measurement led approach. This is entirely consistent with the lean thinking and collaborative approach developed by the Modernisation Agency in England, and adopted widely over the UK. Consistent quality improvement methodology should enable clinicians and managers to work together on service improvement across the number of domains including access, safety and improved outcomes for patients. Clinical governance for me is underpinned by sound job planning and appraisal systems which link activity, teaching and research with quality and personal development.