REPORT ON CLAIRE ROBERTS FOR THE INQUIRY INTO HYPONATRAEMIA RELATED DEATHS IN NORTHERN IRELAND

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INTRODUCTION

My report addresses the briefing I have been given which was in summary to do the following:

> *Provide a detailed analysis and overview of the clinical governance issues arising from Claire's case, with particular regard to issues at a clinical level. Should your interpretation of the term 'clinical governance' and your view of its scope differ significantly from that of the Inquiry, as set out above, then please advise the Inquiry as to the basis upon which you consider the material might be more appropriately considered.*

In approaching my brief I recognise that the main focus of my role is to review the case of Claire Roberts from a clinical governance viewpoint and to identify and comment upon any identified matters which either were not addressed or could have been managed better in services to which Claire received care but also within the context of wider concerns arising from deaths in other children associated with hyponatraemia over a period of years. Consequently in addition to the clinical records available from the Trust I have sight of the extensive documentation relating to investigations by the Coroner and the Police Service of Northern Ireland.

In relation to Claire I am mindful that the events occurred in 2 main phases.

- The first was from the start of the acute illness for which she was admitted to RBHSC aged 9 years in 1996 and from which Claire died and the post death actions which occurred over the next 4 months up to February 1997.
- The second phase was the management by the Trust following the TV programme in October 2004 which led parents to question the part that hyponatraemia may have played in her illness and the reaction of the clinicians and the Trust to that matter in 2004 and subsequently.

I also recognise that the clinical management of Claire took place in the 1990s when there was still a stage of evolution of concepts of clinical governance and towards more structured care standards. Furthermore that the events following 2004 took place in a context of knowledge of and investigation of the part which hyponatraemia had played in other child deaths in Northern Ireland with involvement of the Coroner , the DHSSPS(NI) and the police and the public inquiry.

Clinical Governance

I agree with the scope of clinical governance as set out in the brief and recognise the implicit overlap between the 3 levels set out.

My approach has been to consider and make comments on *i) hospital management and clinical governance; (ii) corporate or Trust level; a*nd I have only touched on the 3rd - *(iii) government or departmental level within the Health and Social Care Services (HSC).*

I also agree with the Inquiry brief that clinical governance :

Is the system through which the HSC organisations are accountable for continuously monitoring and improving the quality of their care and services and safeguarding high standards of care and services. This system largely operates at the clinical level, with reporting lines to Directorate and Trust managers

And

is an 'umbrella' term which encompasses a range of activities in which clinicians should become involved in order to maintain and improve the quality of the care they provide to patients and to ensure full accountability of the systems to patients. On the management side, we understand that term embraces the leadership, procedures and systems that the organisation requires in order to maintain high quality services to patients and for which they are accountable.

Both these interpretations include patient and clinical " safety" which entails anticipation of recognised hazards and steps taken to prevent or reduce (avoidable) adverse outcomes and ensuring that a systemic approach is in place to recognise them, analyse causative (avoidable) factors and to set up means to prevent them happening in future.

The Inquiry also requested attention to the following points

a. An analysis of the documents, including the Reports and Statements, in terms of the main areas of 'management and clinical governance' identified above.

b. The identification of any protocols, guidance, standards or practices (hereafter referred to throughout collectively as "guidance" save where the context indicates to the contrary) that were applicable to the issues raised in Claire's case in 1996 and which the RBHSC may have been expected to take cognisance of and/or comply with. They should include any available guidance in the UK generally on the provision of services to children in hospital and how they were applied at that time, together with an indication of how that guidance and its application has developed since then. Identification of the literature, if any, that was available in 1996 that discusses such issues.

I am basing my report on my professional experience, review of supplied documents and on review and collation of relevant guidance with a focus on 1996.

Professional experience.

My experience has been as a consultant paediatrician (general paediatrics) in a medium-size district general hospital (Pinderfields Hospital Wakefield) for 28 years. For the first 10 years or so after appointment when neurosurgical services were on site in Pinderfields, I

worked with my consultant neurosurgical colleagues in providing an acute encephalopathy service for children for a population of about ¾ m.

Over this time I had experience in medical management having been chairman of the hospital medical committee for four years in the 1980s, acting as deputy member of the district management team and serving on the management board of the local hospital for learning disability. This was followed by appointment in 1993 as divisional coordinator of all non-surgical clinical specialties in Pinderfields Hospital and later by appointment as clinical director for women and children services and then, following the doubling in size of the children's unit after a merger with Pontefract Gen Hospital, becoming clinical director of children's services for what became a fairly large paediatric Department remaining so until just before I retired in 2006.

Over the same period I was Honorary Secretary of the British Paediatric Association and Vice President of its successor body the Royal College of Paediatrics and Child Health. I served on the Council of the Royal College of Physicians of London and was the paediatrician on the RCP working parties on medical audit around 1990. I refer to the reports from this committee. From 1996 I was seconded part-time to the Department of Health London as their paediatric adviser for seven years until the appointment of the National Clinical Director for Child Health after which I continued to assist the Department in the national service framework.

As the DH Paediatric Adviser I selected and commissioned the first NICE guidelines on children‘s problems and arranged for the extension of the Confidential Inquiry Into Stillbirths And Death In Infancy to cover all ages for deaths of children (now CEMACH). I also set up and chaired the national quality management board for newborn blood spot testing, and commissioned and set up the national audits for paediatric intensive care and neonatal intensive care. I have become familiar with the varying processes of hospital paediatric management and case records (and audit on which I have published) in visits to hospitals in the course of the Regional Inquiry into the deaths in Grantham Hospital (Allitt) , in research on presenting problems and investigations in around 20 paediatric departments, in attempts to develop a paediatric appropriateness of admission audit tool funded by DH, in visits acting on behalf the General Medical Council in development of performance assessment tools for consultant paediatricians and, when examining for membership of the Royal College of Paediatrics and Child Health. I have conducted external reviews of children’s services in London, the South East and W Midlands. Together with colleagues in Nottingham we have developed a number of evidence based presenting problem-based guidelines and jointly published a book on how to develop guidelines. Over the past 15 years I have also provided many medico-legal expert opinions in negligence claims.

INTRODUCTION

MY REPORT

The conclusions I draw are based upon my clinical experience, reference to relevant publications and also on my experience in clinical management.

THE REPORT IS STRUCTURED INTO CHAPTERS AND SET OF ANNEXES AS FOLLOWS

CHAPTER [1]

- **Summary of illness and subsequent events**
- **Headline comments on clinical care and clinical governance issues**
- **Headline comments on Trust governance aspects in 1996 and 2004 and after**

CHAPTER [2]

- **Part [1] Claire's illness – Acute Encephalopathy**
- **Part [2] Detailed Commentary on The Clinical Care given to Claire when she was admitted with an acute encephalopathy at the age of nine years in October 1996**
- **Part [3] Detailed Commentary on Clinical Governance aspects of care provided.**

CHAPTER [3]

- **Governance matters arising following Claire's death in October 1996.**
- **Governance matters arising following the television programme in 2004.**
- **Relevance of issues in Claire's case to other children's deaths associated with Hyponatraemia.**

CHAPTER 4

- **Clinical Governance Review : Chronology Of Developments And Sources Of Guidance With Focus On Children's Specialist Services**

Chapter [5]

- **Response to Brief not otherwise covered**

ANNEX A :

GUIDANCE ON ACUTE ENCEPHALOPATHY AVAILABLE IN 1996

ANNEX B :

MIDAZOLAM PRESCRIPTION POTENTIAL DOSE ERROR

ANNEX C

CLAIRE ROBERTS –DETAILED CLINICAL CHRONOLOGY AND COPIES OF SELECTED CLINICAL RECORDS

ANNEX D

COMPILATION : REFERENCE COMPILATION FOR CLINICAL GOVERNANCE REVIEW : Chronology of Developments and Sources of Guidance with Focus on Children's Specialist Services. (a reference working document)

CHAPTER [1]

- **Summary of illness and subsequent events**
- **Headline comments on clinical care and clinical governance issues**
- **Headline comments on Trust governance aspects in 1996 and 2004 and after**

SUMMARY OF ILLNESS AND SUBSEQUENT EVENTS

1. Claire was admitted aged 9y 9m to RBHSC with an acute encephalopathy under the care of the consultant general paediatrician. (admitted 21st of October 1996, died 23rd of October 1996). She had a past history of learning disability of uncertain origin (without cerebral palsy or dysmorphic features) and had been treated for tonic/clonic epilepsy from the age of 8 months until the age of 8 years but had no seizures from the age of 4 years some 5 years before this admission. Her antiepileptic therapy was stopped 18 months before the admission. She was judged to have a post epileptic encephalopathy followed by persistent non-convulsive epileptic status to account for the acute encephalopathy. Claire was treated by the general paediatric registrar and consultant paediatric neurologist on the basis of that diagnosis. She was treated with IV fluids (0.18% saline) and IV antiepileptic drugs. She later developed brain oedema which in turn led to her death. In her management consideration was given to viral or other infection in terms of preventive therapy. On admission on 21 October Claire was found to have a slight reduction in the blood sodium but at 9:30 PM the following day (26 hours after admission) a second blood test showed that the blood sodium was significantly lower at 121 mmol per litre. She had a respiratory arrest at 0300 on 23 October 1996 32 hours following admission with evidence of brain stem death and ventilatory support was withdrawn at 1845 hours on 23 October and she was pronounced dead. The immediate post death clinical diagnosis made was cerebral oedema; status epilepticus; inappropriate ADH secretion; ? Viral encephalitis. The clinicians considered that her death was from brain oedema complicating status epilepticus with a contribution from hyponatraemia and possible infection. The cause of death was revised after autopsy reporting in February 1997 to viral encephalomyelitis (and following an inquest held in 2006 to cerebral oedema due to meningoencephalitis, hyponatraemia due to excessive ADH production and status epilepticus).

2. Six years later following an Insight TV programme shown on 21 October 2004 Claire's parents contacted Royal Group of Hospitals. The Medical Director of the Royal Hospitals Trust, Dr McBride, reviewed the notes of Claire in late 2004 and asked Prof Young Consultant Clinical Biochemist and Professor of Medicine to review the records and provide a verbal report after which Dr McBride held a meeting on 6/12/2004 together with Prof Young and Dr Steen the consultant in general paediatrics under whom Claire had been admitted. From this meeting Dr McBride decided to refer Claire to the Coroner and a meeting was held next day with Claire's parents when it was reported to parents that hyponatraemia had been present in

Claire but that the treatment given to her was appropriate for the time in 1996 although that it had changed in 2004. An Inquest was held in 2006 and gave a verdict on the cause of death as cerebral oedema due to meningoencephalitis, hyponatraemia due to excess ADH production and status epilepticus.

HEADLINE COMMENTS ON CLINICAL CARE OF CLAIRE'S ILLNESS AND CLINICAL GOVERNANCE ISSUES

3. **Claire had an acute encephalopathy.** In summary acute encephalopathy is a disorder in which there is reduction of level of consciousness with or without associated focal neurological signs/paresis and with or without seizures. There is a risk of raised intracranial pressure which can be exacerbated by increased secretion of antidiuretic hormone (SIADH) leading to water retention and hyponatraemia and these both contribute to brain swelling. With advancing coma the brain stem control of respiration is impaired with carbon dioxide retention which in turn adds to brain swelling and threat to life. There is a wide range of causes.

4. Hyponatraemia is a common association with acute encephalopathy of any cause. Standard management for the time included prevention of hyponatraemia and/or therapy for it using intravenous normal saline or no less than 0.45% saline with careful blood test monitoring of the blood sodium and reduction of IV fluid volume. Claire was treated with 1/5 normal saline -a solution by the guidance of the time regarded as " contraindicated " in a child with acute encephalopathy. No reduction in volume below maintenance was made.

5. Claire was treated with antimicrobial therapy for viral and bacterial infection and this was appropriate.

6. No diagnostic investigations were done other than the blood electrolyte and full blood count and viral blood tests.

7. Standard guidance for the time was to carry out a range of blood and urine investigations for metabolic disease, toxins or organ failure such as liver failure. Brain imaging with CT scan was indicated. Strikingly, no EEG was done to confirm or refute the proposed diagnosis. The diagnosis of non-convulsive status epilepsy was not a high likelihood in Claire. She had experienced epilepsy from eight months of age to 4 years of age but this had settled and when present it had been tonic/clonic in nature and not myoclonic. On admission she had been off treatment for 18 months and had had no seizures for five years. No convincing history of an acute seizure prior to admission on 21 October was obtained. During her illness on 22 October she had a few episodes which could have been seizures although very short lasting. However the main problem was persistent reduction in conscious level with some neurological signs. Non-convulsive status epilepticus usually occurs in children with poorly controlled myoclonic or mixed epilepsy and (when present usually is manifest by frequent multisite jerking). Claire did not have this problem as the seizures had been well controlled and indeed she had been off therapy for 18 months.

8. Despite this history Claire was treated with a combination of antiepileptic therapy in the form of intravenous phenytoin and valproate following rectal diazepam. She was also given a drug used in refractory status epilepticus- Midazolam (when used this is usually as an infusion). Midazolam was advised for Claire by the paediatric neurologist both as a bolus IV dose and as a continuous infusion. This drug carries a significant risk of respiratory depression which itself can make brain swelling worse. It is not licensed for use in children for status epilepticus. In practice it has been advised as bolus in some children– e.g. *Medicines for Children 2003.* Mostly when used it has been as a continuous infusion with bolus usage being reserved in formularies for use for inducing anaesthesia or heavy sedation in intensive care. In Claire the *intended* IV bolus dosage calculated by the junior doctor based on Claire's body weight was 2 ½ times the advised bolus for sedation or induction of anaesthesia and for status epilepticus in UK and the written *prescribed* dose was 25 times those doses. (See Table below). It is not evident from the records whether any bolus dose was given although the paediatric neurologist and the nursing records made at the time stated that a bolus had been given. The relevant portion of the prescription sheet which should have been signed to indicate the bolus was given was not completed. The bolus would have been given by a junior doctor. It is not evident what source was used for the calculated dose.

TABLE : Midazolam IV bolus therapy

Indication	***Bolus Dose (microG) per Kg body weight***	***Source***
Sedation for procedure	<100	Medicines for Children 2001
Sedation in Intensive care	<200	Medicines for Children 2001 BNF for Children 2005
Induction for anaesthesia	<150	Medicines for Children 2001 BNF for Children 2005
Sedation for ventilated child	100	Alder Hey Book Childrens Doses 1994
Status epilepticus	Bolus not recommended or mentioned	Medicines for Children 2001 BNF for Children 2005 Alder Hey Book Childrens Doses 1994 Textbook Paediatrics Forfar & Arneil 1984 & 6th Edition 2003 Paediatric Vade Mecum Insley 1992 Advanced Paediatric Life Support Manuals BMJ 1st Ed 1993, 2nd 1997,3rd 2001.
Status epilepticus	<200	Medicines for Children 2003
Status epilepticus	< 300	Nelson T Book Pediatrics (US) 1999
Claire calculated dose	*500*	*Notes*
Claire prescribed dose	*5000*	*Prescription sheet*

9. **Clinical Governance issues**.

10. The clinical management of Claire Roberts was thus wanting in a number of respects. I am highlighting these to illustrate wider shortcomings in clinical governance.

11. The diagnosis and treatment were not consistent with widely available guidance on management of acute encephalopathy in 1996 in the form of advice provided in the major UK Textbook of Paediatrics by Forfar and Arneil. (See Annex A). This advises that 0.18% (1/5th normal) saline is contraindicated in management of this disorder. In Claire this fluid was used and the volume not reduced-a further recommendation.

There is a significant risk of brain oedema in the use of this fluid in acute encephalopathy which was discussed in this and other publications at the time.

12. A diagnosis of status epilepticus of non-convulsive nature was used in the management of Claire's illness and considered to be the cause of her death. There were not strong clinical indications that Claire had this condition and investigations were not carried out to confirm or refute it. Claire was treated with a range of antiepileptic therapy intravenously which included the use of Midazolam. It appears from the records that a potential or actual very significant overdose of this was used in bolus injection followed by an infusion. Midazolam can deepen coma. This dosage error does not appear to have received attention in the Trust reviews of Claire's death in 1996, 2004 or subsequently.

13. Although Claire was seen by a consultant paediatric neurologist 19 hours after admission, she was not seen by the consultant paediatrician responsible for her care until she collapsed some 33 hours after admission. Although advice was sought from the senior resident paediatrician (the registrar) in the evening just prior to her collapse, it is not evident that she was assessed clinically and inappropriate response was made to the low blood sodium which was found at this point. Tests should have been carried out earlier in the course of her illness and her therapy changed in response to findings of hyponatraemia which are likely to have been present.

14. Following Claire 's death an autopsy limited to the brain only was requested. This is problematic because it reduces the amount of diagnostic information available to explain the acute encephalopathy. The cause of Claire's acute encephalopathy remains uncertain, partly because of limited clinical and pathological investigation at the time.

15. There were strong arguments for referring Claire's death to the Coroner after her death but this did not take place until 2004

16. Claire's parents were not fully informed by the clinicians about their perception of the severity of her illness. After her death and following the interview discussing the result of the autopsy findings held four months later, the hyponatraemia which had been a feature of her illness and thought by the clinicians to have contributed to Claire's illness and her death was not mentioned to them. The autopsy findings suggested that Claire had died from meningoencephalitis a finding which subsequently has been challenged.

17. **Further Governance issues arising in Claire's management**:

18. Omission of an EEG to confirm the working diagnosis whilst at the same time using maximum treatment for refractory status epilepticus - with little clinical evidence that she had this condition.

19. Inadequately written records by junior staff after the morning assessment on 22 October until the low blood sodium of 121 mmol per litre at 9:30 PM was reported at 11:30 PM.

20. Failure to monitor the blood sodium on the morning following admission. This was indicated (a) because the first test was below the range of normal and (b) because Claire had an acute encephalopathy with a significant risk of inappropriate ADH secretion and associated hyponatraemia.

21. Absence of more senior paediatric assessment later in the evening of 22 October when the conscious level had fallen again and the reported blood sodium level had been found.

22. Failure to respond to the low sodium level reported at 11:30 PM on 22 October by reducing the volume of intravenous fluid and increasing the sodium concentration.

23. There is no evidence of a handover or communication between the daytime and on-call registrar about Claire.

24. An undetected actual serious overdose incident with Midazolam or alternatively a detected significant potential or actual overdose incident leading to failure to administer the bolus. In the latter case this should have been recorded in the medical and nursing notes and reported to the serious adverse events system within the hospital.

25. Uncertainty about whether the dose of IV bolus Midazolam was given and what the dose used was.

26. A design fault on the blood pathology report form omitting the time of processing leading to difficulty appraising the sequence of blood sodium levels obtained on the intensive care unit.

27. No apparent change in the sodium content of the intravenous fluid in PICU was made until around five hours after the arrest.

28. Inaccurate completion of the first brainstem protocol record.

29. Obtaining a brain only autopsy consent without recording why.

30. A decision made for a hospital rather than a Coroner 's autopsy.

31. Incomplete listing of the medication on the autopsy request report in specifically omitting use of Midazolam.

32. A decision made not to report the death to the Coroner, ascribing her death to brain oedema secondary to status epilepticus contributed to by hyponatraemia. Claire was not a candidate or at high risk of death from status epilepticus. Death from status epilepticus is rare especially in non-convulsive status.

33. HEADLINE COMMENTS ON TRUST GOVERNANCE ASPECTS IN 1996 AND 2004 AND AFTER

34. Although there is limited information available to me to comment with confidence about clinical governance within RBHSC in 1996 and in the early part of the 2000s, the following structures were in place:

35. Regular clinical audit meetings where deaths were discussed.

36. A clinical audit coordinator with responsibility for collating and arranging review of childhood deaths.

37. A clinical directorate structure.

38. Annual reports by the Royal Hospitals Trust on Health and Safety which from the late 1990s was reported to be merged with a clinical risk reporting system which suggests that the latter was in place.

39. Despite these structures which were complying in principle with existing professional and NHS guidance at the time the following shortcomings merit comment:

40. It is not certain that Claire's death was discussed in the audit meeting held in November 1996 as reported verbally or after the autopsy result had become available in February 1997. No issues relating to her care were recorded.

41. No record was made of any issues raised about her death or illness at the audit meeting and no record of the attendance has yet become available . At a minimum Dr Steen (consultant Paediatrician with overall responsibility), Dr Webb (consultant paediatric neurologist) and Dr Sands (paediatric registrar day time) and Dr Bartholome (paediatric registrar night time) should have been present.

42. No evidence either in that meeting or subsequently of reflection around the questions about the clinical diagnosis or treatment. No appreciation that the intravenous fluid used was not consistent with guidance at the time.

43. There was no record made in the 1997 autopsy report of the presence of hyponatraemia

44. Following the autopsy report in February 1997, a further death meeting did not occur (as far as it is possible to tell).

45. The job description of the paediatric neurologist defines his role in teaching junior staff and in holding clinicopathological conferences but It is not evident that the paediatric neurologist discussed the histological findings with the pathologist carrying out the autopsy.

46. It is not evident that a system for identifying, recording and reporting on prescription errors was in place nor how such errors were managed in terms of guidance on reducing risk.

47. There was a hospital *Paediatric Prescriber* document in use. I have not seen a copy of this. It is not evident what sources of information were used by junior staff and consultants in calculating doses of drugs.

48. There were no hospital guidelines for acute encephalopathy management in place in 1996 and it appears none in 2011.

49. There were no hospital guidelines published in RBHSC until 1997-this is unusually late for a regional teaching hospital.

50. There is no indication that the heavy workload of the on call registrar was regarded as excessive.

51. There is no documentation yet available which shows that concerns were raised about the lack of onsite CT scanning in a hospital which housed the regional paediatric neurology and intensive care unit. This was rectified in 2002 which is a comparatively late development.

52. There is no evidence that reviews of consultant job plans were in place. This was recommended practice for the middle and late 90s.

53. There is lack of clarity on which consultant general paediatrician was responsible for Claire's care later on 22 October 1996 (the second hospital day).

54. There is no evidence that the weakness of laboratory reporting process (timing) was identified as a risk.

55. It is evident that regular clinical audit meetings were held and that it was intended that deaths were discussed in these meetings. The advice from Department of Health in England for the time was that annual clinical audit reports should be drawn up and considered within the management arrangements and that the Trust should compile an annual governance report. It is not evident that such reports were made. (But I am not clear to what extent this DH guidance applies to Northern Ireland).

56. The Annual reports by the Royal Hospitals Trust on Health and Safety which I have seen do not show any analysis of clinical adverse events beyond the total annual number.

57. Consequently these shortcomings reduced the opportunity for reflection and consideration of any deficiencies which occurred in the care of Claire or other children. Nor that the lack of the responsible consultant involvement in Claire was highlighted as a significant adverse event.

58. Clinical guidelines were produced in RBHSC in May 1997. They did not include acute encephalopathy nor the management of acute seizure or status epilepticus. A revision in 2003 did not include these either. The 2003 guidelines include no striking caution about the use of 0.18% (1/5th normal) saline. No reference appears to the cautionary advice issued in 2002 by the DHSSPS(NI).

59. Governance matters arising following the Television programme in 2004 and after

60. Following the publicity relating to hyponatraemia in the television programme in October 2004 the review of Claire 's care and the meeting with the parents was not properly conducted in that an external independent opinion was not obtained. In a meeting held with the parents incorrect information was given and incomplete information provided to the Coroner .

61. The Medical Director of the Trust did not seek the opinion of an appropriate paediatric external expert despite being aware of the hyponatraemia in Claire and publicity at the time associated with other cases of death associated with hyponatraemia in children. It was inappropriate to rely upon an adult physician as an independent source of advice to the parents. Incorrect information was given to parents about guidance on management of acute encephalopathy in 1996 in respect of the intravenous fluid regime and investigation.

62. There was a failure to appreciate and address the potential or actual overdose of Midazolam.

63. There was a failure to appreciate that the working diagnoses (of non-convusive status) was not very likely in Claire and that inadequate investigation had been done to confirm or refute it (by EEG).

64. It does not appear that in 2004 review that there was a full appreciation of the role that clinical management in 1996 may have played in Claire ‘s deterioration and thus reducing the opportunity to remedy defects in future.

65. Although there is much documentation about the management of clinical risk from the middle 2000 onwards within the Trust there is little evidence available to me which enables further commentary in the 1990s and up to 2005. It may be the case that such documentation is available which will address some of the remarks that I have made.

66. It is a matter for remark that none of the four consultant experts who provided reports (two for the Coroner and two for the police service of Northern Ireland) included commentary on the dosage of midazolam. Only one of the 4, Dr Evans, noted the dose prescribed.

67. CHAPTER [2]

68. Part [1] Claire's illness – Acute Encephalopathy

69. Part [2] Detailed Commentary on The Clinical Care given to Claire when she was admitted with an acute encephalopathy at the age of nine years in October 1996

70. Part [3] Detailed Commentary on Clinical Governance aspects of care provided.

71. PART [1] CLAIRE'S ILLNESS – ACUTE ENCEPHALOPATHY

72. **Acute Encephalopathy** is a condition which occurs acutely (suddenly) .

73. It is a condition associated with a reduction in conscious level with or without seizures, focal neurological signs or signs of raised intracranial pressure. It can be caused by a variety of conditions. These include bacterial or viral infection of the meninges or brain, vascular disorders such as stroke or vasculitis (the latter occurring in a range of immune diseases), demyelinating conditions including those associated with immune reaction to infection, brain swelling locally or generally associated with head injury, bleeding/ haematoma, brain tumour or abscess, raised intracranial pressure from hydrocephalus; or, impairment of brain function with or without swelling associated with metabolic disorders such as amino acid or organic acids inborn errors of metabolism, acquired mitochondrial disease such as Reyes syndrome, liver failure, renal failure, disturbed electrolytes especially low-sodium, episode of hypoxaemia, sickle cell disease, following severe seizure or associated with non-convulsive status epilepticus or tonic/clonic status epilepticus.. A similar presentation may occur with a range of poisons or toxins which may be medicinal drugs and others taken by accident or intention or household or environmental poisons including lead.

74. In acute encephalopathy, there is an increased incidence of hyponatraemia. Hyponatraemia may be associated with raised intracranial pressure from whatever cause and by causing neuronal swelling makes the pressure rise worse. There is an extensive literature on this which I will not rehearse. Hyponatraemia can be caused by water overload using low solute fluid and/or production of excess antidiuretic hormone. Thus an evolving brain swelling may complicate any of the disorders which cause acute encephalopathy. The use of low sodium intravenous fluid exacerbates this process.

75. The management of acute encephalopathy includes diagnosis and the consideration of differential diagnosis. It requires treatment of specific cause and consideration of prevention and treatment of complicating factors such as hyponatraemia. It also involves treatment of the associated problems of an acute encephalopathy of any cause such as seizures as well as treatment of seizures in epilepsy which may have caused the encephalopathy. New CNS signs may emerge when the brainstem is under pressure from the raised intracranial pressure and in such circumstances odd

movements may occur and the pupils may vary in responsiveness and / or eye movement disorders emerge during the illness.

76. Raised intracranial pressure may arise from brain swelling in any of the listed conditions and require treatment but it is also important to identify any causative conditions which themselves lead to an increase in intracranial pressure such as brain tumour, abscess or haematoma.

77. To identify such conditions imaging by CT is needed. This may indicate a need for neurosurgery. Raised pressure itself may be treated by fluid restriction to an extent although excessive fluid restriction used in the past may not have been helpful. If the condition progresses then elective intubation and ventilation may be used to maintain the blood carbon dioxide at a normal level. In the past and briefly for acute conditions, hyperventilation may be used to reduce blood carbon dioxide levels and thus reduce brain swelling but this is not used as much now as it was 1990s and 1980s.

78. Elective ventilation is used in severe progressive coma in order to prevent carbon dioxide retention which leads to worsening of brain swelling from arising from CO2 retention from impaired ventilatory effort which can result from raised intracranial pressure imposing pressure upon the brainstem respiratory control centre or from sedation drugs.

79. In acute encephalopathy it is conventional to restrict fluid to the minimum necessary for example to produce a urine output of between 1-2ml per kilogram body weight per hour, carefully monitored and to ensure that low-sodium intravenous fluid is not used and the intravenous fluid of choice is either preferably normal or no less than half normal saline.

80. The role of specialist care in acute encephalopathy in summary is to identify the cause by investigation, treat the treatable (such as infection and/or complicating seizures or intracranial space occupying lesions),to take steps to prevent, identify and treat emerging signs of raised intracranial pressure by clinical monitoring, and if necessary to monitor intracranial pressure (which usually requires assistance of the neurosurgeon); treatment includes careful intravenous fluid prescription in volume and type avoiding low sodium fluids such as 0.18 % / 1/5th normal saline and resort when necessary to elective ventilation. In the presence of advancing and clear raised intracranial pressure, mannitol or steroids may be used and it is essential to ensure adequate perfusing pressure of the brain in the face of the raised pressure by circulatory support.

81. PART [2] DETAILED COMMENTARY ON THE <u>CLINICAL CARE</u> GIVEN TO CLAIRE WHEN SHE WAS ADMITTED WITH AN ACUTE ENCEPHALOPATHY AT THE AGE OF NINE YEARS IN OCTOBER 1996 .

Note: a full tabulated chronology of the clinical course is shown in Annex C with selected copy records

I consider the clinical care in the following way:

- **Care provided to Claire in accident and emergency and ward admission on evening of 21st October**
- **Care in the morning of 22 October and later by the general paediatric team**
- **Care in the evening of 22 October and issues relating to hand over at 5 PM on that day from the day registrar to the on-call registrar**
- **Care provided by the paediatric neurologist at 2 PM, 4 PM and 5 PM assessments on 22 October and the prescriptions of antiepileptic drugs**
- **The Collapse 23 October 1996 03:00 Hours and Care In Intensive Care**
- **Communication with Parents**

Care provided to Claire in accident and emergency and ward admission on evening of 21st October;

82. Claire (born 10/1/1987) was admitted aged 9y 9m on 21 October 1996 to RBHSC with an acute encephalopathy manifest as an onset over some hours of alteration in level of consciousness in the form of slurred speech, reduced social responsiveness and ataxia. This had started at school and been accompanied by some vomiting. She had a past history of epilepsy from age 8 months, had severe learning disability and had been treated for an attention deficit disorder. She had been seizure free for five years and had been weaned off antiepileptic medication 18 months before.

83. She was referred for admission by her general practitioner . She was seen in accident and emergency at 7:15 PM, was found to be drowsy and had asymmetry in her neurological signs. She had no fever. A diagnosis of encephalitis was queried and she was admitted after being assessed by the paediatric registrar at around 20:00 hours to the Ward. She was treated with intravenous fluids, blood tests were sent by 10 PM for full blood count, blood culture, urea and electrolytes and viral titres. The first blood test result noted at midnight showed a low sodium at 132 mmol/l and a slightly increased total white blood count at 16.5 (thou/ul) but no other abnormalities. She was observed overnight. She vomited on two occasions while on intravenous fluids.

84. Comment on care in accident and emergency and ward admission on evening of 21st October;

85. Management on the evening of admission in A&E and the in-patient ward (Allen ward) was acceptable in the differential diagnosis considered and initial treatment. Although use of 1/5th Normal Saline for IV maintenance fluid was within the range of current practice for the time for management of ill children, at this time also ideal/high-quality practice for acute encephalopathy any causation should have led to choice of IV fluid with higher sodium concentration. However before a significant

acute encephalopathy can be confirmed a period of observation was necessary to determine the duration of reduction in conscious level.

86. **Care in the morning of 22 October and later by the general paediatric team:**

87. The following morning she was seen by the daytime paediatric registrar Dr Sands responsible for the Ward who noted the changes in the blood tests, and considered that she might have "non-fitting status". Rectal diazepam was given around midday and Dr Sands made a referral to the consultant paediatric neurologist Dr Webb. Dr Webb saw her at 14:00 hours, 19 hours after admission. Claire's conscious level had been reduced throughout since admission and the GCS was 6 when she was seen by Dr Webb. After a clinical assessment, Dr Webb concluded that she had an acute encephalopathy most probably post ictal in nature. He made a note of a "normal" biochemical profile. He advised anti convulsant medication: intravenous phenytoin loading dose and maintenance, advised a blood test to be done at six hours to check the phenytoin level and proposed a CT scan the following day if she did not "wake-up". Claire had one seizure lasting about 5 min at 15:10 hours. Dr Webb then saw Claire again at 4 PM although there is no record made of this attendance (other than the insertion of 4 PM at the two o'clock consultation) and he recalls from his witness statement that he advised a bolus and infusion of Midazolam and this was prescribed at 15.25pm. Claire had an observed tightening of her teeth 16:30 hours lasting a few seconds. Dr Webb then reviewed Claire at 1700h. Intravenous infusion of Midazolam had been started in the interim and Dr Webb recorded that the bolus of Midazolam had been given.. Dr Webb also advised intravenous antibiotic and acyclovir (an anti-viral agent) although he noted that he did not think meningoencephalitis likely. He also advised adding intravenous sodium valproate bolus followed by an infusion every 12 hours.

88. **Comment on care in the morning of 22 October and later by the general paediatric team;**

89. Claire was admitted under the clinical care of the on-call acute general paediatric consultant Dr Steen. In my view she was the responsible consultant throughout Claire's stay. Referral was made for paediatric neurology advice and opinion by the general paediatric team (the registrar Dr Sands who was working under the supervision of Dr Steen). The paediatric neurology advice was provided by Dr Webb on the day following admission. There is no indication that consultant responsibility for Claire's care was transferred to Dr Webb either in documentation or from his own statement; for example, in his view about responsibility for fluid prescription and management upon which I comment later.(see para 222)

90. **The role of Dr Steen Consultant in General Paediatrics**

91. Claire had a persistent reduction in level of consciousness and by the morning following her admission at latest Claire should have been seen by Dr Steen. Claire was significantly unwell and a diagnosis of causation had not been made. It was correct for the paediatric team to refer for paediatric neurology advice but Dr Steen

should have been involved in the decision-making. Dr Steen did not see Claire until after the final and irreversible collapse some 33 hours following admission. There is no documented evidence that Dr Steen was aware of Claire's presence or of her illness. Neither is there documented evidence that the absence of consultant general paediatric input was perceived at the time nor after the review in 2004 as a major significant event. This should have been reported on the clinical significant event database. I review arrangements respecting consultant responsibility here and in Chapter 4 respecting delegation of care, particularly in absence.

92. I have noted the following **: document WS-143-1.** On page 7 there is an important statement which Dr Steen made to the Coroner *"I recalled that I had been aware that Claire was in the Ward at 9 AM on 22 October 1996 and that I had been contacted by the Ward to inform me that Dr Webb had taken over her management".* But there is no record of this discussion.

93. **Dr Sands Paediatric Registrar**. The paediatric registrar Dr Sands reviewed Claire on the Ward round in the morning but did not repeat the blood electrolytes which the previous evening had shown a slightly low sodium. Although there is little agreed guidance on the frequency with which children on intravenous fluid should have repeat sampling, a further sample was indicated specifically because Claire was significantly ill with, by then, persistent reduced level of consciousness and thus had a clear acute encephalopathy and had vomited even while on intravenous fluid. (This is unusual and suggests either gut obstruction or raised intracranial pressure or intracranial pathology). It was necessary to monitor the low sodium particularly in the context of an acute encephalopathy where the syndrome of inappropriate ADH is a well-recognised complication and can be manifest by a low sodium or a level which is falling.

94. The proposed diagnosis of non-convulsive epileptic status, whilst at possibility amongst other causes of acute encephalopathy, was not of high, or even moderate likelihood.

95. In the afternoon and evening of the 22 October 1996 Claire was managed jointly by the paediatric neurologist Dr Webb and by the general paediatric team of SHO and registrar. The general paediatric doctors prescribed the IV fluids used and calculated and prescribed and administered the IV anti epileptic drugs . The anti epileptic drugs were advised by Dr Webb (paediatric neurologist). The IV fluid used was chosen by the general paediatric team – without consultant involvement. I comment separately on the paediatric neurology management below.

96. Comment

97. The medical entries made by the junior staff on Allen Ward in the afternoon and later in the early evening were insufficient particularly in view of her deterioration in level of consciousness.

98. **Midazolam dose:** Antiepileptic drugs advised by the paediatric neurologist were prescribed and administered and this was appropriate in the overall management of

acute encephalopathy of any cause. However one, a bolus of Midazolam advised, was prescribed incorrectly. It is not evident from the contemporary records who advised the dose to be used and when and how. From his later statements (and the report made to parents in December 2004) Dr Webb had advised its use following his assessment of Claire at 2 PM but he did not record that in the notes nor at what time he advised that addition to the drugs he had already suggested. It is not evident whether he advised the dose to be used. If he did not advise the dose it is not evident what source was used by the SHO who carried out and recorded his calculation in the notes, calculating a dose which was a significant overdose for prescription (this was 2.5x the maximum advised for status epilepsy and 1 ½ x the dose for use in an intensive care unit – mostly for children on ventilator support). In writing the prescription the SHO multiplied his calculated dose by 10x. These errors were not noted by Dr Webb when he reviewed Claire at 5 PM when he made a record that the bolus had been given. It is not clear on what basis he made this judgement but if this was by reviewing the prescription, he should have noted the dose errors. Nor is it clear from the records what dose of Midazolam was given as bolus. It does seem that a bolus was given according to the nursing record at 3.25 pm 22 October (090-040-141). If the dose intended or prescribed had been given then the dose was such that it could lead to a significant reduction in conscious level, to potential depression of respiration with associated rising carbon dioxide level in the blood and the latter itself leading to brain swelling or aggravating it on top of the hyponatraemia. This was a major significant dose error in the circumstances. Had it been noticed, Claire should have been intubated and ventilated from around 5 PM. Furthermore this dose error was not noted at any medical audit review of Claire's death in 1996 nor by the pathologist who carried out the post-mortem. In respect of the latter point however, it would have been necessary for the pathologist to have reviewed the records because Dr Steen when completing her autopsy request form, did not mention the use of Midazolam (although she did record the use of rectal diazepam, intravenous phenytoin, intravenous valproate, acyclovir and cefotaxime). This dosage error was not identified in the 2004 case note review. (Nor in the medical reports provided for the Coroner and police service.). The regular drug prescription forms in photocopy notes do not seem to have a section to indicate that the dose has been given – if this is so then that is a deficiency. The once only section has a column for signature as given. This was not signed for the Midazolam bolus. (See Annex B)

99. **Care in the evening of 22 October and issues relating to hand over at 5 PM on that day from the day registrar to the on-call registrar**

100. Over the evening of 22 October the conscious level in Claire as measured by the Glasgow coma Scale, rose from 6 to 7 & 8 but fell again to 6 at 22:00 hr. At 19:15 hours and at 21:00 hours respectively, Claire had an episode of teeth clenching lasting a minute and an episode of screaming and drawing up of arms lasting 30 seconds. A blood test was sent at 21:30 hours to establish the blood phenytoin level and urea and electrolytes were requested. The blood result was available at 23:30 hours showing that the blood sodium had fallen to 121mmol/l. The senior house officer (Dr Stewart) considered the possibility of syndrome of

inappropriate ADH complicating the encephalopathy and consulted with the paediatric registrar (Dr Bartholome), the middle grade resident more senior paediatrician who advised reduction in the intravenous fluid rate from the existing maintenance requirement to 2/3 of maintenance requirement. Throughout Claire was treated with 0.18% saline in 4.3% dextrose. It was planned to send urine for osmolality. The reduction in volume did not take place. Between 2200 h 22 Oct and 0200 23 October Claire received a total of 247.6 ml (127 ml of 0.18% plus 10.6ml as Midazolam infusion plus 110 ml for Phenytoin /Acyclovir) that is 62 ml per hour. Thus the intended reduction of IV fluid volume advised at 23:30 to 2/3 requirement intended to be 41 ml/ hour did not happen. And there will have been additional IV fluid – probably 62ml/hour but not recorded- over 02:00 to 02:30 when the arrest occurred. (See Para 170)

101. The conscious level in Claire remained low with a Glasgow coma scale of 6. Her pupils remained responsive. Suddenly at 03:00 hours on 23 October, Claire had a respiratory arrest, was attended by the paediatric registrar who attempted unsuccessfully to intubate and resuscitated with mask and oxygen until the anaesthetic specialist attended. Claire was intubated and ventilated and transferred to the paediatric intensive care unit where she was found to have fixed dilated pupils. At 04:00 hours Claire was seen by Dr Steen, consultant paediatrician and by Dr Webb consultant paediatric neurologist. Claire was given mannitol, dopamine infusion and a CT scan was arranged which showed severe brain oedema. Further samples of blood were sent while Claire was on the intensive care unit one of which showed serum sodium of 152 and another 129 blood and osmolality was 274 with normal urea and glucose. At 08:00 hours, the intravenous infusion fluid was changed 0.9% saline. At 06:00 hours 23 October and again at 18:25 hours, brainstem death assessment was conducted. With parents agreement in the light of the results, ventilatory support was withdrawn at 18:45 hours. It was considered that on clinical grounds she had cerebral oedema secondary to status epilepticus. An autopsy limited to the brain was arranged with the consent of the parents.

102. **Comment on the care in the evening of 22 October and issues relating to hand over at 5 PM on that day from the day registrar to the on-call registrar.**

103. In the evening of the second admission day, when Claire was under the care of the general paediatric team, her blood sodium level was repeated and two hours later reported showing a significant reduction in blood sodium. By this time the level of consciousness had fallen. It is not evident whether the resident senior paediatrician-the registrar Dr Bartholome made a personal clinical assessment of her. The SHO on Allen ward recorded his concern about the possibility of syndrome of inappropriate ADH and proposed consideration of a change in the sodium content of the IV fluid . He referred the problem to Dr Bartholome who advised reduction in intravenous fluid volume rate but not any change in the intravenous fluid from 0.18%. This should have been done immediately. The intended reduction of infusion to 2/3 volume did not happen. It is not evident whether Dr Bartholome-the registrar on call in the hospital at night, was aware of Claire until this consultation. She should have

been. The daytime registrar (Dr Sands) should have handed over either personally or by telephone. Indeed given the severity of Claire's illness and the reduction in conscious level and the mixture of antiepileptic drugs including Midazolam that she was receiving, she should have been reviewed by the on-call registrar as a routine in the evening. Claire was receiving level I paediatric intensive care/high dependency care. By the standards of the day the handover should have taken place. A written recording of this handover however was not standard practice at the time although advised now. Handover has become a recognised risk area particularly in the 2000s especially as there is more frequent change of junior staff to meet junior staff hours. This was not the case in 1996.

104. The on-call registrar Dr Bartholome should have consulted the on-call paediatric consultant about the low sodium level associated with reduced conscious level. A consultation did not occur and it is not clear who the on-call consultant was. Elective intubation and ventilation should have been considered. A blood sample was sent for repeat sodium at 21:30h on 22 October but it was two hours before the result was seen by the doctors on the Ward. It is not clear why it took so long for this to happen. Nor how the result was transmitted to the Ward-was this by telephone (most likely) in which case why did it take two hours. It is not clear what the arrangements were for management of blood samples out of hours in RBHSC. There is a laboratory on site there but it not known to me if this is used out of hours or is the sample sent to the Royal Hospital main site. Was it necessary to call a technician in from home?

105. A consultant general paediatrician (or paediatric neurologist) should have been consulted by the junior doctors on 22 October at 23:30 when the blood sodium result was found to be low and Claire's conscious level had fallen. As Claire was on a Midazolam infusion (which can depress respiration) and was deteriorating, elective intubation and ventilation should have been considered at or before that time. Especially as the Midazolam dose was increased to 3ml/hour of infusion (160 microG/kg/hour) at 9.30pm (according to the nursing records- which generally are of good quality).

106. **Care provided by the paediatric neurologist at 2 PM, 4 PM and 5 PM assessments on 22 October and the prescriptions of antiepileptic drugs;**

107. After referral by Dr Sands , the general paediatric registrar, who spoke to Dr Webb around lunchtime, Claire was seen by Dr Webb consultant paediatric neurologist at 2 PM on 22 October, 19 hours after admission. By this time no attacks consistent with seizure had been recorded on the seizure chart although at 3 :25 PM she experienced a five-minute "strong seizure". This was followed at 4:30 pm by an episode of teeth tightening and groaning lasting a few seconds and again at 7:15pm lasting a minute and again at 9 PM lasting 30 seconds she had an episode consistent with seizure in the form of screaming and drawing up of arms. However, that was the sum total of her seizure activity.

108. At 2pm Dr Webb found her to have reduced conscious level, brisk reflexes and upgoing planters consistent with long tract signs. She had no papilloedema and

he noted that her facial, palatal and laryngeal movements were normal (he was checking here to ensure that she had a gag reflex was able to protect her airway from secretion or vomit). Dr Webb concluded that she had an acute encephalopathy most probably post ictal. He made a note that biochemical profile was normal. He advised antiepileptic therapy

a. *starting IV phenytoin 18 mg/kilogram stat followed by 2.5 mg/kg 12 hourly. Will need blood levels 6 hours after loading dose. ii) hourly neuroobs iii) CT tomorrow if she doesn't wake up. Signed D Webb*

109. He reviewed her later at 4pm and 5pm. In the meantime a bolus IV dose followed by an continuing infusion of Midazolam were prescribed. The bolus was possibly omitted. If so it is not evident from the records by whom and by what means or why.

110. At 1700 :

a. *090-022-055*

b. *Dr Webb handwriting " Claire has had a loading dose of phenytoin + a bolus of Midazolam . She continues to be largely unresponsive. She responds by flexing her (L) arm to deep supra-orbital pain+ does have facial grimace-but no localisation. She has intermittent mouthing and chewing movements. Background from mum-contact with cousin on Saturday who had a gut upset. Claire had loose motions on Sunday+ vomiting Monday. She had some focal SZS on Monday with right side stiffening. Plan 1) cover with Cefotaxime and Acyclovir from 48 hours I don't think meningoencephalitis very likely.2) check viral cultures ? enterovirus -stool, urine, blood and T/S*

c. *3) add IV sodium valproate 20mg/kg IV bolus followed by infusion of 10 mg/kg IV over 12 hours." Signed D Webb*

111. **Comment on the Care provided by the paediatric neurologist at 2 PM, 4 PM and 5 PM assessments on 22 October and the prescriptions of antiepileptic drugs;**

112. The assessment of the paediatric neurologist on 22 October 1996 has a number of shortcomings. The investigation and management was not consistent with guidance at the time for investigation and management of acute encephalopathy including need for CT and EEG investigation and a range of blood tests (see below). And in particular the fluid management for acute encephalopathy of any cause required a reduction in infusion volume and increase in strength of sodium in the infusion fluid. Guidance available in 1996 even states "***In many cases treatment of cerebral oedema is required to be presumptive. Fluid should be restricted to 60% of estimated daily requirements; low sodium containing infusions like 5% dextrose or 0.18% saline in 5% dextrose are contraindicated……" (*** *Textbook of Paediatrics. Forfar & Arneil Third edition 1984 Page 791 et seq.)*

113. I refer to this later in and more detail is given in Annex A

114. RBHSC did not have guidelines in October 1996 but introduced "Paediatric Medical Guidelines " in May 1997. The second edition was later produced (a copy of which is no longer available) and a third edition in January 2003 which was renamed "Managing Medical Problems In Children. " The letter of 26/10/2011 from DLS encloses editions one and three. A fourth edition is in the process of being drafted but is not yet available.

115. 9/9/2011.Letter from DLS. " RBHSC did not in October 1996 and does not now have guidelines, procedures or protocols on the diagnosis and management of a child with reduced level of consciousness."

116. In a guideline on the child with reduced level of consciousness published in 2006, non traumatic coma (defined as GCS of <=12 for >=6hours) is reported as occurring as 30 per 100,000 children (N.I population = NNNN) *Bowker et at Arch Dis Child Edu&Prac Ed 2006;91:ep115-ep122*. The development of this guideline itself indicates concern that the condition needs to be managing in a more structured way and was produced following encouragement by a parental support group for Reye's syndrome who funded the its development to improve the management of acute encephalopathy in childhood. One of the country's leading experts in the management of Reyes syndrome-an acute encephalopathy mainly but not entirely affecting younger children, was Dr J Glasgow who was based at RBHSC. A more structured standard of management could thus be expected in RBHSC in the middle 1990s. Conventional management of Reye encephalopathy at that time included fluid restriction and monitoring serum osmolality.(e.g. *Recognition and early management of Reye's syndrome Dezateaux et al Arch Dis Child 1986;61:647-651)*.

117. The dose calculation of the bolus Midazolam and the prescribed dose were both well above advised doses (the infusion was within advised dose). Dr Webb did not notice this.

118. However by the time that Claire was seen by the paediatric neurologist she was known to have an established encephalopathy and the IV fluid should have been changed and this should have been part of the advice provided by the paediatric neurologist irrespective of any serum sodium results.

119. Claire had an acute encephalopathy of uncertain origin. The paediatric neurologist Dr Webb confirmed a diagnosis of non-convulsive epileptic status as his working diagnoses following his assessment at 14:00 hours, 16:00 hours and 17:00 hours and managed her specifically for that disorder. The clinical arguments however for this diagnosis were weak. Although Claire in infancy had at one time been considered to have infantile spasms which is a form of myoclonic seizure, the EEG was not consistent with that in 1987 at age 8 months nor was her later clinical course where she experienced episodes of tonic/clonic seizures which became reasonably well controlled. Non-convulsive status usually occurs in children with myoclonic or

mixed epilepsy particularly in children who have poorly controlled epilepsy. Claire had not had seizures since the age of four years and when admitted age 9 years had had no seizures for 5 years. She had been off antiepileptic drugs without seizure recurrence for 18 months. There is no clear record that she had a fit before admission. During the course of this acute illness Claire had a few short lasting events suggestive of seizure but these could have been explained as manifestations of altered pressure from the acute encephalopathy of any causation or a seizures generated by any underlying acute encephalopathy. It would be expected practice to confirm the diagnosis of non-convulsive status (or refute it) by arranging EEG. This investigation was available but not requested.

120. Advised practice at the time in 1996 (*Textbook of Paediatrics. Forfar & Arneil Third edition 1984 Page 791 et seq. and other publications see Annex A)* indicated a range of diagnostic tests including blood tests and CT scanning. These should have been carried out when Dr Webb assessed her-instead he planned to do a CT scan the following day if she did not improve. The CT scan was not on the same site as RBHSC and this investigation would have been cumbersome but was indicated. It is a deficiency of the hospital arrangements that in the mid-1990s a CT scan was not on site. It would help to know whether this deficiency had been documented by clinicians to management through the clinical directorate or medical advisory processes and there may be minutes which relate to this. I have noted that a CT scan is now on site but that it was only from 2002 that this became the case despite the fact that paediatric intensive care was provided in RBHSC and a regional paediatric neurology service which dealt with acute neurological problems. For a major regional children's centre this is a late addition to the range of supporting imaging facilities. An EEG was available within working hours.

121. Dr Webb should have been well aware of the significance of the slightly reduced blood sodium in a child with acute encephalopathy (in which there is a high risk of SIADH) which had been reported the previous night and he should have advised changes in the intravenous fluid regime both in terms of reducing infused volume and changing to a fluid with higher sodium content. He should have ordered further monitoring of the blood sodium but instead erroneously recorded that electrolyte results were normal. Although in his statements he ascribes this oversight to the fact that he thought the test had been done just before he saw Claire, this is difficult to understand because the entry of the result is in the notes in handwriting and timed The guidance available at the time on management of acute encephalopathy included taking steps to anticipate and attempt to prevent or manage the syndrome of inappropriate ADH which is well known to complicate and worsen acute encephalopathy/brain oedema. Instead of advising a fluid regime, as he should have done, he left the fluid management to the general paediatric team.

122. The Collapse 23 October 1996 03:00 Hours And Care In Intensive Care

123. Claire deteriorated suddenly at 2:30 AM in the morning 23 October 1996 rapidly sustaining a respiratory arrest, was resuscitated intubated and ventilated. She was taken to the paediatric intensive care unit. Claire was resuscitated by the

registrar who required assistance from an anaesthetist in order to secure the airway with intubation and ventilation. It is not clear what the interval was between arrest and intubation during which Claire's respirations were managed with bag and mask. No notes were made by the resuscitating doctors-the anaesthetist or the registrar to document timings. This should have been done retrospectively as soon as Claire had been intubated and ventilated. This is a major shortcoming of record keeping.

124. At this point Dr Steen consultant paediatrician who had been on call when Claire was admitted on 21 October, was called to see her. It is not evident whether Dr Steen was on call for acute general paediatrics that night. In addition Dr Webb consultant paediatric neurologist attended at 4 AM 23 October together with Dr Steen. Before this arrest occurred, Claire had been given intravenous phenytoin, intravenous sodium valproate, acyclovir and cefotaxime as advised by Dr Webb at 17:00 hours on 22 October. She had also been given an infusion of Midazolam .

125. Although the admission nursing record to the intensive care unit indicates that the Midazolam infusion was still in place, Dr Steen notes at 04:00 hours that she had a blood phenytoin level at 20:30 hours the previous night of 23mg/l which is within the treatment range and also that the Midazolam was no longer running.

126. A blood sodium level was obtained in the paediatric intensive care unit but it is not evident from the laboratory forms at what time the samples were obtained. Copies are shown below and show one at a level of 152 and another at 139 mmol/l. Although both of these forms show their origin as the intensive care unit, with the name of Dr PM Crean on the top, there is no report of the time of the sample, its processing or reporting although the date is given.

127. This is not a good standard of quality in the laboratory reporting process and documentation. This should have been addressed through governance procedures.

128. Other comments upon the management in the intensive care unit are :

129. The IV fluid does not appear to have been changed from a 0.18% sodium until Dr Mc Kaigne records this at 08:00 hours.

130. Dr Robert Taylor took over in PICU at 0830 and at 10: 00h or thereabouts (7 hours post arrest) made a note.

131. The brainstem death procedures carried out by Dr Steen and by Dr Webb at 06:00 hours use a standard form which is of good quality but in response to the question about whether drugs are in use which might affect level of consciousness, the answer is given as no when in fact Claire had a blood level of phenytoin at or just below the treatment range (a drug which can affect level of consciousness) and also had in the previous hours had Midazolam although it is likely that this had cleared. She had also been given sodium valproate which may still have been present in the bloodstream. Consequently although this is not likely in any way to the affected the

results of the assessment of brain death, it is a failure of adequate and proper documentation. There is a handwritten entry that that the blood sample at the time of brainstem death tests showed Na 129, K 3.6,Cl 94 urea 3.7, glucose 7.2 osmolality 274 but I am unable to find a laboratory report giving these findings nor was I able to find in the notes the printout of the results obtained at 21:30 hours on 22 October which showed significant deterioration in the form of a very low sodium Na (Na 121 K 3.3, Urea 2.9,Creatinine 33).

132. 090-050-154. **Witness statement dated 16/3/2005. Dr Steen.**

133. "Dr Webb and myself discussed Claire 's condition with her parents, emphasising that we felt she had cerebral oedema as confirmed by her CT scan which had resulted in coning of her brain and brainstem death. We also discussed the possibility of organ donation."

134. *"At 06:00 hours Dr Webb and myself completed brainstem death protocol and blood which was drawn for U&E at that time showed a sodium of 129 mmol/l .."*

Comment It is difficult to establish the sequence of blood sampling during the period in intensive care. The laboratory printout reports do not contain information on timing of receipt of sample by the laboratory and this is a significant shortcoming and quality management issue. However it is possible to conclude from the laboratory number on the reports that the blood sodium estimation of 139 with an osmolality of 287 was obtained before the next one because the laboratory number is 20553 whereas the next one showing a serum sodium of 152 with osmolality 313 carries the number 20996.

Lab report number	***Na***	***K***	***Cl***	***Urea***	***Cr***	***Osm (285-290)***	***Ca***
20553	139	3	103	3.4	34	287	
20996	152	2.8		3.3		313	2.69

135. In the clinical note made by Dr McKaigne at 0710 on 23 October 1996 he refers to a serum sodium checked when the brainstem test was done from the blood gas analyser as 133 but then goes on to report a blood sodium from laboratory showing sodium 129, osmolality 274. But I was not able to find the lab report on this. He also reports that Dr Webb/Dr Steen discussed Claire's clinical condition with her parents "they initially appeared to be giving consent for organ donation "Dr Webb will speak again to both parents at 10 AM.

136. Communication with Parents

137. On Allen ward there is little contemporary documentation about communications with the parents. The impression that the parents gained was not of

a child who was very seriously ill and they have stated this in their reports when they decided to leave the Ward in the evening. Yet in retrospect in his witness statement Dr Sands indicates that both he and the nursing staff did feel that Claire was significantly unwell. In these circumstances this information should have been shared with parents. On the PICU at 18:25 hours on 23 October , Dr Steen entered a note "discussed with parents and agree that ventilation should be withdrawn. Consent limited PM given."

138. The nurse records note “explained to parents that Claire's brain had swollen and that CT scanning and brainstem tests showed Claire's brain had died only the ventilation was keeping her heart beating." Relative counselling record. This is a good record.

139. This appears to be the limit of the recording of discussions with parents about Claire's state. I believe that discussions by the doctors with the parents should have been recorded in more detail and why the autopsy was to be limited.

140. Father recalls that Dr Steen told him that there would be no need for an inquest.

141. There is little documentation following the collapse and admission to intensive care about what was said to the parents at that time and also the reason for selecting to choose a brain only autopsy which has limited some of the information which may shed light on the cause of the encephalopathy.

142. The issue of documentation of communication with parents was addressed in the 2010/2011 RCPCH multisite audit on the child with reduced level of consciousness and the results of that are shown in the extract below (full document is attached “ library of documents” accompanying my report) . Lack of recording of communications was frequently recorded

6.8 Question 8: Documentation of Parental or Guardian involvement (Table 7)

Audit Question:
During the initial management and resuscitation of the child or young person presenting to hospital with a decreased conscious level, were their parents or guardians' involvement in their care documented in the clinical record?

- Parent or guardian allowed to stay with their child
- Parent or guardian informed regarding their child's possible underlying diagnosis or treatment
- Parent or guardian informed regarding their child's possible prognosis

Source of the standard:
The Management of a Child with a Decreased Conscious Level guideline and the Decreased Conscious Level Project Board Team

Table 7: Documentation of Parental or Guardian involvement during the initial management and resuscitation: Audit standards

Audit standards	Total audit sample	Cases meeting the standard	% Cases meeting the standard	Median percent (95% Confidence Interval)
parent or guardian allowed to stay with their child	1135	426	37.5%	33.3% (24.3%, 50.0%)
parent or guardian informed regarding their child's possible underlying diagnosis and treatment	1135	532	46.9%	50.0% (40.0%, 60.0%)
parent or guardian informed regarding their child's possible prognosis	1135	400	35.2%	35.1% (22.4%, 50.0%)

143.

144. PART 3 DETAILED COMMENTARY ON CLINICAL GOVERNANCE ASPECTS OF CARE PROVIDED.

145. My comments on the governance issues regarding the clinical care will be considered in the following sections addressing the care provided:

- **by the general paediatric service**
- **by the paediatric neurologist**
- **in the collapse at 03:00 hours 23/10/1996 and management in the intensive care unit**

Followed by comments on

- **Middle grade on call arrangements & handover evening care 22 October 1996**
- **The clinicians' reported experience of hyponatraemia**
- **Nursing documentation**
- **Prescription charts**
- **Fluid management**
- **Laboratory reports forms**
- **Access to imaging**

146. The care provided by the general paediatric service

147. When Claire was admitted she was significantly unwell because she had a reduced level of consciousness which persisted over 32 hours until the respiratory arrest. Coma of this duration is an unusual presentation in acute general paediatric practice but not rare. It is significant because it indicates a moderate or greater severity of illness and the level of consciousness present in her was such that she required careful attention both in nursing care and in medical assessment and treatment.

148. Following the admission on 21st of October : stages in the admission

149. A&E

150. It is expected that when a child attends an accident and emergency department an immediate triage process by a nurse will assess the urgency of need

for attention. This happened with Claire after referral by her general practitioner to RBHSC. Triage was timed at 18: 57 h.

151. She would then be assessed with a history and examination by a doctor in the accident and emergency department within an appropriately short time and if necessary immediate treatment given and /or referral to the paediatric junior doctor responsible for covering accident and emergency at middle grade level.

152. Claire was seen by the accident and emergency doctor Dr J at 19:03 hours who referred her to the paediatric registrar Dr O'Hare who saw Claire at 19:15h some 18 mins after triage.

a. In Document WS-142/1 on page 3, Dr Bartholome describes the duty of the paediatric registrar in 1996 who was the most senior paediatric doctor on-site between 5 PM and 9 AM. Registrars' on-call duty included covering the general paediatric wards, the specialty wards (cardiology, haematology, neurology, nephrology, paediatric surgery and orthopaedics) the SHO working in the paediatric intensive care unit would ask for advice if required. The hospital had about 120 beds that time. The registrar also covered the accident & emergency Department. In 1996 and medical staffing at night was one senior house officer in the accident & emergency Department and two junior senior house officers in the medical and surgical wards. Their shift finished at 22:00 hours. After 2200 h only one SHO covered all wards.

153. ***Comment****:* Indications for referral from an accident and emergency junior doctor to a paediatrician are largely not documented and tend to follow custom and practice and are based upon the assessment by the accident and emergency doctor. However Claire had been referred for admission by her GP which probably prompted immediate referral to paediatrics and she had reduced level of consciousness and thus admission was indicated.

154. The accident and emergency department should have a copy of the on-call rota for junior medical staff and consultant paediatricians and this rota should also be available to the main switchboard and the hospital wards' nursing staff so that it would be immediately clear who should be contacted. The rota supplied for the time did not have a column for the identified consultant. It should have had and omission was a risk for communications in emergencies.

155. Without a listing of the duty consultant there is a potential for confusion particularly in emergencies but also for administration. A hospital information system should also know so allocation of a patient can be made on the system but also the nursing staff and the parents should be aware of the name of the consultant under whom their child is admitted. For all these reasons a clear source of the consultant listing should be in place (and it was for the consultant paediatric surgeon rota).

156. At each stage in the process the doctor involved should make clinical handwritten notes and this was carried out to a satisfactory level except that there was no formal grading of the level of reduced consciousness using either the GCS or

AVPU scales which were both in use in 1996. Plans for investigation and treatment should be recorded and treatment if necessary started in accident and emergency. This was done with Claire. Admission should then take place from the accident and emergency..

157. WARD ADMISSION

158. Claire was admitted to the Allen Ward at 20:00 hours and the case notes written by Dr O'Hare.

159. This Ward takes acute general paediatric admissions although it also provided care for some children under the supervision of Tertiary specialists.

160. The time taken for transfer arrangements was reasonable. The arrangements in which a ward would be allocated to receive acute admissions would differ according to the type of hospital. In a district general hospital it would always be to the children's unit and hospital beds in DGHs may in different wards to take account of the age stratum of the child. In small hospitals there may only be one ward. In a regional centre all general paediatric admissions may be admitted to one ward or alternatively there may be a rota for allocation to take admissions that week or that day. It is not clear what arrangements were in place for the allocation of general paediatric admissions in October 1996 but in the event a speedy admission to Allen Ward took place.

161. Admission nursing documentation is also completed. This latter includes taking detailed accounts of the child's dependencies and needs such as Claire had in terms of her severe learning disability and potential behaviours, what food preferences there were, a documentation of allergies or sensitivities, and a history taken of the social circumstances and communication requirements for the parents in terms of contact numbers etc.

162. A set of hospital case notes would be originated for a new patient to hospital but if she had attended before for admission or outpatients as was the case in Claire , those notes should be available promptly. A full history and examination should be (and were) recorded except for a structured grading of the level of consciousness (also omitted in A&E). The temperature, pulse, respiration and blood pressure measurement and weight and height are recorded but in a child with reduced level of consciousness a structured grading of conscious level as recommended by the advanced paediatric life-support manuals or other source should have been used.

163. A programme of regular observations-routinely four hourly temperature pulse respiration measurements would be set up in all patients and in children with a reduced conscious level, a record made of the degree of reduction in the form of a Glasgow coma scale or at least the simpler system of Alert, not alert but responds to Voice , response only to Pain or Unresponsive AVPU.

164. The admission assessment on the evening of 21 October was otherwise of acceptable standard.

165. Claire was vomiting and unable to drink and needed routine IV maintenance fluid. She had a moderate severity encephalopathy (responding only to pain) and by the standards of the day the initial use of 0.18% saline in 4.3% which was prescribed would be consistent with established practice but not optimal practice in the context of an encephalopathy. (see below)

166. There was no written guidance on the Ward about management of acute encephalopathy or coma in 1996 and on Inquiry in 2011 there was no such guidance. The Paediatric Medical Guidelines written by the RBHSC first published in the spring of 1997, do not contain that information and also head injury management was not covered by the guideline (children with mild to moderate head injuries needing hospital observation should be under the supervision of a paediatric team who can make referral to neurosurgery and then routine GCS observations are common practice by nurses and doctors).

167. Guidance on acute encephalopathy in children was available in 1996 from the major UK Textbook of Paediatrics by Forfar and Arneil.(I refer to this below). In passing however ,it is of note that guidance published in 2006 on management of children with reduced level of consciousness, endorsed by the RCPH and used as a basis of multi site audit reported in 2011, does not address the issue of IV fluid to be used and only mentions Hyponatraemia as follows :

a. Bowker R, Stephenson TJ,Baumer JH. Evidence-based guideline for the management of decreased conscious level *Arch Dis Child Educ Pract Ed 2006;91:ep115–ep122.*

b. "plasma sodium to ensure the cause of prolonged convulsion is not secondary to hyponatraemia…"

c. "Hyponatraemia is a recognised cause of prolonged convulsions in children although there are no studies to determine the incidence. There are no randomised controlled trials of treatment for hyponatraemia in the context of a child convulsing. There is one case series of treating hyponatraemic seizures with 3% saline with beneficial results. The Delphi panel agreed that in the case of severe hyponatraemia hypertonic saline should be infused".

168. *Review at midnight 21 October .* The next stage after admission would be that after a reasonable interval, a further medical review would take place especially if investigations had been requested, in order to review any change clinically and to review the results. This was done in Claire by the registrar at midnight who found Claire to be slightly more responsive and the blood results were entered in the notes by the SHO at midnight. The results were not particularly striking although there was a slight increase in the white count and slightly reduced sodium level at 132.

169. Intravenous fluid prescription had been made of a fluid type then conventionally the one used throughout the NHS in children 0.18% Saline in 4 % dextrose. The assessment and plan was made by Dr O'Hare. A diagnosis of

encephalitis was considered. It was planned to review her overnight and reassess in the morning. The fluid balance chart and fluid prescription forms were completed satisfactorily . As were the nursing records.

170. No change was made to the IV fluid regime after review. The blood sodium result on the evening 21 October was low in that it was outside the normal range it was 132, slightly below the normal range (135-145mmol/l). This is only mild and not sufficient to cause encephalopathy. A commonly used guideline on fluid management, the Paediatric Vade Mecum [ref] , used by senior house officers, registrars and consultants, and on wards, regards hyponatraemia as less than 130 mmol/ litre. (see below).

a. A paediatric vade mecum. Insley 12th edition Edward Arnold. 1990

dehydration (*see* above). In practice it is inadvisable to elevate plasma sodium abruptly, and the additional sodium can be added to the infusion over a few days (unless the patient is symptomatically hyponatraemic, which is rare above 120 mmol/L).

Hypertonic (hypernatraemic) dehydration

Once the circulation has been restored, too rapid a reduction in plasma sodium concentration (and osmolality) will lead to a shift of water into cerebral cells, often resulting in convulsions. The reduction in plasma sodium should not exceed 10 mmol/L per 24 hours.

The administration of 0·18 per cent sodium chloride with 4 per cent dextrose solution, 75 ml/kg over 24 hours, is appropriate; any abnormal ongoing losses should be given additionally. Seizures may be controlled by administering intravenous mannitol (*see* p. 127). Hypocalcaemia may occur during rehydration and can be treated with intravenous calcium gluconate (*see* p. 109).

Correction of other electrolyte imbalances

Hypernatraemia: plasma Na^+ >150 mmol/L

If the patient is not dehydrated or symptomatic, water should be given, by mouth, at the approximate rate of 150 ml/kg/day in children aged 0–1 years or 100 ml/kg/day in an older child. If oral fluids are vomited, even when sipped frequently, and renal function is unimpaired, give fluids i.v. as 4 per cent dextrose/0·18 per cent saline at 75 ml/kg/day *plus* the amount needed to replace any continuing losses (*see* p. 22). If the patient is unwell and the renal function is poor, calculate 'exact' fluid requirements from pages 61–62.

Hyponatraemia: plasma Na^+ <130 mmol/L

Gastroenteritis is by far the most common cause of hyponatraemia in the young infant, but once that is ruled out three other possibilities have to be considered:

congenital adrenal hyperplasia (or other adrenocortical defect) p. 31;
primary forms of renal tubular acidosis;
haemodilution due to inappropriate ADH secretion accompanying respiratory illness, cerebral insult, trauma, burns or surgery.

(In the older, chronically ill child, a low plasma sodium concentration may be an incidental finding, and will return to normal with recovery of the underlying problem.)

Determine the cause whenever possible from clinical assessment, estimation of acid–base balance, and a comparison of Na^+, K^+ and osmolality in plasma and in a random urine test. Also estimate serum creatinine and examine the urine for pH, deposit and protein. Fig. 2.1 should be used as a guide to interpretation of results.

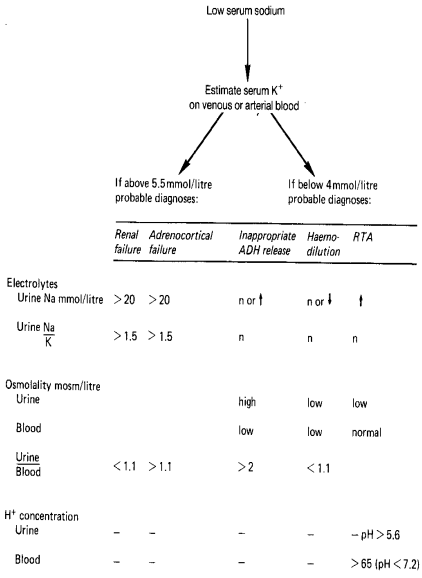

Fig. 2.1 Hyponatraemia; interpretation of results.

Treatment In an acutely ill child with Na^+ <125 mmol/L and:
inappropriate ADH secretion – restrict fluids ± diuretics;
congenital adrenal hyperplasia – *see* page 31;
renal tubular acidosis – replace fluids initially with 0·9 per cent saline i.v. and then orally with electrolyte mixture.

Intravenous therapy and hyponatraemia A low plasma Na^+ usually follows the prolonged use of hypotonic solutions in the face of continuing gastrointestinal losses.

If the child is adequately hydrated and asymptomatic Na^+ can be replaced using 0.9 per cent saline (150 mmol Na^+/L) *plus* the amount needed for continuing needs and losses (*see* p.22) in the

b.

20 *Fluid and electrolyte therapy and parenteral nutrition*

next 24 hours. For the formula for calculating sodium deficit in mmol *see* page 17.

When Na^+ <120 mmol/L and the child is symptomatic (pale and hypotensive, with falling urinary output, but well hydrated), 30 per cent NaCl injection BP (5000 mmol/L of Na^+) can be infused initially to replace *half* the estimated Na^+ deficit over 4–6 hours. Then repeat plasma electrolytes and recalculate needs. For the composition of solutions for intravenous use, *see* Table 2.4 page 17.

Hyperkalaemia: plasma K^+ > 6.5 mmol/L (7.0 in infant) as estimated on venous or arterial sample

Hyperkalaemia occurs principally in renal failure (*see* p.62) or after severe trauma. In these situations monitor the patient with ECG and treat prophylactically with oral calcium resonium 1 g/kg daily in divided doses, or as enemas in methylcellulose solution, retained for nine hours. If signs of K^+ toxicity exist (a prolonged QRS, depression of ST segment and peaking of the T wave on ECG) treat urgently as follows:

correct acidosis with i.v. sodium bicarbonate;
give glucose, 4 g/kg and soluble insulin 1 unit/kg i.v.;
give calcium gluconate 10 per cent solution, 0.3 ml/kg, i.v.;
arrange immediate dialysis.

171. ***Further Comment on 21 October assessment and management.*** Encephalitis is an unusual diagnosis, as is the presentation of a child with persistent reduction in conscious level and acute ataxia. Many junior doctors would choose to discuss with the consultant on call but this step does not seem to have been taken. The extent to which a registrar will inform a consultant on call will depend upon many factors including the level of his own experience. There are rarely firm rules set about this. The presence of junior doctors throughout the 24 hours in a hospital is not merely in order to staff the hospital but to enable them to exercise a degree of responsibility as part of their training and professional development. In a regional centre the threshold at which a registrar might refer to consultant might be higher- often because the registrar has had more experience than junior doctors found in district hospitals and partly because the resources available within a Children's Hospital are such that if deterioration occurs this can be handled quickly and with resort to intensive care on-site etc.

172. Nevertheless I would have expected a telephone notification from the junior doctor to the consultant given the degree of reduced level of conscious and the diagnosis made of encephalitis. It is this sort of issue which comes up in clinical meetings during presentation of cases or at clinical audit meetings. Now there is increasing argument and pressure to have greater involvement of consultants in care including out of hours. In my own unit from around 1993, a consultant was in the hospital every week day until 10:30pm and would do a walk round of the ward before going home. But the low level of experience in the middle grade tier was one reason

for setting up this arrangement which was unusual although a greater involvement of paediatric consultants in ward duties has become much more widespread in the early 2000s and in 2012 the debate is active. (*"The benefits of consultant delivered care"* published by Academy Medical Royal Colleges 2012),

173. Claire was known to have severe learning disability which can be associated with reduced social responsiveness and with speech disorders. At this point Claire presented with both and it may be that the junior doctors were not familiar sufficiently with the degree of change from the normal state. They would rely on the parents account here. There is insufficient recording to determine what the thinking process was about whether or not refer to a consultant.

174. CARE in DAYTIME 22 OCTOBER :

175. **Morning:** On the morning following admission it would be expected that the majority of children admitted would be assessed by a consultant. Not necessarily all however, as children with minor illnesses who have recovered or are recovering would be sent home if necessary by the registrar. Thus there may be a number of children who may have been assessed and discharged by junior medical staff such as those with minor disorders including a minor head injury, a child with mild gastroenteritis who had recovered after a period of observation, a child who had a mild fever and after good observation recovered, or child observed for ingestion of medication who had shown no signs of toxicity, or a child with asthma who had recovered quickly. But any child with significant moderate or severe illness should be seen by a consultant either out of hours or as a minimum on the post take Ward round. Any child with very severe illness or one requiring referral to an intensive care should be seen by a consultant out of hours within a very short time.

176. Given the presentation of significantly altered level of consciousness which had persisted overnight, and her illness severity, I would have expected Claire to have been seen at the latest by the morning following her admission by the consultant responsible for her care. Or, if a consultant was not able to attend Ward round, then at a minimum Claire should have been discussed with her. Claire had a persistent reduction in conscious level amounting to coma as a manifestation of the acute encephalopathy without specific diagnosis.

177. Dr Steen was the consultant on call for general paediatrics when Claire was admitted and would have been her allocated consultant. Claire was not seen that morning by Dr Steen who did not see Claire until after the collapse occurred in the early hours of 23 October, 33 hours after she had been admitted. It is not clear or certain that she knew about the presence of her patient or of her condition before then.

178. It should have been clear who was the consultant responsible. Consultant allocation of patients on a Ward which caters for a number of consultants is made clear in a variety of ways. The name of a consultant may be entered on a board or a card attached to the patient's bed or cubicle. Also in many wards then and now this is

entered onto whiteboard at the nurses' station. It will also often appear on the nursing Kardex and should appear on the hospital information system returns sent from the Ward for hospital activity analysis by the Ward clerk. And on the ' sticky labels' generated on admission to attach to radiology, blood and urine and other investigation forms. I do not know what level of IT support record generation in this respect applied at RBHSC in 1996 but this was in place in many hospitals at that time. A substantial minority of hospitals had IT linkage with the pathology system to access laboratory reports 24 h a day at that time.

179. The consultant Ward round serves the purpose of providing a consultant opinion and treatment plan on a child after an acute admission. It also provides the opportunity for junior medical staff to be supervised and be trained for educational purposes particularly in unusual presentations such as applied to Claire who continued to show a reduced level of consciousness over many hours by this time.

180. The expectation of the work pattern of the consultant Dr Steen who had been on call and was responsible for Claire's care was to carry out a Ward round in the morning. In many hospitals however the consultant Ward round might take place in the afternoon if a consultant had morning commitments such as a clinic. In these circumstances the consultant would usually telephone or visit the Ward before starting a clinic to see if there are any children they would need to see or provide advice on. Claire had a persistent reduction in conscious level of significant degree and the minimum expected would have been a telephone discussion between a consultant and the Ward staff :nurses or doctors.

181. Witness statement **Dr Sands** (090-051-157) dated 6/7/2005 states: *The paediatric consultant under whom Claire was admitted was unavailable: although I believe she was kept informed by telephone.*

182. In the absence of Dr Steen Claire was seen by the paediatric registrar for Allen Ward, Dr Sands (time uncertain) . He carried out a clinical review which was appropriate and considered an explanation for her presentation as non-convulsive or nonfitting status. She was on intravenous fluid because she was unable to drink and had repeated small vomits. Blood tests had shown a slightly low sodium at 132 mmol/l the previous evening but she had no clinical or biochemical signs of dehydration. Dr Sands noted the low sodium which had been present the night before.

183. Dr Sands should have arranged a repeat sample for the blood sodium. There is little firm guidance about how frequently blood urea and electrolyte samples should be sent in children on intravenous fluid. In the 2009 NICE guideline on diarrhoea and vomiting there is no firm guidance on frequency of blood electrolyte monitoring proposed. In a survey of 17 hospitals in 2004 on Hyponatraemia in children on IV fluids serum electrolytes had been measured in in preceding 24h for only 54% and between 24 and 48 h earlier in an additional 25 % of children. (*Armon K et al Arch Dis Child 2008;93:285-287*). Some hospitals have a written policy on managing children on IV fluids, many did not (70% in the Armon study did not) and do not now.

However as a general principle when a test shows a result outside the range it is usual to repeat it either to confirm that it was abnormal and to determine whether it has got worse. In the Textbook of Paediatrics by Forfar and Arneil twice-daily blood electrolyte and urea samples were recommended in encephalopathy in the 1984 edition and in later editions.

184. In her witness statement document WS-143-1. Dr Steen On page 9 there is reference to the hospital policy referred to in the nursing care plan (09-043-146) on administration of IV fluids to paediatric patients. Dr Steen has no recollection of any such policy in 1996.

185. Dr Sands referred for a paediatric neurology opinion. In the circumstances that was appropriate and correct. This was possibly by telephone at around lunchtime after he had seen Claire mid-morning because a dose of rectal diazepam was given at 1215. It is not clear from the case records whether Dr Sands initiated this himself or whether it was following a phone consultation with Dr Webb the consultant paediatric neurologist. Dr Webb saw Claire at 14:00 hours and again at 1600 and 1700 hours. (the clinical history sheet in the notes shows an entry by Dr Webb at his first attendance of 4pm. This cannot be correct because it is followed by SHO entries recording his consultation and regarding drug prescriptions written up after 2pm). It is not clear in the case notes when the addition to Dr Webb's initial plan of IV Midazolam was made – nor whether Dr Webb suggested the doses but from his later witness statement he confirms that he saw Claire at 4 PM and advised Midazolam in a bolus and infusion. There were some significant risk issues in the dosage of Midazolam and I address these in a separate section).

186. In between these consultations there are junior paediatric doctors entries in the notes respecting dose calculations of phenytoin and Midazolam . These are the last notes made by the paediatric team until 23:30 hours.

187. The registrar on duty on the Ward-Dr Sands took all the appropriate steps but did not record in the notes the clinical state of Claire in the afternoon. There was a senior house officer on the Ward and either he or Dr Sands should have made an entry in the late afternoon especially as Dr Sands in his witness statement as indicated that Claire was significantly unwell. And again in the evening.

188. There is no documentation in the notes of communication with parents but from my knowledge of case notes and audit results in a significant number of units I am aware that this is frequent (although undesirable) so cannot be seen as a unusual shortcoming for the time. but is now getting better partly as a result of audit scrutiny. One of the approaches taken to this deficiency has been to create on each ward a portfolio of hand-out leaflets for common conditions and then it is sufficient simply to record "hand-out given " as a shorthand because it is likely that this would be given with some discussion. I do not know what the range of hand-outs or leaflets were on the Ward in 1996. Many hospitals by this time would have had a portfolio but it is unlikely that they would include acute encephalopathy or non-convulsive status.

189. **Dr Sands referral to paediatric neurology**.

190. One advantage of an admission of a child to general paediatrics to a regional children's centre which also locates the tertiary specialist services is that referral for tertiary specialist opinion is facilitated because of the co-location. In the case of paediatric neurology and other specialty referrals, this may be may be direct from consultant to consultant or following consultation by a junior doctor with the consultant responsible for the admission, the junior doctor may make a referral directly to a paediatric neurologist at times in an emergency without consultation with the general paediatric consultant responsible for the child's care. It appears that the latter was the case in the management of Claire when Dr Sands made a referral to Dr Webb without Claire having been seen by Dr Steen or without any telephone contact being made with Dr Steen..

191. Before this referral she should have been seen or at least discussed with the consultant under whom she was admitted. She was not seen before this referral and it is not clear whether or not telephone communications were made with the consultant responsible for her care.

192. It is evident from the notes and from Dr Sands own witness statement that he regarded Claire as seriously ill. The responsible consultant Dr Steen should have made sure that her junior staff knew when to call her and how to call her. If Dr Steen knew that she was not available or likely to be contactable, she should have made arrangements with a colleague to provide cover for her. It is not clear whether another consultant paediatrician was covering the ward during the daytime hours of 22 October nor who was responsible on the evening of 22 October for covering the general paediatric service. In the event however although Dr Steen was not on-call-I believe-when the collapse occurred at 3 AM 23 October it was Dr Steen who was contacted by the registrar Dr Bartholome who had taken over the care at registrar level from Dr Sands at a time which is not evident.

193. 090-051-157. The witness statement dated July 2005 by Dr Sands. "However I (and the Ward team) felt that she was really very unwell. A dose of diazepam was given rectally (5 mg) I believe this was after contacting Dr Webb consultant paediatric neurologist….. I personally went to talk to the consultant paediatric neurologist on-call. The Paediatric consultant under whom Claire was admitted was unavailable: although I believe she was kept informed by telephone. I described Claire's problems the paediatric neurologist to him I thought a CT scan of brain might be required."……. "I do not recall being present in the mid-afternoon."…. "I did administer an intravenous dose of sodium valproate as requested by the neurologist at 5:15 PM."

194. Claire was seen by a consultant paediatric neurologist Dr Webb at 2 pm the day following her admission. Dr Webb was contacted by the registrar but it is not clear at what point in the illness he gave advice. The notes indicate that Dr Webb saw Claire at 14:00 hours but it appears from the witness statement from Dr Sands that a face-to-face discussion had been held around lunchtime and at this time

advice was given about management. This interview should have been recorded in the notes and time but was not. The treatment plan which followed the discussion should have been entered in the notes.

195. **Dr Steen's absence : I consider this in further detail and comment in the context of a consultant's duties below Chapter 2 in discussion of Clinical Governance.**

196. While on call out of hours, a consultant general paediatrician would expect to be called by a member of their junior staff at any time for telephone advice or personal face-to-face consultation with the child and thus expect a return to the hospital to see the child at any time. Such a recall consultation would take place when a child was significantly ill or where a diagnosis or procedure lay outside the competence expected of the junior medical staff in the team. The consultant would be responsible overall both for the care of the child and the supervision of the junior medical staff in the team and at the same time be responsible for the quality of service provided for the patients for whom they were responsible by the medical and nursing staff, Ward accommodation (shortage of beds for example) and the arrangements for specialist investigation or consultation with other consultants such as surgeons, neurologists, cardiologists or intensivist/ anaesthetists and radiologists. Should any problems arise with service general provision, they would be expected to contact the senior nurse and / or general manager on-call to review alternative options and put them into place. It is also expected that any shortfalls were addressed through adverse incident reporting or brought up in an appropriate way with the clinical director and general management either urgently or through the process of meetings in the directorate.

197. If a consultant is not able to carry out a scheduled Ward round, then they should have either telephoned the Ward or the registrar to determine whether any significant cases had been admitted overnight. Also if not able to attend a scheduled Ward round to make other arrangements for the children under her care to have been reviewed. This was a shortcoming in the arrangements for the provision of care for Claire . It may be helpful to establish how frequently a consultant did not carry out a scheduled Ward round.

198. It is the case that consultants who had been on call overnight may, the following morning, have other commitments such as an outpatient clinic and under these circumstances the Ward round to be carried out in the afternoon following the night responsibility. However that consultant would expect to be contacted by the junior medical staff or the nursing staff or they should initiate such contact before starting a clinic by telephone or ward visit in order to see whether there were any unusual or severe cases that they should see.

199. PAEDIATRIC NEUROLOGY CARE

200. Dr Webb : the consultant paediatric neurologist on-call.

201. Dr Webb has explained that he was on a 1:2 on-call Rota. His job description included in papers obtained from DLS includes :

a. *The post holder expected to work with local managers providing high quality efficient service to patients and to assume leadership where appropriate in a team working environment within the management framework of the paediatric directorate and in line with the policy of the trust.*

b. *The post holder will join the incumbent consultant Paediatric neurologist Dr Hicks in a 1:2 Rota for the paediatric neurology emergency cover on a tertiary basis for in-patients in RBHSC and by telephone for paediatric unit province wide.*

c. *The post holder will be expected "to participate in continuing medical education meetings which include neuroscience grand rounds including neuropathology (autopsy and biopsy review) department meetings, journal club, topic and case note review, paediatric grand rounds medical and clinical audit."*

202. This job description usefully summarises the responsibility as seen by the trust as follows for junior staff :

a. *"You have agreed that you have responsibility for the training and supervision of junior medical/dental staff who work with you and you will devote time to this activity on a regular basis. If appropriate, you will be named in the contracts of doctors/dentists in training grades as the person responsible for overseeing their training and as the initial source of advice to such doctors in their careers."*

b. *"Requirements to participate in medical audit and in continuing medical education)."*

c. *DLS reported Dr Webb did a rota of one-week on-call to paediatric neurology consultations every other week. This involved while doing daytime work being available 24/7 for consultation on children and new-borns with neurological problems. He believes he was on-call for the week beginning 21 October 1996.*

203. Dr Webb did a rota of one-week on-call for paediatric neurology consultations every other week. This involved while doing daytime work being available 24/7 for consultation on children and new-borns with neurological problems.

204. Guidance on acute encephalopathy available in 1996 & comments on neurology care of Claire

205. Knowledge sources for a paediatric neurologist in the management of acute encephalopathy include experience gained and the curriculum in training, and continued experience in consultant practice, especially in support of multi-specialties

such as are found in a regional children's hospital and neurosurgical service. Guidance is also available from standard textbooks in general or neurological paediatrics and awareness from published literature in journals.

206. The management of coma and encephalopathy relevant to the time has been included in the Advanced Paediatric Life-Support curriculum and its associated manuals. One important example is from the standard Textbook widely used in United Kingdom containing advice which would have been relevant and updated by the mid-1990s. *Textbook of Paediatrics. Forfar & Arneil Third edition 1984 Page 791 et seq. which includes :*

a. *"The possible presence of raised intracranial pressure in acutely ill children is frequently overlooked and this is particularly the case if clinicians rely on the frequently absent 'classical signs 'of raised intracranial pressure. The only reliable means of excluding raised intracranial pressure is to monitor it……..*

b. ***In many cases treatment of cerebral oedema is required to be presumptive. Fluid should be restricted to 60% of estimated daily requirements; low sodium containing infusions like 5% dextrose or 0.18% saline in 5% dextrose are contraindicated…...***

207. Detail from this guidance is given in the Annex A where I also include the protocol for management of acute encephalopathy used in my own unit (Pinderfields Hospital - a District general Hospital) from the middle of the 1980s. Although the protocol is dated 1999, this would be the one in place in the early 90s and covering the period of time in which Claire was treated. (The reason for later dating is that this is the digital copy and previous copies were photocopies). It is included here to provide an example of how textbook and other authoritative advice can be briefly presented in the ward environment at the point of delivery of care for medical and nursing staff to use to indicate how to manage specific cases.

208. It would be expected that a paediatric neurologist would approach a new acute encephalopathy illness in a structured way which would extend a differential diagnosis beyond the ones that were considered-post ictal or related to infection. No consideration seems to have been given to the possibility of a focal brain lesion such as abscess, tumour or haematoma, nor to the possibility of poisoning or metabolic encephalopathy such as associated with liver problems or Reye syndrome. It would be expected that he would consider doing a CT scan of brain that day and arrange blood investigations and urine investigations for metabolic disease and poisoning. Nor did he attempt to establish that this presentation was epileptic encephalopathy by arranging an urgent EEG.

209. From the guidance I include it is evident that the management should have considered a wide range of causation and investigate appropriately while treating the treatable . Dr Webb did do the latter by covering her with antiepileptic therapy and with anti-infectious medication.

210. Dr Webb did not approach her fluid management properly. Claire was on intravenous fluids, she had an acute encephalopathy of uncertain origin and she should have had higher sodium fluid than was given as part of her intravenous therapy. This would be the case even if there had been no low sodium identified.

211. The level of reduction serum sodium on admission was only marginal the normal range being 135-145. In theory a hyponatraemia is when the blood level is less than 135. In practice however most would consider a level of 132 as only mild Hyponatraemia and levels such as this are not infrequently found in acute illnesses in children.

212. However in the context of an acute encephalopathy, a neurologist should be aware of the risk of the development of raised intracranial pressure even if there were no signs of it at the time. Raised intracranial pressure is manifest by reduced conscious level, especially one which progressively becomes more severe, with or without signs of papilloedema, impairment of pupillary responses and the emergence of gaze deviation, extensor hypertonus of the trunk or stiffness which may be intermittent and as it progresses impairment of swallowing/gag reflex, and the ability to protect the airway and ultimately with increasing pressure upon the brainstem inability to maintain respiration or circulation. Part of the management of acute encephalopathy is to anticipate and attempt to prevent this. Low sodium fluids such as 0.18% should not be used and Dr Webb should have advised a change of the IV fluid. The Textbook of Paediatrics by Forfar and Arneil , the major UK textbook, goes so far as to say that such fluids are contra indicated in the presence of an acute encephalopathy.

213. The low sodium level on admission was not sufficient to be causative of the encephalopathy. However it indicated a risk of development of further hyponatraemia which is a well-recognised complication of any intracranial pathology.

214. Dr Webb misunderstood the timing of the blood test. He thought it had been from a blood sample on the morning of the 22nd which would have been a matter of about seven hours beforehand. It is difficult to understand how this would be the case because the handwritten record of the results in the notes was timed at 12 midnight.

215. The blood result in the notes which may or may not have been present as a printout from the laboratory when Dr Webb saw Claire contains no timing of sample receipt or process. In the mid-1990s and since, it is common for the sample time of receipt in the laboratory and sample time of process to be recorded. Ideally the time of sample taken is recorded but that is often not known to the laboratory when they receive the sample as this has to be moved from the ward to the laboratory and may be sent in batches. The design of the pathology form is thus substandard. Review of other cases in audit can identify examples such as this and lead to a useful dialogue between laboratory and clinician if the problem is identified and, after such incident reporting or audits lead to changes in practice in the laboratory. There is no evidence from the post event discussions that this was a recognised issue. It would be helpful to see case records relating to other children for example in 2001 to see if the

laboratory forms changed in the interval. Also it would be helpful to know what topics were discussed in postgraduate meetings, grand rounds and other environments for the sharing of experience in the hospital to identify if acute encephalopathy management of management of status epilepticus was discussed in any of these meetings

216. Dr Webb has given his views about fluid and sodium issues in the available documents..

217. On page 090-053-174 Dr Webb comments regarding fluid therapy :

a. *"the management of Claire's fluid therapy is clearly an important aspect of her care. It would be routine for children who are admitted with altered consciousness not to be offered oral fluids and therefore to require intravenous fluid replacement. The prescription of fluids for the children admitted acutely to hospital under a general paediatrician is dealt with by the paediatric medical team on-call and are supervised by the paediatric medical registrar on that team. Since being appointed as a consultant paediatric neurologist 10 years ago I cannot recall writing a prescription for intravenous fluids and during this period have never written a fluid prescription for another consultant's patient. I would therefore not have had input into the choice of fluids in Claire 's case. It would be routine for children on intravenous fluids to have their urea and electrolytes measured on a daily basis or more frequently if necessary to facilitate adjustments to the fluids. Blood testing in hospital is routinely undertaken first thing in the morning and I believe I erroneously understood the urea and electrolyte result reported on Claire to have been at mornings result. My entry in the notes referring to her urea and electrolyte results was effectively a memo to myself that they could not have explained her clinical state that day. I believe that if I had understood the results to have been from the previous evening I would have requested an urgent repeat sample. In fact bloods were not repeated the morning after admission and the next urea and electrolyte measurement was on a blood sample obtained at 9:30 PM on October 22. This result returned to the Ward at 11:30 PM that evening."*

b. *"The syndrome of SIADH can complicate a number of clinical conditions. It has been described to occur with the use of several drugs and in the context of malignancy and severe lung and brain disorders. The most likely explanation in Claire 's case was the presence of meningitis (inflammation of the lining of the brain). The treatment of this condition is to restrict fluid intake until the inappropriate secretion resolves. The indication to restrict fluids would be a low sodium value in the presence of a raised urine osmolality (measure of urine concentration). There is evidence of severe hyponatraemia*

is a poor prognostic factor in childhood neurological disorders. In a study of 72 children with acute neurological disorders admitted to hospital 31/35 with mild hyponatraemia recovered fully while 37/37 children with moderate or severe hyponatraemia either had residual deficits or died. Reference (1).

218. **Conclusion on neurology care :** Acute encephalopathy is not an uncommon problem for a paediatric neurology service. There are a number of shortcomings in the management of Claire by the paediatric neurologist. Claire should have had further blood investigations requested, a CT scan arranged that day and an EEG carried out to confirm or refute a diagnosis of epileptic encephalopathy. The CT scan was not on the same site as RBHSC and this investigation would have been cumbersome but was indicated. It is a deficiency of the hospital arrangements that in the mid-1990s a CT scan was not on site. It would help to know whether this deficiency had been documented by clinicians to management through the clinical directorate or medical advisory processes and there may be minutes which relate to this. I have noted that a CT scan is now on site but that it was only from 2002 that this became the case despite the fact that paediatric intensive care was provided in RBHSC and a regional paediatric neurology service which dealt with acute neurological problems. For a major regional children's centre this is a late addition to the range of supporting imaging facilities.

219. An EEG was available within working hours.

220. In the management of acute encephalopathy in 1996 and now careful attention is required to volume and content of intravenous fluid used. Thus the paediatric neurologist should have reviewed the fluid and advised a change in volume and type to at least 0.45% and preferably normal saline. This would be irrespective of knowledge of the serum sodium. It was an oversight and error on his part to fail to notice timing of the test showing low-sodium and the request a repeat.

221. Given the further attention given to Claire's problem (and others) from 2004 onwards, it is surprising acute encephalopathy management was not included in the revised 3rd edition of the hospital Medical Guidelines then re titled *Managing Medical Problems in Children* and that in 2011 the unit still does not have a management guideline for acute encephalopathy.

222. The statements made by Dr Webb in respect of his role in fluid prescribing shed some light on his view about the overall consultant responsibility for Claire. If Dr Webb was expecting the junior staff to supervise the fluid management and prescribe it and he did not see this as his responsibility then this responsibility would be one carried out by the junior paediatric staff on behalf of the general paediatric consultant. However it can be argued strongly that advice on the appropriate fluid regime for an encephalopathy forms part of neuro- intensive care which lies within the responsibility of the paediatric neurologist. It also lies within the range of general paediatric expertise for example when treating bacterial meningitis.

223. Care in the Intensive Unit

224. Following the admission of Claire to the intensive care unit for ventilation and CT scanning, she was seen by Dr Steen who had been called and by the paediatric neurologist Dr Webb and also by the intensivist. No reduction in intravenous rate or change of fluid from low sodium was made or at least recorded even though the low sodium level of 121 was recognised and its potential contribution to the arrest from cerebral oedema also acknowledged. It was some hours later that this change took place

225. The sequence of blood sodium tests after admission to paediatric intensive care unit is difficult to establish and this in part is because the pathology report forms do not include time of sample receipt or processing by the laboratory. Copies of record show a blood sodium level of 152 and another at 139 mmol/l. Although both of these forms show their origin as the intensive care unit, with the name of Dr PM Crean on the top, there is no report of the time of the sample, its processing or reporting although the date is given. This is a shortcoming in the design of the forms which should have portions specified for this information on the printout and governance of pathology processing.

226. The brainstem death procedures carried out by Dr Steen and by Dr Webb at 06:00 hours use a standard form which is of good quality but in response to the question about whether drugs are in use which might affect level of consciousness, the answer is given as no when in fact Claire had a blood level of phenytoin at or just below the treatment range (a drug which can affect level of consciousness) and also had in the previous hours had been given high doses of Midazolam although it is likely that this had cleared. She had also been given sodium valproate which may still have been present in the bloodstream. Consequently although this is not likely in any way to have affected the results of the assessment of brain death, it is a failure of adequate and proper documentation.

227. It is not evident why a brain only autopsy was requested-the records are incomplete.

228. It is not evident at what time repeat urea and electrolyte samples were sent and reported after admission to the paediatric intensive care unit although results were available for the first brainstem death testing at 0600h.

229. MIDDLE GRADE ON CALL ARRANGEMENTS & HANDOVER EVENING CARE 22 October 1996 :

230. Middle grade doctors have a variety of responsibilities in the daytime. These include the supervision of the senior house officer and admitted patients on the Ward for which they are responsible. In a regional tertiary centre registrars may be allocated to a particular tertiary specialty for within working hours. In addition they will be responsible for undertaking study, audit, research, and covering outpatients and at times accident and emergency. Out of hours all the middle grade doctors would be on a rota arrangement of 1 :3 or 1:4 or less frequent to cover the hospital. In a district general hospital in middle grade doctors would be covering the newborn unit as well as providing opinion in accident and emergency and being responsible for supervising admissions on to the children's Ward. These wards however would contain no more than 40 beds in a large district hospital and in a small or medium district hospital 20 to 30 beds in contrast to the regional tertiary centre, where cover is provided for a much larger number of beds and children. Additionally children admitted in a regional centre are likely to have more complex disease and be more ill.

231. An ideal standard for a Children's Hospital would be that the middle grade doctors would make a round of the hospital by walking each of the wards to determine whether there were any unusual or outstanding problems. Dr Bartholome was covering the whole of the hospital at night, several wards, accident and emergency and intensive care unit. It is not evident whether part of the practice of the resident middle grade would have been to walk around the wards once at least on starting their duties at least to see if there were any significant "problems" or, whether the day time registrars would routinely discuss significant cases by face to face or telephone hand over.

232. It is not possible to determine how busy the hospital was on the 22 October 1996.

233. In more recent years with considerable restriction on junior doctors hours, consequent increase in the numbers of doctors incorporated on a rota and doctors being involved in an individual case, more formal handover arrangements have been put in place as it has been recognised that this is a vulnerable clinical safety issue. There is now progress to written documentation of the handover. However in 1996 this point had not been reached but verbal handover would be usual either face to face or as a minimum by telephone. Claire had a serious illness but it is not evident that a handover process took place. (*Good Practice in Handover RCPCH 2005 is relevant on this point*).

234. It is noteworthy that in 1996 when Claire was admitted, only one middle grade doctor was responsible for the whole hospital out of hours between 5 PM and 9 AM. Dr Sands who had been caring for Claire in the daytime was going off duty and the registrar on call was Dr Bartholome. By the 4pm and 5pm consultations with Dr

Webb Claire had a persisting low conscious level. Dr Sands had identified Claire as suffering significant illness and I would have expected him to have handed over in some form even if this was by telephone. There is no evidence that Dr Bartholome knew about Claire on the evening before the low sodium result was available nor whether she saw her after that until the collapse in the early hours of 23 October.

235. Claire had a significant reduction in her level of consciousness although it fluctuated. From the evening however of 22 October the conscious level reduced. At this point given the severity of illness a consultant should have become involved either the consultant paediatrician for general paediatrics who was on call or the paediatric neurologist.

236. The Middle grade doctor Dr Bartholome was involved in Claire on the evening of 22 October by telephone consultation at 23:30 hours when low blood sodium was identified. Claire should have been seen by the medical registrar then at the latest. This was an unusually low sodium level. It is the case that low sodium levels are found in many childhood illnesses but this was a particularly low level and the junior doctors properly ascribed this to the syndrome of inappropriate ADH secretion but did not properly manage this by altering the intravenous fluid to normal or at least 0.45% saline. Further the proposed reduction of IV fluid volume from 67ml/ hour to 41 ml/ hour did not happen. Claire was given 62ml/hour. (See comment on fluid management below).

237. It is not evident that Dr Bartholome saw Claire until or even at the time when the low sodium of 121 mmol/l was discovered at 23:30 PM. She did however advise reduction in fluid volume but she did not advise change to a higher sodium fluid which she should have done because given the knowledge of the sodium with the proposed explanation of inappropriate ADH secretion in a child with coma which had progressed in severity. The SHO had recorded a query option of increasing the IV fluid sodium. (090-022-056)

238. This was a failing and shows a lack of awareness of the management of acute encephalopathy. I would have expected a registrar to be aware of how to manage this condition but it would have helped her and others to have had a protocol in place. In a hospital with a paediatric neurologist service and an intensive care unit, I would have expected even with the lack of a protocol, for the resident middle grade to be aware of the steps to take.

239. The sample for this was taken at around 9:30 PM at the same time the blood phenytoin estimation but it was two hours before the result was available to the Ward. It is not clear at what time the sample reached the laboratory and was processed nor why it took so long for the result to be seen by the SHO. The level was very significantly low at 121 mmol/l but there is no evidence from the records that the laboratory technician telephoned the Ward which would normally be an expected response to such an out of range result. In the event the senior house officer became aware of the result at 23:30 and discussed this with the registrar. Also by

this time it was evident they had been a significant change in the level of consciousness. The GCS score had stepped down from around 8 to 6.

240. Increased secretion of antidiuretic hormone complicating hyponatraemia and making it worse is well recognised in the context of acute intracranial disease. Awareness of this possibility at the time is evident in the conclusion of Dr Stewart senior house officer later that evening when he received the repeat urea and electrolyte result.

241. Whether Dr Bartholome should have consulted the on-call consultant is another issue. In a regional teaching hospital such as RBHSC the middle grade doctors commonly undertake quite extensive responsibility rather than resorting to the consultant on call. In a district general hospital it would be more usual for the middle grade to contact a consultant to discuss the management of such a low sodium in the context of an acute encephalopathy. Implicit in this differing style of practice is the fact that, in the regional centre, there is more awareness of how to manage such serious disease which is likely to be seen more frequently. Given the fall in the level of consciousness on that evening, I believe that the paediatric registrar should have reviewed the child and discussed Claire with an on call consultant either the neurologist or the On-Call general paediatrician (whoever that was). However it is not evident whether the therapy plan would have been changed as Dr Steen has stated in her evidence in WS-143-1. Page 57.

a. *"With our knowledge today we are aware that children with acute neurological problems are at risk of SIADH in a patient presenting with an acute CNS illness. In 1996 it was not routine to fluid restrict such patients at presentation but by 2000 it had become normal practice to fluid restrict such patients."*

242. This statement is not correct in respect of practice in 1996 as can be seen from the textbook advice I provide both in acute encephalopathy and management of the more common bacterial meningitis. (Nelson's T Book of Pediatrics - 16th Edition for example states that in the latter condition IV fluid volume should be reduced and that SIADH occurs in the majority of children with this disorder)

243. On the second day of admission (22 October 1996) it is not evident which consultant general paediatrician was on-call and thus taking responsibility in delegated form for Claire after 5pm nor whether that consultant was informed of Claire's illness in terms of nature or severity nor of the deterioration which occurred over the evening. It is not evident why that consultant was not involved in Claire's care when the very low sodium (121 mmol/l) was detected. When Claire finally collapsed Dr Steen was called but it is not evident why this was the case rather than the acute consultant on-call with responsibility for the Ward/general paediatrics/Claire. The on-call rota for the time does not include a list of the paediatric consultants in a separate column. This omission has significant clinical risk for management of emergencies which may arise in accident and emergency, children's Ward, intensive care and for the switchboard. The design of this on-call rota constitutes a significant short coming in clinical governance.

244. I have noted that Dr Steen in her subsequent witness statements did not wish to comment on the actions of her junior staff although she was responsible for their actions during the on-call period as she was their consultant supervisor.

245. **Medical resident staffing** In 1996 in addition to the medical registrar, the medical staffing at night was one senior house officer in the emergency Department and two junior senior house officers in the medical and surgical wards. Their shift finished at 22:00 hours. After 2200 is only one SHO covered all wards. Given the number of patients for which the registrar had responsibility and the likely complexity of conditions being managed, this medical staffing out of hours is low and thus early involvement of additional staff at consultant level should have been more readily summoned in complex or unusual cases.

246. The resident medical staffing out of hours in RBHSC is low in regard to the range of responsibilities-the cover of accident and emergency, cover of the wards and the numbers of beds concerned and complexity of illness in a tertiary regional centre. I do not know whether the accident and emergency is only for children-paediatric A&E or whether the registrar was obliged to go to the Royal Hospital to see children attending the general accident and emergency. This should be clarified. It appears that there were up to 6 middle grade doctors available to take part in that rota (this is low in relation to the number of beds). It would be helpful to know if the issue of on – call medical staffing was a matter brought up to professional committees or medical management/clinical director at meetings.

247. It would be of relevance to know whether this matter of workload and staffing out of hours had been addressed or discussed within the management structure either through the medical advisory process or through the more formal clinical directorate arrangement. There is some evidence available to show that a paediatric Department is likely to generate a significant emergency workload out of hours in comparison with adult practice even in a district general hospital. (I can provide this evidence if requested from the survey I set up through the Department of Health in the early 2000s when out of hours hospital teams were being considered for adult cover).

248. THE CLINICIANS' REPORTED EXPERIENCE OF HYPONATRAEMIA

249. In discussing the admission sodium in witness statements Dr Steen and Dr Webb give differing views about their experience with low sodium levels. Dr Steen states they are seen quite frequently, Dr Webb reflects upon his experience as infrequent. Dr Webb incorrectly regarded the blood sodium result in Claire as normal. He should have seen the level of 132 mmol/l this as a warning of potential problems. I agree with his later comments that the hyponatraemia was not the cause of the encephalopathy but given the risk in any encephalopathy of a low-sodium, he should at least have requested a repeat sample and advised change of the intravenous fluid volume and content in order to attempt to prevent brain swelling.

a. *Document WS-142/1 Dr Bartholome on page 28 makes the following comment "I have dealt with severely unwell patients throughout the whole period of my paediatric practice. I am therefore unable to provide the data requested. Hyponatraemia is not an uncommon electrolyte abnormality in unwell children for a variety of clinical conditions". Sick children are a highly vulnerable group in a paediatric hospital. She cannot recall how many patients she had treated who had hyponatraemia or their outcome*

b. *WS-138-1. Page 98. Dr Webb. Unable to recall protocol guideline relating to management of a child with reduced level of consciousness or coma. Responding to questioning states that he has seen less than 15 cases over 10 years with a low blood sodium and refers this to his experience in neonatal intensive care.*

250. Comment this is a remarkable statement because low sodium is found after head injury and some children and any encephalopathy.

a. *Document WS-143-1*

b. *On page 112, Dr Steen response to the question relating to previous experience with hyponatraemia as follows. "Maybe dozens per annum on an acute paediatric take over 24 hours a significant number of children will have a serum sodium below 135 without IV fluids being administered. There will be other children with renal, cardiac and surgical problems who also will have low serum sodiums at some time during their admissions"*

251. For background information and context I provide figures here from an analysis of blood sodium levels in my own hospital (a District General Hospital with about half of all child admissions being surgical) over a five-years 2001-2005. From 17,087 samples in 11,056 in-patient children.

Na	***Number***
>= 135 mmol/l	14951
134	792
133	497
132	304
131	200
<=130 > 121	311
<=121	32

252. NURSING DOCUMENTATION

253. The nursing documentation and observation charts, prescription chart for intravenous fluid and completion of the fluid balance chart are up to standard. I accept the difficulty in observing urine output given the reduced conscious level and the learning disability-it appears that Claire was in nappies. Nappies can be weighed if it is thought necessary but on the first evening and in the daytime I would not have expected that step to take place.

254. PRESCRIPTION CHARTS

255. The prescription forms used for writing up the medication for Claire are open to criticism. There does not appear from my copies to be a section which records whether a drug regularly prescribed has been given or when for regularly prescribed medications (or by whom).

256. This failing in the quality of the records system is a design failure and indicates need for a quality improvement approach to the review of medication processes within the hospital. Many hospitals have a fairly active medication or prescribing committee. Many of these had been set up under arrangements of clinical management to agree similar medications for common conditions, often with a view to reducing drug costs but also to improve consistency and in the use of antibiotic to attempt to control drug resistance. I do not know whether the RBHSC had such a committee.

257. One of the advantages which attaches to having a children's hospital is that medication errors and processes for prescribing, dispensing and administering medication can be entirely geared to children. Dose calculations and advisory schedules are often set up and published across the hospital. There has been long-standing recognition of the risk of drug administration errors in children because of the need to adjust the dosage to the age and weight (the age because of differing ways in which the body handles medication at different ages). And the potential for mathematical error to occur in the calculation prior to prescription. Errors also can occur in the dispensing and administration of medication. There are also particular issues in relation to prescribing for children in that any drugs need to be used "off label" or in some instances unlicensed. Midazolam is a good example as the 2005 BNF for Children states that “the injection is not licensed for use in status epilepticus “ yet then proceeds to advise on the dose for the same condition but only as an infusion (dose from 1 microG/kg/min up to 5 microG/kg/min) and does not include advice on bolus usage.

258. As a result of such concerns, a joint publication became available in 2001 *‘Medicines for Children ‘* jointly published by RCPCH & Neonatal and Paediatric Pharmacists group This was replaced in the 2005 by a new publication the British National Formulary for Children. Up to that point the BNF had given specific advice upon medication dosages for children and was widely used. However many hospitals

created their own prescription formulary-especially children's hospitals for example *the Alder Hey Book of Children's Doses 1994.*

259. As part of this process one would expect documentation to be reviewed and to be of high standard. One of the purposes of training in a regional children's centre is to give junior doctors in training and nurses the experience of high standard care for children which they can continue to practice when they move into district hospitals or other areas. This would be a responsibility of governance within the Children's Hospital. Such work would be carried out in teams between nurses, doctors and pharmacists involving anaesthetists and intensivists.

260. I have noted the comment from Miss Chapman when she has reviewed the documentation available on the Ward in respect of the nursing role in the prescriptions. However I found it difficult to see a section-there may be one but it is not apparent from the photocopy-of a section which indicates that of medicine prescribed has been given and by whom for regular medication although it does appear on the forms for individual dose prescription.

261. The dose calculation has been entered into the clinical records by the junior doctor and this is a good standard of recording based upon the Claire 's bodyweight. The regular drug prescription forms in photocopy notes do not seem to have a section to indicate that the dose has been given – if this is so then that is a deficiency. The once only section has a column for signature as given. This was not signed for the Midazolam bolus

262. However this documentation identifies a potential significant overdose of Midazolam and this is addressed in Annex B but detail summarised in Table

263.

Indication	***Bolus Dose (microG) per Kg body weight***	***Source***
Sedation for procedure	<100	Medicines for Children 2001
Sedation in Intensive care	<200	Medicines for Children 2001 BNF for Children 2005
Induction for anaesthesia	<150	Medicines for Children 2001 BNF for Children 2005
Sedation for ventilated child	100	Alder Hey Book Childrens Doses 1994
Status epilepticus	Bolus not recommended or mentioned	Medicines for Children 2001 BNF for Children 2005 Alder Hey Book Childrens Doses 1994 Textbook Paediatrics Forfar & Arneil 1984 & 6th Edition 2003 Paediatric Vade Mecum Insley 1992 Advanced Paediatric Life Support Manuals BMJ 1st Ed 1993, 2nd 1997,3rd 2001.
Status epilepticus	<200	Medicines for Children 2003
Status epilepticus	< 300	Nelson T Book Pediatrics (US) 1999
Claire calculated dose	*500*	*Notes*
Claire prescribed dose	*5000*	*Prescription sheet*

264. **FLUID MANAGEMENT**

265. Volume. Calculation of maintenance total fluid needed for children is based on body weight in a well defined formula (see APLS handbook amongst other sources) as for each 24 h period:

First 10 kg body weight 100ml/kg

Next 10 Kg body weight 50ml/kg

Subsequent kg 20ml/kg

266. For 24 kg body weight as was the case in Claire, this adds up to 1580 ml per 24 hours total (oral and IV) that is 66ml/hour.

267. Over the 8 hours overnight 21-22 October 1996, Claire received 536 ml of 0.18% saline in 4 % dextrose that is 67ml/hour.

268. On the 22 October between 0800 and 2200h Claire received total of 960 ml (68ml/hour) made up as 943ml of maintenance 0.18% saline plus 10.9 ml fluid for the Midazolam infusion and 60 ml for the acyclovir. Phenytoin is also recorded on the fluid chart but it is not clear if this was in additional fluid. The fluid balance chart is not clear on this last point.

269. Between 2200 h 22 Oct and 0200 23 October Claire received a total of 247.6 ml (127 ml of 0.18% plus 10.6ml as Midazolam infusion plus 110 ml for Phenytoin /Acyclovir) that is 62 ml per hour. Thus the intended reduction of IV fluid volume advised at 23:30 to 2/3 requirement intended to be 41 ml/ hour did not happen. And there will have been additional IV fluid – probably 62ml/hour but not recorded- over 02:00 to 02:30 when the arrest occurred.

270. LABORATORY REPORTS FORMS

271. There is a deficiency in the quality of the blood laboratory reports. They are poorly designed. They have no printout of the time of receipt and time of process of sample. Some printed laboratory results are missing from the records.

272. The laboratory report forms contain no section to identify the time at which the laboratory received and processed the specimen. This leads to difficulties in determining sequences of events and results. I have commented on this above. I believe one of the U&E results noted in PICU was from a blood gas analyser but such results are not to be relied upon. It would be helpful to know was what the on-call arrangements for biochemistry out of hours. Was it necessary to call a technician in to the hospital ,was the sample processed in RBHSC or in the main lab in Royal Hospital and if latter how far did it have to travel ?

273. ACCESS TO IMAGING

274. Claire had a CT scan of brain carried out after admission to PICU. This entailed transfer out of the RBHSC to the Royal using an ambulance. The lack of on-site imaging in CT (it was only in 2002 that an on-site scanner was available) is striking. Emergency and urgent CT scans are mostly required to support accident and emergency and neurosurgery but also paediatric neurology and PICU. Off-site scanning is a risk because of the need to move a child across between hospitals when they are most ill.

CHAPTER [3]

- **Governance matters arising following Claire's death in October 1996.**
- **Governance matters arising following the television programme in 2004.**
- **Relevance of issues in Claire's case to other children's deaths associated with Hyponatraemia.**

Chronology Table of events after death 1996-2008 is placed at the end of this Chapter

275. GOVERNANCE MATTERS ARISING FOLLOWING CLAIRE'S DEATH IN OCTOBER 1996.

276. Background

277. Claire had an acute encephalopathy of uncertain origin from which she died after admission to RBHSC in October 1996. The clinical diagnosis made was of brain oedema secondary to status epilepticus. The brain autopsy was reported in February 1997 to show features of cerebral oedema with neuronal migration defect and a low-grade sub-acute meningoencephalitis. The report did not rule out a metabolic cause. (Following the 2005 inquest, cause of death was revised to Cerebral oedema with meningoencephalitis, hyponatraemia due to excess ADH production and status epilepticus as contributory factors).(Dr Harding 's neuropathology review of slides in 2007 found no features consistent with meningoencephalitis or epilepsy.).

278. **COMMENTS**

279. The conclusion drawn by the clinicians after death confirmed by the later pathological assessment was that Claire had suffered a meningoencephalitis. The complicating factor of the low sodium was seen simply as that and not the primary cause of death although a contribution was considered of the hyponatraemia to the brain oedema. In the circumstances given the clinical and autopsy conclusion, the sodium problem should have been highlighted as an issue with the parents at the time. And the clinicians should have appreciated that the low sodium could have been an iatrogenic complication given the existing knowledge in 1996 about SIADH in acute neurological conditions. It is not evident why a brain only autopsy was requested-the records are incomplete.

280. However following death it is not clear on what grounds Doctors Steen and Webb came to the conclusion that the death was secondary to status epilepticus? Dr Steen and Dr Webb were both aware of the low sodium. Dr Steen noted this on the autopsy request form. On what grounds did they not consider that it had a greater contribution to Claire's death and given the inquest information relating to Adam strain did they not consider that intravenous fluids may have contributed to the

hyponatraemia.? The history given by Dr Steen in her autopsy request form before the autopsy was carried out was incorrect. She states that Claire was well until 72 hours before admission and that she had a few loose stools and 24 hours prior to admission started to vomit. This history is not consistent with the history obtained on admission. In the request form Dr Steen reports that Claire had seizures from six months to 4 years of age. A clinical diagnosis recorded on the request form states "cerebral oedema secondary to status epilepticus query underlying encephalitis" and in the clinical problems list she includes inappropriate ADH secretion and viral encephalitis. She indicated she will not attend the review session at 1:45 PM on the day of the autopsy. It is not clear if Dr Steen spoke to Dr Herron before or after this autopsy. When completing her autopsy request form Dr Steen did not mention the use of Midazolam (although she did record the use of rectal diazepam, intravenous phenytoin, intravenous valproate, acyclovir and cefotaxime).

281. Referral To Coroner and Death Certification

282. The clinicians decided not to refer Claire's death to the Coroner. A hospital autopsy limited to the brain was arranged.

283. It is arguable that referral to the Coroner should have been made following Claire's death. There was a working diagnoses of cerebral oedema secondary to status epilepticus but there no clearly established diagnosis at this point. Later autopsy reported findings of meningoencephalitis with the cerebral oedema but subsequent review of the histology has questioned this. The diagnosis can be challenged on clinical grounds in retrospect and the movements which were observed could have been induced from brain swelling or pathology by generating seizures or alternatively inducing movements from brainstem irritation which have simulated seizures. The absence of investigation with EEG is therefore a major shortcoming in her management.

284. Death in epilepsy in children is uncommon. In a national audit including children with reported deaths between September 1999 and August 2000, there were 81deaths under 18 reported nationally in England to the National Sentinel Audit of Deaths in Epilepsy which was sponsored by NICE and the 4 health departments (CMO) of England,Scotland Northern Ireland and Wales and published in 2002.. (Of note here is that the cause of death on certificate was inadequately stated in 41% of post-mortem reports and in 87% of all deaths adults and children, the PM was considered inadequate). Of the 81 deaths in children, 22 were included in the detailed audit. 15 of the 22 children had learning disability. None of the children were seizure free in the year prior to their deaths (most had poorly controlled epilepsy). This audit was not available at the time but is referred to here to emphasise the rarity of death in children and that when death did occur it is usually in children with poor control. When children die in status epilepticus this is nearly always the tonic / clonic variety. Claire did not show this form of epilepsy in the acute illness. She was not a likely candidate for non-convulsive epileptic status.

285. The categories under which, arguably, Claire's death could have been reported to the Coroner were: (from the list provided in the report for the Inquiry from Bridget Dolan)

a. “The death may be related to a medical procedure or treatment whether invasive or not"

b. "The death may be due to a lack of medical care"

c. "There are any other unusual or disturbing features to the case"

286. **Comment** the extent to which the clinical team were aware that the death might be related to the treatment seems to be very limited. There is no real evidence of reflection upon the management of the case by the clinicians. Claire’s death was listed amongst 4 deaths considered at the audit meeting in November 1996. The record of that meeting is blank in respect of the deaths in contrast with moderate detail about discussions of case note review and administrative matters which would have taken up a substantial portion of the allocated time for that meeting. A detailed scrutiny of Claire’s notes should have generated discussion about the lack of referral to a consultant at 23:00 hours on 22 October, consideration given to the low sodium and its potential linkage to the fluids which were used and identified the potential overdose of Midazolam.

287. There should have been in place a more formal process in RBHSC for discussion of children's deaths either in these meetings or in a separate one. Such meetings to review deaths would be in my view the responsibility of the directorate within the context of adverse events. I note that deaths were reported to the audit coordinator and it is not clear what happened with that process nor whether the meetings were organised and coordinated by the audit coordinator. Given the issues relating to the death of Adam Strain and the implications of its investigation and inquest, one would have expected RBHSC to have in place a regular death review. It would help to know how many deaths occurred each year in RBHSC separated by specialty.

288. I understand that it was evident in August 1996 from the management of Adam Strain that fluid volume and type was identified as significant factors and were subject to a public statement a couple of months before Claire’s admission. It is surprising that RBHSC did not institute a review of intravenous fluid management across the Trust because IV fluid management occurs in many areas and communication across the Trust and this in my view, should have taken place. Failing that process, the paediatric medical consultants and junior staff may not have been specifically alerted to the hyponatraemia issue in 1996.

289. Could Claire be considered to have an unexpected death? She certainly had a severe illness with an acute encephalopathy which has a significant mortality. She had underlying epilepsy (although this was well controlled and indeed off therapy) and she had severe learning disability. There is (an often misguided) impression that children with severe learning disability have a life limiting condition with an increased risk of death. Certainly there is an increased incidence of complications with illness both in detection and its severity in children with severe learning disability and to that extent deaths are more common amongst children with this disability. These factors may have impacted upon the thinking process in respect of reporting to the Coroner at that time. and also the pathologist's later report of low-grade meningoencephalitis is likely to confirm their conclusion that this death was of natural causes and thereby support the clinicians that there had been no need to make a referral to the Coroner. It was judged by the one consultant who saw her before her respiratory arrest-a paediatric neurologist-that the most likely diagnosis was post ictal encephalopathy and non-convulsive status epilepticus and this was the clinical conclusion that both he and Dr Steen came to during the admission to the paediatric intensive care unit prior to withdrawal of ventilatory support. A referral for autopsy was made, consent was obtained for hospital autopsy with the implicit decision not to refer to the Coroner and this was a limited autopsy but there is no indication from the records why this limitation was imposed. In retrospect, the basis upon which the diagnosis of status epilepticus was made is open to criticism on a number of counts. There had been a rapid deterioration and the clinicians at the time had recorded causes as cerebral oedema; status epilepticus ; inappropriate ADH secretion ; viral encephalitis. Deaths from epileptic status are not common.

290. The Autopsy

291. Following an autopsy, a period of time is required for processing the brain histology-and thus the report of the autopsy would follow after a few weeks. In the event the autopsy report dated 11.2.1997 by Dr Heron states

292. *"in summary the features here are those of cerebral oedema with neuronal migration defect and a low-grade subacute meningoencephalitis. No other discrete lesion has been identified to explain epileptic seizures. The reaction in the meninges and cortex is suggestive of a viral aetiology, although some viral titres were negative during life and on post-mortem CSF. With the clinical history of diarrhoea and vomiting, this is a possibility although metabolic cause cannot be entirely excluded. As this was a brain only autopsy, it is not possible to comment on other systemic pathology in the general organs. No other structural lesion in the brain like corpus callosum or other malformations were identified."*

293. It is remarkable that the pathologist made no reference to the low sodium given that he had access to the notes and to the autopsy request from completed by Dr Steen. In both of these Hyponatraemia was noted. Review of the histology by another paediatric neuropathologist in 2007 has failed to confirm the findings suggestive of meningoencephalitis or those consistent with epilepsy raising

questions about quality management in the histological reporting. It is not evident whether double reporting was being carried out on some cases.

294. There is no record that any discussion took place between the consultant responsible Dr Steen (or Dr Webb) with the pathologist prior to or subsequent to the report. Good practice supports such a discussion particularly when the death has occurred during care as a sudden deterioration. Nor is there a record or evidence that a neuropathological conference took place with Dr Webb which discussed Claire's death (this activity formed part of his job description and thus be subject to job plan review especially after the introduction of consultant appraisals in 2000).

295. The minutes of the Paediatric Clinical Audit Meeting 8th November 1996 (see Chronology Table below for detail)

296. It has been stated that Claire together with three other child deaths was discussed at the Royal Group Hospitals monthly paediatric directorate clinical audit meeting on 8/11/1996. (308-002-021. Reference letters from DLS dated 24/11/2010 and 10/1/2011.). There appears to be no contemporary record to confirm this.

297. **Comment** There is no record here of the cause of the deaths presented in the meeting nor the issues related to them that were discussed in the meeting. The register of attendance was kept separately and thus it is not evident who was present. Dr Taylor, consultant in paediatric intensive care does not recall attending; Dr Steen, Dr Webb and Dr Sands as a minimum should have been present. One point of the case notes review that one of the points being sought was on patients discharged with or without senior involvement. It would help to know what was defined as a senior involvement?

298. It is therefore not evident what aspects of the care were reviewed or whether any points were drawn from this for further action. The record of the meeting is therefore is not helpful. The main focus of the meeting appears to be on the process of record keeping and quality thereof. This is certainly an element of clinical audit and one recommended at the time but one might have expected some clinical or other issues to have arisen in the audit meeting. It would be expected that the death would be discussed at length but the meeting agenda was likely to be time consuming. Failure to do so could explain why the role of the low sodium was simply accepted as a complication rather than a significant factor, the failure of senior review in the evening before death should have been highlighted and the dose error identified with a view to reviewing safety processes and the lack of review by the consultant on the morning after admission been subject to comment and action.

299. In the interests of anonymity, the recording of detailed patient management in audits at that time was not advised practice. Guidance on expected confidentiality of such meetings was included in the second report on Medical Audit from the Royal College of Physicians of London in 1993 and was endorsed by the Chief Medical Officer (see extract provided in governance section). Consequently the lack of

detailed identifiable clinical information is acceptable. However the clinical management issues related to the death should have been recorded.

300. It would be useful to determine if there was a medical audit committee or structure within the Trust and /or within RBHSC -this is not evident who was the clinical lead responsible. (see Chapter on Governance).

301. It is not evident what process there was of reporting and collating childhood deaths in a summary form either annually or at any other intervals. The role and responsibilities of the audit coordinator to whom all deaths were reported should be clarified. There is no evidence available to show the role of the clinical management system in review of childhood deaths within RBHSC. In her statements to the Coroner in Dr Steen reports that:

302. WS-WS-143-1. Page 113. Queries arising out of Dr Steen's Deposition to Coroner . Dr Steen reported *"The deaths of all children were reported to the audit coordinator and the charts once available were given to the audit coordinator secretary. The coordinator then scheduled in a date for the case to be discussed at the mortality meeting at a time that ensured all relevant specialties could attend and any outstanding results e.g. post-mortem results were available. There were no records kept on the discussion but any learning points would have been disseminated to the relevant professionals within RBHSC* " ……. *"also that now a note is made in the chart that the case has been presented and any issues around care are recorded in minutes."* And *"And that if learning is of importance to teams outside RBHSC this would be forwarded to the Medical Directors office for action."* Dr Steen can recall no such meeting held for Claire

303. **Post death communications with parents 1996/1997**

304. From 308-002-021 At a meeting with parents on the Ward on 11 November at 3:30 PM Dr Sands handwriting in the clinical notes records that *"spoke at length with Mr and Mrs Roberts earlier today. They are naturally still trying to come to terms with what happened to Claire. I talked through events before her death and also talked generally with them. They are naturally anxious to discuss the PM results with someone. I will pass this on to Dr Steen ASAP."*

305. On 18 November 1996 Dr Steen wrote to Mr and Mrs Roberts informing them that she would be happy to meet them and discuss any queries they might have. She also informed that the post-mortem results would not be available until after Christmas and warned them that they may not enable her to answer all their queries. 090-007-006 on 308-002-021 core bundle.

306. No records were made on Allen Ward about what parents were told by the doctors about Claire's illness or its severity during the acute illness. However in UK

this is still commonly a deficiency after a recent audit to which I have referred from 2010 carried out by the Royal College of Paediatrics & Child Health, this is still a recognised deficiency in management of children with reduced level of consciousness. However from the statements made by the parents and their actions in leaving Claire it does appear that they were not alerted to the seriousness of her illness.

307. The bereavement supporting communication with parents after the death is up to standard for the time but ideally there should have been more recording in the notes.

308. On the other hand there are deficiencies in the recording and information sharing of clinical issues including the reason for limiting the autopsy to the brain (which has lead to loss of information which could have shed more light on cause the death).

309. The parents were not informed or alerted to the role of blood sodium in contributing to the brain oedema. Given the fact that hyponatraemia had been identified in Adam Strain in the same hospital and publicity given to this a few months before admission, and the subsequent action taken by the Trust in producing a public statement which includes reference to publications which cover more than the surgical condition from which Adam suffered, it is a matter of remark that more attention had not been paid to the role of low sodium in causation of other deaths or in alerting clinical staff to its importance.

310. Both Dr Steen and Dr Webb then saw parents at some time after the autopsy but the date is not recorded in the notes. Reference is made to the meeting in a letter dated 21st of March 1997 from Dr Webb to parents giving the results of the post-mortem and a letter from Dr Steen to the GP on 5 March 1997 saying that she and Dr Webb have seen parents and discussed the post-mortem findings with them.

a. *Letter from Dr Steen 090-002-002 5/3/1997 to GP Dr McMillin*

b. *" changes in keeping with viral encephalitis meningitis "*

c. *"Dr Webb and myself have since seen Claire's parents and discussed the post-mortem findings with them."*

d. *090-001-001. Date 21/3/1997.*

e. *Letter from Dr Webb reporting to parents the post-mortem findings which were "swelling of the brain of evidence of a developmental brain abnormality (neuronal migration defect) and a low-grade infection (meningoencephalitis……."*

311. **Comment:** One would expect some more documentation in the records about this meeting or in communication such as a letter to parents but this is not incorporated in the notes. There was no mention of Hyponatraemia. It is likely to have been seen by the clinicians as a compounding factor. There appears however

to be a lack of appreciation that the management had not been in keeping with the guidance at the time on management of acute encephalopathy.

312. Adverse event reporting Child Death

313. In the circumstances outlined above it might have been considered adequate for aspects of clinical management in Claire not to have been raised as a particular issue because she had a condition with a significant mortality. Nevertheless the low sodium should have been a point to discuss had there been a case presentation say at a grand round or clinical meeting and reflections made upon whether there should have been any change in the therapy. Had the case been presented the fluid and sodium issues could have received attention as well as the potential Midazolam dose error By the mid-1990s one would have expected a significant event like a death to have received more attention. It may be that death is not so unusual an event in RBHSC. Nevertheless an unexpected death which I would grade this one as should have received more attention. Data on the numbers of deaths each year should be obtained.

314. There is no evidence that the junior medical staff together with nursing and senior staff involved had a meeting to talk through issues arising from the illness and death for their professional and personal development. DLS in response to an Inquiry letter 21/10/2010 reported that that the only event where Claire 's death would have been discussed was the paediatric directorate audit meeting. Audit notes have not been found. Deaths within the previous month would be discussed. And, there were no investigations into Claire 's death before December 2004.

315. OTHER RISK MANAGEMENT ISSUES

316. It is not possible from the documentation to discern the medical management activities taking place in 1996 and its impact on practice in RBHSC. There was a structure in place and documentation should be available (minutes etc). This limits my ability to complete parts of the brief.

317. Medicines Management : It would help to know what the content was of the minutes and agendas of the managerial/ directorate meetings held over the years before and after 1996 and in particular whether there was any process in hand for reviewing prescribing (some kind of equivalent of medicines committee).

318. **Diagnostic and other support services issues .** It would be relevant to determine what meetings were held from time to time with the pathology/biochemistry/haematology specialists. What issues arose during these discussions e.g. imaging and particularly the CT scanner. Or reviews with pathology departments (biochemistry, haematology (note Claire’s admission report did not contain the makeup of the high white count by reporting % neutrophils , lymphocytes etc.). Was a list of complaints made and how and at what level were they handled?

Who was responsible for dealing with medical device agency or drug alerts. What was the adverse incident reporting and recording and action plans.

319. The CT scan was not on the same site as RBHSC. It is a deficiency of the hospital arrangements that in the mid-1990s a CT scan was not on site. It would help to know whether this deficiency had been documented by clinicians to management through the clinical directorate or medical advisory processes and there may be minutes which relate to this. I have noted that a CT scan is now on site but that it was only from 2002 that this became the case despite the fact that paediatric intensive care was provided in RBHSC and a regional paediatric neurology service which dealt with acute neurological problems. For a major regional children's centre this is a late addition to the range of supporting imaging facilities.

320. **Medical Staffing I**n particular in relation to out of hours medical resident staffing and the workload, It would be of interest to know whether the out of hours workload of the on-call medical registrar out of hours had been addressed or discussed within the management structure either through the medical advisory process or through the more formal clinical directorate arrangement. There is some evidence available to show that a paediatric Department is likely to generate a significant emergency workload out of hours in comparison with adult practice even in a district general hospital. (I can provide this evidence if requested from the survey I set up through the Department of Health in the early 2000s when out of hours hospital teams were being considered for adult cover). What processes were in hand for consultant job plan reviews and patterns of work.

321. Decision support for junior medical staff. It would be relevant to determine what were the knowledge sources which were expected to be used by junior staff and what educational programmes were in place at the time. I address Guidelines below**.** It is not evident what sources of decision support were available in 1996 in the paediatric practice in the Royal Belfast Hospital for Sick Children. Many units around the country have used the Birmingham Children's Hospital Vade Mecum and in addition had textbooks on the Ward most including the textbook I have made reference to : Forfar & Arneil.

322. **General Risk Management and Clinical Adverse Event Handling.**

323. Significant clinical incidents and adverse outcomes should be reported within a Trust structure. The first stage in any such process however is recognition of the event in the first place. In respect of the management of Claire this recognition does not appear to have happened. It appears that in the late 1990s, there was a process in hand because reference is made in the Royal Hospital Trust's Annual Health And Safety report to bringing together the two processes of health and safety and clinical risk. The reports are quite detailed about staff and patient injuries and accidents but clinical incidents are reported only briefly in terms of numbers.

324. It is likely that there is a separate document on the numbers of and clinical make up of clinical incidents which were reported. A breakdown of these by age and by the RBHSC could prove helpful.

325. One way of reducing clinical risk is the sharing of common experience in productive discussions which lead to change in practice. There are a number of ways in which clinicians are engaged. These include clinical presentations of cases of interest or series of cases within an organisation at clinical departmental meetings or postgraduate meetings or teaching sessions including journal clubs-or attention given to an interesting publication. One model is a grand round both within a specialty involving a range of consultants within it and between specialties such as paediatrics, surgery, anaesthesia, pathology, radiology etc. Within the hospital and within a region or nationally postgraduate meetings are attended organised by clinicians. Clinicians also come together in reviewing and developing questions for postgraduate examinations and when examining for postgraduate diplomas. It is the responsibility of individual clinicians to be involved in continuing medical education a term which was changed into continuing professional development in the late 90s and later to be involved in annual appraisal in which there would be a personal review of engagement in these activities to ensure our that these were being undertaken. This is not evident from the papers that I have seen what activities were undertaken by consultant staff in 1996. However it would be the responsibility of the employer to ensure that clinicians were involved in these activities and one method is through the clinical directorate.

326. A further form of identification of clinical risk is through clinical safety alerts either provided by the Department of Health or its agencies including the Medicines Control Agency/MHRA, NPSA and in the issuing of guidance through for example NICE. I have listed a range of these in the Governance Chapter 4 and Annex D but it is the individual personal responsibility of clinicians to be aware of these but also of the employing Trust to ensure that these matters are brought to the attention of clinicians and that any recommended changes are put in place.

327. Communication in relation to safety is conducted to a variety of mechanisms as these detailed above. In Northern Ireland following the events in 2001 an alerting process was put in place about the use of intravenous fluid and low sodium fluid and issued in March 2002. I have noted that on the circulation lists there is no reference made to the neurosurgical services which care for children either for acute head injury or for acute and planned neurosurgery. It would be helpful to know whether the fluid issues relating to intravenous care have been implemented in the neurosurgical unit given the risk of syndrome of inappropriate ADH secretion related to neurological problems.

328. It is noteworthy that following the guidance issued by DHSSPS(NI) it was a further 20 months or so before the Royal College of Paediatrics/Royal College of Anaesthetists produced a warning about hyponatraemia. It was 5 years before the NPSA issued a warning. What measures were taken by DHSSPS(NI) to share the

2002 guidance with the Chief medical officers of England and Scotland or with the Royal Colleges? Has there been any survey to determine the speed and extent of implementation of the guidance within the province. Dr Taylor in September 2001 sent a yellow card to MCA /MHRA about his concern about 1/5 normal saline. It should be possible to determine what other such alerts were received by MCA at that time.

329. **Medication Guidance** One of the advantages which attaches to having a Children's Hospital is that reduction in medication errors and processes for prescribing, dispensing and administering medication can be expected as services are centred only on children. Dose calculations and advisory schedules are often set up and published across the hospital. There has been long-standing recognition of the risk of drug administration errors in children because of the need to adjust the dosage to the age and weight (the age because of differing ways in which the body handles medication at different ages). And the potential for mathematical error to occur in the calculation prior to prescription. Errors also can occur in the dispensing and administration of medication. There are also particular issues in relation to prescribing for children in that many drugs need to be used "off label" or in some instances unlicensed. Midazolam is a good example as the 2005 BNF for Children states that “the injection is not licensed for use in status epilepticus “ yet then proceeds to provide advice on the dose for the same condition but only as an infusion (dose from 1 microG/kg/min up to 5 microG/kg/min) and does not include advice on bolus usage.

330. It is thus important to know what the RBHSC *Paediatric Prescriber* in 1996 contained and if possible a copy made available. Also given the knowledge of risk of medication errors in children, one would expect reasonably robust checking mechanisms to be in place. For example following the Grantham (Allitt) childhood deaths and the production of the Clothier report (1994) it became common practice that all medications administered to children on wards would be cross checked by two nurses. A particular vulnerability however relates to when medication is being given by a doctor. Intravenous medication is usually given by the doctor and is made up by him/her. Contemporary practice (which was often not recorded in protocols in 1996 and subsequently) is that this drawing up of dosage as well as the calculation of dosage according to body weight would be cross checked with the nurse. This offers the opportunity for a nurse to challenge if the dosage appears excessive. In respect of the Midazolam bolus dose, it is not clearly evident whether this was given (but equally not evident that it was not given). If it was not given was this because a nurse challenged the dosage? If so that should have been recorded both in the medical and nursing records and raised as a serious potential clinical adverse event. Dr Webb records that the bolus had been given and presumably came to this conclusion from review of the prescription. The dose written up on prescription was a significant overdose with significant risk of respiratory depression. The failure to note this and the failure to identify this later in the clinical audit death review and later in

2004 is striking. Furthermore the consultants who were asked to review the case of Claire by the Coroner did not comment on it.

331. **Clinical Audit** Clinical audit takes place within the overall clinical governance of a Trust. It is also a professional requirement by clinicians to be involved as advised by the GMC, NHS and by their professional bodies who provide specific advice relating to their specialty. It was well-established by 1996. It remains to be seen to what extent and how RBHSC coordinated and managed this process because there is a responsibility for Trust management to ensure that audit is in place and that there are processes set up by which issues which arise of safety and quality or of resource deficiencies identified can be addressed. (Department of Health, NHS, King's fund, publications, RCPCH and other Medical Royal Colleges-Anaesthetics, Radiology, Surgeons, Pathologists). In the main report I provide a review of the chronology of audit development.

332. Also in such a unit I would have expected to see guidance upon prescribing. It appears there is a document referred to in the Paediatric Medical Guidelines First Edition referred to as the *Paediatric Prescriber*.

333. It would help to see if the *Paediatric Prescriber* advises on intravenous fluid use. If not it would help to know what documentation was relied upon during routine practice for selection of fluid and calculation of requirement. The latter was done according to the usual rules and the selection of fluid *on admission* using 0.18% saline for maintenance was acceptable as it was only from the mid-2000s that reduction or omission of this usage became common practice.

334. GUIDELINES/PROTOCOLS

335. There were no guidelines on the Ward in 1996 for management of common medical conditions although they were first produced in May 1997. In this respect the RBHSC was out of step and timing with introduction of guidelines in the NHS in England and is particularly remarkable in that the hospital is a teaching centre for paediatricians, nurses and other specialists in training. It would be helpful to know at what point the process of drawing up guidelines was started and in the meantime what knowledge sources were used by the junior doctors until they became available.

336. The use and availability of guidelines was at the time evolving but from the early 1990s I would have expected to see these on Ward particularly in a Tertiary teaching centre. Given the focus in the 1990s on clinical audit with its implicit requirement for standards against which to judge practice, it is noteworthy and a shortcoming that a range of guidance was not available in print for the staff from the early 1990s.. By the mid-90s it would be expected that a Ward would have a range of protocols/guidelines applicable to common conditions. The document produced in 1997 appears to have been the first hospital wide guidance available for the medical junior staff based upon consensus views of the hospital clinicians. That basis is reasonable for the time. The 3rd version 2003 refers to four ' evidence based'

guidelines, but it should be noted that a level of evidence taken in developing the guidance is in many (if not the majority) of the statements based on clinical opinion and experience and the reading of clinicians – that is, a form of consensus which the guideline process tried to structure using Delphi processes. Thus use of clinical opinion is and was acceptable practice.

337. Guidelines were produced in RBHSC in the early part of 1997 and it was possible that this process was already in hand in the October preceding that when Claire was admitted. The guidelines produced in 1997 are fairly comprehensive but not totally so for example is no section on the management of status epilepsy nor in the third edition. There is no section on the management of acute encephalopathy. Dr Bartholome was involved as one of the contributors to these guidelines.

338. The latest edition which I have seen (3rd) available from 2003 shows a deficiency of paediatric neurology input in respect of acute presentations. For example there is no protocol for management of acute seizure/status epilepsy. The omission of management of status epilepticus is difficult to understand as there had been guidance offered in publications which changed the usual approach (e.g. APLS) and it is not an uncommon emergency.

339. By 1996 most general paediatric units had some Ward guidelines/protocols in place-usually compiled in a folder or less commonly printed as a hospital compendium. This would be particularly expected in a regional Tertiary specialist centre housing a range of specialties associated with the university teaching hospital department and which trained paediatricians. This would be required both for clinical care standards and educational purposes. The absence of these in 1997 thus constitutes a major shortcoming in standards of clinical governance.

340. There was no guidance on the frequency for repeat sampling of blood urea and electrolytes for children on intravenous fluids. In this respect the hospital was not out of step with the majority of hospitals even in late 2000s. (see (*Armon K et al Arch Dis Child 2008;93:285-287)*

341. By 1996 a regional centre housing specialty paediatric neurology could be expected to have a protocol in place for the management of acute encephalopathy including advice not to use 1/5th Normal Saline IV. This was still not present in 2011 and represents a major deficiency in clinical governance. Such a protocol based upon Text Books available at the time in 1996 as well as clinical expertise would have included cautions about the use of low sodium fluid. I have referred to the widely used British Textbook Of Paediatrics by Forfar and Arneil as well as to a guideline/protocol available on my DGH paediatric unit (Pinderfields Hospital) in the mid-90s both of which advise against the use of low sodium fluid intravenously in acute encephalopathy.

342. By 1996, paediatric clinical audit was well-established and I make reference in the Givernance Chapter to the national guidance available on this. It is evident that in RBHSC , regular paediatric medical audit meetings were being held. It is not

evident however what the content of these were at the time although good practice dictates an annual listing of topics covered and issues raised. This practice also relates to the absence of guidelines/protocols because in order properly to audit the process of care, it is necessary to measure or record actual practice with what had been the agreed standard in a hospital. Thus the absence of guidelines leads to less good quality and substandard clinical audit. This again constitutes shortcomings in the quality of clinical governance at that time within RBHSC and indeed within the Trust generally. The clinical management structure was in place and documentation should be available on the audit topics covered and issues which arose from adverse events or significant clinical events such as a childhood death particularly one which could be regarded as "unexpected" or avoidable. The scale and nature of medication errors forms part of this process.

343. RBHSC Guidelines – some further detailed comments

344. Paediatric Medical Guidelines First edition May 1997

345. Compiled by Dr McGovern senior registrar community paediatrics and Dr Moira Stewart consultant paediatrician and senior lecturer in the Department of Child health and lists the contributors. Based upon consensus on the broader details of management. Points out that they will be changed and updated in time.

> *"These guidelines have been compiled to help junior medical staff of the Royal Belfast Hospital for sick children with the management of common paediatric medical conditions. They reflect the current thinking of many medical consultants. Details of drugs mentioned in this Handbook can be found in the paediatric prescriber. It is hoped that the Paediatric Prescriber and the paediatric medical guidelines can be used as sister handbooks."……*
>
> *"Consultation with an experienced colleague remains a cardinal rule when managing a sick child"*

346. The First Edition runs to some 142 pages. There is an extensive range of conditions in these guidelines starting with some general problems and then broken into cardiology, dermatology, endocrine and metabolic, haematology, infectious disease, neurology, renal and respiratory. The neurology contains sections on ataxia, headache, hyponatraemia and muscle weakness, macrocephaly, microcephaly, migraine. But no section on acute encephalopathy and no links or references to other sources of guideline or evidence references are included. Gives guidance upon the difference between Coroner 's autopsy and hospital autopsy and lists when to refer to Coroner . "When the patient has been under the care of the paediatric neurologists or neurosurgeons, the autopsy whether Coroner s or hospital is generally carried out by the neuropathologist"

347. In the management of diarrhoea which is on pages 84-87, there is guidance given on fluid management. This is spilt into guidance for patients with normal serum sodium, with low serum sodium and with hypernatraemic dehydration.

For those patients with low serum sodium :

"treat shock if present. Then use 0.45 % saline +2.5% dextrose as the intravenous fluid over 24 hours."

348. In the Third edition 2003, now *Managing Medical Problems in Children* compiled by the same editors points out that each topic has been reviewed by one or more medical consultants in RBHSC and its contents reflect their current medical practice. It also lists a four evidence based references and states that the RCPCH publication *Medicines For Children* should be consulted for details of drugs mentioned in the handbook.

349. There is a separate section on fluids page 7 and choice of maintenance fluid is now

a. *" 0.45% saline and 2.5% dextrose is usually suitable but added KCl is often necessary." [page 8]*

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350. GOVERNANCE MATTERS ARISING FOLLOWING CLAIRE'S DEATH IN OCTOBER 1996. – see relevant chronology in Table below

351. Following concerns raised by the parents after the television programme, Dr McBride, medical director of the Royal Trust requested an opinion from Prof Young consultant in clinical biochemistry which he provided verbally after scrutiny of the case notes,. This was appropriate for a quick review to determine whether the low sodium level was significant in Claire's illness but in my view, a written report should have been obtained given both the publicity and the circumstances of Claire's death in respect of hyponatraemia, from an independent consultant paediatric neurologist or a consultant paediatrician with expertise in management of acute encephalopathy.

352. That report should have been available to the meeting held with parents and ideally the independent expert should have been present at the meeting. Instead as well as being attended by Dr Steen and Dr Sands, Prof Young attended and stated that he was offering an independent view. Ms Rooney Clinical Psychologist attended to report back to parents.

353. Incorrect information given to parents

354. From the notes of the meeting incorrect information was given to the parents as follows.

355. *"Treatment today differs from that used eight years ago".*

356. This is not correct in that the treatment of acute encephalopathy in terms of fluid management and in particular in selection of the sodium content of the fluid did not differ in 2004 from 1996.

357. "The doctor gave her standard fluid intravenously-which is the textbook recommendation".

358. I have provided the information in relation to fluid management in acute encephalopathy. The textbook recommendation is not to use 0.18% saline. Consequently the statement is incorrect.

359. *"… With the sodium level at 121, the doctor had responded appropriately."*

360. This is not correct. The correct action was to change the sodium level of the intravenous fluid and to reduce the rate of infusion. Neither was done.

361. Prof Young confirmed that Claire's sodium level had not been monitored between arriving at the hospital and 24 hours later but stated this was not unusual at the time. This is also incorrect in the sense that it is usual to repeat blood sample if one has been found abnormal generally but in a child with persistent reduction of the level of consciousness, it was essential to monitor the blood sodium level the

following morning or at latest when the paediatric neurologist reviewed when further investigations should have been carried out.

362. It was stated that Claire's CNS observations had remained stable over a period of time and no clinical signs of further deterioration were noted. This is not correct, the GCS reduced over the evening and had done so by the time the blood sodium level was available

363. In a letter from Ms Rooney responding on behalf of the Trust to parents further requests after the meeting, (dated 12/1/2005) further incorrect statements were made as follows

364. The letter reiterated that treatment has now changed (it has not for acute encephalopathy in respect of fluid volume and sodium content).

365. Also that Claire had been seen by a doctor at 9 PM for a seizure based upon the nurse records. I have not been able to find this record.

366. Parents were informed :

367. *"Practice now would involve approximately six-hour checks and the use of the CT scan. However, in 1996, before there was such extensive knowledge about hyponatraemia, it would be normal practice to monitor sodium level every 24 hours"…… "The treatment has now changed and Claire would be given small amounts of different types of fluid following admission".*

368. There is an implication here that CT scanning was not indicated in 1996 in management of Claire on the second admission day. Guidance and practice at the time was to include CT scanning in initial evaluation and management of acute encephalopathy

369. Incorrect information given to Coroner

370. Mr Walby from Litigation Management Office Royal Hospitals NHS Trust wrote to the Coroner on 16th December 2004. In this he stated that Claire

" had a history of epileptic seizures since age 10 months and had learning disability…..".

And

" [Claire] developed hyponatraemia and consideration was given to whether this was from fluid overload with low sodium fluids or a stress induced antidiuretic hormone effect and her fluid management was altered…"

371. **Comment :** This has the implication that Claire had continuing epilepsy and this was not the case. In 1996 there is no record that consideration was given to fluid overload with low sodium fluid. Her fluid management was not altered.There was no mention of the Midazolam potential (or actual) overdose.

372. Had an independent report been available from a paediatric neurologist, it is likely that these information errors would not have been made and, also likely that after review of the case records, the contribution of hyponatraemia to the progression of Claire's illness would have been judged to be greater and, it is likely also that the dosage and prescription error relating to midazolam bolus would have been highlighted(but not certain –see comments in headline issues). Furthermore other aspects of the clinical management such as I have detailed would have been revealed. The Coroner and the parents would then have been appropriately informed. The reliance upon an adult physician on the part of the medical director to review the clinical management and report to parents relating to acute encephalopathy in paediatric practice was not in keeping with optimal clinical governance practice.

373. The senior clinical director, responsible for clinical governance within RBHSC was not present at that meeting. He/she should have been as part of general governance management. The medical director should also have reviewed the aspects of the death within the context of clinical audit and clinical reviews of children's deaths within hospital. There is no indication from the documentation that these steps were taken.

374. RELEVANCE OF ISSUES IN CLAIRE'S CASE TO OTHER CHILDREN'S DEATHS ASSOCIATED WITH HYPONATRAEMIA

375. The relevance of Claire's death to Adam Strain was that both children were at high risk of Hyponatraemia : for different reasons. In Claire's case this was a known associated risk with syndrome of inappropriate ADH secretion because of the acute encephalopathy. This was not appropriately managed. Attention and focus on low sodium by the treating clinicians should have been given in any event in an acute encephalopathy but with the recent publicity given to Adam Strain, heightened awareness might have been expected within RBHSC . In Adam's case, complicated electrolyte disturbances could be anticipated but that is the only relevance to Claire who was at high risk of SIADH and hyponatraemia . In respect of the other children, it seems that the occasional and unusual complication of inappropriate ADH secretion may have played a part but I believe there are other issues in respect of volume of administered fluid.

376. Relevant Chronology 2001-2004

26/6/2001. Core bundle	26/6/2001. 093-035 PSNI meeting of Sick Children Liaison Group at Antrim area hospital. The minutes record "hyponatraemia: B Taylor presented several papers which indicated the potential problems with the use of hypotonic fluids in children. Work to take place on agreed guidelines from the Department of Health on the subject."
25/9/2001. Core bundle	25/9/2001. Dr Taylor send yellow card relating to Raychel. Seizures. Sodium 118.
26/9/2001. Core Bundle	26/9/2001. From 308-002-028. 26/9/2001. Dr Miriam McCarthy senior medical officer Department of Health SSPS convenes the first meeting of the hyponatraemia working group attended by Dr Taylor, Dr Lowry, Dr Nisbet, Mr Marshall et al.
25 March 2002	Guidance on the Prevention of Hyponatraemia published by DHSSPS(NI)
13/1/2003. Core Bundle	13/1/2003. DHSSPS publishes guidelines governance in HPSS clinical and social care governance guidelines. The Chief Executive of each organisation will designated a senior professional at board level by 28th of February 2003 to support him or her in the discharge of his or her role as an accountable officer of the delivery of quality care and treatment. The senior professional will also develop local systems engaging the views of users and staff and mechanisms that will support the dissemination of clinical and social care standards , best practice and innovation.”
21/10/2004	Insight Television Programme
6/12/2004	Prof Ian Young consultant in clinical biochemistry, was asked verbally by Dr McBride then Royal Hospitals Medical Director to review the medical and nursing records to determine whether hyponatraemia could possibly have been a contributing factor to Claire 's death. Dr McBride had reviewed the notes of Claire in late 2004 but is unable to recall the date. Dr McBride held a meeting on 6/12/2004 together with Prof Young and Dr Steen. It was not formally minuted. From this meeting he decided to refer Claire to the Coroner . Prof Young, Dr Steen, Dr Sands have no knowledge of meetings other than on 7/12/2004
7/12/2004	Meeting between the Roberts family and Trust personnel those attending listed as Dr Rooney, Dr Steen, Dr Sands and Prof Young. Dr Rooney was the trust clinical psychologist who Dr McBride, medical director asked to liaise with and support the family at the meeting. Dr Steen and Dr Sands were clinicians who had been involved with Claire Roberts care. Prof Young was the Queen's University professor of medicine who Dr McBride asked to review Claire 's notes. Dr Webb did not attend the meeting. By 2004 he had moved to another consultant post in Dublin and was not a trust employee.

16/12/2004 Core Bundle	308-002-035. At the request of the family Dr Walby associate medical director from the litigation management office of the Royal hospitals refers Claire's case to the Coroner for investigation.
17 December 2004	17 December 2004 letter from Dr McBride medical director of the Royal hospitals to Mr and Mrs Roberts. D 19 Extracts Medical case notes review has suggested that there may have been a care management problem in relation to hyponatraemia and that this may have significantly contributed to Claire's deterioration and death. In such circumstances it is necessary for the trust to report the death to the Coroner for further investigation.
7/1/2005 Core Bundle	Parents meet Mr Leckey , the Coroner to discuss their concerns relating to hyponatraemia and Claire's treatment
17/1/2005	Mr Roberts writes to Mr O'Hara
27/9/2005	Coroner Mr Leckey informs Mr O' Hara that parents would like Claire's death to be part of the Inquiry
4/5/2006 Core Bundle	Verdict on the inquest delivered: cerebral oedema due to meningoencephalitis, hyponatraemia due to excess ADH production and status epilepticus. 308-002-036 and 091-002-002

The August 2007 Neuropathology report

377. 097-044-302. And following pages up to 097-044-306. Date August 2007

378. Witness statement Dr Brian Harding. Only full-time paediatric neuropathologist in the UK. At the request of PSNI reviewed the autopsy report from Dr Heron, letter from Dr Walby, the inquest verdict and stained slides. Pathological report summarised as follows

379. Brain swelling (macroscopic description) Acute hypoxic damage to nerve cells (probably terminal); No evidence of acquired or inherited disease.;

In answer to questions posed to him he answers as follows:

No evidence of acquired infection (meningitis or encephalitis)

The cause of death on the death certificate and the inquest verdict remains in his opinion not concordant with his observations.

No information regarding the other internal organs of the body)

380. Concludes that meningoencephalitis is excluded both by microbiology and the post-mortem neuropathology.

381. "The child was said to suffer from seizures. None were witnessed prior to hospital admission, and certainly not status epilepticus. Moreover the neuropathological sequelae of status were not present. Nor was there damage to the hippocampus which may be seen in children with chronic epilepsy."

382. Conclusion: "Although the data are incomplete in my opinion the evidence suggests brain swelling was the immediate cause of death and hyponatraemia is the only causative factor that has been positively identified"

383. HYPONATRAEMIA (and Coma) - some relevant milestones

Year	*Item*
26 September 2001	Dr Miriam McCarthy Senior Medical Officer Department of Health SSPS convenes the first meeting of the hyponatraemia working group
25 March 2002	Guidance on the Prevention of Hyponatraemia published by DHSSPS(NI)
November 2003	Statement published by RCPCH and Royal College Anaesthetists "possibility of water overload with severe hyponatraemia developing after the infusion of 4% dextrose/0.18% saline"
2006	Bowker R, Stephenson TJ,Baumer JH. Evidence-based guideline for the management of decreased conscious level *Arch Dis Child Educ Pract Ed 2006;91:ep115–ep122.*
28 March 2007	Reducing the risk of **hyponatraemia** when administering intravenous infusions to children. Alert no. 22. London : National Safety Patient Agency,
2011	Care of Children and Young People Presenting to Hospital with a decreased conscious level Multi site Audit 2010-2011 report. RCPCH

384. **Comment:** The RBHSC 1st Guideline of May 1997 addresses what IV fluid to give in the presence of low serum sodium. The interval before the NPSA issued its warning in 2007 of some 5 years from the DHSSPS (NI) guidance on Hyponatraemia and 3 years 4 months between the RCPCH/ RCAnaesthetists warning on Hyponatraemia is noteworthy in the context of *Organisation with a Memory* .

385. Detailed Chronology 1996-2008

Date	*Item*	*Comment*
October 1996	*Autopsy request form*. Completed in handwriting by Dr Steen. "*Clinical presentation* : 9 1/2-year-old girl with a history of mental handicap admitted with increasing drowsiness and vomiting. *History of present illness:* well until 72 hours before admission. Cousin had vomiting and diarrhoea. She had a few loose stools and then 24 hours prior to admission started to vomit. Speech became slurred and she became increasingly drowsy. Felt to have subclinical seizures. Treated with rectal diazepam/IV phenytoin/IV valproate. Acyclovir and cefotaxime given. Serum Na dropped to 121 at 23:30 hours 22-10-96. Intubated and transferred ICU. CT scanning cerebral oedema. Brainstem death criteria fulfilled zero 600 and 18:15 hours. *Past medical history* mental handicap seizures from six-month-four years. Investigations see chart. *Clinical diagnosis* cerebral oedema secondary to status epilepticus query underlying encephalitis *List clinical problems in order of importance (this list will enable the pathologist to produce a more relevant report.:* Cerebral oedema status epilepticus inappropriate ADH secretion viral encephalitis *Death certificate*: if a death certificate has *already been prepared please copy below for our records: disease or condition directly leading to death* : cerebral oedema due to status epilepticus *Will you or a colleague be attending the review session at 1:45 PM on the day of the autopsy* response no.	

Date	*Item*	*Comment*
24/10/1996	Autopsy	
29/10/1996	112-030-045. Discharge summary from intensive care. To GP. Principal diagnosis cerebral oedema. Other diagnosis status epilepticus, hyponatraemia.	There is a copy of the consent form signed by Mr Roberts indicating limited post-mortem brain only in handwriting
8/11/1996	**Paediatric audit meeting Claire's death discussed** Royal group hospitals paediatric directorate clinical audit meeting Attendance: see register Mortality meeting-four cases presented. Audit (blank) Topic depth of coding. The depth of coding was reviewed. This showed there is room for considerable improvement particularly in certain areas. The amount of work carried out is not being reflected accurately encoding etc……." Topic case note review a number of chart audited on a monthly basis Results demographic information etc. etc rate of signing, height and weight, developmental history immunisation history "in all cases the patient had been seen by a senior Dr" "In only 26% of the cases did each page of the notes have a patient unique ID number (this is an A standard of the King's fund) Then on the recording of proportions of those with problem is, parental information given discharge letter etc. Topic patient satisfaction survey medical outpatients Recommendations more booklets etc, better feeding and changing areas, the input to domestic services to toilet area etc	How is it known that Claire was discussed. Note using King's Fund standard

Date	*Item*	*Comment*
11/11/1996	3.35 pm New handwritten entry "spoke at length with Mr and Mrs Robert earlier today. They are naturally still trying to come to terms with what happened to Claire . I talked through the events before her death and also talked generally with them. They are naturally anxious to discuss the PM results with someone. I will pass this on to Dr Steen ASAP" signature (Dr Sands)	
18/11/1996	090-004-006. Letter from Dr Steen to parents offering a meeting. Includes a leaflet from the meningitis research foundation on death "I know meningitis was not Claire's problem but when I read the leaflet I thought some of the comments in it were very real and perhaps would be of help to you."	
28/11/96 Autopsy records	record made that "cut up" "blocked" store 28/11/96.Diagnosis in handwriting "viral and encephalitis and epilepsy	
11/2/1997 Papers PSNI	096-025-200. Date of necropsy 24/10/96 11:30 AM. Restrictions brain only. **Anatomic summary** History of recent diarrhoea and vomiting, cerebral oedema (brain weight 1606 g) brainstem necrosis. Subacute inflammation meninges in perivascular space . History of epileptic seizures since 10 months of age. Neuronal migration disorder. **Clinical summary** She was well until 72 hours before admission. She had visited her cousin who had vomiting and diarrhoea. She had similar symptoms and 24 hours prior to admission started to vomit. Her speech became slurred and she became increasingly drowsy. She was felt to have subclinical seizures. She was treated with rectal diazepam, intravenous phenytoin and intravenous valproate. She also had acyclovir and cefotaxime. Her serum sodium dropped to 121 and there was a query of inappropriate ADH secretion. Her fluids were restricted that she had respiratory arrest at 3 AM on 23/10/96. She was intubated and transferred to intensive care	

Date	*Item*	*Comment*
	where a CT scan showed cerebral oedema. Brainstem criteria were fulfilled at 6 AM. In her past history she had iatrogenic epilepsy since 10 months and mental handicap." **Autopsy report** "in summary the features here are those of cerebral oedema with neuronal migration defect and a low-grade subacute meningoencephalitis. No other discrete lesion has been identified to explain epileptic seizures. The reaction in the meninges and cortex is suggestive of a viral aetiology, although some viral titres were negative during life and on post-mortem CSF. With the clinical history of diarrhoea and vomiting, this is a possibility although a metabolic cause cannot be entirely excluded. As this was a brain and the autopsy, it is not possible to comment on other systemic pathology in the general organs. No other structural lesion in the brain like corpus callosal or other malformations were identified." Dr Herron	
5/3/1997	090-002-002 Letter from Dr Steen to GP Dr McMillin "Claire's post-mortem results are now available. Cerebral tissue showed abnormal neuronal migration, a problem which occurs usually during the second trimester of pregnancy and would explain Claire has learning difficulties. Other changes were in keeping with viral encephalitis myelitis meningitis. Dr Webb and myself have since seen Claire's parents and discussed the post-mortem findings with them. They are obviously both finding this an extremely difficult and traumatic time but do not want any further professional counselling at present, however they know our doors are open and we will be happy to see them if they want to discuss things further with ourselves. Mr Roberts wanted a short summary of the post-mortem report which Dr Webb will send him shortly. If there are any concerns at all please do not hesitate to contact us	
21/3/1997	Letter from Dr Webb dictated 28/2/1997. (090-001-001)To parents "in summary of the findings were of swelling of the brain with evidence of a developmental brain abnormality (neuronal migration defect) and a low-grade infection (meningoencephalitis). The reaction in the covering of the brain (meninges) and the brain itself (cortex) is suggestive of a viral cause. The clinical	

Date	*Item*	*Comment*
	history of diarrhoea and vomiting would be in keeping with that. As this was a brain only autopsy it is not possible to comment on other abnormalities in the general organs. No other structural abnormality in the brain has been identified."	
21/10/2004	Insight TV programme After this Claire's parents contacted Royal Group of hospitals (see Mr Walby's letter to Coroner 16/12/2004).	
	Dr McBride reviewed the notes of Claire in late 2004 but is unable to recall the date. He asked Prof Young to review the records. Dr McBride did not request or receive a written report from Prof Young. The latter gave Dr McBride a verbal report.	
6/12/2004	Dr McBride held a meeting on 6/12/2004 together with Prof Young and Dr Steen. It was not formally minuted. From this meeting he decided to refer Claire to the Coroner . Prof Young, Dr Steen, Dr Sands have no knowledge of meetings other than on 7/12/2004.	
7/12/2004 Roberts papers	089-002-002 in the clinical psychology Department RBHSC . Present Mr and Mrs Roberts, Dr Nicola Rooney consultant clinical psychologist, Dr Andrew Sands consultant paediatrician, Dr Heather Steen consultant paediatrician, Ian Young Prof of medicine Queens University Belfast. Lists Mr and Mrs Roberts main areas of concern as What led to Claire's sudden deterioration after they had left the hospital and before they were called at 3:30 AM. Was Claire's condition diagnosed? What role, if any did Claire's fluid and sodium management play in her death? (Review of clinical events) reports that Dr Webb arrived quite promptly (lunchtime Tuesday) "at 3 PM Dr Webb additionally prescribed Midazolam (rectal diazepam had already been administered that	No record of this in notes

Date	*Item*	*Comment*
	morning)." Mrs Roberts reported that they left the Ward around 9:30 PM not unduly concerned. Neither she nor her husband got the impression from the staff that the situation was in such a critical phase otherwise they would not have left Claire Prof Young then explained that he was there as an independent advisor and pointed out that "treatment today differs from that used eight years ago." "The doctor gave her standard fluid intravenously-which is the textbook recommendation" in respect of the low sodium "Prof Young feels this may have contributed to swelling of Claire's brain and therefore ultimately to her death but that it was not possible to say to what extent" ".. With a sodium level at 121, the doctor had responded appropriately. However Prof Young added that he believed the swelling of the brain had already occurred by this stage, therefore further intervention would probably not have helped." "Prof Young explained that treatment today is very different. At the Royal hospitals lessons have been learnt regarding management of sodium levels in children-which is still not the case in many UK hospitals." " Mr Roberts asked if Claire's sodium level had been monitored in between arriving at hospital and 24 hours later. Prof Young confirmed that it had not, but this was not unusual at the time. Treatment today, however, involves approximately 6 hourly checks and the use of the CT scanner." There was discussion about referral to the Coroner and whether Mr and Mrs Roberts would like to approach John O'Hara QC	Prof Young does not seem aware of guidance on fluid management of acute encephalopathy which related to 1996 and before
16/12/2004	089-004-008 Letter from Mr Walby R Hospital Trust Ligation Office to Coroner extracts "Claire had a history of epileptic seizures since age 10	Claire had been off treatment for over a year when reviewed on 30/5/1996 by Dr Gaston . She had no fits since the age of 4

Date	*Item*	*Comment*
	months and had learning disability… She was admitted to the paediatric medical Allen Ward under the care of consultant paediatrician Dr Heather Steen with a provisional diagnosis of a viral illness." "She developed hyponatraemia and consideration was given to whether this was from fluid overload with low sodium fluids or a stress induced antidiuretic hormone effect, and her fluid management was altered."….. "A meeting was held with Mr and Mrs Roberts on 7 December 2004 at which clinicians Dr Steen and Dr Sands involved in Claire's care were present. Prof Ian Young, Prof of medicine ,QUB and consultant in clinical biochemistry has examined the notes and in his opinion there is indication that hyponatraemia had played a part in Claire's death and he reported this to the parents. Mr and Mrs Roberts wished the case to be reported to the investigation and I'm doing so now……"	years. Her fluid management was not changed although it was intended to be so in terms of volume but not type.
17/12/2004	letter from Dr McBride, medical director to Mr and Mrs Roberts. Extract "As you have been informed by Prof Ian Young of the Queens University Belfast, our medical case note review has suggested that there may have been a care management problem in relation to hyponatraemia and that this may have significantly contributed to Claire's deterioration and death. In such circumstances it is necessary for the trust to report the death to the Coroner for further investigation."	
12/1/2005	Letter to parents written by the clinical psychologist. Nicola Rooney 097-022-221 In response to questions raised by parents after the meeting. extracts States based on the history and clinical presentation admitting registrar suspected she had possible encephalitis. "Subparagraph (b) Claire's symptoms were attributed to encephalitis which was confirmed at post-mortem." "Claire's condition was not underestimated as she was	The working diagnoses for the clinical team was post-ictal encephalopathy, the diagnosis of encephalitis had been scratched out although was written in notes on admission. Not clear when it was scratched out)

Date	*Item*	*Comment*
	considered to be very unwell, with a diagnosis of non-convulsive status epilepticus and encephalitis/encephalopathy. Claire consequently received intensive medical intervention." ……. "practice now would involve approximately 6 hourly checks and use of the CT scan. However, in 1996, before there was such extensive knowledge about hyponatraemia, it would be normal practice to monitor sodium level every 24 hours." States in paragraph 5 the treatment has now changed and Claire would be given small amounts of different type of fluid following admission. Dr Webb has noted that he spoke to Mr Mrs Roberts at 5 PM although the content of this or other conversations between medical staff and the family were not summarised. (6b) with regard to why Claire was not moved to PICU, her hourly CNS observations had remained stable for a period of time and no clinical signs of further deterioration were noted. PICU may not have been viewed therefore as appropriate/necessary Then goes on to say that hyponatraemia was not thought the time to be a major contributor to Claire's condition. It was indicated in the clinical summary provided to the neuropathologist. Refers to metabolic cause cannot be entirely excluded as a reference to the low-sodium. " "The Coroner had not been informed of the time as it was believed that the cause of Claire's death was viral encephalitis" Dr Nicola Rooney consultant clinical psychologist. The parents asked in their letter of 8/12/2004 whether Claire had been seen by a doctor between 5 PM and 11 PM on Tuesday 22nd. This was answered by Nicola Rooney as follows "according to nursing records Claire was seen by doctor at 9 PM after having been informed about a possible seizure. At this time Claire had her bloods. At 9:30 PM the doctor erected her acyclovir infusion."	It seems from this response in 2005 and the clinicians had still not appreciated that it was their responsibility to anticipate low-sodium in the context of an acute encephalopathy. This was well known at the time Nursing records at 9 PM do not to being called for a seizure-if so then the doctor should have entered the assessment in the notes.
3/2/2005	308-002-035. Letter from Dr Herron to the Coroner in	

Date	*Item*	*Comment*
	which he states "I have reviewed the pathological findings in the case. It seems that Mr Walby has referred the case to you because there is indication that hyponatraemia may have played a part in the death. The cerebral oedema (brain swelling) that was present may have many causes, one of which is hyponatraemia. The autopsy did not exclude this as a cause of the brain swelling nor did it show any specific findings (structural changes) to make the diagnosis of hyponatraemia. I am unclear from the letter as to whether it is thought that the hyponatraemia was a primary factor in this case i.e. caused the brain swelling, always secondary to the brain swelling."	
4/8/2006	Letter from **Mr Roberts** to Mr Barr. 097-024—227 Autopsy summary Dr Steen "I have grave concerns regarding the accuracy of the autopsy summary submitted to Dr Herron clinical pathologist Belfast Royal hospital. The summary stated that Claire was unwell to 72 hours prior to admission. That statement is incorrect. The first indication that Claire was unwell was on Monday 21st October on returning home from school. The report states that Claire was vomiting on the Sunday prior to admission. That statement is incorrect sub Clare did not vomit on Sunday the day before admission. This report stated that Claire had diarrhoea symptoms. That statement is incorrect. As stated on the hospital admission noted 8 PM Monday 21st October Claire had no diarrhoea. The autopsy summary makes a rather vague comment that there was a query about low-sodium. It does not define the rapid fall in Clare sodium from 132 mmol/l to 121 mmol/l within 23 hours." Then goes on to state that Dr Herron stated inquest that he was aware of Clare sodium but was not aware of the rate and fall in sodium levels. Dr Herron also stated that the degree of encephalopathy is found would be more severe in a typical death.	
26/6/2001.	26/6/2001. 093-035 PSNI meeting of Sick Children Liaison Group at Antrim area hospital. The minutes	

Date	***Item***	***Comment***
Core bundle	record "hyponatraemia: B Taylor presented several papers which indicated the potential problems with the use of hypotonic fluids in children. Work to take place on agreed guidelines from the Department of Health on the subject."	
25/9/2001. Core bundle	25/9/2001. Dr Taylor send yellow card relating to Raychel. Seizures. Sodium 118.	
26/9/2001. Core Bundle	26/9/2001. From 308-002-028. 26/9/2001. Dr Miriam McCarthy senior medical officer Department of Health SSPS convenes the first meeting of the hyponatraemia working group attended by Dr Taylor, Dr Lowry, Dr Nisbet, Mr Marshall et al.	
25 March 2002	Guidance on the Prevention of Hyponatraemia published by DHSSPS(NI)	
13/1/2003. Core Bundle	13/1/2003. DHSSPS publishes guidelines governance in HPSS clinical and social care governance guidelines. The Chief Executive of each organisation will designated a senior professional at board level by 28th of February 2003 to support him or her in the discharge of his or her role as an accountable officer of the delivery of quality care and treatment. The senior professional will also develop local systems engaging the views of users and staff and mechanisms that will support the dissemination of clinical and social care standards , best practice and innovation."	
21/10/2004	Insight Television Programme	
7/1/2005 Core Bundle	Parents meet Mr Leckey , the Coroner to discuss their concerns relating to hyponatraemia and Claire's treatment	
18/5/2005	Coroner receives report from Dr Bingham of Great Ormond St who advises obtaining opinion from Dr McConnachie. "In particular in this case there has been much recent publicity in both the lay and medical press which has led to a better appreciation of the dangers of hyponatraemia in children and helped to clarify the cause of this tragedy. Much of this information has only been available in the last five years." "I feel that Claire's initial diagnosis and management was reasonable….. This is a fluid prescription was in	Neither of the Coroner 's experts seem aware of guidance on fluid management of acute encephalopathy which related to 1996 and before aiming to prevent hyponatraemia

Date	*Item*	*Comment*
	line with the practice of the time and although current guidance would be to use fluid with a higher sodium content in this situation this advice did not exist in 1996" "The initial and subsequent anticonvulsants treatment was logical, given the working diagnoses and it is unlikely you would have worsened the consequences of hyponatraemia although it may have masked the symptoms." I think it is most likely that hyponatraemia was the cause of the neurological deterioration on the evening of 22 October, culminating in the respiratory arrest. "Although the measures taken at 2330 when the sodium result was available were the correct type they were too little and too late"	
15/9/2005	Coroner receives report from Dr McConnachie. Considers the diagnosis of encephalopathy is/encephalopathy was made at an early stage of her admission and measures taken to treat the likely diagnosis of non-convulsive epilepsy. There was a background of seizure activity in her past medical history and hence the probability of this diagnosis was high given her presentation…… The management plan to treat the possibility of non-convulsive status epilepticus was correct at the time of practice…….. Claire Roberts subsequent management was correct and her course of management on the Ward and PICU was appropriate. "I have not commented upon the hyponatraemia which has been addressed by Dr Bingham…. Dr Webb and other members of the team looking after Claire gave careful and informed advice"	
17/1/2005	Mr Roberts writes to Mr O'Hara	
27/9/2005	Coroner Mr Leckey informs Mr O' Hara that parents would like Claire's death to be part of the Inquiry	
4/5/2006 Core	Verdict on the inquest delivered: cerebral oedema due to meningoencephalitis, hyponatraemia due to excess ADH production and status epilepticus. 308-002-036	

Date	*Item*	*Comment*
Bundle	and 091-002-002	
9/9/2008	Dr Gupta (paediatric neurologist) provides report on request by PSNI	Midazolam dose not mentioned
23/1/2008	PSNI instruct Dr Evans (consultant paediatrician) to provide report	Midazolam noted given as 0.5mg/kg but no comment made

CHAPTER 4 CLINICAL GOVERNANCE REVIEW : Chronology of Developments and Sources of Guidance with Focus on Children's Specialist Services

This Chapter addresses the following matters raised in my brief and aims to provide an overview. In addition I have provided a compilation ** of relevant publications and for some have made an annotated bibliography for the Inquiry Team as a source of reference.

> *BRIEF : The identification of any protocols, guidance, standards or practices (hereafter referred to throughout collectively as "guidance" save where the context indicates to the contrary) that were applicable to the issues raised in Claire's case in 1996 and which the RBHSC may have been expected to take cognisance of and/or comply with. They should include any available guidance in the UK generally on the provision of services to children in hospital and how they were applied at that time, together with an indication of how that guidance and its application has developed since then. Identification of the literature, if any, that was available in 1996 that discusses such issues.*

The Chapter is set out as follows:

- **EVOLUTION OF CLINICAL GOVERNANCE (Paras 386-387)**
- **EVOLUTION OF CLINICAL AUDIT (Paras 388-404)**
- **EVOLUTION OF GUIDELINE DEVELOPMENT (Paras 405-413)**
- **CONSULTANTS IN MANAGEMENT (Paras 414-436)**
- **CONSULTANT RESPONSIBILITY AND ACCOUNTABILITY (Paras 437-468)**
- **ADVERSE EVENTS REPORTING IN CHILDREN (Paras 469-489)**
- **GUIDANCE ON HOSPITAL SERVICES FOR CHILDREN (Paras 490-491)**
- **ROLE OF ROYAL COLLEGES AND OTHER CLINICAL PROFESSIONAL BODIES (Paras 492-505)**
- **CONTEXT OF CARE FOR CLAIRE ROBERTS – ROYAL BELFAST HOSPITAL FOR SICK CHILDREN (RBHSC) (Paras 506-535)**
- **WHAT GOVERNANCE ARRANGEMENTS COULD BE EXPECTED TO BE IN PLACE IN RBHSC IN 1996 & 2004 (introduction of clinical governance) (Paras 536-547)**
- **RESPONSIBILITIES OF A CLINICAL DIRECTOR (Paras 548-543)**
- **CLINICAL MANAGEMENT STRUCTURES IN RBHSC (Paras 554-556)**
- **RELEVANCE OF ISSUES IN CLAIRE'S CASE TO OTHER CHILDREN'S DEATHS ASSOCIATED WITH HYPONATRAEMIA (Paras 557-568)**

- **LIST OF KEY PUBLICATIONS**

<u>COMPILATION</u> The ** compilation is placed in Annex D and includes more detail and aims mainly to be a source of reference as a working document *(the para numbers refer to those in the compilation):*

- **DEVELOPMENT OF STANDARDS FOR HOSPITAL SPECIALIST CARE FOR CHILDREN 1980s onwards and CLINICAL GOVERNANCE IN CHILDREN'S SPECIALIST SERVICES. *(Paras 1-80)***
- **CLINICIANS AND MANAGEMENT *(Paras 81-118)***
- **CONSULTANT RESPONSIBILITIES AND ACCOUNTABILITY *(Paras 119-184)***
- **METHODS BY WHICH CLINICIANS GAIN KNOWLEDGE and SHARE EXPERIENCE : Continuing Medical Education *(Paras 185-192)***
- **CLINICAL MANAGEMENT DIRECTORATES including Role of Clinical director and list of governance questions to enable comment to be made on clinical governance in RBHSC *(Paras 193-243)***
- **SOURCES AND USES OF KNOWLEDGE IN CHILD HEALTH (with supplement) *(Paras 244-284)***
- **ROLE OF ROYAL COLLEGES AND PROFESSIONAL ASSOCIATIONS *(Paras 285-300)***
- **ROLE OF GMC *(Para 301)***
- **DEVELOPMENT OF MEDICAL AUDIT *(Paras 302-321)***
- **DEVELOPMENT OF CLINICAL GUIDELINES *(Paras 322-356)***
- **NHS NATIONAL SERVICE FRAMEWORK FOR CHILDREN 2003 -relevant extracts *(Paras 357-395)***
- **REPORTING SYSTEMS FOR ADVERSE EVENTS *(Paras 396-410)***
- **ADVERSE AND CRITICAL EVENTS INVESTIGATION SYSTEMS CHILDREN *including Royal Hospitals Annual Health & Safety Reports (Paras 411-471)***
- **ANNEX C TO RCP REPORT ON MEDICAL AUDIT ANONYMITY AND CONFIDENTIALTY GUIDANCE *1993 (between Paras 471 and 472)***
- **ANNOTATED BIBLIOGRAPHY OF IMPORTANT REPORTS AND GUIDANCE WITH TIMELINES (*Para 472)***

EVOLUTION OF CLINICAL GOVERNANCE.

386. Key documents relating to clinical governance have been referred to in the papers for the Inquiry from Prof Aidan Mullen dated July 2011 and Stephen Ramsden dated February 2012. These include *Organisation With a Memory* DH 2000 referring to the White Paper of 1997 setting out a ten-year modernisation strategy for the NHS-*The New NHS Modern Dependable*. One of the main proposals set out in that paper was to bring a major improvement in clinical care referring to clinical governance as "a framework through which NHS organisations are accountable and continuously improving the quality of their services and safeguarding high standards of care by creating an environment which excellence in clinical care will flourish. Reference was made in this to the National Service Frameworks and the National Institute for Clinical Excellence (NICE).

387. However from the late 1980s and early 1990s, before these documents were published, there were a number of actions expected of NHS Trusts and professional bodies aiming to improve the quality of clinical care and which fall within the concept of Clinical Governance. These include:

- Clinical (formerly "Medical") Audit (from 1989)
- Introduction of Consultant Job plans (from 1990)
- Greater use of Clinical Guidelines (from mid 1990s)
- Greater and more structured engagement of Consultants in Management (from 1993)
- More attention to Adverse Clinical Event reporting, investigation and auctioning (from mid 1990s) and monitoring of certain specialty service outcomes by the DH National Specialty Commissioning Group
- Guidance from GMC, Royal Colleges and Specialty Associations and Departments of Health (e.g. Paediatric Intensive care, medication risks and standards for care and practice) (from late 1990s)
- Requirements for registering Continuing Professional Development (from 1999) and consultant appraisals (2000).
- From 2000 onwards : output of guidance on children from NICE, National Service Framework, and from 2007 NPSA; (and from DHSS(I) in 2002 on Hyponatraemia)

388. EVOLUTION OF CLINICAL AUDIT

389. One of the earliest formal structures for auditing care was the practice within hospitals of perinatal mortality review meetings and reports (from the late 1960s) . These conducted relatively structured evaluations of obstetric care involving midwives, obstetricians, pathologists, anaesthetists, paediatricians and general

practitioners often with support from the local public health department. The Department of Health supported the National Confidential Enquiry Into Maternal Deaths. From 1989, the Confidential Enquiry Into Perioperative Deaths (CEPOD) was another major national audit: one of its first reports addressed issues relating to children. The regional confidential Enquiries into Stillbirth and Infant Deaths were collected into a DH supported national CESDI from early 1990s. The DH National Specialty Commissioning Group monitored outcomes in certain specialty services for children, notably liver surgery and cleft palate and after centralising to a smaller number of units documented clinical outcome improvement.

390. From the early 1990s there was increasingly widespread adoption of clinical audit and this was expected in all units both by the professions and by the Department of Health and the General Medical Council. Recommendations regarding medical audit were embraced by the professions in a series of reports and recommendations. Medical audit as a concept was introduced widely in 1988/89.

391. The government **White Paper Working for Patients 1989 and Department of Health circular HC (91) Advice on medical audit of hospital and community health services stated**

a. *"Within the next two years, the government would like to see all hospital doctors taking part in what doctors themselves have come to call "medical audit" a systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome for the patient." And in Medical Audit-Working Paper 6 HMSO. February 1989 defined audit as: "the systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome of quality of life of the patient" it can therefore be seen that the primary purpose of clinical audit is to improve practice"*

392. At the same time the following sequence of guidance was issued:

- *Hospital Medical Audit, Kings Fund 1989*
- *Medical audit-a first report: What, Why And How Royal College of Physicians 1989*
- *The Quality Of Medical Care. Report of the Standing Medical Advisory Committee Department of Health 1990. HMSO*
- *Specialty Medical Audit-King's Fund Centre. Charles Shaw. 1992*
- *BPA Paediatric Medical Audit 1992.*
- *Medical Audit : a second report Royal College of Physicians of London 1993*
- *Children first-a study of hospital services. Audit commission 1993*

- *RCPCH . Clinical Audit in Paediatrics and Child Health – Some Examples. London: Royal College of Paediatrics and Child Health, 1997.*
- *Organisation with a memory DH 2000*
- *Principles for Best Practice in Clinical Audit a joint publication of NICE , commission for health improvement, Royal College of nursing and the University of Leicester. 2002.*
- *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary DH 2001*

393. Requirement to participate in National Audits

394. In 1998 the Health Secretary England stated that:

a. "… *from next year [1999], all hospital doctors will be required to participate in a national audit programme appropriate to their speciality or subspecialty externally endorsed by the new Commission for Health Improvement*.", and that:

b. "... individual doctors will be required to share their results confidentially with the Medical Director of their Trust and the Trust 's lead clinician responsible for clinical governance. In turn, doctors on the Commission for Health Improvement will have access to these data …".

395. The NHS Plan set out the requirement – to be being taken forward within the Quality Taskforce - that:

a. "*All doctors employed in or under contract to the NHS will, as a condition of contract, be required to participate in annual appraisal, and clinical Audit, from 2001. This will underpin, and provide much of the data to support, the General Medical Council's mandatory five-yearly revalidation process, which is likely to begin in 2002. Subject to Parliament, by April 2001 all doctors working in primary care, whether principals, non-principals or locums, will be required to be on the list of a health authority and be subject to clinical governance arrangements. These will include annual appraisal and mandatory participation in clinical audit*". (para 10.10)

396. This strengthened the existing requirement in the HSC1999/065 on clinical governance issued in March 1999 for all NHS hospital doctors to participate in clinical audit programmes, including speciality and sub-speciality national audit programmes endorsed by the Commission for Health Improvement. NHS Trusts are responsible for ensuring that their doctors meet this requirement. **In addition, all NHS organisations were required to report on their participation in, and the impact of, their clinical audit activities in their annual clinical governance reports.**

397. The General Medical Council makes clear in *Good Medical Practice: Duties of a Doctor* 1995 that doctors should "take part in regular and systematic medical and

clinical audit." The requirement for clinical audit results were to be part of GMC revalidation,.

398. DH view on mechanisms for ensuring the impact of clinical audit on service quality (2003)

399. Individual doctors are required to share their clinical audit results with the Medical Director and the lead clinician responsible for clinical governance in their Trust . In turn, doctors from the Commission for Health Improvement (CHI) (now CQC) will have access to these data when they visit the Trust to review each NHS organisation's local standards and clinical governance processes. Where clinical audit identifies problems in service quality, and especially where these have wider implications for resource investment and service management, the NHS Trust and Health Authority, Chief Executives should also have access to the results.

400. NHS Trusts must show the impact of clinical audit in their **annual clinical governance reports.** These annual reports are public documents available to the local health community.

401. As one mechanism for ensuring participation in clinical audit, CHI's 4-year rolling programme of clinical governance reviews will pick up cases where this is not happening - publishing these within its reports and requiring an action plan to be agreed with the relevant NHS through performance management of clinical governance to identify and act on cases of poor uptake in national confidential enquiries. Other possible mechanisms could form part of standard processes for performance management of the NHS or, alternatively, could be agreed through the Royal College s' own mechanisms.

402. Following the 1998. Department of Health. *"First class service"* expectation that all clinicians should be involved in a national audit the Department of Health proposed the establishment of a national audit into in-hospital children's deaths. There were delays in process as a pilot study was funded followed by transfer of identified funds to NICE and later transferred the responsibility for the development of this process to the existing Department of Health funded Confidential Inquiry Into Still Births and Deaths In Infancy *(*CESDI) one of the earliest national audits already in existence. This focused on deaths in the perinatal period and up to one year but under the newly setup arrangements as a result of the negotiation starting in 1999, the Confidential Inquiry Into Maternal and Child Health was set up in the early 2000s and reported its first study in 2006 and later was supported by the need to enquire into deaths which possibly related to abuse/neglect.

403. Some specialist paediatricians in tertiary centres are involved in audit processes of their associations. Surgeons and anaesthetists are involved in CEPOD. The paediatric intensive care audit network was set up by the Department of Health in 2002 and followed shortly by the neonatal intensive care audit network. All paediatric intensive care units and/or neonatal units would be expected to return

information and receive reports back from this process. DH funded through its audit programme (between 1992 and 1996) the following national audits through the RCPCH (and its fore runner the BPA) –

a. *Diagnosis of urinary tract infections*

b. *Management of nephrotic syndrome*

c. *Management of idiopathic thrombocytopaenic purpura*

d. *Audit of acute paediatric admissions.*

e. *Development of instrument for assessment of appropriateness of paediatric admission.*

f. *Screening for retinopathy of prematurity.*

g. *And DH asked NICE to set up the following audit :Parenteral (IV) nutrition in premature infants (sent to NPSA)*

404. The Children's Cardiac services database acted as a national audit and in 2011 a national audit on diabetes is in development under arrangements provided by the Health Quality Improvement Programme.

405. EVOLUTION OF GUIDELINE DEVELOPMENT

406. The acceptance of guidelines by professionals in the later 1990s was gradual. There was much scepticism voiced about "Cook book medicine" and apprehension about curtailment of consultant clinical freedom. Many held a view that there was little evidence basis to support the content of guidelines-a reservation which had some justification because even now many are based upon the lowest level of evidence, that is: clinical consensus.

407. From the early 2000s there was an increasing focus on evidence-based medicine and through the processes of registering Continuing Medical Education/Continuing Professional Development there was the implicit commitment to a lifelong learning experience. The professions themselves encouraged this (for example guidance from specialty groups in the various professional associations and Royal Colleges and for paediatrics the advanced paediatric life-support courses with supporting manuals). Later this became more structured with guidance offered from the National Institute for clinical excellence. However the reports available from NICE relating to children were only published in the early 2000s. The Royal College of Surgeons Report from Children's Surgical Forum first reported 2000. The Department of Health England National Service Framework for Children published in 2003 a large series of recommendations including all aspects of hospital care for children with some attention to clinical standards.

408. By the mid-1990s a within hospital system should have been in place including reviews of deaths. The report *Organisation with a Memory* by the Chief

Medical Officer's (England) expert group was of considerable importance in this respect. There was greater emphasis on more consistency in practice for patient safety, education, rational use of resource and working with colleagues. In general there was more openness about sharing adverse event experiences in the processes of audit and reflective processes encompassed in the annual appraisal process. It was a responsibility of the employing Trust through the clinical director and directorate to ensure that an individual clinician was engaged in annual appraisal and the Royal Colleges provided a process of endorsing a consultant' s good standing through the process of registering defined continuing professional development points and taking part in annual appraisal. A clinical directorate would encourage demonstration of attendance and certification from the advanced paediatric life-support course or paediatric advanced life support course for nursing staff on the children's wards as well as the medical staff and in the case of the surgical teams on advanced life support courses or trauma courses. The volume of surgical practice in terms of numbers of particular operations and the numbers of anaesthetics administered would also be taken into account. Nursing staff did not undergo the 360° appraisal which was in practice for consultants but nursing individual professional development was regularly reviewed by senior nursing staff. Pathology laboratory biochemical and haematological systems took part in external quality management processes and clinicians requesting radiological examinations were supposed to attend courses which increased awareness of indications and risks. Radiologists carried out double reporting of selected numbers of cases. Histological examination in pathology had a similar quality control management. Oncology care was largely with the tightly set therapy care pathways at a national level. It was a responsibility of a clinical directorate to ensure that all these activities were taking place and documented.

409. Increasingly in the 2000s consultants were aware of the need to be answerable for their practice in a more robust way and in order to do so would rely upon adherence to guidelines and would want to be able to demonstrate standards of practice through audit and listing of complaints and complimentary letters. Consultants also became increasingly aware of the requirement to be able to answer complaints which had been raised by patients, colleagues or management through the processes of referral to the GMC or through litigation. To a large extent these processes still apply with the expected process reaccreditation also providing a more tightly drawn structure within which clinical practice takes place.

410. A further strong impetus for the availability of guidelines came with clinical audit.

411. The introduction of clinical audit carries the implication that practice should be evaluated against clinical guidance to determine whether what was done was what ought to have been done. Clinical audit also addressed issues such as structure and process including the quality and extent of clinical records and availability of appropriate facilities for diagnosis and treatment, communication and decision support. Consequently the presence of agreed clinical guidelines was fundamental to

this process. The Department of Health in England supported development of some national guidelines in selected specialties. The British Association of Paediatric Surgeons and children's Anaesthetic organisations also produced guidance. I have listed key documents in Annex D. The General Medical Council has also issued guidance upon record-keeping and audit.

412. Sharing of experience within and between directorates and within and between hospitals as a potent form of improving clinical guidelines and also enabling presentation of Audit results for educational purposes more widely to share lessons learned. The BPA/Royal College of paediatrics and child health assembled and published in 1997 a compilation of experience from around the UK. Key relevant guidance on clinical audit for the time is listed below.

413. Many units had a children's formulary either developed in house or using one developed by another children's unit such as Alder Hey guidance. In the middle 1990s concerns about potential and actual drug errors were voiced amid the consciousness that much medication in children is used off-licence or "off label". This led to the publication of a document produced by BPA/RCPCH and Neonatal And Paediatric Pharmacists Group "*Medicines For Children*" in 2001 to be used with the British National Formulary guidance on doses and selection of therapy. The British National Formulary at this time also included extensive information based upon age ranges and weight for medication in children.

414. CONSULTANTS IN MANAGEMENT

415. History and Milestones

416. The involvement of clinicians in NHS management with senior nursing and medical professionals working together with general managers evolved in the 1960s with Cogwheel divisions feeding professional advice into the management structure (which often had a lead medical and nursing individual linked to general management). Later following the **Griffiths Report of 1983** recommendations management incorporated a triumvirate of general manager/Chief Executive, senior nurse and senior medical professional.

- *NHS Management Inquiry (1983) Report (The Griffiths Report). London: HMSO Department of Health and Social Security (1984)*
- *Working for patients 1989 and the NHS and Community Care Act 1990*
- *Managing the New NHS 1993 and the Health Authorities Act 1995*

417. Evolution occurred through a process in England where a District Management Team with such a triumvirate would link to equivalent structures within the health service provider units for which they had responsibility in a locality such as a hospital or community mental health or child health service.

418. Although nursing had a well-defined hierarchy headed in the past by matron whose title changed to chief nursing officer or senior nursing officer within an organisation, medical consultant organisation lagged behind. In part this reflected the concept of consultant practice as being to a large extent autonomous.

419. In the 1980s and until 1993, in England consultant appointments were made at the Regional Health Authority which employed them. The consultants however were located for their work in provider units under the supervision of a district or area Health Authority. The line management relationship between a consultant and his local management was not defined but largely developed and evolved by custom and practice. From 1993 in England consultant contracts after HC (91) 8 were removed from Regional Health Authority to the local hospital Trust in which they worked. Before then however in University Teaching Hospitals with regional tertiary services were frequently linked to the university academic departments and contracts were held with the Teaching Hospital Board with a more defined line management relationship with the management of the hospital service itself. Consultants working in regional centres were in the majority employed by the NHS with Honorary University contracts, others however in the same team, might be employed by the University responsible for undergraduate education and research, and then the consultant / academic held an honorary NHS contract. This led to some blurring and ill definition of line management responsibilities.

420. It was a on this background that initiatives to improve and clarify relationships and responsibilities took place and one of the steps towards this was increasing and encouraging clinicians to be involved in management. This intention was affirmed in the government White Paper of 1989 *Working for Patients:* HMSO. February 1989 which stated

a. *"the government's objective is to create an organisation in which those who are actually providing the services are also responsible for day-to-day decisions about operational matters…….DHAs can then concentrate on ensuring that the health needs of the population for which they are responsible are met……. The government will expect authorities to provide themselves to medical and nursing advice they will need if they are to undertake these tasks effectively"*

421. From 2003 the new consultant contract led to much more structured job plans for consultants

a. http://www.nhsemployers.org/PayAndContracts/MedicalandDentalContracts/ConsultantsAndDentalConsultants/Pages/Consultants-KeyDocuments.aspx

422. A structure was put in place to enable engagement and communication with clinical staff in the wide range of specialties that are found within hospitals. It was within the structure that developments occurred of identification of **clinical leads** within specialties who may have come together in groups under the **clinical directorship** of one consultant who might have covered several specialties but who

liaised with the lead clinicians from each individual specialty. Differing arrangements were put in to enable and free up clinical time to take up these roles either by backfilling their clinical responsibilities or by these continuing but with additional sessions funded. Additional resource in the form of extra secretarial and PA functions were also identified. One of the motives to putting in place the structures was a need for management have an identified voice and responsible leader for each specialty especially, as the number of consultants was increasing.

423. These developments took place in the mid-to late 1980s and were fairly well established from the early 1990s. Major safety issues which arose would be addressed within the structure but there was initially at least little proactive approach to quality management. There was more focus upon how to make best use of existing resources and at the same time with resource constraint to maintain existing services seem to be under threat from tight financial management.

424. In the later 1990s and early part of the 2000s and since the engagement of clinicians in management has become much more structured and formalised. Clinicians have undertaken management development roles and courses, and quality issues taking account of the increasing range of national guidance have been more part of regular agendas. For each Trust it has become a requirement to appoint a Medical Director on its board and the clinical directorship structure has become more defined and resourced. Increasingly a board member was identified as the lead for clinical safety/audit. In the early stages of clinical lead/clinical director, much of the arrangements were administrative in the form of ensuring coordination of annual leave so that the 24-hour service is properly covered at consultant and junior staff level, ensuring guideline development and quality review, ensuring proper allocation of sessional time for clinicians to engage in audit and professional development, to ensure that there was proper equipment available and serviced including for resuscitation, to ensure adequate theatre equipment and anaesthetic equipment, to ensure sufficient nursing staff available to meet the case mix on the wards and that nursing staff were supported in professional development by allocated courses and time, to ensure that there was a schedule of clinical meetings such as described in the knowledge section in the Annex D to ensure that annual appraisal was in place and in medical audit processes were taking place in a structured way. Part of this would include ensuring that communication with parents and children was optimal in the form of documentation or verbal support from specialists and from support groups.

425. In the surgical specialties attention was given to ensure that there was adequate cover available 24 hours, and to review theatre allocation and usage to ensure that this was optimal while leaving sufficient space for emergency work and , to ensure that there was adequate anaesthetic support for theatres and resuscitations in accident and emergency, the children's wards and the theatres and intensive care and that there was sufficient medical and nursing staffing to permit a safe and ideally a high quality of care to be delivered. These responsibilities included

making protocols for care available at the point of care and monitoring their use. They may have either been " adopted" or drawn up within the departments.

426. By 1996 clinicians were firmly engaged within structures in Trusts across the UK for achieving clinical input to management. However there was (and is) considerable variation between Trusts in how these arrangements were put in place. In some specialties a clinical lead was identified whereas in others a clinical director would be appointed. Sometimes a single children's directorate would be in place with a paediatrician and lead surgeon for children, anaesthetist for children and radiologist. In others the children's structure was placed in a larger directorate such as all acute services, women and children's and then children's issues relating to surgery would then be addressed through a surgical directorate.

427. Clinical leads and Clinical Directors across a Trust would meet regularly to address cross Directorate issues. The structure of nursing hierarchy should be geared to ensure that there was senior nursing advice available with a focus on children both in the directorate and throughout a Trust as well as setting standards for the wards and other areas in which children were treated. Some of the senior managers supporting clinical directorates had a nursing background. It was good practice to ensure that there was proper representation within the directorates from the other clinical specialties treating children such as physiotherapy speech therapy, psychology and occupational therapy. A further critical linkage between a children's clinical directorates structure was with the supporting diagnostic pathological and imaging services.

428. However the activity of the clinical directorate or clinical lead would be similar and responsibilities undertaken are listed in my main report but critically involve resource allocation, Information systems, staffing -nursing and medical, ensuring postgraduate education and training of good quality was in place and that there were arrangements for professional development. Of considerable importance was the need to ensure development of and access to clinical guidelines and that audit was well-established and updated and also that clinical adverse events reporting, investigation and collation were in place with a focus on safety and prevention of recurrence of adverse events. At the same time annual job plans for consultants should have been reviewed and the on-call and annual leave rotas were constructed to ensure full coverage of all grades of staff.

429. Thus by 1996 RBHSC should have taken note of national guidance and that all necessary change was made and by 1996 these should have been reasonably well embedded. I do not have sufficient information about the systems in place then in RBHSC to be able to comment further. A major part of clinical leadership is to ensure a consciousness of acute and potential significant adverse events and to encourage a reflective "non-blame" approach to clinical governance through audit, death review meetings, clinical meetings etc. The responsibility of the clinical directorate would include implementation of necessary change and to ensure that there was proper representation of children's services within larger Trusts at senior level and board level. RBHSC is open to criticism for its late introduction of clinical

guidelines (only from 1997) and even in the 3rd edition these are deficient in focus on acute neurological conditions (relevant, to Claire). I have not been able to comment on the formulary referred to in the background papers-"*Paediatric Prescriber*" in use in RBHSC at the time as I have not seen a copy.

430. Over the mid-1990s until now there has been an increasing recognition by clinical staff of the need for **professional accountability** not only to the patient and the GMC but colleagues and to their employing Trust with line management responsibilities and subordination to the Chief Executive-a role largely but not entirely delegated to the Trust medical director. Part of this professional accountability has led to more structured engagement in professional development including the use of annual appraisal (introduced regularly in 1999/2000) and the registration of continuing professional development with the relevant Royal College to be able to demonstrate that the individual is held in good clinical standing. This process has now evolved further into reaccreditation of specialists. In this process clinicians will need to demonstrate that they maintain their professional knowledge and skills and increase and modernise their knowledge and practice in keeping with the latest developments and national guidance. More focus now takes place on outcomes of clinical care and safety.

431. Some were supported to go on management courses. However regular scheduled meetings within management structure are time-consuming and it is necessary for a clinical director to attend in order that specialty was properly represented and it was possible for a clinical director/lead to discharge their duties.

432. Later as job plans became more structured there was a role in identifying the workload and number of sessions undertaken by clinicians, organising and arranging rota and annual leave for consultant and junior staff with a view to ensuring continuity and safety. Around 2000 as consultant appraisal became embedded and a more structured approach to continuing professional development became part of this process, the clinical director/lead was responsible for ensuring that all members of the consultant and junior medical staff took part in this process. There were additional processes inherent for mentoring of medical trainees and of supervision and education. This was often undertaken by the identified tutor in paediatrics (and the same would be in other specialties) who related to the postgraduate tutor of a hospital or Trust and, to the regional networks of postgraduate training led by the regional adviser appointed by the relevant Royal College .

433. Consultant appraisals.

434. Consultants are now expected to undergo an appraisal process annually. This together with registration with Royal Colleges for Continuing Professional Development form part of the initiatives in the late 1990s and early and mid-2000 onwards for providing a more structured approach to consultant development and maintenance of standards. The introduction of an appraisal scheme for consultants was linked closely with job planning arrangements for the new consultant contract arrangement. The GMC's proposals call for a five-yearly demonstration of all doctors'

fitness to practice. Under the scheme currently being proposed, this will be based on information and evidence to be seen by GMC panels.

435. In 2000 DH wrote to all CEs of Trust's regarding **Consultant Appraisals. AL(MD) 6/00.** Documentation was provided designed to provide a systematic approach to the collection and presentation of information for appraisal. It will be of immediate use in the next round of annual appraisals and is also designed to be the vehicle for the delivery of GMC revalidation in due course.

436. Every consultant being appraised should prepare an *appraisal folder*. This is a systematically recorded set of all the documents: information, evidence and data which will help inform the appraisal process.

437. CONSULTANT RESPONSIBILITY AND ACCOUNTABILITY

438. Consultant practice was not accountable to clinical directors or directorates or to their employing Trust in respect of individual patient management. Rather the consultant was answerable to the patient and the GMC alone (but also answerable to litigation or complaints' challenges about standards of practice). Nevertheless a consultant was accountable for usage of resource to the clinical directorate and to attend audit meetings in which colleagues as peers could challenge practice by requesting justification or response to criticism on individual patient management. Indeed this culture was encouraged by the audit process and also by the investigation and judgements made about adverse clinical events. More formal accountability from an individual consultant was in place in respect of extreme personal attitudes to patients or colleagues or in failure to be present when on duty or when absent from an agreed fixed clinical commitment set by the review of job plans under the new contractual arrangements. A clinical directorate could become involved in the context of unreasonable or excessive demands placed upon what were always limited resources. Junior medical staff were answerable to the consultant to whom they were responsible when working in teams.

439. From the early 1990s onwards with the review of consultant job plans there was an attempt to firm up the way in which consultants in all specialties worked with annual reviews of job plans and identification of clinical commitments which could be expected-this included cover out of hours.

440. Consultants

441. A consultant takes responsibility for all patients admitted under their care either by planned or acute admission and then responsibility for continuing care of patients admitted on their day on-call for on-going care during that admission and the subsequent follow-up. If problems arose for which they wish to seek another colleagues opinion, say a neurological problem or nephrology problem, the consultant conventionally would remain "in charge" or the lead consultant while the tertiary specialist would offer an opinion and advice. Exceptionally a tertiary specialist would indicate that they will take over the care of such a patient and usually this is

indicated by an entry into the case record. (In these circumstances the hospital Information Systems would allocate the discharged case to that specialist).

442. For out of hours arrangements (usually after 5 PM and up to 9 AM the next day), the consultant on-call takes responsibility for continuing care of patients admitted under their colleagues as well. This applies in all hospitals admitting children. In regional centres however with a range of tertiary specialties, there may additionally be on-call consultants who would be consulted directly by the junior resident staff in certain specialties for problems arising in the patient admitted under the care of that tertiary specialist. The extent to which an on-call consultant covering the whole hospital would be responsible for direct contact about say a nephrology or a neurology or a cardiology patient would vary and on the whole be limited.

443. Much of this is by custom and practice rather than be documented but if there were adverse events or patterns whereby an individual consultant did not conform, this would be raised with the clinical director and general management.

444. The surgical specialties would each have a separate consultant rota. Paediatricians may be asked to offer an opinion at consultant level or at middle grade level on children admitted under a surgeon but the lead consultant would remain the consultant surgeon in whatever specialty.

445. After admission to PICU arrangements vary. In many hospitals there is joint care between the intensive care consultant and the consultant with lead responsibility. For patients transferred in from other hospitals the intensive care consultant is the lead and may invite opinions from a range of specialists.

446. A consultant is also responsible for supervising and directing the junior staff supporting them at the time both in terms of clinical opinion and for educational purposes.

447. **Out of hours on-call** Out of hours the consultant would provide cover from home by telephone or on occasion recall consultation. The consultant would need to be satisfied from their experience or knowledge of the junior doctors that these doctors were competent to undertake the clinical competencies including diagnostic and technical in support of her or his responsibility. Consultants will expect to be called by their senior house officer or registrar to assess unusual cases by discussion or consultation. They would also expect to be called by a senior nurse should the nurse be concerned about any aspect of care. Some consultants, less familiar with the junior medical staff routinely would telephone the Ward at around 9 or 10 pm to check whether there were any problems. In 1996 that practice was very variable. This would be custom and practice rather than in written documentation and be regarded as a means of discharging a consultant's professional responsibility.

448. **Middle grade doctors** : usually registrars or senior registrars but occasionally non-consultant career grades such as associate specialist or more commonly staff grade. Out of hours resident doctors with more experience and greater competencies are drawn from this group. Such doctors are specialists in

training. In paediatrics the majority are training in general paediatrics and rotate through district hospitals as well as a regional children's centre. The rotation to the latter is to offer a range of experience in the tertiary specialties. Some trainees at this grade however are aiming at a consultant post in a tertiary specialty and may remain only in the regional centre.

449. Senior house officers may have less than 12 months experience in paediatrics, they may be paediatric trainees, but may be trainees in other specialties such as paediatric surgery, anaesthetics, accident and emergency or general practice. If they have less than 12 months experience in paediatrics then they cannot cover a service without middle grade cover at resident level. In some district general hospitals, especially small units, a senior house officer with 12 months or more experience will provide the resident care reporting directly to a consultant.

450. **Consultant Contractual arrangements regarding on call.**

451. Hospital policies on this tend to be based upon convention rather than be set out in documentation although consultant job plans in place in England in the 1990s would set out the frequency of the expected on-call rota commitment.

452. The original consultant contract which used in 1970s included the following :

a. *"continuing clinical responsibility of patients in your charge, allowing for proper delegation to and training of your staff."*

b. *"Arrangements for leave and other absences shall in the first instance be made with the Area Health Authority"*

453. (The appointment was with the Regional Health Authority)

454. In Consultants Contracts and Job Plans HC (90) 16 May 1990

a. *Following the paper Working For Patients, there was devolution from Regional Health Authorities of day-to-day management of consultant contracts to their districts and required "all health authorities responsible for the management of consultants contracts to introduce a system of job plans for all hospital consultants." This was to be in place by 1 April 1991.*

b. *"For their part general managers need to have a clear understanding of the work which is being undertaken by consultants and to be in a position to make changes following discussion and agreement with them."*

c. *The job plan will henceforth be part of every contract.*

455. This included a requirement to participate in medical audit under local arrangements (in the light of the relevant department of guidance). and .... include details of out of hours responsibility, including rota commitment.

456. In paragraph 11 of the circular

a. *"The assessment of duties should be made in accordance with the revised paragraph 61 of the terms and conditions of service. The general manager may seek the advice of the Director Of Public Health and make use of any other appropriate source of medical or dental advice (including any relevant College or Faculty guidelines) when drawing up or evaluating a proposed job plan or work programme, in order to facilitate agreement between the consultant and the general manager."*

457. It was from this time that the frequency of the on-call arrangements was specified in the contracts but did not include any specific wording relating to transfer of responsibilities to one's colleagues out of hours.

458. Although the minimum working week was 35 hours in the 1980s, the wording relating to out of hours duties and how this should be taken into account was very non-specific.

459. In an example job description drawn up in 1989 for a new appointment, the acute on-call rota commitment was identified as 1:3 and .

a. *"The person appointed will be required to provide cover for colleagues on a mutually agreed basis in respect of absences from duty."*

b. And

c. *"There is in addition a collective responsibility falling on all consultants to consult with colleagues and, hence, to coordinate their individual activities in order to ensure that the particular clinical services in which they are involved operates effectively."*

460. The contract included an agreement upon the number of fixed commitments from which a consultant should not deviate without agreement with the general local management. The job plan was to be reviewed each year.

461. It was expected that arrangements would be made between consultants to cover overnight and weekend periods and annual and study leave although locums might be put in place for the latter.

462. It would be a responsibility of general and clinical management through HR and Clinical Directorates to ensure that 24 hour cover was in place and met adequate standards . In acute general paediatric practice wording was often inserted to the effect that a consultant should reside within ½ hour recall time and may have specified a distance. It was thus implicit that they had recall capacity at all times to attend within ½ hour of a call.

463. It would also be the case that the on call frequency would be reviewed in a new contract by the R College approval process (usually the RC Regional Adviser)

and also by the RC representative on the (statutory) Advisory Appointment Committee for a Consultant.

464. From the early 1990s the BPA and also other professional bodies were making it clear that acute out of hours responsibilities should not be on a continuous basis. Paediatrics was recognised to be a high out of hours recall specialty in a report commissioned by the Department of Health (England) .Dowie R. *Patterns Of Hospital Medical Staffing-Paediatrics*. Postgraduate Medical Federation. London HMSO 1991. She found that consultants in paediatrics spent the most time on emergency recall any of the specialties studied. In her study Dr Dowie commented on the extra responsibility for consultants in the 1990s such as involvement in management, resource management initiatives and medical audit. She noted to have been added to an already existing heavy workload and recommended that medical assistance should be provided to sustain the clinical services normally provided by consultants who became clinical directors or clinical tutors. She noted that by the mid-1990s, the BPA was advising that consultant paediatricians should be on rota of 1 :4 or less. Dr Dowie wrote that the complexity of work in teaching hospitals (regional centres) was recognised where teams provided specialist and general paediatric cover and also cover at times the neonatal unit frequently requiring more than one junior team on call. In regional centres the specialty care provided is often from academic departments with competing pressure on staff who are responsible for undergraduate and postgraduate teaching and research.

465. In *Hospital Paediatric Medical Staffing. 1993 The BPA* advised that continuity of care should be provided by responsible consultant. And that job plans for consultants should not be overburdened by excessive hours of work or duties inappropriate to experience and skill example resident duties covering SHOs Opportunities should be included for continuing education and professional development.

466. In respect of **consultant management responsibilities** the following paragraph 16 was relevant

467. "where a consultant takes on significant additional management responsibilities in one or more of the following roles: in coordinating the development and operation of medical audit in a hospital district; as a clinical director (or equivalent e.g. consultant in administrative charge) ; in leadership of the resource management initiatives. "

468. The Health Authority in reviewing the job plan of the consultant may enter into a contract up to 1 temporary additional notional half day or, where appropriate, up to 2 temporary additional notional half days. Alternatively a consultant who takes on additional clinical duties as result of, consultant colleague dropping some clinical duties to take on such additional management responsibilities may, instead, qualify for one temporary additional notional half day.

469. ADVERSE EVENTS REPORTING

470. As a specialty, obstetrics and paediatrics together with midwifery had been one of the pioneers of reviewing potential adverse events in their service during perinatal mortality reviews from the early 1970s and the reporting system of the National Confidential Enquiry Into Stillbirth And Death (CESDI) in infancy and this has now extended its age range re-designated as CEMACH into all ages of childhood. However CEMACH only produced first pilot study in 2008.

471. Further in respect of children guidance on the structure and process and to an extent the clinical elements of provision of paediatric intensive care was issued from the Department of Health in England 1997. *Paediatric Intensive Care : a framework for the future.*

472. In the mid-1990s most hospitals had a process in place for reporting serious adverse events and logging them within the organisation. In some regions a regional adverse events process was in place. For children receiving surgical care and anaesthesia a well-defined process was in place- CEPOD from late 1980s

473. The use of adverse event reporting processes still remains very variable. Some are reported but not investigated in detail. Further, there was often no specific definition of what constituted an adverse event. Unexpected or unexplained death would be investigated. For deaths in infancy under the age of 12 months, there was a national reporting system through regions which had developed from regional reporting systems, it was funded and supported by the Department of Health: Confidential Inquiry Into Still Birth And Death In Infancy CESDI . Beyond the new-born period, the main focus was on death which had occurred at home to consider all factors which may have led to the outcome. Hospital deaths formed but a small subset examined in detail. As a result of the Department of Health initiative from around 1999, the confidential Inquiry into maternal and child health (CEMACH) was set up based on CESDI and extended enquiries into all deaths in children. It has reported for the first time in 2008. At the same time because of deaths occurring in children from abuse and neglect, a more structured process has been put in place for the examination of all factors which may contribute a child's death and this process is in hand now over the country following recommendations of joint working party of the Royal Colleges of Pathologists and Paediatrics And Child Health chaired by Baroness Kennedy. *Sudden unexpected death in infancy-a multiagency protocol for care and investigation. 2004.*

474. Where hospital and regional reporting systems were in place in the mid-1990s and even in the late 1990s and early 2000, it was difficult-in my experience-to obtain feedback. For example, in my own trust it was not possible to obtain age stratified drug or medication errors. From a paediatrician this is clearly a major drawback because we were not able to define the child incidents from the system and yet it was known that these were particularly common in children.

475. The National Patient Safety Agency set up a reporting system. However feedback of information and patterns of adverse events in the early 2000 was rudimentary and did not exist in the mid-1990s.

476. Some adverse events in children come to light through death and Coroner's inquests. Others through patient complaint and the need to investigate this at hospital organisation level or through litigation. Some come to light and prominence through the reporting process by hospitals or patients/parents of practitioners to the General Medical Council.

477. The professional defence societies Medical Defence Union, Medical Practitioners Society and others did from time to time published cameo examples of risky events and adverse outcome. A few of these related to children particularly in the diagnosis of meningitis.

478. In the late 1990s in my own experience from the Department of Health perspective, it was not possible to get feedback on age-specific types of adverse events from the National Health Service Litigation Authority. It is only recently that individuals have published from the data sources held by that body relating to children. Recent publications have reviewed litigation cases.

- *An analysis of successful litigation claims in children in England . Raine J Arch Dis Child 2011;96:838–840. Raine J Arch Dis Child August 2011 Vol 96 No 8*
- Some other examples of some adverse event investigations are available
- Deaths from intrathecal vincristine in children
- Deaths from cardiac tamponade in newborn babies
- Investigation of adverse events at Pinderfields.
- NPSA patient safety for children –see below
- *Republished paper: The quest to eliminate intrathecal vincristine errors: a 40-year journey Douglas J Noble, Liam J Donaldson Postgrad Med J 2011;87:71e74.*
- *The Prevention of Intrathecal Medication Errors A report to the Chief Medical Officer 2001 Professor Kent Woods Department of Health*

479. *Department of Health. Review of the deaths of 4 babies due to cardiac tamponade associated with the presence of central venous catheter. London. HMSO 2001.* And *Beardsall K et al. Pericardial effusion and cardiac tamponade as complications of neonatal long lines: are they really a problem? Archives Disease in Childhood. Fetal Neonatal edition. 2003 ;88:F292-295.* which reported a survey which they initiated to as many consultants in neonatal care as possible

identified from a national database.

480. Investigation of adverse events at hospital level.

481. Most hospitals have now set up in a structured process of investigation following reporting of adverse clinical events. These should include all unexpected deaths. Reviews should be through regular meetings or ad hoc meetings held shortly after a major event. Some hospitals-and I include my own here and provide an example of its output-have set up a system beyond that by reporting and logging *all* critical events (such as resuscitations or transfer to ICU) and incidents regardless of outcome. The approach taken here was to review to see whether even if things had been done well, they could have been done better and if not then to log this as well as the more negative connotation only of examining adverse events - because each provide a learning opportunity.

482. The extent to which these arrangements are in place has not, as far as I know , been subject of any survey for paediatrics in the 1990s although the CEPOD data on children is available as also are reports of adverse drug reaction and medication errors for the time through the CSM and MHRA.

483. **Key current publications are** :

484. From US :Woods D et al Adverse events and preventable adverse events in children. Pediatrics 2005;115:155 Most adverse events related to birth and newborn care. It was also found that adolescent experienced high rates. Medication errors were the most studied aspect of patient safety problems in children's medical care but adverse events resulting from medication error were relatively infrequent. It was founded overall that events related to diagnosis which were preventable were greater in children than in adults except for the elderly. The study found adverse event rates to be 1% and preventable adverse event rate to be 0.6 % of hospitalised children.

485. In UK : The NPSA has a data base on children's adverse events now and a method for investigating adverse events has been developed for use in UK http://www.institute.nhs.uk/safer_care/paediatric_safer_care/the_paediatric_trigger_tool.html

486. **Review of patient safety for children and young people NPSA 2010**

487. **NHS Institute for Innovation and Improvement.** Dr Peter Lachman (from Great Ormond Street) has taken a lead in this area.

488. **The NPSA publication Review of patient safety for children and young people NPSA National reporting and learning service. June 2009 :** This report

contains numbers and types of events logged in middle to late 2000s. The majority of patient safety incidents were reported to have resulted in no harm or low harm to the child. Medication errors with the most common reported incident 17%, followed by treatment procedure 13 % and patient accident 11%. Calculations involving decimal points medication were considered a factor in the occurrence of tenfold dosing errors within children's and newborn environment. Slips, trips and falls made over half of reported accidents.

489. The **Healthcare Commission** review of services to children in hospital in 2006 found only 24% of nurses and 7-9% of surgeons and anaesthetists had received any type of communication training relating to children.

a. *"Children with disabilities and complex needs, and their families, in particular expressed concern that they were often not listened to by healthcare professionals about a change or deterioration in their child's condition. They also felt that some healthcare staff did not understand how to communicate with non--verbal children"*

490. GUIDANCE ON HOSPITAL SERVICES FOR CHILDREN

491. In 1991 the Department of Health (England) issued its report-*The Welfare Of Children And Young People In Hospital*. This was mainly focused on the need for hospital services to make particular arrangements for the needs of children and their supporting families/carers when receiving hospital care. Over three quarters of care provided to children in the National Health Service in hospital is provided in district general hospitals. The main emphasis of the report was on ensuring that staff involved with children had clinical expertise in their care and were sensitive to their emotional and development needs and were able to communicate well with children and their parents/carers. Clinical aspects received rather less attention although emphasis was given to the management of pain with pain protocols and some discussion about medication. In respect of clinical expertise, much consideration was given to the need for surgeons and anaesthetists who mainly practised with adults but who also as a portion of their care service provided for children had special training in and maintained expertise in the care of children. Furthermore attention was given the need for nurses on children's wards and in accident and emergency to have the children's nursing qualification. There was concern at that time also about the extent to which children were being treated on adult wards. It was intended that children up to the age of 16years should all be treated in children's facilities. To a large extent children's hospitals were able to meet the needs specified set out. Nevertheless RBHSC should have had had a process of reviewing the document and considering whether the requirements were met and in particular to consider whether arrangements for children over the age of 13 years were being attended to.

The *National Service Framework for Children DH 2003.* Covers hospital services for children extensively including advice on clinical safety and governance.

492. ROLE OF ROYAL Colleges AND PROFESSIONAL BODIES

493. The Royal College and professional associations were able in the 1990s and before and to an extent still to exercise influence upon the quality of training and range of experience in two ways within a hospital.

494. Firstly they were responsible for reviewing the quality of the training available for trainees in the specialty and in many district general hospitals senior house officers rotating through specialty aiming at a principal post in general practice. Regular reviews of hospitals was undertaken by the (Medical) Royal Colleges under the umbrella of the joint committee on higher medical training JCHMT (until mid 2006). If the training available to a post was found substandard, a report would be provided to the consultants involved, to the postgraduate tutor responsible for the specialty, to the postgraduate tutor responsible for the hospital and, to general management through the Chief Executive. Training approval could be withdrawn but usually this would be a qualified approval pending appropriate changes to bring the quality up to standard. The sanction of withdrawal of training approval had significant impact upon a hospital. It would not be possible to employ junior doctors in training as resident doctors for example to cover 24-hour 365 days a year service. Rather this responsibility would need to fall upon consultants or rely on employment of non-consultant career grades such as staff grade or associate specialist. In practice It would be very difficult for a hospital to recruit sufficient consultants or non-consultant career grades to cover the service and this would have significant management implications possibly even leading to closure of a service. General management and the Chief Executive and clinical directors would be under considerable pressure to bring the training up to standard.

495. In the past the influence which (Medical) Royal Colleges and professional associations had on individual consultants was limited. Opportunities arose when a new consultant post was established or when a consultant was retiring to be replaced. In these circumstances the consultant post would need to be approved by the appropriate Royal College in respect of its workload, responsibilities, and the support available for a consultant to discharge their responsibilities including time for postgraduate continuing education and professional development and audit. If a job description did not contain sufficient time or resources to enable this to happen in the view of the Royal College , to enable the new appointment to discharge his/her responsibilities (excessive workload, insufficient secretarial support, appropriate time allocated etc.) then a post would not be approved for advertisement. A further opportunity existed for the Royal College to influence the service and the consultant post was during the appointment interview itself where there was a statutory requirement under the advisory appointments committee arrangements of the NHS to have a Royal College representative present at the interview and appointment procedure who could if necessary prevent the appointment progressing. This would cause a service to be under considerable pressure to meet the requirements set.

496. From the 1980s and expanding in the 1990s and beyond, (Medical) Royal Colleges have provided guidance upon standards not only have individual professional practice but also on the standards to be achieved by services within the specialty in respect of hospital facilities and supporting staff with a commentary also upon workload. This was with high quality care in mind rather than protecting individual doctors from exploitation. It was within this context that the Colleges issued guidance upon medical audit later relabelled as clinical audit.

497. The (Medical) Royal Colleges also provided advice to the Department of Health either on their own initiative or following consultation. The Department of Health had a series of structures to enable such advice to be sought by the Department. This was through the Academy of medical (Medical) Royal Colleges or through the Standing Medical Advisory Committee or through ad hoc working groups and parties. The chief medical officer had an adviser in each specialty and this role was gradually supplanted as was the role of the standing medical advisory committee.

498. **The Academy of Medical Royal Colleges** :The Academy's role is to promote, facilitate and where appropriate co-ordinate the work of the Medical Royal Colleges and their Faculties for the benefit of patients and healthcare. The Academy comprises the Presidents of the Medical Royal Colleges and Faculties who meet regularly to agree direction. The Academy's membership comprises Medical Royal Colleges and Faculties across the UK. The Academy seeks to support and co-ordinate the work of Medical Royal Colleges on issues of concern. (It was renamed from the original 1974 The Conference of Royal Colleges and Faculties.) It is undertaking an increasing role in the process of re-validation. And has recently (2012) considered the evidence for benefits of consultant delivered care .

499. **Standing Medical Advisory Committee** : SMAC and the standing nursing and midwifery advisory committee SNMAC. These committees were supported by the secretariat from the Department of Health and had members nominated by the Colleges including the presidents of the College s. Unlike the joint consultants committee and initially conference of medical Royal College s, SMAC had GP and public health representation. At times SMAC would consider clinical matters and issue guidelines. For example for children care of haemoglobinopathies and sickle cell disease ; Licensing and prescribing of drugs in children 2001, Evidence Into Practice.

500. The **British Medical Association and the Royal Colleges of Nursing and Midwives** would also be consulted by the Department of Health or at times through working groups constituted by themselves offer advice on standards.

501. **The British Paediatric Association** was the main professional association to which all paediatricians in United Kingdom belonged. In 1994/5 this became the Royal College of Paediatrics and Child Health and from that time undertook all the responsibilities which (Medical) Royal Colleges take on. Until that time the responsibility for approval of training posts and for approval of consultant posts on

appointment was held by the Royal College of Physicians either of London, Edinburgh or Glasgow. (I will check upon whether Northern Ireland was covered by RCP (L.) The paediatric advice available to the Royal College of Physicians was through the paediatric vice president of the Royal College of Physicians of London and the paediatric committee of the Royal College which was made up of senior officers of the BPA. The regional advisers who had responsibility for implementing College policy and for supervising postgraduate training within the regional behalf of the College were appointed jointly by the Royal College of Physicians and the BPA until the Royal College of paediatrics and child health took on the responsibility themselves. It was the (Medical) Royal Colleges which set up in paediatrics the regular reviews but this would also apply to the Royal College of Surgeons and the Royal College of Anaesthetists in respect of other posts and the faculty of accident and emergency medicine in relation to accident and emergency. Equal arrangements would be in place for the specialties of anaesthesia, pathology, radiology within a hospital. In 1994 example the BPA produced a document on the training requirements for as the job description model, consultant in paediatrics with special interest in community child health. This was then approved by the BPA Council and the Royal College of Physicians .

502. The **Association of Paediatric Anaesthetists** and the **British Association of Paediatric Surgeons** were each one of the professional associations which undertook many of the advisory roles of Royal Colleges usually through the relevant Royal College committee processes. (Royal College of Anaesthetists, Royal College of Surgeons respectively.)

503. The Royal College of Surgeons (England) has a Children's Surgical Forum. Its first report was in 2000. This is its current description

- The principal role of the Children's Surgical Forum is to enable the College to meet its commitment to improving the quality of surgical care for children. The Children's Surgical Forum brings together a range of professionals involved in delivering surgical services to children. This includes representatives from the College, the surgical specialist associations, other medical royal colleges, the College's Patient Liaison group and the Department of Health. The Children's Surgical Forum's main objectives are:
- To monitor the implementation of the recommendations contained in *Surgery for Children – delivering a first class service,* particularly those relating to professional standards, education, training, assessment, CPD and audit.
- To keep under review and where necessary update the standards contained in the report.
- To formulate guidance on matters relating to the provision or delivery of children's surgery.
- To collaborate with other Royal Colleges, specialty associations and statutory bodies to develop a more integrated approach to healthcare planning and provision for children and young people.

- To enable the College to respond promptly and constructively to concerns relating to the provision of surgical care to children, at a national or local level.
- To promote involvement in external policy development by fostering communication links with relevant stakeholders (eg. DH, SHAs, Trusts, commissioners, etc)
- To provide quality information to professionals, parents and children on the College website.

504. The **Royal Colleges of Pathology and Radiology** provide similar functions – for example the latter produced guidance on referral for imaging in children in the mid 1990s.(see Knowledge supplement for more examples)

505. **The ROYAL COLLEGE OF NURSING** has had a children's nursing adviser over at least the past 20 -25 years. The Royal College has been represented in many national working parties and groups e.g. the National Service Framework and close relationships have been maintained between the RCN and the BPA/Royal College of Paediatrics and Child Health and the Royal College of Surgeons over the years with much collaborative work.The RCN had a major contribution to the Bristol Inquiry and the Department of Health production of guidelines on the Care Of Children in Hospital and on the design of children's units.The RCN has produced a number of publications which are listed on their website.

506. CONTEXT : THE ROYAL BELFAST HOSPITAL FOR SICK CHILDREN : GENERAL AND SPECIALTY PAEDIATRICS

507. The hospital to which Claire was admitted is a children's hospital situated within a complex of hospitals on the same site which treat adults forming the Royal Hospitals and Dental Hospital, Health and Social Services Trust. Claire was admitted to the centre of excellence in Northern Ireland for hospital care of children. RBHSC is the main children's hospital for the province and provides a range of Tertiary services for the population. It is also a teaching centre for junior doctors and nurses in high-quality practice so that they can carry this high standard with them wherever they work in future.

508. Such regional centres usually also provide *general paediatric* care for the local population. The advantages which are gained for a children admitted into a Children's' hospital are they are cared for in an environment which is specifically matched to children's needs and it is expected that there will be high standards of knowledge and practice amongst nursing, medical staff and that laboratory and other investigation facilities are specially geared to the needs of children with easy access to tertiary care specialist care or intensive care when needed.

509. The Children's Hospital- Royal Belfast Hospital for Sick Children RBHSC - sits within the health services for children in Northern Ireland as the hub /centre of a network of general hospitals providing specialist children's healthcare to the children of the province. As such it provides the *regional tertiary specialty services* as well as

providing a general paediatric specialty service for its population. From the job description for the Ambulatory Consultant in ? 1996 it was stated that the hospital treats approximately 40,000 outpatients and 10,000 inpatients per annum with a further 25,000 patients attending the accident and emergency department each year.

510. Regional specialty services are recognised as Tertiary services in contrast to the general paediatric specialty services which are regarded as Secondary specialist care.

511. **Tertiary services for children and young people. British Paediatric Association (BPA) 1995 described these** :

512. " Children's tertiary services are those specialist services which are not provided routinely at district general hospitals because the medical conditions involved are relatively uncommon and the treatments required may be complex and require involvement of specialists are experts both in the care of children and in the specific condition." The list of tertiary services includes

513. Cardiology and cardiothoracic surgery, endocrinology, gastroenterology, clinical genetics, haematology, immunology, infectious disease, metabolic disease, neonatal intensive care, nephrology and urology, neurology and neurosurgery, oncology, paediatric intensive care and anaesthesia, paediatric pathology, paediatric surgery, plastic surgery and Burns, radiology, respiratory medicine, rheumatology, specialist services for disabled children

514. **Secondary and tertiary relationships in paediatrics.**

515. District general hospitals provide the majority of secondary general paediatric care and a range of surgical specialty services for children such as general surgery, ENT and ophthalmology, trauma and orthopaedics.

516. Referrals from the district general hospitals : -secondary to tertiary- take place from consultant to consultant or at times directly from the general practitioner to the Tertiary specialist. In this respect RBHSC is similar to other regional Tertiary Children's Hospital services within the United Kingdom. The vast majority of similar services -other than Great Ormond Street- provide a secondary care level general paediatrics for the surrounding population. The London Implementation Group Report of an Independent Review Of Specialist Services In London-Children in 1993 recommended that hospitals which aim to provide Tertiary services should first aim to provide a full range of child health services for the local population (supporting the view of the BPA).

517. The consultant paediatrician hospital staffing numbers of Tertiary children's services tends to be greater in number because of the concentration of the specialties. In a regional/ tertiary service such as in RBHSC, the general paediatric care for the surrounding population is provided by general consultant paediatricians

and to varying degree also by the "organ" specialty tertiary paediatric consultants the latter especially for out of hours cover. Because of the nature and range of the specialties concerned, paediatric neurologists, paediatric cardiologists and frequently paediatric nephrologists and oncologists do not take part in the acute general paediatric rota or cover arrangement because they need to cover their own in-patients and provide 24 hour cover for the specialist aspects of their service in the region/province. On the other hand consultants in endocrinology, gastroenterology, respiratory medicine, infectious disease etc. frequently share in the general paediatric rota. Neonatal paediatrics in a regional centre is usually located at a maternity hospital, sometimes on the same site and neonatal consultants usually (but not always) do not take part in the acute general paediatric rota. In some services, the consultant paediatricians who work largely in the community with responsibilities for child protection, the care of children with neuro disability etc. do not take part in the acute general rota but in other services they do including in RBHSC. In the Ambulatory Consultant job description (in DLS papers) there were 12 consultants listed in RBHSC with general paediatric as well as specialty responsibilities:

a. Dr A Redmond general paediatrics (cystic fibrosis), Dr M Reid general paediatrics (neonatology), Prof J Dodge general paediatrics (gastrology/cystic fibrosis),Dr J Glasgow general paediatrics (accident and emergency medicine),Dr D Carson general paediatrics (endocrinology/metabolism),Dr Shields general paediatrics (respiratory disease), Dr M Stewart general paediatrics (community paediatrics),Dr P Jackson general paediatrics (infectious diseases),Dr A Hill general paediatrics (community paediatrics),Dr M Savage general paediatrics (nephrology),Dr M O'Connor general paediatrics (nephrology),Dr H Steen general paediatrics (community).

518. The paediatric neurologists 9 Drs Webb and Hicks) and psychiatrists are listed separately.

519. <u>General paediatric practice</u>

520. General paediatric practice includes inpatient care and outpatient management of acute and chronic disorders both for diagnosis and treatment. The general paediatrician will take responsibility for diagnosis and management of a wide range of high and medium prevalence disorders which lie within their competence. With low prevalence or complex disorders they will usually contribute initially by making or assisting in the diagnosis or arrange referral to a specialist in a regional centre for diagnosis of unusual presentations or management of diagnosed rare disease. They then contribute to the joint long-term management of long-term illness or complex disorder in collaboration with the regional Tertiary specialist. Some children will remain only under the care of the Tertiary specialist and the GP. However when those children develop an intercurrent illness or experience a deterioration of an acute nature in their long-term or complex disorder, often they will be provided initially with care by the acute general paediatrician. Acute illness in

children occurs throughout the 24-hours but there are frequent peaks of presentation to hospital of undifferentiated illness for diagnosis and management in the evening.

521. The BPA in the 1990s recommended that there should be a minimum of 4 consultants able to take part in the on-call rota for acute paediatrics.

522. In 1996 and the adjacent years, consultant general paediatricians in district general hospitals would usually cover the newborn as well as general paediatrics. They would expect to take part in an acute on-call rota of around 1: 4 or 1:5 for out of hours 24-hour cover of the hospital. In regional specialty hospitals such as RBHSC the rota commitment may have been around the same but in larger hospitals with more consultants the frequency of rota 24-hour cover would be less and they would not cover neonatal paediatrics if the service is located on a separate maternity unit as it was in Belfast.

523. The BPA produced a range of guidance at this time some of which is listed. *In Purchasing Health Services For Children And Young People, 1994, it states:*

524. "general paediatric practice encompasses the diagnosis and treatment of many childhood medical problems. Many of these are transient illnesses requiring in some instances, fairly high dependency care, but generally have a good outcome. ……. Children present with illness throughout the 24 hours with frequently an evening peak. Easy ability to change the care of a child from one stage therapy to another is essential to prevent complications or chronic illness, disability or mortality. Thus children admitted with acute illness should be cared for in a unit which can move its level of care very quickly and flexibly from the commonly used lower level to the less commonly used high-level

525. **Ambulatory Paediatrics**. The term consultant paediatrician in ambulatory care which was used in one of the job descriptions in RBHSC in 1996 ? has been variously used either to describe consultants who work largely in the community or, in contrast, to describe consultants in emergency paediatric medicine who provide cover for the accident and emergency department or for supervision of an associated unit with that department the paediatric or children's acute assessment centres aiming to reduce duration of hospitalisation. This latter service is an evolving one. In the mid-90s the service was in its early stages. *Ambulatory Paediatrics. BPA 1997*

526. It appears that in RBHSC , the consultant responsibility for providing paediatric specialty input into accident and emergency was the general paediatric consultant on call supported by junior staff. I do not know the location of accident and emergency department or whether this was a specialty children's accident and emergency department or whether paediatric input was provided for the general accident and emergency department in the main hospital. More lately accident and emergency departments located within regional children's hospitals or services are staffed by consultants in the specialty of accident and emergency medicine who have specialised in paediatrics. Other consultant paediatricians have developed a special interest in accident and emergency medicine and this development has occurred in

the 2000 although in 1996 one consultant in RBHSC Dr J Glasgow was identified as having A&E as a special interest.

527. To demonstrate the context within which RBHSC sits in United Kingdom I provide some information on the size of RBHSC in contrast with other regional specialty services in United Kingdom in the Table NN . The size of a population served has impact upon the size of service in respect of numbers of consultants and beds provided. The population of Northern Ireland in the mid-90s was[to determine].

528. <u>Paediatric neurology</u>

529. Recommendations for Paediatric neurology From *Tertiary Services For Children And Young People. BPA 1995*. Extracts

530. In 1981 working party set up by the BPA, BPNA and the Royal College of Physicians produced the Tizard sent to all 4 CMOs. This report recommended that consultant paediatric neurologist duties and responsibilities should include

- *An efficient Tertiary consultant service, 24-hour telephone advisory service, responsibility for the care of in- patients with serious neurological disorders, follow-up clinics for selected children with neurological and developmental problems, peripatetic regional clinical service, postgraduate education of consultant paediatricians and senior registrars in paediatrics and in paediatric neurology, research, in some instances membership of the local district handicap team.*

- *The care of in patients with serious neurological disorders requires access to a paediatric intensive care unit. Children with acute encephalopathy at risk from complications of raised intracranial pressure should be managed in the unit which has frequent experience of such patients and rapid access to neurosurgical services.*

- *The pattern of work at a regional centre should be to provide, in addition to diagnosis and management of acute neurological problems, diagnosis and management of chronic neurological disability as part of a combined regional service.*

- *Paediatric neurologist services need to be part of the paediatric unit with access to paediatric specialty services including intensive care.*

- *Each paediatric neurology centre is to have ready access to neuroradiology including magnetic resonance imaging, neurophysiology, neuropathology, a child assessment centre and the paediatric subspecialties of intensive care, neurosurgery, oncology, radiotherapy, orthopaedics, ophthalmology, audiology, psychiatry and clinical genetics. Most other tertiary paediatric subspecialties require input from paediatric neurology. It recommends that there should be more than one paediatric neurologist at each centre.*

531. The job description provided for the consultant paediatric neurologist post to which Dr Webb was appointed in around 1995 describes the hospital as : (from DLS) ,

532. The Royal Hospitals and Dental Hospital, Health And Social Services Trust is the largest hospital complex in Northern Ireland, comprising the Royal Victoria Hospital, Royal Maternity Hospital, Royal Belfast Hospital for Sick children, and the Dental hospital. There are approximately 900 beds on-site and most of the regional specialties are concentrated on campus. The Royal Belfast Hospital for Sick children (RBHSC) is a 140 bed hospital which functions as a district general paediatric unit and in addition houses most of the paediatric regional specialties the Northern Ireland, including intensive care, neonatal surgery, trauma and orthopaedics, plastic surgery and burns, child psychiatry, nephrology, neurology, cardiology, respiratory paediatrics including cystic fibrosis, oncology and dentistry. There is a child development clinic and a paediatric A&E department. There is a laboratory on site which provides limited haematology, biochemistry and bacteriology with the main hospital laboratory complex including the regional endocrine laboratory and virus reference laboratory a short distance away on-site. Within RBHSC also is a radiology department, a dietetic department, physiotherapy Department, clinical psychology, speech therapy, occupational therapy and play specialist Department. A new development is currently in an advanced stage of planning for RBHSC . This building will provide significantly upgraded accommodation with extra space for a new A&E department, outpatient Department, theatres and intensive care unit and medical records Department. The Royal Victoria Hospital provides the regional neuroscience facilities including neurology, neurosurgery, neurophysiology, neuropathology, neurochemistry and electron microscopy, neuroradiology including CAT and MRI and many other regional specialties including ophthalmology and ENT/audiology. The regional neonatal unit is located in the Royal Maternity Hospital.

533. The Royal hospitals trust was established in April 1993. It has established a system of clinical directorates with devolved budgetary responsibility to a clinical management team led by a clinical director, assisted by a directorate manager. The majority of services provided within RBHSC are managed by the paediatric directorate.

(The list of medical paediatric consultants is as above)

Dr Hicks paediatric neurology.

<u>Paediatric cardiology</u>

Dr Mulholland

Dr Craig

<u>Paediatric psychiatry 4 consultants</u>

<u>Paediatric surgeons</u>

Mr Boston ,Mr Brown,Mr Potts

Paediatric radiology-Dr Thomas and Dr Sweeney.

Junior medical staff

534. RBHSC has six senior registrars/registrars in medical paediatrics and two in paediatric surgery. There are four second term senior house officers of whom eight are in-house rotations and nine first term senior house officers.

535. *There is one full-time equivalent senior registrar/registrar-paediatrics shared with neurodevelopmental paediatrics and one full-time equivalent senior house officer (RBHSC second term rotation) shared with neurodevelopmental paediatrics and paediatric dermatology.*

536. WHAT GOVERNANCE ARRANGEMENTS COULD BE EXPECTED IN RBHSC.

537. Towards the end of the 1990s and by 2004, a much more structured approach was being taken to the use of clinical guidelines and adoption of them by units. At the same time personal development of clinicians was receiving greater attention in the form of continuing medical education/continuing professional development and later by the process of annual appraisal. More attention was being given to safety. The identification of the hyponatraemia related deaths in Northern Ireland is a good example-pioneering for its time of sharing of adverse event and implementing change. I do not know whether audits have been carried out to determine compliance with the guidance. I do not know to what extent the Hyponatraemia guidance and alert was shared nationally in UK.

538. Key clinical documents relating to governance in Children's services for this time are listed after this section. In addition the first NICE guidance on children became available from 2002 (and the topics covered are listed and dated in main report). From the Department of Health (England) came the paediatric intensive care reports including high dependency care, the National Service Framework For Children and the establishment by the Department of Health of some national audits: the paediatric and neonatal intensive care audit networks from late 1990s. In 2000 the Royal College of Surgeons produced a report and guidance on standards : *Children's Surgery: A First Class Service 2000*. A key milestone was the publication in 2001 of the report of the Bristol Inquiry with its wide implications for governance in Children's services. DH (England) published in 2003 The National Service Framework for Children which included advice on hospital services (including governance).

539. I am not clear as to what extent DHSSPS(NI) commended these documents but I would expect RBHSC to have reviewed these within the clinical directorate structure

540. Specialty audits either within paediatrics or surgery or within specialties of paediatrics and paediatric surgery were being carried out. For example the BPA/RCPCH, gives advice upon management of guidelines and audit and published a document compiled from reported experience of methods. The children's national cardiac surgery audit is a good example of national audit networks developed by specialty groups and CEPOD covered children's surgical care.

541. The British Paediatric Surveillance Unit reporting systems were well-established in the early 1990s but by the late 1990s and early 2000s were increasing their portfolio and reporting back-important because rather like CEPOD, all practising consultant paediatricians were involved regularly-with regular negative reporting as well as positive. One of the responsibilities of a clinical directorate and an employing Trust is to ensure that clinicians and services take part in national audits.

542. The degree to which RBHSC complied with this above activity remains to be seen. There was a Royal Trust clinical risk reporting system in place at least by the late 1990s but I have not seen any analysis of the clinical events and whether there was particular focus on children. A robust medication policy should have been in place for children and later ready access to the British National Formulary for children which was available from 2005. Up to that point one would expect an adopted paediatric formulary to be in place throughout the Royal Hospitals Trust and the neurosurgical unit as well as accident and emergency including a medication or prescribing checking process and reporting system of adverse events. In the late 1990s there was considerable focus on medication safety in children with the emergence of improved published advice coming in the publication by the RCPCH and Neonatal And Paediatric Pharmacists Group *Medicines For Children* (2001 and 2005) and then later in the British National Formulary for Children 2005. It would be helpful to see what reviews of medication safety were in place in RBHSC and also whether its in- hospital prescribing document had been updated since the one referred to in 1996. Other children's hospitals have created their own in-hospital formularies. It may be that these were adopted by RBHSC but if so some documentation should be available and involvement of paediatric medical anaesthetic and surgical staff with formularies together with nursing colleagues and pharmacists should have been in place through some form of Medicines Committee within the Trust .

543. **COMMENT ON EVOLUTION OF CLINICAL GOVERNANCE**

544. The acceptance of guidelines by professionals in the later 1990s was gradual. There was much scepticism voiced about "Cook book medicine" and apprehension about curtailment of consultant clinical freedom. Many held a view that there was little evidence basis to support the content of guidelines-a reservation which had some justification because even now many are based upon the lowest level of evidence, that is: clinical consensus.

545. Consultant practice was not accountable to clinical directors or directorates or to their employing Trust in respect of individual patient management. Rather the consultant was answerable to the patient and the GMC alone (but also answerable to litigation or complaints' challenges about standards of practice). Nevertheless a consultant was accountable for usage of resource to the clinical directorate and to attend audit meetings in which colleagues as peers could challenge practice by requesting justification or response to criticism on individual patient management. Indeed this culture was encouraged by the audit process and also by the investigation and judgements made about adverse clinical events. More formal accountability from an individual consultant was in place in respect of extreme personal attitudes to patients or colleagues or in failure to be present when on duty or when absent from an agreed fixed clinical commitment set by the review of job plans under the new contractual arrangements. A clinical directorate could become involved in the context of unreasonable or excessive demands placed upon what were always limited resources. Junior medical staff were answerable to the consultant to whom they were responsible when working in teams.

546. From the early 2000s there was an increasing focus on evidence-based medicine and through the processes of registering Continuing Medical Education/Continuing Professional Development there was the implicit commitment to a lifelong learning experience. There was greater emphasis on more consistency in practice for patient safety, education, rational use of resource and working with colleagues. In general there was more openness about sharing adverse event experiences in the processes of audit and reflective processes encompassed in the annual appraisal process. It was a responsibility of the employing Trust through the clinical director and directorate to ensure that an individual clinician was engaged in annual appraisal and the Royal Colleges provided a process of endorsing a consultant' s good standing through the process of registering defined continuing professional development points and taking part in annual appraisal. A clinical directorate would encourage demonstration of attendance and certification from the advanced paediatric life-support course or paediatric advanced life support course for nursing staff on the children's wards as well as the medical staff and in the case of the surgical teams on advanced life support courses or trauma courses. The volume of surgical practice in terms of numbers of particular operations and the numbers of anaesthetics administered would also be taken into account. Nursing staff did not undergo the 360° appraisal which was in practice for consultants but nursing individual professional development was regularly reviewed by senior nursing staff. Pathology laboratory biochemical and haematological systems took part in external quality management processes and clinicians requesting radiological examinations were supposed to attend courses which increased awareness of indications and risks. Radiologists carried out double reporting of selected numbers of cases. Histological examination in pathology had a similar quality control management. Oncology care was largely with the tightly set therapy care pathways at a national level. It was a responsibility of a clinical directorate to ensure that all these activities were taking place and documented.

547. Increasingly in the 2000s consultants were aware of the need to be answerable for their practice in a more robust way and in order to do so would rely upon adherence to guidelines and would want to be able to demonstrate standards of practice through audit and listing of complaints and complimentary letters. Consultants also became increasingly aware of the requirement to be able to answer complaints which had been raised by patients, colleagues or management through the processes of referral to the GMC or through litigation. To a large extent these processes still apply with the expected process reaccreditation also providing a more tightly drawn structure within which clinical practice takes place.

548. **RESPONSIBILITIES OF A CLINICAL DIRECTOR OR CLINICAL LEAD (MacFaul views)**

549. These should include the following

a. Representing the specialty and/ or service within the management structure of the Trust and relating to the Medical Director of the Trust who is responsible at board level for medical management issues within the Trust as well as corporate responsibility as a board member. This will entail regular scheduled meetings as well as the need to meet regularly (minuted) with the senior nurse and general manager responsible for the service. A management structure within the hospital Trust would be in place and a clinical director / lead should ensure appropriate representation of the specialty or areas within the Directorate by negotiation with the Trust Board, CE and Medical Director.

b. The varying responsibilities of a directorate/ clinical director includes as a minimum:

c. Reviewing the resources available for the service, identifying shortfalls and making plans and budget arguments or administrative arrangements to rectify shortfalls. This includes nursing staff in the wards or outpatients and the therapies, and clerical and secretarial support to ensure speedy communication by discharge letter to general practitioners or others, and the availability of equipment.

d. To be responsible for ensuring that annual leave is coordinated with consultant colleagues and with junior medical staff to be sure that the service is adequately and properly covered and at the same time that staff are able to take the entitlement. This may have involved engagement of locum staff.

e. To review the financial position of the directorate although the degree to which a clinical director/lead has influence on or responsibility for this varies considerably. This will entail resource management and budget reviews necessary to achieve Trust wide strategies in cost improvement programmes and to ensure that there is proper representation at higher

level within the Trust management of the services within the directorate to ensure that quality and safety is not threatened.

f. To consider problems which arise in daily routine care such a shortage of or availability of medical or nursing staff, excessive pressure on beds, access to imaging, pathology etc. especially out of hours.

g. To consider developments for additional staff, and replacement or purchase of new equipment.

h. The clinical director together with senior nursing and senior management representative should hold regular meetings (with agendas and minutes) at least monthly with ad hoc meetings in between. The meetings would allocate responsibility for implementing issues requiring change and monitoring the implementation. The regular clinical directorate meetings (held as an executive core group) should ensure in that systems are in place to receive reports on the range of activities listed below at least annually.

i. In addition within the clinical directorate meetings should be set up at not so frequent intervals to include all members of the clinical and investigation teams dealing with patients and services in support of their care. In paediatrics and child health this would include nursing, pharmacy, and therapists as well as doctors.

j. To ensure there is adequate support with IT the process of patient management, clinical audit and eventually the presence of decision support and linkage with laboratories and x-ray departments when this is in place. (This is a slow process).

k. To act in a leadership role with all professional colleagues within the service including the therapists, nursing, pharmacy, doctors, play therapists outpatient staff etc.

l. Ensuring that clinical audit (topic audit, case note audit,) is in place, supported and recorded. To ensure that the department is involved in the relevant national audits such as CEPOD , CESDI , diabetes and other national audits of the specialties such as anaesthetics and any of the specialty Associations.

m. Investigating adverse events and preferably setting up a regular system of critical events reviews including death review. Also investigating and assessing complaints.

n. Together with the general manager to review the job plans and work commitments for all consultants within the directorate-ideally at an annual level.

o. To ensure that staff within the directorate are fully trained in child protection.

p. To ensure that there is development of and updating of guidelines or protocols available on the wards and that staff are familiar with these.

q. Responsible with HR for the appointment to the appointment procedures within the Trust of junior and senior medical staff and at times appointment of senior nursing and managerial staff.

r. To ensure that weekly meetings or other frequency clinical meetings are in place and that there is a proper agenda for its content.

s. To review medicines safety and quality issues often relating to the Trust 's medicines committee

t. To ensure that staff involved in the care of acutely ill children are up-to-date with advanced life support usually through attendance and certification at courses such as the advanced paediatric life-support course or paediatric advanced life support course.

u. To monitor the process of consultant appraisal and ensure that all doctors are engaged with this. There is no equivalent system for appraisal of nursing staff by the clinical director. This is usually carried out by the senior nurse managers. Nor is there a 360 degree appraisal process for general managers although doctors are expected to engage in 360° appraisal with contributions from all with whom they came into contact. To review the working patterns of consultants annually to review their job plans-in the 1990s a regular event conducted through a management process but in the 2000 onwards through the process of consultant appraisal.

v. To ensure that a and appropriate postgraduate training programs in place with a tutor for trainees, continuing medical education in a structured way in place all consultants and noncareer grades registered with their College . To ensure that the postgraduate tutor and the tutor for the specialty is supported in their roles.

w. To ensure that there is proper representation of the directorate on Trust wide committees responsible for resuscitation, medicines and safety, prescribing, etc.

550. Many of the elements of these responsibilities can be undertaken by the clinical lead/director but there are a number of areas where the responsibility is delegated to a colleague to take the lead. This would include appointment on or nomination to internal hospital committees such as the medicines committee, clinical audit, postgraduate education-CME-usually through the postgraduate tutor, mentoring of junior staff etc. It would also include the supervision of and mentoring of medical students if they are placed within the directorate**.**

551. Audit

552. The clinical director would also be responsible to the Trust through the Medical Director or directly to ensure that clinical audit was in place and that the results of the clinical audits in terms of need for change or issues of safety would be drawn to the attention of general management. Having done so it would be for the clinical director and others within the Trust to ensure that changes were made and after an interval to audit again to check both that the changes were implemented and that improvements were occurring and in safety areas that incidents were reduced or prevented.

553. CLINICAL MANAGEMENT STRUCTURES IN RBHSC

554. In a letter from DLS of January 2012, the current management structure for RBHSC is described.

a. *The Belfast Health and Social Care Trust is managed through a system of clinical and non-clinical Directorates of which Specialist Hospitals, Women and Child Health is one and RBHSC is managed within this. The Director, along with the Co-directors, is responsible for the management arrangements within the directorate. An Associate Medical Director is responsible for the Directorate and a Clinical director is responsible for the Medical and Surgical Specialties within RBHSC.*

555. In the attached documentation also provided organisational structure charts for arrangements 1995/1998 and now.

Comment: from this documentation a number of issues arise on which it would be helpful to have greater understanding. These are

a. What were the job descriptions and responsibilities of the clinical director responsible for the medical and surgical specialties within RBHSC.

b. At what level within the structure was there a review of the adverse events, clinical audit, consultant job plans etc.

c. What representation at Trust board level is there for children services.

d. In the 1995/8 structure there is identified within the Medical Director' s infrastructure a clinical director for paediatrics. There is also a clinical director for "clinical professions"

e. What was encompassed in the role of the director for clinical professions.

f. To clarify whether the clinical director for paediatrics was responsible for the arrangements within RBHSC for all of the specialties located there-children's surgery, paediatric medicine, the intensive care, anaesthetics, laboratory investigations, neurophysiology. Also to what extent there was a schedule of meetings between the paediatric lead and laboratory and imaging leads etc.

g. Are there any minutes from this time which provide the agendas and topics discussed?

h. Was there a process for review of adverse events and deaths?

i. Was there a process for receiving lists of audits (in this matter however although the intention of the Department of Health guidance has been that reports of audits would be sent up to the Chief Executive, in practice this rarely occurred).

j. It will also help to see the job descriptions of the clinical directors for women's and children's and for the paediatric directorate.

k. It would help to see records of the content and type of meetings were held of the directorate group.

l. What was the make-up and general management support to the clinical director and what was the relationship with the senior nursing officer and nursing management..

556. **RELEVANCE OF ISSUES IN CLAIRE'S CASE TO OTHER CHILDREN'S DEATHS ASSOCIATED WITH HYPONATRAEMIA**

557. The relevance of Claire's death to Adam Strain was that both children were at high risk of Hyponatraemia : for different reasons. In Claire's case this was a known associated risk with syndrome of inappropriate ADH secretion because of the acute encephalopathy. This was not appropriately managed. Attention and focus on low sodium by the treating clinicians should have been given in any event in an acute encephalopathy but with the recent publicity given to Adam Strain, heightened awareness might have been expected within RBHSC. In Adam's case, complicated electrolyte disturbances could be anticipated but that is the only relevance to Claire who was at high risk of SIADH and hyponatraemia . In respect of the other children, it seems that the occasional and unusual complication of inappropriate ADH secretion may have played a part but I believe there are other issues in respect of volume of administered fluid.

558. n respect of the 2001 management of Raychel, had more widespread awareness occurred within the region across district hospitals of the risk of hyponatraemia complicating acute surgical disorders, then it is possible that more caution would have been exercised in the volumes used and sodium concentration of intravenous fluid in her. But use of 1/5 normal saline for intravenous maintenance and replacement was normal practice in 2001 across children's units in United Kingdom. Post-operative hyponatraemia from SIADH/excessive volume replacement is an unusual but recognised occasional complication. Had hyponatraemia and its complication been highlighted and publicised following Claire's death, it is not necessarily the case that this would have impacted upon the care of Raychel. This is because the use of 1/5 Normal saline in Clare was inappropriate given her underlying acute encephalopathy. It was thus outside the existing guidance in 1996

and it is more likely that this would have been highlighted in any adverse outcome investigation rather than offering a more generalised message. It was only from early 2001/2 onwards that changes in practice began to occur with the use of 1/5th saline across the UK. For example, in my own hospital, following development of cerebral oedema in a girl admitted with a minor head injury whose conscious level fell associated with intravenous fluid replacement for vomiting that we instituted a change across our unit after a literature review and adverse event review. We had the advantage that the children's Wards were shared between surgery and paediatrics and it was relatively straightforward to implement change after agreement between the anaesthetists and surgeons. However even then it took a matter of some six months before practice fully switched. I have data on this to show our monitoring and how we instituted change if this would be valuable to the Inquiry.

559. Wider dissemination of alerts.

560. The problems identified in Raychel led to the development of guidance throughout Northern Ireland in the spring of 2002 with changes in IV fluid policy advised. What is remarkable thereafter is the long time base over which further guidance was issued within the National Health Service on hyponatraemia risk in children. It was 2003 before the Royal Colleges of Paediatrics and Anaesthetists issued their guidance and a further five years after the Northern Ireland guidance before the National Patient Safety Agency issued its guidance.

561. It would also help to know when the MCA/ MHRA first became aware of the risks with 0.18% saline.

562. **NPSA** In respect of the NPSA alert it is noteworthy that acute encephalopathy is not identified as a risk factor in itself for hyponatraemia. Central nervous system infection and head injury is mentioned. In practice however any cause of acute encephalopathy or conditions which lead to an increase in intracranial pressure such as haemorrhage, brain tumour or hydrocephalus can lead to excess secretion of antidiuretic hormone. The mechanism is probably a reaction of the body to ensure that the brain is perfused even if there is no hypovolaemia when the brain gets tight. ADH is a powerful pressor agent increasing the blood pressure. The 2006 guidelines endorsed by the Royal College of Paediatrics and Child Health on non-traumatic coma in children issued as a guidance on management of reduce conscious state in children gives little attention or advice on the volume and nature of intravenous fluid to be used. It does mention that in treatment of raised intracranial pressure, hypotonic fluid should be avoided. It does not attempt to address the fact that prevention of raised intracranial pressure should be part of management in reduced consciousness by careful attention to volume of fluid prescribed and prescribing normal saline or as a minimum half normal saline. Nor does it pay enough attention in my view to the frequency of blood urea and electrolyte measurements.

563. It is these factors which deserve some remark in the context of guideline development and dissemination. In clinical practice the responsibility still lies in the hands of the clinicians to apply the appropriate therapy for their patient taking account of guidelines or modifying them for their own use within a unit. This seems have happened in Northern Ireland following Raychel Ferguson's death. Yet there was no guideline for acute encephalopathy management in RBHSC in 2011 (and ?? the neurosurgical unit) despite the risk of hyponatraemia in this disorder.

564. Investigation of childhood hospital deaths (and possible information sources)

565. Practice in the NHS in investigation of children's deaths has been very variable. Dr Keeling's report points out that in Edinburgh it was not until 2002-3 that a formal meeting was convened to consider hospital deaths except within the obstetric department. He makes reference to the value of the recorded cause of hospital deaths within hospital systems. Dr Goldacre in Oxford has reviewed data held on deaths and finds the death certification of secondary and tertiary conditions on the certificate to vary very considerably and that this data is not easily accessed.. Dr Keeling refers to the obligation of local authorities to hold a child death overview which was brought into practice from the middle 2000s onwards.

566. It is for this reason that the Confidential Inquiry Into Maternal And Child Health emerged from the previous experience developed in the confidential Inquiry into stillbirth and death in infancy aiming to extend the age range covered to all of childhood. A method has been developed as a pilot for CEMACH by Dr Gale Pearson, paediatric intensivist at Birmingham Children's Hospital and was used in the pilot study which reported in 2006. Their framework in use may offer an opportunity to determine how widespread the practice has become of routinely investigating and reviewing children's deaths in hospital. Furthermore it may be possible to determine how many of these have been associated with hyponatraemia.

567. Similar information may be obtainable from the Paediatric Intensive Care Audit Network. Data may be held in the group which reported in this publication following CMO England's alert to the NHS about epilepsy deaths.

a. *Hanna N J, Black M, Sander JWS, Smithson WH, Appleton R, Brown S, Fish D (2002) The National Sentinel Clinical Audit of Epilepsy-Related Death: Epilepsy–death in the shadows. The Stationery Office.*

568. <u>LIST OF KEY DOCUMENTS</u>

- Department of Health document the *Welfare Of Children In Hospital* 1991

- Learning From Bristol: The Report Of The Public Inquiry Into Children's Heart Surgery At The Bristol Royal Infirmary 1984–1995 DH 2001
- National Specialist Commissioning Advisory Group (now the Advisory Group for National Specialised Services (2010).
- Organisation with a Memory DH 2000
- Getting The Right Start: National Service Framework For Children Standard For Hospital Services Department Of Health 2003

569. CLINICIANS AND MANAGEMENT :

- Working for Patients 1989 and the NHS and Community Care Act 1990
- Consultants Contracts and Job Plans HC (90) 16 May 1990
- Managing the New NHS 1993 and the Health Authorities Act 1995
- New Consultant Contract Arrangements 1993 (professional accountability)
- Consultant Appraisals. AL(MD) 6/00 2000 Consultant appraisals.

570. Key documents for 1996 – care of Children in Hospital

- White Paper Working for Patients 1989 (Audit)
- Welfare of children and young people in hospital. Department of Health HMSO 1991 *followed by a review based on the DH guide* : 1993 Children first-a study of hospital services. Audit Commission
- CEPOD The Confidential Inquiry Into Perioperative Deaths, located in the Royal College of Surgeons 1989 (Focus on Children)
- Medical audit-a first report: What, Why And How Royal College of Physicians 1989
- The Quality Of Medical Care. Report of the Standing Medical Advisory Committee. Department of Health 1990. HMSO.
- Hospital Medical Audit, Kings Fund 1989 and Specialty Medical Audit-King's Fund Centre. Charles Shaw. 1992
- BPA *Paediatric medical audit 1992*
- Medical audit: a second report Royal College of Physicians of London 1993

- Transfer of infants and children for surgery joint working group BPA and British Association of Paediatric Surgeons, Paediatric Anaesthetists and the Royal College of Surgeons And Physicians (Glasgow). 1993
- Advanced Paediatric Life Support Course manuals were available from 1993.
- The Care of Sick Children review of the guidelines in the wake of the Allitt Inquiry RCN 1994
- GMC Good Medical Practice 1995 (Audit and records)
- Tertiary services for children and young people. British Paediatric Association (BPA) 1995
- Future Configuration of paediatric services report of working party BPA 1996
- RCPCH Clinical Effectiveness Programme began in 1996.
- **Key documents for 2004**
- RCPCH . Clinical Audit in Paediatrics and Child Health – Some Examples. London: Royal College of Paediatrics and Child Health, 1997.
- Organisation with a Memory DH 2000
- RCN Clinical Practice Guidelines-recognition and assessment of acute pain in children-an audit protocol.2002. and Skill-Mix and staffing in Children's Wards and Departments RCN 1999
- Children's Surgery: A First Class Service 2000. Paediatric Forum of the Royal College of Surgeons.
- Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary DH 2001
- Principles for Best Practice in Clinical Audit a joint publication of NICE , commission for health improvement, Royal College of nursing and the University of Leicester. 2002.
- NICE was asked by DH to set up the following audit :Parenteral (IV) nutrition in premature infants (sent to NPSA)and Investigation into all in hospital deaths in children (CEMACH)
- Principles for Best Practice in Clinical Audit a joint publication of NICE , commission for health improvement, Royal College of nursing and the University of Leicester. 2002.
- The Prevention of Intrathecal Medication Errors A report to the Chief Medical Officer 2001 Professor Kent Woods Department of Health 2001

571. Guidance on registering with RCs for Continuing Medical Education (professional development) was published from 1996 onwards.

Chapter [5] RESPONSE TO BRIEF not otherwise covered (My comments in Italics)

a) Medical Care and Services insofar as they bear upon 'risk management', 'lessons learned' and/or 'governance' in respect of:

(i) Attendance of the Consultant with patient admitted under his/her care

(ii) Organisation of and co-ordination between the Consultant and medical team with responsibility for care of Claire and any specialist advice/input

(iii)

(iv) Transfer of responsibility and care from one Consultant to another; or Joint care for patient

(v) Transfer of responsibility and care from an unavailable/absent consultant;

(vi) Management of handover arrangements, if any, between clinicians and also medical teams;

(vii) Accountability and responsibility of junior medical staff and Consultants;

(viii) Testing serum electrolytes, ensuring any request for this testing is recorded, carried out and the test results checked.

(ix) Checking the prescription, calculation of dose and administration of drugs

(x) Nurses ensuring amendment of Nursing Care Plan when appropriate Transfer and handover to PICU;

(xi) Systems/ Policies for junior medical staff to inform Consultant of changes or concerns, especially in 'after hours' period;

(xii) Systems/ Policies for nursing staff to contact Registrar/ Consultant if unhappy with responses of JHO/ SHO;

(xiii) Systems for the supervision of junior staff;

(xiv) Systems for keeping Consultants informed and arrangements for reporting to more senior team members when Consultant unavailable;

(xv) Role of Ward Sister;

(xvi) Arrangements and criteria for use of CT/ EEG facilities;

(xvii) Provision/ availability of guidance in respect of a) measuring and recording of fluid balance b) frequency of electrolyte testing c) CNS observations;

(xviii) Guidance as to the provision for incoming doctor of patient history, differential diagnoses, relevant physical findings, results of investigations/ those needed and awaited and current clinical management plan.

b) The accuracy and adequacy of Claire's notes and records insofar as they bear upon 'risk management', 'lessons learned' and /or 'governance' in respect of:

(i) Accurate, signed and timed clinical and nursing notes.

(ii) Recording of request for testing serum electrolytes, blood sample being taken for that test and results recorded.

(iii) Fluid balance sheets;

(iv) Observations including GCS, including the threshold for concern;

(v) Test results;

(vi) Drug prescription, calculation of dose and administration;

(vii) Nursing care plans, their review and update;

(viii) Identification of medical teams i.e. a) Lead Consultant with responsibility for Claire and her attendance on the ward b) Ward Sister with responsibility for ward and her attendance thereon c) those present on ward rounds and tasked with undertaking directions;

(ix) The maintenance and preservation of ward round diary;

(x) Information given to the Roberts family and discussions held with them;

(xi) Responsibility for the monitoring and correction of notes and records;

(xii) The co-relation of medical and nursing notes;

(xiii) The monthly paediatric directorate audit;

(xiv) Whether the severity of Claire's condition should have been reflected in the clinical and nursing notes.

With the exception of (ix) I believe I have addressed all the above. The retention of a ward diary which is not a formal record is variable practice between Trusts and in the late 1990s it would be unusual for this to be archived although later it has come to be regarded as a valuable source of information in governance.

c) Communications with the Roberts family, including the accuracy and sufficiency of the information/ advice given to them during or in relation to:

(i) The working diagnoses, care plans, treatment and prognosis at time of admission and throughout the course of 22nd October and to time of death;

(ii) Upon the seriousness of her condition between her admission and 23rd October 1996, particularly on 22nd October 1996, especially during the ward round, the afternoon and evening and also just prior to when the Roberts family left the ward at 21:30 on 22nd October 1996;

(iii) When the critical nature of her condition became apparent;

(iv) Upon admission to PICU;

(v) Upon her unexpected death- being both before and after the performance of brain stem tests;

(vi) As to the causes of death;

(vii) As to the identity of the medical team responsible for her care;

(viii) As to the reasons for non-referral to the Coroner ;

(ix) As to obtaining the consent for a limited brain-only post mortem;

(x) As to the post mortem findings;

(xi) Following the UTV documentary on 21st October 2004;

(xii) Following the meetings at the Royal Hospitals on 7th December 2004;

(xiii) Together with that information, sought from the Roberts family as to history, concerns and perceptions relevant to Claire's illness;

(xiv) Together with comment as to how parental concerns where managed in the context of established practices for handling complaints and concerns and how these practices related to departmental and professional guidance.

d) The procedures adopted after Claire's death with particular reference to the post mortem investigations and the establishment an accurate and independent view as to the causes of death, including:

(i) The accuracy, impartiality and quality of information given to the Pathologist in light of the content of the medical records;

(ii) The process of certification of cause of death for death certificate;

(iii) The decision not to refer the death to the Coroner nor seek his advice nor have the reasons for that decision documented;

(iv) The decision to seek a post mortem limited to brain autopsy only and how it was documented;

(v) The consent obtained in respect of the restricted post mortem;

(vi) The policies regarding the reporting of 'an unexplained death' to the clinical or medical Directors;

(vii) The extent to which treating Clinicians were trained in the production of information for the Pathologist;

(viii) The presentation of Claire's case to the monthly paediatric Directorate Audit;

(ix) The Autopsy Report with particular regard to a) prolonged period of preparation b) being the unsigned work of an unnamed author c) whether it identified causes of death;

(x) Whether the Autopsy or Autopsy Report be reviewed by the Clinician concerned;

(xi) The promptness and quality of the information given to the Roberts family in respect of post mortem findings;

(xii) Whether the post mortem process was subject to audit, review or monitoring;

(xiii) The review carried out for the RBHSC by Professor Young;

(xiv) The timing of the final decision to refer the death to the Coroner in 2004 and whether there was delay and whether further investigation was warranted;

(xv) The procedures consequent to Claire' Inquest and the verdict of 'cerebral oedema due to meningo-encephalitis, hyponatraemia due to excess ADH production and status epilepticus'.

e) Dissemination of information and Institutional links, including steps taken to:

(i) Investigate Claire's treatment and death by way of audit, review, learning, formal conference or informal discussion ;

(ii) Assess (and develop) the competence of staff involved in her treatment;

(iii) Assess (and develop) the competence of staff involved in the determination of her cause of death;

(iv) Disseminate outcomes and lessons learned internally and externally in respect of both Adam Strain and Claire and whether this prompted any change;

(v) Provide information to RBHSC, Trust Management, DHSSPS and/ or medical community for the purposes of dissemination in 1995/96 and 2006 6. Identify those post holders who might have been expected to undertake such tasks.

f) And additional comment as to:

(vi) The extent to which any deficiencies in the dissemination of information in respect of Adam's death in 1995 and lessons learned from his Inquest in 1996 could have played a role in the death of Claire (i.e. changes in patient care; especially fluid management and record keeping with particular regard to hyponatraemia);

(vii) The extent to which any such deficiencies in respect of dissemination of information in respect of Claire's death and lessons learned could have played a part in the death of Raychel on 10th June 2001;

(viii) The policies and practices within the RBHSC, other parts of the NIHSS and the coronial system for the dissemination of information on deaths in hospital to ensure lessons learned and shared and responses implemented. Were such procedures followed and if not was this a failure of system or individual?

(ix) The obligations on RBHSC in 2006 to revise its database in the light of the information deriving from Claire's Inquest;

(x) How Northern Ireland compared with the rest of the UK in respect of the above.

Comment Regarding (viii)- (x)

Dissemination of information on hospital deaths in children is not widespread practice in UK then or now. The Confidential Enquiry in Stillbirth and Deaths In Infancy CESDI has produced a series of publications in the 1990s and some have addressed care in hospital in relation to investigation of contributory factors. The successor organisation CEMACH was charged with investigation of deaths in all child ages but so far has produced a pilot report only in 2008 on a selected sample. This was followed in late 2000s by reports of enquiries with a focus on abuse and neglect. Dissemination of reports is still patchy and thus Northern Ireland does not differ in this respect. The RCPCH arranged for a national study on management of all deaths in England from meningococcal disease and published most of its findings identifying or relevance to this Inquiry that lack of

consultant involvement early in a child's illness was a contributory factor in a number of deaths.(Clinical recognition of meningococcal disease in children and adolescents. Thompson MJ, Ninis N, Perera R, Mayon-White R, Phillips C, Bailey L, Harnden A, Mant D, Levin M. Lancet. 2006 Feb 4;367(9508):397-403.)

<u>Comment on (i)-(vii)</u>

Following Adam Strain's inquest a statement was made by the Royal Hospitals NHS Trust and awareness raised regarding the use of 1/5 normal saline. The extent to which this information was shared across the Trust is not clear. Mechanisms could include the use of grand rounds or interdisciplinary meetings or, critical events reviews and reports. It is not evident that such processes in relation to adverse events was managed on a structured way. Had awareness been raised across the Trust , the clinicians involved with Claire might have been more aware of the risk of hyponatraemia in any condition with the use of 1/5 normal saline. But the main issue in the management of Claire Roberts was that use of 1/5 normal saline in management of her disorder: acute encephalopathy was outside the guidance available at the time. For acute encephalopathy higher sodium concentration intravenous fluid should be used both to anticipate and, if necessary treat , the relatively the high-risk of SIADH with its complication of cerebral oedema. The main focus of Adam Strain's management review was on surgical conditions- particularly complex ones given his underlying pathologies. However it is the case that reference was made in the public statement to a publication which drew attention to attention to the risk in a range of clinical disorders. The main point remains that with Claire Roberts there was a high risk of SIADH in any event.

In respect of the 2001 management of Raychel, had more widespread awareness occurred within the region across district hospitals of the risk of hyponatraemia complicating acute surgical disorders, then it is possible that more caution would have been exercised in the volumes used and sodium concentration of intravenous fluid in her. But use of 1/5 normal saline for intravenous maintenance and replacement was normal practice in 2001 across children's units in United Kingdom. Post-operative hyponatraemia from SIADH/excessive volume replacement is an unusual but recognised occasional complication. Had hyponatraemia and its complication been highlighted and publicised following Claire's death, it is not necessarily the case that this would have impacted upon the care of Raychel. This is because the use of 1/5 Normal saline in Clare was inappropriate given her underlying acute encephalopathy. It was thus outside the existing guidance in 1996 and it is more likely that this would have been highlighted in any adverse outcome investigation rather than offering a more generalised message. It was only from early 2001/2 onwards that changes in practice began to occur with the use of 1/5th saline across the UK. For example, in my own hospital, following development of

cerebral oedema in a girl admitted with a minor head injury whose conscious level fell associated with intravenous fluid replacement for vomiting that we instituted a change across our unit after a literature review and adverse event review. We had the advantage that the children's Wards were shared between surgery and paediatrics and it was relatively straightforward to implement change after agreement between the anaesthetists and surgeons. However even then it took a matter of some six months before practice fully switched. I have data on this to show our monitoring and how we instituted change if this would be valuable to the Inquiry.

I was also asked to provide a commentary on the Role of the THE WARD SISTER which follows

The ward sister on a children's Ward always is a specialist children's nurse and now in all hospitals treating children, nursing staff will have children's nurse qualification.

The ward sister is responsible for the nursing teams. Scheduling adequate staffing, responding to peaks in demand by bringing in additional staff or by allocating additional staff from the existing team to specific patients.

The Sister has responsible for managing the ward in general in relation to supervision of processes and ward rounds. Ward sisters contribute to the compilation of guidelines and information sheets for parents. The nursing staff has a major role in communication with parents often "interpreting" or discussing at length comments that have been made by medical staff about a child's condition and explaining this.

Ward sisters have particular expertise in the management of monitoring and resuscitation equipment and intravenous infusions. They administer medications and intravenous fluids which have been prescribed and dispensed. In order to do so it has become a necessary standard to have two nurses checking the dosages. (Allitt) Nurses are very often more familiar with the formulation than the medical staff and will influence how a prescription might be written having calculated this from bodyweight and when rounding up or rounding down is necessary. They also act as a safeguard to cross check or challenge the dosage or drug used in a child from the knowledge of children's medication. Increasingly a small number of medications may be given intravenously by

nursing staff that this was not so widespread in the 1990s. And now and then a bolus dose of IV treatment such as Midazolam would be given by a doctor and the extent to which nursing staff would assist in drawing it up and cross checking varies now and then.

Nursing staff are responsible for the regular measurements such as temperature, pulse respiration BP and Glasgow coma Scale. They have a responsibility to summon medical staff at any grade if they are concerned about their patient's condition. There are also skilled in recognition of deterioration in overall condition of the child and initiating resuscitation when necessary.

Nursing staff maintain their own separate documentation from the medical record although in some hospitals these records are integrated. They tend to be completed at the end of the shift. Each ward will have a formalised handover at the end of shifts.

The ward sister/manager has responsibilities for appraisal and training of staff in her care and identification of developmental needs professionally linking with the senior nurse management of a hospital or directorate.

Some nursing staff at senior level will be responsible for several wards working with ward managers/sisters.

The nursing staff will report adverse events and should be engaged and involved in discussion about these and may be involved in determining the action plans which result. Ideally it should be possible for senior nursing staff to attend grand rounds or clinical presentations but this is less now than it was in the past because of pressure on the time of the nursing staff. They are involved in the drawing up of guidelines and also draw up their own documentation supporting nursing practice.

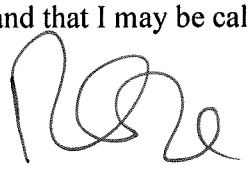
Statement of Truth

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:  Date: 5 Aug 2012

CRODERICK MACFAUL

Witness Statement Ref. No. 263/1

NAME OF CHILD: Claire Roberts

Name: Roderick MacFaul

Title: Consultant Paediatrician (Retired)

Present position and institution: Retired from Pinderfields Hospital Wakefield (2006)

Previous position and institution:

See attached cv

Membership of Advisory Panels and Committees:

See attached cv

Previous Statements, Depositions and Reports:

N/A

OFFICIAL USE:
List of reports attached:

Ref:	Date:	

Particular areas of interest:

General and Emergency Paediatrics with Special Interest in Paediatric Neurology

Development of Standards of Clinical Practice and Services including Clinical Governance and Audit (including National Audits)

See cv

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

Signed: [signature] **Dated:** 5 Aug 2012

SUMMARY CV Dr Roderick MacFaul

Clinical practice.

From 1978 consultant paediatrician Pinderfields Hospital Wakefield and Hon Senior Lecturer University of Leeds (retired March 2006). Special interests in emergency paediatrics and care of childhood disability (having trained in paediatric neurology and general paediatrics). Research interests continue and are in use of acute paediatric services and acute illness management.

National professional contributions.

Former Honorary Secretary British Paediatric Association and first Vice President of its successor body the Royal College of Paediatrics and Child Health.

For 7 years up to summer 2003 Paediatric Adviser Department of Health England responsibilities included child health policy and service development inter alia set up and chaired national DH neonatal care review and DH paediatric high dependency working party, established the national paediatric intensive care and neonatal care audit programmes, facilitated the development of the British National Formulary for Children, provided supporting arguments for NHS plan targets, the set up of the National Service Framework and involvement in a number of its working groups and contributing to the NSF publications released in 2004 and 2005. Chaired the UK national newborn screening programme board until December 2005. Retired from Mid Yorks NHS Trust in March 2006 but part time national clinical lead for Connecting for Health child health programme set up in 2007 until June 2008.

CURRICULUM VITAE - RODERICK MACFAUL

Date of birth: [redacted]

Home Address:

[redacted]

Telephone: [redacted]

Present Position:

Consultant Paediatrician
Pinderfields General Hospital

Aberford Road
WAKEFIELD
WF1 4DG

Honorary Senior Clinical Lecturer
Department of Paediatrics & Child Health
University of Leeds

Tel: [redacted] Fax: [redacted]

Professional Interests:

Paediatric Neurology
Handicapped children and the care of physically disabled children
Member of British Paediatric Neurology Association
Member of North of England Neurological Association

Qualifications:

MB ChB	University of Leeds 1968
DCH	Royal College of Physicians and Surgeons, Glasgow 1970
MRCP (UK)	1973
FRCP	1986
FRCPCH	1997

Posts Held:

1968	House Surgeon, Otley General Hospital
1969	House Physician (Paediatrics), Seacroft Hospital, Leeds
1969 - 1971	General Practice in Army in Colchester
1971 - 1973	SHO and Registrar in Paediatrics, British Military Hospital, Singapore
1973 - 1975	Registrar in Paediatrics, British Military Hospitals, Germany
1975 - 1976	Registrar in Paediatric Neurology at Hospital for Sick Children, Great Ormond Street and in Developmental Medicine and Child Neurology at Newcomen Centre, Guy's Hospital, London Paediatric Registrar, Northwick Park Hospital
1976 - 1978	Senior Registrar in Paediatric Neurology, Hospital for Sick Children, Great Ormond Street Senior Specialist in Paediatrics, Cambridge Military Hospital, Aldershot

1978 - Consultant Paediatrician, Pinderfields General Hospital, Wakefield

Prizes etc:

MB (Distinction in Medicine), University of Leeds (1968)

West Riding Practitioners Prize in Medicine, University of Leeds (1968)

Montefiore Prize in Military Surgery, Royal Army Medical College (1969)

Elected Honorary Fellowship Royal College of Paediatrics and Child Health (2000)

Elected Honorary Membership British Association Perinatal Medicine 2004

Administrative Activities:

Chairman	Wakefield Hospital Medical Committee (1982 - 85)
Chairman	District Research and Ethical Committee (1982 - 85)
Chairman	Medical and Surgical Equipment Sub-Committee (1982 - 85)
Chairman	Special Professional Committee (1982 - 85)
Consultant Member	General Unit Management Group (1984 - 86)
Deputy Consultant Member	District Management Team (1982 - 86)
Member	Yorkshire Regional Health Authority Neurological Services Working Group (1981 - 1991)
Divisional Co-ordinator	Medical Division. Pinderfields Hospital NHS Trust (1993 - 1996)
Clinical Director	Women & Children's Services, Pinderfields Hospital NHS Trust (1997 -98)
Clinical Director	Children's Services, Pinderfields & Pontefract NHS Trust(1998-2005)

Professional Activities:

Secretary	Yorkshire Regional Paediatric Society (1981 - 86)
Regional Representative	Council British Paediatric Association (1984 - 85)
Honorary Assistant Secretary	British Paediatric Association (1985 - 89)
Honorary Secretary	British Paediatric Association (1989 - 94)
Vice President	Royal College of Paediatrics and Child Health (1994 - 1997)
Medical Adviser Paediatrics & Child Health	Department of Health (1996 -2003) [part-time]

Committees & Working Parties:

Paediatric Committee Royal College of Physicians of Edinburgh (1987 - 1994)

Paediatric Committee Royal College of Physicians of London (1988 - 92)

Health Statistics Committee British Paediatric Association (1988 - 89)

Caring for Children in Health Services Committee (NAWCH, NAHA, RCN, BPA) (1986 - 89)

Medical Audit Working Party, Royal College of Physicians of London (1987 - 93)

Working Party Workload in Paediatric Units (BPA) (1986 - 87)

Central Manpower Committee (1989 - 95)

Standing Medical Advisory Committee (DoH) (1990 - 1996)

Working Party District Indicators of Quality of Care, Faculty of Public Health Medicine (1990 - 92)

Paediatric Board Royal College of Physicians of London (1992 - 1995)

Manpower Committee RCP London (1991 - 1994)

Audit Commission: Advisory Panel for Care of Sick Children in the NHS (1991 - 93)

Joint Working Party on Medical Services for Children BMA/Conference MRC + DoH (1992)

BPA Academic Board, Health Services Committee etc

London Implementation Group 1993 Children's Specialist Services

College Manpower Advisory Panel of CMC (Paediatric Rep) 1992 - 95

RCP Working Party on Staff Grade 1993

RCP Working Party on Alcohol and the Young 1993 - 94

Steering Committee BPA Appropriateness of Admission Audit (Chair)

Subgroup of Joint Working Party on Medical Services for Children on Training for CMO's and SCMO's (Chair)

Regional Advisers Committee BPA (Secretary) 1989 - 94

Executive Committee and Council BPA (Secretary) 1989 - 1994

BPA Research Unit Steering Committee 1994 - 1997

Council of National Association for Education of Sick Children 1994 - 1995

Medical Scientific Advisory Committee Children Nationwide (Chairman) 1994 -

SMAC Working Party on Sickle Cell and Haemoglobinopathy

SMAC Working Party on Community Care

Chairman Health Services Committee, British Paediatric Association/RCPCH 1994 - 1997

Member JCC Working Party on Paediatric Staffing

Chairman BPA/RCPCH Working Party on Future Configuration of Paediatric Units 1996

Chairman joint RCPsych/RCPCH Working Party on Dangerous and Disruptive Children 1996 -

Chairman RCPCH Working Party on Ambulatory Care 1996

Council member Royal College of Physicians 1994 - 1997

GMC Professional performance review development project for paediatrics 1996-1998

Medical Vice Chair Yorks and Humber Regional Clinical Excellence Awards Committee 2002-5

Examiner: Diploma in Child Health, RCP (1985 - 1991)
University of Sheffield - School of Medicine (Speech Therapy) 1985 - 1991
MRCP RCP London (1993 -)

Publications:

MacFaul R, Grant D B. Early detection of Congenital Hypothyroidism, Archives of Disease in Childhood 1977; 52: 87.

MacFaul R, Miller G. Clonidine poisoning in children. Lancet 1977; 8024 (i): 1266.

Winfield C, MacFaul R. Clinical Study of prolonged jaundice in breast and bottle fed infants. Archives of Disease in Childhood 1978; 53: 506.

MacFaul R, Dorner S, Brett E M, Grant, D B. Neurological abnormalities in patients treated for hypothyroidism from early life. Archives of Disease in Childhood 1978; 53: 611.

MacFaul R, Mason M, Turner T. Downs/Turners Mosaicism: double aneuploidy as a rare cause of missed prenatal diagnosis of chromosomal abnormality. Archives of Disease in Childhood 1981; 56: 962.

Holton J B, Gillett M G, MacFaul R, Young R. Galactosaemia: a new severe variant due to epimerase deficiency. Archives of Disease in Childhood 1981; 56: 885

MacFaul R, Cavanagh N, Lake B D, Stephens R, Whitfield A E. Metachromatic Leucodystrophy: a review of 38 cases. Archives of Disease in Childhood 1982; 57.

Holton J B, Gillett M E, MacFaul R. Prenatal determination of uridine diphosphate galactose-4-epimerase activity. Prenatal Diagnosis 1983; Vol 3: 57-59.

Henderson M J, Holton J B, MacFaul R. Further observations in a case of uridine diphosphate galactose-4-epimerase deficiency with a severe clinical presentation. Journal of Inherited Metabolic Disease 1983; 6: 17-20.

Green A, MacFaul R. Duration of admission for febrile convulsions? Archives of Disease in Childhood 1985; 60: 1182-1184.

MacFaul R. Medical care in severe mental handicap. Archives of Disease in childhood 1986; 61: 533-536.

Ismail A A A, Walker P L, MacFaul R, Jindal B. Diagnostic value of serum testosterone measurement in infancy; two case reports. Annals of Clinical Biochemistry 1989; 26: 259-261.

MacFaul R. Much data but limited information in the NHS. Archives of Disease in Childhood 1988; 63: 1276-1280.

Primavesi R, MacFaul R. Paediatric medical audit. Archives of Disease in Childhood 1988; 63: 1170-1174.

MacFaul R, Long R. Major problems with paediatric bed usage statistics. Archives of Disease in Childhood 1991; 66: 504-507.

MacFaul R. How to audit children's services. Current Paediatrics 1991; 1: 166-173.

Igbal J B, Bradley N, MacFaul R, Cameron M M. Syringomyelia in children: six case reports and review of the literature. British Journal of Neurosurgery 1992; 6: 13-20.

MacFaul R. Paediatrics in the Nineties: a time for change. British Journal of Hospital Medicine 1992; 47: 799-801.

MacFaul R, Long R. Paediatric outpatient utilisation in a district general hospital. Archives of Disease in Childhood 1992; 67: 1068-1072.

MacFaul R. Paediatric medical manpower. Archives of Disease in Childhood 1993; 68: 70-72.

MacFaul R . Special Considerations for the Care of Children with Haemoglobinpathies Chapter 8 in Report of Working Party on Sickle Cell, Thalassaemia and Other Haemoglobinopathies Standing Medical Advisory Committee Committee Department of Health 2003.

MacFaul R. Screening for biliary atresia. Lancet 1993; 342: 811.

MacFaul R, Glass E J, Jones S, Appropriateness of paediatric admission. Archives of Disease in Childhood 1994; 71:50-58

Thakker Y, Sheldon T A, Long R, MacFaul R. Paediatric inpatient utilisation in a district general hospital. Archives of Disease in Childhood 1994; 70: 488-492

Werneke U, MacFaul R. Evaluation of appropriateness of paediatric admission. Archives of Disease in Childhood. 1996; 74: 268-273

Curley P J, MacGregor B, Ingoldby C J H, MacFaul R. The Management of Pyloric Stenosis in a District Hospital. J R College of Surgeons Edin. 1997; 42: 265-268

MacFaul R. Planning for the future: the experience of implementing a children's day assessment unit in a district general hospital. Commentary. Arch Dis Child. 1997; 77: 292-3.

Werneke U, Smith H, Smith I J, Taylor J, MacFaul R. Validation of the paediatric appropriateness evaluation protocol in British practice. Arch Dis Child. 1997; 77: 294-299.

MacFaul R, Stewart M, Werneke U, Taylor-Meek J, Smith H E, Smith I J. Parental and professional perception of need for emergency admission to hospital: prospective questionnaire based study. Arch Dis Child 1998; 79: 213-218.

Stewart M, Werneke U, MacFaul R, Taylor-Meek J, Smith H E, Smith I J. Medical and social factors associated with the admission and discharge of acutely ill children. Arch Dis Child. 1998; 79: 219-224.

Armon K, Stephenson TJ,MacFaul R, Eccleston P, Werneke U, Gabriel V. Determining the common presenting problems to paediatric aciident and emergency. Paediatrics Today 1999;7:20.

MacFaul R, Jones S, Werneke U. Clinical training experience in district general hospitals. Arch Dis Child 2000; 83: 39-44

P.Eccleston, U. Werneke, K. Armon , T.J. Stephenson, R. MacFaul. Accounting for overlap?: an application of Mezzich's kappa statistic to test inter-rater reliability of interview data on parental Accident and Emergency attendance. J Adv Nurs. 2001 ;33:784-90.

Armon K, Stephenson T, Gabriel V, MacFaul R, , Eccleston P, Werneke U, Smith S, What are the common medical presenting problems to accident and emergency ? Arch Dis Child. 2001 ;84:390-2..

Armon K, Stephenson T, MacFaul R, , Eccleston P, Werneke U, An evidence and consensus based guideline for acute diarrhoea management. Arch Dis Child 2001; 85:132-142.

MacFaul R, Werneke U. Recent trends in hospital use by children in England. Arch Dis Child 2001;85:203-207

Lakhanpaul M, Armon K, Eccleston P, Werneke U,Smith S, MacFaul R,Stephenson T. Implementing clinical guidelines for paediatric care services: an overview. J Integrated Care Pathways 2002;6:18-25.

Armon K, Stephenson T, MacFaul R, Hemmingway P, Werneke U, Smith S. An evidence and consensus based guideline for the management of a child after a seizure. Emergency Medicine J. 2003 ;20:13-20

Armon K, Stephenson T, MacFaul R, Hemmingway P, Werneke U, Smith S. The impact of presenting problem based guidelines for children with medical problems in an accident and emergency department. Arch Dis Child 2004; 89:159-164

MacFaul R et al Provision and use of services. Chapter 2 in The health of children and young people. Office of National Statistics. 2004

MacFaul R Trends in asthma hospitalisation: is this related to prevention inhaler usage**?** Arch. Dis. Child., 2004; 89: 1158 - 1160.

Bowker R, Lakhanpaul M, Atkinson M, Armon K, MacFaul R, Stephenson T How to write a guideline from start to finish. A Handbook For Health Professionals. Churchill Livingstone 2008.

Lakhanpaul M, Stephenson T, MacFaul R et al An evidence-based guideline for children presenting with acute breathing difficulty. Emergency Medical Journal 2009 : 26:850-853.

Brent AJ, Lakhanpaul M, Ninis N, Levin M, MacFaul R, Thompson M. Evaluation of temperature–pulse centile charts in identifying serious bacterial illness: observational cohort study. *Arch Dis Child* 2011;**96**:368–373.

Brent AJ, Lakhanpaul M, Thompson M, Collier J, Ray S, Ninis N, Levin M, MacFaul R. Risk score to stratify children with suspected serious bacterial infection: observational cohort study.*Arch Dis Child* 2011;**96**:361–367.

Lead author of:

Paediatric Medical Staffing for the Nineties
British Paediatric Association 1991.

Towards a Combined Child Health Service
British Paediatric Association 1991.

Management Models for a Combined Child Health Service
British Paediatric Association 1992.

Hospital Paediatric Medical Staffing
British Paediatric Association 1993.

Paediatric Medical Audit
British Paediatric Association 1993.

Purchasing Guide to Paediatrics and Child Health Services: 1994

Purchasing Health Services for Children and Young People. Vol I: Summary. British Paediatric Association 1994.

Future Configuration of Paediatric Units. 1996

Ambulatory Paediatrics. 1997

On Steering Committee of Caring for Children in the Health Services Consortium: RCN, NAWCH, BPA, NAHAT, producing following documents:

Where are the Children 1987.

Hidden Children 1988.

Parents Staying Overnight with their Children 1988.

DoH Advisory Groups:

Advisor to Nucleus Design 1992 and Health Building Note 1994 for Children's Departments (NHS Estates).

Advisor to National Casemix Office on Healthcare Resource Groups and Consultant Episodes.

Integrated Clinical Workstations Project Board and pilot project in England for Clinical Coding and Classification Centre (IMG).

OP HRGs for paediatrics NHSIA

Children's National Service Framework 2003/4 : (a) hospital services for children, (b) the ill child, (c) medicines for children

Paediatric Service and Standards Reviews 1992-2006

Paediatric Member of Regional Inquiry into Paediatric Services Grantham and Baby deaths (Allitt)

Review of Paediatric Services in London Region (& with Sir David Hull constructed the report and recommendations)

Review of Children's Services South Downs HA

Review of Children's Neurosurgical Services for South of Thames

Review of Paediatric Services (various dates) in : Northwick Park Hospital, Bradford, Heart of England – Birmingham, E London

Current Research Activities

Development of UK Appropriateness of Paediatric Admission Protocol (DOH/BPA Funding)

Paediatric Medical Episodes. National Casemix Office/BPA

Development of guidelines for paediatric admission. Queen's Medical Centre, Nottingham. Children Nationwide.

Development of acute illness severity scale for use in acute general paediatric practice. Research Unit RCPCH/ Well Child funding

Chair Scientific Medical Advisory committee Children Nationwide now WellChild

Referee Archives of Disease in Childhood

Evaluation of video telemedicine assessment of acutely ill children for Modernisation Agency

MEDICAL ADVISER IN PAEDIATRICS AND CHILD HEALTH- Department of Health England 1996 to 2003.

During the period of secondment the following have been undertaken

Screening

- Establishing the child health subgroup of the National Screening Committee and identifying a chairman and its terms of reference. Developing its interplay with child health surveillance and costing the child health services

- Specified and set up the national newborn bloodspot programme board and, for the health departments of England , Wales, Scotland and Northern Ireland, Chair UK Programme Board for blood spot screening 2003-2005.

Critical care for children

- Implementation of the Paediatric Intensive Care agenda.

- Specified and set up in 2001 a national PIC audit PICANet.

- Set up and chaired DH working party setting standards for high dependency care (level 1 intensive care) services in all hospitals where children are treated.

- Set up and chaired external reference group for national review of neonatal intensive care and produced its report in 2001 and the successful argument to ministers for £ 75m additional funding

- Specified, set up and agreed funding for national Neonatal Intensive care audit – chair DH steering group with Healthcare commission to commission it. Started January 2005.

Medicines for children

- Producing national guidance on the use of Vitamin K in new-born babies.

- Dealing with the issue of unlicensed medications for children. Involved in the establishment of the CSM paediatric strategy group jointly with the then MCA.

- With R&D division brokered drafted and agreed specification and funding for a national paediatric pharmacology research network

- Brokered the successful proposal to provide a BNF for children

Acute care for children

- Set up via RCPCH a profile of all paediatric units in E&W to enable service configuration reviews and assist in workforce planning

- Provided the workforce planning model used by DH and by RCPCH.

- Advised DH and NHS Estates in the requirement for the built environment for children's care in hospital

- Provided Emergency Care Clinical Director with report on the needs for emergency care in children highlighting the yet unresolved interplay in UK between primary accessed and hospital based specialist care..

- Carried out a study of out of hours needs of children for the Hospital at Night project showing that Paediatrics needed a different solution from adult services

- Specified and commissioned a study on impact of short stay paediatric units on hospital utilisation and costs (increases them)

- In 2000 originated the project and commissioned DH DVD training materials ' Spotting the Sick Child' for recognition of acutely ill children released with the NSF.

- Characterised the training and CPD needs for surgical and anaesthetic services for children for DH working with the RCs. Inter alia assisting with the identification of the range of speciality services for children and chairing a review on the retinoblastoma service.

- Identified the need and provided the argument in 2002 on the requirements for nurses with enhanced skills in general, neonatal and community paediatric practice

Child health

- Initiated work on the health needs of looked after children though later fully developed by Professor Margaret Lynch.

- Ensured that the health input to the millenium cohort study was strengthened

- Initiated work on children's well-being indicators for Social Care, commissioned report from NCHOD and with LRO arranged pilot in London.

- Commissioned a report on the health needs of school aged children.
- Commissioned ALSPAC to provide data on health demands in 7 year old children.

- Reviewed the school health services and provided a comprehensive document as foundation work for national service framework.

- Provided the advice and information to set the 'Quality Protects ' programme for the care of disabled children.

- Provided arguments for set up of NSF and the targets for child mortality and morbidity which are in the NHS plan Information strategy

- Arranged funding for scoping of child health information needs in 2001

- Worked with Healthcare commission to develop targets to be in place based on existing data collections

- Argued to get greater priority to the major information needs of children bridging the primary, community and hospital based service IT needs

- Initiated and steered together with Professor Paul Johnson and Dr Yvonne Arthurs the report on the Health of the Nations Children produced by NE PHO and published 2005.

Evidence based care

- Initiated the existing children's programme of topics for NICE : asthma inhalers, growth hormone, urinary tract infection, head injury and feverish illness in children.

- Set up and funded a pilot project for a structured enquiry into each in-hospital child death subsequently proposed to NICE and then to CEMACH now being adopted as a new confidential enquiry.

- Developing specification for an R&D programme for children's acute and chronic disorder health needs and care including what parents and cares expect from services. Liaised with NPSA.

- Provided a comprehensive horizon scanning overview of future paediatric demand and needs

DH continuing work 2004-7
Chair UK National Programme Board for newborn screening (retired June 2005)

Chair Programme Board for Healthcare commission National Neonatal Intensive Care Audit Programme

Steering group for report of the state of health of the nation's children for DH and DFES

Project lead for Connecting for Health on Children's Prescribing

Lead for CfH on digital development of the BNF for Children

2007-2008 National clinical lead child health programme NHS IT programme Connecting for Health
END

ANNEX A

GUIDANCE ON ACUTE ENCEPHALOPATHY AVAILABLE IN 1996

Textbook of paediatrics. Forfar & Arneil Third edition 1984 Page 791 et seq (similar in later editions)

.."the large number of possible causes of acute encephalopathy makes early specific diagnosis difficult or impossible; treatment may often need to be instituted urgently on empirical grounds (anticonvulsants, antimicrobial therapy, anti-brain oedema measures) while the results of investigations are awaited. A diagnosis of "viral encephalitis" should not be accepted until further investigation has excluded numerous other systemic or neurological disorders which may present with similar findings. Excluding accidental head injury, the most important causes of acute encephalopathy in infancy and childhood in temperate climates are infection (33%), asphyxia (20%) intracranial haemorrhage (16%), toxic/metabolic conditions (12%)….. In porphyria, a rare disorder, it is mentioned in this book on page 83 that inappropriate ADH secretion may occur).

"It should also be remembered that part of the spectrum of child abuse includes the intentional administration of drugs or other agents. These infants and children present difficult diagnostic problems if this possibility is not borne in mind."

"Continuing convulsions maybe subclinical (and detectable only with EEG monitoring) or easy to miss e.g. episodes of paroxysmal nystagmus or contribute deviation of the eyes: sucking chewing and swallowing movements frequently represent brainstem release phenomena secondary to swelling of the brain. Mid brain compression from cerebral shifts causes ophthalmoplegia. Further evidence of raised intracranial pressure and the celebration may be obtained by examining for evidence of the cerebral posturing and opisthotonus.."…

Decerebrate rigidities often accompanied by cycling movements of the lower limbs and doggy paddling movements of the upper limbs. It is important to note that papilloedema may be a late or absent sign even in the presence of significantly raised intracranial pressure.

The list of investigations advised similar to that in the later edition

In this text (Forfar and Arneil 1984) it is recommended on page 807 that children who have an acute encephalopathy with coma should have their urea, electrolytes, creatinine, calcium and osmolality done twice daily. The EEG should be carried out daily or continuously. Intracranial pressure monitoring in selected cases. Blood glucose four hourly. Treatment includes treatment of convulsions.

"The possible presence of raised intracranial pressure in acutely ill children is frequently overlooked and this is particularly the case if clinicians rely on the frequently absent 'classical signs 'of raised intracranial pressure. The only reliable means of excluding raised intracranial pressure is to monitor it.

……..

In many cases treatment of cerebral oedema is required to be presumptive. Fluid should be restricted to 60% of estimated daily requirements; low sodium containing infusions like 5% dextrose or 0.18% saline in 5% dextrose are contraindicated…...

On page 809, the prognosis listed is that death occurs in 27% of coma, mild handicap and 13% and complete recovery 45%.

THE RELEVANT PAGES ARE SHOWN BELOW

Table 14:16

Suggested Investigations in Infants and Children Presenting with Undiagnosed Coma and Convulsions

Blood glucose (or Dextrostix)
Capillary or arterial gases
Haemoglobin; white cell count; differential with platelet count
ESR. Blood film
Coagulation screen
Blood culture; viral serology (paired sera)
Tuberculin testing
CSF examination (*see text)
Viral and bacterial cultures (nose; throat; urine; faeces)
Urea and electrolytes; creatinine; osmolality
Calcium, phosphate, alkaline phosphatase
Bilirubin; transaminases; ammonia (collect onto ice)
Chest X-ray; skull X-rays; skeletal survey
Urinalysis—Labstix; Phenistix; microscopy
Serum and urinary aminogram
Urinary porphyrins
Serum and urinary amino acids
Serum and urinary organic acids (if persistently ketotic or acidotic)
Serum and urinary toxicology (drugs; solvents; heavy metals)
Toxicology of gastric aspirate
Ultrasound (skull)
CT scan
EEG

fluid for diagnostic purposes if CSF pressure is not elevated above 15–20 mmHg. Once obtained, cerebrospinal fluid should be examined as soon as possible for cell count, glucose and protein levels, by Gram staining and in selected cases by Ziehl-Neelson staining. The more widespread application of microcentrifugation techniques (e.g. 'cytospin') has facilitated the early identification of unusual CSF constituents, e.g. tumour cells, macrophages, and the monitoring of treatment of meningitis and encephalitis. Modern immunological techniques (e.g. radioimmuno assay, countercurrent immunoelectrophoresis and enzyme linked immunadsorbent assay) are invaluable for the early detection of bacterial antigens e.g. pneumococcus and haemophilus. This allows the clinician to anticipate the natural history of a given meningitis and plan optimum antibiotic therapy. If blood-stained CSF is obtained and a traumatic tap is suspected this may be excluded by serial clearing of samples as CSF collection is undertaken; if clearing does not occur and intracerebral bleeding is suspected, CSF spectrophotometry may be undertaken. Fresh bleeding causes an oxyhaemoglobin peak whilst old blood from an established intracerebral bleed is associated with detectable bilirubin and methaemoglobin.

No potentially useful samples from patients suffering from encephalopathy should be discarded. *Gastric aspirate* may yield detectable drugs and toxins; analysis of *urine* may detect toxic metabolites and drugs undetected on assay of serum.

Ultrasound examination of the intracranial space is becoming increasingly accurate and may detect intracranial bleeding, significant brain shift, and ventricular dilatation. This is particularly applicable in infants where the patent anterior fontanelle provides a convenient ultrasonic window. As noted above the increasing availability of *CT scanning* has greatly facilitated the diagnosis of numerous brain lesions, e.g. cysts, tumour, abscess, necrotizing encephalitis (herpes simplex), tuberculoma, intracranial bleeding, cerebral oedema and hydrocephalus (see Fig. 14:63). Scanning should be carried out as early as possible to avoid inappropriate treatment or delay in specific measures, e.g. drainage of an abscess, antiviral chemotherapy, or clipping of a leaking aneurysm.

Early *EEG examination* may reveal continuing unsuspected epilepsy indicating the need for more aggressive anticonvulsant therapy. Focal epileptic discharges or focal slow waves may indicate a local lesion such as focal necrotizing encephalitis due to herpes simplex or focal suppuration due to a pyogenic abscess. Most often the EEG in acute encephalopathy demonstrates diffuse slow wave activity compatible with recent convulsions, cerebral oedema, or diffuse viral or post-viral encephalitis.

MANAGEMENT OF INFANTS AND CHILDREN WITH ACUTE ENCEPHALOPATHY

The management of infants and children with acute disorders of the CNS depends on the nature and severity of the underlying condition and the results of preliminary investigations noted above. It is important to ensure that the patient's general condition is closely monitored and in selected cases admission to a medical intensive care area may be desirable. It is suggested that adequate monitoring should include measurement and close recording of the parameters listed in Table 14:17.

In addition, regular recordings should be made of pupillary reactions, response to stimuli, pulse, temperature, respiratory rate (with ventilator settings if applicable), fluid input and output, and daily weight. Care should be taken in ensuring regular changes of position to avoid pressure sores and positional deformity. Attention should be paid to oral hygiene, eye care, state of hydration and nutrition, and the presence of abdominal distension potentially due to bladder enlargement, ileus or severe constipation. Specific therapy is considered under the following headings.

1. Correction of ischaemia and hypoxia
2. Treatment of convulsions
3. Reduction of intracranial pressure
4. Treatment of infection
5. Correction of shock, homeostatic defects and intoxication.

Table 14:17

Intensive Care Monitoring in Patients with Encephalopathy and Coma

Blood gases	4 hourly
Dextrostix or blood glucose	4 hourly
Urea, electrolytes, creatinine, calcium, osmolality	Twice daily
Coagulation screen Liver function tests	Once daily (reducing after 48 hours)
ECG	Continuous
BP	Continuous
EEG	Daily or continuously
Intracranial pressure (see text)	Continuously (selected cases)

CORRECTION OF ISCHAEMIA AND HYPOXIA

An adequate airway must be ensured and in cyanosed patients oxygen administered empirically with early measurement of blood gas status. Carbon dioxide retention and hypoxaemia cause cerebral congestion and will exacerbate the cerebral oedema often seen in these patients. Mechanical ventilation may be required if there is evidence of respiratory failure or if apnoea occurs; hyperventilation is also an effective means of reducing cerebral blood flow and thus intracranial pressure. With these principles in mind many clinicians now choose to ventilate empirically where there is a history suggesting an ischaemic anoxic insult. For prolonged ventilation tracheostomy may be desirable. Care should be taken not to reduce the P_{CO_2} too quickly since this is associated with an early fall in CSF pH (in advance of serum) which may itself be responsible for an encephalopathy (Posner encephalopathy). Optimum reduction of intracranial pressure is obtained by reducing P_{aCO_2} so as to maintain it at 4–4.5 kPa (25 mmHg). Other measures to minimize and reduce cerebral oedema include fluid restriction, mannitol and dexamethasone (see Reduction of Intracranial Pressure). The use of high dose barbiturate therapy for the purpose of 'cerebral protection' remains controversial because of the dangers of hypotension and respiratory depression. The effectiveness of this group of drugs in ameliorating the effects of ischaemic anoxic cerebral injury in man has yet to be established. High dose barbiturate therapy should be restricted to centres where ventilation facilities exist and intensive monitoring is possible. Close supervision is necessary with regular measurements of serum barbiturate level, attention to problems of drug accumulation and maintenance of the EEG at a 'burst-suppression' level coinciding with maximal depression of cerebral metabolism.

TREATMENT OF CONVULSIONS

Convulsions must be terminated as soon as possible. Diazepam given by slow intravenous injection is the drug of first choice; a common error is to administer diazepam intramuscularly—it is ineffective in convulsing children given by this route. Paraldehyde by deep intramuscular injection into the lateral thigh is also highly effective, and may be preferred where veins are difficult to cannulate. As noted above fits may often occur in a partial form or be combined with chewing, lip smacking and swallowing movements with conjugate deviation of the eyes. A high index of clinical suspicion should therefore be maintained and in selected cases EEG monitoring arranged; this often reveals marked subclinical epilepsy responsible for an increase in metabolic demands of convulsing brain. Where continuing fits are a problem clinical action should be as outlined in the management of status epilepticus (see pp. 818–821). Drugs of choice include intravenous diazepam by continuous infusion, intermittent intravenous phenytoin, or in resistant cases thiopentone, chlormethiazole, or lignocaine by continuous infusion.

REDUCTION OF INTRACRANIAL PRESSURE

The possible presence of raised intracranial pressure in acutely ill children is frequently overlooked and this is particularly the case if clinicians rely on the frequently absent 'classical' signs of raised intracranial pressure (vide supra). As noted above the only reliable means of excluding raised intracranial pressure is to measure it. Continuous monitoring of intracranial pressure may be performed using a transducer measuring via a ventricular cannula or ventriculostomy reservoir. This renders CSF sampling easy and relief of pressure is possible by removal of cerebrospinal fluid or continuous drainage. In cerebral oedema where the ventricles are compressed a 'subarachnoid bolt' or subdural or epidural transducer may be used. The possibility of cerebral oedema should always be considered in states of disturbed consciousness or convulsions and is a particularly frequent component of cerebral asphyxia and trauma, status epilepticus, meningitis, encephalitis, Reye's syndrome, lead encephalopathy and cerebral abscess. Cerebral oedema or congestion is often exacerbated by injudicious administration of low-sodium-containing fluids. Intracranial pressure monitoring techniques have also demonstrated marked elevations in intracranial pressure during sleep, accompanying small upward fluctuations of P_{CO_2}, with coughing, airways suction and intubation. Spontaneous plateau waves (Lundberg plateau waves) may also occur with high sustained levels of intracranial pressure with no clinical sign other than sudden death.

In many cases the treatment of cerebral oedema will require to be presumptive. Fluid should be restricted to 60 per cent of estimated daily requirements; low sodium-containing infusions like 5 per cent dextrose or 0.18 per cent saline in 5 per cent dextrose are contraindicated. The osmotic diuretic mannitol may be administered in a dose of 7 ml/kg of 20 per cent solution given over 20 min. This may be repeated if necessary and monitored by regular checks of osmolality which may be allowed to rise if indicated to 320 mosmol/kg. Other diuretics, e.g. frusemide may be required in the presence of pulmonary oedema. Dexamethasone 1–4 mg may be given early to stabilize cerebral capillaries and minimize endothelial leakage of albumin. Other measures to reduce intracranial pressure include hyperventilation (see above). and induced hypothermia using an autoregulated cooling blanket to maintain the body temperature at 31.5°C for 2–3 days. If shivering raises the core temperature chlorpromazine may be administered in a dose of 1 mg/kg. Reported experience with thiopentone and pentobarbitone in cerebral oedema and cerebral congestion related to Reye's syndrome and head injury suggests that an intravenous dose range of 1.5–5 mg/kg hourly may be effective in reducing raised intracranial pressure. Serum values are maintained between 25–40 mg/l (110–165 μmol/l). Again, intensive care monitoring with ventilation (p. 600) facilities and EEG monitoring (p. 683) are essential.

More widespread application of measures to control raised intracranial pressure is resulting in improved survival and reduced morbidity in conditions previously associated with high mortality, e.g. Reye's syndrome (see Shaywitz *et al.*, 1980).

INFECTION

When infection is suspected from preliminary history, physical examination or from examination of blood and CSF, specific therapy should be introduced early. Treatment may need to be presumptive pending full laboratory confirmation; a combination of penicillin and chloramphenicol will provide cover against commonly encountered bacterial pathogens. Some clinicians prefer high dose intravenous ampicillin (400 mg/kg per 24 hours), even though this drug provides inferior brain penetration to

chloramphenicol, particularly in the absence of meningeal inflammation. Metronidazole may be added if the possibility of cerebral abscess arises and neuro-surgical advice should also be sought in case surgical drainage of an abscess becomes necessary. A diagnosis of tuberculosis may be difficult to confirm early and again specific therapy may be indicated if a low CSF glucose in association with lymphocytes in CSF is seen, even if preliminary Ziehl-Neelson staining proves negative.

Initiating therapy to combat infection may be only part of the treatment required and the possibility of other problems (e.g. hydrocephalus, cerebral oedema, inappropriate ADH secretion) complicating CNS infection must not be overlooked. Specific antiviral chemotherapy may be indicated when herpes simplex is confirmed by immunofluorescence of tissue obtained at brain biopsy. Although this technique allows a definitive diagnosis treatment with adenine arabinoside (Ara A; Vidarabine) may need to be commenced using clinical criteria only and the results of EEG and CT scanning (vide supra).

Specific chemotherapy for fungal, helminth and protozoal infection is discussed in Chapter 24.

CORRECTION OF SHOCK, HOMEOSTATIC DEFECTS AND INTOXICATION

General supportive measures including plasma expansion and pressor agents like dopamine or noradrenaline may be necessary to correct *shock* states. Severe *hypertension* (e.g. as in haemolytic uraemic syndrome or acute nephritis) should be corrected with diazoxide or hydralazine. *Bradycardia*, asystole, or ECG changes resembling myocardial infarction may be seen in association with cerebral lesions. If these are not abolished by reduction of intracranial pressure atropine should be given.

Coagulation disorders must be appropriately corrected; a coagulopathy which returns after correction carries a poor prognosis and usually implies multi-organ damage.

Hypoglycaemia should be corrected if necessary by 5 per cent intravenous glucose infusion with extra bolus doses of 20 per cent glucose as required. *Hyperglycaemia* is sometimes seen early with coma and fits and should be managed by appropriate manipulation of the infusion fluid. Insulin is rarely required. *Hypernatraemia* should be corrected *slowly* with fluids containing not less than 0.45 per cent saline because of the danger of precipitating cerebral oedema. *Hyponatraemia* due to water intoxication is a common finding: sodium levels less than 120 mmol/l may cause coma and fits. Hyponatraemia frequently results from over-administration of low sodium containing fluids combined with inappropriate ADH secretion. Management of hyponatraemia should include fluid restriction to at least 60 per cent of known daily requirements combined with diuretics e.g. 20 per cent mannitol 7 ml/kg or frusemide (4–40 mg depending on age). *Hypocalcaemia* should be corrected by continuous infusion of 10 per cent calcium gluconate as part of an intravenous electrolyte cocktail; bolus injections of calcium gluconate have a short-lived effect and may also impair cardiac function.

The management of *renal* (p. 1078) and *hepatic failure* (p. 491) may include consideration of dialysis and further modification of fluid balance and nutritional policy.

Nutrition should not be overlooked in patients with protracted coma. Parenteral nutrition carries a high risk of infection; amino acid mixtures may also exacerbate acidosis and hyperlipidaemic states produce spuriously low electrolyte values on assay. Continuous naso-gastric or naso-jejunal feeding with specially prepared mixtures (e.g. Clinifeed) are being increasingly employed. The dangers of aspiration should not be overlooked and infusion should be discontinued in the presence of abdominal distension or on obtaining excessive aspirate. *Acute gastric erosions* occur in comatose patients particularly when treated with dexamethasone and occasionally massive haematemesis may be seen. Alkali should be administered via the naso-gastric tube as a prophylactic measure; intravenous cimetidine (3 mg/kg 6 hourly) should be used with caution because of the risk of infection due to total loss of the gastric acid protective barrier.

The numerous examples of toxic encephalopathy may generally be managed by intensive supportive therapy (see the management of poisoning, Ch. 31). *Specific antivenins* may be appropriate for bites and stings which will generally be available in areas where these problems are endemic. *Chelating agents* may be employed in cases of heavy metal poisoning.

PROGNOSIS IN ENCEPHALOPATHY

The overall prognosis in infants and children presenting with acute encephalopathy is poor, particularly after ischaemic anoxic insults and in the presence of decerebration and coma (see Table 14:18). The prognosis is better following acute intoxication. Improvement in function may continue for several weeks after an acute illness. Vision may continue to improve up to 6 months after an episode of apparent total visual loss (cortical blindness). A 'locked in' state of akinetic mutism may persist for several months followed by complete recovery of speech. This may be potentially embarrassing for medical and nursing attendants who may have made inappropriate comments at an earlier stage in the illness assuming the patient to be comatose or in a vegetative state. As noted above intensive monitoring and early treatment of detected complications is at least as important as the underlying cause in many examples of encephalopathy. Prevention aside, attention to these aspects of management should help to reduce the mortality and morbidity in this group of conditions.

C.R. Steer

Table 14:18

Prognosis in Infants and Children Presenting with Acute Encephalopathy (Excluding Accidental Injury)

Outcome	Status Epilepticus	Decerebration	Coma
Death (%)	8	31	27
Significant Handicap (%)	19	20	15
Mild Handicap (%) or Complete Recovery (%)	73	11 or 38	13 or 45

FACIAL PALSIES

UPPER MOTOR NEURONE FACIAL PALSIES

The upper facial masculature has bilateral representation in the cerebral cortex. Thus a bilateral lesion is necessary to produce

PINDERFIELDS HOSPITAL PAEDIATRIC UNIT PROTOCOL (1999) FOR

12) COMA AND ACUTE ENCEPHALOPATHY

Acute coma and acute encephalopathy can be caused by a variety of disorders (see below)

It is :

- a reduced level of consciousness
- with or without fits
- with or without focal neurological signs

Beware brain swelling and raised intracranial pressure.

Inappropriate ADH secretion (low sodium in the blood).

Ensure blood pressure and perfusion is maintained.

Fluid balance should be two thirds of calculated requirement. Start with 0.45% saline in 5% or 10% Dextrose. Ensure that the urine output is 2 mls/kg of body weight/hour. If it drops below this consider winding fluid intake up.

Acute Encephalopathy

Airway, Breathing, Circulation [and record level of consciousness on AVPU or GCS]

Maintain airway, empty stomach with nasogastric tube

Full physical examination of the child noting particularly:

Signs of head trauma, blood pressure, papilloedema or bleeds in the retina.

Pulse rate and rhythm

Pupillary reactions

Record CNS signs and particularly focal signs

Is there a murmur

Has the child cyanotic congenital heart disease (brain abscess)

Do urgent capillary glucose and if hypoglycaemia give Dextrose intravenously in 10% solution intravenously in a dosage of 4 to 6 ml/kg of body weight.

Do full blood count and CRP, culture, PCV and do sickle test in a child with racial skin pigmentation.

Coagulation studies

Calcium, phosphate, alkaline phosphatase

Urea and electrolytes

Liver enzymes, ammonia and ALT; get results out of hours.

Blood gases

Blood glucose

Blood lead

Urine for metabolic and drug/ toxicology screen

Urine can be also analysed urgently as follows

Ketostix

Clinitest

Dinitrophenylhydrazine (these are particularly important in babies as they may provide an indication of a metabolic disorder

Skull x-ray

Chest x-ray

X-ray wrist for lead line or metabolic bone disease in renal failure

6) CT scan of brain

7) If pupils are sluggish or non responsive give Mannitol 20% solution intravenously in a dose of 1 g/kg of body weight over 10 minutes.

Consider ventilation and reducing PCO2 to 3.5 kpa.

Do not do a lumbar puncture

8) If Dexamethasone is given consider gastric protection with oral or IV Ranitidine or Cimetidine and also oral antacids.

Treat fits.

Consider cause.

9) Specific treatment. Cover with IV Ceftriaxone and also especially If fitting or focal signs use Acyclovir and consider urgent EEG. **If low sodium fluid restict and use normal or half normal saline**. Watch blood glucose and remember Addisons disease.

CAUSES

Head Injury (subdural and epidural haematomas), NAI.

Infections: Cerebral abscess, systemic infection, meningitis, encephalitis (eg herpes).

Cerebral anoxia/ischaemia:

Cardiorespiratory arrest and failure, airway obstruction

Shock, drowning, SIDS, suffocation.

Epilepsy: Post-ictal

Vascular: Intracranial bleeding

Hypertensive encephalopathy

Metabolic: Diabetes mellitus (hypoglycaemia, DKA) hepatic failure, Reye's Syndrome

Renal Failure

Hypo & hypernatraemia

Inborn error of metabolism

7) Poisoning/ingestion:

Alcohol, paracetamol, salicylates

Barbiturates, opiates, Iron, lead

Antidepressant, anticonvulsants

Glue Sniffing

8) Raised ICP:

Cerebral oedema

Hydrocephalus, tumour

NEXT PAGES EXTRACTS FROM TEXTBOOK OF PAEDIATRICS. FORFAR & ARNEIL 6TH EDITION

Table 20.53 Important causes of acute encephalopathy

Infectious and parainfectious encephalopathies
Meningitis (mainly bacterial, rarely fungal, protozoal and viral)
Cortical thrombophlebitis
Cerebral abscess and empyema
Primary viral encephalitis
Postinfectious encephalitis
Acute disseminated encephalomyelitis
Cerebral malaria
Severe systemic infections, including septicemia

Hypoxic ischemic encephalopathies
Perinatal asphyxia
Severe pulmonary disease
Carbon monoxide poisoning
Methemoglobinemia
Severe anemia
Status epilepticus
Near miss sudden infant death syndrome
Post cardiac arrest
Cardiac bypass surgery
Near drowning
Cardiac arrhythmias
Congestive cardiac failure
Hypotension
Disseminated intravascular coagulation
Hypoglycemia
Anesthetic accidents
Vitamin or cofactor deficiencies (B_{12}, B_6, folate, etc.)

Trauma
Accidental
Non-accidental

Exogenous toxins
Drugs:
Antihistamines, anticholinergics, antidepressants, hypnotics & sedatives, analgesics, antiepileptics, anti-inflammatory, antimetabolites, antibiotics, etc.

Illicit substances:
Alcohol, solvents, cannabis, cocaine, amfetamines, opiates

Environmental toxins:
Carbon monoxide, phosphates, DDT, iron, lead, pesticides, heavy metals, insect & snake venoms, plants, etc.
Hypothermia
Heat stroke

Endogenous agents
Water intoxication
Electrolyte imbalances, esp. hypo & hypernatremia
Acidosis & alkalosis
Scalds

Endocrine disorders:
Diabetes mellitus, hypoglycemia, hypo & hyperthyroidism, hypo & hyperparathyroidism, hypopituitarism, hypoadrenalism

Organ failure:
Hepatic, renal, pancreas
Hypertension

Inborn errors of metabolism:
Aminoacidopathies, organicacidurias, urea cycle defects, fatty acid oxidation defects, mitochondrial disorders, carnitine deficiency, porphyria

Cerebrovascular disease
Hemorrhagic stroke
Ischemic stroke
Epileptic seizure related
Postictal
Nonconvulsive status epilepticus
Postconvulsive status epilepticus

Annex

Table 20.55 Useful investigations in coma

Basic hematological & biochemical investigations, including glucose, Ca, Po_4, Alk P & LFTs
Markers of inflammation, including ESR & CRP
Blood & urine osmolality
Blood clotting studies
Bacteriological & virological studies including cultures, serology, PCRs, Mantoux, etc.
Neuroimaging: Ultrasound, CT, MRI
Blood gases
Plasma ammonia
Plasma lactate
Urine toxicology
Blood toxicology – alcohol, lead & specific toxins where indicated
Blood anticonvulsant levels
Urine metabolic screen
Urine amino and organic acids
CSF examination including lactate and glycine if indicated
TFTs & other endocrine investigations if indicated
Blood & urinary porphyrins
Skeletal survey
EEG

AND FOLLOWING PAGES SHOW COPIES OF THE ADVANCED PAEDIATRIC LIFE SUPPORT COURSE MANUAL 1993

PATHOPHYSIOLOGY AND AETIOLOGY

Coma is a sign of significant "brain failure" and requires emergency treatment to prevent or minimise central nervous system damage.

In children, coma is caused by a diffuse metabolic insult (including cerebral hypoxia and ischaemia) in 95% of cases, and by structural lesions in the remaining 5%. Metabolic disturbances can produce diffuse, incomplete, and asymmetrical neurological signs. Early signs of metabolic encephalopathy may be subtle with reduced attention and blunted affect. The most common causes of coma are summarised in the box.

Disorders causing coma in children

Hypoxic – ischaemic brain injury
  Following respiratory or circulatory failure
Epileptic seizures
Trauma
  Intracranial haemorrhage, brain swelling
Infections
  Meningitis
  Encephalitis
Poisons
Metabolic
  Renal, hepatic failure, Reye's syndrome, hypoglycaemia, diabetes, hypothermia, hypercapnia
Vascular lesions
  Bleeding, arteriovenous malformations, arterial or venous thrombosis
Hypertension

Cerebral perfusion pressure

The initial priority in the management of the unconscious child is the maintenance of adequate airway breathing, circulation, and metabolic homoeostasis. Once this has been done, attention may then be given to the possibility of raised intracranial pressure and its effects.

In very young children, before the cranial sutures are closed, considerable expansion in the intracranial volume may occur if the process is slow. However, if the process is rapid and in children with a fixed-volume cranium, increase in volume due to brain swelling, haematoma, or cerebral spinal fluid (CSF) blockage will cause raised intracranial pressure (ICP). Initially cerebrospinal fluid and venous blood within the cranium decrease in volume. Soon, this compensating mechanism fails and as the intracranial pressure continues to rise the cerebral perfusion pressure (CPP) falls and arterial blood flow is reduced.

$$CPP = MAP - ICP$$

where MAP is mean arterial pressure. Reduced CPP reduces cerebral blood flow (CBF). Normal CBF is over 50 ml/100 g brain tissue/min. If the CBF falls below 20, the brain suffers ischaemia.

Increasing intracranial pressure will push brain tissue against more rigid intracranial structures. Two clinical syndromes are recognisable by the site of localised brain compression.

Central syndrome

The whole brain is pressed down towards the foramen magnum and the cerebellar tonsils herniate through it ("coning"). Neck stiffness may be noted. A slow pulse, raised blood pressure, and irregular respiration leading to apnoea are seen terminally.

Uncal syndrome

The intracranial volume increase is mainly in the supratentorial part of the intracranial space. The uncus, which is part of the hippocampal gyrus, is forced through the tentorial opening and compressed against the fixed free edge of the tentorium. If the pressure is unilateral (for example, from a subdural or extradural haematoma), this leads to third nerve compression and an ipsilateral dilated pupil. Next, an external oculomotor palsy appears, so the eye cannot move laterally. Hemiplegia may then develop on either or both sides of the body, depending on the progression of the herniation.

Further signs that may be indicative of raised intracranial pressure are discussed below under "Assessment and management".

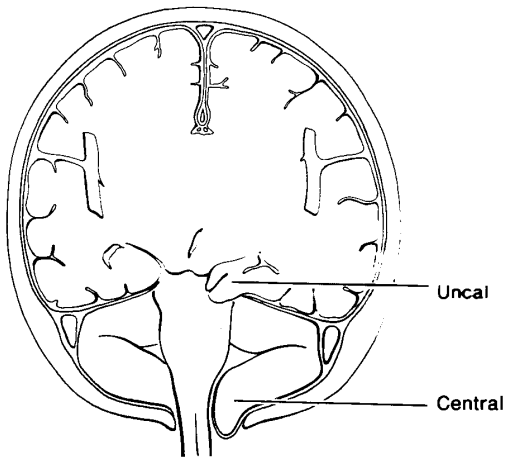


Figure 12.1. Herniations of the brain

ASSESSMENT AND MANAGEMENT

This must be sequential and methodical. Every effort should be made both to prevent secondary brain damage from hypoxia or ischaemia, from hypoglycaemia or from infection, and to minimise increased intracranial pressure.

Primary assessment and management

In the *primary* phase, airway, breathing, and circulation are assessed and stabilised. Urgent problems such as hypoglycaemia, sepsis, and raised intracranial pressure are addressed.

Airway

Establish and maintain an adequate airway.

Breathing

Give high-flow oxygen. Intubation and ventilatory support will be needed under the following conditions:

- Breathing is inadequate.
- There is no protective cough reflex or gag reflex.

Anr

A

1993	Recent advances in paediatrics. Author TJ David. Volume 11 in a series by Churchill Livingstone. Date 1993. If	In a chapter on management of acute encephalopathy is in infancy, the following statements were made in relation to management. "Maintenance of blood pressure and therefore vital organ perfusion is a priority. The quantity and type of fluids will be tailored to the circumstances. It is important to avoid large quantities of hypotonic solutions as they can promote cerebral oedema." Refers to methods of intracranial pressure monitoring and the use of mannitol and frusemide

1998	Hospital paediatrics. Third edition. Milner `and Hull. Churchill Livingstone	"If the Glasgow coma score is nine or less, where the airway is not secure or where there are bulbar signs the child should be sedated, intubated and ventilated." Treatment for raised intracranial pressure is suggested including sedation with Midazolam infusion in a dosage of 100 to 300 µg/kg/h In brainstem death assessment it is advised that it should be recorded if other drugs which affect consciousness had been given during the preceding 12 hours.

2003	Textbook of paediatrics. Forfar & Arneil 6th Edition Churchill Livingstone	Hyponatraemia: "there are some patients whose plasma sodium concentrations remain below the lower limit of the normal range (e.g. 132mmol/l) without symptoms and to excrete supplemental sodium to maintain this new steady-state. Hyponatraemia occurs as a result of water intoxication, prescription of hypotonic IV fluids, syndrome of inappropriate ADH, missed cases of acute renal failure.

		"Syndrome of inappropriate ADH is well recognised but it is frequently a misnomer. ADH secretion can be considered an appropriate evolutionary physiological response to illnesses or injuries which are sufficient severity to preclude drinking for several days. The most common causes are CNS injury and bacterial pneumonia. The retained water however often does not come from a physiological source but from a prescription to administer fluid in quantities that did not anticipate the ADH secretion. In any case the clinical picture water intoxication (hyponatraemia) develops. The diagnosis is made by proving that urine osmolality exceeds that of a hyperosmolar plasma and the treatment is usually fluid restriction." ….. "Rapid correction of hyponatraemia is justified in circumstances where severe symptoms have resulted from a rapid fall in serum sodium. If a good history is not available, symptoms are severe and serum Na is <120mmol/l a rapid initial correction is justified to values of 125mmol/l.. Further increase in serum sodium is best achieved more gradually was fluid restriction. In all other circumstances slow correction is advised by fluid restriction alone and the provision of normal rather than increased sodium supplements. The neurological symptoms associated with acute hyponatraemia are in part due to cerebral oedema and may improve with a hypertonic saline as the brain shrinks."…

ANNEX B

MIDAZOLAM PRESCRIPTION POTENTIAL DOSE ERROR

After Dr Webb had seen Claire at 2pm, the SHO made an entry in the notes (page 55) as follows

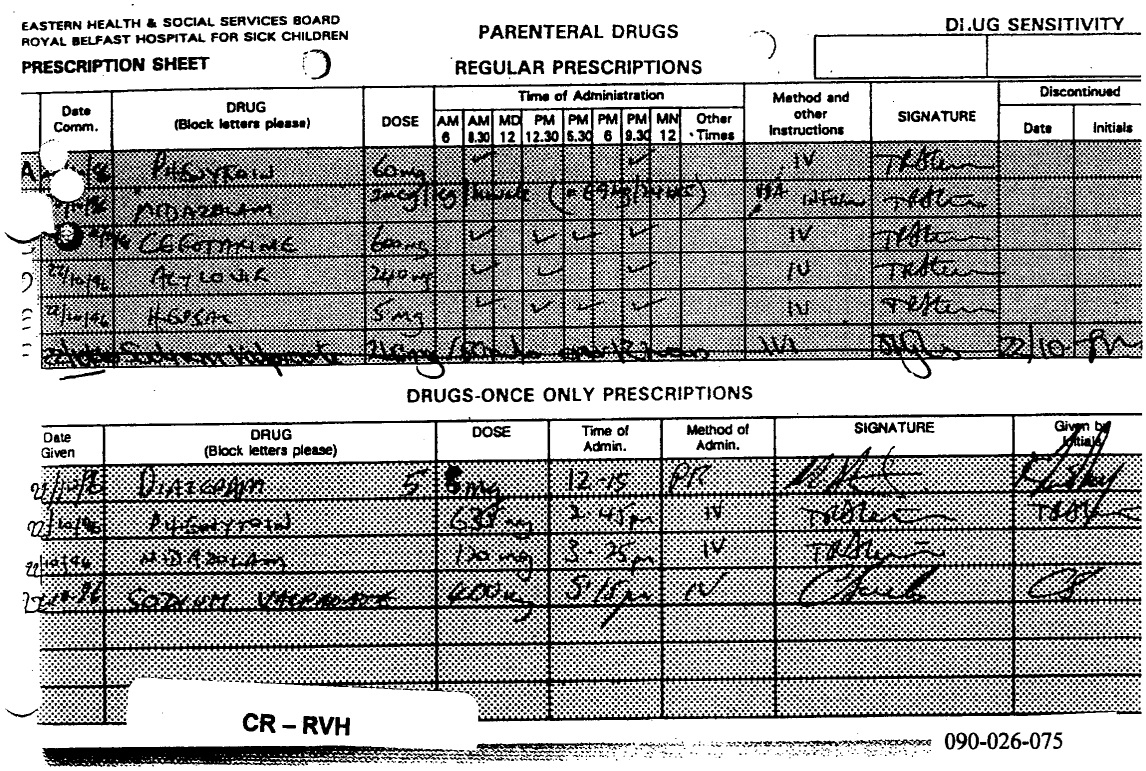
:

CH 528770 Page

DATE	CLINICAL HISTORY, EXAMINATION AND PROGRESS
22/10/96	S/B. Dr Webb
	Still in theatre
	1. MIDAZALAM 0.5 mg/kg STAT DOSE = 0.5 x 24
	= 12 mg IV Stat
	2. MIDAZALAM 2 mcg/kg/min = 2 x 24 mcg/min
	= 48 mcg/min
	= 48 x 60 mcg/Hr
	= 2880 mcg/Hr
	= 2.88 mg/HR INFUSION
	= 69 mg/24 HRS.

At the same time a prescription was written by the SHO :

up:



EASTERN HEALTH & SOCIAL SERVICES BOARD
ROYAL BELFAST HOSPITAL FOR SICK CHILDREN

PRESCRIPTION SHEET

PARENTERAL DRUGS

DRUG SENSITIVITY

REGULAR PRESCRIPTIONS

Date Comm.	DRUG (Block letters please)	DOSE	Time of Administration: AM 6	AM 8.30	MD 12	PM 12.30	PM 5.30	PM 6	PM 9.30	MN 12	Other Times	Method and other Instructions	SIGNATURE	Discontinued: Date	Initials

DRUGS-ONCE ONLY PRESCRIPTIONS

Date Given	DRUG (Block letters please)	DOSE	Time of Admin.	Method of Admin.	SIGNATURE	Given by Initials

CR – RVH

090-026-075

The *regular* prescription was written up as an infusion 2 mcg/kg/minute.

The *Drugs once only prescriptions* section shows a bolus dose written up of 120 mg (whereas the intended bolus was to be – from the history sheet note – 12mg). The column of the sheet recording as given is not completed by a signature. Was this given ? If so this was an overdose by x10 on intended and 25x the advised dose for status epilepticus.

The doses of Midazolam advised by the RCPCH *Medicines for Children* 2001 differ according to intended use.

184 Midazolam continued

DOSAGE continued

Child

Indication	Route	Age			Frequency	Notes
		1 month–2 years	2–12 years	12–18 years		
Premedication	IM	←	70–100 microgram/kg	→	single dose	Administer 30–60 minutes prior to surgery.
	Oral	←	500 microgram/kg (maximum dose 15mg)	→	single dose	
Sedation for procedures	IV bolus	–		2mg	single dose	If after 2 minutes sedation is not adequate, incremental doses of 500 microgram – 1mg can be given. Doses >5mg are rarely needed.
	IV bolus or IM	←	50–100 microgram/kg →	–	single dose	Doses up to 300 microgram/kg may sometimes be needed.
	Oral	←	500 microgram/kg (maximum dose 15mg)	→	single dose	
	Rectal	←	500–750 microgram/kg	→	single dose	
	Intranasal	←	200–300 microgram/kg	→	single dose	Half the dose can be given into each nostril.

185 Midazolam continued

Child continued

Indication	Route	Age			Frequency	Notes
		1 month–2 years	2–12 years	12–18 years		
Sedation in intensive care	IV bolus (over 3–5 minutes)	←	100–200 microgram/kg	→	single dose	This may not be needed if the patient is already receiving morphine. Reduce the dose in hypovolaemia, vasoconstriction and hypothermia. Low doses may also be adequate if the patient is also receiving an opiate. Adjust according to response.
			then			
	IV infusion	←	30–200 microgram/kg/hour	→	continuous	
Induction of anaesthesia	Slow IV bolus	–	>7 years 150 microgram/kg	200–300 microgram/kg	single dose	In adults the dose should be titrated against individual response. Young fit unpremedicated patients may require at least 300 microgram/kg. Those premedicated with an opiate usually only require a dose of 200 microgram/kg.

NOTES

- **Administration: rectal, intranasal:** the injection may be given intranasally and rectally. **Oral:** if the injection is used orally the bitter taste may be disguised by apple or blackcurrent juice or chocolate sauce, however, oral liquids are available.
- Caution in patients with respiratory failure.
- Drug interactions: erythromycin and other macrolide antibiotics, cimetidine,

(i) DOSE CALCULATION

(ii) Claire was aged 9 years and weighed 24 kg – according to the history sheet calculation. Thus the maximum **bolus** dose for IV used should be 100 microG per Kg body weight. (2400 microG= 2.4 mg) when used for sedation for procedures or up to 300 microG/kg body weight when used for sedation in intensive care (7.2 mg) . But for status epilepticus (from Medicines for Children 2003) up to 200 microG/kg is advised. Thus the *intended* bolus dose of 12 mg was 5 x advised dose for procedure

dose and 1.6x advised dose for intensive care and 2.5x the advised dose for status epilepticus . The *prescribed* bolus dose was 120 mg to be given at 3.25 pm is thus 25x the advised dose for status epilepticus.

(iii) If that ***bolus dose*** was given then it would have been a large overdose with excessive (potentially dangerous) sedation and potential respiratory depression with CO2 retention worsening brain swelling. A particular vulnerability however relates to when medication is being given by a doctor rather than a nurse. Intravenous medication is usually given by the doctor and is then made up by him/her. Current practice which was often not recorded in protocols in 1996 and subsequently is that this drawing up of dosage as well as the calculation of dosage according to body weight would be cross checked with the nurse. This offers the opportunity for a nurse to challenge if the dosage appears excessive. In respect of the Midazolam bolus dose, it is not evident whether this was given (but equally not evident that it was not given). If it was not given was this because a nurse challenged the dosage? If so that should have been recorded both in the medical and nursing records and raised as a serious potential clinical adverse event. Dr Webb records that the bolus had been given and presumably came to this conclusion from review of the prescription. The dose written up on prescription was a significant overdose with significant risk of respiratory depression. The failure to note this and the failure to identify this later in the clinical audit death review and later in 2004 is striking. Furthermore the consultants who were asked to review the case of Clare by the coroner did not notice this or comment on it.

(iv) If the ***bolus dose*** was omitted then this should have been written in the notes as "bolus not given" and the prescription entry scored through. In order to draw up a bolus dose for administration, the doctor would have had to use a number of ampoules/vials to do so.

a. The nurse records refer to "Hypnovel" a trade name. And this formulation may have been the one in use on the ward. The BNF 2005 gives non proprietary formulations as well. A number of ampoules may well have been used to assemble to 69mg dose added to the IV fluid for infusion. It would be helpful to know what formulation(s) were available in 1996 on Allen ward.

Source	***Concentration***	***Ampoule/vial volume -ml***	***Contains***
Proprietary	1mg/ml	50	50mg
Proprietary	5mg/ml	2	10mg
Proprietary	5mg/ml	5	25mg
Proprietary	5mg/ml	10	50mg
Proprietary	5mg/ml	18	90mg

Source	***Concentration***	***Ampoule/vial volume -ml***	***Contains***
Hypnovel	2mg/ml	5	10mg
	5mg/ml	2ml	10mg

b. However the following nurse record suggests a bolus dose was given .

i. 090-040-141. Nursing Kardex. Refers to period 2 PM-8 PM.

ii. "Continues on hourly CNS observation GCS 6-7. Stat dose IV phenytoin at 2:45 PM to have BD. S/B Dr Webb still status epilepticus given stat IV hypnoval at 3:25 PM. Continuous infusion running at 2mls/hr of hypnoval to be increased by 0.1 ml /5min until up to 3 mls per hour. Dr to write up. Given stat dose Epilim at 5:15 PM. Very unresponsive. Only to pain. Remains pale. Occasional episodes of tooth clinching. Commenced on IV [probably Cefotaxime] and IV acyclovir. First dose Cefotaxime due 9:30 PM some parents in attendance"

iii. additional note due phenytoin levels at 9 PM and then followed by tick and a entry of 23.4

(v) The intended ***infusion*** dosage from the history sheet calculation and prescription was 2 microG per kg body weight per minute. The IV prescription chart shown below indicates this was 64mg in 50 ml to be given at 2ml per hour. This would give 2560 microG per hour = 106 microG per kg body weight per hour.

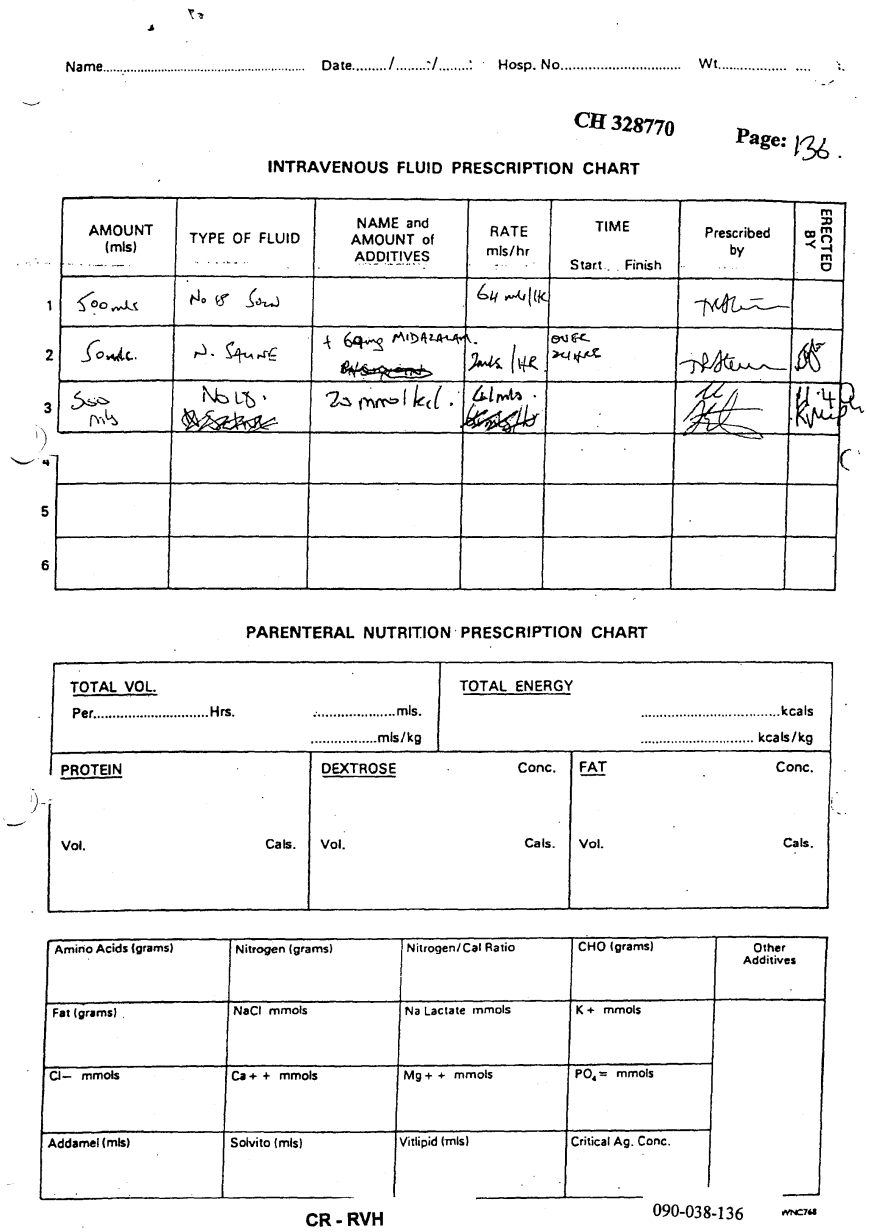
(vi) This infusion dose is within the infusion rate advised in *Medicines for Children (2001)* of 30-200 microG per kg body weight per hour.(And up to 300 microG/kg/hour in an intensive care unit)

(vii) It appears this infusion dose was given. It is not clear when Dr Webb advised this dose or why he added Midazolam to the regime he had already advised at the 2pm visit.

(viii) ***Comment***: It is not certain that ***the bolus dose*** was given at all. But the error with the dosage intended and dosage written up should have been picked up by Dr Webb at his review of Claire at 17:00 h on the 22 October and also it could have been noted at the review of deaths in the audit meeting and reported as a major medicines error. There is no indication that it was. A ward pharmacist should review all prescriptions daily both as a safety and educational process. The signature space

on the prescription chart to indicate as given is not ticked and this bolus dose probably was not given even though Dr Webb noted it as having been given.

(ix) Was a process of ward pharmacist review in place in 1996? It was in in place in many hospitals and a major teaching Children's hospital should have been particularly alert to drug errors. It is not clear what source of advice was used for the Midazolam dose used. Midazolam is not listed in the Paediatric Vade Mecum 1990 edition (Birmingham Children's Hospital reference). It is listed as 100 microG per kg body weight as bolus in intensive care for ventilated patients in the Alder Hey Hospital Book of Children's Doses 6th Edition 1994 and as 50-300 microG/kg/hour as infusion. (see scan of the page below) . Although not available at the time I give the relevant page from the BNF for Children from 2005. It may be possible to obtain a copy of the BNF for 1996 to check if ampoule sizes have changed.



Name..... Date...../...../..... Hosp. No..... Wt.....

CH 328770 Page: 136.

INTRAVENOUS FLUID PRESCRIPTION CHART

	AMOUNT (mls)	TYPE OF FLUID	NAME and AMOUNT of ADDITIVES	RATE mls/hr	TIME Start Finish	Prescribed by	ERECTED BY
1	500mls	No 18 Solw		64 mls/HR			
2	Sondc.	N. Saline	+ 60mg MIDAZOLAM.	3mls/HR	OVER 24 HRS		
3	500 mls	No 18.	25 mmol/kcl.	64mls.			
4							
5							
6							

PARENTERAL NUTRITION PRESCRIPTION CHART

TOTAL VOL.	TOTAL ENERGY
Per.....Hrs. .....mls. .....mls/kg	.....kcals .....kcals/kg

PROTEIN	DEXTROSE	Conc.	FAT	Conc.
Vol. Cals.	Vol. Cals.		Vol. Cals.	

Amino Acids (grams)	Nitrogen (grams)	Nitrogen/Cal Ratio	CHO (grams)	Other Additives
Fat (grams)	NaCl mmols	Na Lactate mmols	K+ mmols	
Cl− mmols	Ca++ mmols	Mg++ mmols	PO_4= mmols	
Addamel (mls)	Solvito (mls)	Vitlipid (mls)	Critical Ag. Conc.	

CR - RVH 090-038-136

FURTHER ADVICE SOURCES ON DOSAGE OF MIDAZOLAM IN CHILDREN

The following are relevant pages from British National Formulary for Children 2005 and from *Medicines for Children* 2003 (RCPCH and NPPA) and the last from Alder Hey Book of Children's Dosages 1994

FROM BNF CHILDREN 2005

Induction of anaesthesia

- By slow intravenous injection
  Child 7–12 years 150 micrograms/kg increased if necessary

  Child 12–18 years with premedication, initially 150–200 micrograms/kg; without premedication, initially 300–350 micrograms/kg; increase dose in steps of not greater than 5 mg every 2 minutes (max. 600 micrograms/kg)

Sedation in intensive care

- By intravenous injection and continuous intravenous infusion
  Child 1–6 months 60 micrograms/kg/hour *by continuous intravenous infusion* adjusted according to response

  Child 6 months–12 years initially 50–200 micrograms/kg *by slow intravenous injection* over at least 3 minutes followed by 30–120 micrograms/kg/hour *by continuous intravenous infusion* adjusted according to response

  Child 12–18 years initially 30–300 micrograms/kg *by slow intravenous injection* in steps of 1–2.5 mg every 2 minutes followed by 30–200 micrograms/kg/hour *by continuous intravenous infusion* adjusted according to response

  Note Initial dose may not be required and lower maintenance doses needed if opioid analgesics also used; reduce dose (or omit initial dose) in hypovolaemia, vasoconstriction, or hypothermia

Status epilepticus section 4.8.2

Administration For *intravenous infusion* dilute with glucose 5% or sodium chloride 0.9% or sodium chloride and glucose intravenous infusion; for neonates and children under 15 kg dilute to a concentration of 1 mg/mL.

For rectal administration of the injection solution, attach a plastic applicator onto the end of a syringe; if the volume to be given rectally is too small, water for injection may be added.

Injection solution may be given intranasally (unpleasant and may cause severe irritation of nasal mucosa)

Midazolam (Non-proprietary) PoM

Injection, midazolam (as hydrochloride) 1 mg/mL, net price 50-mL vial = £6.00; 5 mg/mL, 2-mL amp = 79p, 5-mL amp = 91p, 10-mL amp = £4.70, 18-mL amp = £6.80

Oral liquid, midazolam (as maleate), 2.5 mg/mL, 100 mL

Available as a manufactured special from Special Products Ltd.

Hypnovel® (Roche) PoM

Injection, midazolam (as hydrochloride) 2 mg/mL, net price 5-mL amp = 75p; 5 mg/mL, 2-mL amp = 90p

TEMAZEPAM

Cautions see notes above and under Diazepam (section 4.1.2 and section 4.8.2); **interactions:** Appendix 1 (anxiolytics and hypnotics)

Contra-indications see notes above and under Diazepam (section 4.1.2)

Side-effects see notes above and under Diazepam (section 4.1.2)

Licensed use tablets not licensed for use in children

Indication and dose

Premedication

- By mouth
  Child 1–12 years 1 mg/kg (max. 30 mg) 1 hour before surgery

  Child 12–18 years 20–30 mg 1 hour before surgery

[1]**Temazepam** (Non-proprietary) CD

Tablets, temazepam 10 mg, net price 28-tab pack = 95p; 20 mg, 28-tab pack = £1.65. Label: 19

Oral solution, temazepam 10 mg/5 mL, net price 300 mL = £9.95. Label: 19

Note Sugar-free versions are available and can be ordered by specifying 'sugar-free' on the prescription

Dental prescribing on NHS Temazepam Tablets or Oral Solution may be prescribed

1. See p. 16 for prescribing requirements for temazepam

15 Anaesthesia

Phenytoin (Non-proprietary) PoM
Injection, phenytoin sodium 50 mg/mL with propylene glycol 40% and alcohol 10% in water for injections, net price 5-mL amp = £3.40

Epanutin® Ready-Mixed Parenteral (Pfizer) PoM
Injection, phenytoin sodium 50 mg/mL with propylene glycol 40% and alcohol 10% in water for injections. Net price 5-mL amp = £4.88

Oral preparations
Section 4.8.1

MIDAZOLAM

Cautions section 15.1.4

Contra-indications section 15.1.4

Side-effects section 15.1.4

Licensed use *injection* not licensed for use in status epilepticus

Indication and dose

Status epilepticus

- By intravenous administration

Neonate initially 150–200 micrograms/kg as a single dose followed *by a continuous infusion* of 1 microgram/kg/minute (increased by 1 microgram/kg/minute every 15 minutes until seizure controlled; max. 5 micrograms/kg/minute)

Child 1 month–18 years *by continuous infusion* of 1 microgram/kg/minute (increased by 1 microgram/kg/minute every 15 minutes) until seizure controlled; max. 5 micrograms/kg/minute

- By buccal administration (preferred) or by intranasal administration

Neonate 300 micrograms/kg as a single dose

Child 1–6 months 300 micrograms/kg as a single dose

Child 6 months–1 year 2.5 mg as a single dose

Child 1–5 years 5 mg as a single dose

Child 5–10 years 7.5 mg as a single dose

Child 10–18 years 10 mg as a single dose

Administration injection may be diluted in glucose 5% or sodium chloride 0.9%; rapid intravenous injection (less than 2 minutes) may cause seizure-like myoclonus in preterm neonate. Buccal liquid may be given intranasally. Injection may be given bucally, intranasally or by mouth

Preparations
Section 15.1.4
Epistatus® (midazolam buccal liquid 10 mg/mL) is available from specialist manufacturers
Amsed® (midazolam oral liquid, sugar-free, 2.5 mg/mL) is available from specialist manufacturers

4 Central nervous system

FROM MEDICINES FOR CHILDREN 2003 (BELOW)

412 Miconazole continued

EXCIPIENTS
See manufacturers SPC for further details.

LICENSED STATUS
Licensed for use in all age groups.

Midazolam

Short-acting benzodiazepine with hypnotic, anxiolytic, amnesic, muscle relaxant and anticonvulsant activity.

USES
Premedication, sedation prior to short procedures and in intensive care situations, anticonvulsant, induction of general anaesthesia. In palliative care, for relief of anxiety (including for sedation during acute terminal haemorrhage), dyspnoea, intractable seizures and terminal agitation.

PRESENTATION
Injection: (as hydrochloride) 10mg in 2mL and 10mg in 5mL – Hypnovel®; 1mg in 1mL, 50mL – non-proprietary; 5mg in 1mL, 2mL, 5mL, 10mL and 18mL – non-proprietary.
Syrup (buccal liquid): 10mg in 1mL – Epistat (manufactured 'special').
Syrup: 2.5mg in 1mL – Amsed (manufactured 'special').

DOSAGE
Newborn infant (birth to 1 month)

Indication	Route	Age	Frequency	Notes
		birth–1 month		
Sedation	IV infusion	1 microgram/kg/minute for the first 24 hours then decrease to 500 nanograms/kg/minute in babies <33 weeks post-conceptional age to avoid accumulation.	continuous	Can be used for up to 4 days with apparent safety in the ventilated newborn baby.

Child

Indication	Route	Age			Frequency	Notes
		1 month–2 years	2–12 years	12–18 years		
Premedication	IM	← 70–100 microgram/kg →			single dose	Administer 30–60 minutes prior to surgery. Monitor from time of administration.
	Oral	← 500 microgram/kg (maximum dose 15mg) →			single dose	
Sedation for procedures	IV bolus	–		2mg	single dose	If after 2 minutes sedation is not adequate, incremental doses of 500 microgram – 1mg can be given. Doses >5mg are rarely needed.
	IV bolus or IM	50–100 microgram/kg		–	single dose	Doses up to 300 microgram/kg may be needed.
	Oral	← 500 microgram/kg (maximum dose 15mg) →			single dose	
	Rectal	← 500–750 microgram/kg →			single dose	
	Intranasal	← 200–300 microgram/kg →			single dose	Half the dose should be given into each nostril.

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Midazolam continued

Child continued

Indication	Route	Age			Frequency	Notes
		1 month–2 years	2–12 years	12–18 years		
Sedation in intensive care	IV bolus (over 3–5 minutes)	← 30–300 microgram/kg →			single dose	This may not be needed if the patient is already receiving morphine, or is sedated post-op. Reduce the dose in hypovolaemia, vasoconstriction and hypothermia. Low doses may be adequate if the patient is also receiving an opiate. Adjust according to response.
	IV infusion	then 500 nanogram - 3.3 microgram/kg/minute			continuous	
Induction of anaesthesia	Slow IV bolus	-	>7 years 150 microgram/kg	200–300 microgram/kg	single dose	In adults the dose should be titrated against individual response. Young fit unpremedicated patients may require at least 300 microgram/kg. Those premedicated with an opiate usually only require a dose of 200 microgram/kg.
Status epilepticus	IV bolus	← 150–200 micrograms/kg →			single dose	Initial bolus. Follow with infusion as below.
	IV infusion	1 microgram/kg/minute increasing by 1 microgram/kg/minute every 15 minutes until the seizure stops Maximum of 5 microgram/kg/minute			continuous	Start with the initial bolus above before commencing the infusion. Not yet an established drug in this area. Most experience in PICUs.
	Buccal/ intranasal	DOSE BY WEIGHT <6 months 300 microgram/kg	1–4 years 5mg	10mg	single dose	Buccal administration is the preferred route over intranasal administration.
			5–9 years 7.5mg		single dose	
		DOSE BY AGE ≥6 months 2.5mg	≥10 years 10mg		single dose	
Intractable seizures in palliative care	IV infusion/ SC infusion	← 5mg/24 hours →			continuous	Initial dose can be titrated up to 40mg/24 hours.
Anxiety in palliative care	IV infusion/ SC infusion	← 2.5mg/24 hours →			continuous	

Dose adjustment in renal and liver disease: dose should be reduced in severe renal impairment and liver failure.

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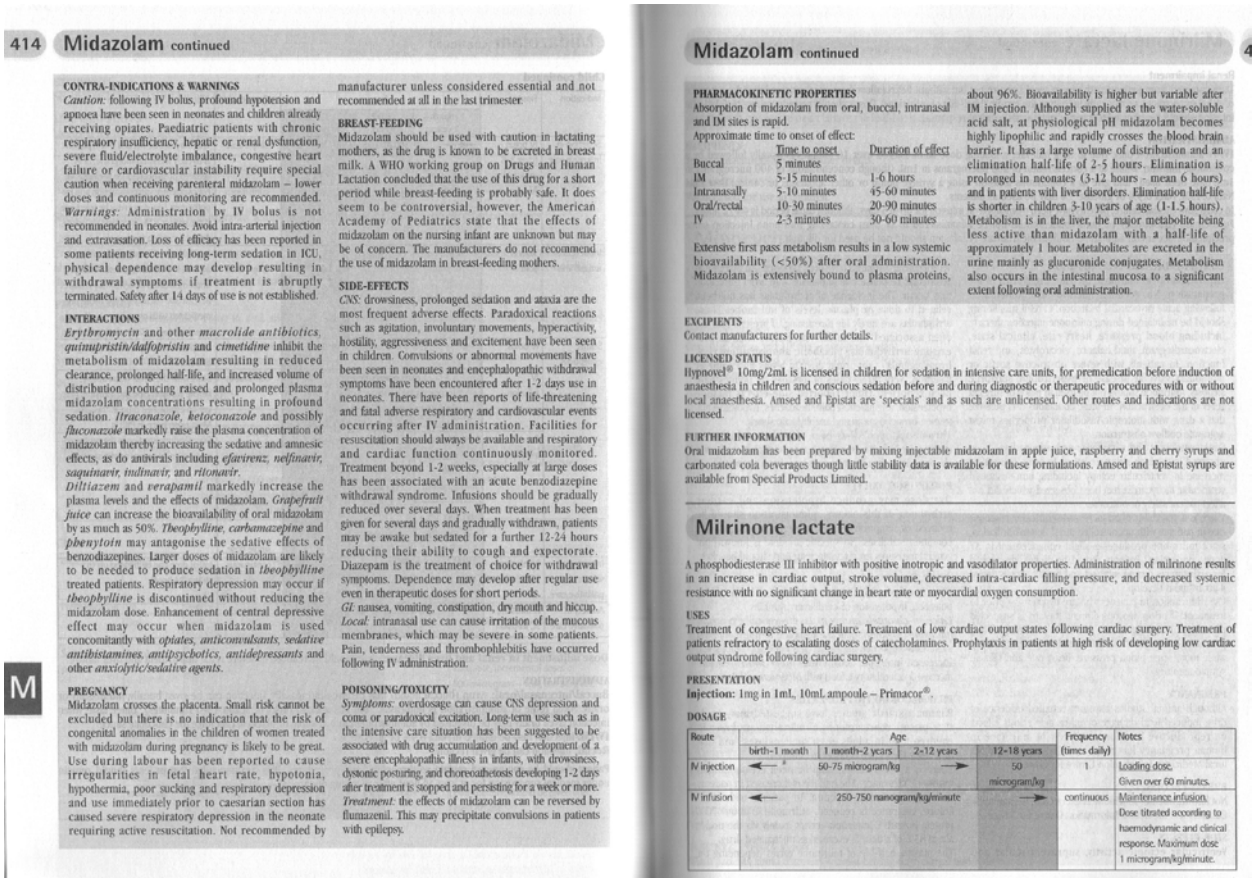
ADMINISTRATION

Buccal/intranasal/oral: syrup (buccal liquid) may be given intranasally. Injection can be given bucally, intranasally or orally. Nasal route of administration is unpleasant, but has a rapid onset of action (5–15 minutes). Bitter taste when injection given orally may be disguised by administration in e.g. apple or blackcurrant juice, or chocolate sauce.
IV/IM: injection may be diluted in NaCl 0.9% or glucose 5%.
Rectal: injection can be given rectally.

Patient should be supine and remain so throughout any procedures. It is recommended that patients should remain under medical supervision for at least an hour after receiving midazolam.



414 **Midazolam** continued

CONTRA-INDICATIONS & WARNINGS

Caution: following IV bolus, profound hypotension and apnoea have been seen in neonates and children already receiving opiates. Paediatric patients with chronic respiratory insufficiency, hepatic or renal dysfunction, severe fluid/electrolyte imbalance, congestive heart failure or cardiovascular instability require special caution when receiving parenteral midazolam – lower doses and continuous monitoring are recommended. *Warnings:* Administration by IV bolus is not recommended in neonates. Avoid intra-arterial injection and extravasation. Loss of efficacy has been reported in some patients receiving long-term sedation in ICU, physical dependence may develop resulting in withdrawal symptoms if treatment is abruptly terminated. Safety after 14 days of use is not established.

INTERACTIONS

Erythromycin and other *macrolide antibiotics, quinupristin/dalfopristin* and *cimetidine* inhibit the metabolism of midazolam resulting in reduced clearance, prolonged half-life, and increased volume of distribution producing raised and prolonged plasma midazolam concentrations resulting in profound sedation. *Itraconazole, ketoconazole* and possibly *fluconazole* markedly raise the plasma concentration of midazolam thereby increasing the sedative and amnesic effects, as do antivirals including *efavirenz, nelfinavir, saquinavir, indinavir,* and *ritonavir.*

Diltiazem and *verapamil* markedly increase the plasma levels and the effects of midazolam. *Grapefruit juice* can increase the bioavailability of oral midazolam by as much as 50%. *Theophylline, carbamazepine* and *phenytoin* may antagonise the sedative effects of benzodiazepines. Larger doses of midazolam are likely to be needed to produce sedation in *theophylline* treated patients. Respiratory depression may occur if *theophylline* is discontinued without reducing the midazolam dose. Enhancement of central depressive effect may occur when midazolam is used concomitantly with *opiates, anticonvulsants, sedative antihistamines, antipsychotics, antidepressants* and other *anxiolytic/sedative agents.*

PREGNANCY

Midazolam crosses the placenta. Small risk cannot be excluded but there is no indication that the risk of congenital anomalies in the children of women treated with midazolam during pregnancy is likely to be great. Use during labour has been reported to cause irregularities in fetal heart rate, hypotonia, hypothermia, poor sucking and respiratory depression and use immediately prior to caesarian section has caused severe respiratory depression in the neonate requiring active resuscitation. Not recommended by manufacturer unless considered essential and not recommended at all in the last trimester.

BREAST-FEEDING

Midazolam should be used with caution in lactating mothers, as the drug is known to be excreted in breast milk. A WHO working group on Drugs and Human Lactation concluded that the use of this drug for a short period while breast-feeding is probably safe. It does seem to be controversial, however, the American Academy of Pediatrics state that the effects of midazolam on the nursing infant are unknown but may be of concern. The manufacturers do not recommend the use of midazolam in breast-feeding mothers.

SIDE-EFFECTS

CNS: drowsiness, prolonged sedation and ataxia are the most frequent adverse effects. Paradoxical reactions such as agitation, involuntary movements, hyperactivity, hostility, aggressiveness and excitement have been seen in children. Convulsions or abnormal movements have been seen in neonates and encephalopathic withdrawal symptoms have been encountered after 1-2 days use in neonates. There have been reports of life-threatening and fatal adverse respiratory and cardiovascular events occurring after IV administration. Facilities for resuscitation should always be available and respiratory and cardiac function continuously monitored. Treatment beyond 1-2 weeks, especially at large doses has been associated with an acute benzodiazepine withdrawal syndrome. Infusions should be gradually reduced over several days. When treatment has been given for several days and gradually withdrawn, patients may be awake but sedated for a further 12-24 hours reducing their ability to cough and expectorate. Diazepam is the treatment of choice for withdrawal symptoms. Dependence may develop after regular use even in therapeutic doses for short periods.

GI: nausea, vomiting, constipation, dry mouth and hiccup. *Local:* intranasal use can cause irritation of the mucous membranes, which may be severe in some patients. Pain, tenderness and thrombophlebitis have occurred following IV administration.

POISONING/TOXICITY

Symptoms: overdosage can cause CNS depression and coma or paradoxical excitation. Long-term use such as in the intensive care situation has been suggested to be associated with drug accumulation and development of a severe encephalopathic illness in infants, with drowsiness, dystonic posturing, and choreoathetosis developing 1-2 days after treatment is stopped and persisting for a week or more. *Treatment:* the effects of midazolam can be reversed by flumazenil. This may precipitate convulsions in patients with epilepsy.

M

Midazolam continued

PHARMACOKINETIC PROPERTIES

Absorption of midazolam from oral, buccal, intranasal and IM sites is rapid.

Approximate time to onset of effect:

	Time to onset	Duration of effect
Buccal	5 minutes	
IM	5-15 minutes	1-6 hours
Intranasally	5-10 minutes	45-60 minutes
Oral/rectal	10-30 minutes	20-90 minutes
IV	2-3 minutes	30-60 minutes

Extensive first pass metabolism results in a low systemic bioavailability (<50%) after oral administration. Midazolam is extensively bound to plasma proteins, about 96%. Bioavailability is higher but variable after IM injection. Although supplied as the water-soluble acid salt, at physiological pH midazolam becomes highly lipophilic and rapidly crosses the blood brain barrier. It has a large volume of distribution and an elimination half-life of 2-5 hours. Elimination is prolonged in neonates (3-12 hours - mean 6 hours) and in patients with liver disorders. Elimination half-life is shorter in children 3-10 years of age (1-1.5 hours). Metabolism is in the liver, the major metabolite being less active than midazolam with a half-life of approximately 1 hour. Metabolites are excreted in the urine mainly as glucuronide conjugates. Metabolism also occurs in the intestinal mucosa to a significant extent following oral administration.

EXCIPIENTS

Contact manufacturers for further details.

LICENSED STATUS

Hypnovel® 10mg/2mL is licensed in children for sedation in intensive care units, for premedication before induction of anaesthesia in children and conscious sedation before and during diagnostic or therapeutic procedures with or without local anaesthesia. Amsed and Epistat are 'specials' and as such are unlicensed. Other routes and indications are not licensed.

FURTHER INFORMATION

Oral midazolam has been prepared by mixing injectable midazolam in apple juice, raspberry and cherry syrups and carbonated cola beverages though little stability data is available for these formulations. Amsed and Epistat syrups are available from Special Products Limited.

Milrinone lactate

A phosphodiesterase III inhibitor with positive inotropic and vasodilator properties. Administration of milrinone results in an increase in cardiac output, stroke volume, decreased intra-cardiac filling pressure, and decreased systemic resistance with no significant change in heart rate or myocardial oxygen consumption.

USES

Treatment of congestive heart failure. Treatment of low cardiac output states following cardiac surgery. Treatment of patients refractory to escalating doses of catecholamines. Prophylaxis in patients at high risk of developing low cardiac output syndrome following cardiac surgery.

PRESENTATION

Injection: 1mg in 1mL, 10mL ampoule – Primacor®.

DOSAGE

Route	Age				Frequency (times daily)	Notes
	birth–1 month	1 month–2 years	2–12 years	12–18 years		
IV injection	← *	50–75 microgram/kg	→	50 microgram/kg	1	Loading dose. Given over 60 minutes.
IV infusion	←	250–750 nanogram/kg/minute	→		continuous	Maintenance infusion. Dose titrated according to haemodynamic and clinical response. Maximum dose 1 microgram/kg/minute.

FROM ALDER HEY BOOK OF CHILDREN'S DOSES 1994

Sulphoacetate 5 mg Sorbic Acid with glycerin, sorbitol and water.		use Relaxit®			Insert whole nozzle into rectum.
MIDAZOLAM injection 2 mg/ml, 5 mg/ml ampoules. continued	i.v. bolus over 3-5 minutes **then** i.v. infusion	100 mcg/kg **then** 50-300 mcg/kg/hr		single dose **then** continuous	Benzodiazepine. Sedation for ventilated patients. **Loading dose.** **Maintenance dose.** Adjust according to response. Infuse in D5 or NaCl 0.9% at a concentration of 0.5 mg/ml (or see "Infusion" section).

NOTE:DOSE GIVEN IS TOTAL DAILY DOSE UNLESS STATED OTHERWISE 137

ANNEX C

CLAIRE ROBERTS –DETAILED CLINICAL CHRONOLOGY AND COPIES OF SELECTED CLINICAL RECORDS

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
4/9/87			090-015-028. Discharge letter from paediatrics RBHSC diagnosis aged eight months was salaam attacks. Dr Hicks consultant paediatric neurologist. Generalised seizures lasting up to 3 min over three days some three seizures prior to admission and followed by two absence attacks and then six generalised convulsions within one day each of lasting and minute with cyanosis. Tonic/chronic. Treated with Tegretol, then phenytoin. Full investigations for the time but no sca13 n. Concern about development. Aged eight months. seizures following discharge continued at this time on Epilim and taken off Tegretol. EEG no hypsarhthymia.
30/5/1996			090-013-018. Letter from Dr Gaston to Dr McMillin. Clinic attendance. "Has moderate learning difficulties and history of seizures from six months to 4 years of age. She has been off Epilim for the past year and seizure free"
2/8/1996			090-013-016. A copy of a letter to Dr McMillin from Dr Gaston consultant community paediatrician. Summarising a recent assessment. Extracts-performance school not good easily distracted inattentive and active. Learning disabilities. Trial of Ritalin. 10 mg of breakfast. One week first as placebo. On the next page 7 handwritten updating phone call on 11/9/96. One week Ritalin 10 mg in the morning mother to phone. 20/9/1996, doing well staleness. 2/10/96 dry mouth, viscous, pacing, query

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			agitated/unsettled 30 min after Ritalin?? Social awareness. Therefore restart on weekend just 5 mg mother to call five days later.
21/10/96			Accident and emergency department record. 090-010-012. Triage 1857 complaint lethargy, vomiting and pale. Epileptic. Medication non-. H/o typewritten off form and lethargy. GP referral with H/O seizure. Apyrexial O/A pale and drowsy O/A H/O mental handicap. 1903 temperature 36.9, pulse rate 96, respiratory rate 24, PEARL bag urine >. Handwriting Emla 715 S/B medical registrar admit Allen Ward. Records signed Jackson 2045.
21/10/96			090-011-013. GP handwritten referral letter. "Nine-year-old girl with severe learning disabilities and past history of epilepsy. Fit free for three years-weaned off Epilim 18 months ago. No speech since coming home. Very lethargic at school today. Vomited x 3 speech slurred. Speech slurred earlier. O/E pale, pupils reacting-does not like light. No neck stiffness, temperature. Tone ↑↑ Right side planter↑↑ Left planter↓↓ ENT NAD. Chest clear. Query further fit query underlying infection
21/10/96			090-012-014. Medical note by Dr O'Hare. 7:15 PM. Nine-year-old girl. H/O learning difficulties, epilepsy-no fits for three years, off antiepileptic medication. Today vomiting (-

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			non-bilious) since this evening. ^{0} diarrhoea/cough/pyrexia speech very slurred, hardly speaking. O/E drowsy, tired. Apyrexial. ^{0} Lymphadenopathy.PERLA ^{0} neck stiffness. Ears NAD, Heart Sounds I + II + O. Pharynx-unable to examine. (Diagram abdomen) soft, non-tender, ^{0} mass, ^{0} KLS, BS √ (diagram chest) resonant, A/E good nil added. Planters↓↓ R+L (but see GP letter) no apparent weakness, tone ↑ R L B + ++ T + ++ S + ++ K + ++ A + ++ admit Encephalitis query. 2045
21/10/96	8pm	1	090-022-050. Admission notes written in same handwriting "nine-year-old admitted via A&E. PC vomited at 3 PM and every hour since. Slurred speech and drowsy. Off from yesterday. Loose motions three days ago. HPC severe learning difficulties, seizures six months-year. Controlled by Na valproate age 4 – X1 seizures. Anticonvulsant gradually weaned until Epilim stopped

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			H&S speech-speech in sentences, meaningful. Hearing N vision N scribbling, feed herself with supervision, cannot dress herself. Gross motor walking, running, up-and-down, stairs, favours left side of body, T??? Special school Dun xx rd road. Dr Gaston ??? Previously Dr???. Recently tried Ritalin.-Dry mouth then became agitated-dry mouth.DH nil ALL nil FH [scheme drawn] O/E 37 CVS I&II 80/minute. RS clear, abdomen soft not tender no masses, CNS fundi normal, discs not blurred, PERLA VII, √IX √,X √ LOS (?) Sit up and staring vacantly? Ataxic power not assessed. Tone upper limbs right cogwheel rigidity, left ↑tone lower limb ↑tone ↑tone (reflexes my summary 2 ++ right, + left apart from knee 2+ planters down going. Ankle clonus + +) SENS not responding to parents voice/intermittently responding, responding to deep pain. (DD symbol) 1. viral illness,2. Encephalitis (scratched out) Inv F BC,U&E,BCx viral titres +/- LP – afebrile Mx IV fluids, IV diazepam if? Seizure activity. Reassess after fluids Signed Dr O'Hare
21/10/1996	12mn	5	090-022-052 12 midnight. Slightly more responsive-no

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			meningism. Observe and reassess a.m. Signed same Dr [possible different writing below with results] Na 132 ↓ K 3.8,U 4.5,Gluc 6.6,Cr 36,Cl 96 Hb 10.4,PCV 31,WBC 16.5 ↑,Platelets 422,000 signed SHO xxxxxxxx??
21/10/1996			090-038-133. Intravenous fluid chart. By 23:00 hours had 24 mls given. Thereafter cumulative amounts aiming at 64 mls per hour. By 07:00 hours 22/10 had total 536 mls. Over this time had six small vomits and passed urine once
21/10/1996	10 PM	3h	090-040-140. Nursing Kardex. Extracts. Child pale and lethargic. Apyrexic observations within normal limits. Bloods taken. IV fluids 5/N saline commenced at 64 mls per hour. Two small bile stained vomits following admission to ward. S/B Dr and registrar-to be reviewed following blood results and direction of IV fluids. Blood investigations ticked.
22/10/1996	7 AM	12 hours	090-040-140. Nursing Kardex. Slept well. Much more alert and brighter this morning. One further bile stained vomit. IV fluids continued as listed. No oral fluids taken. Apyrexic , observation satisfactory
22/10/96	??		Ward round Dr Sands Admitted? Viral illness. Usually very

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			active, has not spoken to parents as per normal. Wretching, no vomiting. Vagueness/vacant (apparent to parents) no seizure activity observed. Attends Dr Gaston. Six month old seizures and Ix for this NAD. U&E Na 132 F BC-WCC ↑16.5 Gluc 6.6. O/E apyrexic pale colour. Little response compared to normal CNS pupils sluggish to light. Difficult to see fundi. Bilateral long tract signs. Ears-blank-throat difficult to full see. Impression non-fitting status [then in another handwriting is inserted at sometime/encephalitis/encephalopathy] page 090-022-053. Plan rectal diazepam. Dr Webb. D/W Dr Gaston re-PMHx.
22/10/1996	2 PM	19	090-040-140. Nursing Kardex. (This refers 8 AM-2 PM) Slept for periods during early morning. Bright when awake. No vocalisation but indecipherable active. Late morning Claire became lethargic and "vacant". Parents can sound as Claire is usually very active. Seen by Dr Sands. Status epilepticus-non-fitting-continues overleaf. 090-040-141. Nursing Kardex. Rectal diazepam 5 mg PR given and commenced on CNS observations hourly. To be seen by Dr Webb and query CT scan in a.m. Seen by Dr Webb-to have IV phenytoin. Parents not in attendance.

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
22/10/1996	2pm	19	"Neurology thank you Nine-year-old girl was known learning difficulties-parents not available. Grandmother Hx vomiting+ listless yesterday p.m.-followed by prolonged period of poor responsiveness. On no AED . Note appeared to improve following rectal diazepam 5 mg at 12:30 PM O/E afebrile, no meningism, pale. Rousable. eye opening to voice, non-verbal, withdraws from painful stimulus. Reduced movements right side? Against gravity all 4 limbs. Mild increase tone both arms. Reflexes symmetrically brisk. Clonus -sustained both ankles.Toes ↑↑. Sits up, eyes open and looks vacantly. Not obeying commands.PEARL -5 mm. Optic discs pale. No papilloedema. Facial palatal and laryngeal movements appear (N) impression-I don't have a clear picture of prodrome+ yesterdays episodes. Her motor findings today are probably long standing but this needs to be checked with notes. The picture is of acute encephalopathy most probably post ictal in nature. I note (N) biochemical profile. Suggest i) starting IV phenytoin 18 mg/kilogram stat followed by 2.5 mg/kg 12 hourly. Will need blood levels 6 hours after loading dose. ii) hourly neuroobs iii) CT tomorrow if she doesn't wake up. Signed D Webb
22/10/96	Between the 2 documented Paed		In a different handwriting by TP Sxxx below the end of Dr Webb's entry on page

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
	neurolo consults		090-022-054 24 kg. Phenytoin 18 mg/kg loading dose= 18x 24= 632 mg. 24 kg phenytoin 2.5mg kg xxx= 60 mg 12 hourly either IV or orally check levels at 9 PM
22/10/1996	1510	20	From the Record of attacks observed : " Lasted frequently strong seizure at 3.25pm " duration 5 min
22/10/1996	1600	21	090-053-165 from statement made by Dr Webb "It would appear from the notes that I reviewed Clare during the afternoon and because of concerns about on-going seizure activity recommended the use of Midazolam (anticonvulsant). The next note reads "seen by Dr Webb, still in status" and then goes on to document the calculations undertaken to prescribe Midazolam was a bolus and then as a low-dose infusion. Following the therapy I reviewed and examined Claire again and this contact is documented in the notes timed 5 PM" This visit is confirmed by Mr Roberts in his chronology.
22/10/1996	???		Handwritten entry by probably SHO on 090-022-055 S/B Dr Webb. Still in status. Midazolam 0.5MG/KG stat dose= 0.5X24=12mg IV STAT Midazolam 2 mcg/kg/min = 2x24mcg/min=48mcg/min =48x60 mcg/hr =

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			2880mcg/hr=2.88mg/hr infusion= 69mg/24 hrs
22/10/1996	1700	22	090-022-055 Dr Webb handwriting " Claire has had a loading dose of phenytoin + a bolus of Midazolam . She continues to be largely unresponsive. She responds by flexing head (L) arm to deep supra-orbital pain+ does have facial grimace-but no localisation. She has intermittent mouthing and chewing movements. Background from mum-contact with cousin on Saturday who had a gut upset. Claire had loose motions on Sunday+ vomiting Monday. She had some focal SZS on Monday with right side stiffening. Plan 1) cover with Cefotaxime and Acyclovir from 48 hours I don't think meningoencephalitis very likely.2) check viral cultures ? enterovirus -stool, urine, blood and T/S 3) add IV sodium valproate 20mg/kg IV bolus followed by infusion of 10 mg/kg IV over 12 hours." Signed D Webb
22/10/1996	8 PM		090-040-141. Nursing Kardex. Refers to period 2 PM-8 PM. "Continues on hourly CNS observation GCS 6-7. Stat dose IV phenytoin at 2:45 PM to have BD. S/B Dr Webb still status epilepticus given stat IV hypnoval at 3:25 PM. Continuous infusion running at 2mls/hr of hypnoval to be increased by 0.1 ml /5min until up to 3 mls per hour. Dr to write up. Given stat dose Epilim at 5:15 PM. Very unresponsive. Only to pain.

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			Remains pale. Occasional episodes of tooth clinching. Commenced on IV [probably Cefotaxime] and IV acyclovir. First dose Cefotaxime due 9:30 PM some parents in attendance" additional note due phenytoin levels at 9 PM and then followed by tick and an entry of 23.4
22/10/1996	9:30 PM	26 ½	090-040-138. Nursing Kardex. [undated on form] 1/5 N at 64 mls per hour. Cannula resited this afternoon. 9:30 PM First dose of IV acyclovir erected by Dr and run over one hour. Hypnoval infusion increased by 0.1 ml every 5 min until running at 3 ml/hr as prescribed by Dr-completed at 10:40 PM.
22/10/1996	11 PM	28	090-040-138. Nursing Kardex. [undated on form] IV phenytoin erected by Dr and run over one hour-cardiac monitor in situ throughout infusion. Due to U&E results No. 18 solution with 20 mmol KCL directed as ordered by registrar. To have fluid restriction at 41 mls/Hour. Hourly CNS observations recorded. Temperature elevated at 10 PM-paracetamol given by day staff. Other observations within normal limits In column to the right is Glasgow coma Scale 6.
22/10/1996	2330	28 ½	Handwritten entry into note. 090-022-056 Na 121 K 3.3, Urea 2.9,Creatinine 33 Phenytoin 23.4 m?/L (10-20) hyponatraemia-? Fluid overload with low sodium fluids? SIADH Imp ? Need for ↑ Na concentration in fluids. -D/W registrar-↓ Fluids to 2/3 of present

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			value-41 mls/hour send urine for osmolality. SHO[//name]
22/10/1996			090-038-135. Intravenous fluid chart from 08:00 hours until 02:00 hours (23/10). Total 1070. Important here is that Midazolam prescription appears from 16:30 hours. The cumulative volume of this being 21.5 mls. Phenytoin started IV at 23:00 hours and an amount of 60 mls and 110 mls with a total of 170 mls is included in the oral column but is probably the IV volume. Passed urine three times. Two small mouthfuls of vomit. Weight recorded 24.1 kg
22/10/1996			090-039-137 neuro observation chart. Includes TPR and BP. Stable. Indicates severe weakness of arms and legs.
22/10/1996			090-042-144. Record of attacks observed. 3:10 PM "lasted frequently strong seizure at 3.25" duration 5 min state afterwards sleepy. For 30 seconds teeth tightened slightly duration few seconds state afterwards asleep 7:15 PM teeth clenched and groaned. Duration 1 min state afterwards asleep 9 PM episode of screaming and drawing up of arms. Pulse rate ↑ 165 bpm pupils large but reacting to light. Dr informed. Duration 30 seconds state afterwards asleep.
23/10/1996	2:30 AM	31 ½	090-040-138.& -139 Nursing Kardex.

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			Slight tremor right hand noted lasting a few seconds. Breathing became laboured and grunting-respiratory rate 20 per minute.02 saturation is 97%. Claire stopped breathing. Dr contacted immediately. Oxygen and suction given. Registrar attempted to pass ET tube but unsuccessful-anaesthetist called and ET tube inserted. Transferred to intensive care unit at 3:25 AM. No medication/drugs given.
[Presumed 23/10/1996]	3 AM	32	Medical note Reg "Called to see. Had been stable when suddenly she had a respiratory arrest and developed fixed dilated pupils. When I saw her she was Cheyne Stoking and requiring oxygen via face and mask. Saturation with bagging in high 90s good volume pulse. I attempted to intubate-not successful. Anaesthetic colleague came and intubated her orally with 6.5 tube transferred to PICU
Presumed 23/10/1996]	4 AM	33	Handwritten entry on 090-022-057. Looks like Dr Steen. "9 ½ year girl with learning difficulties admitted 32 hours ago with ↓ Level of consciousness.SB Dr Webb with [SYMBOL diagnosis] acute encephalopathy? Aetiology. Covered with acyclovir and Cefotaxime. Loaded with phenytoin + valproate added at 17:00 hours. ??XX p.m. phenytoin level equals 23.4.Na 121 K 3.3 fluids restricted to 2/3 maintenance observations otherwise stable. 3 AM Registrar asked to see because of respiratory difficulties Cheyne Stoke breathing -intubated and transferred to ICU. At present intubated+ ventilated

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			has had some Midazolam but it is no longer running. Pupils fixed and dilated. Bilateral papilloedema L>R no response to painful stimuli BP 90/65 HR= 100 /minute plan mannitol stat, dopamine infusion, urgent CT scan. " In the margin are written the results of the blood tests.
23/10/1996	4:40 AM	33 ¾	Neurology Dr Webb. SIADH- hyponatraemia, hypo osmolality and cerebral oedema + coning following prolonged epileptic seizures pupils fixed and dilated following mannitol diuresis no eye movements for CT scan
23/10/1996	05:30 hours	34 ½	090-022-058 CT scan report that " there is severe diffuse hemispheric swelling, with complete effacement of the basal systems. No focal abnormality is identified. Dr Kennedy.
23/10/1996	6 AM	35	Dr Webb. Brain stem death evaluation pupils 8.9 mm unresponsive Dolls eye movements Corneals absent-no gag response Iced calorics 14 mls to both ears-no response. No response (motor or autonomic) to deep supra-orbital pain.

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			Apnoea test in progress. CT cerebral herniation. Under no sedating/paralysing medication Claire fulfils criteria for brainstem death. The evaluation should be repeated in 4-6 hours.
23/10/1996			090-031-102 U&E sample untimed from PICU Na 152 Serum osmolality 313
23/10/1996	0710	36	090-022-058 Dr McKaigne [Con Anaesthetist PICU] "nine year old girl admitted to PICU from Allen Ward. Suffered a respiratory arrest. Was initially bagged and intubation performed by ?? Clark(SpR) anaesthetics on the Ward. At the time of intubation vomitus was noted in Oro pharynx-liquid material. No solid material. Following intubation trachea was sucked out and a small amount of watery material was aspirated. Oral ET tube then changed to nasal tube in PICU. Initially admitted to hospital with decreased level of consciousness with the clinical picture of acute encephalopathy. Status epilepticus subsequently developed requiring phenytoin, valproate, and Midazolam . Serum Na also noted to be low ↓ 121 presumably on the basis of SIADH In PICU hyperventilated and given mannitol 0.5G/KG pupils fixed and dilated. BP ~95 systolic. Peripheral dopamine infusion commenced. Arterial line right dorsalis pedis and right ??? Triple 5/8. Then transferred to CT. Transfer uneventful. CT shows severe cerebral

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			oedema. One set of brainstem tests performed by Dr Webb/Dr Steen. Serum Na also checked at the same time (133 - blood analyser) PIC no respiratory effort with ABGs pH 7.13, pO2 124.5 pCO2 79.2 Plan maintain circulatory support Claire is a potential organ donor, dopamine infusion to maintain SBP ~100 mmHg close check on serum Na and osmolality and urine output if serum Na > 150 and osmolality > 300 then commence desmopressin. One need conc K infusion. Maintenance fluids with dextrose 4%/saline/18% ventilate to pCO2 35 Dr Webb/Dr Steen had discussed Claire's clinical condition with her parents. They initially appeared to be giving consent for organ donation but Dr Webb will speak again to both parents at ~ 10 AM. Chest x-ray shows central line and ET tube in good position. There is some mottling of both hilar regions more so on the right side. There has been a deterioration in ABGs pO2 76 on FI O2 0.6 I would be concerned that this picture could be explained by pulmonary aspiration or early neurogenic pulmonary oedema. Any potential transplant centre should be alerted to possibility of pulmonary aspiration. Lab sample at time of brainstem tests: Na 129, K 3.6,Cl 94 urea 3.7, glucose 7.2 osmolality 274
23/10/1996	0800	37	Check two hourly U&Es change maintenance fluids to 0.9% saline

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			Signed McKaigne 090-022-060
23/10/1996	??		090-022-061 hypotensive BP 70/? With D.I given HPPF 500 mls needs DDAVP to limit polyuria . Appears BS death informally but only seven hours post arrest. Na 129 (from 121). Plan maintain BP > 100 DDAVP
23/10/1996	1825	47 ½	090-022-061 " Diagnosis of brainstem death protocol completed. No spontaneous respirations– CO2 70mmHg. Discussed with parents and agree that ventilation should be withdrawn. Consent limited PM given." Dr Steen
23/10/1996	1845	47 ¾	Dr McKaigne ventilation discontinued at 1845. Dr Steen writing "Death certificate issued - cerebral oedema 2 ^{o} to status epilepticus
29/10/1996			Handwritten discharge letter "case note discharge summary" 090-009-011 reports cerebral oedema, status epilepticus, hyponatraemia, ventilated, central line, CT scan. Ventilation withdrawn after discussion with parents at 18:45 hours on 23/10/96.
1/11/1996			Letter from SHO on intensive care unit to GP. Discharge summary. 090-006-008
11/11/1996	3.35pm		New handwritten entry difficult to decipher not the same handwriting as before "spoke at length with Mr and Mrs Robert earlier today. They are naturally still trying to come to terms with what happened to

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			Claire . I talked through the events before her death and also talked generally with them. They are naturally anxious to discuss the PM results with someone. I will pass this on to Dr Steen ASAP" signature indecipherable
18/11/1996			090-004-006. Letter from Dr Steen to parents offering a meeting. Includes a leaflet from the meningitis research foundation on death "I know meningitis was not Claire's problem but when I read the leaflet I thought some of the comments in it were very real and perhaps would be of help to you."
11/2/97			090-003-003. Autopsy report Date of necropsy 24/10/96. This report dated 11/2/97. Pathologist Dr Herron. "In summary the features here are those of cerebral oedema with neuronal migration defect and a low-grade sub acute meningoencephalitis. No other discrete lesion has been identified to explain epileptic seizures……. A metabolic cause cannot be entirely excluded…….. as this was a brain and the autopsy, it is not possible to comment on the other systemic pathology in the general organs……."
5/3/1997			Letter dictated by Dr Heather Steen to Dr McMillin, general practitioner. Reporting cervical tissue showing abnormal neuronal migration which would explain Claire's learning difficulties. States that Dr Webb and Dr Steen have seen Claire's parents and discussed the post-mortem findings with them. "Mr Roberts wanted a short summary of the post-mortem report which Dr Webb will

Date	***Time***	***Hours post ad***	***Events(source) CH 328770 RH papers***
			send to him shortly."
21/3/1997			Letter from Dr Webb dictated 28/to/1997. (090-001-001)To parents "in summary of the findings were of swelling of the brain with evidence of a developmental brain abnormality (neuronal migration defect) and a low-grade infection (meningoencephalitis). The reaction in the covering of the brain (meninges) and the brain itself (cortex) is suggestive of a viral cause. The clinical history of diarrhoea and vomiting would be in keeping with that. As this was a brain in the autopsy it is not possible to comment on other abnormalities in the general organs. No other structural abnormality in the brain has been identified."

ANNEX B CLINICAL CHRONOLOGY FROM RECORDS-CLAIRE ROBERTS (born 10/1/1987) for 21-23 October 1996

090-026-075. Prescription chart. The dates are obscured partly by the folder punch but the following points. Phenytoin 60 mg is prescribed IV for 8:30 AM and 9:30 PM. There does not appear to be any column to indicate whether it has been given. Diazepam was given rectally at 1215 on 22nd/10/1996. Phenytoin was given 2:45 PM IV 635 mg there is there a column for who has given it on the drugs once only section IV. Sodium valproate 400 mg IV 5:15 PM and that is indicated as given.
090-027-018 PICU admission section

NUTRITION/HYDRATION RECORD urinary catheter inserted 22/10/96 mentions Midazolam infusion in situ .
090-028-088 record of relative counselling which mentions respiratory arrest and ventilatory support. Dr Webb Dr Steen. The form is incorrectly dated 22/10/96.
090-038-136 IV fluid prescription chart. Indicates 50 mls normal saline used for the Midazolam at 2 mls an hour over 24 hours to include 60 mg of Midazolam or could be 64. Also number 18 solution with 20 mmol KCl at no time at 41 mls but then scratched out and unclear what this means.

LABORATORY RESULTS

Lab results. 090-030-096. Blood tests taken 21/10/96. IgM for mumps, measles, herpes simplex and zoster CMV or negative. No and no significant growth also adenovirus, Q fever, Mycoplasma, PLGV influenza a and B. Reported 31/10/1996.

On 090-031-099.

The result of the blood electrolytes on 21/10/1996. Date of report 22/10/96. There is no time given on this report. Time the sample/receipt by laboratory is usually kept and would have been expected.

The next sample is on 090-031-100. From intensive care. Data specimen 23/10/1996. Blood sodium 139. What was the time of the sample.

090-031-101. Not clear whether this was from PIC or from the ward. Blood phenytoin level report. Specimen received 23/10/1996 at 4:20. Why is a date of receipt on this report but not on others. No time was stated on the form. Phenytoin 19.2 mg/L (range 10 to 20)

090-031-102. Electrolyte results no time. Date of specimen 23/10/1996 and from intensive care unit.

090-031-105. Minor acid chromatography from the urine reported normal also mucopolysaccharides. Ketones. Date of the specimen is when she was admitted under Dr Hicks as an infant but not clear which date.[Important because makes metabolic encephalopathy is unlikely from inborn error]. Similarly blood derivate and lactate were done.

090-032-108. Haematology report. Leucocytes given 16.52. No differential white count. No time on specimen but was from Allen Ward on 21/10/1996.

ROYAL BELFAST HOSPITAL FOR SICK CHILDREN

Fluid Balance and I.V. Prescription Sheet

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Date 22/10/96

Weight 24.1 Kg

Name	D.O.B.	Hosp. No.
Claire Roberts	10/1/87	328770

IVsite

TIME (hr)	INTAKE						OUTPUT			
	INTRAVENOUS				ORAL		Urine	Aspirate or Vomit	Stool	Comment
	1 Level	Amount	2 Level	Amount	Fluid	Amount				
08.00	No 1	68								Sfd
09.00		110								Sfd
10.00		179			Cup of water.					Sfd
11.00		259					P.U large - clear			Vs. Sfd
12.00		308								Sfd
13.00		356								Sfd
14.00										
15.00		527								
16.00		562	#2 Maintenance 2ml/hr.							
17.00		616		0.8						
18.00		677		2.7						
19.00		769		5.5			P.U			
20.00		806		6.7						
21.00		868		8.7	I.V Acyclovir 60	—	P.U.			
22.00		943		10.9		60				Urine red
23.00		1014	23mls	13.9	PHENYTOIN					Dunkcoloured
24.00		1037		16.8	110	—		small mouth fuls		Empty
01.00		1037		19.3		170		small mouth fuls		Urine
02.00		1070		21.5						Empty
03.00										
04.00										
05.00										
06.00										
07.00										

Total Intake		Total Output			
Intravenous.....ml	Oral.....ml	Urine	Aspir^{n}	No. of Vomits	No. of Stools
		.....ml	.....ml	.....	.....

24 – Hour INTAKE	24 – Hour OUTPUT
.....ml	.....ml

090-038-135

CR - RVH

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EASTERN HEALTH & SOCIAL SERVICES BOARD
ROYAL BELFAST HOSPITAL FOR SICK CHILDREN

PRESCRIPTION SHEET

PARENTERAL DRUGS

REGULAR PRESCRIPTIONS

DRUG SENSITIVITY

Date Comm.	DRUG (Block letters please)	DOSE	Time of Administration: AM 6	AM 8.30	MD 12	PM 12.30	PM 5.30	PM 6	PM 8.30	MN 12	Other Times	Method and other instructions	SIGNATURE	Discontinued: Date	Initials

DRUGS-ONCE ONLY PRESCRIPTIONS

Date Given	DRUG (Block letters please)	DOSE	Time of Admin.	Method of Admin.	SIGNATURE	Given by Initials

CR – RVH

090-026-075

CH 328770 Page: 1/1

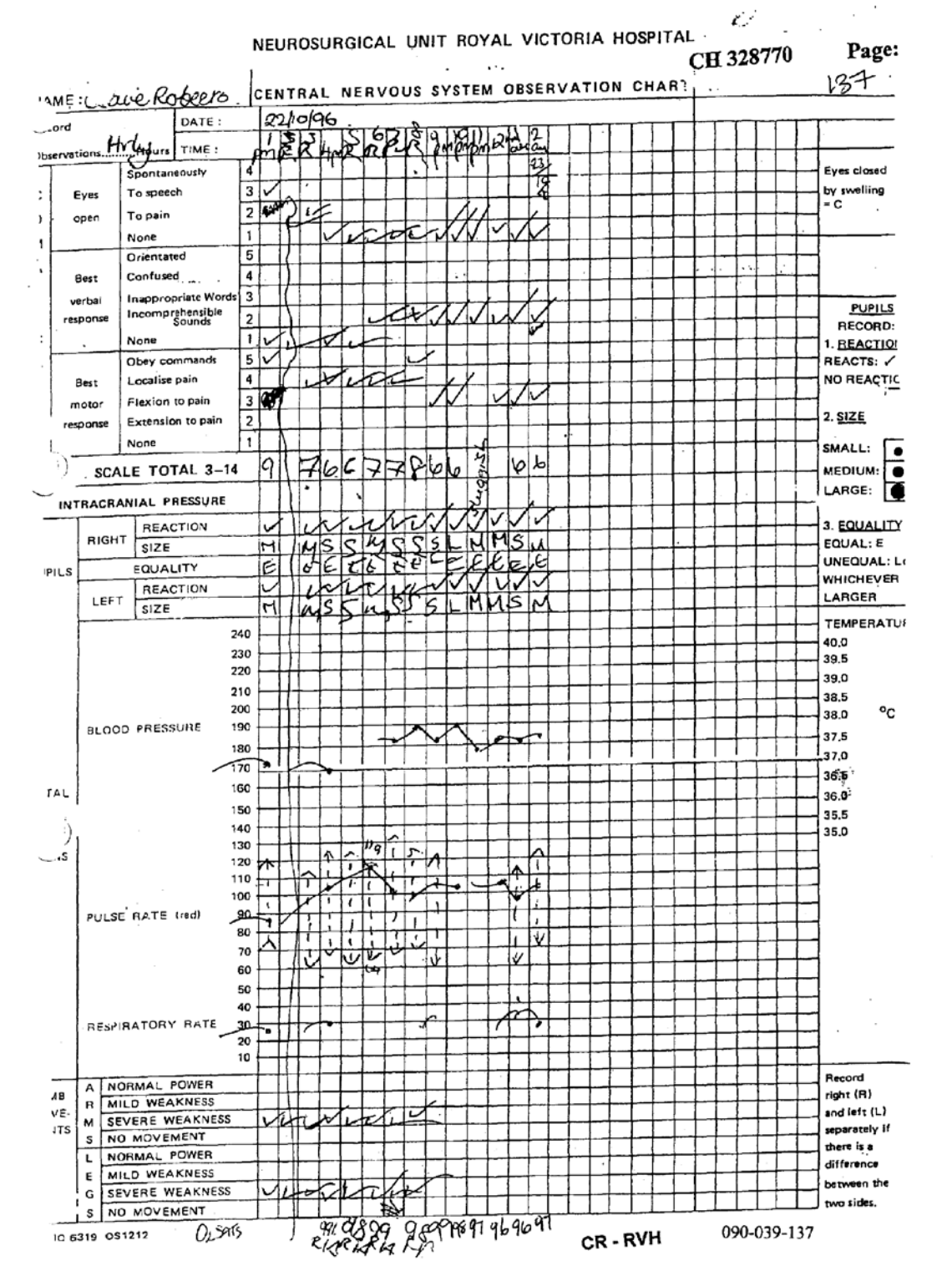
ROYAL BELFAST HOSPITAL FOR SICK CHILDREN

RECORD OF ATTACKS OBSERVED

NAME: Claire Roberts U.N. AGE: WARD: Allen

DATE	TIME	EXACT DESCRIPTION OF ATTACK	DURATION	STATE AFTERWARDS	INITIAL
22/10	3.10 a.m.	Lasted frequently Strong Seizer at 3.25	5min	Sleepy.	NUM =
	4.30.	teeth tightened slightly	few secs	asleep.	
	7.15 p.m.	teeth clenched + groaned	1min	asleep.	
	9pm	Episode of screaming and drawing up of arms. pulse rate ↑ 165 bpm. pupils large but reacting to light. Dr Informed.	30secs	asleep	LMcCan

CR – RVH 090-042-144



NEUROSURGICAL UNIT ROYAL VICTORIA HOSPITAL

CH 328770

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NAME: Claire Roberts

CENTRAL NERVOUS SYSTEM OBSERVATION CHART

DATE: 22/10/96

Observations Hrly 4hours

TIME:

Eyes open: Spontaneously 4; To speech 3; To pain 2; None 1

Best verbal response: Orientated 5; Confused 4; Inappropriate Words 3; Incomprehensible Sounds 2; None 1

Best motor response: Obey commands 5; Localise pain 4; Flexion to pain 3; Extension to pain 2; None 1

SCALE TOTAL 3–14

INTRACRANIAL PRESSURE

PUPILS: RIGHT REACTION; RIGHT SIZE; EQUALITY; LEFT REACTION; LEFT SIZE

BLOOD PRESSURE

PULSE RATE (red)

RESPIRATORY RATE

TEMPERATURE °C

Eyes closed by swelling = C

PUPILS RECORD:
1. REACTION
REACTS: ✓
NO REACTION
2. SIZE
SMALL:
MEDIUM:
LARGE:
3. EQUALITY
EQUAL: E
UNEQUAL: L
WHICHEVER LARGER

A R M S NORMAL POWER / MILD WEAKNESS / SEVERE WEAKNESS / NO MOVEMENT
L E G S NORMAL POWER / MILD WEAKNESS / SEVERE WEAKNESS / NO MOVEMENT

Record right (R) and left (L) separately if there is a difference between the two sides.

IC 6319 OS1212 O2 SATS

CR - RVH 090-039-137

CH 328770 Page: 102.

R.B.H.S.C.
INTENSIVE CARE UNIT

DR P.M.CREAN

Surname ROBERTS
Forename CLAIRE
Age/DOB 10\01\87 Sex F
Hosp.No. 328770

ML

SERUM		VALUE		ADULT RANGE
Sodium	=	152* mmol/l	(135 TO	145)
Potassium	=	2.8* mmol/l	(3.5 TO	5.0)
Urea	=	2.3 mmol/l	(3.3 TO	8.8)
Calcium	=	2.69* mmol/l	(2.10 TO	2.57)
Ser.Osmolality	=	313* mmol/kg	(285 TO	290)

Date of Specimen 23\10\96
Lab.No. 20996
Date of Report 24\10\96

G.S.Nesbitt
R.V.H. BIOCHEMISTRY

CR - RVH

090-031-102

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R.B.H.S.C.
INTENSIVE CARE UNIT

DR P.M.CREAN

Surname ROBERTS
Forename CLAIRE
Age/DOB 10\01\87 Sex F
Hosp.No. 328770

GSN

SERUM		VALUE		ADULT RANGE
Sodium	=	139 mmol/l	(	135 TO 145)
Potassium	=	3.0* mmol/l	(	3.5 TO 5.0)
Chloride	=	103 mmol/l	(	98 TO 108)
Urea	=	3.4 mmol/l	(	3.3 TO 8.8)
Creatinine	=	34* umol/l	(	40 TO 110)
Ser.Osmolality	=	287 mmol/kg	(	285 TO 290)

Date of Specimen 23\10\96
Lab.No. 20553
Date of Report 23\10\96

G.S.Nesbitt
R.V.H. BIOCHEMISTRY

CR – RVH 090-031-100

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R.B.H.S.C.
ALLEN WARD

Admission

Surname ROBERTS
Forename CLAIRE
Age/DOB 10\01\87 Sex F
Hosp.No. 328770

ML

SERUM		VALUE		ADULT RANGE	
Sodium	=	132*	mmol/l	(135 TO	145)
Potassium	=	3.8	mmol/l	(3.5 TO	5.0)
Chloride	=	96*	mmol/l	(98 TO	108)
Urea	=	4.5	mmol/l	(3.3 TO	8.8)
Creatinine	=	36*	umol/l	(40 TO	110)
Glucose	=	6.6	mmol/l	(4.0 TO	8.0)

Date of Specimen 21\10\96
Lab.No. 19924
Date of Report 22\10\96

G.S.Nesbitt
R.V.H. BIOCHEMISTRY

CR – RVH 090-031-099

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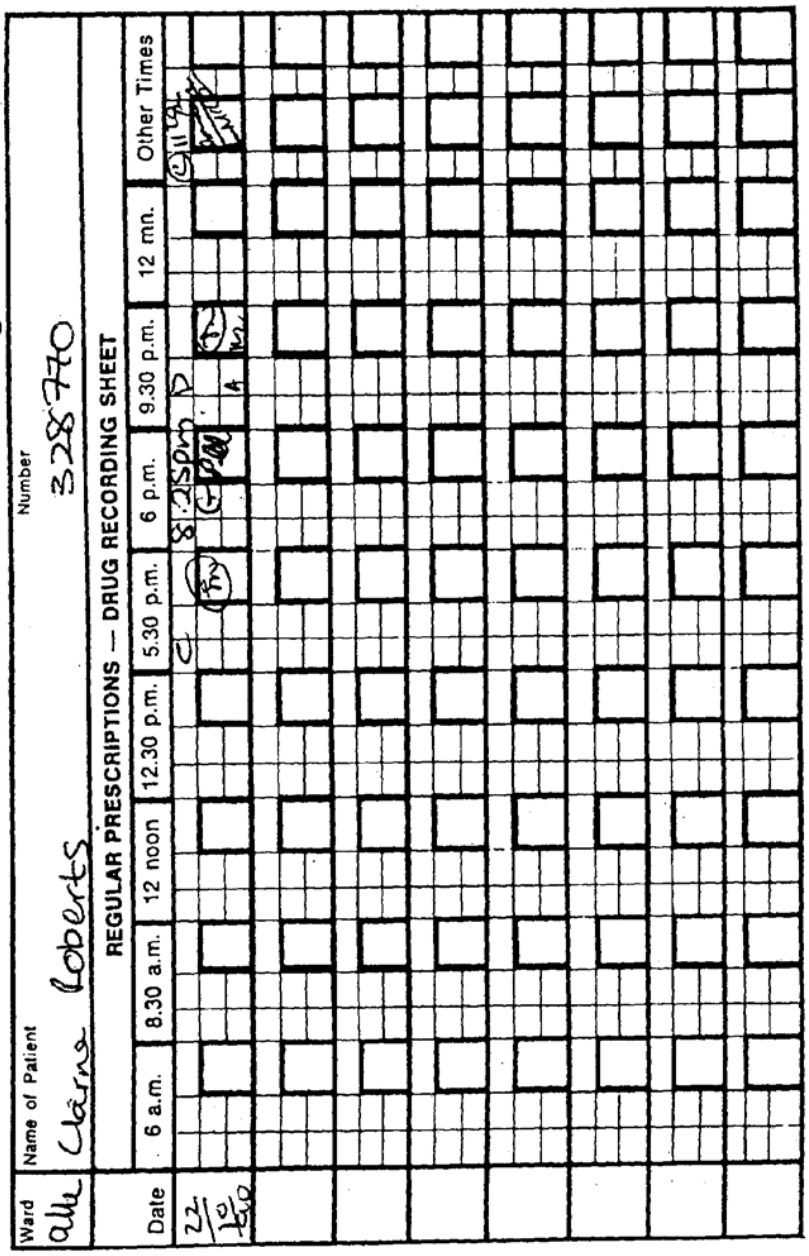

Ward: alle
Name of Patient: Clarice Roberts
Number: 328770

REGULAR PRESCRIPTIONS — DRUG RECORDING SHEET

Date	6 a.m.	8.30 a.m.	12 noon	12.30 p.m.	5.30 p.m.	6 p.m.	9.30 p.m.	12 mn.	Other Times
22/10/10						8.25pm			

Annex c.d

CR - RVH

090-026-077

1.

CR - EXPERT

238-002-217

CH 328770 Page: 52. Claire Roberts

CLINICAL HISTORY, EXAMINATION AND PROGRESS

Δ. 1. Viral illness
2. Encephalitis

Inv. FBC –
U+E –
BCx –
Viral titres ± LP – afebrile.

Mx. IV fluids.
IV diazepam if ? seizure activity.
Re-assess after fluids.

12 MN Slightly more responsive – no meningism.
Observe + reassess am.

Na 132. ↓	Hb 10.4
K⁺ 3.8.	PCV .31
U 4.5	WCC 16.5 ↑
Gluc. 6.6.	platel. 422.000
Cr 36.	
Cl. 96.	

Nofsom (S.60)

22/10/96 W/R Dr Sands
Admitted ? Viral illness.
Usually very active, has not spoken to parents as per normal.
Wretching. No vomiting.
Vagueness/Vacant (apparent to parents)

090-022-052

CR – RVH

(i)

(ii) **CLAIRE NEUROLOGICAL OBSERVATION CHART**

Time (22-23/10/96)	***GCS x/15***
1 pm	9
2 pm	Not done
3 pm	7
4 pm	6
5 pm	6
6 pm	7
7 pm	7
8 pm	8
9 pm	6
10 pm	6
11 pm	Blank [calc at <6 by me] entry omits pain response " sluggish"
12mn	Blank but [calc by me 6]
1am	6
2am	6

ANNEX D COMPILATION : REFERENCE COMPILATION FOR CLINICAL GOVERNANCE REVIEW : Chronology of Developments and Sources of Guidance with Focus on Children's Specialist Services.

This Annex contains the detail supporting Chapter 4 Review of developments in Clinical governance which addresses the following matters raised in my brief

The identification of any protocols, guidance, standards or practices (hereafter referred to throughout collectively as "guidance" save where the context indicates to the contrary) that were applicable to the issues raised in Claire's case in 1996 and which the RBHSC may have been expected to take cognisance of and/or comply with. They should include any available guidance in the UK generally on the provision of services to children in hospital and how they were applied at that time, together with an indication of how that guidance and its application has developed since then. Identification of the literature, if any, that was available in 1996 that discusses such issues.

It aims mainly to be a source of reference as a working document

I have arranged this compilation in the following way.

DEVELOPMENT OF STANDARDS FOR HOSPITAL SPECIALIST CARE FOR CHILDREN 1980s onwards and CLINICAL GOVERNANCE IN CHILDREN'S SPECIALIST SERVICES. ***(Paras 1-80)***

CLINICIANS AND MANAGEMENT ***(Paras 81-118)***

CONSULTANT RESPONSIBILITIES AND ACCOUNTABILITY ***(Paras 119-184)***

METHODS BY WHICH CLINICIANS GAIN KNOWLEDGE and SHARE EXPERIENCE : Continuing Medical Education ***(Paras 185-192)***

CLINICAL MANAGEMENT DIRECTORATES including Role of Clinical director and list of governance questions to enable comment to be made on clinical governance in RBHSC ***(Paras 193-243)***

SOURCES AND USES OF KNOWLEDGE IN CHILD HEALTH (with supplement) ***(Paras 244-284)***

ROLE OF ROYAL COLLEGES AND PROFESSIONAL ASSOCIATIONS ***(Paras 285-300)***

ROLE OF GMC ***(Para 301)***

DEVELOPMENT OF MEDICAL AUDIT ***(Paras 302-321)***

DEVELOPMENT OF CLINICAL GUIDELINES ***(Paras 322-356)***

NHS NATIONAL SERVICE FRAMEWORK FOR CHILDREN 2003 -relevant extracts ***(Paras 357-395)***

REPORTING SYSTEMS FOR ADVERSE EVENTS ***(Paras 396-410)***

ADVERSE AND CRITICAL EVENTS INVESTIGATION SYSTEMS CHILDREN ***including Royal Hospitals Annual Health & Safety Reports (Paras 411-471)***

ANNEX C TO RCP REPORT ON MEDICAL AUDIT ANONYMITY AND CONFIDENTIALTY GUIDANCE ***1993 (between Paras 471 and 472)***

ANNOTATED BIBLIOGRAPHY OF IMPORTANT REPORTS AND GUIDANCE WITH TIMELINES (*Para 472)*

DEVELOPMENT OF STANDARDS FOR HOSPITAL SPECIALIST CARE FOR CHILDREN 1980s onwards

1) In the 1980s much of the focus on provision of good quality specialist care for children was on ensuring that if they required inpatient care this would be provided in a children's unit rather than in adult facilities and much effort was put into describing how a children's inpatient facility should have staffing with a built environment suitable for them including provision of facilities for parents and with attention to better communication. Care in operating theatres and investigation departments was also included.

2) Many children received care from specialists whose main workload was with adults because around half children receiving care in hospital are treated by surgeons. Paediatric surgeons form a small subset of surgical consultants who work only with and have special expertise in the care of children including small babies and newborns. For many children (and in the past infants) care was provided by surgeons who also cared for adults and this was the same for anaesthetists and radiologists. The majority of children cared for in hospital services received this in in district general hospitals. Only a small proportion of children receive care in a children's hospital. The latter largely providing tertiary care services. Some regions provide their tertiary children's services within a block or series of departments within a large hospital providing care for adults only a few regions have a specialised Children's Hospital and which sometimes does not provide a full range of specialties, for example neurosurgery and cardiothoracic surgery may be located elsewhere. Some examples of the problems that arise from the situation were highlighted in the Bristol Inquiry.

3) Remedies to this situation was the main focus of the Department of Health document the *Welfare Of Children In Hospital* 1991 which was produced following pressure from a consortium Caring For Children Health Services- led by the National Association for the Welfare Of Children In Hospital a collaborative with the Royal College of Nursing, Health Visitors Association and the BPA which carried out a number of surveys identifying the extent of need..

4) The aim was to ensure that children would be treated in an appropriate environment for their age group (up to the age of 16 at this stage) and by clinicians who had been trained in the overall care of children and the diseases and disorders which affect them and who had the necessary technical skills to provide the care - together with a sensitivity for the special needs of children and young families.

5) There was a presumption that the care delivered to children by children's specialists medical, surgical and anaesthetic was of high quality and specific to their needs. But there was increasing awareness of some problems in the delivery of care to children and this was highlighted in the Bristol Inquiry 2001 which followed the first (or second) report of CEPOD 1989 which had drawn attention to particular problems with surgical care of children.

6) Arguments have been proposed to develop and expand separate children's hospitals but these are being met by arguments to embed a children's hospital within a hospital in the regional centre. The argument for the latter being that the "organ specialists" like

cardiologists, nephrologists, neurologists, etc. require investigation facilities in imaging and pathology and neurophysiology which can be shared with other age ranges and for the close working arrangements needed and sharing of experience and knowledge between tertiary specialist for adults and children.

7) One of the main advantages of a children's hospital however is the ability to focus entirely upon the needs of children and their families in relation to the environment, the knowledge of the different ranges of normal which apply to haematological and biochemical tests and the awareness of the particular needs when prescribing , dispensing and administering medications to children. The psychological and emotional environment can be entirely focused upon the needs of children of different ages.

8) Although the aim of children's services in the 1980s and early/mid 1990s was to cater for children up to the age of 16 years, since the NHS National Service Framework for Children 2003 recommendations the aim now is to provide for young people up to 19 years of age in one unit. In the 1990s a number of hospitals were unable to achieve the up to 16 year goal so the children over the age say of 13 or 14 years would not be cared for within a children's hospital. This seems to have applied in the Belfast complex in the mid-1990s.

9) There are some disorders which are only found in young children and others which affect adults but have different manifestations in children whose size is smaller, whose physiology is at different stage of maturity (such as handling of fluids and medications) and the diagnostic challenges and therapies have to be modified to take account of these. Some disorders only affect children. Sometimes techniques used in surgery or anaesthesia differ not only on the size of the child but on the stages of anatomical development. Hence the need for clinical skills appropriate to their needs.

10) The nursing care of children not only requires an awareness of the needs of particular stages of development emotional, psychological and physiological but also knowledge of the different nutritional, fluid and electrolyte and medication requirements. All involved with children need to be able to develop skills in communication with them and with their parents.

11) **Implementation (delays) of modern standards** Progress towards the required standards has been relatively slow and this was highlighted in the Bristol Inquiry where one witness made the point the British guidance on the care of children in hospital was amongst the best in the world but that it was not being implemented. The clinical recommendations of the Bristol Inquiry , and in particular that cardiac surgery for children should be located onto a smaller number of sites has been very slow to be implemented and in 2012 is not yet been fully in place/. Partly this has been resistance for such from the NHS clinicians and managers but also parental groups change despite good evidence that improvements in outcome will result.

12) Evidence from better outcome by concentration of certain specialist care into fewer sites led to a process within the Department of Health England to identify some services which would be better located in certain (fewer) hospitals. A good example which has been shown through follow-up to have led to better outcome is the location of children's liver

services into about three units as a result of which the outcomes for surgery of biliary atresia have improved significantly. (Department of Health directive for England and Wales (DOH 199/0268 30.4.99) in 1999.

13) This process began in the Department of Health with 'highly specialised' services started with the Supra-Regional Services Advisory Group. This later became the **National Specialist Commissioning Advisory Group** (1990s), then National Commissioning Group (2007) and now the Advisory Group for National Specialised Services (2010). . Children's cleft palate and craniofacial surgery services have also been reduced to a smaller number with more concentrated workload and experience. In the last year, a similar process to the reduction of numbers of sites for cardiothoracic surgery at which has been proposed is now being considered for a children's neurosurgery. http://www.specialisedservices.nhs.uk/safe_sustainable/childrens-neurosurgical-services

14) **Royal College of Nursing** has issued a number of documents relating to the quality of care provided for children.

15) THE WARD SISTER

16) The ward sister on a children's Ward always is a specialist children's nurse and now in all hospitals treating children, nursing staff will have children's nurse qualification.

17) The ward sister is responsible for the nursing teams. Scheduling adequate staffing, responding to peaks in demand by bringing in additional staff or by allocating additional staff from the existing team to specific patients.

18) The Sister has responsible for managing the ward in general in relation to supervision of processes and ward rounds.
19) They contribute to the compilation of guidelines and information sheets for parents. The nursing staff has a major role in communication with parents often "interpreting" or discussing at length comments that have been made by medical staff about a child's condition and explaining this.

20) They have particular expertise in the management of monitoring and resuscitation equipment and intravenous infusions. They administer medications and intravenous fluids which have been prescribed and dispensed. In order to do so it has become a necessary standard to have two nurses checking the dosages. (Allitt) Nurses are very often more familiar with the formulation than the medical staff and will influence how a prescription might be written having calculated this from bodyweight and when rounding up or rounding down is necessary. They also act as a safeguard to cross check or challenge the dosage or drug used in a child from the knowledge of children's medication. Increasingly a small number of medications may be given intravenously by nursing staff that this was not so widespread in the 1990s. And now and then a bolus dose of IV treatment such as Midazolam would be given by a doctor and the extent to which nursing staff would assist in drawing it up and cross checking varies now and then.

21) Nursing staff are responsible for the regular measurements such as temperature, pulse respiration BP and Glasgow coma Scale. They have a responsibility to summon medical staff at any grade if they are concerned about their patient's condition. There are also skilled in recognition of deterioration in overall condition of the child and initiating resuscitation when necessary.

22) Nursing staff maintain their own separate documentation from the medical record although in some hospitals these records are integrated. They tend to be completed at the end of the shift. Each ward will have a formalised handover at the end of shifts.

23) The ward sister/manager has responsibilities for appraisal and training of staff in her care and identification of developmental needs professionally linking with the senior nurse management of a hospital or directorate.

24) Some nursing staff at senior level will be responsible for several wards working with ward managers/sisters.

25) The nursing staff will report adverse events and should be engaged and involved in discussion about these and may be involved in determining the action plans which result. Ideally it should be possible for senior nursing staff to attend grand rounds or clinical presentations but this is less now than it was in the past because of pressure on the time of the nursing staff. They are involved in the drawing up of guidelines and also draw up documentation supporting nursing practice.

26) CLINICAL GOVERNANCE IN CHILDREN'S SPECIALIST SERVICES.

27) I have taken note of the papers produced by Prof Aidan Mullan (27/7/2011) and by Stephen Ramsden (29/2/2012). In this document I aim to cover issues relating to clinical governance with particular focus on *children's specialist services* which are largely based on hospital although some are located in community settings.

28) Children's specialist services are : accident and emergency, paediatrics, children's surgery across all the specialties of surgery, anaesthetics and pathology and supporting services such as imaging, neurophysiology, pharmacy and therapy services- physiotherapy, occupational therapy, psychology and speech and language therapy.

a. The following are key documents :

29) <u>Organisation with a Memory DH 2000</u>

30) "The introduction of clinical governance provides NHS organisations with a powerful imperative to focus on tackling adverse health care events"

31) In December 1997, the Government published a White Paper *The New NHS: Modern, Dependable* , which set out a ten year modernisation strategy for the NHS. One of the

main aims of the proposals set out in the White Paper is to bring about a major improvement in the quality of clinical care delivered to patients in the NHS.

32) Clinical Governance "A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish"

33) 1.3 Clinical governance is thus an organisational concept. It requires the creation of a culture as well as systems and methods of working which will ensure that opportunities for quality improvement are identified in all the organisation's services and that over time there is a major step up in the quality of care provided throughout the NHS.

34) 1.4 Under these new policies local clinical governance is reinforced by new national structures: National Service Frameworks and the National Institute for Clinical Excellence (NICE) will set standards, a new NHS Performance Assessment Framework will provide a better-balanced means of gauging NHS performance and the Commission for Health Improvement (CHI) will review local clinical governance arrangements. The Commission will also have a 'trouble-shooting' role to help individual NHS organisations identify the root causes of serious difficulties and advise on the measures needed to resolve them.

35) In 2001 Aidan Halligan, Director of Clinical Governance in the NHS and Liam Donaldson Chief Medical Officer England in a paper (Implementing clinical governance: turning vision into reality. BMJ 2001;322:1413-7) described clinical governance as:

a. *Clinical governance was the centrepiece of an NHS white paper introduced soon after the Labour government came into office in the late 1990s. (Department of Health. The new NHS. London Stationary Office 1997). The white paper provides the framework to support local NHS organisations as they implement the statutory duty of quality, which was placed on them through the 1990 NHS act.[2] Clinical governance provides the opportunity to understand and learn to develop the fundamental components required to facilitate the delivery of quality care—a no blame, questioning, learning culture, excellent leadership, and an ethos where staff are valued and supported as they form partnerships with patients. These elements have perhaps previously been regarded as too intangible to take seriously or attempt to improve. Clinical governance demands the re-examination of traditional roles and boundaries—between health professions, between doctor and patient, and between managers and clinicians—and provides the means to show the public that the NHS will not tolerate less than best practice.*

36) They refer to an earlier paper : " In 1998 Scally and Donaldson set out the vision of clinical governance:

a. *"A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."[3] Scally G Donaldson LJ. Clinical Governance and the drive for quality improvement in the new NHS in England. BMJ 1998:317:61-5*

37) ***GETTING THE RIGHT START: NATIONAL SERVICE FRAMEWORK FOR CHILDREN STANDARD FOR HOSPITAL SERVICES DEPARTMENT OF HEALTH 2003***

a. *1.16 Following The NHS Plan and the Kennedy Report a number of changes have already been set in train to transform the quality and governance of services. This NSF signposts relevant policy and guidance, and identifies the particular response required for children and young people. Providers and commissioners need to look carefully at local implementation of other key guidance and to check first that services for children and young people are included; and second that they are not adversely affected. Implementation of this standard must sit firmly within the Trust 's overall clinical governance framework, for which the Trust chief executive is responsible to the board.*

38) The most relevant chapter from the NSF relating to clinical governance is appended in annex A but the **headline issues for clinical governance are**

- Safeguarding
- The use of medicines in children
- The use of clinical equipment
- Infection control
- Major incident planning
- Training and continuing professional development
- Pain management
- Care of critically ill children
- Paediatric intensive care (PIC) and high dependency care
- Growing up and moving on to adult services

LEARNING FROM BRISTOL: THE REPORT OF THE PUBLIC INQUIRY INTO CHILDREN'S HEART SURGERY AT THE BRISTOL ROYAL INFIRMARY 1984–1995 DH 2001 This report has many relevant points I have extracted some for emphasis. (A copy of the report is included in the Library of Documents which accompanies my report)

39) POINTS

40) The contractual relationship between trusts and consultants should be redefined. The trust must provide the consultant with the time, space and the necessary tools to do the job. Consultants must accept that the time spent in the hospital and what they do in that time must be explicitly set out

41) THE RECOMMENDATIONS INCLUDE ADVICE ON:

42) Keeping patients informed about treatment and care and communicating with patients[1]

43) Consent to treatment

44) The regulation of the quality and safety of healthcare

45) Broadening the notion of professional competence

i. Greater priority than at present should be given to non-clinical aspects of care in six key areas in the education, training and continuing professional development of healthcare professionals: skills in communicating with patients and with colleagues; education about the principles and organisation of the NHS, and about how care is mmanaged, and the skills required for management; the development of teamwork; shared learning across professional boundaries; clinical audit and reflective practice; and leadership.

46) Clinicians who hold managerial positions

47) The safety of care

a. Every effort should be made to create in the NHS an open and non-punitive environment in which it is safe to report and admit sentinel events

b. A sentinel event is defined as 'any unexplained occurrence involving death or serious physical or psychological injury, or the risk thereof'

48) *All* sentinel events should be subject to a form of structured analysis in the trust where they occur, which takes into account not only the conduct of individuals, but also the wider contributing factors within the organisation which may have given rise to the event.

49) Incentives to encourage the reporting of sentinel events

50) **113** The reporting of sentinel events must be made as easy as possible, using all available means of communication (including a confidential telephone reporting line).

51) **114** Members of staff in the NHS should receive immunity from disciplinary action by the employer or by a professional body if they report a sentinel event to the trust or to the national database within 48 hours, except where they themselves have committed a criminal offence.

52) **115** Members of staff in the NHS who cover up or do not report a sentinel event may be subject to disciplinary action by their employer or by their professional body.

53) **116** The opportunity should exist to report a sentinel event in confidence.

54) **117** There should be a stipulation in every healthcare professional's contract that sentinel events must be reported, that reporting can be confidential, and that reporting within a specified time period will not attract disciplinary action.

55) 118 The process of reporting of sentinel events should be integrated into every trust's internal communications, induction training and other staff training. Staff must know what is expected of them, to whom to report and what systems are in place to enable them to report.

56) ON SERVICE ARRANGEMENTS

a. Each health authority and each primary care group or primary care trust should designate a senior member of staff who should have responsibility for commissioning children's healthcare services locally.

57) **171** All trusts which provide services for children as well as adults, should have a designated executive member of the board whose responsibility it is to ensure that the interests of children are protected and that they are cared for in a paediatric environment by paediatrically trained staff.

58) Children's acute hospital services should ideally be located in a children's hospital, which should be physically as close as possible to an acute general hospital. This should be the preferred model for the future.

59) **179** In the case of existing free-standing children's hospitals, particular attention must be given to ensuring that, through good management and organisation of care, children have access when needed to (a) facilities which may not routinely be found in a children's hospital and (b) specialists, the appointment of whom in a children's hospital could not be justified given the infrequent call on their services.

60) **180** Consideration should be given to piloting the introduction of a system whereby children's hospitals take over the running of the children's acute and community services throughout a geographical area, building on the example of the Philadelphia Children's Hospital in the USA.

61) **181** *Specialist* services for children should be organised so as to provide the best available staff and facilities, thus providing the best possible opportunity for good outcomes. Advice should be sought from experts on the appropriate number of patients to be treated to achieve good outcomes. In planning and organising specialist services, the requirements of quality and safety should prevail over considerations of ease of access.

62) **182** Where *specialist* services for children are concentrated in a small number of trusts spread throughout England, these trusts should establish Family Support Funds to help families to meet the costs arising from travelling and staying away from home. The Funds should be administered flexibly and should not be limited to those on income support or with low incomes.

63) **183** After completion of a pilot exercise, all trusts which provide acute hospital services for children should be subject to a process of validation to ensure that they have appropriate child- and family-centred policies, staff, and facilities to provide a good standard of care for children. Trusts which are not so validated should not, save in emergencies, provide acute hospital services for children.

64) AND

65) Education in communication skills must be an essential part of the education of all healthcare professionals. Communication skills include the ability to engage with patients on an emotional level, to listen, to assess how much information a patient wants to know, and to convey information with clarity and sympathy.

66) Communication skills must also include the ability to engage with and respect the views of fellow healthcare professionals.

67) The education, training and Continuing Professional Development (CPD) of all healthcare professionals should include joint courses between the professions.

68) There should be more opportunities than at present for multi-professional teams to learn, train and develop together.

69) All those preparing for a career in clinical care should receive some education in the management of healthcare, the health service and the skills required for management.

70) Greater opportunities should be created for managers and clinicians to `shadow' one another for short periods to learn about their respective roles and work pressures.

71) We support and endorse the broad framework of recommendations advocated in the report `*An Organisation with a Memory*' by the Chief Medical Officer's expert group on learning from adverse events in the NHS. The National Patient Safety Agency proposed as a consequence of that report should, like all other such bodies which contribute to the

regulation of the safety and quality of healthcare, be independent of the NHS and the DoH.

72) Every effort should be made to create in the NHS an open and non-punitive environment in which it is safe to report and admit sentinel events. Major studies should, as a matter of priority, be carried out to investigate the extent and type of sentinel events in the NHS to establish a baseline against which improvements can be made and measured.

73) The reporting of sentinel events must be made as easy as possible, using all available means of communication (including a confidential telephone reporting line).

74) Members of staff in the NHS should receive immunity from disciplinary action by the employer or by a professional body if they report a sentinel event to the trust or to the national database within 48 hours, except where they themselves have committed a criminal offence.

75) Members of staff in the NHS who cover up or do not report a sentinel event may be subject to disciplinary action by their employer or by their professional body.

76) The opportunity should exist to report a sentinel event in confidence.

77) There should be a stipulation in every healthcare professional's contract that sentinel events must be reported, that reporting can be confidential, and that reporting within a specified time period will not attract disciplinary action.

78) The process of reporting of sentinel events should be integrated into every trust's internal communications, induction training and other staff training. Staff must know what is expected of them, to whom to report and what systems are in place to enable them to report.

79) **Comment** For the purposes of the Inquiry it would be helpful to know whether there were meetings held as follows with associated minutes : Hospital grand rounds, postgraduate courses and presentations, journal clubs, clinicopathological meetings, meetings with multiple specialty, radiology meetings. Within the region, regional audits, development of regional care protocols or pathways, regional meetings of specialty societies and associations or colleges with associated minutes. (All relating to mid-90s).

80) **There are a number of other areas in which it would help to have information in order to gauge activity relating to clinical governance :**

Was the staffing at middle grade out of hours in RBHSC discussed in clinical director at meetings?.
Why are some blood electrolyte laboratory results missing from the records? Was this an identified shortcoming in order to meetings and if so what steps were taken to address this in the directorate or by the records committee?
Was there a medical records committee in the Royal hospital and if so was

there a paediatric representative?
Was there a records committee in the RBHSC directorate?
Was there a medicines committee in either Royal hospital or RHSC and if the former was there a paediatric representative.?
There is reference made to the paediatric prescriber in the medical guidelines produced in May 1997 as a source of information for junior doctors. When was the paediatric prescriber first introduced, what was its content?. Is a copy of the paediatric prescriber for 1996 available?
There was no CT scan in RBHSC in 1996 and one was not put in until 2002 despite there being a paediatric intensive care unit and a paediatric neurology service. What records are there relating to the deficiency of the service on-site in the clinical directorate or other meetings?
There was an error in the dosage of Midazolam . When did the practice of a pharmacist reviewing clinical prescriptions on the wards start?
In 1996 what processes were in place for identifying, reporting and acting upon drug errors.?
The Royal hospitals Annual Health And Safety reports record that for 1999, clinical risk management was merged with the management system. In 2000/2001 clinical risk issues made up 20% of all reported incidents (the remainder were mainly accidents and injuries to staff and accidental injury to patients and are analysed in tables) in the following year 2001/2, 37% (1532 of 4158) were clinical risk issues. There is no detailed analysis or listing of the nature of these. Is there a separate detailed report for each year on clinical issues? Does this show incidents in RBHSC? Is there a record of what steps were taken to address identified problems after the analysis? Is there a report of what events and actions took place in RBHSC?
Is the trust able to provide copies of the minutes relating to the years 1996-2005 which indicate the activities and responsibilities of the clinical directorates relating to children.?
How was the RBHSC included in the King's Fund accreditation process?
In 2003 the Department of Health produced a series of publications including a document on hospital services for children in the National Service

Framework. To what extent did DHSSPS(NI) and RBHSC take account of the recommendations made? How was this done

81) **CLINICIANS AND MANAGEMENT**

82) Initiatives in clinical governance with focus upon quality and leadership and implicit incorporation of safety and quality for patients has been incorporated in existing arrangements for the management in NHS.

83) **History and Milestones**

84) The involvement of clinicians in NHS management with senior nursing and medical professionals working together with general managers evolved in the 1960s with Cogwheel divisions feeding professional advice into the management structure (which often had a lead medical and nursing individual linked to general management). Later following the Griffiths recommendations management incorporated a triumvirate of general manager/Chief Executive, senior nurse and senior medical professional.

85) Cogwheel Report 1967

86) Encouraged the involvement of clinicians in management, recommending the creation of clinical divisions to ensure efficient deployment of resources and to cope with the management issues that arose within clinical fields. *Ministry of Health (1967) First Report of the Joint Working Party on the Organisation*

87) Griffiths Report 1983

88) The report found that the NHS had no coherent system of management at a local level and lacked any continuous evaluation of its performance against normal business criteria. In the report, Roy Griffiths famously said, 'If Florence Nightingale were carrying her lamp through the NHS today she would be searching for the people in charge.' Key among its recommendations was that general managers be introduced into the NHS and that clinical doctors should become more involved in local management. The government's response to the Inquiry accepted this shift from consensus management: 'We do not undervalue the importance of consensus in a multi-professional organisation like the NHS. But we share the Report's view that consensus, as a management style, will not alone secure effective and timely management action, nor does it necessarily initiate the kind of dynamic approach needed in the health service to ensure the best quality of care and value for money for patients**.'**

89) *NHS Management Inquiry (1983) Report (The Griffiths Report). London: HMSO Department of Health and Social Security (1984) Griffiths Report: Health Authorities to Identify General Managers. Press Release no. 84/173, 4 June*

90) Working for patients 1989 and the NHS and Community Care Act 1990

91) Due to concern about health service funding in the late 1980s, the Prime Minister announced a fundamental review of the NHS, which was published as the White Paper, *Working for Patients*, proposing an internal market in the NHS by separating purchasers from providers. GPs also would be offered the option of becoming fundholders, able to

purchase most services on behalf of their patients. The subsequent act created the necessary structures and introduced greater local diversity, competition and choice.

92) *Department of Health (1989) Working for Patients. London: HMSO, Cm 555*

93) Managing the New NHS 1993 and the Health Authorities Act 1995

94) This White Paper and subsequent act of parliament introduced another restructuring, abolishing the regional health authorities and creating eight regional offices and the merger of district health authorities and family health services authorities.

95) *Department of Health (1993) Managing the New NHS. London: HMSO, Cm 555*

96) Evolution occurred through a process in England where a District Management Team with such a triumvirate would link to equivalent structures within the health service provider units for which they had responsibility in a locality such as a hospital or community mental health or child health service.

97) Although nursing had a well-defined hierarchy headed in the past by matron whose title changed to chief nursing officer or senior nursing officer within an organisation, medical consultant organisation lagged behind. In part this reflected the concept of consultant practice as being to a large extent autonomous.

98) Indeed in the 1980s and until 1993, in England consultant appointments were made at the Regional Health Authority which employed them. The consultants however were located for their work in provider units under the supervision of a district or area Health Authority. The line management relationship between a consultant and his local management was not defined but largely developed and evolved by custom and practice. From 1993 in England consultant contracts after HC (91) 8 were removed from Regional Health Authority to the local hospital Trust in which they worked. Before then however in University Teaching Hospitals with regional tertiary services were frequently linked to the university academic departments and contracts were held with the Teaching Hospital Board with a more defined line management relationship with the management of the hospital service itself. Consultants working in regional centres were in the majority employed by the NHS with Honorary University contracts, others however in the same team, might be employed by the University responsible for undergraduate education and research, and then the consultant / academic held an honorary NHS contract. This led to some blurring and ill definition of line management responsibilities.

99) It was a on this background that initiatives to improve and clarify relationships and responsibilities took place and one of the steps towards this was increasing and encouraging clinicians to be involved in management. This intention was affirmed in the government White Paper of 1989 *Working for Patients:* HMSO. February 1989 which stated

    a. *"the government's objective is to create an organisation in which those who are actually providing the services are also responsible for day-to-day decisions about operational matters…….DHAs can then concentrate on ensuring that the health needs of the population for which they are*

responsible are met……. The government will expect authorities to provide themselves to medical and nursing advice they will need if they are to undertake these tasks effectively"

100) From 2003 the new consultant contract led to much more structured job plans for consultants

101) http://www.nhsemployers.org/PayAndContracts/MedicalandDentalContracts/ConsultantsAndDentalConsultants/Pages/Consultants-KeyDocuments.aspx

102) Up to the 1990s

103) Consultants up to that point across all specialties were represented in a remnant of the cogwheel division known variously as a Hospital Medical Committee, Hospital Staff Committee, Clinical Advisory Committee etc. The chair of that committee was regarded as the voice piece of the consultants and the channel through which management could communicate and influence cohesion. These committees were drawn up in the constitution defined by guidance from the Department of Health and were attended by the senior management of a hospital Trust or provider unit (and provided organised and minuted these meetings) : some provider units being managed by the district management team, while others were hospital Trust s which managed their own organisation. The arrangements within Northern Ireland probably reflected this evolution.

104) Engagement of consultants, senior nurses and senior members of the professions working with medical professionals in management progressed in the late 1980s and early 1990s. Such arrangements included senior laboratory professionals such as biochemists, microbiologists, haematological staff and senior radiologists, senior clinical psychologists, directors of physiotherapy and chief pharmaceutical officers (who had within their own departments well-defined managerial roles identified with clear grade/salary levels).

105) At first clinical management arrangements had their main focus on the following: Resource management-finances, bed numbers, use of theatres, control of medications, infection control, equipment purchasing and replacement plans, development of new posts and the management of existing human resource/personnel issues but they also a contribution to strategic planning.

106) A structure was put in place to enable engagement and communication with clinical staff in the wide range of specialties that are found within hospitals. It was within the structure that developments occurred of identification of **clinical leads** within specialties who may have come together in groups under the **clinical directorship** of one consultant who might have covered several specialties but who liaised with the lead clinicians from each individual specialty. Differing arrangements were put in to enable and free up clinical time to take up these roles either by backfilling their clinical responsibilities or by these continuing but with additional sessions funded. Additional resource in the form of extra secretarial and PA functions were also identified. One of the motives to putting in place the structures was a need for management have an identified voice and responsible leader for each specialty especially, as the number of consultants was increasing.

107) These developments took place in the mid-to late 1980s and were fairly well established in the early 1990s. Major safety issues which arose would be addressed within the structure but there was initially at least little proactive approach to quality management. There was more focus upon how to make best use of existing resources and at the same time with resource constraint to maintain existing services seem to be under threat from tight financial management.

108) In the later 1990s and early part of the 2000s and since the engagement of clinicians in management has become much more structured and formalised. Clinicians have undertaken management development roles and courses, and quality issues taking account of the increasing range of national guidance have been more part of regular agendas. For each Trust it has become a requirement to appoint a Medical Director on its board and the clinical directorship structure has become more defined and resourced. Increasingly a board member was identified as the lead for clinical safety/audit. In the early stages of clinical lead/clinical director, much of the arrangements were administrative in the form of ensuring coordination annual leave so that the 24-hour service is properly covered at consultant and junior staff level, ensuring guideline development and quality review, ensuring proper allocation of sessional time for clinicians to engage in audit and professional development, to ensure that there was proper equipment available and serviced especially for resuscitation, to ensure adequate theatre equipment and anaesthetic equipment, to ensure sufficient nursing staff available to meet the case mix on the wards and that nursing staff were supported in professional development by allocated courses and time, to ensure that there was a schedule of clinical meetings such as described in the knowledge section below, to ensure that annual appraisal was in place and in medical audit processes were taking place in a structured way. Part of this would include ensuring that communication with parents and children was optimal in the form of documentation or verbal support from specialists and from support groups. In the surgical specialties to ensure that there was adequate cover available 24 hours, to review theatre allocation and usage to ensure that this was optimal why leaving sufficient space emergency, to ensure that there was adequate anaesthetic support for theatres and resuscitations in accident and emergency, the children's wards and the theatres and intensive care and that there was sufficient medical and nursing staffing to permit a safe and ideally a high quality of care to be delivered. These responsibilities included making protocols for care available at the point of care and monitoring their use. They may have either been " adopted" or drawn up within the departments.

109) It was on this backdrop of evolutionary change within management structures including clinical management, that **medical audit** came to be embedded from the early 1990s.

110) Over the mid-1990s until now there has been an increasing recognition by clinical staff of the need for **professional accountability** not only to the patient and the GMC but colleagues and to their employing Trust with line management responsibilities and subordination to the Chief Executive-a role largely but not entirely delegated to the Trust

medical director. Part of this professional accountability has led to more structured engagement in professional development including the use of annual appraisal (introduced regularly in 1999/2000) and the registration of continuing professional development with the relevant Royal College to be able to demonstrate that the individual is held in good clinical standing. This process has now evolved further into reaccreditation of specialists. In this process clinicians will need to demonstrate that they maintain their professional knowledge and skills and increase and modernise their knowledge and practice in keeping with the latest developments and national guidance. More focus now takes place on outcomes of clinical care and safety.

111) Some were supported to go on management courses. However regular scheduled meetings within management structure are time-consuming and it is necessary for a clinical director to attend in order that specialty was properly represented and it was possible for a clinical director/lead to discharge their duties.

112) Later as job plans became more structured there was a role in identifying the workload and number of sessions undertaken by clinicians, organising and arranging rota and annual leave for consultant and junior staff with a view to ensuring continuity and safety. Around 2000 as consultant appraisal became embedded and a more structured approach to continuing professional development became part of this process, the clinical director/lead was responsible for ensuring that all members of the consultant and junior medical staff took part in this process. There were additional processes inherent for mentoring of medical trainees and of supervision and education. This was often undertaken by the identified tutor in paediatrics (and the same would be in other specialties) who related to the postgraduate tutor of a hospital or Trust and, to the regional networks of postgraduate training led by the regional adviser appointed by the relevant Royal College .

113) Consultant appraisals.

114) Consultants are now expected to undergo an appraisal process annually. This together with registration with Royal Colleges for Continuing Professional Development form part of the initiatives in the late 1990s and early and mid-2000 onwards for providing a more structured approach to consultant development and maintenance of standards. The introduction of an appraisal scheme for consultants was linked closely with job planning arrangements for the new consultant contract arrangement. The GMC's proposals call for a five-yearly demonstration of all doctors' fitness to practice. Under the scheme currently being proposed, this will be based on information and evidence to be seen by GMC panels. As far as is possible, we have designed the documentation to allow the information and evidence gathering processes of appraisal and the summaries of outcomes to fulfill the requirements *of* revalidation as soon as it is introduced. This means that doctors will be able to produce the evidence they need for revalidation as part of a seamless process which avoids complexity and duplication

115) In 2000 DH wrote to all CEs of Trust s regarding **Consultant Appraisals. AL(MD) 6/00.** Documentation was provided designed to provide a systematic approach to the collection and presentation of information for appraisal. It will be of immediate use in the

next round of annual appraisals and is also designed to be the vehicle for the delivery of GMC revalidation in due course.

116) Every consultant being appraised should prepare an *appraisal folder*. This is a systematically recorded set of all the documents: information, evidence and data which will help inform the appraisal process. Once the folder has been set up it can be updated as necessary. The documentation will allow access to the original documents in the folder in a structured way, record what the appraisal process concluded from them and, finally what action was agreed as the outcome following discussion. It was suggested that the approach can be based upon reflections on the following:

a. how good a consultant am I?

b. how well do I perform?

c. how up to date am I?

d. how well do I work in a team?

e. what resources and support do I need?

f. how well am I meeting my service objectives?

g. what are my development needs?

117) Audit

118) The clinical director would also be responsible to the Trust through the Medical Director or directly to ensure that clinical audit was in place and that the results of the clinical audits in terms of need for change or issues of safety would be drawn to the attention of general management. Having done so it would be for the clinical director and others within the Trust to ensure that changes were made and after an interval to audit again to check both that the changes were implemented and that improvements were occurring and in safety areas that incidents were reduced or prevented.

119) CONSULTANT RESPONSIBILITIES AND DR STEEN

120) In this I consider the contractual and professional aspects of on call consultant responsibilities and then comment on the absence of Dr Steen on the morning of 22 October 1996.

121) **PROFESSIONAL ACCOUNTABILITY OF DOCTORS.**

122) Doctors have accountability to patients, to the GMC, and from around the year 2000 through the process of being in " good standing" , with their Royal College and to their employers (through line accountability to the Chief Executive). In recent years to 2012 the GMC and Royal College relationship is being consolidated into reaccreditation.

123) The accountability to employers is maintained through review of job plans, appraisal and through the process of investigation of complaints from patients or other staff (the

latter sometimes involving human resources to a considerable degree). More structured guidance on this dates from 1990/91.

124) Professionals in all branches need to maintain and develop professionally. In this paper I am not considering here the processes for nurses, pharmacists laboratory technicians etc. but these processes should also be under the umbrella of general management/clinical governance.

125) Medical personnel maintain and develop their professional standards by meeting CME requirements from 1996 and Continuing Professional Development Points set by their Royal Colleges from around 1999 by engaging in internal (within their own trust) activities and external activities (outside the trust) gaining a requisite number of points each year.

126) Internal activities include clinical meetings where experience and new knowledge is shared gained through case presentations courses, reading journals, audit, investigation of events.

127) Interdisciplinary meetings should be encouraged and seen to be in place within a Trust and would include such examples as meetings of surgeons and anaesthetists, paediatricians and anaesthetists, clinicopathological meetings with surgeons and paediatricians, clinical radiology meetings equally, meetings attended by the pharmacists, paediatricians and surgeons and anaesthetists including intensive care.

128) External activities include the attendance at courses, scientific meetings within and outside the United Kingdom, regional meetings with their college organised by the postgraduate tutor or a regional secretary of a national body such as a professional association or college. This activity includes engagement in the development of audit of guidelines, protocols and care pathways. The latter activity has increased from the late 90s and become widespread in the 2000s. One example additional to R College or NICE processes was a process in which in which 6000 professionals were engaged-The '*Do Once And Share Program* 'funded and supported by the Connecting For Health IT programme (this included paediatric prescribing for example but also the development of care pathways for the elderly with falls, epilepsy chest pain arrhythmia etc. – a full list is available if requested child health care was covered by some of these).

129) Within regions and nationally professionals should be seen to be involved in the development of care pathways and associated audit of moderate prevalence conditions together with tertiary specialists and practitioners in the district hospitals - medical and nursing for such conditions in paediatrics as diabetes, epilepsy, paediatric intensive care cases and neonatal intensive care. The paediatric oncology protocols for care have been a long established and contribute to well recognised quality service with improved outcomes..

130) From the start of R College registration of consultant CME from 1996 (CPD from 1999/2000) each consultant should maintain a folder listing their activities which should include details of meetings held and audits in which they were involved. They should have copies of their original contract on appointment and also any changes which

followed reviews of job plans. This documentation is also a requirement for annual appraisals which came in around 1999/2000.

131) General paediatric staffing arrangements and contract in 1996

132) (As part of the Inquiry, the rota schedules for the SHO, medical registrar and consultant paediatric surgeons has been found but not the consultant paediatric rota).

133) Conventional staffing arrangements within a general paediatric service constitute an arrangement as follows:

a. Consultant

b. Middle grade doctors

c. Senior house officer

134) Additionally in some hospitals there was a fourth tier of a junior house officer but this was not so common in paediatrics.

135) Consultants

136) A consultant takes responsibility for all patients admitted under their care either by planned or acute admission and then responsibility for continuing care of patients admitted on their day on-call for on-going care during that admission and the subsequent follow-up. If problems arose for which they wish to seek another colleagues opinion, say a neurological problem or nephrology problem, the consultant conventionally would remain "in charge" or the lead consultant while the tertiary specialist would offer an opinion and advice. Exceptionally a tertiary specialist would indicate that they will take over the care of such a patient and usually this is indicated by an entry into the case record. (In these circumstances the hospital Information Systems would allocate the discharged case to that specialist).

137) For out of hours arrangements (usually after 5 PM and up to 9 AM the next day), the consultant on-call takes responsibility for continuing care of patients admitted under their colleagues as well. This applies in all hospitals admitting children. In regional centres however with a range of tertiary specialties, there may additionally be on-call consultants who would be consulted directly by the junior resident staff in certain specialties for problems arising in the patient admitted under the care of that tertiary specialist. The extent to which an on-call consultant covering the whole hospital would be responsible for direct contact about say a nephrology or a neurology or a cardiology patient would vary and on the whole be limited.

138) Much of this is by custom and practice rather than be documented but if there were adverse events or patterns whereby an individual consultant did not conform, this would be raised with the clinical director and general management.

139) The surgical specialties would each have a separate consultant rota. Paediatricians may be asked to offer an opinion at consultant level or at middle grade level on children admitted under a surgeon but the lead consultant would remain the consultant surgeon in whatever specialty.

140) After admission to PICU arrangements vary. In many hospitals there is joint care between the intensive care consultant and the consultant with lead responsibility. For patients transferred in from other hospitals the intensive care consultant is the lead and may invite opinions from a range of specialists.

141) A consultant is also responsible for supervising and directing the junior staff supporting them at the time both in terms of clinical opinion and for educational purposes.

142) **Out of hours on-call** Out of hours the consultant would provide cover from home by telephone or on occasion recall consultation. The consultant would need to be satisfied from their experience or knowledge of the junior doctors that these doctors were competent to undertake the clinical competencies including diagnostic and technical in support of her or his responsibility. Consultants will expect to be called by their senior house officer or registrar to assess unusual cases by discussion or consultation. They would also expect to be called by a senior nurse should the nurse be concerned about any aspect of care. Some consultants, less familiar with the junior medical staff routinely would telephone the Ward at around 9 or 10 pm to check whether there were any problems. In 1996 that practice was very variable. This would be custom and practice rather than in written documentation and be regarded as a means of discharging a consultant's professional responsibility.

143) **Middle grade doctors** : usually registrars or senior registrars but occasionally non-consultant career grades such as associate specialist or more commonly staff grade. Out of hours resident doctors with more experience and greater competencies are drawn from this group. Such doctors are specialists in training. In paediatrics the majority are training in general paediatrics and rotate through district hospitals as well as a regional children's centre. The rotation to the latter is to offer a range of experience in the tertiary specialties. Some trainees at this grade however are aiming at a consultant post in a tertiary specialty and may remain only in the regional centre.

144) Senior house officers may have less than 12 months experience in paediatrics, they may be paediatric trainees, but may be trainees in other specialties such as paediatric surgery, anaesthetics, accident and emergency or general practice. If they have less than 12 months experience in paediatrics then they cannot cover a service without middle grade cover at resident level. In some district general hospitals, especially small units, a senior house officer with 12 months or more experience will provide the resident care reporting directly to a consultant.

145) **Consultant Contractual arrangements regarding on call.**

146) Hospital policies on this tend to be based upon convention rather than be set out in documentation although consultant job plans in place in England in the 1990s would set out the frequency of the expected on-call rota commitment.

147) The original consultant contract which used in 1970s included the following :

a. *"continuing clinical responsibility of patients in your charge, allowing for proper delegation to and training of your staff."*

b. *"Arrangements for leave and other absences shall in the first instance be made with the Area Health Authority"*

148) (The appointment was with the Regional Health Authority)

149) In Consultants Contracts and Job Plans HC (90) 16 May 1990

a. *Following the paper Working For Patients, there was devolution from Regional Health Authorities of day-to-day management of consultant contracts to their districts and required "all health authorities responsible for the management of consultants contracts to introduce a system of job plans for all hospital consultants." This was to be in place by 1 April 1991.*

b. *"For their part general managers need to have a clear understanding of the work which is being undertaken by consultants and to be in a position to make changes following discussion and agreement with them."*

c. *The job plan will henceforth be part of every contract.*

150) This included a requirement to participate in medical audit under local arrangements (in the light of the relevant department of guidance). and .... include details of out of hours responsibility, including rota commitment.

151) In paragraph 11 of the circular

a. *"The assessment of duties should be made in accordance with the revised paragraph 61 of the terms and conditions of service. The general manager may seek the advice of the Director Of Public Health and make use of any other appropriate source of medical or dental advice (including any relevant College or Faculty guidelines) when drawing up or evaluating a proposed job plan or work programme, in order to facilitate agreement between the consultant and the general manager."*

152) It was from this time that the frequency of the on-call arrangements was specified in the contracts but did not include any specific wording relating to transfer of responsibilities to one's colleagues out of hours.

153) Although the minimum working week was 35 hours in the 1980s, the wording relating to out of hours duties and how this should be taken into account was very non-specific.

154) In a job description drawn up in 1989 for a new appointment, the acute on-call rota commitment was identified as 1:3 and .

a. *"The person appointed will be required to provide cover for colleagues on a mutually agreed basis in respect of absences from duty."*

b. And

c. *"There is in addition a collective responsibility falling on all consultants to consult with colleagues and, hence, to coordinate their individual activities in order to ensure that the particular clinical services in which they are involved operates effectively."*

155) The contract included an agreement upon the number of fixed commitments from which a consultant should not deviate without agreement with the general local management. The job plan was to be reviewed each year.

156) It was expected that arrangements would be made between consultants to cover overnight and weekend periods and annual and study leave although locums might be put in place for the latter.

157) It would be a responsibility of general and clinical management through HR and Clinical Directorates to ensure that 24 hour cover was in place and met adequate standards . In acute general paediatric practice wording was often inserted to the effect that a consultant should reside within ½ hour recall time and may have specified a distance. It was thus implicit that they had recall capacity at all times to attend within ½ hour of a call.

158) It would also be the case that the on call frequency would be reviewed in a new contract by the R College approval process (usually the RC Regional Adviser) and also by the RC representative on the (statutory) Advisory Appointment Committee for a Consultant.

159) From the early 1990s the BPA and also other professional bodies were making it clear that acute out of hours responsibility is should not be on a continuous basis. Paediatrics was recognised to be a high out of hours recall specialty in a report commissioned by the Department of Health (England) .Dowie R. *Patterns Of Hospital Medical Staffing-Paediatrics*. Postgraduate Medical Federation. London HMSO 1991. She found that consultants in paediatrics spent the most time on emergency recall any of the specialties studied. In her study Dr Dowie commented on the extra responsibility for consultants in the 1990s such as involvement in management, resource management initiatives and medical audit. She noted to have been added to an already existing heavy workload and recommended that medical assistance should be provided to sustain the clinical services normally provided by consultants who became clinical directors or clinical tutors. She noted that by the mid-1990s, the BPA was advising that consultant paediatricians should be on rota of 1 :4 or less. Dr Dowie wrote that the complexity of work in teaching hospitals (regional centres) was recognised where teams provided specialist and general paediatric cover and also cover at times the neonatal unit frequently requiring more than one junior team on call. In regional centres the specialty care provided is often from academic departments with competing pressure on staff who are responsible for undergraduate and postgraduate teaching and research.

160) In *Hospital paediatric medical staffing. 1993 The BPA* advised that continuity of care should be provided by responsible consultant. And that job plans for consultants should not be overburdened by excessive hours of work or duties inappropriate to experience and skill example resident duties covering SHOs Opportunities should be included for continuing education and professional development.

161) In respect of **consultant management responsibilities** the following paragraph 16 was relevant

162) "where a consultant takes on significant additional management responsibilities in one or more of the following roles:

163) In coordinating the development and operation of medical audit in a hospital district

164) as a clinical director (or equivalent e.g. consultant in administrative charge)

165) In leadership of the resource management initiatives.

166) The Health Authority in reviewing the job plan of the consultant may enter into a contract up to 1 temporary additional notional half day or, where appropriate, up to 2 temporary additional notional half days. Alternatively a consultant who takes on additional clinical duties as result of, consultant colleague dropping some clinical duties to take on such additional management responsibilities may, instead, qualify for one temporary additional notional half day.

167) Comment

168) It was from this time that the frequency of the on-call arrangements was specified in the contracts but did not include any specific wording relating to transfer of responsibilities to one's colleagues out of hours.

169) Although the minimum working week was 35 hours in the 1980s, the wording relating to out of hours duties and how this should be taken into account was very non-specific.

170) In a job description are worded in 1989 for a new appointment, the acute on-call rota commitment was identified as 1:3 . "The person appointed will be required to provide cover for colleagues on a mutually agreed basis in respect of absences from duty." And stated

a. *"There is in addition a collective responsibility falling on all consultants to consult with colleagues and, hence, to coordinate their individual activities in order to ensure that the particular clinical services in which they are involved operates effectively."*

171) In the Job Description provided by DLS for an Ambulatory Paediatric Consultant in ? 1996

a. *"There are three consultant paediatricians in community child health in neighbouring trusts who have sessional commitments to general paediatrics in the hospital. The hospital treats approximately 40,000 outpatients and 10,000 inpatients per annum with a further 25,000 patients attending the accident and emergency department each year.....*

b. *The Faculty of Medicine at Queens University Belfast trains approximately 150 medical students annually high proportion of clinical training occurring at the Royal group of hospitals. The Department of child health is situated on the Royal Hospital site.*

c. *Medical members of the Department of child health are consultants within the paediatric directorate and contribute to clinical services in RBHSC . Teaching programmes in child health have a large component occurring within about RBHSC and contributed to by all medical staff on site.*

d. *The Royal hospitals trust was established in April 1993. It has established a system of clinical directorates with devolved budgetary responsibility to a clinical management team led by a clinical director, assisted by a directorate manager. The majority of services provided within the RBHSC are managed by the paediatric directorate."*

172) The job description or time table does not indicate an on call commitment

173) Paediatric Staffing in RBHSC in 1996.

174) On page 13 of WS-143-1, Dr Steen reports the junior medical staffing in 1996 as follows:

a. *4 grades of junior doctors : First term-junior doctors with less than one year paediatric experience, Second term junior doctors with usually 1-3 years paediatric experience, Registrars-junior doctors with more than 3-4 years' experience who would usually have completed specialist examinations (membership) and senior registrars who would have had five years paediatric experience.*

b. *Allen Ward had first term SHO, second term SHO and registrar. During the working day the registrar or if this doctor was not available, second term SHO oversaw the Ward. The nursing staff and first term SHO would initially relate to them and if they felt necessary, they contacted me by telephone or by bleep. Out of hours there was a first term doctor, the second term doctor and a registrar on call for inpatients with the registrar also supporting consultations in A and E. The reporting system was the same as during the day.*

175) But this arrangement for out of hours differs slightly from that described by Dr Bartholome, the registrar on call on the evening of 22 October which was:

a. Document WS-142/1 on page 3 Dr Bartholomew. Describes the duty of the paediatric registrar in 1996. *The most senior Dr on-site between 5 PM and 9*

AM. Registrars on-call duty included covering the general paediatric wards, the specialty wards (cardiology, haematology, neurology, nephrology, paediatric surgery and orthopaedics) the SHO working in the paediatric intensive care unit would ask for advice if required. The hospital had about 120 beds that time. The registrar also covered the emergency Department. In 1996 and medical staffing at night was one senior house officer in the emergency Department and two junior senior house officers in the medical and surgical wards. Their shift finished at 22:00 hours. After 2200 is only one SHO covered all wards..

176) Dr Steen Consultant Paediatrician under whose on call arrangement Claire was admitted

177) The general paediatric consultant cover arrangements were on the basis of a 1: xx frequency rota for out of hours care. It would be helpful to see Dr Steen's contract or failing that a model contract of the time

178) Dr Steen was the consultant paediatrician on-call for general paediatrics on the evening on which Claire was admitted. She has explained in her witness statement that the rota responsibilities would at minimum have started at 5 PM the previous evening and would extend overnight finishing at presumably 9 AM the following day but followed by a post take Ward round the following morning.

a. From the document WS-143-1. Dr Steen explained that she was the consultant on-call from 1700 hours on 21 October 2 1996 . She reports that she would then have been in the hospital the next day between 0845 and 13:00 hours on Tuesday, 22 October for "post-take Ward round". But the only recollection Dr Steen has is meeting the parents and seeing Claire before and after the CT scan on 23rd of October 1996 having attended at 0400 hours after Claire had collapsed. Dr Steen's clinical notes entries start at 04:00 hours on 23 October 1996. On page 7 there is an important statement which she made to the coroner "I recalled that I had been aware that Claire was in the Ward at 9 AM on 22 October 1996 and that I had been contacted by the Ward to inform me that Dr Webb had taken over her management" there is no record of this discussion. (document WS-143-1. Dr Steen)

179) It is not clear whether Dr Steen would have had responsibility for the cover of the general paediatric service and wards during the daytime of 21 October nor who was the consultant responsible for covering general paediatric admissions on to Allen Ward in the daytime on 22 October. But Dr Steen was responsible for providing consultant cover for the time in question when Claire was admitted (7 PM 21st of October). Whether she was responsible for a 24 hour duty 5pm to 5pm is not clear. But a morning ward round was expected.

180) It is conventional that should a consultant appreciate that they are not available or will be away during any period of responsibility for patients, that they make arrangements

with a consultant colleague usually by telephone or face-to-face discussion to ensure that their responsibilities are covered by another consultant. This would also be the case if they are not contactable by telephone or are beyond around half an hour distance from the hospital should they be the recalled.

181) While on call out of hours, a consultant general paediatrician would expect to be called by a member of their junior staff at any time for telephone advice or personal face-to-face consultation with the child and thus expect a return to the hospital to see the child at any time. Such a recall consultation would take place when a child was significantly ill or where a diagnosis or procedure lay outside the competence expected of the junior medical staff in the team. The consultant would be responsible overall both for the care of the child and the supervision of the junior medical staff in the team and at the same time be responsible for the quality of service provided for the patients for whom they were responsible by the medical and nursing staff, Ward accommodation (shortage of beds for example) and the arrangements for specialist investigation or consultation with other consultants such as surgeons, neurologists, cardiologists or intensivist/ anaesthetists and radiologists. Should any problems arise with service general provision, they would be expected to contact the senior nurse and / or general manager on-call to review alternative options and put them into place. It is also expected that any shortfalls were addressed through adverse incident reporting or brought up in an appropriate way with the clinical director and general management either urgently or through the process of meetings in the directorate.

182) It would be expected that most children admitted under the care of consultant paediatrician would be seen by them but this is not always the case. There may be a number of children who may have been assessed and discharged by competent junior medical staff such as those with minor disorders.

183) If a consultant is not able to carry out a scheduled Ward round, then they should have either telephoned the Ward or the registrar to determine whether any significant cases had been admitted overnight. Also if not able to attend a scheduled Ward round to make other arrangements for the children under her care to have been reviewed. This was a shortcoming in the arrangements for the provision of care for Claire . It may be helpful to establish how frequently a consultant did not carry out a scheduled Ward round.

184) It is the case that consultants who had been on call overnight may, the following morning, have other commitments such as an outpatient clinic and under these circumstances the Ward round to be carried out in the afternoon following the night responsibility. However that consultant would expect to be contacted by the junior medical staff or the nursing staff or they should initiate such contact before starting a clinic by telephone or ward visit in order to see whether there were any unusual or severe cases that they should see.

185) CONTINUING MEDICAL EDUCATION FOR CAREER GRADE PAEDIATRICIANS.

186) From document produced November 1997 by the Royal College of Paediatrics and Child Health.

187) This refers to the national scheme for continuing medical education (CME) starting in January 1996.

188) It defines CME as the continuing education-part of the professional development-of all practising consultants in the NHS and universities, and those in independent practice, and other non-training career grades of staff (associate specialists, senior clinical advances, medical officers and staff grade paediatrician's) who look after children in hospital and the community.

189) The aim of this initiative was to define and structure engagement with CME and to record this with the College breaking it into internal CME and external CME. The target CME was to be 50 credits per year. With one whole study day being credited with six credits. At least 50% should come from external CME. Internal CME included weekly clinical meetings/hospital community educational meetings/journal clubs/audit meetings.

190) The RCPCH regional adviser was nominated to identify and approve both internal and external CME activities.

191) The RCPCH tutor was to inform the regional adviser of CME activities taking place in the area.

192) This process having been set up with individual consultants regularly submitting their records to the College , was followed by renaming this to Continuing Professional Development (CPD) from 2000.

193) CLINICAL MANAGEMENT DIRECTORATES

194) By 1996 medical management structures in Trusts were well-established. There may , however, still have been a remnant within the Royal Hospitals group or in RBHSC of the old Griffiths/cogwheel process whereby clinical specialties met together in divisions, with general management feeding into a medical advisory committee which can be attended by all consultants and supported by general management and administration. This arrangement is a separate pathway for medical advice to be offered to general management outside the clinical medical management structures of directorates. As the latter increased, this function decreased by the mid-90s but in some hospitals still continues.

195) The Medical Director would sit at board level, and, as described in the Royal Hospitals account in the job descriptions, a management structure of clinical directorates would be expected to be in place.

196) The Chief Executive and Medical Director with general management would coordinate meetings of all the clinical directorate leaders-clinical directors-sometimes called clinical leads. These would also be ideally with nursing and other professional staff.

197) The makeup of each directorate would vary between Trusts. Sometimes a directorate could include all non-surgical specialties, another directorate all surgical specialities and anaesthetists , another might include laboratories or alternatively the directorate for investigation facilities which would include laboratories imaging neurophysiology etc.

198) A separate mother and children's directorate was frequently in place. Sometimes a children's directorate would be standing alone and some included the community child health service..

199) Within RBHSC there would be advantages to be gained on the basis of the Children's Hospital by having a directorate responsible for the hospital itself rather than separately within each specialty.

200) The inclusion of all specialties within the Children's Hospital in one directorate would have advantages thereby including the paediatric radiologists, paediatric surgeons, the neurophysiologist, laboratory representative and possibly include a patient representative .

201) The NHS NSF for Children in 2003 advised that a Board member should be identified who has a lead for children in every Trust.

202) **RESPONSIBILITIES OF A CLINICAL DIRECTOR OR CLINICAL LEAD (MacFaul views)**

203) These should include the following

204) Representing the specialty and/ or service within the management structure of the Trust and relating to the Medical Director of the Trust who is responsible at board level for medical management issues within the Trust as well as corporate responsibility as a board member. This will entail regular scheduled meetings as well as the need to meet regularly (minuted) with the senior nurse and general manager responsible for the service. A management structure within the hospital Trust would be in place and a clinical director / lead should ensure appropriate representation of the specialty or areas within the Directorate by negotiation with the Trust Board, CE and Medical Director.

205) The varying responsibilities of a directorate/ clinical director includes as a minimum:

206) Reviewing the resources available for the service, identifying shortfalls and making plans and budget arguments or administrative arrangements to rectify shortfalls. This includes nursing staff in the wards or outpatients and the therapies, and clerical and secretarial support to ensure speedy communication by discharge letter to general practitioners or others, and the availability of equipment.

207) To be responsible for ensuring that annual leave is coordinated with consultant colleagues and with junior medical staff to be sure that the service is adequately and properly covered and at the same time that staff are able to take the entitlement. This may have involved engagement of locum staff.

208) To review the financial position of the directorate although the degree to which a clinical director/lead has influence on or responsibility for this varies considerably. This will entail resource management and budget reviews necessary to achieve Trust wide strategies in cost improvement programmes and to ensure that there is proper representation at higher level within the Trust management of the services within the directorate to ensure that quality and safety is not threatened.

209) To consider problems which arise in daily routine care such a shortage of or availability of medical or nursing staff, excessive pressure on beds, access to imaging, pathology etc. especially out of hours.

210) To consider developments for additional staff, and replacement or purchase of new equipment.

211) The clinical director together with senior nursing and senior management representative should hold regular meetings (with agendas and minutes) at least monthly with ad hoc meetings in between. The meetings would allocate responsibility for implementing issues requiring change and monitoring the implementation. The regular clinical directorate meetings (held as an executive core group) should ensure in that systems are in place to receive reports on the range of activities listed below at least annually.

212) In addition within the clinical directorate meetings should be set up at not so frequent intervals to include all members of the clinical and investigation teams dealing with patients and services in support of their care. In paediatrics and child health this would include nursing, pharmacy, and therapists as well as doctors.

213) To ensure there is adequate support with IT the process of patient management, clinical audit and eventually the presence of decision support and linkage with laboratories and x-ray departments when this is in place. (This is a slow process).

214) To act in a leadership role with all professional colleagues within the service including the therapists, nursing, pharmacy, doctors, play therapists outpatient staff etc.

215) Ensuring that clinical audit (topic audit, case note audit,) is in place, supported and recorded. To ensure that the department is involved in the relevant national audits such as CEPOD , CESDI , diabetes and other national audits of the specialties such as anaesthetics and any of the specialty Associations.

216) Investigating adverse events and preferably setting up a regular system of critical events reviews including death review. Also investigating and assessing complaints.

217) Together with the general manager to review the job plans and work commitments for all consultants within the directorate-ideally at an annual level.

218) To ensure that staff within the directorate are fully trained in child protection.

219) To ensure that there is development of and updating of guidelines or protocols available on the wards and that staff are familiar with these.

220) Responsible with HR for the appointment to the appointment procedures within the Trust of junior and senior medical staff and at times appointment of senior nursing and managerial staff.

221) To ensure that weekly meetings or other frequency clinical meetings are in place and that there is a proper agenda for its content.

222) To review medicines safety and quality issues often relating to the Trust 's medicines committee

223) To ensure that staff involved in the care of acutely ill children are up-to-date with advanced life support usually through attendance and certification at courses such as the advanced paediatric life-support course or paediatric advanced life support course.

224) To monitor the process of consultant appraisal and ensure that all doctors are engaged with this. There is no equivalent system for appraisal of nursing staff by the clinical director. This is usually carried out by the senior nurse managers. Nor is there a 360 degree appraisal process for general managers although doctors are expected to engage in 360° appraisal with contributions from all with whom they came into contact. To review the working patterns of consultants annually to review their job plans-in the 1990s a regular event conducted through a management process but in the 2000 onwards through the process of consultant appraisal.

225) To ensure that a and appropriate postgraduate training programs in place with a tutor for trainees, continuing medical education in a structured way in place all consultants and noncareer grades registered with their College . To ensure that the postgraduate tutor and the tutor for the specialty is supported in their roles.

226) To ensure that there is proper representation of the directorate on Trust wide committees responsible for resuscitation, medicines and safety, prescribing, etc.

227) Many of the elements of these responsibilities can be undertaken by the clinical lead/director but there are a number of areas where the responsibility is delegated to a colleague to take the lead. This would include appointment on or nomination to internal hospital committees such as the medicines committee, clinical audit, postgraduate education-CME-usually through the postgraduate tutor, mentoring of junior staff etc. It would also include the supervision of and mentoring of medical students if they are placed within the directorate**.**

228) CLINICAL MANAGEMENT STRUCTURES IN RBHSC

229) In a letter from DLS of January 2012, the current management structure for RBHSC is described.

a. The Belfast Health and Social Care Trust is managed through a system of clinical and non-clinical Directorates of which Specialist Hospitals, Women and Child Health is one and RBHSC is managed within this. The Director, along with the Co-directors, is responsible for the management arrangements within the directorate. An Associate Medical Director is responsible for the

Directorate and a Clinical director is responsible for the Medical and Surgical Specialties within RBHSC.

230) In the attached documentation also provided organisational structure charts for arrangements 1995/1998 and now.

231) **Comment:** from this documentation a number of issues arise on which it would be helpful to have greater understanding. These are

232) What were the job descriptions and responsibilities of the clinical director responsible for the medical and surgical specialties within RBHSC.

233) At what level within the structure was there a review of the adverse events, clinical audit, consultant job plans etc.

234) What representation at Trust board level is there for children services.

235) In the 1995/8 structure there is identified within the Medical Director' s infrastructure a clinical director for paediatrics. There is also a clinical director for "clinical professions"

236) What was encompassed in the role of the director for clinical professions.

237) To clarify whether the clinical director for paediatrics was responsible for the arrangements within RBHSC for all of the specialties located there-children's surgery, paediatric medicine, the intensive care, anaesthetics, laboratory investigations, neurophysiology. Also to what extent there was a schedule of meetings between the paediatric lead and laboratory and imaging leads etc.

238) Are there any minutes from this time which provide the agendas and topics discussed?

239) Was there a process for review of adverse events and deaths?

240) Was there a process for receiving lists of audits (in this matter however although the intention of the Department of Health guidance has been that reports of audits would be sent up to the Chief Executive, in practice this rarely occurred).

241) It will also help to see the job descriptions of the clinical directors for women's and children's and for the paediatric directorate.

242) It would help to see records of the content and type of meetings were held of the directorate group.

243) What was the make-up and general management support to the clinical director and what was the relationship with the senior nursing officer and nursing management..

244) METHODS BY WHICH CLINICIANS GAIN KNOWLEDGE and SHARE EXPERIENCE

245) Specialist recertification was expected to be conducted by the Medical Royal Colleges in the United Kingdom on behalf of the GMC. The process will be left to individuals to justify what they have done over the preceding period to their annual appraisal and to plan and justify their future portfolio at their personal development plan. Delivery of high-quality knowledge resources to support individuals is thus of particular importance.

246) Trainees

247) Clinicians in training are educated and supervised by senior doctors and in hospital practice this includes the consultant under whom they are working as well as the specialty postgraduate tutor appointed or nominated by the appropriate Royal College or professional association who links to the postgraduate tutor within a hospital at responsible for postgraduate education within the organisation. This applies both to district general hospitals and to regional tertiary specialty hospitals which house the regional specialties and on which undergraduate training is based (although increasingly much undergraduate training is carried out also in district general hospitals). Trainees in the hospital at senior house officer and registrar level (now named and graded differently as foundation year as an specialist years) provide much service delivery but in doing so are in a training and educational environment for their professional advancement and learning. To do so they require supervision by the consultants and the opportunity to learn from the experience-this ties will mean reflecting upon the management of their cases but also referring to the consultant when they reach the limit of their competence or technical expertise. Trainees progress through the training period would be specified by the joint committee on higher medical training with its specialist input from the (Medical) Royal Colleges. The training periods and content of the training programs differed according to which College was involved between example surgeons and anaesthetists, Physicians , paediatricians, pathologists, obstetricians and gynaecologists, radiologists, or oromaxillary and dental etc. The Royal Colleges set examinations and/or diplomas awarded to those who pass the examinations which are required before completion of higher specialist training when a trainee becomes eligible for a consultant post. The content of the higher specialist training courses is provided from a variety of sources that includes contributions from the Royal Colleges often through the examination processes but not entirely because completion of higher specialist training requires further progression and experience gained after an examination has been passed.

248) Fully trained doctors are those who hold a certificate of completion of training or a certificate of eligibility specialist registration and thus eligible to be on the GMC specialist register.

249) Consultants

250) Clinicians who have completed postgraduate training and have become consultants in their specialty have in the past undertaken informal personal professional development with their responsibility principally being to the GMC to ensure that there are up-to-date

and have maintained and developed their competencies and skills. Increasingly, especially over the past 15 years, there has been movement towards a much more structured process by which consultants demonstrate that they have and are continuing to develop professionally.

251) In the early 1990s this would be largely left to the individual. The (Medical) Royal Colleges and professional associations provided advice and support and also took on responsibility for continuing professional education as well as supervision of and examining for diploma awarding specialists in training and were part funded to do so by the Department of Health.

252) At all grades of specialist programmes both as a trainee and as a consultant allocated time is required to maintain and expand knowledge of the disorders and therapies needed by patients.

253) **Clinical governance entails an individual professional ensuring that they engage in such activities but also that the employer ensures that they have sufficient time and access to resources in order to enable them to do so**. Clinical governance also entails a form of monitoring to ensure that members of the team are keeping up-to-date but also share their experience. The sharing of experience has become an important aspect of continuing professional development. This is particularly the case as a number of consultants and indeed trainees has expanded substantially but in some areas-for example paediatrics-the range and number of children with particular disorders has remained stable or even reduced. Thus an individual clinician may require shared and pooled experience to maintain skills and knowledge. This is achieved through a variety of means including audit. Other methods are the grand round when a number of consultants would discuss an individual child or even see that child. Another conventional and well-established method is the clinical meeting.

254) **Clinical meetings held within the specialty Department**-usually weekly, often at a lunchtime, attended by all consultants if possible within the unit, all junior medical staff when available, and at times attended by other consultants such as anaesthetists, accident and emergency consultants, haematologists/biochemists etc. and often by radiologists and pharmacists. The content of these meetings would include presentation by a consultant or junior doctor of an interesting case or series of cases, results of topic and other audits or a lecture or paper presented by a consultant or junior doctor on a particular topic including reviews of recently published papers which had interested them. Also in clinical meetings of this nature, other specialists would be invited to give a presentation such as a surgeon on the management of pyloric stenosis or appendicitis from within or outside the hospital. Sometimes these meetings would be supported by drug companies in terms of teaching materials or catering arrangements or payment for external lecturers.

255) These meetings tended to be held in the postgraduate medical centre hospital or within the paediatric department itself in a tutorial room or equivalent. The presence of such activity would be one of the factors taken into account by the Royal College

/professional association visitors when approving junior posts for training and when reviewing consultant job descriptions prior to appointment.

256) In time one or these meetings would be set aside at regular intervals for clinical audit. The attendance at these meetings of nursing staff was variable. For clinical audit at present was encouraged and usually nursing staff is available were welcome to attend.

257) The arrangements for clinical audit became more regularly established following the guidance issued upon the need for this to be in place. General management-apart from its responsibility to ensure that training posts were able to meet the set standards for approval, provided support for the clinical meetings in the form of the postgraduate medical centre and teaching materials at times. This varied. But for clinical audit general management was under an obligation to support clinical audit activity and this was done in the form of clerical staff within the audit department obtaining case records for a series of case record reviews, identification from the hospital information systems of a series of a particular diagnosis, support and advice to junior doctors who are developing an audit process pro forma, assistance in the extraction of data from case records when this was needed either by support to the doctor / nurse carrying out the audit or clerical staff doing this themselves. The clinical director had a responsibility to ensure that audit activity was in place and that the findings were documented and at times reviewed.

258) Clinical audit in a more formal way as just described began to take off in the early 1990s. In order for clinical audit to be carried out properly, it is necessary to be able to match what is found being done in the unit with standards set either by the unit itself-for example guidelines or protocols used, all the standards set from external sources such as the Royal College or professional associations or groups of specialties or specialty associations. When the National Institute for clinical excellence developed guidelines, it would be expected that audits would be carried out to ensure that the implementation was being put in place and also if possible to determine outcomes.

259) **External courses.** Individual consultants would arrange to attend conferences and teaching courses which they themselves would select. This included as far as paediatrics was concerned the large annual meeting of the British Paediatric Association/Royal College of paediatrics and child health. In addition paediatric specialties such as paediatric neurology, nephrology, cardiology, cystic fibrosis, respiratory, etc. would hold similar postgraduate meetings and teaching sessions. Some postgraduate Institutes such as Great Ormond Street would organise regular seminar type/teaching courses. Attendance at such courses both in this country and overseas was supported by the employment contract arrangements with a number of days study leave set aside each year and supported with travel arrangements by the employer. The employer would also support junior doctors to attend such meetings.

260) It is still the case that the range of content within a given period of the courses attended and individual study is set by the individual consultant. However this has been formalised a much greater extent with the emergence of continuing professional development arrangements and now under the auspices of the GMC the requirement for

consultants and others to be re-accredited which includes proof of attendance at such courses and professional development including audit.

261) Consultants would also use published literature on a regular basis journals etc. as well as textbooks for private study. It was their individual responsibility to keep up-to-date but this is increasingly being appraised. The appraisal process by which a consultant is required to review annually their professional development emerged in the late 1990s. Central returns to the College that they meet the requirements set by the College is in hand so that an individual consultant can be "certified" as in good professional standing. Some consultants would publish the results of the audit while others would be engaged in research both of these processes regarded as educational and professionally developing. Some junior doctors in training would also be involved in research with a named publication and a few the involved in undertaking thesis work for a Ph.D. or in some regions a Masters in medical science or equivalent.

262) **Regional meetings.** Meetings held at intervals (1-3 times per year) with regional colleagues for postgraduate education and training purposes or for audit or care pathway development offer valuable opportunities for exchange of experience and learning and ' networking'. These may arranged by regional Association secretaries , College regional leads or as part of audits. Their agendas are often recorded in papers held by the Honorary secretary (a professional). Some form part of regional service networks such as neonatal care or diabetes.

263) One of the responsibilities of general management within a hospital or Trust exercised usually through either the postgraduate tutor but more likely the clinical director would be to ensure that individual members of the team were engaged in these postgraduate activities for professional development and training and that they were supported to do so.

264) **Comment** For the purposes of the Inquiry it would be helpful to know whether there were meetings held as follows with associated minutes : Hospital grand rounds, postgraduate courses and presentations, journal clubs, clinicopathological meetings, meetings with multiple specialty, radiology meetings. Within the region, regional audits, development of regional care protocols or pathways, regional meetings of specialty societies and associations or colleges with associated minutes. (All relating to mid-90s).

265) **There are a number of other areas in which it would help to have information in order to gauge activity relating to clinical governance :**

Was the staffing at middle grade out of hours in RBHSC discussed in clinical director at meetings?.
Why are some blood electrolyte laboratory results missing from the records? Was this an identified shortcoming in order to meetings and if so what steps were taken to address this in the directorate or by the records committee?

Was there a medical records committee in the Royal hospital and if so was there a paediatric representative?
Was there a records committee in the RBHSC directorate?
Was there a medicines committee in either Royal hospital or RHSC and if the former was there a paediatric representative.?
There is reference made to the paediatric prescriber in the medical guidelines produced in May 1997 as a source of information for junior doctors. When was the paediatric prescriber first introduced, what was its content?. Is a copy of the paediatric prescriber for 1996 available?
There was no CT scan in RBHSC in 1996 and one was not put in until 2002 despite there being a paediatric intensive care unit and a paediatric neurology service. What records are there relating to the deficiency of the service on-site in the clinical directorate or other meetings?
There was an error in the dosage of Midazolam . When did the practice of a pharmacist reviewing clinical prescriptions on the wards start?
In 1996 what processes were in place for identifying, reporting and acting upon drug errors.?
The Royal hospitals Annual Health And Safety reports record that for 1999, clinical risk management was merged with the management system. In 2000/2001 clinical risk issues made up 20% of all reported incidents (the remainder were mainly accidents and injuries to staff and accidental injury to patients and are analysed in tables) in the following year 2001/2, 37% (1532 of 4158) were clinical risk issues. There is no detailed analysis or listing of the nature of these. Is there a separate detailed report for each year on clinical issues? Does this show incidents in RBHSC? Is there a record of what steps were taken to address identified problems after the analysis? Is there a report of what events and actions took place in RBHSC?
Is the trust able to provide copies of the minutes relating to the years 1996-2005 which indicate the activities and responsibilities of the clinical directorates relating to children.?
How was the RBHSC included in the King's Fund accreditation process?
In 2003 the Department of Health produced a series of publications including a document on hospital services for children in the National Service

Framework. To what extent did DHSSPS(NI) and RBHSC take account of the recommendations made? How was this done

266) In 2001 the Inquiry into Cardiac care for children at Bristol Royal Infirmary published its findings. What was the process for review of RH services and what changes resulted ?

267) Dr MacFaul has listed a series of responsibilities for a clinical director which include the following. Questions are to what extent did the clinical director in RBHSC carry out these responsibilities?).

268) What summary conclusions were drawn on the following issues in the directorate meetings, consultant staffing, middle grade staffing, adverse events, mortality meetings, laboratory reporting, access to imaging, prescribing, consultant job plans, CME/CPD, appraisals (the notes of the November 1996 medical audit meeting shows that the numbers present were aware of the King's fund criteria-what was the input and analysis for the King's fund processes in hand at the time 1996.
269) What opportunities were there in 1996 for paediatricians in the region to meet together in postgraduate meetings, audit etc. Is there any record of the content of these meetings?
270) The first production of paediatric medical guidelines for RBHSC was in May 1997. What triggered the process of the production and when did the team start to work on producing them.?
271) Before the paediatric medical guidelines were available, what was the knowledge source used by junior doctors during their daily practice?
272) The senior house officer at 2330 on 22 October 1996 was aware of the need to increase sodium and intravenous fluid following the low result. How did he acquire this knowledge? What was the curriculum at the time for training of junior doctors in paediatric neurology or intensive care?
273) Who was the paediatric tutor or lead consultant in postgraduate education in RBHSC in 1996? 274) Who organised postgraduate meetings/grand rounds? Is any existing record of the content of these meetings? How frequently did they occur?

What was the range of specialties that attended?

275) Were there clinicopathological meetings or other meetings which were multi-professional (surgical, anaesthetics, radiology, pathology, paediatrics)?

276) Where are children are admitted the head injury observation in Belfast? Was that unit circulated with information following the inquest on Adam Strain?

277) Where are children admitted for neurosurgical treatment in Belfast?

278) Was that unit circulated with information following the inquest on Adam Strain?

279) Was the neurosurgical unit circulated with the guidance on fluid management which was issued in RBHSC. The Ward/unit is not mentioned on the circulation list?

280) The key to linkage with Adam Strain is guidance issued about fluid. From my own quick appraisal (I know you have much more experienced and detailed reports) it appears that Adam was given fluid to replace 1200 ml of blood loss, but in doing so his central venous pressure was higher than ideal and so there was fluid overload and that he had hyponatraemia. The fluids given to replace the blood were Hartmann solution 500 ml (131mmol/ Na vs normal saline 150mmol/l) , HPPF 1000ml and packed cells 500ml. The latter two fluid having high sodium the exact concentration can be determined from references) . There was thus a combination of renal disease with a greater tendency to lose electrolyte and excessive volume and fluid with a reduced sodium given. After the inquest the guidance referred to major paediatric surgery was potential for electrolyte imbalance. Yet the reference quoted relates to the potential for hyponatraemia occurring in the course of acute illness as well as surgery. What was the reason for restricting the circulation of this guidance? Given the publicity around the Inquest what discussions took place in the multi-professional meetings in RBHSC about Adam and about the fluid management issues.

281) Was the potential for hyponatraemia shared widely with the paediatric consultants and if so how ?

282) Was this information made available to the neurosurgical unit (which has a significant potential for hyponatraemia complicating and leading to brain swelling)?

283) SOURCES AND USES OF KNOWLEDGE IN CHILD HEALTH – I provide more reference information in a Supplement to this report on Knowledge

284) Uses include :

- Teaching
- Training
- Education-of doctors, nurses and professionals allied to medicine
- CPD and re accreditation
- Decision support for diagnosis, management and treatment
- Guideline production, updating dissemination and implementation (use at the point of care)
- Personal updating on ad hoc basis.
- Communication
- Health care users
- Commissioners use e.g. health intelligence and interpretation of evidence and statistics
- Reference and to promote high standards of practice

In the next sections I will consider the following

- **Medical Audit And Its Development**
- **The role of the Royal College s**
- **The role of the Department of Health and its associated bodies**
- **The role of the General Medical Council**
- **The development of guidelines**
- **Risk management and adverse events**

285) ROLE OF ROYAL Colleges AND PROFESSIONAL ASSOCIATIONS

286) The Royal College and professional associations were able in the 1990s and before and to an extent still to exercise influence upon the quality of training and range of experience in two ways within a hospital.

287) Firstly they were responsible for reviewing the quality of the training available for trainees in the specialty and in many district general hospitals senior house officers rotating through specialty aiming at a principal post in general practice. Regular reviews of hospitals was undertaken by the (Medical) Royal Colleges under the umbrella of the joint committee on higher medical training JCHMT (until mid 2006). If the training available to a post was found substandard, a report would be provided to the consultants involved, to the postgraduate tutor responsible for the specialty, to the postgraduate tutor responsible for the hospital and, to general management through the Chief Executive. Training approval could be withdrawn but usually this would be a qualified approval pending appropriate changes to bring the quality up to standard. The sanction of withdrawal of training approval had significant impact upon a hospital. It would not be possible to employ junior doctors in training as resident doctors for example to cover 24-hour 365 days a year service. Rather this responsibility would need to fall upon consultants or rely on employment of non-consultant career grades such as staff grade or associate specialist. In practice It would be very difficult for a hospital to recruit sufficient consultants or non-consultant career grades to cover the service and this would have significant management implications possibly even leading to closure of a service. General management and the Chief Executive and clinical directors would be under considerable pressure to bring the training up to standard.

288) In the past the influence which (Medical) Royal Colleges and professional associations had on individual consultants was limited. Opportunities arose when a new consultant post was established or when a consultant was retiring to be replaced. In these circumstances the consultant post would need to be approved by the appropriate Royal College in respect of its workload, responsibilities, and the support available for a consultant to discharge their responsibilities including time for postgraduate continuing education and professional development and audit. If a job description did not contain sufficient time or resources to enable this to happen in the view of the Royal College , to enable the new appointment to discharge his/her responsibilities (excessive workload, insufficient secretarial support, appropriate time allocated etc.) then a post would not be approved for advertisement. A further opportunity existed for the Royal College to influence the service and the consultant post was during the appointment interview itself where there was a statutory requirement under the advisory appointments committee arrangements of the NHS to have a Royal College representative present at the interview and appointment procedure who could if necessary prevent the appointment progressing. This would cause a service to be under considerable pressure to meet the requirements set.

289) From the 1980s and expanding in the 1990s and beyond, (Medical) Royal Colleges have provided guidance upon standards not only have individual professional practice but also on the standards to be achieved by services within the specialty in respect of hospital facilities and supporting staff with a commentary also upon workload. This was with high quality care in mind rather than protecting individual doctors from exploitation. It was within this context that the Colleges issued guidance upon medical audit later relabelled as clinical audit.

290) The (Medical) Royal Colleges also provided advice to the Department of Health either on their own initiative or following consultation. The Department of Health had a series of structures to enable such advice to be sought by the Department. This was through the Academy of medical (Medical) Royal Colleges or through the Standing Medical Advisory Committee or through ad hoc working groups and parties. The chief medical officer had an adviser in each specialty and this role was gradually supplanted as was the role of the standing medical advisory committee.

291) **The Academy of Medical Royal Colleges** :The Academy's role is to promote, facilitate and where appropriate co-ordinate the work of the Medical Royal Colleges and their Faculties for the benefit of patients and healthcare. The Academy comprises the Presidents of the Medical Royal Colleges and Faculties who meet regularly to agree direction. The Academy's membership comprises Medical Royal Colleges and Faculties across the UK. The Academy seeks to support and co-ordinate the work of Medical Royal Colleges on issues of concern. (It was renamed from the original 1974 The Conference of Royal Colleges and Faculties.) It is undertaking an increasing role in the process of re-validation. And has recently (2012) considered the evidence for benefits of consultant delivered care .

292) **Standing Medical Advisory Committee** : SMAC and the standing nursing and midwifery advisory committee SNMAC. These committees were supported by the secretariat from the Department of Health and had members nominated by the Colleges including the presidents of the College s. Unlike the joint consultants committee and initially conference of medical Royal College s, SMAC had GP and public health representation. At times SMAC would consider clinical matters and issue guidelines. For example for children care of haemoglobinopathies and sickle cell disease ; Licensing and prescribing of drugs in children 2001, Evidence Into Practice.

293) The **British Medical Association and the Royal Colleges of Nursing and Midwives** would also be consulted by the Department of Health or at times through working groups constituted by themselves offer advice on standards.

294) **The British Paediatric Association** was the main professional association to which all paediatricians in United Kingdom belonged. In 1994/5 this became the Royal College of Paediatrics and Child Health and from that time undertook all the responsibilities which (Medical) Royal Colleges take on. Until that time the responsibility for approval of training posts and for approval of consultant posts on appointment was held by the Royal College of Physicians either of London, Edinburgh or Glasgow. (I will check upon whether Northern Ireland was covered by RCP (L.) The paediatric advice available to the Royal

College of Physicians was through the paediatric vice president of the Royal College of Physicians of London and the paediatric committee of the Royal College which was made up of senior officers of the BPA. The regional advisers who had responsibility for implementing College policy and for supervising postgraduate training within the regional behalf of the College were appointed jointly by the Royal College of Physicians and the BPA until the Royal College of paediatrics and child health took on the responsibility themselves. It was the (Medical) Royal Colleges which set up in paediatrics the regular reviews but this would also apply to the Royal College of Surgeons and the Royal College of Anaesthetists in respect of other posts and the faculty of accident and emergency medicine in relation to accident and emergency. Equal arrangements would be in place for the specialties of anaesthesia, pathology, radiology within a hospital. In 1994 example the BPA produced a document on the training requirements for as the job description model, consultant in paediatrics with special interest in community child health. This was then approved by the BPA Council and the Royal College of Physicians .

295) The **Association of Paediatric Anaesthetists** and the **British Association of Paediatric Surgeons** were each one of the professional associations which undertook many of the advisory roles of Royal Colleges usually through the relevant Royal College committee processes. (Royal College of Anaesthetists, Royal College of Surgeons respectively.)

296) The Royal College of Surgeons (England) has a Children's Surgical Forum. Its first report was in 2000. This is its current description

> The principal role of the Children's Surgical Forum is to enable the College to meet its commitment to improving the quality of surgical care for children. The Children's Surgical Forum brings together a range of professionals involved in delivering surgical services to children. This includes representatives from the College, the surgical specialist associations, other medical royal colleges, the College's Patient Liaison group and the Department of Health

The Children's Surgical Forum's main objectives are:

To monitor the implementation of the recommendations contained in *Surgery for Children – delivering a first class service,* particularly those relating to professional standards, education, training, assessment, CPD and audit.

To keep under review and where necessary update the standards contained in the report.

To formulate guidance on matters relating to the provision or delivery of children's surgery.

To collaborate with other royal colleges, specialty associations and statutory bodies to develop a more integrated approach to healthcare planning and provision for children and young people.

To enable the College to respond promptly and constructively to concerns relating to the provision of surgical care to children, at a national or local level.

To promote involvement in external policy development by fostering communication links with relevant stakeholders (eg. DH, SHAs, Trusts, commissioners, etc)

To provide quality information to professionals, parents and children on the College website.

297) The **Royal Colleges of Pathology and Radiology** provide similar functions – for example the latter produced guidance on referral for imaging in children in the mid 1990s.(see Knowledge supplement for more examples)

298) **The ROYAL COLLEGE OF NURSING** has had a children's nursing adviser over at least the past 20 -25 years. The Royal College has been represented in many national working parties and groups e.g. the National Service Framework and close relationships have been maintained between the RCN and the BPA/Royal College of Paediatrics and Child Health and the Royal College of Surgeons over the years with much collaborative work.

299) The RCN had a major contribution to the Bristol Inquiry and the Department of Health production of guidelines on the Care Of Children in Hospital and on the design of children's units.

300) They have produced a number of publications which are listed on their website.

301) ROLE OF GMC (From Good Medical Practice 1995)

Para	Statement
3	Keep accurate and contemporaneous patient records which report the clinical findings, the decisions made, information given to patients and any drugs are the treatment prescribed
5	You must maintain the standard of your performance by keeping your knowledge and skills up to date throughout your working life. In particular you should take part regularly in educational activities which relate to your branch of medicine
6	You must work with colleagues to monitor and improve the quality of healthcare. In particular you should take part in regular and systematic clinical audit.
30	You must be satisfied that, when you are off duty, suitable arrangements are made fewer patients medical care. These arrangements should include effective handover procedures and clear communication between doctors.

302) MEDICAL AUDIT

303) Medical audit as a concept was introduced widely in 1988/89.

304) The government **White Paper Working for Patients 1989**

305) "Within the next two years, the government would like to see all hospital doctors taking part in what doctors themselves have come to call "medical audit" a systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome for the patient." And in *Medical Audit-Working Paper 6* HMSO. February 1989 defined audit as:

a. *"the systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome of quality of life of the patient" it can therefore be seen that the primary purpose of clinical audit is to improve practice"*

306) Recommendations regarding medical audit were embraced by the professions in a series of reports and recommendations. I provide extracts here from some of the key documents.

307) Department of Health circular HC (91) Advice on medical audit of hospital and community health services.

308) Secretary of State said in a speech on 9 June 1998 that:

a. "… *from next year [1999], all hospital doctors will be required to participate in a national audit programme appropriate to their speciality or subspecialty externally endorsed by the new Commission for Health Improvement*.", and that:

b. *"... individual doctors will be required to share their results confidentially with the Medical Director of their Trust and the Trust 's lead clinician responsible for clinical governance. In turn, doctors on the Commission for Health Improvement will have access to these data …".*

309) Requirement to participate

310) The NHS Plan sets out the requirement - which is being taken forward within the Quality Taskforce - that:

a. "*All doctors employed in or under contract to the NHS will, as a condition of contract, be required to participate in annual appraisal, and clinical Audit, from 2001. This will underpin, and provide much of the data to support, the General Medical Council's mandatory five-yearly revalidation process, which is likely to begin in 2002. Subject to Parliament, by April 2001 all doctors working in primary care, whether principals, non-principals or locums, will be required to be on the list of a health authority and be subject to clinical governance*

arrangements. These will include annual appraisal and mandatory participation in clinical audit". (para 10.10)

311) This strengthens the existing requirement in the HSC1999/065 on clinical governance issued in March 1999 for all NHS hospital doctors to participate in clinical audit programmes, including speciality and sub-speciality national audit programmes endorsed by the Commission for Health Improvement. NHS Trust s are responsible for ensuring that their doctors meet this requirement. In addition, all NHS organisations are required to report on their participation in, and the impact of, their clinical audit activities in their annual clinical governance reports.

312) The General Medical Council makes clear in *Good Medical Practice: Duties of a Doctor* that doctors should "take part in regular and systematic medical and clinical audit." The requirement for clinical audit results to be part of GMC revalidation, which is likely to begin in 2002, will reinforce 100% participation.

313) <u>DH view on mechanisms for ensuring the impact of clinical audit on service quality (2003)</u>

314) Individual doctors are required to share their clinical audit results with the Medical Director and the lead clinician responsible for clinical governance in their Trust . In turn, doctors from the Commission for Health Improvement (CHI) (now CQC) will have access to these data when they visit the Trust to review each NHS organisation's local standards and clinical governance processes. Where clinical audit identifies problems in service quality, and especially where these have wider implications for resource investment and service management, the NHS Trust and Health Authority, Chief Executives should also have access to the results.

315) NHS Trust s must show the impact of clinical audit in their annual clinical governance reports. These annual reports are public documents available to the local health community.

316) As one mechanism for ensuring participation in clinical audit, CHI's 4-year rolling programme of clinical governance reviews will pick up cases where this is not happening - publishing these within its reports and requiring an action plan to be agreed with the relevant NHS through performance management of clinical governance to identify and act on cases of poor uptake in national confidential enquiries.

317) Other possible mechanisms could form part of standard processes for performance management of the NHS or, alternatively, could be agreed through the Royal College s' own mechanisms.

318) In 1998. Department of Health. *"First class service"* there was an expectation that all clinicians should be involved in a national audit. It was at this time that the Department of Health proposed the establishment of a national audit into in-hospital children's deaths. There were delays in process as a pilot study was funded followed by transfer of identified funds to NICE and later transfer the responsibility for the development of this

process to the existing Department of Health funded confidential Inquiry into still births and deaths in infancy CESDI one of the earliest national audits already in existence. This focused on deaths in the perinatal period and up to one year but under the newly setup arrangements as a result of the negotiation starting in 1999, the Confidential Inquiry Into Maternal And Child Health was set up and later supported by the need to enquire into deaths which possibly related to abuse/neglect.

319) Most clinicians would be involved to a greater or lesser extent in the Confidential Inquiry For Still Births And Deaths In Infancy CESDI , the majority of paediatricians were involved in returns to the British Paediatric Surveillance Unit which assembled information upon rare conditions and produced reports. Some specialist paediatricians in tertiary centres are involved in their audit processes of their associations. The paediatric intensive care audit network was set up by the Department of Health and followed shortly by the neonatal intensive care audit network. All paediatric intensive care units and/or neonatal units would be expected to return information and receive reports back from this process.

320) Surgeons and anaesthetists are involved in CEPOD.

321) **IN ANNEX D I INCLUDE A TABLE LISTING KEY DOCUMENTS WITH A CHRONOLOGY AND ANNOTATION SHOWING THE STAGES IN WHICH MEDICAL AUDIT HAS BEEN INTRODUCED INTO THE NHS WITH A PARTICULAR FOCUS ON CHILDREN AND THE 10 YR PERIOD FROM MID 1990s AND PROVIDES SOME OTHER DOCUMENTS ON STANDARDS FOR CHILDREN'S SERVICES .**

322) DEVELOPMENT OF GUIDELINES

323) "Clinical guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances. "

324) ***(Institute of medicine. Guidelines for clinical practice: from development to use. Washington DC. National Academic press 1992.)***

325) The development of guidelines and the next step the transformation of these into protocols for daily use has been an evolving process.

326) In order for clinical audit to consider such matters other than structure such as records-quality of completion etc, it is necessary for some form of standard to be adopted by which a clinical topic management may be judged. Thus the presence of guidelines or protocols within the unit is an important component of clinical audit.

327) Their use was very variable in the early 1990s and 1980s. Although some national bodies were producing or developing guidelines, it is not possible for clinical units to await their delivery because clinical work continues and with an increasing focus on evidence-based medicine in the 1990s, it was often necessary for units to develop their own not least because the number being produced nationally was addressing only a small subset of the clinical problems presenting daily to clinicians.

328) By the mid-1990s most hospitals in United Kingdom had some form of guidance that they gave in written form the junior doctors, including resuscitation protocols.

329) Some of the documentation referred to in my report indicates where and when these guidelines were being produced in the 1990s. For an example, in the Department of Health funded project which I led in the BPA / RCPCH on an appropriateness of paediatric admission audit tool, it became evident that there was no nationally agreed guidance for admission to hospital. (In the event over some 12 years or so using Delphi processes it was not possible to reach consensus among clinicians on criteria to be used for judging an admission appropriate).

330) It also became evident that although guidelines were available upon the management of identified diagnosis, there were very few relating to the presentation of a child with an undiagnosed condition. From our studies we identified that the commonest presenting problems in acute general paediatrics were breathing difficulty, feverish illness, diarrhoea and vomiting and a fit and these presenting problems represented 80% of paediatric inpatient and accident and emergency attendance and were replicated in general practice. Consequently a process was set up funded by charity to develop guidelines using a Delphi consensus process and systematic evidence review. Guidelines on the management of diarrhoea and vomiting and on breathing difficulty were produced by the group based in Nottingham. Because of limitation of resource and time it was not possible to develop a guideline on feverish illness. In my role in the Department of Health England I was able to identify this as a topic to be taken through the process for NICE -one of the

first topics dealing with a presenting problem rather than an identified condition. This chronology is presented here on some guidelines relevant to paediatric practice here to indicate the state of evolution in the 1990s.

Topic	***Date process started***	***Date published***	***Source***
Appropriateness of Paediatric Admission Protocol	1992		Not possible to gain consensus DH project
Advanced Paediatric Life Support manual First Edition		1993	
Advanced Paediatric Life Support manual 2nd Edition		1997	
Diarrhoea & vomiting	1996	2001	Nottingham Paediatric A&E group (funded part RCPCH mainly Charity)
Breathing Difficulty	1996	2009	Nottingham Paediatric A&E group
Seizure	1996	2003	Nottingham Paediatric A&E group
Asthma inhalers	1998	2002	NICE
Growth Hormone	1998	2002	NICE
Inquiry into Childhood Deaths	1999	2006	CEMACH via DH
Feverish Child	2001	2007	NICE
Head Injury	~2000	2002	NICE
PICAuditNetwork	2001	2002	DH handed to CQC
Neonatal Audit National		2003	DH handed to CQC
Epilepsy	~2000	2004	NICE

Topic	***Date process started***	***Date published***	***Source***
Urinary tract Infection in children	2001	2007	NICE
Evidence-based guideline for the Management of decreased Conscious level	~2002	2006	It is noteworthy that the syndrome of inappropriate ADH secretion is mentioned once only in passing. Hyponatraemia receives attention [note 1]
Diarrhoea and vomiting		2009	NICE Which defines hyponatraemia as an electrolyte disturbance in which the plasma sodium concentration is less than 135mmol/l. But refers to studies in which the definition has been variously < 132 or < 130mmol/l

331) Guideline Development The RCPCH and other R Colleges have produced guidance on Clinical Guidelines over the years. One recent document is embedded herewith

RC_Standards06.pdf

332)

333) Note [1] ; Bowker R, Stephenson TJ,Baumer JH. Evidence-based guideline for the management of decreased conscious level *Arch Dis Child Educ Pract Ed 2006;91:ep115–ep122.*

a. *"plasma sodium to ensure the cause of prolonged convulsion is not secondary to hyponatraemia…"*

b. *"Hyponatraemia is a recognised cause of prolonged convulsions in children although there are no studies to determine the incidence. There are no randomised controlled trials of treatment for hyponatraemia in the context of a child convulsing. There is one case series of treating hypernatraemic seizures with 3% saline with beneficial results. The Delphi panel agreed that in the case of severe hyponatraemia hypertonic saline should be infused".*

334) The process of drawing up protocols for use in day-to-day practice at the point of clinical care delivery has been undertaken by many different children's units. The process used by them, the content of their guidelines and the extent to which they are based upon personal opinion or evidence is very variable and remains so.

335) One of the problems in relation to common as opposed to rare conditions is that there is an inverse relationship between the amount of research available on rare disorders compared with common ones. Consequently when drawing up guidelines for daily use, clinicians may use their personal opinion and refer to reviews or textbooks in doing so. The development of more structured guidance as examples by the process used by NICE is firstly very time-consuming and expensive in resource and second it takes time. Furthermore it is necessary to revise such guidance from time to time and this in itself acts as a snowball effect. There are a number of guidelines on children's conditions which NICE has produced but it is not possible for them to cover anything like the field which relates to daily clinical practice. The Royal College of Paediatrics And Child Health set up a process by which it approves to a greater or lesser extent guidelines which have been submitted by clinicians to it for approval and then provides a dissemination process for them. Individual clinical units may then choose to adopt these guidelines for their protocol development.

336) RCPCH The College 's Clinical Effectiveness Programme began in 1996 as part of the Research Division. It is overseen by the Quality of Practice Committee (QPC), which acts as the College 's 'guardian' for paediatric practice. Its first output was in 2005. The programme aims to promote evidence-based practice amongst paediatricians through: the development of evidence based guidelines; the appraisal and endorsement of

evidence based clinical guidelines; the dissemination of child health resources relating to evidence based practice; supporting the implementation and audit of guidelines.

337) Other sources are reviews published such as from the Cochrane and HTA. I refer to a number of these in my supplement on child health knowledge sources.

338) Ideally guidelines or protocols put in place in a unit should have references. In the absence of good evidence it has been necessary to grade consensus statements as a form of evidence. The development of consensus takes place through a variety of means including Delphi process using two or three rounds of circulation of guidelines to determine the degree to which people involved agree. This itself is a time and resource consuming process and thus is limited in the extent to which it contributes.

339) Clinicians in any day meet presentations of a many different disorders and individual children's characteristics vary and may not fit the guidance (for example presence of co-morbidities) which means that clinicians need to adapt any guidance to the particular predicament they face.

340) In doing this clinicians wish firstly do no harm, strive to do some good and to maximize the good and minimize risk of harm. They rely on their experience and knowledge but also on assessment of factors present in the individual faced. Decisions made are only partly influenced by evidence based medicine. Some are sceptical about EBM approach because what is available may not relate to an individual predicament.

341) There is a polarity between evidence based medicine approach and what might be termed "clinical pragmatism". In the latter doctors are using what has been learnt during training, continuing professional development, clinical meetings, peer discussions, reviews of individual patients or clustered reviews of patients such as audit and experiential learning gained over time. However there is increasing and questioning approach being adopted by all professionals to check that what they know or have learnt fits in to current state of knowledge (and also opinion) and thus seek an external resource to do so. When there has been an absence of good evidence one step has been to rely on consensus which at least provides a reassurance that what is undertaken is at least not outwith what a reasonable body of equivalent clinicians would do. However cautions must be expressed about this-for example in the 1970s the majority of paediatricians would have suggested prone lying position for babies with good hypotheses advanced to support this. Yet evidence later emerged countering this advice leading to the *Back To Sleep* campaign which reduced the number of sudden infant deaths.

342) It is common for a time lag between god evidence being available and issue of guidelines and then their implementation in practice. The Hyponatraemia problem provides an illustration of this time base.

Year	***Item***
26 September 2001	Dr Miriam McCarthy Senior Medical Officer Department of Health SSPS convenes the first meeting of the hyponatraemia working group
25 March 2002	Guidance on the prevention of Hyponatraemia published by DHSSPS(NI)
November 2003	Statement published by RCPCH and Royal College Anaesthetists "possibility of water overload with severe hyponatraemia developing after the infusion of 4% dextrose/0.18% saline"
28 March 2007	Reducing the risk of **hyponatraemia** when administering intravenous infusions to children. Alert no. 22. London : National Safety Patient Agency,

343) Other examples of evolution of guideline development and change in advice based on emerging evidence

344) 1] Steroids in Acute upper airway obstruction / Croup in Children : an example of the influence of systematic review on the introduction of a therapy for a common condition. (References are available if requested)

345) Late 1980s rather advised against.

346) Early 1990s used in more severe cases and those intubated

347) Mid 1990s recognition of the value that may be obtained from the use of inhaled and also high dosage systemic steroid.

348) Late 1990s consensus that should be used in moderate and severe hospitalised cases and in many milder hospitalised cases.

349) Early 2000's most paediatric units using steroid either orally or by inhalation in all moderate and severe cases and many milder cases

350) Middle 2000's almost all paediatric units using in most hospitalised cases and increasing use in general practice and accident and emergency departments.

351) ***<u>BELOW FROM EVIDENCE BASED HEALTHCARE Muir Gray 1997</u>***

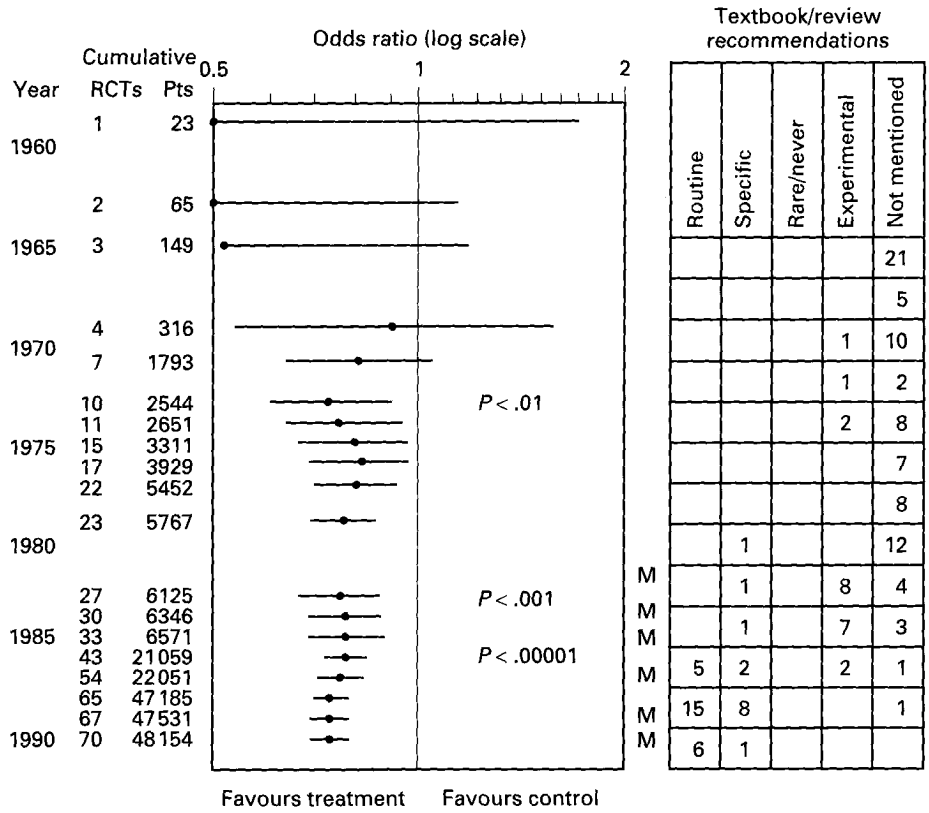

Fig. 2.4
Thrombolytic therapy: delay between evidence of effectiveness of the intervention appearing and its inclusion in textbooks (Source: Antman et al[1], JAMA, 8 July 1992, vol 268, p. 242. Copyright 1992, American Medical Association)

352)

2.1 THE EVOLUTION OF EVIDENCE-BASED HEALTHCARE (FIG. 2.1)

2.1.1 Doing things cheaper

During the 1970s, financial pressure began to mount in the NHS after two decades during which investment in healthcare had increased steadily. The OPEC crisis and its financial consequences initiated an era in which healthcare decision makers became more cost conscious. They were exhorted to increase efficiency, although this was actually manifest as an increase in productivity. Productivity is the relationship between inputs and outputs [e.g. number of bed days (therefore money necessary) per operation],

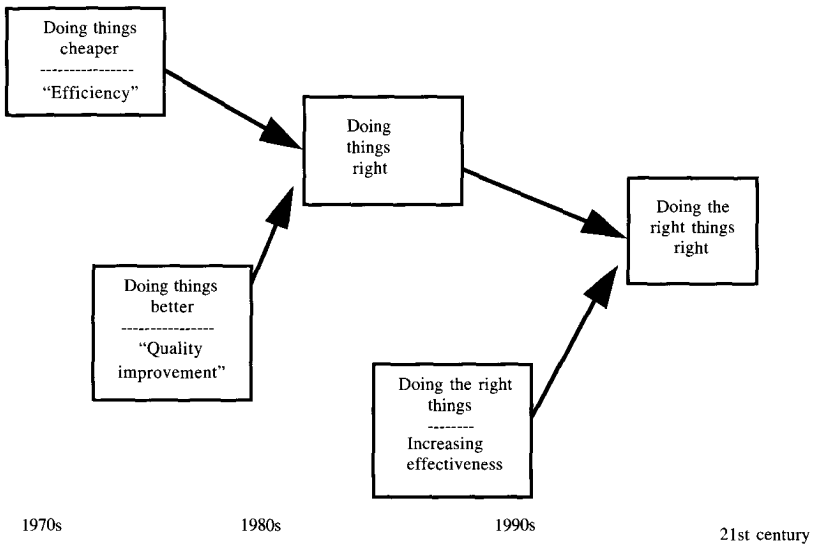

Fig. 2.1
The evolution of evidence-based healthcare

353) FROM HOW TO WRITE A GUIDELINE the "How to write a guideline. From start to finish. A handbook for healthcare professionals. Bowker R. Lakhanpaul M, Atkinson M, Armon A, MacFaul R, Stephenson T. Churchill Livingstone 2008

354) I include here a diagram from the book of which I was a co-author which points out that each Trust Chief Executive is ultimately responsible for the quality assurance of the Trust although individuals Trusts have developed their own governance plans. They are required to provide evidence to the Healthcare commission of local activities that promote the quality of care for patients they serve.

355) It is our view that individual professional groups including hospital directorates are responsible in their own clinical area for developing and implementing risk management strategies, clinical guidelines, protocols, personal development plans and appraisals and has a revalidation of group members..

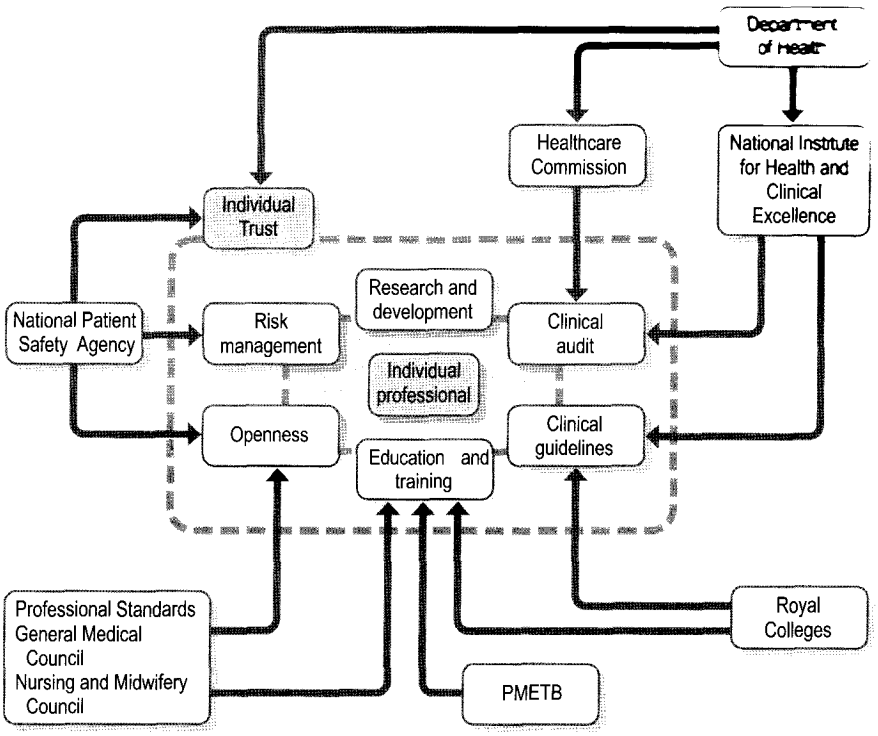

Figure 1.1 Some of the elements and relationships in clinical governance. PMETB, Postgraduate Medical Education and Training Board.

356)

357) G***EXTRACT FROM NHS NATIONAL SERVICE FRAMEWORK FOR CHILDREN 2003***

358) Chapter 4: Hospital Standard Part Two Quality and Safety of Care Provided

359) Standard

a. Children and young people should receive appropriate high quality, evidence-based hospital care, developed through clinical governance and delivered by staff who have the right set of skills.

360) Interventions

361) Clinical governance systems with a focus on children

362) 4.1 Clinical governance is an inherent part of the way that services are planned and delivered, and therefore spans every part of the hospital standard. However, this section draws attention to those aspects that require a particular and separate response for children, within a Trust 's overall clinical governance framework.

363) 4.2 Clinical governance systems do not always explicitly recognise children and young people as a separate and vulnerable client group. In addition to the particular issues of child protection, hospital procedures and systems themselves can jeopardise the safety and wellbeing of children. In view of this, it is essential that the care of children is given a specific focus within the clinical governance arrangements of a Trust and that this focus is reinforced by appointing a board level children's lead within the Trust . The clinical governance arrangements should be approached on a multi-disciplinary and, where appropriate, multi-agency basis to include social work staff and other professionals (including those employed by a local authority or a voluntary organisation). These arrangements should be clearly identified within the Clinical Governance Development Plan, and an action plan for implementation of any additional clinical governance arrangements for children should be developed as part of this process. This would include producing an annual report to the Board on children's services in the hospital.

364) 4.3 There should be a reliable system in place to ensure that prior records are available whenever, and wherever, children are seen and assessed. It may be necessary to investigate prior attendance at other hospitals, particularly where there are child protection concerns. Records should be contemporaneous, clear, accurate and comprehensive, attributable to, and signed by, a health care professional and countersigned by the responsible consultant where appropriate. *The Victoria Climbié Inquiry (8)* emphasises the importance of this requirement in safeguarding children and makes various recommendations around it, including the following:

a. When concerns about the deliberate harm of a child have been raised, doctors must ensure that

ii. comprehensive and contemporaneous notes are made of these concerns. If doctors are unable to make their own notes, they must be clear about what it is they wish to have recorded on their behalf;[8]

a. When a child is admitted to hospital and deliberate harm is suspected, the doctor or nurse admitting the child must inquire about previous admissions to hospital. In the event of a positive response, information concerning the previous admissions must be obtained from the other hospitals. The consultant in charge of the case must review this information when making decisions about the child's future care and management. Hospital chief executives must introduce systems to ensure compliance with this recommendation.[9]

b. The record should also specify which hospital consultant is responsible for the child's care. Staff assessing children should know who to contact in social services at any time, in the event of having concerns about whether or not a child may have suffered significant harm.

365) 4.4 New or experimental treatments should only be offered by, or under the guidance of, a specialist team following a comprehensive clinical governance appraisal of the treatment.

366) Safety of treatment and care

367) 4.5 Hospital Trust s' health and safety policies should be robust and explicitly cover children and young people. They should be subject to regular audit to ensure that they are being met.

368) 4.6 Serious events and near misses will need to be thoroughly investigated and reported to the National Patient Safety Agency, in line with national requirements. Reporting should include stratification by age group and highlight particular issues regarding children. Significant events in delivering services to children and young people should also be reported to the Trust board, discussed regularly, and used as a learning opportunity in a non-threatening, multi-disciplinary setting (including administrative staff). The Trust should be able to demonstrate how learning has occurred from the monitoring of such events and how improvements in care have resulted from this learning. A risk register of actual and potential risks in the processes of care for children and young people across the Trust should be developed. Risks to children will need to be managed and

addressed explicitly, as an integral part of the overall clinical governance arrangements.

369) 4.7 At every location within the hospital where care is provided to children there must be staff trained in life support. Basic life support is generally sufficient in most areas of the hospital. However, in clinical areas such as A&E, on inpatient medical and surgical wards, and in surgical recovery areas and day case facilities, this should be to advanced life support levels: for example, to Advanced Paediatric Life Support (APLS) or Paediatric Advanced Life Support (PALS) standard, or equivalent; and equipment and appropriate drugs should be available to resuscitate and stabilise a collapsed child. In these settings, ideally, there should be at least one person trained in APLS or PALS, or equivalent, on a shift at any time. As a minimum, an A&E receiving children should have someone trained in paediatric airways management and venous access on duty at all times. It is vital that paediatric life support trained staff receive regular updates and regular scenario practice.

370) 4.8 Requirements for the transfer and safe retrieval of a child to a specialist centre in an emergency include staff with expertise in stabilisation prior to retrieval by a paediatric intensive care team. These arrangements should include a lead clinician and multi-disciplinary group that reviews the local arrangements for procedures, equipment, training and communication. Details are given in *Paediatric Intensive Care (39)* and *High Dependency Care for Children (40)*.

371) Safeguarding children's welfare

372) 4.9 Promoting children's wellbeing and safeguarding them from harm is the responsibility of all staff working with children, parents, significant carers, or other adults who may pose a threat to children. Guidance already exists that is not always implemented correctly (*Working Together to Safeguard Children*

a. *(18); Framework for the Assessment of Children in Need and their Families (20); Safeguarding Children in whom Illness is Fabricated or Induced (19), Safeguarding Children Involved in Prostitution (41)*).

b. In response to *The Victoria Climbié Inquiry (8)*, the government will issue a summary of the guidance, particularly aimed at practitioners responsible for safeguarding children.

373) Evidence-based practice

374) 4.15 Evidence-based protocols and guidelines can be instrumental in achieving high standards of care for children and young people, particularly if their development involves the whole multi-disciplinary team and patient representatives. Protocols should be in place across the hospital, particularly in A&E and surgical

services, as well as on children's wards, and should cover: resuscitation; pain management and sedation; fluid management; antibiotic regimes; and management of the conditions with which children most commonly present to hospital – feverish illness, breathing difficulty, diarrhoea and vomiting, seizure, abdominal pain, rash, and head injury. NICE appraisals and guidelines that apply to children should be available to all clinical staff, and translated into local protocols. Protocol and guideline development needs to be linked into a programme of staff education and training. The protocols themselves should be monitored, reviewed and subject to version control.

375) 4.16 Multi-disciplinary child-specific clinical audit should be undertaken in all specialties in which children are treated. Trust s should also participate in, and respond to the findings of, the Confidential Inquiry into Maternal and Child Health *(44)* and the Confidential Inquiry into Perioperative Deaths *(45)*.

a. In addition, Improvement, Expansion and Reform sets out a requirement that all appropriate units should participate in national comparative audits for paediatric cardiac surgery which applies to surgical and transcatheter treatment of congenital heart disease.[10] The UK Central Cardiac Audit Database is the appropriate register for this purpose.

376) 4.17 Information and the information management and technology infrastructure needed to deliver and support clinical audit and decision-making, including electronic prescribing and decision support systems suitable for paediatrics, should be incorporated as it is developed and becomes available.

377) AND :

378) SURGERY

379) 4.34 Every hospital Trust that receives children must have a policy for securing both emergency and non-urgent surgical services for children. This applies to all areas of surgery – including general surgery, orthopaedics, ear, nose and throat surgery, plastics, burns, and neurosurgery – and can be delivered in several different ways. It is equally vital for every acute hospital to secure and maintain a rota that includes emergency skills for resuscitation of very sick children, covering children's services, A&E and elsewhere. Over time, all surgeons operating on children should also have basic training in resuscitation and life support, and emergency care in their designated branch of service.

380) 4.35 It is desirable that all surgeons and anaesthetists expected to provide care to children should undergo child-specific training, education (including communication skills) and assessment as required by the relevant Specialist Advisory Committee. They should, in addition, undertake continuing professional development in the care of children.

381) 4.36 Children who have had surgery and have to stay in hospital overnight need nursing, anaesthetic and

a. medical aftercare provided by appropriately trained staff. These are most likely to be found on a site with in-patient general paediatrics. For single specialty hospitals, in the short term, special arrangements will be needed for the provision of paediatric cover. New split-site arrangements should be avoided. Where these already exist, and where feasible, they should be phased out in time.

382) 4.37 As the *Day Surgery: Operational Guide (51)* points out, day surgery is ideal for children, since overnight admission is often the most distressing part of visiting hospital for them. Day case surgery can be carried out to a safe standard on a site where there is no paediatric service, but only if staff are able to deliver paediatric life support, and if a neighbouring children's service takes formal responsibility for the children being managed there (see *Children's Surgery – A First Class Service (50)*. Registered children's nurses should be available to care for children in day surgery. Play specialists should be available and the environment should be child-friendly. Day surgery units must develop and implement a pain control policy that includes advice about pain management at home, and the provision of 'take home' analgesia where appropriate.

383) 4.38 Dedicated operating lists for children are the ideal, but in many specialties this is not practical or feasible. In these circumstances, children should be put to the start of the list with appropriately trained staff in the reception, anaesthetic room, theatre and recovery areas. Policies and protocols specific to the needs of children are required on issues such as preoperative starving.

384) 4.39 Children who need surgery also need a range of supporting services outside the theatres. They need paediatric nursing, radiology, pathology, physiotherapy, occupational therapy, dieticians and pharmacists, and the necessary paediatric equipment. They also need staff to have a full understanding of what it means to be cared for in an appropriate child- and family-friendly environment. In outpatient clinics where children are seen side-by-side with adults, there needs to be some geographical separation, for example, through partitioning waiting areas.

385) TERTIARY SERVICES

386) 4.40 Children's services should have robust arrangements for timely access to tertiary care when needed, both for emergency transfers to a specialised (regional) centre, for instance, for paediatric intensive care or surgery, and for planned referrals, for example, to cardiology, neurology, or renal care, for assessment. These arrangements need to cover:

a. Conditions that are so serious or rare that diagnosis and all treatment will be considered specialised. These have been listed and defined for Regional Specialised Commissioning *(52)*.

b. Severe or intractable cases of otherwise common conditions.

c. Relatively straightforward procedures, but in children with other serious underlying problems, or those that need repeating because they were not effective when first performed.

d. Simple procedures, but in neonates and very young patients who need specialised support services, such as anaesthetics, or neonatal intensive care.

387) 4.41 Many children have complex disorders that cross specialty boundaries. They need access to a whole range of services, such as genetics, audiology, ophthalmology; specialist nurses, physiotherapists, speech and language therapists, imaging, dietetics, and pharmacy services; specialist laboratory services; radiologists and pathologists familiar with paediatric disorders and procedures; mental health liaison services; and social workers. These staff need to collaborate closely to ensure that children and their families are receiving consistent and co-ordinated support, and the NHS locally will need to design services to achieve this.4.42 Ideally, children should only need to visit the tertiary centre for complex assessment and investigations

a. or specialised treatment. Otherwise tertiary care can be delivered locally through outreach services operating within a clinical network, provided that the network itself is adequately commissioned, funded and staffed, and that there are clear systems for information sharing, clinical governance, accountability and staff development. This requires tertiary centres, working with local services, and with the support of commissioners, actively to remodel the way their services are provided across the care pathway.

b. The recommendations of the *Paediatric and Congenital Cardiac Services Review (53)* (published for consultation in November 2002); www.doh.gov.uk/childcardiac are based on the same strong principles of collaboration and outreach. They aim to achieve a clear and logical network of services, with the child and family at the centre.

388) 4.43 Each tertiary service will need to work together with a lead local clinician on behalf of local children's services and primary care to set up referral protocols and arrangements for local service provision. The ideal specialised service:

a. Diagnoses and manages unusual problems, delivers unusual or complex treatments, and where

ii. these are new or experimental, does so in the context of a clinical trial.

    a. Has sufficient staff to provide safe, round-the-clock cover for acutely ill children, and at the same time undertake a range of outreach services, including peripheral clinics, nursing support services, telephone support lines, teaching programmes and exchanges for staff.

    b. Provides supportive nursing, therapy, and help in the community to meet physical, mental

iii. health and social care needs – at home and at school. Most aspects of care for even the most complex disorders can be carried out away from hospital and only occasionally does the child need repeat visits or admission to the specialised centre.

    a. Admits as inpatients only those children for whom local hospital admission is not a safe or acceptable option, for instance, because surgical intervention might be needed urgently, or complex treatments, investigations or specialised nursing care are required.

    b. Keeps duration of admission to a safe minimum.

    c. Involves local medical, nursing, therapy, mental health and other staff, such as social workers.

iv. Establishes clinical networks, including named network leads and lead clinicians, agrees evidence-based referral guidelines, treatment and shared care protocols, and develops records of shared care and information sharing protocols, recognising the requirements of Caldicott *(54)* and the Data Protection Act *(55)*.

    a. Has reliable arrangements for paediatric intensive care retrieval and other emergency transfers.

    b. Provides a liaison service both for families and for local clinicians, including support to enable the child to be treated locally for minor illnesses or an injury.

    c. Audits quality and outcomes of the care provided across the local and specialised service, and gives parents confidence in the whole package of care.

    d. Plans transition into adult care for long term conditions.

    e. Develops and maintains close links with relevant patient and parent organisations and ensures

v. that families know how to contact them.

389) **Quality and safety of care provided – key points for early consideration**

390) The hospital's clinical governance arrangements will need to reflect the additional arrangements required to meet the explicit needs in all areas of the hospital where children and young people are treated. A board level children's lead should be appointed within every Trust to oversee these arrangements. The Trust board should consider regularly the hospital's performance in relation to child protection and ensure close liaison with the ACPC. The named doctor and nurse should have the training, time and support to carry out this role which should be reflected in their job plan.

391) Hospital policies in a number of areas, such as infection control, health and safety, medicines and the use of equipment, should be reviewed or put in place to ensure that they reflect the particular concerns involved in caring for children. Hospitals will wish to consider the arrangements for disabled children and young people, for those with mental health problems where improved liaison may be needed, and for those requiring in-patient elective and emergency surgery. Every Trust dealing with young people should have a policy on transition to adult services.

392) In line with Improvement, Expansion and Reform, all appropriate units should participate in national comparative clinical audits for paediatric cardiac surgery, which applies to surgical and transcatheter treatment of congenital heart disease.[14]

393) Hospitals will need to look at the clinical network arrangements for all paediatric services, starting with neonatal intensive care as funding comes on stream, and the funded, proposed improvements to paediatric intensive care. Mechanisms will be needed to plan, support and sustain tertiary services for children with specialised conditions.

394) Workforce development and training

395) Hospitals will need to assess the needs of their staff for child-specific education and training in:

a. Child development, parents as partners in care, resuscitation, use of medicines, child protection, news breaking, pain management and care of parents after the death of their child.

b. The technical skills and competencies required to provide treatment and care for children.

c. Assessing and meeting the needs of disabled children in hospital.

d. Operating on, and anaesthetising children.

e. Robust infection control for children.

f. Awareness of promoting children's mental health in

paediatric settings and of managing

ii. acute mental health crises.

396) FROM THE ORGANISATION WITH MEMORY, THE FOLLOWING REPORTING SYSTEMS IN THE NHS WERE LISTED

397) Confidential Inquiry Suicides And Homicide Events

398) Confidential Inquiry maternal deaths

399) Confidential Inquiry perioperative deaths

400) Confidential Inquiry still births and deaths in infancy

401) Complaints data

402) NHS litigation authority claims data

403) Regional serious untoward and incident reporting systems

404) Medical devices agency

405) Medicines control agency.

406) We believe that, if the NHS is successfully to modernise its approach to learning from failure, there are four key areas that must be addressed. In summary, the NHS needs to develop:

407) unified mechanisms for reporting and analysis when things go wrong;

408) a more open culture, in which errors or service failures can be reported and discussed;

409) mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;

410) a much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

a. the NHS Litigation Authority should work with the medical defence
b. organisations to ensure that maximum learning is drawn from analyses of the extensive information available on clinical negligence litigation. This learning should in turn be fed into the new overall analysis and dissemination proposed at R.4.;
c. patient and carer input, which can be of tremendous value in learning from
d. adverse events, should be actively sought at each stage of the process. Systematic efforts should be made to involve patients and carers in work to implement the recommendations of this report.

411) ADVERSE AND CRITICAL EVENT INVESTIGATION –children

412) There is considerable current attention to patient safety now. In this section my main focus has been on the period 1996-2005.

413) A Key report is *An Organisation With A Memory* Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer Stationery Office 2000

414) but for a *current* overview

415) **Review of patient safety for children and young people NPSA 2010**

416) And a useful review is on Department of Health England (attached as Annex C)

417) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4936867

418) Which opens :

a. *4.9 There are no universally accepted criteria for identifying the occurrences or outcomes of health care that should constitute a basis for recording or reporting poor quality. Neither does the NHS have a single comprehensive system of gathering data to enable service failure to be recognised, but information is available from different sources. Some are specifically set up to monitor adverse events, whilst others are designed to gather more general health information.*

419) In the mid 1990s

420) The children receiving care in hospital, most hospitals in the mid-1990s had a process in place for reporting serious adverse events and logging them within the organisation. In some regions a regional adverse events process was in place. For children receiving surgical care and anaesthesia a well-defined process was in place- CEPOD from late 1980s

421) The use of adverse event reporting processes still remains very variable. Some are reported but not investigated in detail. Further, there was often no specific definition of what constituted an adverse event. Unexpected or unexplained death would be investigated. For deaths in infancy under the age of 12 months, there was a national reporting system through regions which had developed from regional reporting systems, it was funded and supported by the Department of Health: Confidential Inquiry Into Still Birth And Death In Infancy CESDI . Beyond the newborn period, the main focus was on death which had occurred at home to consider all factors which may have led to the outcome. Hospital deaths formed but a small subset examined in detail. As a result of the Department of Health initiative from around 1999, the confidential Inquiry into maternal and child health (CEMACH) was set up based on CESDI and extended enquiries into all deaths in children. It has reported for the first time in 2008. At the same time because of deaths occurring in children from abuse and neglect, a more structured process has been

put in place for the examination of all factors which may contribute a child's death and this process is in hand now over the country following recommendations of joint working party of the Royal Colleges of Pathologists and Paediatrics And Child Health chaired by Baroness Kennedy. Sudden unexpected death in infancy-a multiagency protocol for care and investigation. 2004.

422) Where hospital and regional reporting systems were in place in the mid-1990s and even in the late 1990s and early 2000, it was difficult-in my experience-to obtain feedback. For example, in my own trust it was not possible to obtain age stratified drug or medication errors. From a paediatrician this is clearly a major drawback because we were not able to define the child incidents from the system and yet it was known that these were particularly common in children.

423) The National Patient Safety Agency set up a reporting system. However feedback of information and patterns of adverse events in the early 2000 was rudimentary and did not exist in the mid-1990s.

424) *It was however possible in the early 2000 to obtain data from the Australian and New Zealand reporting system. I provide some of this data in the annex from their report* Principle Incident Types by Paediatric Age Group Report for NPSA (UK) 2002 (note this report is not generally available). ***Data source:*** **All available general AIMS incident reports from Australia and New Zealand involving subjects aged from birth to 19 years.** ***Results*****: 4900 incident reports were retrieved for paediatric age groups (Birth to 19 years). Tables of All Incident Types, plus individual tables for each Principal Incident Type (with subtypes) are provided**

425) From this I selected those events which related to medication or device and this is shown in the table below.

All=N	***Age***	***Medication***	***Device***	***Of all***
1719	0-1yr	26.4%	10.4%	35%
633	2-5yr	22.3%	7.7%	13%
702	6-12yr	26.5%	8.3%	14%
1841	13-19yr	17.5%	4.2%	38%
4895				

426) And in the Annex I provide a larger Table.

427) IN UK

428) Some adverse events in children come to light through death and Coroner s inquests. Others through patient complaint and the need to investigate this at hospital organisation level or through litigation. Some came to light and prominence through the reporting process by hospitals of patients of practitioners to the General Medical Council.

429) The professional defence societies Medical Defence Union, Medical Practitioners Society and others did from time to time published cameo examples of risky events and adverse outcome. A few of these related to children particularly in the diagnosis of meningitis.

430) In the late 1990s in my own experience from the Department of Health perspective, it was not possible to get feedback on age-specific types of adverse events from the National Health Service Litigation Authority. It is only recently that individuals have published from the data sources held by that body relating to children.

431) An analysis of successful litigation claims in children in England . ***Raine J Arch Dis Child*** **2011;96:838–840. Extracts**

a. *The Freedom of Information department of the NHSLA was contacted in order to obtain a record of claims involving children in the last 5 years. Details of cases reported to the NHSLA from 1 April 2005 to 31 March 2010 together with the status of the claim on 30 September 2010 were received. The specialty involved was paediatrics in 124 (64%) cases, neonatology in 40 (21%) cases, pediatric surgery including the different surgical sub-specialties in 29 (15%) cases and anaesthetics in two (1%) cases.*

b. *Many hospitals now have a clinical risk department. However, feedback and the dissemination of lessons from errors is often limited. Regrettably, the same*

error may have to recur several times before effective action is taken.[5] Despite the encouragement of the former Chief Medical Officer, Professor Sir Liam Donaldson, for doctors and hospitals to learn from their mistakes, this is only happening to a limited extent. Furthermore, the more open culture in which errors and service failures can be reported and discussed has still not materialised.

c. *Publications such as Why Children Die[6] from the Centre for Maternal and Child Enquiries provide useful educational information. There is also a surgical online site, CORESS,[7] sponsored by the Association of Surgeons of Great Britain and Ireland, which enables the confidential reporting of surgical errors with the aim of improving patient safety and of providing an important educational resource. A similar paediatric site would be very useful.*

d. *It is regrettable that institutions tasked to deal with errors often do not classify their data in a manner that is conducive to its analysis. [2] Doing so would help to produce a useful national picture of common errors in paediatrics and other medical specialties*.

432) Raine J *Arch Dis Child* August 2011 Vol 96 No 8. Extracts

a. *The three Medical Defence Organisations (MDOs) in the UK all publish journals every few months or annual reports, which contain case reports from the different specialities. These case reports are based on real claims. They are anonymised to preserve confidentiality and are primarily published as an educational tool to try and diminish the risk of the errors recurring. The MDOs deal primarily with general practitioner and private practice litigation, whereas the NHS litigation authority deals with NHS Hospital Trusts. However, the MDOs also provide medico legal support to hospital doctors, most of whom are members of a MDO. Though there may well be a degree of selection bias in the cases that the MDOs choose to publish, they nevertheless provide a very useful educational resource. By contacting the MDOs and accessing the internet, the paediatric case reports from the Medical Protection Society from 2001 to 2010, from the Medical and Dental Defence Union of Scotland from 2004 to 2010 and from the annual reports of the Medical Defence Union from 2007 to 2009 were obtained. There were 52 paediatric cases in these publications during this time. Nine of the cases resulted in the claim being successfully defended, in it being dropped by the claimant or in no claim being made. In one case, the claim was dropped following an apology. The remaining 42 cases in which there were acknowledged errors and in which litigation was successful were examined.*

433) OTHER EXAMPLES OF ADVERSE EVENT MANAGEMENT IN CHILDREN

434) One of the most long standing structured reviews of adverse events has been the Perinatal Mortality and Morbidity reviews held (by custom and practice) which regularly reviewed newborn deaths and poor outcomes from the mid-1960s (or earlier). These

meetings were attended by obstetric and paediatric medical staff, midwives, neonatal nurses and often GPs. Most paediatricians will have been familiar with this process.

435) In order to provide a context for the Hyponatraemia Inquiry , I will give some other examples of some adverse event investigations.

436) Deaths from intrathecal vincristine in children

437) Deaths from cardiac tamponade in newborn babies

438) Investigation of adverse events at Pinderfields.

439) NPSA patient safety for children

440) Deaths from intrathecal vincristine

441) One notorious adverse event was the inappropriate injection of vincristine into the spinal cord fluid of children who required the cytotoxic drug for the treatment of leukaemia or other tumours. Vincristine should not be injected into the spinal-cord fluid rather it should have been given intravenously. The same syringe and medication ampoule would be used and intravenous as well as intrathecal. The connection between the syringe containing the medication and the needle which is inserted in the spine is the same. If vincristine was injected into the spinal space, the child would die. Several of these events occurred and consideration was given on how to change the system and also whether or not equipment should be changed so that it would not be possible attach a syringe to lumbar spine needle. The latter was discounted because it is necessary from time to time to inject drugs into the spinal space for example for spinal anaesthesia. The system when examined nearly always implicated delegation inappropriately to an inexperienced junior doctor. There was insufficient knowledge on the part of that doctor about the inappropriate use of the drug into the spine, he may not been familiar with the patient having been delegated the task in an off-the-cuff fashion. There were insufficient processes in place to ensure that the ampoule of the drug had sufficient warning upon it and it was for the doctor and the nurse in the treatment room to make up this fluid. The solution eventually put in place was to ensure that no one should give this drug intrathecally who was not aware of the risk, the pharmacy would label and make up the drug and deliver it with sufficient warning to the Ward. This was regarded as enough to prevent the injection using a syringe containing the fluid into the spinal-cord. The adoption of the safety processes was slow and has been described in detail by two reports.

a. **1] Republished paper: The quest to eliminate intrathecal vincristine errors: a 40-year journey Douglas J Noble, Liam J Donaldson Postgrad Med J 2011;87:71e74.**

b. Extracts

c. In the Nottingham case, a skilled non-medical accident investigator was called in. He catalogued over 40 weaknesses in the hospital system that

led to the fatal error. (32. Toft B. External inquiry into the adverse incident that occurred at Queen's Medical Centre, Nottingham, 4th January 2001. London: UK Department of Health, 2001.)

d. *This report remains the most authoritative investigation of such an incident anywhere in the world and reveals this source of catastrophic error as a classic multifactorial system failure. This validated the prevailing scientific theory of patient safety that medical error is largely due to system failure.*

e. *The UK also analysed the real stories of harm caused to patients and their families; this included the stories of the first and last patients to die due to intrathecal vincristine in the UK, Lee Duggins in 1976 and Wayne Jowett in 2001.[34] A similar approach was adopted by the WHO.*

f. *However, despite this renewed focus on the 'system error,, the promotion of a 'no blame, culture and the galvanising of patient champions, deaths continued, and individual doctors faced consequences. Following the death of Wayne Jowett, the supervising doctor was suspended and charged with manslaughter.[36 37] This was not the first time legal action had been taken against doctors. Two doctors had been charged with manslaughter in 1991,[38] their actions described as: 'momentary, but untypical recklessness., An appeal in 1993 failed*

g. *Important references in this report :*

h. *Learning how to Learn. Compliance with patient safety alerts in the NHS. On the state of public health: annual report of the chief medical officer. UK Department of Health, 2004.*

i. The Prevention of Intrathecal Medication Errors A report to the Chief Medical Officer 2001 Professor Kent Woods Department of Health

j. Recommendations are made for an immediate action plan, implemented by national guidance and reinforced by clinical governance. Key elements are:

442) formal designation within each Trust of medical staff competent to give intrathecal chemotherapy;

443) steps to ensure that intrathecal and intravenous cytotoxic drug treatments are given at different times, by different people and in different clinical locations.

444) It is recommended that there should be urgent assessment of the feasibility and safety of dispensing Vinca drugs either in an infusion bag or in a non-Luer syringe allowing intravenous administration only. This would add a level of design safety to the measures set out above.

445) **Deaths from cardiac tamponade in newborn babies .** In 2000 a number of instances of deaths of babies receiving neonatal intensive care came to light through the process of perinatal mortality reviews and publications. These resulted from cardiac tamponade -a condition in which fluid accumulates in the pericardial sac which surrounds the heart impeding the heartbeat. The fluid accumulated because of irritation of the pericardium resulting from placement of long line feeding catheters well into the right side of the heart through veins in the arm by which medication and nutrition liquid was given. Manufacturers had intended that placement of these catheters was such that the end of the catheter would lie in a vein outside the heart and the position of the tip should be checked either by having a radiopaque line or injecting an opaque material into the line. It was not intended that the line should lie in the right ventricle of the heart. However standard advisory handbooks of neonatal care at the time widely in use advocated placement in the right ventricle and thus by some practitioners this was intended and in others it occurred by adverse event. The Chief Medical Officer commissioned a report and following its recommendations the Medical Devices Agency published a Device Alert and also invited manufacturers to include recommendations in the literature which accompanies the venous catheters. The Department of Health drew the attention of the Royal College of Paediatrics and Child Health and the British Association of Perinatal Medicine to the issue and requested that they bring its recommendations to the attention of the members. Guidance was given that this placement should be avoided and that the practice be changed. stopped. *Department of Health. Review of the deaths of 4 babies due to cardiac tamponade associated with the presence of central venous catheter. London. HMSO 2001.* And *Beardsall K et al. Pericardial effusion and cardiac tamponade as complications of neonatal long lines: are they really a problem? Archives Disease in Childhood. Fetal Neonatal edition. 2003 ;88:F292-295.* which reported a survey which they initiated to as many consultants in neonatal care as possible identified from a national database.

446) Investigation of adverse events at hospital level.

447) Most hospitals have now set up in a structured process of investigation following reporting of adverse clinical events. These should include all unexpected deaths. Reviews should be through regular meetings or ad hoc meetings held shortly after a major event. Some hospitals-and I include my own here and provide an example of its output-have set up a system beyond that by reporting and logging *all* critical events (such as resuscitations or transfer to ICU) and incidents regardless of outcome. The approach taken here was to review to see whether even if things had been done well, they could have been done better and if not then to log this as well as the more negative connotation only of examining adverse events - because each provide a learning opportunity.

448) The extent to which these arrangements are in place has not, as far as I know , been subject of any survey for paediatrics in the 1990s although the CEPOD data on children is available as also are reports of adverse drug reaction and medication errors for the time through the CSM and MHRA.

449) *Comment:* It may be useful to determine the rate of change of implementation of the DHSSPS(NI) advice on hyopnatraemia in the province.

450) **KEY CURRENT PUBLICATIONS ARE** :

451) From US :Woods D et al Adverse events and preventable adverse events in children. Pediatrics 2005;115:155 Most adverse events related to birth and newborn care. It was also found that adolescent experienced high rates. Medication errors were the most studied aspect of patient safety problems in children's medical care but adverse events resulting from medication error were relatively infrequent. It was founded overall that events related to diagnosis which were preventable were greater in children than in adults except for the elderly. The study found adverse event rates to be 1% and preventable adverse event rate to be 0.6 % of hospitalised children.

452) The NPSA has a data base on children's adverse events now and a method for investigating adverse events has been developed for use in UK http://www.institute.nhs.uk/safer_care/paediatric_safer_care/the_paediatric_trigger_tool.html

453) NHS Institute for Innovation and Improvement. Dr Peter Lachman (from Great Ormond Street) has taken a lead in this area.

454) The NPSA publication Review of patient safety for children and young people NPSA National reporting and learning service. June 2009 - extracts

455) In the period April 2007 to March 2008, there were 910,089 incidents reported to the NPSA over a one-year period October 2007 to September 2008. 2% were found to relate to the care of newborns at 5% to the care of children

456) The majority of patient safety incidents were reported to have resulted in no harm or low harm to the child.

457) Medication errors with the most common reported incident 17%, followed by treatment procedure 13 % and patient accident 11%.

458) Calculations involving decimal points medication were considered a factor in the occurrence of tenfold dosing errors within children's and newborn environment.

459) Slips, trips and falls made over half of reported accidents.

460) The report contains numbers and types of events logged in middle to late 2000s

461) The Healthcare commission review of services to children in hospital in 2006 found only 24% of nurses and 7-9% of surgeons and anaesthetists had received any type of communication training relating to children.

a. *"Children with disabilities and complex needs, and their families, in particular expressed concern that they were often not listened to by healthcare professionals about a change or deterioration in their child's condition. They also felt that some healthcare staff did not understand how to communicate with non--verbal children"*

462) The document then lists a number of steps being taken currently to address child patient safety. It has a useful reference list. (Document attached in Library of Documents submitted with my report)

463) **THE ROYAL HOSPITALS ANNUAL HEALTH AND SAFETY REPORTS**.

464) From 1995-1996. The main focus here appears to be on accidental injury either to patients or staff with the majority being reported on staff. This was also the case in the subsequent reports until the report of April 1999 to March 2000 when it reports "this was a year of change during which health and safety was fully integrated into a risk management system that includes clinical risk management."

465) But from this time on the reports still mainly focus on detailed analysis of injuries to staff and patients from such as slips and falls, problems associated with sharps injuries, with diagnostic or therapeutic equipment etc.

466) In the report April 2000 to 31 March 2001 adverse clinical incidents made up a proportion of 20% of adverse incident reports. "Defined as an adverse health care event or omission arising through clinical care and causing physical or psychological injury to patient".

467) As far as I was able to see this however there has been no detailed breakdown of these events compared with the detailed breakdown in relation to staff injuries. Despite the report April 2001-March 2002, pointing out it was the second full year reporting both clinical and nonclinical adverse events and that Clinical incidents made up a significant number of the events (1532 of the total of 4158).

468) Again however I was unable to see any detailed breakdown of these clinical events. These comments also applied to the 2002-2003 report 2003/4, and in the 2004/5 report there is a breakdown of adverse incidents over the period 2000 to 2005 showing what appears to be an increase in clinical incidents.

469) In the 2005/2006 the report "the reporting of clinical incidents has increased markedly this year and is the main contributory factor in the overall rise in incidents reported from 2004-2005."

470) This pattern of report has continued until the latest 2010/2011. There is no separate analysis given of the clinical incidents.

471) Comment : Is there a separate clinical events log or report with comment on outcomes for the patient and actions taken?

APPENDIX C Interim guideline on confidentiality and medical audit

Conference of Medical Royal Colleges and their Faculties in the United Kingdom 1993

Medical audit is primarily an educational activity and will be professionally led (HC(91)2, para 3). It is designed to improve the standards of patient care. As part of the implementation of the National Health Service and Community Care Act 1990 all doctors working in the NHS are required to undertake medical audit and,: while recognising the need for confidentiality, it is required that managers and health authorities are provided with regular reports (HC(91)2, para 4). Potential conflicts of interest, therefore, arise in relation to the data required for medical audit and the needs of patients and clinicians for confidentiality and the need of management for information.

The Data Protection Act 1984 already allows patient access to data held on computers and word processors. The Access to Health Records Act 1990 will allow such access to manual records by the end of 1991. It is possible that medical audit data will be considered part of the medical record. Such records are likely to be discoverable at law in relation to litigation conducted on behalf of patients_ interests and also may be used by employing authorities for disciplinary purposes. The colleges have been advised that the only exception to discovery in relation to litigation would be that the disclosure of records was not in the public interest. Such protection seems to have been implied for large regional or national audits (for example, the confidential enquiries into maternal and perioperative deaths), but has never been tested in the courts. The audit records of individual clinicians and units are almost certainly discoverable. No record of an audit meeting should contain any information that could allow identification of patients or clinicians or other hospital staff.

There are particular problems relating to issues of medical audit and confidentiality for patients, clinicians, and management which need separate consideration:

Patients-The confidentiality of all personal health information has been recently emphasised (NHS/90) (GEN/22). Usually patient consent is implicit, or explicit consent is obtained before passing on such information to other health professionals. This will not generally apply to medical audit. The necessity to anonymise patient data related to audit meetings is, therefore, emphasised. Only aggregated data or general conclusions should be passed on to management or to health authorities, to ensure that individual patients cannot be identified (HC(91)2, para 6e). However, the Audit Commission has rights of access to such information as it thinks necessary for audit without consent of patients or clinicians.

Clinicians-To achieve the goals of improved patient care and professional education, open and frank discussion during peer review or medical audit meetings is essential. The likelihood of discoverability of the records of such

meetings poses a difficult problem for clinicians. All records of audit meetings, written or computerised, must be anonymised. There is no need to retain working protocols or proformas used for recording data from patient records as they duplicate information already available in the primary medical record. Serious problems relating to patient care identified by medical audit should be dealt with within the established professional procedures.

Management -The primary educational aims of medical audit in improving the overall standard of patient care rather than attempting to identify _bad apples_ should be emphasised. Management needs to ensure that adequate medical audit procedures are in place, involving all doctors, and that the activity is both efficient and effective. It is the responsibility of local managers to ensure that adequate resources are available to support the agreed audit programme, together with the associated educational and training programmes. Support staff and appropriate information systems will be necessary in all units (HC(91)2, para 14). The requirements of confidentiality for both patients and clinicians mean that regular reports of audit activities to management must be anonymised. The reports should cover the general areas of activity audited, the overall conclusions and recommendations made, and plans for action or procedural changes, the necessity for which has been revealed by the audit (HC(91)2, para 8). There should also be a record of when a review of the results of the changes should be made and the proposed methods of review. These reports will normally be submitted to management through the medical audit committee.

These interim guidelines have been endorsed by the Chief Medical Officer of the Department of Health. Conference is grateful to Drs Peter Beck and Anthony Hopkins for their help in preparing this guidance.

472) ANNOTATED BIBLIOGRAPHY AND CHRONOLOGY OF RELEVANT GUIDANCE

Document	***Points***
Medical audit-a first report: What, Why And How Royal College of Physicians 1989 (extracts)	"today the rapid advances in medical technology and the growing opportunities for medical intervention are accompanied by public questioning of the appropriateness and adequacy of medical care. Providers of resources-both public and private-look for higher efficiency and greater productivity at optimum quality. This has led to the need for a more systematic evaluation of the quality and effectiveness of doctors work. This evaluation can now be regarded as an important professional obligation." ……. And Adequate audit should measure quality as well as quantity of care." …. In paragraph 1.5 "Britain is party to an agreement that by 1990 all European WHO member states should have built effective mechanisms for ensuring quality of patient care within their healthcare systems." In chapter 2 defines medical audit is primarily a mechanism for assessing and improving the quality of patient care; enhancing medical education by promoting discussion between colleagues about practice; Identifying ways of improving the efficiency of clinical care;…. Three main categories of clinical care can be measured and are interrelated-structure, process and outcome." There is reference to the audit cycle of setting standards, observing practice and compare a standard, implementing change, setting standards. Actions which should follow audit being publication and dissemination, application of resources, remedial action if mistakes are repeatedly made by individuals or groups. Confidential records of audit meetings, including attendance should be kept. Written record of the discussion may be important evidence for both funding and accrediting authorities. "Confidentiality is a prime consideration. The identity of patients discussed should never be

Document	***Points***
	revealed or capable of being traced, both to protect the anonymity of individual patients, and to avoid any danger of documents used in audit being employed in legal proceedings." Refers to existing schemes of audit as confidential enquiries into maternal deaths began in 1952; The National quality control scheme for pathology laboratories began in 1969.;The confidential Inquiry into perioperative deaths (CEPOD) . paragraph 4.9 reports "contacted the tutors appointed by the Royal College of Physicians in every health district in England and Wales to enquire whether any form of audit clinical review existed in their respective hospitals. Apart from neonatal death surveys the replies indicated a low level of audit activity and considerable variation in its quality. Many districts had no perceptible audit process; although most have regular "grand rounds" these cannot be considered as an audit activity" it refers to 65% of all health districts have used some form of nursing systematic review quantitatively scored enabling comparisons between wards or individuals underlying serial assessments indicate process."
The Quality Of Medical Care. Report of the Standing Medical Advisory Committee Department of Health 1990. HMSO.	This stated that the aims of medical audit include :An educational exercise of peer review, an audit of services provided , identification of poor practice, a search for good practice which can be made widely and easily available at the least cost. The report states that the College tutors in each district will have an important role. Teams appointed by the joint committee on high medical training visit hospitals to inspect junior training posts. JCHMT. Enquiries and Ward will be made by the visiting fellows. They do not regard grand rounds as a sufficient form of audit for a number of reasons including bias towards unusual medical conditions and often lack of attention to administrative and communication matters.
CEPOD The Confidential Inquiry	Was one of the first major structured national audits in the late 1980s. The first (or possibly the

Document	***Points***
Into Perioperative Deaths, located in the Royal College of Surgeons 1989	second) report published in 1989 focused on children's surgery. (There is no electronic copy available).
Transfer of infants and children for surgery joint working group BPA and British Association of Paediatric Surgeons, Paediatric Anaesthetists and the Royal College of Surgeons And Physicians (Glasgow). 1993	Followed CEPOD report as advice on implementation of recommendations.
Perinatal Mortality meetings .late 1960s onwards	At a local level, one of the earliest developments in regular audit was the perinatal mortality meeting. In place in the late 60s and reviewed all deaths within a obstetric units at a local level and also major adverse outcomes such as birth asphyxia. These meetings were attended by the junior and senior obstetricians, midwives, paediatric staff and anaesthetic staff and often general practitioners. Minutes and reports were kept and implications of service shortcomings were addressed.
Confidential Inquiry Into Maternal Deaths	One of the earliest national audit processes.
How to audit children's services. MacFaul R Current Paediatrics 1991;1: 166-173	Introduced paediatric audit. In 1991 there was still debate about the issue medical clinical audit with the balance of argument being strongly to clinical being multi-professional. Medical audit mainly involve doctors, clinical audit nurses, professions Allied to medicine, information staff records to bolt on to be supported by managerial audit-clinicians, managers, accountants, information staff and quality assurance. It listed methods of audit and advised that audit may take place in medical audit meetings, or in unit meetings, all meetings of clinical directorates and will include both the assessment of clinicians activities and equally, evaluation and assessment by clinicians of the facilities provided for their practice by the Health Authority or "in the new era,

Document	***Points***
	by the provider units themselves" The practice of audit requires exercise of judgement, evaluation or measurement of a practice or service against standards which may already exist; or they can be set or developed at :National ,Regional or sub regional, District or departmental level. The paper reviewed a selection of national standards which were available at that time for paediatrics which could be used in audit processes. These were BPA documents on joint working party between faculty of ophthalmologists and BPA 1984 BPA Report of working party on the needs and care of adolescence July 1985 BPA working party on cystic fibrosis 1985 Report of the joint working party on liver transplantation in children BPA/British Association of Paediatric Surgeons 1986 BPA report of the working party on paediatric intensive care March 1987 Joint statement on children's attendances at accident and emergency departments. February 1988 together with the BAPS and Casualties Surgeons Association Neurophysiological services for children (with British Paediatric neurology Association and Association of British clinical neurologists January 1989. BPA the organisation of services for children with diabetes in the UK 1989 Reference was made to sources of standards for the provision of health services for children including NAWCH quality review, *Department of Health circular 1991 Welfare of Children and Young people in Hospital.*

Document	***Points***
	Medical Care The Newborn In England And Wales Royal College Of Physicians . Paediatric medical staffing for the 90s BPA Caring for children in the health services and hospital accommodation for children health building Note. On guidelines it recommended *"Departmental written guidelines, on common disorders, agreed between consultants in the Department proved most helpful in audit and have educational value for junior staff. It is then possible to audit whether patients are managed according to the locally agreed guidelines and if not to question why this was so and to seek remedies "which might include the rewriting of guidelines".* Reference was made to Guidelines available in 1991. Upper airway obstruction, investigation and treatment of urinary tract infections, guidelines for the management of convulsions with either emblaze Royal College of Physicians), asthma a consensus statement, cystic fibrosis, pyloric stenosis, actor meningitis, diabetes, epilepsy.
Welfare of children and young people in hospital. Department of Health HMSO 1991	the implementation of the government's reforms the NHS will enable districts to define explicitly and contract with provider units the standards they require for high-quality child health service and to monitor compliance with the standards. The guide is intended to assist districts in this task and providers in achieving these standards. Refers to Department of Health circular HC (91) which contains advice on medical audit of hospital and community health services. The document recommends the model of a children's department or a children's hospital. Also that a children's physician or surgeon participate in the general management and

Document	***Points***
	professional oversight of the Department. Emphasises the need for district and provide a hospitals to ensure the good practices are followed on seeking consent to the treatment of children. Considerable emphasis encased in this document to the quality and ease of communication with other health care professionals as well as with parents and children. Provides advice on management when a child dies. It contains a section on training of nursing, paramedical and medical specialists.
Report of a working party BPA Outcome Measures For Child Health 1992	Referred to a previous report in 1990 and rehearsed the evaluation of a health-care program by looking at structure, process and outcome. It recommended that outcome measurement is an essential part of service evaluation but should be the start not the end of Inquiry . Reference was made to the Griffiths management Inquiry 1983. It recommended the following outcome measurement is Birthweight specific neonatal mortality rates; Screening processes; Notification of measles and pertussis and immunisation cover. Management of insulin-dependent diabetes and asthma. Children on adult wards.
BPA *Paediatric medical audit 1992*	"Departmental written guidelines, agreed between consultants, are likely to be helpful in audit and in junior staff teaching, especially when they deal with a commonly encountered disorder.

Document	***Points***
	Their presence permits auditing whether patients are being managed according to locally agreed protocols and, if not, to question why this is so, and to seek remedies (which might include revising the guidelines". In some specialties (e.g. oncology) protocols have been agreed to management are less common disorders, so that a child is likely to receive similar treatment wherever he is admitted. Such practice assists in studies of outcome such as overall survival of children with cancer is and in the understanding of rare disorders. Departmental guidelines may differ between units but there is potential for agreement between those working in hospitals within the locality or region to allow comparison of outcomes or for mutual audit. Added on to the previous list in MacFaul 1991 are references to guidelines published on : neonatal respiratory distress syndrome, nephrotic syndrome, idiopathic thrombocytopenia purpura, head injuries, chronic diarrhoea, neonatal prolonged jaundice. It recommended examples for guidance in clinical practice as Paediatric vade mecum. Birmingham Children's Hospital. Jackie Insley. Edward Arnold publishers Manual of neonatal intensive care Roberton Hospital paediatrics Milner and Hull (from Nottingham) Emergency paediatrics JA black second edition London Butterworth. Relevant review articles appear in journals such as Archives of Disease in Childhood, Pediatrics J journal of paediatrics, Acta paediatrica, Current Paediatrics, Current Opinion In Paediatrics, Paediatric Clinics Of North America, Paediatrics In Review, Yearbook of Pediatrics.

Document	***Points***
	And on Guidelines: In the absence of national, regional specialty guidelines, departments may devise their own standards, based upon clinicians experience in research and from reviewing the available literature on the subject in question. It is advisable that practice in all units lies within current balance of opinion in the specialty, or if not, is made subject to the scrutiny of peers at scientific meetings or within the specialties literature. In this area there is an interface between audit and the application and conduct of clinical research. Guidelines also serve to promote debate with colleagues in other specialties. Having guidelines available should help clinical decision-making, even in a considered decision is to deviate from them. It is never mandatory to follow them to the letter, and they should be seen not as prescriptive but as aids to management. Ideally guideline should be based on review published scientific evidence of efficacy and should be devised by specialists and generalist working together. Preferably they should be published in medical journals and thereby be open to peer review. Each department from time to time and at least annually to publish a report of their audit activity and to share their results with colleagues in the same and other specialties. By such means collaborative audit projects can be arranged for standardisation of data collection and analysis which would be helpful in extending audit outside an individual unit. Paediatric audit is part of continuing medical education and postgraduate training for doctors. District medical audit committees would expect paediatricians to become involved. At intervals discussion should take place with senior management on the results from audit exercises; this is particularly cogent because issues will have been raised relevant service provision, resources and contractual obligations.
Hospital Medical Audit, Kings Fund	

Document	***Points***
1989	
Specialty Medical Audit-King's Fund Centre. Charles Shaw. 1992	In the wake of the 1989 *Working For Patients* White Paper many doctors, though pleasantly surprised by the offer of central funding, were at that stage concerned about the purpose of audit and who should it." "Many of the Colleges and national professional associations have issued advice on the organisation and practice of audit within their specialty." Notes RCP and BPA reports including the records audit checklist
1993 Medical audit a second report Royal College of Physicians of London	At the Council of the RCP December 1990 it was decided that visiting teams for audit should be the same as teams visiting hospitals the purpose of assessing the suitability of posts for postgraduate medical education. Before the second report was produced with views from regional advisers was sort and they reported that almost all hospitals undertake regular audit; there are a few exceptions and these were in major teaching hospitals rather than in isolated district general hospitals." Regional advisers report that the frequency of audit meetings varies between one half day a month being the average. The conference of medical Royal Colleges and their faculties in United Kingdom has recently recommended that 5% of the consultants time should be spent in relation to medical audit. More time only to be set aside for lead clinician in medical audit. Concluding paragraph 6.2 that the development of guidelines by individual hospitals is time-consuming and it would be better to have an expert group a can review the medical literature and set guidelines which are scientific validity rather than being based merely upon the consensus views of practising clinicians. The College research unit is undertaking this role. The discussions around this time extended to involvement in the patient experience. Paragraph 13.1. Audit activities and greatly increased in the last three years. Much of the activity remains based upon the review of case records but increasingly topical audits are being

Document	***Points***
	undertaken. The content and tidiness of clinical medical records has been considerably improved by the introduction of medical audit." Paragraphs 10.2 "since the passage of the National Health Service and community care act 1990, there has been a split between the purchasers of health care (the district health authority in general practice fundholders) and the provider unit. Provider units are now setting up their own medical audit committees. The first central funds being provided to support audit. The Department of Health has set up a clinical outcomes group chaired jointly by the CMO and CNO officer to integrate audit of the care of doctors and other healthcare professionals. **Paragraph 13.16. "New ideas about medical audit should not displace popular and effective older methods of case review. Post-mortems, clinical pathological conferences, death conferences, reviews of prescribing and so on are all well tried methods of reviewing care, and are also thought to have educational value."** In appendix G the RCP report lists projects undertaken by the research unit and by fellows and members of the College with the support of the research unit some relate to children ; International neonatal network to study the outcome of care for very low birthweight babies funded by the medical research Council. Development of audit measures and guidelines for good practice in the management of neonatal respiratory distress syndrome Department of Health funding; Transfer of children with chronic illness from paediatric and adult care. Funded through the College appeal fund Guidelines are good practice and audit measures in the management of childhood nephrotic syndrome. Funded by the Department of Health Pilot project for auditing paediatric asthma. Department of Health
1993 Medical audit a second report Royal College of Physicians of	This working group obtained advice from a professor of law University of London and the secretary of the joint coordinating committee of the medical defence organisations. A document on confidentiality in relation to medical audit was subsequently approved by the conference of

Document	***Points***
London	medical Royal Colleges and their faculties in United Kingdom. This is in appendix C of the report (which I attach)
1993 Children first-a study of hospital services. Audit commission	This advises that there should be a senior management focus the children's services in every hospital to ensure that the special needs of children and family are recognising all aspects of care. Written policies that make standard clear to all concerned are needed as our key indicators that are capable of being monitored. Its findings were that the outcomes of many treatments for which children are admitted to hospital and not routinely monitored. "There is a lack of clear guidance on when admission is appropriate and a lack of consideration of the alternatives." Recommends that health authorities that commission healthcare have an important role to play. This audit was carried out shortly after the Department of Health published its new guide on the welfare of children and young people in hospital 1991 with the recommendation that it should form the basis of health service contract provision of children's services. Paragraph 12 "although the principles which underlie health care for children are agreed by national bodies, there is a lack of awareness of them and their importance at local level, resulting in poor implementation in some hospitals." The audit carried out found considerable variations in the quality of management and provisioning over the country. England, the district health authorities became responsible for commissioning services in April 1991. Few DHAs have clear strategies for children's services and few have firm plans for developing a strategy.

Document	***Points***
	The lack of strategy included a lack of clarity on when Tertiary care is appropriate and lack of attention to the quality of services. It recommends that at the very least each hospital have a written policy for the care of sick children. Selecting a number of key indicators for monitoring. This included written guidelines on the management of conditions.
Report of an independent review of specialist services in London-children 1993	Recommended that hospitals which aim to provide Tertiary services should first aim to provide a full range of child health services for the local population. Recommends a paediatric neurosurgery should be based on a specialist centre providing comprehensive services for children, and provided by surgeons with special training in paediatric neurosurgery. Paediatric neurology has essential links in neuroradiology, neurophysiology and paediatric neuro anaesthesia. At least one third of children in intensive care units have neurological problems. The document also made recommendations respecting other Tertiary specialties including nephrology.
The Care of Sick Children review of the guidelines in the wake of the Allitt Inquiry **RCN 1994**	Mainly on service provision and staffing arguing for greater speed in staffing children's wards with children's trained nurses
Skill-Mix and staffing in Children's Wards and Departments **RCN 1999**	Paediatric Nurses forum RCN designed as a check list to be used in considering staffing paediatric areas. Includes advice on critical incident reporting, risk management amongst other guidance with a reference list
Future Confederation of paediatric services report of working party	Recommends consideration of rotating staff to larger companion units if there are small district general hospitals in a locality for geographical reasons. Small units should establish companion

Document	***Points***
BPA 1996	relationships with larger units. Clinicians and clinical directors involved should take the lead in regional reviews to identify potential training and service consortia. District paediatric tutors and regional advisers should quantify the experience advised in the general professional handbook. Makes recommendations about the support to consultants in terms of time for management, continuing medical education/CDP, audit.
Organisation with a memory DH 2000	In addition, there is evidence that some specific types of relatively infrequent but very serious adverse events happen time and again over a period of years. Inquiries and incident investigations determine that 'the lessons must be learned', but the evidence suggests that the NHS as a whole is not good at doing so. Still less is known about the situation in primary care, despite the fact that it accounts for the great majority of NHS patient contacts and can still experience service failures which have serious consequences for individual patients. Learning from adverse events. Prioritising action and dissemination Following the recommendations of confidential enquiries Using information systems to aggregate and disseminate findings NICE should explore options for enabling confidential enquiries to generate specific recommendations where there is a serious on-going threat to patients. Developing a review and reporting system to clinical governance using the commission for health improvement Using the NHS litigation authority resources to provide a stronger educational remit to work with professional bodies and the defence organisations to publicise high risk areas and risk reduction activities amongst managers and technicians

Document	*Points*
Principles for Best Practice in Clinical Audit a joint publication of NICE , commission for health improvement, Royal College of nursing and the University of Leicester. 2002.	."important that clinical governance should support a process of continuous quality improvement throughout the NHS. Clinical audit is at the heart of clinical governance." . It provides the mechanisms for reviewing the quality of everyday care provided to patients with common conditions like asthma or diabetes. . It builds on a long history of doctors, nurses and other healthcare professionals reviewing case notes and seeking ways to serve their patients better. . It addresses quality issues systematically and explicitly, providing reliable information. . It can confirm the quality of clinical services and highlight the need for improvement. Points out in introduction that in the past local and national clinical audits have failed to bring about change and refers to the Bristol Inquiry as an example of how clinical audit is necessary as a contribution to the maintenance of quality. The document defines clinical governance as a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating a quality environment in which excellence in clinical care will flourish. Department of Health. A first class service in the new NHS. HMSO London 1998.
RCPCH . Clinical Audit in Paediatrics and Child Health – Some Examples. London: Royal College of Paediatrics and Child Health, 1997.	Contents: over 30 clinical audits contributed by paediatricians working in both the acute and community sectors.
Children's Surgery: A First Class	from of the Paediatric Forum of the Royal College of Surgeons provides standards for the care

Document	***Points***
Service 2000	of children both in the National Health Service and independent sector
Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary **DH** **2001**	http://www.bristol-inquiry.org.uk/index.htm Includes : The contractual relationship between trusts and consultants should be redefined. The trust must provide the consultant with the time, space and the necessary tools to do the job. Consultants must accept that the time spent in the hospital and what they do in that time must be explicitly set out Other points re safety in detail and some extracted are set out in in the adverse events section of my report
DH internal note 2003	**DH has funded** through its audit programme (between 1992 and 1996) -before NICE took over this responsibility - the following national audits through the RCPCH (and its fore runner the BPA) – Diagnosis of urinary tract infections Management of nephrotic syndrome Note Management of idiopathic thrombocytopaenic purpura Note Audit of acute paediatric admissions. Development of instrument for assessment of appropriateness of paediatric admission.

Document	***Points***
	Screening for retinopathy of prematurity. **NICE was asked by DH to set up** the following audit :Parenteral (IV) nutrition in premature infants (sent to NPSA)and Investigation into all in hospital deaths in children (CEMACH)
DH Audits funded and contracted	Paediatric intensive care audit network. Neonatal audit project located RCPH (both to provide an audit framework for the implementation of the PICU and Neonatal reports)
RCPCH audit activities 2003 et seq	A national audit on diabetes is in development and the arrangements provided by the health quality improvement programme. Including (relevant to the Inquiry an audit process for children presenting with reduced level of consciousness)
RCN Clinical Practice Guidelines-recognition and assessment of acute pain in children-an audit protocol.2002.	
Good Practice in Handover RCPCH 2005	
HQUIP	The Healthcare Quality Improvement Partnership (HQIP) was established in April 2008 to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. It is led by a consortium of the Academy of Medical Royal College s, the Royal College of Nursing and National Voices (formerly the Long-term Conditions Alliance). The 2007 White Paper ' Trust , Assurance and Safety' called for the revitalisation of clinical audit in order to deliver its full potential. The subsequent strategy embodied in the Next Stage Review,

Document	***Points***
	'High Quality Care For All', in 2008, stressed more broadly that quality and quality improvement, including clinical audit, was the centre of improving the NHS, and launched a stream of activity to drive quality, including work to improve clinical audit.
Review of patient safety for children and young people **NPSA 2010**	The first major report from NPSA re children. Many useful references and data. Recommendations are made for further actions.

Year	***Item***
26 September 2001	Dr Miriam McCarthy Senior Medical Officer Department of Health SSPS convenes the first meeting of the hyponatraemia working group
25 March 2002	Guidance on the prevention of Hyponatraemia published by DHSSPS(NI)
November 2003	Statement published by RCPCH and Royal College Anaesthetists "possibility of water overload with severe hyponatraemia developing after the infusion of 4% dextrose/0.18% saline"
2006	Bowker R, Stephenson TJ,Baumer JH. Evidence-based guideline for the management of decreased conscious level *Arch Dis Child Educ Pract Ed 2006;91:ep115–ep122.*
28 March 2007	Reducing the risk of **hyponatraemia** when administering intravenous infusions to children. Alert no. 22. London : National Safety Patient Agency,
2011	Care of Children and Young People Presenting to Hospital with a decreased conscious level Multi site Audit 2010-2011 report

473)

ANNEX D data from the ANZ reporting system for children adverse events. This included such events as failure to feed a child or giving the wrong meal as well as falls and other accidental injury during hospital stay. (The full report can be available on request from me)

Principal Incident Type	Age0-1	%	Age2-5	%	Age6-12	%	Age13-19	%	Totals	%
Ungrouped	239	13.903	83	13.112	107	15.242	302	16.404	731	14.934
Behaviour	18	1.047	6	.948	39	5.556	458	24.878	521	10.644
Blood	19	1.105	3	.474	5	.712	6	.326	33	.674
Documentation	86	5.003	37	5.845	31	4.416	44	2.390	198	4.045
Fall	227	13.205	153	24.171	110	15.670	141	7.659	631	12.891
Injury	263	15.300	71	11.216	90	12.821	135	7.333	559	11.420
Medication	453	26.353	141	22.275	186	26.496	322	17.490	1102	22.513
Nutrition	88	5.119	13	2.054	10	1.425	17	.923	128	2.615
Other incident	112	6.515	55	8.689	47	6.695	269	14.612	483	9.867
Safety	36	2.094	22	3.476	19	2.707	70	3.802	147	3.003
Device	178	10.355	49	7.741	58	8.262	77	4.183	362	7.395
Total	**1719**		**633**		**702**		**1841**		**4895**	**100.000**

Principal Incident Type	Totals	%
Ungrouped	731	14.934
Behaviour	521	10.644
Blood	33	.674
Documentation	198	4.045
Fall	631	12.891
Injury	559	11.420
Medication	1102	22.513
Nutrition	128	2.615
Other incident	483	9.867
Safety	147	3.003
Device	362	7.395
Total	**4895**	**100.000**

ANNEX E CRITICAL INCIDENT REVIEW: PINDERFIELDS PAEDIATRIC DEPARTMENT

Numbers

1] Over 54 months starting in May 1997, all resuscitations on children have been included in a multi disciplinary review to learn lessons from each event. These have included medical and nursing staff from A&E, and when appropriate, anaesthetists as well as the paediatric team including the senior pharmacist.

Transfers

2] Of the 86 resuscitations concerned, 66 resulted in a transfer for intensive or neuro or trauma surgery. Of the 51 PIC transfers 8 had to go out of region (18%) 3 by own paediatric team. Other transfers were by in house anaesthetic team for neurosurgery care.

Disorders

3] The disorders are listed below.

Disorder	*Comment*
Meningococcal disease	*Only one past 12 m to November 2001*
Bronchiolitis	*Especially in babies under 4 m age*
Acute encephalopathy	
Metabolic	
Respiratory	*Croup 3*
Other	*One cardiac, Burns 5*
Sepsis	
Head injury	*3 extradurals subdural 1 and in 2, presented over 48 hr after injury*
Trauma	

Surgical *Post operative problems*

Blocked vp shunt

Expected death

Post op cleft palate

Asthma

Results

4] Themes from review and actions since taken

Theme	*N*	*Action*
Equipment	*10*	*Resus bag assembled, new ventilators and oxygen points put in. Need for small transfer bag for neurosurgery or trauma identified & outstanding*
Crash call & standby from A&E	*6*	*Reinforce that use crash paediatric bleep for standby and for collapse. Still on going incidents despite this action*
Staff communication usually medical : juniors not contacting senior paed. Also several with radiology for urgent CT	*6*	*Meetings and agreeing protocols reminding when not adhered to.*
Drug availability	*3*	*None for 12 m*
Surgical teams to involve paed with sick infants and major trauma	*3*	*Improving communication and involvement*
Resus facilities and training A ward	*4*	*In hand*
Change protocols for clinical management	*8*	*Note protocols were updated in 1998 yet need revision/ review*

R MacFaul

10 Dec 2001

ANNEX

Current NHS mechanisms for learning from adverse events

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4936867

ANNEX F USES OF KNOWLEDGE IN CHILD HEALTH – Supplement to report by Dr R MacFaul of April 2012 for The Inquiry into Hyponatraemia-related Deaths (Northern Ireland)

(based on a review conducted by R MacFaul in 2008 for the Director Of Knowledge Services of NHS England)

These include :

Teaching

Training

Education-of doctors, nurses and professionals allied to medicine

CPD and re accreditation

Decision support for diagnosis, management and treatment

Guideline production, updating dissemination and implementation (use at the point of care)

Personal updating on ad hoc basis.

Communication

Health care users

Commissioners use e.g. health intelligence and interpretation of evidence and statistics

Reference and to promote high standards of practice

NHS PROVIDED CHILD HEALTH KNOWLEDGE

National Library for Health (NLH)

NICE guidelines

CRD

Map of Medicine

National Patient Safety agency

Department of Health e.g. immunisation information or guidance on consent or safeguarding

NHS Institute for Improvement and Innovation

Data from DH or ONS statistical sources

NHS e- learning site (limited materials on children mainly safeguarding)

Part NHS PROVISION OF CHILD HEALTH KNOWLEDGE e.g.

RCPCH
Specialist societies such as B Paediatric Neurology Association or B Society Paediatric Endocrinology and others which may have associated journals
RCAnaes
Royal College of Surgeons
College of Optometrists provides guidance on professional conduct examining the younger child
RCPsychiatrists
RCGP
RCRadiologists
GMC

INDEPENDENT PROVISION OF CHILD HEALTH KNOWLEDGE

Journals such as

Archives Disease in Childhood (J of the RCPCH)

BMJ

BMJ Clinical Evidence

Evidence Based Medicine Journal

Other (many) specialist journals which include relevant child health knowledge and have a peer review process. Many require subscriptions.

Evidence Based Reviews

Bandolier,

Cochrane Library,

DARE,

HTA Database,

NHS EED

Annex d.doc

Guidance

CKS (incorporating Prodigy),

National Library of Guidelines,

NICE Guidance,

Protocols and Care Pathways

and selected International Guidelines

Specialist Libraries

Collections of the best available evidence for different communities of practice

Books, Journals and Healthcare Databases

AMED,

British Nursing Index,

CINAHL,

E-books,

EMBASE,

HMIC,

MEDLINE,

My Journals,

PsycINFO,

CENTRE FOR REVIEWS AND DISSEMINATION

The Centre for Reviews and Dissemination (CRD) is part of the National Institute for Health Research (NIHR) and is a department of the University of York. CRD, which was established in 1994, is one of the largest groups in the world engaged exclusively in evidence synthesis in the health field. The Centre comprises experienced health researchers, medical information specialists, health economists and a dissemination team.

CRD undertakes systematic reviews evaluating the research evidence on health and public health questions of national and international importance. The findings of CRD reviews are widely disseminated and have impacted on health care policy and practice, both in the UK and internationally.

CRD produces the DARE, NHS EED and HTA databases which are used extensively by health professionals, policy makers and researchers around the world.

CRD undertakes methods research and produce internationally accepted guidelines for undertaking systematic reviews.

JOURNALS

It is not known from any formal study which journals are most valued by the generality of health care professionals in regard to child health knowledge but for paediatric trainees and career doctors the journal of the RCPCH (Archives of Disease in Childhood) will be used by all.

TRIP – Turning Research into Practice –

This is an American database which identifies the following as lead paediatric journals

Journal of the American Academy of Child and Adolescent Psychiatry
Pediatrics
Pediatric Research
Journal of Pediatrics
Journal of Child and Adolescent Psychopharmacology
Pediatric Infectious Dsease Journal
Mental Retardation and Developmental disabilities Research Reviews
Developmental Medicine and Child Neurology
Archives of Disease in Childhood
Archives of Disease in Childhood. Fetal and Neonatal Edition
Journal of Pediatric Gastroenterology and Nutrition

Archives of Pediatrics & Adolescent Medicine
Pediatric Rheumatology

ARCHIVES OF DISEASE IN CHILDHOOD

This is a highly rated international journal which is the official journal of the RCPCH and co-owned by RCPCH and the BMJ.

For subscribers it has on line alerts and an on line advanced sight of forthcoming papers.

It includes original papers,(subject to peer reviews) and editorial control, some reviews (narrative) are commissioned and others submitted and it has a section every other month based on EBM called Archimedes (Editor Bob Phillips). It also has a supplement called Education and Practice edited by Drs Monica Lakhanpaul and Ian McConachie. This aims at providing papers to assist clinicians in continuing professional development and signposts to guidelines aiming at a full range and to provide quick updating on research rather than research itself. The editors create the priorities and select the topics and identify where guidelines are present. They identify topics and discuss controversies and conflicts and commissions articles on the basis of word-of-mouth knowledge of individuals. The best practice contributions are provided by selected authors. Contributions are peer reviewed by the editors who acknowledge there is some overlap with the Archimedes section of the Archives.

The Education and Practice supplement has the following structure

Best practice

Problem solving in clinical practice

Pharmacy update

Guideline review

Journal Watch

Archivists

Other

Some degree of distillation
Problem-solving by using a case
Produces reviews of guidelines done by Harry Baumer

The Archives regularly makes reference to JournalWatch – (see below).

JOURNALWATCH is signposted from Archives Disease in Childhood whose editor **Howard Bauchner is the Guideline Watch Editor**

http://pediatrics.jwatch.org/misc/about.dtl

COCHRANE

The Cochrane resource and its specialist Child Health journal is a valued source of EBM. The chief editors are supported by 7 other editors 2 from USA, 2 from Canada, one other from Netherlands and from Australia and one from UK.

Evidence-Based Child Health: A Cochrane Review Journal

PROFESSIONAL RESOURCES

RCPCH

The RC offers a range of knowledge services and management. It has a major educational role and sets standards for the profession including the content of the examinations for trainees and approves Continuous Professional Development (CPD) courses.

The annual scientific meeting provides a way for sharing and dissemination child health knowledge and each of the specialist groups is allied to the RCPCH. It also has a website which signposts to other sources as well as providing access to RCPCH produced materials.

The College's Clinical Effectiveness Programme began in 1996 as part of the Research Division. It is overseen by the Quality of Practice Committee (QPC), which acts as the College's 'guardian' for paediatric practice.

Reviews and comments on some guidelines
Commissions some systematic reviews
Signposts on the Royal College website a set of knowledge sources and thus has some extent, shortlisted these through some process of selection

The programme aims to promote evidence-based practice amongst paediatricians through:

The development of evidence based guidelines.
The appraisal and endorsement of evidence based clinical guidelines.
The dissemination of child health resources relating to evidence based practice.
Supporting the implementation and audit of guidelines.

The RCPCH journal Archives of Disease in Childhood has editorial freedom and thus its content is not influenced by RCPCH so that content of Archimedes and Education and Practice and reviews is not within RCPCH role and this was equally so for other BMJ publications child health outputs (EBMJ, Clinical Evidence, Learning etc).

RCPCH has reservations about its role in approving guidelines but sees that there is a potential significant role in the Royal College for the following

Transfer of knowledge into practice for example through support for audit and other means

Focusing on steering and signposting to knowledge sources (as it currently does see RC website content below) on which the Royal College places a value by a process

National guidelines relating to child health are signposted from RCPCH site

(see ANNEX)

Published clinical guidelines " This is not an exhaustive list and these guidelines have not been considered for endorsement with the College unless indicated".

The Education Courses and Programmes section site :

http://www.rcpch.ac.uk/Education/Education-Courses-and-Programmes

Education

Adolescent Health Project

CPD

Education Courses and Programmes

- **Child In Mind**
- **Court Skills in Child Protection**
- **Diploma in Paediatric Nutrition**
- **Paediatric Educators Programme**
- **Safeguarding Children**
- **Teaching Child Health in Palestine**

And signposts to educational courses without " approving " them :

e.g. Postgraduate Diploma in Paediatric Neurodisability (Distance Learning) - 2 year Course Sheffield University

and

Paediatric Epilepsy Training (PET) course Level 1 (Organised by the BPNA)

The education department is involved in

the examinations for Diploma in Child Health and MRCPH (and a Diploma in Child Nutrition)
Continuing professional development(CPD)
The College Spring annual meeting where there are scheduled research presentations and best practice educational presentations for trainees and established specialists
A collaboration which produces the publication *Paediatric Masterclass* a digital e-learning package for MRCPCH which is used by trainees and trainers
In educational projects resourced and commissioned from outside the College e.g. the Department of Health adolescent health, children safeguarding e-learning packages and the Child In Mind mental health training

A major constraint in the expanding these functions is time limitation of college members who provide their input on a voluntary basis

Specialist recertification is to be conducted by the Medical Royal Colleges in the United Kingdom on behalf of the GMC. The process will be left to individuals to justify what they have done over the preceding period to their annual appraisal and to plan and justify their future portfolio at their personal development plan. Delivery of high-quality knowledge resources to support individuals is thus of particular importance.

OTHER ROYAL COLLEGES

Royal College of Radiologists has produced guidelines which affect children . For example they have been asked by DH to develop guidelines on the investigation and treatment of intussusception in children. To do this a sub specialist group meeting involving both the central and peripheral paediatric radiology service to develop guidelines. Other Paediatric issues e.g. Non Accidental Injury are to be discussed in this a group. There is a British Society of Paediatric Radiologists http://www.bspr.org.uk/ which identifies key journals.

Pediatric Radiology

Archives of Disease in Childhood Online

Clinical Radiology

British Journal Of Radiology

Radiology

American Journal Of Radiology

Also RCR offers guidance on

MRI Imaging in paediatric Brain Tumours

NAI standard for skeletal surveys

Technical Standard - Neonatal Cranial Ultrasound Scans

Royal College of Anaesthetists

Children's issues are addressed in the RC Anaesthetists Professional standards committee and RCAn is preparing information leaflets for children (three for different age groups), and hope that these will be completed by the end of the year. They will be available via the website. The College website also has :

Guidelines for the Provision of Paediatric Anaesthetic Services: http://www.rcoa.ac.uk/docs/GPAS-Paeds.pdf

The Paediatric chapter of the Audit Recipe Book: http://www.rcoa.ac.uk/docs/ARB-section9.pdf

Child Protection and the Anaesthetist: http://www.rcoa.ac.uk/docs/child_protection1.pdf

These are all publicly available on the website and would have been highlighted in the news area or 'featured publications' on the homepage when first published. The first document has not been printed yet, as it will part of the the whole 'Guidelines' series (GPAS) which we hope to complete and get printed within a few months. The Audit Recipe Book and the Child protection document were both printed and circulated to Anaesthetic departments within the UK.

The College and the Association of Paediatric Anaesthetists liaise closely on matters to do with paediatric anaesthesia and a representative of the RCoA is on APA Council,.

Royal College of Surgeons

RCS have produced leaflets regarding operations on children for the parents / children.

The Royal College of Psychiatrists

RCPsych produces guidance on the use of video recording in child psychiatric practice. It has a section on child and adolescent mental health and is involved in NICE guidance development and other guideline work

The Royal College of Nursing (RCN)

Has a new focus on learning and improving and particularly on delivering knowledge resources into the hands of practitioners to support development of knowledge into practice. To do so it is aiming to provide "Short Best Practice " guidance across all areas of nursing although there is no particular systematic process for selection of children's topics.

The RCN has an infrastructure both for the production of best practice statements and the development of audits.

Nurses find it difficult to obtain time or funding to enable attendance at courses or conferences. This creates a significant potential market for distance and e-learning . The website is particularly used by paediatric nurses with special responsibilities for audit and governance.

OTHER NHS KNOWLEDGE RESOURCES

NHS e- learning

The NHS e- learning process will be used to develop supporting materials for the DH Child Health Promotion Programme announced in 2008. It has already produced materials on adolescent health but this does not yet appear on the website. Governance includes quality assurance and content acquisition.

The website includes material for the NSF for older people and diabetes NSF are but nothing there for the children's NSF which is concerning given the workforce training issues for children. There is some content on Safeguarding on the database and some on calculating doses which could have

considerable potential for improving safety of children's medicines administration . Some of the material signposted needs to be purchased.

NATIONAL AUDITS

The DH supported national audits for child health are Confidential Inquiry into Maternal and Child Health (CEMACH) , paediatric cardiac services , paediatric intensive care and one for neonatal care. A portal for dissemination of the findings of these and Health care Commission reviews is required.

There appears to be little specific child related output from National Patient Safety Agency in terms of frequency of adverse events and means of avoidance but some exist e.g. risks of errors in intrathecal chemo therapy

INDEPENDENT SITES

BMJ Clinical Evidence : This has around 28 systematic reviews on child health section._Search on child produces 162 topics covered. Evidence Plus is Subscription based Child health Section Advisor Mary Rudolf, UK and Virginia Moyer, USA

This site offers decision support including diagnosis, management, treatment (medication is for example BNFC). Search “Child “ led to 287 papers . A subscription based update service is a valued resource.

http://ebm.bmj.com/

BMJ Learning have just included a paediatric module on feverish child as a contracted project from NICE implementation team. However there was no coordination with the NICE development team as such although the included video material is provided by a member of the group.

LIBRARY OF DOCUMENTS SUPPLIED R MacFaul

Getting the right start: National Service Framework for Children Standard for Hospital Services DH 2003

Bowker R, Stephenson TJ,Baumer JH. Evidence-based guideline for the management of decreased conscious level Arch Dis Child Educ Pract Ed 2006;91:ep115–ep122.

Glasgow J Reye syndrome—insights on causation and prognosis Arch Dis Child 2001;85:351–353

Armon et al .Hyponatraemia and hypokalaemia during intravenous fluid administration Arch Dis Child 2008;93:285–287.

Marcovitch H When are paediatricians negligent? Arch Dis Child February 2011 Vol 96 No 2

Recognition and early management of Reye's syndrome Dezateaux et al Arch Dis Child 1986;61:647-651

THE BENEFITS OF CONSULTANT–DELIVERED CARE Academy Medical royal Colleges January 2012

Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary DH 2001

Why Children Die: A Pilot Study 2006 CEMACH

Consultant Job Description Checklist Advice for Regional Advisers RCPCH 2006

Consultants' Contract: Annual Appraisal For Consultants April 2001 DH

Review of Four Neonatal Deaths due to Cardiac Tamponade associated with the resence of a Central Venous Catheter Recommendations and Department of Health Response DH 2001

Good Practice in Handover RCPCH 2005

Review of patient safety for children and young people NPSA 2010

Woods D et al Adverse events and preventable adverse events in children. Pediatrics 2005;115:155

The recognition and assessment of pain in children RCN 2002

Skillmix and Staffing in Children's Wards and Departments RCN 1999

Appendix C Interim guidelines on confidentiality and medical audit Conference medical Royal Colleges and Faculties 200x(3) second rep

RCPCH "DeCon" Report on Care of Children and young people presenting to hospital with a decreased level of consciousness 2010-2011 report December 2011

RCPCH guidance on the role of the consultant paediatrician in providing acute care in the hospital May 2009

Sudden unexpected death in infancy A multi-agency protocol for care and investigation
The report of a working group convened by The Royal College of Pathologists and
The Royal College of Paediatrics and Child Health Baroness Kennedy 2004

An analysis of successful litigation claims in children in England . Raine J Arch Dis Child 2011;96:838–840 and Raine J Arch Dis Child August 2011 Vol 96 No 8.

Principles for Best Practice in Clinical Audit a joint publication of NICE , Commission For Health Improvement, Royal College of Nursing and the University of Leicester. 2002.

ANNEX C WORKLOAD AND STAFFING IN UK CHILDRENS HOSPITALS IN 1999 (DH /RCPCH units survey RBHSC had 6 middle grade doctors (? all on call)

Hospital	*Beds*	*Med Adm*	*Total O/P*	*Con Paeds*	*ConAcuteCall*	*MiddeGradeon*
John Radcliffe, Oxford	64	4000	12670	21	12	16
Leicester Royal Infirmary	153	10347	14687	20	10	20
Royal Victoria Infirmary	119	5930	9482	15	15	
Hammersmith	20	928	4842	0		
Leeds General Infirmary	64	2528	9712	0		
Addenbrooke's, Cambridge	62	2500	4364	0	6	12
St James University Hospital	100	8550	19369	16	15	13
Queen's Medical Centre, Nottingham	118	6670	31000	15	13	13
St Mary's Hospital Manchester	32	3571	6581	7	7	7
Jessop, Sheffield	0	430	0	5	4	5
St Bartholomew's Hospital	122	3308	12159	15	5	8
Chelsea & Westminster, London	62	0	0	12	11	12
Royal London	77	2109	7194	0		
St Thomas'	26	3092	8804	5	4	5

Annex d.doc

Hospital	***Beds***	***Med Adm***	***Total O/P***	***Con Paeds***	***ConAcuteCall***	***MiddeGradeon***
Hospital						
St George's, London	72	3084	6468	22	13	18
St Mary's Hospital (Paddington)	58	2474	5040	15	14	28
Royal Free Hospital, The (London)	49	2856	13839	10	7	14
University Hospital, Lewisham	84	2700	5938	7	5	6
University College, London	16	1149	4987	10	5	5
Guy's Hospital	100	5714	12124	28	4	5
Royal Liverpool Childrens Hospital	283	13445	30096	38	10	27
Birmingham Children's	224	11187	88106	40	6	10
Great Ormond Street	372	7547	41659	137	100	95
Royal Hospital for Sick Children, Edinburgh	155	6199	16990	15	6	6.5
Sheffield Children's	160	6006	13290	17	10	10
Royal Manchester Children's	157	5707	30885	0	8	18
Booth Hall Children's Hospital,	151	5359	15658	0	8	12

Annex d.doc

Hospital	***Beds***	***Med Adm***	***Total O/P***	***Con Paeds***	***ConAcuteCall***	***MiddeGradeon***
Manchester						
Royal Aberdeen Children's Hospital	109	3647	15094	7	6	5
Royal Hosp for Sick Children, Belfast	125	3500	9621	0		
Bristol Royal Hosp. for Sick Children	132	2870	6135	34	11	12
Royal Brompton Hospital, London	57	1777	8935	13	10	13
Southampton General	129	8287	15995	20		