Witness Statement Ref. No. 059/1

NAME OF CHILD: Raychel Ferguson

Name: John Gordon Jenkins

Title: Dr

Present position and institution:

Senior Lecturer in Child Health (Queens University Belfast)

and Consultant Paediatrician (Antrim Hospital)

Previous position and institution:
[As at the time of the child's death]
As above

Membership of Advisory Panels and Committees:
[Identify by date and title all of those between January 1995-December 2004]

Chief Medical Officer's Working Group on Acute Hyponatraemia in Children – started September 2001

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

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

Ref:	Date:	
012-023-132	30.01.03	Statement
012-030-153	05.02.03	Deposition at the Inquest into the death of Raychel Ferguson

Particular areas of interest
[Please attach additional sheets if more space is required]

1. **Specify the information that was provided to you to prepare your statements in relation to the death of Raychel Ferguson, to include:**
   (i) any discussions you had and with whom;
   (ii) all documents; and
   (iii) all non–documentary records (such as slides etc).

Photocopy of Altnagelvin Hospital casenotes
Photocopy of autopsy report
Photocopies of statements from doctors and nurses
Photocopy of report from Dr Sumner
Photocopy of Altnagelvin Hospital draft press statement
Photocopies of articles from medical literature by Arieff and Huskisson

2. **Explain fully your observation that solution 18 is rarely associated with any acute electrolyte disturbances as occurred in Raychel's case.**

This observation was based on my experience in Paediatrics since 1975 (and as a Consultant since 1982) that until June 2001 I had not been aware of any case in N Ireland where death or serious brain damage had occurred in association with the use of this solution, which was a standard solution used in Paediatric medical intravenous fluid therapy.

Dr Bob Taylor (Consultant Paediatric Intensivist) at the Royal Belfast Hospital for Sick Children informed the Committee on the Safety of Medicines of concerns in October 2001. He received an initial reply in November 2001, followed by a substantive reply dated 26 November 2001 from the Medicines Control Agency (copy enclosed for information). No amendment was made to the product information relating to this solution.

Dr Ted Sumner who was an expert witness called by the Coroner stated in an email to Dr McCarthy dated 17 December 2001 - "Postoperatively, fluid should be restricted for the first 24-48 hours because of inappropriate ADH associated with surgical stress. At GOS we give 2ml per kg of 4% (10% for newborns) dextrose/.18% saline for the first 24hours BUT replace colloid losses with the appropriate colloid and intestinal losses with an equal amount of normal saline with 10mmol potassium in 500ml."

The 2003 edition of the standard guidance 'Medicines for Children' makes reference to dilutional hyponatraemia, but also goes on to specify solution 18 as an example of a standard solution used to meet the maintenance fluid requirements of children (copy of relevant page also enclosed).

Particular areas of interest (Cont'd)

3. Give details of your knowledge of hyponatraemia in 2001 and why, in your view, the condition was not widely known about within the medical profession in Northern Ireland at that time.

The topic of fluid and electrolyte balance and their disorders is taught in general terms at medical school, and was of particular interest to me as I had an interest in physiology. After qualification I decided to specialise in Paediatrics and quickly realized that these are areas of vital importance in the care of infants and children, partly as a result of the smaller amounts of fluids involved and also the relative immaturity of the body's control mechanisms. As I specialised further in the areas of paediatric and neonatal intensive care I learnt more about the management of these conditions in ill children and particularly in premature infants where they have a critical role in managing the early days after preterm birth. After my appointment as a Consultant, as part of my duties as a general Paediatrician I was also responsible for the care of older children with disorders of fluid and electrolyte balance, and regularly took responsibility for supervising the prescribing of intravenous fluids for them. Although the management of children with surgical disorders (including postoperatively) was mainly dealt with by surgical and anaesthetic colleagues I would be asked to advise if particular difficulties arose with fluid or electrolyte balance.

In June 2001 I was first made aware informally within my own hospital that concerns had been raised about the appropriateness of the use of hypotonic solutions for hydration in patients with a low sodium. This issue had recently been highlighted by the death of a child in the Province. Colleagues in the Children's Hospital in Belfast had begun to consider the need for a change in the routine use of solution 18 (0.18% saline in Dextrose), particularly for older children. I was then asked to become a member of the Working Group set up by Dr Campbell which met first on 26 September 2001 under the Chairmanship of Dr Paul Darragh. When I first became aware of these concerns I was surprised, as this had not been my own experience. It was only in reviewing the literature following this that I became aware of the papers which had been published on this topic, mainly in specialist journals. I have no reason to believe that I was any different from other Paediatric colleagues in this respect, although it is certainly possible that some (perhaps particularly those working in Paediatric Anaesthesia or Intensive Care) may well have been aware of the papers published in the specialist literature for their areas of practice. One sector of the medical profession can become aware of risks associated with particular disease processes or procedures through their own specialist communication channels, but where this is not more widely disseminated to colleagues in other specialties who may provide care for patients at risk from the relevant condition. At that time there were no established national or local systems to ensure that such issues were brought to the attention of clinicians more widely.

Solution 18 has been routinely used in Paediatric medical practice for a very long time and is rarely associated with any acute electrolyte disturbances such as were seen in this tragic case. However, this is largely related to the range of conditions commonly seen by Paediatricians and cared for within the medical (as opposed to surgical) environment. By and large these are not associated with the syndrome of inappropriate secretion of antidiuretic hormone. It has become increasingly recognised in recent years that a regime utilising solution 18 may not provide the right balance of sodium and free water for some children with certain clinical conditions, and particularly where there is an increased likelihood of failure to excrete water. This would include situations of stress, pain and nausea, and may be particularly common in the post-operative period. It is the combination of excessive loss of sodium (for example in vomitus) with water retention (as a result of excessive secretion of antidiuretic hormone) which leads to a fall in the concentration of sodium in body fluids and increased risk of brain swelling (cerebral oedema).

This was well described in an editorial in the Journal "Paediatric Anaesthesia" in 1998 by Dr Arieff, but did not receive widespread publicity in journals likely to be read by most Paediatricians or Surgeons caring for children at that time. The potential dangers were highlighted to a wider clinical community in an article published in the British Medical Journal of 31 March 2001 by Halberthal et al. However, this topic was not well covered in a number of standard paediatric texts. Most Paediatric Units were still using their traditional regimes based on solution 18 until further concerns were raised within Northern Ireland in September 2001.

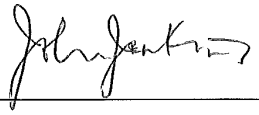
It is important to recognise that this is still an area of very active debate and indeed controversy in the Paediatric literature. What is agreed is that there is little reliable research evidence on which to base specific guidance regarding the use of individual fluid regimes. The development of guidelines locally has taken this uncertainty into account and sought to emphasise the principles of good practice on which each individual clinical situation can be judged and appropriate fluids prescribed. It seems that some individuals can develop this condition in circumstances which are clinically no more severe than those experienced by many patients in the post-operative period, but the reasons for this variation in susceptibility are currently not well understood. It has been suggested that females and children may be particularly at risk. It is for this reason that guidance has now been prepared and issued to increase awareness of this previously poorly recognised condition, and to ensure that Units providing care for children take steps locally to introduce care pathways and/or fluid management regimes which take account of this possibility and minimise the risks of occurrence.

The Working Group moved with considerable speed to review the literature and develop recommendations for the Province. Based on the Working Group's analysis Dr Campbell issued guidelines in March 2002, well in advance of any that we have been aware of elsewhere in the UK. Indeed, these were applauded as an example of good practice by Dr Ted Sumner who was an expert witness called by the Coroner. Together with colleagues I also prepared an article which was submitted to the Archives of Disease in Childhood in November 2002. We were subsequently informed that, while the Journal did not wish to publish this in full, they would be prepared to accept a letter. This letter subsequently appeared in the issue of January 2004. In the meantime, because we recognised the importance of bringing this condition to the attention of not just Paediatricians but other professionals involved in the care of children in Northern Ireland, we contacted the Editor of the Ulster Medical Journal who readily agreed to publish an editorial written jointly by myself, Dr Taylor and Dr McCarthy (Senior Medical Officer at the Department of Health, Social Services and Public Safety). This appeared in the November 2003 issue of the journal.

We are also aware of a letter published in the Archives of Disease in Childhood (in July 2003) by a Dr S Playfor (Consultant Paediatric Intensivist at the Royal Manchester Children's Hospital) entitled "Fatal Iatrogenic Hyponatraemia". In this letter Dr Playfor points out that they had recently cared for a 13 month old girl with a short history of diarrhoea and vomiting who subsequently died as a result of hyponatraemia. He went on to point out that "despite clear and repeated warnings over the past few years, the routine administration of 4% Dextrose/0.18% saline remains standard practice in many Paediatric Units". This was despite the fact that our guidelines had been issued locally in March 2002.

Other points you wish to make including additions to any previous Statements, Depositions and or Reports
[Please attach additional sheets if more space is required]

My involvement with the case of Raychel Ferguson who died on 10 June 2001 after transfer from Altnagelvin Hospital to RBHSC began when I received a letter from the Directorate of Legal Services, Central Services Agency dated 1 November 2002 asking me to prepare a report for the Coroner's inquest. I submitted a report and later gave evidence at the Inquest which took place in February 2003.

Signed:  **Dated:** 1 July 2005

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Department of Health

MEDICINES CONTROL AGENCY

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Dr Bob Taylor
Consultant Paediatric Intensive Care
The Royal Belfast Hospital for Sick Children
180 Falls Road
Belfast BT12 6BE

26 November 2001

Dear Dr Taylor

4% DEXTROSE/0.18% SALINE AND HYPONATRAEMIA

Thank you for your helpful letter dated 23 October 2001. The MCA has conducted a review of 4% dextrose/0.18% saline and hyponatraemia in children. This has now been considered by the Working Group on Paediatric Medicines, a subgroup of CSM. The Working Group considered that although hyponatraemia is a risk in children during the use of 4% dextrose/0.18% saline, electrolyte imbalance is a risk with the use of all intravenous solutions. The Working Group noted that careful monitoring of children after surgery is crucial and in particular, care should be taken not to overload patients with intravenous fluids if they were oliguric as part of the normal response to surgery. The Working Group advised that there should be no amendments to product information.

With kind regards.

Yours sincerely

Katharine Cheng

Dr Katharine Cheng
Medical Assessor
Post Licensing Division

KC/2611-1

INVESTOR IN PEOPLE

INTRAVENOUS FLUID THERAPY

Intravenous fluid and electrolytes are given to maintain or restore normal body composition when it is not possible or desirable to use the enteral route. Fluid and electrolytes are given as maintenance and/or replacement therapy. In each situation, it is necessary to be cautious as both hyper and hyponatraemia can occur.

Caution

Though uncommon, dilutional hyponatraemia is often an unheralded, but potentially fatal condition. It is due to complex neuro-endocrine mechanisms that can occur in children with a variety of conditions especially in the postoperative period. It is characterised by oliguria and a rapid fall in serum sodium concentration leading to cerebral oedema causing seizures and/or coning of the medulla oblongata. Slow correction and careful monitoring are required to prevent serious morbidity.

To prevent dilutional hyponatraemia and sodium overload, it is recommended that:

1 Body weight be accurately measured or estimated by a professional with substantial paediatric experience. The estimation of body weight can be made using the child's age; Body weight (kg) = (AGE+4) x 2. This weight should be plotted on a centile chart as a crosscheck. If the weight is beyond the 3rd or 97th centile range then the weight must be re-examined.

2 Fluid administration should reflect the composition of fluid lost or in deficit, especially as regards sodium content.

3 A baseline blood sample be sent for serum sodium, potassium, urea and blood sugar estimation. Regular and frequent serum sodium and blood sugar estimation is required and should be documented. This will usually mean at least one specimen per day in general maintenance situations, and at least two blood samples daily in the postoperative period and in deficit and significant ongoing loss situations. An indwelling heparinised cannula or capillary sample will avoid sampling difficulties in the anxious child or those with poor veins. Blood samples must not be taken from the same limb as the intravenous infusion.

4 An experienced doctor must assess fluid balance daily and take appropriate action to correct fluid loss or retention. Measurement of urinary sodium, potassium and urea should be helpful.

5 A child with acute hyponatraemia (<130 mmol/L) needs urgent referral to a hospital with paediatric high dependency facilities (asymptomatic hyponatraemia).

MAINTENANCE THERAPY

For this purpose fluid and electrolytes (chiefly sodium [Na^+], chloride [Cl^-] and potassium [K^+]) are given together with glucose to replace the normal losses of water and electrolytes in quantities needed to maintain correct body composition. In infants and children, maintenance fluid and electrolyte requirements vary as a function of metabolic activity. The following normal requirements are derived from the relationship that exists between body weight and metabolic rate and may be used outside the neonatal period. The glucose requirement is that needed to minimise gluconeogenesis from amino acids obtained as substrate from muscle breakdown.

It is usual to meet these requirements by using a standard solution. For example, glucose 4% with NaCl 0.18% given in the volumes suggested below meets the fasting fluid, saline and glucose requirements for the purposes of most children under basal conditions. Solutions containing 20mmol/L of potassium chloride (KCl) also meet usual potassium requirements when given in the suggested volumes. Adjustments will need to be made if there is an inability to excrete fluids or electrolytes, excessive renal loss or continuing extra-renal losses. The exact requirements depend upon the nature of the clinical situation and types of losses incurred. See cautionary note about dilutional hyponatraemia above.

Fluid requirements/24 hours

Body weight <3kg	150mL/kg (start at 40–60mL/kg if newborn)
3–10kg For each kg between 10–20 kg For each kg over 20kg	100mL/kg add 50mL/kg add 20mL/kg to maximum of 2000mL in adult female and 2500mL in adult male
Sodium requirement	3mmol/kg
Potassium requirement	2mmol/kg
Glucose requirement	2.4–4.8g/kg