

INTRODUCTION OF NEW PAEDIATRIC IV FLUIDS MAINTENANCE POLICY
July 2007

The background and wider context of this issue was set out in a briefing to CMT on July 8th, 2007, by Dr Patrick Stewart, and Dr Geoff Nesbitt (*Appendix A*).

The proposed policy had been discussed and approved at a meeting of Altnagelvin's Risk Management and Standards Committee on 27th February 2007.

The issue was raised at a joint Chief Medical Officer/ Medical Directors meeting on June 5th, 2007. The Western Health & Social Care Trust policy differs from regional guidance in that the fluid recommended in regional policy (*Appendix B, July 2007*) is Hartman's Solution + 5% glucose or Hartman's Solution + 2.5% glucose. Based on Dr Stewart's audits, Trust policy will be Hartman's Solution + 3% glucose.

The Director of Pharmacy (*Altnagelvin*) submitted a briefing to CMT for consideration on licensing issues and summarizing her discussions with Linda Matthews, National Patient Safety Agency Pharmacy Advisor (*Appendix C*).

CMT considered the matter further at its meeting on July 26th, 2007. Based on consideration of the audit and recommendations, the briefing note by the Director of Pharmacy, and the foregoing approval process in Altnagelvin Trust, CMT approved the policy for phased implementation.

The policy will be implemented with immediate effect in Altnagelvin. A Trust-wide working group will be established to oversee the introduction to the Erne Hospital over the next three months.

Key to successful implementation is the support of nursing staff who do not erect fluid stands for patients without the proforma being accurately and properly completed by medical staff. Fluid is not renewed until a blood sample is taken and reported. Audits over the last three years have confirmed 98% compliance with the policy in its previous forms.

Trust Board Chair and Chair of the Clinical and Social Care Governance Committee will be briefed. An update on implementation will be brought to the October Clinical & Social Care Governance Committee masters.

Care Governance Committee meeting.

DR ANNE KILGALLEN Medical Director

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Corporate Management Team C/O Mrs Elaine Way Chief Executive Western Health and Social Care Trust

Summary of Briefing to CMT on Paediatric IV Fluids July 5th 2007 - Dr G Nesbitt & Dr P Stewart

The background to this issue was set out by Dr Nesbitt; paediatric IV fluids issues have come to the fore in the last six years in the province following on from the death of a child here in 2001 and three other Children in the preceding ten years elsewhere in Northern Ireland.

Until the 2001 case in particular, it had been usual practice to prescribe very dilute solutions to children. While this practice had been based on good theoretical science, problems occurred when children had certain disorders, particularly those which increased antidiuretic hormone (ADH) levels. This category includes children with a wide range of illnesses and the perioperative population. These children retained water and in certain circumstances developed a dilution hyponatraemia, which can be fatal if undetected.

Dr Nesbitt summed up by saying that when he was Medical Director, Altnagelvin Hospital led the way by being the first to exclude dilute solutions such as "Number 18 Solution" (0.18% sodium chloride with 4% glucose) and this move on its own probably did much to eliminate much of the risk associated with dilutional hyponatraemia. He noted finally that the position now being advocated by the National Patient Safety Agency alert issued in March, is identical to that which he had suggested to the NI Chief Medical Officer in 2001.

I then set out our objective which was to obtain approval of the Corporate Management Team to prescribe a solution which we have long believed to be superior to the available solutions. That solution is Hartmann's Solution with 3% glucose. While similar solutions are available in other countries including the USA (where it has FDA approval), no product license exists for it in the UK because other licensed solutions such as "No 18 solution" have been used so widely.

I pointed out that since Dr Nesbitt's intervention in 2001, Altnagelvin has led the field of paediatric fluid governance - we insist on 12 hourly electrolyte sampling for all children on IV fluids, we have written guidelines on IV fluid prescribing, we have a custom designed prescription sheet restricting the choices of fluids and we have now extensive audit data on all children on IV fluids in this hospital.

Furthermore, we have through participation in the NI Regional Paediatric Fluid Therapy Working Group been influential in the development of regional and even national guidelines by our practice and experience. We also have contributed to the peer reviewed literature and are continuing so to do. We are the only centre in Northern Ireland to do so in five years.

We have also been the first to implement new recommendations ahead of schedule and other centres. We have done so confidently because we monitor our practice so closely. Through this process we have uncovered problems with specific to each of the available

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solutions. Firstly non-glucose-containing Hartmann's solution causes children to become hypoglycaemic. Secondly 0.45% sodium chloride with glucose does not contain sufficient sodium to correct hyponatraemia, the very problem which we are trying to prevent. Finally 0.9% sodium chloride with glucose, the latest recommendation, induces a further biochemical change in that it causes unacceptably high rates of hyperchloraemia (about 70% of cases in 24 hours). While this in itself may be well tolerated by most people, it is our contention that in time, and if given to enough children, then there will most likely be clinical problems with this solution also. I have presented this data at the NI regional group and for this reason they have for the first time included on their guidance Hartmann's Solution with Glucose.

The literature contains only one well-constructed, randomised, controlled trial on IV fluids in children and this is Neville's paper in 2006. This is a comparison of 0.9% sodium chloride compared (without glucose) with 0.45% sodium chloride with glucose in re-hydrating infants with gastroenteritis. This paper suggested that 0.9% sodium chloride was superior, but the authors had to add a rider to their findings in 2007 in connection with hyper-chloraemia, which they admitted had been a problem and had been omitted from their previous paper.

Nearly all of the remaining published data in this area is in the realm of case report, short series and expert opinion, usually relating to hyponatraemia. The topic is very well summed up in Ms Linda Matthew's NPSA briefing paper of 2005, which I have attached. Trials have not been carried out as they are expensive, the products themselves are not patentable and one authority estimates that many thousands of subjects would have to be enrolled to obtain clinical endpoints.

We then addressed the questions of the team;

On the issue of licensing, many medicines used in our practice including even life saving drugs often do not have a product license, or are used in a way which is contrary to any license they may have. While licensing theoretically provides a level of protection for the practitioner under the 1968 Medicines Act, the unlicensed use of medicines is part and parcel of medical practice. Moreover some of the more harmful products such as "Number 18 solution" have retained their license.

It was acknowledged that from a public relations point of view, the word "unlicensed" is problematic. Hartmann's solution with glucose will get a product license if sufficient units are sold in the UK. The industry target figure is usually about 20,000 per annum. Glucose containing solutions of Hartmann's and glucose have product licenses in the USA, France, Germany and Japan.

On the issue of harm caused by hyponatraemia, there was a belief that this was an idio-syncratic, or non preventable/predictable event, specific to the patient. Current thinking is that this was not the case and it is believed now that hyponatraemia will result from a set of prevailing circumstances being present; these are administration of dilute fluids, relative over hydration, an unmonitored environment and finally the secretion of ADH by the patient. The variability in this last factor probably led to a belief that fatalities were not preventable. However our systems are set up to assume that this ADH secretion is present and we therefore compensate accordingly. In particular the close monitoring of electrolytes serves two purposes; in addition to the detection of biochemical imbalance this requirement greatly reduces the number of unnecessary fluid units prescribed.

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On the issue of opinion of colleagues in RBHSC, I outlined that they are represented on the NI regional paediatric fluids group, that Dr Loan's views are similar to my own, whereas Dr Crean's views are more circumspect, although he too has supported the addition of Hartmann's with glucose to the guidance.

On the issue of practice from elsewhere, I am familiar with an APA (Association of Paediatric Anaesthetists) survey in 2005. Alarmingly this indicated that about 60% of mixed institutions in the UK continue to use dilute IV fluid solutions in an unmonitored environment. It is my contention that our data puts us in a stronger position than certainly every hospital in Northern Ireland, and probably the UK. Furthermore the high standards which we set here continues to empower us to make strong judgments without adhering necessarily to practice elsewhere.

On the issue of whether to conduct research, we have decided that while we are happy to cooperate with other units in a regional database, such as that being planned by Dr Mike Smith (RBHSC) and myself in the future. However this will take some time to initiate and longer to report. There is little point in undertaking anything else beyond publishing our audit data.

Regarding the implementation trust wide, this will have to occur, but issues surrounding its policing and day to day implementation and monitoring will have to be explored and this will require a longer time frame.

Finally we face time pressures centred on the medical staff changeover on August 1st. We have successfully reduced fluids incidents by addressing all new staff on the induction day in August. Should we fail to be ready for this August we might potentially have to persist with 0.9% saline and glucose with the problems which I have outlined above.

I expect to oversee the introduction of Hartmann's solution with glucose well before the August changeover. I am attaching the NPSA briefing paper for your perusal. If there are further questions please get in touch.

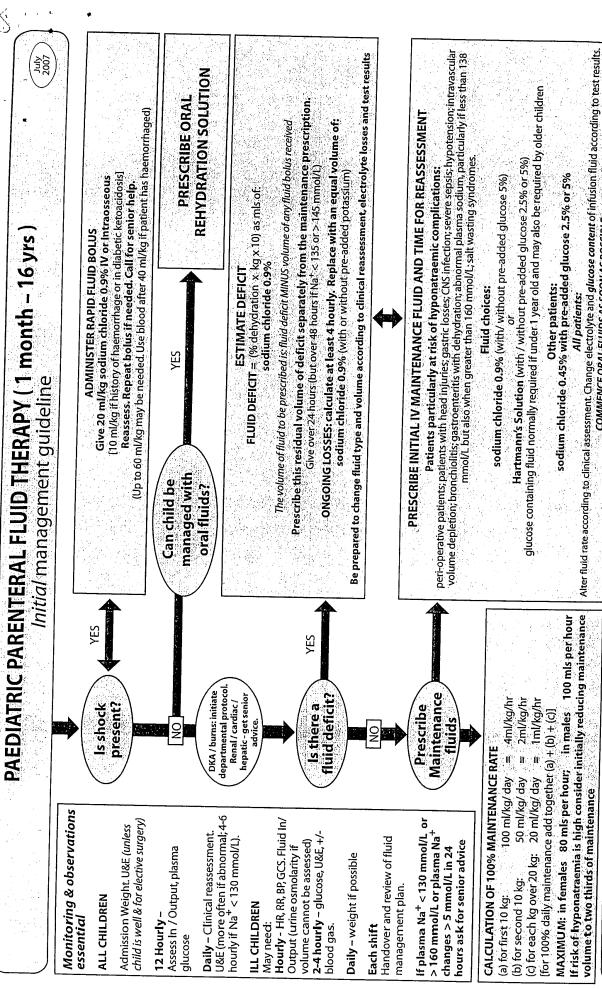
Sincerely

My Sours.

Dr Patrick Stewart

Lead Consultant Paediatric Anaesthetist

July 15th 2007



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Hypoglycaemia (<3 mmol/L). Medical Emergency: give 5 ml/kg bolus of glucose 10%. Review maintenance fluid, consult with senior and recheck level after 15-30 mins. INTRA-OPERATIVE PATIENTS: consider monitoring plasma glucose. Hypokalaemia (< 3.5 mmo//L): Check for initial deficit. Maintenance up to 40 mmo//L IV potassium usually needed after 24 hrs using pre-prepared potassium infusions as far as possible. Consult Trust Policy on IV strong potassium. Symptomatic Hyponatraemia: check U&E if patient developes nausea, vomiting, headache, irritability, altered level of consciousness, seizures or apnoea. This is a Medical Emergency and must be corrected. Oral intake and Medications: volumes of intake, medications & drug infusions must be considered in the fluid prescription. Commence infusion of sodium chloride 2.7% at 2 ml/ka/hour initially and aet senior advice immediately.

COMMENCE ORAL FLUIDS AS SOON AS POSSIBLE.

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