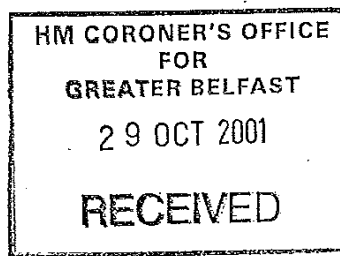


24/10/01



Dear Mr Leckey,

Please find enclosed correspondence from
Medicine Control Agency. I reported an
"Adverse event" associated with the use of
the iv fluids (0.18 NaCl/4% glucose) and also
asked the MCA to consider issuing
a "Hazard Notice" with this fluid.
They are keen to have a copy of the
postmortem which is your property.

Yours

Bob Taylor
Consultant Paed

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Department of Health

MEDICINES CONTROL AGENCY

Market Towers 1 Nine Elms Lane London SW8 5NQ

Tel [REDACTED] - fax [REDACTED] - www.mca.gov.uk



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

17 October 2001

Dear Dr Taylor

HYPONATRAEMIA AND 4% DEXTROSE/0.18% SALINE SOLUTION
YELLOW CARD NO: 433167

Thank you for your letter of 1 October 2001. We are currently initiating a review of the safety of 4% dextrose and 0.18% saline solution in children. We will be in contact again when we have the results.

In the meantime I would be grateful if you could provide me with some details about the case (R F) you reported to us:

- the date of the appendicectomy and the results of pre-op electrolytes, if measured
- the date when the headaches and vomiting started
- the date when seizures started
- date of death
- a copy of the hospital summary
- a copy of the post-mortem results

With kind regards

Yours sincerely

K Cheng.

Dr Katharine Cheng
Medical Assessor
Post Licensing Division

Copy ADROIT

Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

23rd October 2001

Medical Report. Re; Yellow card 433167 (RF)

Dear Dr Cheng,

Thank you for your correspondence of the 17th October. I enclose the answer to your questions as follows;

1. RF admitted to a large DGH with abdominal pain (no vomiting or diarrhoea) on 7/6/01 at 20.30. iv fluids commenced, serum sodium = 137 mmol/l
2. Appendicetomy (mildly inflamed) at 23.30 on 7/6/01
3. iv fluids in operating theatre (100 mls Hartmanns solution). Recommenced on 0.18% NaCl/4% Glucose at 80 mls/hour on return to ward.
4. Vomited 6-7 times on 8/6/01 from 12.30-13.00, complaining of headache. Sips of water allowed from 17.00 on 8/6/01
5. Seizures commenced at 03.00 on 9/6/01. Treated with diazepam 5mg PR followed by 10 mg iv.
6. Pupils fixed and dilated at 04.10 on 9/6/01. Intubated and ventilated for CT scan, which showed cerebral oedema. Serum sodium = 118 mmol/l
7. Transferred to PICU at our hospital (RBHSC)
8. Brain Stem tests performed 10.00 on 10/6/01
9. Ventilation discontinued at 12.09 on 10/6/01
10. Coroner informed and postmortem conducted by Neuropathologist for Forensic.

Unfortunately I am not in a position to supply a postmortem result as it is a Coroners case. I have spoken to the neuropathologist who has confirmed that the cause of death was cerebral oedema leading to herniation. I have copied this response to both these men who I hope will supply you with further details of this important matter.

I am also conducting an audit of all infants and children admitted to the PICU with hyponatraemia. My initial results indicate at least 2 other deaths attributable to the use of 0.18NaCl/4%Glucose.

Yours sincerely,


Dr Bob Taylor, MA, MB, FFARCSI
Consultant in Paediatric Intensive Care

Dr Brian Herron, Consultant Neuropathologist, Royal Victoria Hospital, Belfast
Mr John Leckey, Coroner.

Summary of events

20.30, 7/6/01

9 yr old female, est 25kg body wt
Admitted with abdominal pain.

Serum sodium = 137 mmol/l

Iv fluids commenced
0.18%NaCl/4% Glucose @ 80 ml/hr

23.30, 7/6/01

Appendicetomy performed

Hartmanns solution given in theatre

Recommenced on ward 0.18%NaCl/4% Glucose @ 80 ml/hr

13.00, 8/6/01

Talking, playing and standing up as normal
6-7 episodes of vomiting
continues on 0.18%NaCl/4% Glucose @ 80 ml/hr

03.00, 9/6/01

Generalised seizure, treated with diazepam

04.10, 9/6/01

Pupils fixed and dilated, CT scan shows cerebral oedema

Serum sodium = 118 mmol/l

Iv fluids changed to
0.9%NaCl @40 ml/hr

10.00, 10/6/01

Brain stem tests confirm death

12.09, 10/6/01

Ventilation discontinued,
Coroner informed

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