Witness Statement Ref. No. 156/2

NAME OF CHILD: Claire Roberts

Name: James Patrick McKaigue

Title: Dr.

Present position and institution:

Consultant Paediatric Anaesthetist- Royal Belfast Hospital for Sick Children

Previous position and institution:
[As at the time of the child's death]
Consultant Paediatric Anaesthetist- Royal Belfast Hospital for Sick Children ("RBHSC").

Membership of Advisory Panels and Committees:
[Identify by date and title all of those between October 1996-August 2012]

Association Paediatric Anaesthetists Executive Committee 2002-2006

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:	
WS-129/1	17th May 2012	Witness Statement to the Inquiry (Adam Strain)
WS-156/1	30th January 2012	Witness Statement to the Inquiry (Claire Roberts)

IMPORTANT INSTRUCTIONS FOR ANSWERING:

Please attach additional sheets if more space is required. Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number. If the document does not have such a number then please provide a copy of the document.

(1) Please specify any changes occurring in the period from November 1995 to October 1996 in respect of the following:

(a) Your professional and/or medical qualifications;

None

(b) Your job, role and functions;

I took on the role of Anaesthetic Rota Organiser, Children's Hospital (January 1996)

(c) Your responsibilities and accountability.

Please see (b) for responsibilities. There were no changes in accountability

(2) Please specify all investigations in relation to the treatment and death of Claire Roberts.

I am only aware of the inquest.

(3) Please state when you were first asked to make a statement in relation to the case of Claire Roberts, by whom and for what purpose?

Mr Walby asked me to make a statement on 1st December 2011 for the purpose of providing evidence to The Inquiry into Hyponatraemia-related Deaths

(4) Please state whether in 1996 you considered that hyponatraemia was a condition that was:

(a) Preventable?

No

(b) Treatable?

Yes

(5) Please specify to whom the death of Claire Roberts was reported in 1996, and in particular please state whether any of the following were informed of her death:

(a) Dr. Peter Crean;

(b) Dr. Elaine Hicks;

(c) Dr. Ian Carson;

(d) Dr. George Murnaghan;

(e) Dr. Joseph Gaston;

(f) **Mr. William McKee;**

(g) **Nurse Manager in Paediatric Directorate;**

(h) **Miss Elizabeth Duffin;**

(i) **Mr. George Brangam.**

I did not report the death of Claire Roberts to anybody in 1996, including any of the above.

(6) **Please specify the date, nature and content of any such reports.**

Please see (5)

(7) **To your knowledge was the death of Claire Roberts discussed informally by the staff of the RBHSC in October 1996?**

I am not aware of the death of Claire Roberts being discussed informally by staff of the RBHSC in October 1996

(8) **Please state whether you regarded the death of Claire Roberts as 'expected' or 'unexpected'.**

When I first saw Claire in PICU shortly after 03:45, I expected her to die

(9) **Did you forward the PICU Discharge Summary and PICU Discharge Advice Note to the Pathologist after they were issued?**

I do not believe that I forwarded the PICU Discharge Summary Ref: 090-006-008, or the PICU Discharge Advice Note Ref: 090-009-011 to the Pathologist. It was not my customary practice to do so.

(10) **Please state whether you were asked for your opinion as to whether or not Claire Roberts' death should have been referred to the Coroner, and if so what opinion you gave.**

I was not asked for my opinion as to whether or not Claire Roberts' death should have been referred to the Coroner

(11) **Please state if any advice was sought from the Coroner's office in respect of referral.**

I am not aware if any advice was sought from the Coroner's Office in respect of referral

(12) **Please state why you did not report the death of Claire Roberts to the Coroner.**

The clinical picture as I understood it was that Claire died from naturally occurring disease processes. She had developed fatal cerebral oedema, due to meningoencephalitis, status epilepticus and SIADH. Please also see WS-156/1 33(c) page 31.

Dr Steen and Dr Webb would have to take a view on whether or not Claire's death needed to be referred to the Coroner and as paediatricians, who would have looked after children with similar disease processes to Claire's, were better qualified than I, to make those judgements. With this in mind I initiated a conversation with Dr Steen as detailed in WS-156/1 (5) page 8

(13) **Please state whether any advice was sought from you, or whether you had any input into the**

causes of the death included on the death certificate of Claire Roberts?

No advice was sought from me and I did not have any input into the causes of death included on the death certificate of Claire Roberts

(14) Please state whether the advice of the Director of Medical Administration, Dr. George Murnaghan, was sought in relation to referral of Claire Robert's death to the Coroner in 1996.

I did not seek advice from the Director of Medical Administration, Dr. George Murnaghan, in relation to referral of Claire Roberts' death to the Coroner in 1996

(15) Did you accept the Coroner's findings:

(a) In the case of Adam Strain (Ref: 011-016-114)?

When I became aware of the Coroner's findings, I fully accepted them

(b) In the case of Claire Roberts (Ref: 091-002-002)?

I did accept the Coroner's findings and note that while the rate of administration of No18 solution was reduced when the sodium fell to 121 mmol/l, on consideration of the fluid balance chart at this stage, there is no overall decrease in fluids

(16) Was the Arieff et al paper BMJ 1992, (Ref: 011-011-074)circulated in the RBHSC in 1996 amongst:

(a) Paediatric Clinicians;

Not to my knowledge

(b) Anaesthetists?

Not to my knowledge

(17) Was there a heightened awareness amongst clinicians in the RBHSC in 1996 as to hyponatraemia, sodium levels, fluid administration, cerebral oedema and SIADH?

I do not believe so

(18) Please state whether your opinion was sought as to whether or not a full or restricted post-mortem examination of Claire Roberts should be requested, and if so what opinion you gave.

My opinion was not sought as to whether or not a full or restricted post-mortem examination of Claire Roberts should be requested.

(19) What, in 1996, did you understand the purpose of an Autopsy Report to be?

I believed in 1996 that the purpose of an Autopsy Report was to provide information on the presence or not, as the case may be, of disease processes identified in the deceased. The information provided by the pathologist may then shed light on the cause of death, either by identifying the cause(s) of death if previously unknown, or providing additional information on the cause(s) of death.

(20) Please state whether any guidelines or conventions existed in 1996 governing post-mortem examinations with specific reference to:

(a) **When consent was required for a post-mortem examination;**

I believe it was the convention to obtain consent for a post-mortem examination

(b) **When a limited post-mortem could be requested;**

When the clinician and/or family were seeking additional information on the cause of death, it was a convention to request only a limited post-mortem in some cases

(c) **Authorisation for the same;**

If I understand the question correctly, the pathologist would have a say on the appropriateness of the request

(d) **The information and options given to the parents of the deceased child in respect of this decision;**

I do not recall guidelines detailing what information or options were given to the parents of a deceased child in respect of getting consent for a post-mortem. I believe it was a convention to discuss in very general terms only what a post-mortem involved. 20(b) would also apply

(e) **Whether parents of the deceased child should be asked for their views on whether or not the Coroner be notified;**

I do not recall guidelines relating to this issue. I do not believe it was convention that parents' views were sought on whether or not the Coroner be notified of a death.

(f) **Whether parents of the deceased child should be asked for their views on whether a full or restricted post-mortem should be carried out;**

I do not recall guidelines relating to this issue. I believe it was the convention at the time to discuss the type of post-mortem with the parents taking into account 20(b) and 20(d)

(g) **Whether the Autopsy Report should have been shared with the parents and GP of the deceased child?**

I do not recall guidelines relating to this matter. It was convention for information resulting from the Autopsy Report to be shared with the GP, although I cannot be certain if a copy of the Autopsy Report was provided to the GP. Information arising from the Autopsy Report would also have been shared with the parents I believe.

(21) **What was the origin of the pro-forma consent form used for the limited post-mortem presented to Mr. Roberts for signature (Ref: 090-054-185).**

I have no knowledge of the origin of the pro-forma consent form detailed in Ref: 090-054-185

(22) **Please specify all meetings, discussions, reviews and audits which took place touching on the death of Claire Roberts; identifying those who attended the meetings, where such meetings took place and whether a note was taken of the same.**

Following the death of Claire Roberts, the next time I saw Dr Taylor (#1) I said that Claire had died later in the evening of the day of her admission to PICU. I did not make a note of this conversation.

I recall that I had a brief discussion with Dr Steen (#2), when she commented on the neuropathology report.

The report was in keeping with a clinical diagnosis of meningoencephalitis. I did not make a note of this brief discussion.

Dr Steen presented Claire's death at the Audit meeting in RBHSC (#3) at which I was present. I do not recall who else was present at that meeting, or the date of the meeting. I did not make a note of this meeting.

I recall Dr Nicola Rooney visiting PICU one evening (#4) with Claire Robert's chart and inquiring if Dr Taylor was about. I believe that this occurred after the UTV Documentary was broadcast and the parents had contacted the hospital seeking information. Dr Taylor was not there. However I examined the chart and was able to identify my entry in the notes. Dr Rooney left shortly after this, with Claire's chart in her possession I believe. I did not make a note of this encounter.

I mentioned Dr Rooney's visit to PICU, a short time later to Dr Taylor (#5). I did not make a note of the discussion.

I believe I mentioned Dr Rooney's visit to PICU to Dr Crean (#6). I did not make a note of the discussion.

(23) Please provide information detailing those meetings which took place:

(a) Before the Autopsy report became available;

#1

(b) After the Autopsy report became available.

#2, #3, #4, #5, #6

(24) Did the Pathologist attend the meeting(s), and if so please identify who the Pathologist was?

I cannot recall if the pathologist was present at the Audit meeting when Claire's death was presented

(25) Was any learning gained from any such meetings? If so what?

I do not recall if learning points were highlighted at the Audit meeting

(26) Please state whether Dr. Taylor played any role in mortality meetings/discussions? If so what was that role?

When Dr Taylor was Audit Coordinator in RBHSC his role at Audit meetings was as a facilitator. This did not exclude him from contributing to discussions.

(27) How many patients died annually in PICU in 1995 and 1996?

Deaths were identified from the PICU Ledger

In 1995 there were 26 deaths

In 1996 there were 23 deaths

(28) Were there any guidelines or conventions in the RBHSC in 1996 regarding the criteria for admittance of children to PICU; and if there was doubt as to admission, whether a PICU consultant would have been asked for advice in relation to the same.

I was not aware of any guidelines in RBHSC regarding the criteria for admittance of children to PICU.

The convention was that other doctors made a request for their patient to be admitted to PICU. This referral would have initiated a discussion with a PICU consultant and a decision would have been made. Sometimes a patient's care would continue to be provided by not admitting the patient to PICU, with the proviso that they be kept under careful observation and if there were any concerns, to contact PICU again. If there was doubt as to whether or not a patient needed to be admitted to PICU, it was normal practice for a PICU consultant to have been asked for advice on the matter.

(29) After admission to PICU please identify the clinician who was in charge of Claire's case.

I believe that Dr Steen was in charge of Claire's case after admission to PICU

(30) What responsibility did the PICU consultants have in respect of communication with the parents of an admitted child, and what was his/her role in relation to the same?

I believe the PICU consultants had a responsibility to ensure that communication with the parents of an admitted child was taking place. Their role would be to liaise with other members of the clinical team and parents to arrange suitable times when all parties could talk. Quite often they would be used to relay messages between the parties. The PICU consultants themselves could also answer general questions/ queries and concerns about a child on behalf of other members of the clinical team. With respect to our role in PICU as anaesthetists, we then had an additional responsibility to take the lead in communicating to parents on matters pertaining to ventilation, vascular access, resuscitation, need for inotropes, sedation, airway, general matters to do with keeping the patient safe and ultimately informing them when we thought their child no longer needed to be cared for in PICU.

(31) Was there any appraisal of staff performance in the aftermath of Claire's death?

I do not know if there was any appraisal of staff performance in the aftermath of Claire's death

(32) Did any change in the training/teaching provided by the RBHSC/ Trust to clinicians result from Claire's death?

I am not aware of any change in the training/teaching provided by RBHSC/Trust to clinicians specifically resulting from Claire's death.

(33) With respect to the biochemistry reports sought and received in the course of Claire's treatment, please state:

(a) Whether the pro-forma notification report form was subsequently amended to communicate the timing of sample, analysis and report? If so when and upon whose instruction;

I have no knowledge of the 'proforma notification report form'

(b) Whether any complaints or requests were made in relation to report forms before or after the treatment and death of Claire Roberts?

I have no knowledge whether any complaints or requests were made in relation to report forms before or after the treatment and death of Claire Roberts

(34) Please state whether you would have expected nursing staff to mount an investigation into the death of Claire Roberts and whether you would have expected statements to have been obtained from the nurses in respect of same?

I did not have any knowledge of nursing practice with respect to investigations

(35) Was there an audit of the following aspects of the case of Claire Roberts:

(a) Record keeping;

I do not know if there was an audit of record keeping in the Claire Roberts case

(b) Drug prescription and administration?

I do not know if there was an audit of drug prescription and administration in the Claire Roberts case

(36) Do you think that there was an iatrogenic contribution to the death of Claire Roberts?

I do not think that there was an iatrogenic contribution to the death of Claire Roberts. However others may be better qualified to answer this question.

(37) If there was a possibility that medical care and treatment might have contributed to a death would you have expected that care and treatment to have been investigated?

If medical care and treatment might have contributed to a death, I would expect that to be investigated

(38) In October 1996 were you aware of:

(a) Circular ET 5/90 (as amended) January 1991?

I cannot recall if I was aware of 'Circular ET 5/90 (Amended)' in October 1996

(b) A Charter for Patients and Clients (Northern Ireland Health and Personal Social Services) March 1982:

I cannot recall if I was aware of 'A Charter for Patients and Clients (Northern Ireland Health and Personal Social Services)' in October 1996

(c) Directive PEL (93)36?

I cannot recall if I was aware of 'Directive PEL (93)36' in October 1996

(d) Welfare of Children and Young People in Hospital (HMSO 1991);

I was aware of the existence of 'Welfare of Children and Young People in Hospital (HMSO 1991') in October 1996, but not the detail.

(e) The Paediatric Intensive Care Society (UK) Standards document, 1992.

I cannot recall if I was aware of 'The Paediatric Intensive Care Society (UK) Standards' document in October 1996

(39) With reference to document (Ref: 090-006-008), please state:

(a) Does the handwritten note in the top right hand corner, namely *"File per S McK 22/11"* refer to your initials? If so why was this note made?

The handwritten note "File per S McK 22/11" probably does refer to me. I do not know why this was written, unless it was for routine administrative purposes

written, unless it was for routine administrative purposes

(b) Were the papers of Claire Roberts filed with a cause of death categorisation of 'respiratory arrest'?

Yes

(c) Who is the *"Dr. Allen"* copied in at the foot of this note, and what was his/role role in relation to this matter?

I cannot identify this 'Dr Allen'

(d) What were the usual filing procedures in relation to these matters?

I believe the Trust should deal with this question. The person I recall, who dealt with the paper flow and filing has just retired and I cannot provide a definitive answer

(40) How was the death of Claire Roberts categorised within the RBHSC statistical data in 1996?

I do not know how the death of Claire Roberts was categorised within the RBHSC statistical data in 1996

(41) Was this classification subsequently amended in the light of the Coroner's findings at her Inquest?

I do not know if the classification/categorisation was subsequently amended in the light of the Coroner's findings at Claire's Inquest

(42) Were you aware of the RBHSC's engagement with the Kings Fund Organisational Audit in 1996? If so how did it affect the advices given to you or others in respect of:

(a) Communication with patient's parents and record of the same;

(b) Investigation of patient's death;

(c) Review of medical records;

(d) Systematic programme of audit;

(e) Implementation and compliance with published guidance?

I was aware of the RBHSC's engagement with the Kings Fund Organisational Audit but I am unsure of the date. I do not recall any specific advices arising from the Kings Fund Organisational Audit either given to myself or others in respect of (42) (a) to (e)

(43) When do you believe the following individuals become aware of the death of Claire Roberts:

(a) Dr. George Murnaghan;

I do not know

(b) Dr. Peter Crean;

I do not know when Dr Crean first became aware, but I believe that I mentioned the death of Claire

Roberts to Dr Crean sometime after Dr Rooney visited PICU with Claire Roberts chart. Please see (22)

(c) Dr. Joseph Gaston;

I do not know

(d) Dr. Ian Carson;

I do not know

(e) Mr. A.P. Walby;

I do not know

(f) Mr. George Brangam;

I do not know

(g) Miss Elizabeth Duffin.

I do not know

(44) Please provide details of any changes in patient care relevant to hyponatraemia between the death of Adam Strain in 1995 and the admission of Claire Roberts, including:

(a) Any changes that you made in respect of your own practice;

I ensured that No 18 solution was given at normal maintenance rates only. I did not want there to be any chance that junior anaesthetists could misinterpret the administration of No 18 solution at faster than normal maintenance rates, as to be seen by them, as me endorsing a potentially unsafe practice. This allowed me to have a simple message, No 18 solution should <u>never</u> be administered at faster than normal maintenance rates, ie it should never be administered as a bolus to replace a fluid deficit, because of the risk of hyponatraemia. If I had to replace a fluid deficit in a child, I used an iv fluid which contained a sodium level of 131 mmol/l or greater.

(b) How such changes were formulated and disseminated;

I formulated them on knowledge I acquired through the Adam Strain case. The changes were disseminated through informal teaching in the operating theatre and PICU.

(c) To what extent any such changes affected or informed your approach to the treatment of Claire Roberts, or her treatment in general.

My approach to the treatment I provided to Claire Roberts did not need to be changed on the basis of anything I have stated in 44(a). The treatment she received in general was consistent with the principle stated in 44(a).

(45) Please state whether you received any training or guidance (including details of the same) in respect of:

(a) The compilation and completion of death certificates;

Undergraduate teaching on the above was provided by Professor T K Marshall, Professor of Forensic

Medicine, The Queen's University of Belfast

(b) Referral of deaths to the Coroner;

Please see 45(a)

From recall it appeared to be standard teaching on what deaths needed to be referred to the Coroner. I do not recall any specific details on reporting hospital deaths to the Coroner

(c) The principles governing post-mortem requests.

I do not recall undergraduate teaching on this subject. I believe my knowledge was acquired through my post-graduate clinical experiences. In the early 2000's there was a major change in procedures to be followed governing post-mortem requests. These have been well documented and the Trust have provided training in this matter. When a post mortem request is now being made, there is a comprehensive information pack to guide clinical staff and also to provide information for the next of kin.

(46) In respect of the Forfar and Arneil *"Textbook of Paediatrics"* please state:

(a) Whether this was known to you in October 1996;

The existence of this book was known to me in October 1996

(b) Whether this was in use in the RBHSC in October 1996;

I cannot give a definitive answer to this question, it may have been in use in October 1996

(c) Whether this was available to staff in the RBHSC in October 1996;

I cannot give a definitive answer to this question, it may have been available to staff in October 1996

(d) If this text was not available or commonly in use in the RBHSC in October 1996 please state what text was.

I cannot recall what texts were available or commonly in use in the RBHSC in October 1996

(47) Was there any system or process for the audit of referrals to post-mortem and referrals to Coroner? Was this system or process subject to any external scrutiny or review?

I was not aware of any system or process for the audit of referrals to post-mortem and referrals to Coroner.

(48) Did you learn any lessons from the death of Claire Roberts and with hindsight were lessons to be learned from it? If so, what were those lessons?

I learned that there is a link between both meningoencephalitis and also status epilepticus and a risk of developing SIADH.

With hindsight I would have preferred any discussion I had with Dr Steen and Dr Webb to have been documented.

(49) Please identify whether any lessons deriving from the case of Claire Roberts were disseminated either before or after the Inquest. If so please state how, where, when and to whom.

I am not aware of any lessons deriving from the case of Claire Roberts being disseminated either before or after the Inquest

(50) With hindsight could or should anything have been done to heighten awareness of hyponatraemia amongst practising clinicians after the death of Claire Roberts, and if so what?

With hindsight the lesson to be learned from Claire Roberts' death was that in a child with potential neurological issues, there is a clear risk of SIADH, which can result in decreased sodium levels and therefore extreme caution needs to be exercised in prescribing No 18 solution.

The practice of administering No 18 solution as a maintenance fluid, in virtually all clinical scenarios, was deeply embedded in paediatrics. A major cultural shift would have been required. I believe that this could only be driven nationally with strong professional leadership, working in tandem with the Medicine Controls Agency.

For practising clinicians there were no independent authoritative warnings, clearly stating the risks of prescribing No 18 solution to patients who may be at risk of SIADH. The British National Formulary did not pick up on this until March 2003 Reference 1. The British National Formulary March 1995 can be compared Reference 2.

Packaging for No 18 solution, a prescription only medicine (POM), did not contain an information sheet, which could have included useful content from the 'Summary of the Product Characteristics' document. A sample 'Summary of Product Characteristics' Reference 3, however does not contain any warnings under the headings 'Contraindications' or 'Special Warnings and Special Precautions for Use' about the use of No 18 solution in patients who may be at risk of SIADH. There are warnings however in place for other more obvious medical conditions.

(51) Please describe how the 'culture' within the RBHSC has changed since 1996?

No 18 solution has gone from being widely used in RBHSC, to being banned from most wards and in PICU kept under lock and key.

There is a serious adverse incident (SAI) procedure in place.

(52) Was any consideration given to inviting external specialists to review the case of Claire Roberts?

I do not know

(53) Please provide any further comments you think may be relevant, together with any documents or materials.

Reference 1 BNF March 2003

Reference 2 BNF March 1995

Reference 3 Summary of Product Characteristics No 18 solution

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: JP McHaigue Dated: 16/9/12

Relating to Dr McKague's Statement

THE ROYAL [redacted]
HOSPITALS

WITH THE COMPLIMENTS OF
MRS RHONA FAIR, ASSISTANT DIRECTOR
THE PHARMACEUTICAL DIRECTORATE

PATRON : HRH The Duchess of Kent
The Royal Victoria Hospital
The Royal Maternity Hospital
The Royal Belfast Hospital for Sick Children
The Dental Hospital

THE ROYAL GROUP OF HOSPITALS AND DENTAL HOSPITAL
HEALTH AND SOCIAL SERVICES TRUST

Grosvenor Road, Belfast BT12 6BA Northern Ireland
Telephone : 02890 634404
Fax: 02890 634879 Textphone : 02890 263393

SUMMARY OF PRODUCT CHARACTERISTICS

1. Trade name of the Medicinal Product

Sodium Chloride 0.18% w/v and Glucose 4% w/v Intravenous Infusion BP

2. Qualitative and Quantitative Composition

2.1 Active Ingredient

Sodium Chloride
Glucose Monohydrate
or Anhydrous Glucose

2.2 Quantitative Composition

Sodium Chloride BP	1.8g/l
Glucose Monohydrate Ph.Eur	44g/l
or	
Anhydrous Glucose BP	40 g/l

This provides 30 mmol/l Na^+ and 30 mmol/l Cl^-

3. Pharmaceutical Form

Solution for infusion.
Sterile, non-pyrogenic, clear, colourless, aqueous Solution for Infusion.

4. Clinical Particulars

4.1. Therapeutic Indications

For use in prophylactic and replacement therapy requiring the use of glucose and sodium chloride.

4.2. Posology and Method of Administration

Dosage:

The dosage is dependant upon the age, weight and clinical condition of the patients.

Administration:

Intravenous.

4.3 Contraindications

Administration in congestive heart failure, or in conditions of severe renal impairment.

4.4 Special Warnings and Special Precautions for Use

Administration should be carried out under regular and careful surveillance.

The fluid should only be administered with great care to patients with diabetes mellitus or renal insufficiency.

4.5 Interactions with Other Medicaments and Other Forms of Interaction

Do not transfuse blood through the same giving set.

No other medication or substance should be added unless compatibility is known.

4.6. Pregnancy and Lactation

Not specified.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Undesirable effects

Venous irritation and thrombophlebitis may occur at the injection site.

4.9. Overdose

Discontinue if adverse reaction occurs.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

None specified.

5.2. Pharmacokinetic Properties

None specified.

5.3. Preclinical Safety Data

Not applicable.

6. Pharmaceutical Particulars

6.1. List of Excipients

Water for Injection Ph.Eur.
Hydrochloric Acid, concentrated Ph.Eur.

6.2. Incompatibilities

No other medications or substances should be added unless compatibility is known.

6.3. Shelf Life

The shelf life is 24 months providing the unit has not been opened.

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5. Nature and Contents of Container

A clear, collapsible, Viaflex® infusion bag, composed of plasticised poly (vinyl chloride) (PVC), effectively sealed in High Density Polyethylene or Polypropylene overpouch and containing 500ml or 1000ml of solution.

6.6. Instructions for Use/Handling

Do not use unless solution is clear and the container is undamaged.

7. Marketing Authorisation Holder

Baxter Healthcare Ltd.,
Caxton Way,
Thetford,
Norfolk,
IP24 3SE
United Kingdom

8. **Marketing Authorisation Number**

PA 167/50/1-2

9. **Date of First Authorisation/Renewal of Authorisation**

1st April 1983/ 1st April 1998

10. **Date of (partial) revision of the text**

18 February 1999

Relating to Dr McKaigue's Statement

Dose: see notes above

Sodium Bicarbonate (Non-proprietary)

Capsules, sodium bicarbonate 500 mg (approx. 6 mmol each of Na^+ and HCO_3^-). Net price 20 = £6.08

Available from Generics, IVAX

Tablets, sodium bicarbonate 600 mg, net price 20 tabs = 50p

IMPORTANT. Oral solutions of sodium bicarbonate are required occasionally; these need to be obtained on special order and the strength of sodium bicarbonate should be stated on the prescription

POTASSIUM BICARBONATE

Indications: see notes above

Cautions: cardiac disease, renal impairment; interactions: Appendix 1 (potassium salts)

Contra-indications: hypochloraemia; plasma potassium concentration above 5 mmol/litre

Side-effects: nausea and vomiting

Dose: see notes above

Potassium Tablets, Effervescent (Non-proprietary)

Effervescent tablets, potassium bicarbonate 500 mg, potassium acid tartrate 300 mg, each tablet providing 6.5 mmol of K^+. To be dissolved in water before administration. Net price 100 = £4.29.

Label: 13, 21

Available from Alpharma, Hillcross

NOTE. These tablets do not contain chloride; for effervescent tablets containing potassium and chloride, see under Potassium Chloride, section 9.2.1.1

9.2.2 Parenteral preparations for fluid and electrolyte imbalance

9.2.2.1 Electrolytes and water

Solutions of electrolytes are given intravenously, to meet normal fluid and electrolyte requirements or to replenish substantial deficits or continuing losses, when the patient is nauseated or vomiting and is unable to take adequate amounts by mouth. When intravenous administration is not possible large volumes of fluid can also be given subcutaneously by hypodermoclysis.

In an individual patient the nature and severity of the electrolyte imbalance must be assessed from the history and clinical and biochemical examination. Sodium, potassium, chloride, magnesium, phosphate, and water depletion can occur singly and in combination with or without disturbances of acid-base balance; for reference to the use of magnesium and phosphates, see section 9.5.

Isotonic solutions may be infused safely into a peripheral vein. Solutions more concentrated than plasma, for example 20% glucose are best given through an indwelling catheter positioned in a large vein.

Intravenous sodium

Sodium chloride in isotonic solution provides the most important extracellular ions in near physiological concentration and is indicated in *sodium depletion* which may arise from such conditions as gastro-enteritis, diabetic ketoacidosis, ileus, and ascites. In a severe deficit of from 4 to 8 litres, 2 to 3 litres of isotonic sodium chloride may be given over 2 to 3 hours; thereafter infusion can usually be at a slower rate. Excessive administration should be avoided; the jugular venous pressure should be assessed, the bases of the lungs should be examined for crepitations, and in elderly or seriously ill patients it is often helpful to monitor the right atrial (central) venous pressure.

Chronic hyponatraemia should ideally be corrected by fluid restriction. However, if sodium chloride is required, the deficit should be corrected slowly to avoid the risk of osmotic demyelination syndrome; the rise in plasma-sodium concentration should be limited to no more than 10 mmol/litre in 24 hours.

Compound sodium lactate (Hartmann's solution) can be used instead of isotonic sodium chloride solution during surgery or in the initial management of the injured or wounded.

Sodium chloride and glucose solutions are indicated when there is combined *water and sodium depletion*. A 1:1 mixture of isotonic sodium chloride and 5% glucose allows some of the water (free of sodium) to enter body cells which suffer most from dehydration while the sodium salt with a volume of water determined by the normal plasma Na^+ remains extracellular. Maintenance fluid should accurately reflect daily requirements and close monitoring is required to avoid fluid and electrolyte imbalance. Illness or injury increase the secretion of anti-diuretic hormone and therefore the ability to excrete excess water may be impaired. Injudicious use of solutions such as sodium chloride 0.18% and glucose 4% may also cause dilutional hyponatraemia especially in children and the elderly; if necessary, guidance should be sought from a clinician experienced in the management of fluid and electrolytes.

Combined sodium, potassium, chloride, and water depletion may occur, for example, with severe diarrhoea or persistent vomiting; replacement is carried out with sodium chloride intravenous infusion 0.9% and glucose intravenous infusion 5% with potassium as appropriate.

SODIUM CHLORIDE

Indications: electrolyte imbalance, also section 9.2.1.2

Cautions: restrict intake in impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema, toxaemia of pregnancy

Side-effects: administration of large doses may give rise to sodium accumulation and oedema

Dose: see notes above

Sodium Chloride Intravenous Infusion (Non-proprietary) [CD]

Intravenous infusion, usual strength sodium chloride 0.9% (9 g, 150 mmol each of Na^+ and Cl^-/litre), this strength being supplied when normal saline for

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WATER

The term water used without qualification means either potable water freshly drawn direct from the public supply and suitable for drinking or freshly boiled and cooled purified water. The latter should be used if the public supply is from a local storage tank or if the potable water is unsuitable for a particular preparation. (Water for injections, section 9.2.2.)

9.2.2 Intravenous administration

Solutions of electrolytes are given intravenously, to meet normal fluid and electrolyte requirements or to replenish substantial deficits or continuing losses, when the patient is nauseated or vomiting and is unable to take adequate amounts by mouth.

In an individual patient the nature and severity of the electrolyte imbalance must be assessed from the history and clinical and biochemical examination. Sodium, potassium, chloride, magnesium, phosphate, and water depletion can occur singly and in combination with or without disturbances of acid-base balance; for reference to the use of magnesium and phosphates, see section 9.5.

Isotonic solutions may be infused safely into a peripheral vein. Solutions more concentrated than plasma, for example 20% glucose are best given through an indwelling catheter positioned in a large vein.

INTRAVENOUS SODIUM

Sodium chloride in isotonic solution provides the most important extracellular ions in near physiological concentration and is indicated in *sodium depletion* which may arise from such conditions as gastro-enteritis, diabetic ketoacidosis, ileus, and ascites. In a severe deficit of from 4 to 8 litres, 2 to 3 litres of isotonic sodium chloride may be given over 2 to 3 hours; thereafter infusion can usually be at a slower rate.

Excessive administration should be avoided; the jugular venous pressure should be assessed, the bases of the lungs should be examined for crepitations, and in elderly or seriously ill patients it is often helpful to monitor the right atrial (central) venous pressure.

Compound sodium lactate (Hartmann's solution) can be used instead of isotonic sodium chloride solution during surgery or in the initial management of the injured or wounded.

Sodium chloride and glucose solutions are indicated when there is combined *water and sodium depletion*. A 1:1 mixture of isotonic sodium chloride and 5% glucose allows some of the water (free of sodium) to enter body cells which suffer most from dehydration while the sodium salt with a volume of water determined by the normal plasma Na^+ remains extracellular. An example of combined sodium chloride and water depletion occurs in persistent vomiting.

SODIUM CHLORIDE

Indications: electrolyte imbalance, also section 9.2.1.2

Cautions: restrict intake in impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema, toxaemia of pregnancy

Side-effects: administration of large doses may give rise to sodium accumulation and oedema

Dose: see notes above

PoM Sodium Chloride Intravenous Infusion, usual strength sodium chloride 0.9% (9 g, 150 mmol each of Na^+ and Cl^-/litre), this strength being supplied when normal saline for injection is requested. Net price 2-mL amp = 28p; 5-mL amp = 31p; 10-mL amp = 33p; 20-mL amp = 69p; 50-mL amp = £1.52

In hospitals, 500- and 1000-mL packs, and sometimes other sizes, are available

Note. The term 'normal saline' should not be used to describe sodium chloride intravenous infusion 0.9%; the term 'physiological saline' is acceptable but it is preferable to give the composition (i.e. sodium chloride intravenous infusion 0.9%).

With other ingredients

PoM Sodium Chloride and Glucose Intravenous Infusion, usual strength sodium chloride 0.18% (1.8 g, 30 mmol each of Na^+ and Cl^-/litre) and 4% of anhydrous glucose

In hospitals, 500- and 1000-mL packs, and sometimes other sizes are available

PoM Ringer's Solution for Injection, calcium chloride (dihydrate) 322 micrograms, potassium chloride 300 micrograms, sodium chloride 8.6 mg/mL, providing the following ions (in mmol/litre). Ca^{2+} 2.2, K^+ 4, Na^+ 147, Cl^- 156

In hospitals, 500- and 1000-mL packs, and sometimes other sizes, are available

PoM Sodium Lactate Intravenous Infusion, Compound (Hartmann's Solution for Injection; Ringer-Lactate Solution for Injection), sodium chloride 0.6%, sodium lactate 0.25%, potassium chloride 0.04%, calcium chloride 0.027% (containing Na^+ 131 mmol, K^+ 5 mmol, Ca^{2+} 2 mmol, HCO_3^- (as lactate) 29 mmol, Cl^- 111 mmol/litre)

In hospitals, 500- and 1000-mL packs, and sometimes other sizes, are available

INTRAVENOUS GLUCOSE

Glucose solutions (5%) are mainly used to replace water deficits and should be given alone when there is no significant loss of electrolytes. Average water requirements in a healthy adult are 1.5 to 2.5 litres daily and this is needed to balance unavoidable losses of water through the skin and lungs and to provide sufficient for urinary excretion. Water depletion (dehydration) tends to occur when these losses are not matched by a comparable intake, as for example may occur in coma or dysphagia or in the aged or apathetic who may not drink water in sufficient amount on their own initiative.

Excessive loss of water without loss of electrolytes is uncommon, occurring in fevers, hyperthyroidism, and in uncommon water-losing renal