STATEMENT OF WITNESS

STATEMENT OF: **WILLIAM RICHARD CROSS** *Name* **D/SERGEANT** *Rank*

AGE OF WITNESS *(If over 18 enter "Over 18"):* **OVER 18**

To be completed when the statement has been written

I declare that this statement consisting of 1 pages, each signed by me is true to the best of my knowledge and belief and I make it knowing that, if it is tendered in evidence at a preliminary enquiry or at the trial of any person, I shall be liable to prosecution if I have wilfully stated in it anything which I know to be false or do not believe to be true.

Dated this 18 day of November 2006

***SIGNATURE OF MEMBER** by whom Statement was recorded or received*

PRINT NAME IN CAPS

SIGNATURE OF WITNESS

I am a Detective Sergeant of the Police Service of Northern Ireland presently attached to a Major Investigation Team, Crime Operations and stationed at Gough, Armagh. On 17 October 2006 at 1000 hrs I was on duty at Grosvenor Road Police Station, Belfast when I met a person whom I now know to be Robert Henry Taylor, date of birth 12/06/1958, a Consultant Paediatric Anaesthetist at the Royal Belfast Hospital for Sick Children. I briefed Mr Gary Daly, a solicitor accompanying Doctor Taylor and after a Declaration of Voluntary Attendance (PACE 10) had been completed by Detective Constable Denise Graham and signed by Doctor Taylor I commenced to interview Doctor Taylor at 1026 hrs. I informed Doctor Taylor that he was not under arrest, that he was free to leave at any time and that he was entitled to legal advice and for that purpose had been accompanied to the Police Station by a solicitor. I ensured Doctor Taylor was aware of the nature of our enquiries and of the purpose of the interview. I cautioned Doctor Taylor in the following words: "You do not have to say anything, but I must caution you that if you do not mention when questioned something which you later rely on in court, it may harm your defence. If you do say anything it may be given in evidence." Doctor Taylor made no reply. I explained the caution to Doctor Taylor. At the commencement of this interview Doctor Taylor read a statement which he had prepared for a Public Inquiry. I marked a copy of this statement WRC 99. The interview ended at 1141 hrs when two tapes selected by Doctor Taylor were

sealed as Master Tapes. One tape recording the interview from 1026 hrs to 1107 hrs was sealed with Master Tape Seal number T0175882A and labelled WRC100, and the second tape recording the interview from 1108 hrs to 1141 hrs was sealed with Master Tape Seal number T0176410A and labelled WRC101. After a break I recommenced interviewing at 1201 hrs and finished at 1327 hrs. Two tapes selected by Doctor Taylor were sealed as Master Tapes. One tape recording the interview from 1201 hrs to 1243 hrs was sealed with Master Tape Seal number T0176411A and labelled WRC102, and the second tape recording the interview from 1244 hrs to 1327 hrs was sealed with Master Tape Seal number T0176146A and labelled WRC103. A break was taken for lunch. At 1508 hrs I recommenced interviewing Doctor Taylor as before. This interview continued until 1634 hrs. Two tapes selected by Doctor Taylor were sealed as Master Tapes. One tape recording the interview from 1508 hrs to 1551 hrs was sealed with Master Tape Seal number T0176147A and labelled WRC104, and the second tape recording the interview from 1552 hrs to 1634 hrs was sealed with Master Tape Seal number T0176148A and labelled WRC105. After a break during which Doctor Taylor consulted with his solicitor another interview took place from 1641 hrs to 1703 hrs when a tape selected by Doctor Taylor was sealed with Master Tape Seal number T0176149A and labelled WRC106. Copies of all these tapes were provided to Mr Daly, solicitor, at the end of the interviews. I informed Doctor Taylor that the facts would be reported to the Public Prosecution Service for a direction on prosecution and Doctor Taylor left the station at 1710 hrs.

DECLARATION OF VOLUNTARY ATTENDANCE ETC

Tape Reference No BD 1612/06 Master Seal No T0175882A.

Interview Notes No _____ Voluntary Record No 'V' BDV 260/06.

District PSNI. Station GRANVILLE RD Date and Time 17.10.06 1012

Reason for Interview MANSLAUGHTER BY GROSS NEGLIGENCE

PART A

I, (name, age and address) DR ROBERT HENRY AULDER [redacted]

DOB [redacted] Occupation CONSULTANT PAEDIATRIC ANESTHETIST

Agree to remain for interview.

Signature [signature]

I, (name, age and address) _____

Parent/Guardian of _____

agree that *he/she remain with the police for interview.

Signature _____

Type of Offence _____ Notifiable Crime *Yes/No

PART B

This part is to be read to the person being interviewed before seeking completion of the certificate below.

PACE 12/2 (Legal Advice) will be given to the person interviewed for retention.

You do not have to say anything, but I must caution you that if you do not mention when questioned, something which you later rely on in court, it may harm your defence. If you do say anything it may be given in evidence. (C10.5)

You are not under arrest. (C3.15A)

You are not obliged to remain at the police station. (C3.15)

If you remain you may obtain legal advice if you wish. (C3.15A)

I have been cautioned in the manner described above *(and been provided with a notice explaining how I may obtain legal advice, C3.16 refers.)
I understand that I am not under arrest, that I am not obliged to remain at the police station and may obtain legal advice if I wish.

*I do not want a solicitor at this time.

*I want a solicitor as soon as practicable, I nominate: MR GARY KELLY PRESENT.

Do you need a doctor, or are you suffering from any illness, taking drugs/medication of any kind? YES/NO

Signature [signature]

PART C

*LEFT THE PREMISES/~~ARRESTED~~ *BEING REPORTED/~~NO CHARGE/FOR PROSECUTION/FOR CAUTION/DEALT WITH BY OTHER MEANS/NO FURTHER ACTION~~

Date 17.10.06 Time 1710 Interviewing Officer [signature]
(BLOCK CAPITALS)

Rank DI No 1829 Signature W Cross.

(Delete as applicable)

POLICE SERVICE OF NORTHERN IRELAND

Police Identification Mark WRC107

SUMMARY OF TAPE RECORDED INTERVIEW

TAPE REF NO:

BOV260/06

Master Tape Seal Number(s):

T0175882A

T0176410A

PERSON INTERVIEWED: ROBERT HENRY TAYLOR

ADDRESS: C/o Royal Belfast Hospital for Sick Children

DOB: [redacted]

PLACE OF INTERVIEW: Grosvenor Road PSNI, Belfast

DATE OF INTERVIEW: 17/10/2006

TIME COMMENCED: 1026 HOURS

TIME TERMINATED: 1141 HOURS

INTERVIEWING OFFICERS:

1 William R Cross, D/Sergeant

2 Denise Graham, D/Constable

3

OTHER PERSON(S) PRESENT:

1 Gary Daly, Solicitor

2

3

MADE BY: D/Sergeant Cross

Tape Number and Tape Times:

T0175882A

0203 Police introduced themselves, explained rights under PACE, explained they were intending to interview on the circumstances surrounding the death of Adam Strain as part of an investigation into manslaughter by gross negligence. Cautioned, no reply. Caution explained

0350 and the reason given as to Dr Taylor being interviewed after caution.

0410 Dr Taylor is invited "to give an account in his own words and time of your responsibilities and the steps that you took in relation to the operation on Adam in November 1995". In reply Dr Taylor read a lengthy statement which he had prepared for the Public Inquiry in a number of child deaths. This document was later exhibited as WRC99. No questions were asked during the reading of this statement. The reading of the statement continues to the end of the first tape at 1107.

T0176410A Dr Taylor continued to read his statement at 1108 after confirming that no questions had been asked while the tapes were being changed and after being reminded that he remained under caution.

1452 Reading of statement concludes. Police explain they will exhibit a copy of Dr Taylor's statement obtained already from the Public Inquiry as WRC99 and do not need to seize the document which Dr Taylor had just read.

1542 Dr Taylor is unable to identify the Ward Nurse mentioned by him on P2 of his statement.

PERSON INTERVIEWED: ROBERT HENRY TAYLOR

Tape Number and
Tape Times:

1602 Dr Taylor is unable to identify the doctor who failed to gain IV access prior to the operation on Adam. He stated it would have been an SHO.

1630 Dr Taylor is asked with whom he discussed the lack of post-dialysis U&E checks. He suspected it was with the surgeons as he did not think Dr Savage or Dr O'Connor had arrived until after the anaesthetic had been started.

1705 Dr Taylor was asked who had informed him that it was usual for Adam's electrolytes to remain stable. He thought it was the nurse who was with Adam that morning.

Discussion followed on possible means of administering anaesthetic and that used for Adam.

1925 Dr Taylor was asked who the "experienced theatre staff" were (P4 of statement). He replied that it was the night staff who had started and then there was a change to the day staff. He explained it was possible, especially for the scrub nurse, that the day staff had been told to start early. Changing the scrub nurse during operation leads to difficulty with the needle and swab counts. It was possible that the delay in starting the operation at 0600 may have been caused by the desire to start with the day shift nurses.

It was Dr Taylor's recollection that Dr O'Connor was present at times.

2205 Dr Taylor was asked regarding the part of his statement in which he said he and/or Dr Montague were present at all times. He explained that he was present for the whole procedure except for a brief comfort place.

Dr Taylor states that the anaesthetic record entries are almost all his. He confirmed that it was possible at times when he relaxed that Dr Montague may have been more involved but states that personally while he could not maintain intense concentration throughout, he did remain involved and aware of all that was happening.

2445 Dr Taylor confirms that the "anaesthetic nurse" was definitely female but he could not recall her identity. Dr Taylor stated that his understanding was that an operation required the presence of three nurses. Dr Taylor explained that the role of anaesthetic nurse would solely have been to assist him in obtaining tubes etc.

2700 Dr Taylor was asked about "visualising the impact on the surgical field" mentioned in P5 of his statement. He explained this meant looking for blood being lost, blood spurting as this would not register instantly on the monitors. It also assisted in seeing swabs being placed on the site of a blood loss as those swabs may not be weighted for perhaps 30 minutes. It was also

helpful to view the colour of the kidney.

2908 Dr Taylor "I have given anaesthetic where the kidney has not worked. Surgeons blame anaesthetists for that. You haven't got enough fluid in, you haven't given in and the impact on us is dramatic. We don't want to be responsible for taking the blame, taking the rap, because for sure they will go back and tell the parent that the anaesthetic did not give enough blood to make the kidney work. They will never say 'I messed up'. That is human nature, that is surgical nature and that unfortunately has happened to me in the past".

3010 Dr Taylor confirmed that he had not previously been so criticised by either Drs Keane or Brown. He explained that Dr Brown was not a transplant surgeon and could not comment on Dr Keane's experience other than to indicate that paediatric transplants were not weekly events.

3115 Dr Taylor explained that visualising the surgical field was important for blood loss, blood colour, general perfusion throughout arteries and veins.

Tape was stopped at 1141 hrs.

POLICE SERVICE OF NORTHERN IRELAND

Police Identification Mark WRC108

SUMMARY OF TAPE RECORDED INTERVIEW

TAPE REF NO:

BOV260/06

Master Tape Seal Number(s):

T0176411A

T0176146A

PERSON INTERVIEWED: ROBERT HENRY TAYLOR

ADDRESS: C/o Royal Belfast Hospital for Sick Children

DOB: [redacted]

PLACE OF INTERVIEW: Grosvenor Road PSNI, Belfast

DATE OF INTERVIEW: 17/10/2006

TIME COMMENCED: 1201 HOURS TIME TERMINATED: 1327 HOURS

INTERVIEWING OFFICERS:

1 William R Cross, D/Sergeant

2 Denise Graham, D/Constable

3

OTHER PERSON(S) PRESENT:

1 Gary Daly, Solicitor

2

3

MADE BY: D/Sergeant Cross

Tape Number and Tape Times:

T0176411A

0300 Introductions made, cautioned, no reply. Caution explained. Purpose of interview explained.

Dr Taylor is asked to explain his role in relation to Adam and the surgeons role in relation to Adam. Dr Taylor explained his role to be:

1. Provide safe anaesthesia;
2. Ensure respiratory system is supported;
3. Prevent inadvertent injuries;
4. Warmth;
5. Provide pain relief;

Administer drugs/fluids to ensure a safe operation;

The surgeons responsibilities are:

1. Perform procedure;
2. Perform it within a reasonable time;
3. Prevent infection by ensuring sterile conditions;

Minimise blood loss;

Dr Taylor stated he could only give an opinion on the surgeons role since he was not trained as a surgeon.

0850 When asked regarding the role of surgeon in fluid management Dr Taylor replied that they

have other duties on which they focus but at times may inform the anaesthetist of blood loss and before they release the clamps they become very aware of the circulation and will question blood pressure and circulation. Generally the surgeons "will expect the anaesthetists to be sufficiently skilled to provide a safe environment for them to operate".

1100 Dr Taylor confirmed that he had no role in deciding where in the body the kidney would be placed or in relation to the arterial and nervous venous connections.

1245 Dr Taylor states he cannot remember any kidney transplant operation in which he was not asked to provide more fluids by the surgeons.

Dr Taylor stated decisions as to which fluids were given are taken jointly "liaison decisions".

In relation to the demarcation of responsibility between Dr Montague and himself, Dr Taylor took full responsibility as this was a difficult case. "I did mostly everything technically with his anaesthetic and was ..... present for ..... the vast element (of his anaesthetic). Dr Montague was there to learn and to help.

1525 Dr Taylor confirms that Dr Savage was responsible for Adam's preparation for surgery.

1544 Dr Taylor was asked for his opinion on Adam's suitability for the operation at that time. He replied that Adam had no acute illness, had no respiratory tract or chest infection, no viral illness and was not unwell. Dr Taylor explained that Adam's general condition of chronic rephrotic syndrome did not make him a perfect candidate. For Adam it was as good a time as any for such an operation.

1 Dr Taylor – "The presence of his native kidneys with this very large output complicated my anaesthetic enormously. It is uncommon for a patient to have the underlying medical condition that Adam had".

1728 Q: "Do you believe that Adam's preparation for surgery was adequate and appropriate"?

A: "At the time and in retrospect I would like Adam to have been better prepared ..... with paediatric anaesthesia there is a compromise to be made ..... we knew from many times on dialysis that his blood chemistry and his water content of his blood were ..... fixed so we could assumptions, do we hurt him with needles or do we assume that this management of dialysis was the same as before ..... I would have liked an intravenous line to have been erected ..... that would have meant that he was not fasting. The fact he was fasting meant we had to back calculate what he should have been given and also his chemistry could have

become deranged in that time, if his sodium had been low ..... hypothetically, at the start of anaesthesia it would have been a factor in the decision to proceed with the surgery".

2200 Doctor Taylor confirmed that there was no overall control in a surgeon, it is teamwork.

2315 Q: "Who was responsible for planning of the fluids"?

A "Me".

Explained the planning is discussed with others.

2500 Dr Taylor was asked who was responsible for implementing the plans that had been drawn up for fluid management. He replied, "Me, with others".

2600 Dr Taylor was asked who was responsible for monitoring the fluid management and he replied "primarily myself". Dr Montague and a nurse will also have a role in this.

2700 Dr Taylor explained the purpose of fluid administration during an operation. In relation to maintenance he explained this referred to water, salts and sugar. He explained children do not have the same access to sugar reserves as adults, that epidurals reduce the stress response and therefore sugar maintenance is more important in children than adults.

3115 Discussion ensued on the range of possible fluids available and Dr Taylor indicated there were few options.

3245 Dr Taylor explained the information which he required in order to plan fluid management and the reasons for this. He had sought the relevant information from the hospital staff, from Adam's mother.

3[illegible] In regard to the administering of the fluids, Dr Taylor confirmed that he was present for the changing of every bag and there was no question of him writing fluid prescriptions for others to implement.

3900 In regard to the equipment which he used, Dr Taylor confirmed that he had used the equipment referred to in the report of Dr Gibson. He had experience in using the equipment, as had Dr Montague and Mr Shaw, the technician. He had checked the equipment personally but this is also done by the technician.

4200 Dr Taylor was asked how the implementation of the fluid management matched the plans which he had made. Dr Taylor stated that he had made his calculations on paper which is not part of the record, there were figures on top of his anaesthetic record.

1243 tapes changed.

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Tape Times:
T0176146A

1244 Dr Taylor confirmed that no questions had been asked while the tapes were being changed and he was reminded that he was still under caution.

Dr Taylor showed from his record that Adam weighted 20 kgs, his intraoperative maintenance was 200 mls/hr, his deficit was 300 mls and his total blood volume was 1600 mls.

0119 These were the basic fluid calculations. He gave the first 500 mls of 1/5 N Saline over 30 mins and started the second bag as he felt he had not yet replaced the deficit at 0740 and was given over the next 1¼ hrs. Other fluids were administered according to blood loss. He stated that the fluid administration did reflect the planning up to the point when ongoing blood loss was problematic and additional fluids were required. The type of fluid was as planned and the quantity was as appropriate.

0530 It was put to Dr Taylor that others had stated the fluid administered, particularly in the early stages of the operation, had exceeded the planned volumes. Dr Taylor replied that to have given the quantities recorded was justifiable and there was no reason for it.

0630 It was put to Dr Taylor that Dr Alexander had stated that a "great deal more fluid was infused" and therefore while his plans had perhaps been appropriate, an excess had been given in practice. Dr Taylor replied that he had been working to a plan, that he knew surgery would lead to blood loss and he wished to cater for these at the start.

0740 Comparisons were made between a previous anaesthetic regime administered by Dr Loan. Dr Taylor - "I agree with Drs Sumner and Alexander that any other child would not have been given that quantity of fluid. Adam was very exceptional and I don't feel that those two individuals really understood Adam. Dr Taylor confirmed that the 300 mls given by Dr Loan

0920 was given over one hour. The knowledge that Dr Taylor had "was that Adam could tolerate very high quantities of this fluid without any loss from his body and recover safely.

0940 It was put to Dr Taylor that the evidence from Dr Loan's anaesthetic was that Adam could cope with 300 mls in one hour. He was asked how that equated to 500 mls in half an hour. Dr Taylor answered "it showed that Adam was not a normal child because normal children should not cope with 300 mls over an hour so I was confident by the previous anaesthetic that Adam was exceptional". Dr Taylor explained that for the previous operation Adam had a drip and therefore there was no deficit to cope with on that occasion. Dr Taylor explained that he needed to address the deficit urgently. He explained that the deficit was for 2 hours fluid and

possibly more since there was a further delay in starting the operation.

1100 It was put to Dr Taylor that the lesson of the previous operation was that Adam could withstand 150 mls in 30 mins and that it was not safe to assume that he could then withstand 500 mls in 30 mins. Therefore the 500 mls in 30 mins was excessive.

1208 Dr Taylor did not accept this since he was dealing with a child who had fasted, potentially had low blood sugar and in the previous procedure had no blood loss and therefore no need to enhance circulation. In Dr Taylor's case he needed to "get ahead of himself" to provide an environment in which there was no deficit. His kidneys were removing fluid and therefore Dr Loan's situation was simpler. Dr Taylor contended he understood Dr Loan's position that Adam could tolerate 300 mls safely without a deficit and a need to increase circulation.

1350 Dr Taylor stood by the position that he had to administer that fluid "jolly sharpish".

1402 It is put to Dr Taylor that he is busiest at the start of the operation as he had to achieve an IV line, a central nervous line and this required multiple attempts and then an epidural had to be achieved. Dr Taylor agreed with this.

1520 Q: "Is it possible ..... that you set up the IV line and the fluid is connected to it and you are busy with your other procedures and half an hour later you see that 500 mls has run straight through and you did not plan to give that quantity of fluid that quickly but you are honest and you record it in the notes any way. Were you shocked to see that had happened or was that a plan.

A: "I can't remember how I felt ... but the fact that I was doing other things would not have distracted me from such an important element of Adam's care ..... I would discount that as a possibility ..... my assistants would also have made me aware ..... I think it was a deliberate need that we felt had to be achieved right away".

1650 Dr Taylor described in resuscitation practice it is common to give 20 ml/kg of fluid instantly and therefore he could not accept that 500 mls was dangerous. Dr Taylor also stated that anaesthetic agents also depress blood pressure and this increases the need for fluids. Also he was not to know exactly when surgery would commence and therefore he had to redress the deficit quickly. Surgery could have commenced within 30 mins. He was not able to know how long the central venous line would take to place.

2150 Dr Taylor explains that a salt based fluid is more commonly used in giving a XXXXX.

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Tape Number and Tape Times:

2210 Dr Taylor – "I can see why other people who have not anaesthetised a child like Adam would fee its unusual. I would not give that to a child other than Adam".

2413 Dr Taylor again stated that his fluid administration was a deliberate act.

2514 Dr Taylor confirmed that the parameters which he measured were heart rate, blood pressure from arterial line, central venous pressure, temperature and oxygen saturation.

2602 It was put to Dr Taylor that he had earlier stated in his deposition that the monitoring showed no cause for concern, whereas Dr Sumner was of the opinion that an initial CVP of 17 was cause for concern. Dr Taylor replied that he did not expect a CVP of 17 but of 8-12. He had re-zeroed the equipment after seeing 17 about 8.00 am. He had confirmed by palpation that the catheter had gone into the jugular. He had observed that he could affect the trace by pressing on the neck and therefore it was not a reliable indicator of fluid volume. Dr Taylor noted that Dr Sumner had said the high CVP was an indicator of excess fluid in circulation but Dr Taylor commented that Adam was still dry at that time and therefore he continued to regard CVP as an unreliable indicator of fluid in circulation. He would use other indicators as well – heart rate, blood pressure, check if veins are dilated and if the wound is moist or dehydrated.

2858 Dr Taylor - "[CVP] is a useful indicator taken in conjunction with the other signs but on its own ..... it is absolutely useless because it depends on where the tip of the catheter is".

Police then asked how much depended on the position of the catheter tip.

2' Dr Taylor replied "massively". Dr Taylor described previous neck surgery and the effect it would have on his procedure. He was therefore not surprised to have seen such a high figure because it did not reflect the blood returning to the heart and was useful as a zero point but not as a measure of fluid volume.

3305 Dr Taylor was not surprised by a figure of 17. He did not confirm that he had seen this in another child. When asked about the higher figure of 21 he did not confirm that he had seen this figure in other children.

3530 Dr Taylor confirms that he accepted the figures of 17 and 21 were accurate measurements at the end of the catheter and that there was no question of equipment malfunction.

3545 It was put to Dr Taylor that others had told police that it was very difficult to achieve a CVP of 21 mm mg in a child because their veins are very distensible. Dr Taylor replied that he

Tape Number and
Tape Times:

agreed but only for measurements of the heart but that he had seen such figures in children

3800 with heart disease. It was put to Dr Taylor again that to achieve a CVP of double the expected CVP at the heart where the veins are distensible was impossible if the blood volume was normal, or nearly normal, no matter where the catheter is placed. Dr Taylor states he has pushed the CVP to 16-17 to ensure a successful transplant. He continued to maintain the position of the catheter was significant in producing such a reading.

3945 Dr Taylor was asked if Adam's position on the table was a contributory factor in producing this figure.

4100 Dr Taylor – "We eliminated the possible antefact ..... reasons why this was not a genuine pressure reading".

4200 It was put to Dr Taylor that the mistake was to give too much fluid too quickly but that what should have alerted him to the mistake was the high CVP reading and this could have allowed him to address the problem. It appeared to police that his response was that a CVP reading of 17 was not an indicator of excess fluid but of the catheter being in the wrong place.

Dr Taylor responded that police view was correct but that the experts had failed to account for the position of the catheter.

At 1327 the interview terminated.

POLICE SERVICE OF NORTHERN IRELAND

Police Identification Mark WRC109

SUMMARY OF TAPE RECORDED INTERVIEW

TAPE REF NO:

BOV260/06

Master Tape Seal Number(s):

T0176147A

PERSON INTERVIEWED: ROBERT HENRY TAYLOR

ADDRESS: C/o Royal Belfast Hospital for Sick Children

DOB: [redacted]

PLACE OF INTERVIEW: Grosvenor Road PSNI, Belfast

DATE OF INTERVIEW: 17/10/2006

TIME COMMENCED: 1508 HOURS

TIME TERMINATED: 1634 HOURS

INTERVIEWING OFFICERS:

1 William R Cross, D/Sergeant

2 Denise Graham, D/Constable

3

OTHER PERSON(S) PRESENT:

1 Gary Daly, Solicitor

2

3

MADE BY: D/Sergeant Cross

Tape Number and Tape Times:

T0176147A

0828

Introductions made. Cautioned, no reply. Caution explained.

Agreed sodium level at 2300 hrs on night before Adam's operation was 139, located in clinical notes at P144.

Put to Dr Taylor that Dr Savage had recorded in the notes (P133) that he wanted the blood tests repeated before the operation. Dr Taylor read the relevant entry from the notes.

Q: "Would you have been aware of that doctor before the operation started"?

0901

A: "Yes".

It was put to Dr Taylor that the operation proceeded until 0930 before the electrolyte test was repeated and Dr Taylor was asked to account for this. He explained his priorities focused on induction of anaesthesia, placing the lines, tubes, drips, epidurals and he needed all his experienced personnel in theatre to monitor Adam. To have done a blood test would have involved absenting an important team member during the early part of the operation.

Dr Taylor explained that in 1995 the blood gas machine gave an approximately reading for electrolyte but not a reliable one. He explained that at present a nurse could do a blood gas analysis but in 1995 this was not possible and required an anaesthetist or possibly a medical technician to operate it. It was not until 0930 that a person could be released from theatre to check a blood gas sample.

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1135 When asked how long such analysis would have taken Dr Taylor replied, "5 mins" and a lab sample would have taken 30 mins to arrange.

1217 Dr Taylor confirmed that at the start of the operation he was aware that the electrolytes had not been checked but as a priority, other things relating to Adam's safety took precedence.

Dr Taylor then proceeded to argue that he had no reason to suspect an unusual loss of

1600 sodium as for years of dialysis it was known what Adam's salt loss was (29-52 units in urine).

1630 He also knew that Adam could not cope with a sodium load as other children may and as the 'experts' thought and salt poisoning was a possibility because Adam's underlying condition "congenital nephritic syndrome". Adam had passed 200 mls/lm of urine for 4 years and this contained 30 mmls of sodium. This was a key fact which perhaps our experts had missed.

1754 To have given normal fluids containing sodium would have been "catastrophic".

Police asked then if Dr Taylor had commenced the operation on the assumption that the blood sodium had remained at 139 mmls/litre? Dr Taylor replied that was not quite true because his research of Adam's case indicated that his blood sodium did vary and at a time

1940 had been 124 but was usually 130-140. Dr Taylor was safe to assume that Adam could tolerate swings in his sodium.

2023 Police asked if it was safe to make this assumption, why would Dr Savage have asked for the tests to have been repeated? Dr Taylor replied that doctors liked blood tests but it was not a priority to Dr Taylor as he focused on the anaesthetics.

2[illegible] It was put to Dr Taylor that Dr Sumner an anaesthetist was of the opinion that electrolyte measurement was mandatory. Dr Taylor replied he would have neglected Adam by leaving him improperly monitored while having such a test done. If enough staff had been available a different course of action may have been taken.

2445 Police put to Dr Taylor the possibility that there was a difference in this case to previous operations in that overnight his normal feeding had been discontinued and 900 mls of dioralyte (the same dehibe fluid) given and this may have depressed Adam's blood sodium.

In talking to Adam and his mother Dr Taylor had not suspected a pre-operative hyponatremia.

2800 It was again put to Dr Taylor that there was a possibility that giving a child of Adam's weight 900 mls of dioralyte would depress his blood sodium. Dr Taylor replied by stating that we failed to understand the effect of Adam's high urine output and his inability to retain fluid.

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Tape Number and
Tape Times:

When pressed further he referred to previous years of stability and stated that he would not have expected the fluid regime to lead to harm. It was again put to Dr Taylor that in the past Adam had been given Nutrazon, not dioralyte and the regime is not different and therefore what had been seen demonstrated in the past could not be expected to be repeated in

3030 November 1995. Dr Taylor referred to the times, not specifically identified, when Adam's feed would have been stopped due to vomiting or diarrhoea and he would have been given dioralyte, without coming to harm.

3140 Police put to Dr Taylor that it was now common knowledge in the population was that hypotonic solutions if enough is taken, will depress the sodium concentration. This was advice given to marathon runners. Police were therefore putting to Dr Taylor that overnight until 0600 Adam was given 900 mls, then nothing for 2 hours and then 500 mls in the next 30 mins, making a total of 1400 mls and in the next 1¼ hrs he got a further 500 mls.

Police then asked again if that quantity of dilute saline could have been responsible for

3240 depressing his blood sodium. Dr Taylor responded by describing the difficulty in investigating the theory of dilutional hyponatremia: there has never been a "double bind" research trial nor ever will be, therefore we rely on descriptive studies and the Aruff study related to healthy children. For the dilutional hyponatremia theory to work intact kidneys were required which in periods of dehydration shut down and retain water. This was the mechanism in the deaths of Raychel Ferguson and Lucy Crawford who had passed small volumes of concentrated urine, retaining free water while losing sodium and hence suffered dilutional hyponatremia. It was

3440 impossible for Adam to suffer from dilutional hyponatremia contrary to the view of the Coroner and the experts because he could not concentrate urine. Therefore Adam could not fit Dr Sumner's theory.

3625 Police asked Dr Taylor if he was saying that if fluid was put into Adam his blood sodium could not be affected by diluting his blood because he was losing so much urine. Dr Taylor replied by saying that was not quite what he had said. He stressed that dilutional hyponatremia was only a theory, that cases had been described but only in children with intact kidneys.

Dr Taylor said that police were suggesting a different but possible theory but it was different to the theory dilutional hyponatremia due to he had retention of water. Dr Taylor agreed that dilution of sodium by adding water was possible. Dr Taylor contended that the losses of fluid

due to Adam's kidneys and surgery would have required "vast quantities of water" to dilute the sodium in his body but this was theoretically possible.

3830 It was put to Dr Taylor that the damage was done by diluting the sodium in Adam's blood alone, not in the cells. Dr Taylor denied this, saying that osmosis would equalise the concentrations. Police suggested that if the first instance the blood was diluted by the fluid and it was in the attempt to equalise that cerebral oedema occurred. Dr Taylor stated that in Adam's case we failed to account for the fact that he was losing as much fluid as was being infused. Police asked if this was true since he had administered 500 mls in 30 minutes when Adam was losing 200 mls/hr. Dr Taylor then contended that it was possible that if Adam was given 500 mls he could pass 500 mls in urine. No-one knew what his maximum output was, only that his minimum output was 200 mls. Dr Taylor's knowledge of the disease was such that he believed Adam could pass an unlimited amount of fluid. No one had established a maximum output for Adam.

4200 Police asked Dr Taylor if it were possible that Adam's potential for urinary output was higher than had been measured, what may have been the mechanism that produced the reduced sodium figure of 124 at 0932 hrs. Dr Taylor stated he wished he could explain it but referred to low sodium figures previously in Adam's history and asked what may have caused them. He stated that the theory of dilutional hyponatremia was improperly applied to Adam and involved making the diagnosis for a known disease. He stated there was no evidence that a child like Adam could get dilutional hyponatremia, it was known that his sodium varied, that due to good care and attention from his mother that he could maintain a stable course with the odd rogue result. Dr Taylor stated also that the sodium result from the blood gas analyser was not necessarily accurate.

At 1551 the tapes were changed.

T0176148A At 1552 the interview continued.

Dr Taylor referred to the history of the use of blood gas analysers. This led to his belief in the unreliability of blood gas results, depending on the use of heparin. Dr Taylor confirmed that a laboratory analysis of blood at the end of the operation produced a result of 119 for blood sodium, from blood taken at 1130 hrs.

0622 Dr Taylor confirmed that when he got a figure of 124 at 0952 he took action to address the

low sodium by reducing the amount of No 18 fluid. Dr Taylor agreed that in spite of his actions at 1130 the sodium level was even more depressed.

0745 Police reviewed the position that at 2300 hrs the sodium was 139, that we do not know how or when it began to fall but 12 hours later it is 119. These are accurate results. Police asked Dr Taylor to explain what had happened in those 12 hours to reduce sodium from 139 to 119.

Dr Taylor replied that he did not know. He stated dilutional hyponatremia did not occur.

0930 Dr Taylor stated it was known that when patients are sick and near death their sodium levels drop and there is

1312 Police put to Dr Taylor that it appeared to them that if Adam is losing 200 mls/hr and you are giving him 500 mls in 30 mins you achieve a dilutional effect. There was no proof that Adam could pass more than 200 mls urine/hr and it was possible to achieve a dilutional hyponatremia in that time span. Dr Taylor said he had given other children similar quantities and none had died or shown ill effects and many paediatric doctors would concur. He maintained that many children had received similar fluids to Raychel Ferguson, Lucy Crawford or Adam Strain and had come to no harm and he failed to see how people can say the fluids were the cause.

Police put it to Dr Taylor that while the Chief Medical Officer had taken a similar view to him in stating the response to fluids was an aberration in the case of an individual child, while Dr Sumner maintained that if any child were given the same fluid in the same time span, they will react similarly and suffer terminal cerebral oedema. Dr Taylor maintained that Arieff and other experts believed the reaction was idiosyncratic, happening to some and not others. He stated that Arieff had stated the response was unusual, unheralded and unpredictable.

1605 Police put to Dr Taylor that Dr Sumner had stated that in an operation of this complexity it was standard to take a blood gas result as soon as vascular access was achieved to obtain a baseline figure for electrolytes. He then stated in an operation of this length that it was expected further levels would be sought in the middle and at the end of the operation. Dr Taylor replied by referring to his previous response relating to his priorities at the start of the operation.

1700 Police asked Dr Taylor what he meant by saying in his deposition that it had not been practical to carry out electrolyte tests at the commencement of surgery. Dr Taylor stated that

he assumed this referred to the difficulties in getting samples to the lab – this would take between 1-3 hours and before the result was received it was out of date.

1740 Police asked Dr Taylor regarding his deposition comment that the blood gas result at 0930 where he said that there were no indication of problems and that the conditions likely to precipitate osmatic fluid shifts were not present. Police showed the relevant sections to Dr Taylor. In relation to his comment that there were no problems was a reference solely to the blood gases and the conduct of the anaesthetic in that it confirmed that he was being well ventilated and there were acid problems. In relation to the osmatic problems, Dr Taylor stated this referred to Adam's albumin levels which is abnormal, can lead to osmatic shifts. No dilutional effect involved. Often in patients who die, a pre-morbid test will show a fall in sodium, so just before you die your sodium can be very low. That does not mean that you have been given too much water. No-one will ever know what happened to Adam but I am strongly of the view that it cannot have been dilutional hyponatremia.

1055 Police put to Dr Taylor that the Coroner's verdict was dilutional hyponatremia that Dr Sumner concerned, as did Dr Savage and although police were not at the Inquest, it was

1215 probably that other medical experts had agreed with this verdict. Dr Taylor replied that he was frustrated since when he spoke to Dr Sumner and Dr Savage outside the Inquest they both acknowledged that the cause of the paper (?) hyponatremia could not have happened to Adam and yet in court they said that it did.

Police suggested the comment appeared more to refer to the blood gas at 0930 and the low sodium level ought to have highlighted that there was every likelihood of an osmatic shift.

2240 Dr Taylor repeated that the advice at that time was that they should not rely on blood gas results for sodium, in particular because of the method employed which used heparin.

Police asked since the sodium level produced by the blood gas analyser was markedly down on the previous result, if Dr Taylor had taken any action to confirm the result. Dr Taylor explained that to send blood to the lab was problematic and would not have produced a result until after the conclusion of the case. At the time he had other responsibilities as the kidney was being perfused.

2600 Police put it to Dr Taylor that in a child of Adam's size, a drop in sodium of that magnitude, in that time span, was likely to be fatal and that he should have known that. Dr Taylor replied

that firstly the figure of 124 was unreliable, secondly that he had been at a level of 124 before without problem. Police put it to Dr Taylor that it may be the case that it may be possible to have sodium levels as low without ill effect, if the low level was reached slowly but the rate of change was as important as the magnitude of the change. Dr Taylor described some of the other medical events and explained the anaesthetic protects the brain. Dr Taylor agreed with the police suggestion for a patient who was not anaesthetised, as a sodium drop would produce symptoms. He stated that even in his anaesthetised state, Adam should have displayed some evidence of hyponatremia symptoms but had not. Dr Taylor stated he was at a loss to associate the change in sodium with any clinical deterioration.

Police asked Dr Taylor if he had been distracted at 0930 by other aspects of the case and had missed the significance of the lowered sodium result and was not addressed. Dr Taylor denied this He stated he gave blood and this would have the effect of raising blood sodium, he gave HPPF which contains some sodium (although Dr Sumner had chosen to say there was no sodium in HPPF, perhaps to fit this theory), he had reduced the rate of flow of 0.18% saline and the sodium solutions which he had given to Adam were there in sufficient quantities to correct the measured low sodium. Dr Taylor asserted he was aware of the low sodium and took steps to address "diluting hyponatremia" (accepting the point police had made) as opposed to "dilutional hyponatremia".

3115 Police put it to Dr Taylor that if he had taken steps to address the low figure he must have recognised that whether 124 was an absolute figure or not there was a possibility of the sodium being low and needed to be addressed. Dr Taylor agreed.

3128 Police asked if Dr Taylor had taken any further tests to confirm if the remedial action was effective. Dr Taylor stated he did not until the end of the case because in his list of priorities checking the result having taken corrective measures was less important.

3215 Police confirmed that Dr Taylor had referred often to blood loss as 1411 mls and Adam's total blood volume is 1600 mls. Dr Taylor confirmed that this represented a significant blood loss. It was put to Dr Taylor that Dr Keane had told police there was very little blood loss.

Dr Taylor stated he kept contemporaneous records of blood loss. It was agreed that both the record and his recollection confirmed significant blood. Dr Taylor stated the sometimes surgeons sometime try to suggest there has been less blood loss.

PERSON INTERVIEWED: ROBERT HENRY TAYLOR

Tape Number and
Tape Times:
3545

Police put to Dr Taylor that it had been alleged to police that the surgery in this case was inappropriate and incompetent and that had complicated Dr Taylor's task. Police asked if it was the case that the surgery had been poor but they had left Dr Taylor to "carry the can". Police reminded Dr Taylor and he agreed that he had said earlier that he had been blamed in the past by surgeons for failures that were not his fault. Dr Taylor commented on blood loss and the efforts he had made to get it right for Adam and it was his role to cope with blood loss. Dr Taylor confirmed that the blood loss encountered in Adam's operation was not unexpected and he had ordered 4 units of blood for the operation but had used 2 units.

1634 tapes changed.

POLICE SERVICE OF NORTHERN IRELAND

Police Identification Mark WRC110

SUMMARY OF TAPE RECORDED INTERVIEW

TAPE REF NO:

BOV260/06

Master Tape Seal Number(s):

T0176149A

PERSON INTERVIEWED: ROBERT HENRY TAYLOR

ADDRESS: C/o Royal Belfast Hospital for Sick Children

DOB: [redacted]

PLACE OF INTERVIEW: Grosvenor Road PSNI, Belfast

DATE OF INTERVIEW: 17/10/2006

TIME COMMENCED: 1641 HOURS

TIME TERMINATED: 1703 HOURS

INTERVIEWING OFFICERS:

1 William R Cross, D/Sergeant

2 Denise Graham, D/Constable

3

OTHER PERSON(S) PRESENT:

1 Gary Daly, Solicitor

2

3

MADE BY: D/Sergeant Cross

Tape Number and Tape Times:
T0176149A

Introductions made, cautioned, no reply.

Caution explained. Agreed Dr Taylor had been allowed time to consult with his solicitor.

Police informed Dr Taylor that it had been alleged to police that the donor kidney may have been infracted before transplant. Dr Taylor was asked if he was aware of any discussions during the operation to that effect.

Dr Taylor stated he had no role in a decision to use or not to use a kidney but he was aware that the kidney did not "pink up" easily and the impact on Dr Taylor was to re-assess his fluids and worry that he was still in deficit and despite his best efforts that he had failed to increase the blood volume enough to perfuse the kidney.

0450 Dr Taylor could not recall if the new kidney produced urine.

0550 It was put to Dr Taylor that Adam's mother was clear that no consultant spoke to her before the operation. He maintained he would always speak to the parents and in this case it may have been in the anaesthetic room. His recollection was not certain, other than that he definitely spoke to her in theatre.

0650 Dr Taylor was asked to account for the differences in his fluid calculations between his deposition and his statement to the Public Inquiry. He was unable to specify why this had happened. If he had to rely on figures he would use his own figures from the anaesthetic

chart.

0820 Police asked why he had reviewed his deficit figure from 300 mls to 400 mls. He based this on figures from the pre-operative fluid chart, having seen there was a deficit of 2 hours as opposed to 1½ hours.

0850 It was put to Dr Taylor that Dr Sumner's figure for fluid deficit was very different – 160 mls. Discussion ensured re the origins of the various figures. The fluid management was based on Adam's usual night time physcology, not average figures for a day.

1045 Police asked if Dr Taylor had at one time used a figure of 150 mls/hr for maintenance and had later changed this to 200 mls/hr. Dr Taylor based 200 mls/hr on Adam receiving 200 mls/hr over an 8 hr period at night and he tried to mimic the night time regime.

1300 Police suggested the effect of changing the figures was to reduce the apparent excess in fluid infused by 500 mls.

1450 Police showed Dr Taylor his deposition and pointed out where he had mentioned many parameters to the Coroner but had failed to mention the sodium result. Police asked if that was a conscious decision to divert attention away from hyponatremia having led to cerebral

1834 oedema. Dr Taylor denied this. It was put to Dr Taylor that a sodium of 124 was a significant figure but was not mentioned in the deposition and that is because Dr Taylor knew it was significant and avoided mentioning it.

1850 Dr Taylor stated that he knew sodium played an important role, that he was aware of Dr Arieff's paper, had worked with a Toronto doctor who was on Arieff's references but he did not believe dilutional hyponatremia was the cause of death and he had looked for all other possible causes of death because hyponatremia is an unusual cause of death. More common things happen such as problems with the anaesthetic machine, wivy gases, increased blood loss. Hyponatremia had been raised by others but he remained

2010 unconvinced.

Dr Taylor had many patients in intensive care whose sodium is low at the time of death, whether that was the cause of death or the result of a dying process is debatable. He

2045 acknowledged that hyponatremia was present but not that it caused his death.

Police put to Dr Taylor that he had said in a letter to a solicitor that 0.18% saline was isotonic, when in effect, its effect once infused is hypotonic. Dr Taylor stated that depended on the

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Tape Times:

metabolism of the patient, depending on how quickly he burned the glucose. Dr Taylor explained that Adam did not need too much glucose as the body burns less under anaesthetic. This enhances the ability of the fluid to remain isotonic. This was another reason for the theory of dilutional hyponatremia to be inapplicable – none of Arieff's patients had died on the table, they had all died post-operatively.

1703 interview terminated.

WRC 99.

Witness Statement Ref. No. 008

NAME OF CHILD: Adam Strain

Name: Robert Taylor

Title: Consultant Paediatric Anaesthetist

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]
Same as above

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

1997-98, Provision of Paediatric Surgical Services Working Party,
30th September 1997. Regional Working Group on the care of Acutely Ill Children; Sub-Group on Paediatric Intensive Care
1997-2005, Local Advisory Paramedic Steering Committee,
1997-98, EH&SSB Working Party on Meningococcal Disease,
1999-2005, Sick Child Liaison Group,
Sept 2001-Jan 2002, Hyponatraemia Working Party, —
2002, Paediatric Long-Term Ventilation Working Party,
Jun 2003-Feb 2004, Neonatal/Paediatric Interhospital Transport Working Party,
2003-2005, Chairman Clinical Audit Committee, RGH Trust
2002-2005, Member Clinical Ethics Committee, RGH Trust

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

011-005-035,036	Statement to Coroner 30.11.95	(same as 059-067-155/156)
011-017-108-121	Deposition at Inquest 21.06.96	
059-004-007	Note to Mr Brangam	
059-009-028	Note to Mr Brangam 07.06.96	
059-036-071,072	Letter to Dr Murnaghan 08.05.96	
059-053-108	Letter to Dr G Murnaghan 02.02.96	
059-012-031,032	Fax to Mr Brangam 07.06.96	

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

Ref:	Date:	
011-005-035	30.11.95	Statement
011-017-108	21.06.96	Deposition at the Inquest on Adam Strain
		Transcript of oral evidence at the Inquest on Adam Strain

508

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

1. Describe in detail your role in the preparation for the transplant surgery on Adam, including:
(i) meetings with other medical personnel
(ii) information sought and provided to other medical personnel; and
(iii) calculations made.

(i) I was on call for RBHSC – Friday, Saturday & Sunday, which was a typical busy weekend. Prof Maurice Savage phoned me on Sunday night 26th November 1995, to inform me that a Renal Transplant was scheduled on Adam Strain for early next morning. I was informed that Adam retained his native kidneys. I suggested coming in to assess him, but we concluded that relevant information could be given by phone and that I would be required to start case at 06.00 hrs next morning (058-003-005). This meant leaving home at 05.15 hrs on the 27th November 1995, to prepare the patient, drugs and perform my pre-anaesthetic equipment checks.

During this phone call pre-transplant information was given and my many questions were answered (058-002-002). However I knew I would have to make a more detailed examination of the medical records and Adam before embarking on the transplant anaesthetic. It was agreed that this would be best done early the following morning. I asked for 4 units of blood and to check FBC/U&E, etc, fasting instructions, and a request to erect IV fluids at the usual maintenance rate. The next morning, on 27th November 1995 I was told by a ward nurse that blood tests and IV fluids were not done because of poor venous access and repeated attempts had caused Adam to be upset. At about 05.45 hrs I met with Adam and his mother and reviewed all available information pre-operatively. I now discussed the effect of having no post-dialysis, U&E results and the impact of no intravenous fluids for the fasting period of the previous two hours since his night feeds were stopped with Dr Montague. I reviewed his fluid balance sheet (057-010-013) and noted that he was to have received 200 ml/hour of oral fluids (I think this was by artificial feeding tube). In actual fact Adam had received in excess of this 200 ml/hr which suggested to Dr Montague and myself that he was capable of tolerating rates of fluid in excess of the normal amounts because of his underlying high-output renal failure.

This meant that we had to make several unusual fluid calculations (see below). I also checked his most recent blood test results from 23.00 on the 26th November which indicated a sodium value of 139 mmol/l and a Haemoglobin of 10.5 (058-035-144). Although I noted that he did have a sodium of 124 mmol/l on one occasion without apparent ill-effects I was informed that it was usual for Adam's electrolytes to remain stable following dialysis for 24 hours as demonstrated in a summary of his biochemistry results in 1995 (058-041-187-224). It was clear that Adam produced very dilute urine with a sodium content of 29-52 mmol/litre as seen in a summary of his urine biochemistry results from 28th November 1991-5th December 1991 (050-018-055) and again confirmed in a test done on the 14th December 1991 (050-018-051) which meant that he was unable to cope with a high sodium load.

008

gas needle

Particular areas of interest (Contd.)

(ii) I then sought information on Adam's previous anaesthetic management. He had undergone a shorter procedure on 18th October 1995. I examined the anaesthetic record (058-025-069 to 074). This indicated a brief summary of significant medical history and of note he was distressed on arrival in theatre. The anaesthetist (Dr Loan) recorded that "much better co-operation when IV induction offered". Otherwise there were no difficulties noted with his anaesthetic management. I noted the size of the endotrachael tube (4.5mm) and that a butterfly needle was used to induce anaesthesia in the left ante cubital fossa. Although there were no fluid calculations performed on this, I noted that 300mls of "1/5 NSaline/4%" were given over approximately 1hr.

No other fluids were administered and no blood loss was recorded. Adam appeared to have recovered well and uneventfully from this surgery. His heart rate and blood pressure appeared to follow a "standard course". I checked recent medical history, drug history, whether he was allergic or sensitive to any medications, and his most recent evaluation of fluid and electrolyte status. I therefore had to make a decision about further delaying surgery to gain IV access and blood tests against prolonging the "cold ischaemic time" of the donor kidney.

The decision to delay surgery to the morning was to ensure that the operating room staff were not too exhausted, that new day staff would be coming on duty, that a Paediatric Intensive Care bed would be available. Also, that an emergency theatre would not be "blocked" by a semi-elective case. In our hospital, only one operating theatre is available at nights and weekends. There were therefore many complex, inter-dependent factors that made it difficult to determine when the optimum conditions existed for Adam's transplant to take place. In close discussion with the nursing staff in PICU, Theatres, Nephrology Ward and Mr Keane, a "team" decision was made to go ahead with the kidney transplant on Adam at about 0700hrs on 27th November 1995.

(iii) From about 0630 or 0640 I spent some time with my experienced senior registrar, Dr Terence Montague, calculating the dose of anaesthetic drugs and fluids. We double checked the syringes and fluid bags with each other and agreed on their accuracy. The drug calculations were made on standard text-book dosing schedules. The need to replace fluid deficit is calculated on the known urine and insensible losses and it was agreed that there was an urgency to replace this deficit so that Adam did not become dehydrated or suffer from low blood circulation prior to transplant. We knew that Adam was unable to concentrate urine by the natural hormonal influences, Anti-Diuretic Hormone (ADH) and Renin-angiotensin. Therefore we needed to provide at least 200mls per hour of similar fluid to his renal losses. The concentration of sodium in his urine was low, 29-52 mmol/l (050-018-055) and replacement for this was most closely represented by the 0.18 NaCl/ 4% Glucose fluid (sodium = 30 mmol/l). This then required 400mls to replace his 2hr fasting deficit and a further 200mls for his first hour of surgery or 600mls in the first hour. There was also the need to replace any ongoing losses of blood initially with crystalloid. We agreed that we would keep a close watch on blood loss and replace such losses with a ratio of 3mls crystalloid to 1ml blood loss. This was a well established ratio used by anaesthetists worldwide at that time. We also recognised that there would be the need to replace the type of fluid lost by the body by that type of fluid which it most closely resembled, i.e. replace water with water, salt with salt and blood with blood.

008

4/kg/hr.

Particular areas of interest (Cont'd)

In summary, pre-operative fluid calculations were:-

1. Replace fluid deficit (mainly dilute urine) 2hrs @ 200mls = 400mls total
2. Provide fluid maintenance requirements each hour in theatre, i.e. 200mls = 200mls/hr
3. Replace any blood loss by monitoring swabs and suction and replace blood with crystalloid in a ratio of 3mls crystalloid to 1ml blood loss. This would also include blood products when indicated in a ratio of 1ml for each ml of loss.
4. Further fluid management would depend on BP, HR, CVP and organ perfusion
5. The need to ensure that Adam's blood volume was certainly not deficient BUT with careful monitoring was actually increased in order to adequately perfuse the new, adult sized donor kidney.

2. Describe in detail the course of the transplant surgery, including:
(i) your own actions;
(ii) tests requested and results received;
(iii) results received from monitoring; and
(iv) condition of Adam at the completion of the surgery.

Chart Nyto Staff, then charge.

(i) In a long case lasting over four hours, it is not possible to provide patient safety with a single anaesthetist. I only agreed to provide general anaesthesia for Adam with an experienced senior registrar, Dr T Montague, experienced theatre nursing staff and the ready access to experienced surgeons, and nephrologists who were in theatre dress and present beside me in theatre for large parts of the procedure. S/O'C

who? K/B

✓ all by Dr T.

Therefore, my actions are as a team member and a team leader (for anaesthesia). Dr T Montague and/or myself were present with Adam in theatre at all times. The degree of vigilance and personal comfort cannot be provided by a single individual.

who?

I cannot remember the exact reasons why Adam's surgery did not start at 06.00 as originally planned. I can only speculate that it took a considerable amount of time to work out an agreed management plan and review previous notes despite my very early attendance at the hospital that morning. At 07.00 I worked closely with Dr T Montague and the anaesthetic nurse to induce anaesthesia and provide all the technical skills necessary to secure the airway, breathing, access to intravenous lines, arterial access, central venous access and epidural catheter placement. I am dependent on my statement (011-005-035,036) when I report that Adam was anaesthetised "without undue difficulty". We continued to record the anaesthetic drugs and procedures on the appropriate chart (058-003-005).

must be 3 nurses.

?

(ii) The IV fluids were reassessed several times during the first hour. The total fluid now needed
& during the 1st hr was 400ml (deficit) + 200 ml current hrs maintenance giving an total of 600 mls.
(iii) Therefore the first 500mls (being 1 bag) of 0.18NaCl/4% Glucose was increased to be completed in the first half hour and a second bag (500mls) to make up that volume and type of fluid lost by the kidneys ie approximately 600-700 mls given in the first hour.
During the second hour ie 08.00-09.00 of surgery the blood loss from Adam's swab count (058-007-020,021) became the crucial factor in relation to his fluid management. The computerised record (058-008-023) indicated that the Central Venous Pressure (CVP) was being recorded from 08.00. This means that the anaesthetic tasks were complete and the operation could begin from that time.

093-035-110d

008

Particular areas of interest (Cont'd)

No time-line was present on the swab count form (058-007-020,021) nor was there a time-line of blood volume lost in the suction or spilled on to towels. We noted that initially the swabs were light, i.e. 6-10gms (net wt recorded) but this increased with several heavier swabs including one of 67gms (equivalent to 67mls). It was becoming clear that about 200 mls of blood was lost in the swabs in the first hour plus a similar amount in the suction bottle and on the towels; about 600 mls in total. We were concerned about this loss and together with others present, decided to commence a second fluid infusion of Human Plasma Protein Fraction (HPPF) which had a similar electrolyte profile to the type and quality of fluid being lost. HPPF contains 130-150 mmol/litre of sodium as well as albumin which is retained in the blood circulation and is used as a blood volume replacement.

8-09

This HPPF, 400mls was administered over the second hour of surgery. Towards the end of the second hour of surgery, we had therefore given 1000mls of 0.18NaCl/4% Glucose and 400mls HPPF, giving a total input of 1400mls and a loss exceeding 500mls of blood and urine lost by Adam's native kidneys. We were reasonably satisfied toward the end of the 2nd hour of surgery that the renal losses were now adequately replaced and therefore erected a 3rd bag (500 mls) of 0.18NaCl/4% Glucose to be given at a much reduced rate, over the following two hours twenty minutes to maintain the loss of dilute urine by Adam's native kidneys. This infusion of glucose containing fluid was also needed to provide sufficient sugar for Adam's metabolic requirements. It is well recognised that epidural anaesthesia reduces the "stress-response" to surgery. This can limit the increased blood sugar normally seen in patients undergoing general anaesthesia and surgery. All aspects of the anaesthetic were reassessed throughout the 2nd hr and in respect of fluids another type of fluid, Hartmann's solution (Sodium content 130 mmol/litre) was commenced near the end of the 2nd hour of surgery. This is a much more usual type of fluid given to patients under anaesthetic for maintenance of fluid and electrolyte requirements but does not provide glucose needs. Hartmann's solution was given over the remaining two hours fifteen minutes of surgery. This fluid was provided to "preload" the new kidney so that there would be sufficient fluid for its function. A review of his BP and HR at the end of the 2nd hr of surgery indicated a stable BP 90-95 mmHg systolic, and a HR initially of 140 settling to 110 associated with the initial dose of atropine wearing off.

The computerised record (058-008-023) indicated that Adam's Central Venous Pressure CVP was initially 17 mmHg at 08.00hrs and had risen to 20 mmHg at 0900 hrs a modest rise of 3 mmHg after 2 hours of surgery. Although the initial CVP of 17 is higher than normally expected (8-12 normal range), we concluded that the tip had curved upward into the neck vessels as confirmed by compression. Therefore, as indicated in my statement (011-005-035,036), we accepted the 17 mmHg as a marker to look for a relative change rather than an absolute level. It is usual practice to increase the CVP by 5-10 cms above the initial level to ensure adequate blood flow to the new or donor kidney. We concluded that the CVP was of value as a relative measure of venous pressure rather than an absolute measure. When continuously re-assessing Adam's fluid replacement we used all the information available from the anaesthetic monitors as well as visualising the impact on the surgical field.

By the third hour , 0900 – 1000hrs (058-003-005), the blood loss was continuing and Adam's blood pressure, CVP and general status indicated that we may still require further fluid to be administered. We were moving to a stage when more blood products were now appropriate. During the third hour 0900 – 1000hrs, the blood loss continued in all three areas, swabs, suction

008

Particular areas of interest (Cont'd)

and towels. A blood gas analysis was taken at 09.32hrs which confirmed, good gas exchange and acid base balance, an estimated haemoglobin of 6.1 and a sodium of 123mmol/L(058-003-003).

This result led to an immediate re-appraisal of the blood loss and a unit of packed red blood cells was given over the following hour to replace the measured blood loss. This blood test suggested that the fluids administered so far had maintained the blood volume necessary to tolerate the imminent connection of the donor kidney. The saline/glucose infusion was further reduced following this blood test to stop any further reduction in the serum sodium and only fluids containing sodium at 130 mmol/l or greater were administered in addition. We were aware that Adam had sodium levels as low as this previously without any ill effects (058-041-187 to 224).

The new kidney was in place toward the end of the 3rd 10:00 hour of surgery. This can be interpreted from the anaesthetic record (058-003-005) as being the time when Prednisone and Azothiaprone were given under the direction of Dr O'Connor. This was another opportunity for the team to review the fluid management, blood loss and general status of the new kidney. In that review it was clear that the appropriate amount of fluid was being delivered ie;

1. 1100 mls of 0.18NaCl/4% Glucose had been given to replace the amount lost by Adam's native kidneys and provide maintenance sugar requirements (5 hrs@200 ml/hr=1000mls).

2. 800 mls of HPPF and 250 mls of Blood had been given to replace that lost in swabs, suction and towels and to help to restore the low Haemoglobin.

3. Hartmann's solution was commenced to maintain the CVP and provide the new kidney with sufficient preload to ensure its function. The sodium and electrolyte content of this fluid is physiological and therefore appropriate for the function of the donor kidney.

The fluids were again reassessed during the 4th 10 - 11:00 hour of surgery. They included 0.18 NaCl /4% glucose at 200 ml/hour for renal losses, HPPF and Packed red blood cells for replacement of blood loss and Hartmann's solution at 200 mls/hour to support preload for the new donor kidney. The estimated losses from Adam's circulation were noted in his swab count record (058-007-021);

1. Swabs weighed 411 mls
2. Suction bottle 500 mls
3. Towels "heavily soaked" 500 mls

My anaesthetic record finishes at 11.00 indicating that the surgery was completed. However there was a further 30-40 minutes when Adam was being prepared for transfer to PICU. The computerized record clearly shows that HR and BP monitoring continued until after 11.30 (058-008-023). Thus the total anaesthetic time was 4 hours 30 minutes.

(iv) It was therefore a terrible shock to me and all those present when Adam did not wake-up when his anaesthetic was switched off. Throughout the kidney transplant there had been no episodes of instability in his breathing or circulation or neurological state. In fact when his anaesthetic record was reviewed immediately after surgery it appeared very stable with no unexplained episode of low heart rate or blood pressure or oxygen levels. I printed off a computerised record of his actual recordings to re-examine in greater detail any possible adverse episodes which may have been overlooked (058-008-023).

6½ hrs in surgery
(need 200 ml/hr
1000 ml needed)
+ 300 lost 1300
2 hrs pre-op

normally 2 l/day 2000 ml
+ 1000 ml urinary output

0058

Particular areas of interest (Cont'd)

even at 28% extra 14.5%
or 24.5% at 40%

I also re-examined his losses from the surgery and took account of the measurements taken (swabs and suction) as well as an estimate of that lost in the towels and on the floor. In particular there was no sign that inappropriate or excessive fluids had been given for Adam's complex surgery and pre-existing medical problems. The blood sugar test performed at the end of surgery was 4 mmol/l. This is a low normal level. If I had not provided the same quantity of glucose as I had done then there would have been a serious risk of Adam developing hypoglycaemia.

To assist the Inquiry I have summarised the total fluids given to Adam (058-003-005) with reasons;

1. 1500 mls of 0.18NaCl/4% Glucose had been given to replace the amount lost by Adam's native kidneys and provide basic sugar needs (6½ hrs@200 ml/hr=1300mls). 13% more extra 200
depletion 150 mls/hr required ★

2. 1000 mls of HPPF and 500 mls of Blood had been given to replace that lost in swabs, suction and ★ towels and to help to restore the low Haemoglobin. (Estimate of losses 1411 mls) 6% more extra 80 or 24% more extra 289
This also contains Sodium
Lost 2nd 1411 ml in deplection.

3. 500 mls of Hartmann's solution to maintain the CVP and provide the new kidney with sufficient preload to ensure its function.
extra 500

789
989

In my previous experience of anaesthesia for renal transplantation there has always been the option to institute renal dialysis after surgery if there is evidence of fluid overload. This gives anaesthetists and nephrologists an opportunity to give generous intravenous fluids provided careful and continuous monitoring is provided to ensure the function of the donor kidney. In most of the cases I have been involved with there has been evidence of pulmonary oedema following renal transplants. Often the patient needs oxygen therapy or even mechanical ventilation to manage this complication. Therefore we were administering fluids to Adam with the express purpose of increasing his blood volume to ensure that the donor kidney (with a long cold ischaemic time) would have sufficient preload and be given the best possible chance of working. All our calculations confirmed that this was the case.

At 1140 I transferred Adam to the Paediatric Intensive Care unit for further evaluation. A short time later I accompanied Dr Savage to speak to Adam's mother. We passed on our concerns on why Adam hadn't woken up at the end of surgery. Unfortunately Adam never regained consciousness following the transplant surgery and was declared dead on the 28th November 1995. I worked closely with other medical staff to determine the cause of his death so that his mother could be given as much information as possible. It was also important to investigate the cause of his death so that other patients could benefit from knowledge learned by Adam's tragic death during renal transplantation.

008

Particular areas of interest (Cont'd)

3. **Explain the reasons for the actions that you took in the operating theatre, including:**
   (i) when and why tests were requested; and
   (ii) what fluids were administered and when and why they were changed

(i) arterial blood gas 09.32 (058-003-003) This test was done primarily to confirm adequate respiratory function. It also provided a estimate for the haemoglobin since there was a continued blood loss and active bleeding. It also provided an estimate of sodium levels. (Na 123 mmol/l).

(ii) Fluid administration was described in Q2 (i). This was a continuous assessment of fluid deficits, losses and projected needs to adequately perfuse a donated adult kidney. Fluids were changed in response to on-going blood loss and metabolic requirements. This was based on preoperative fluid plan (Question 1 (i)):

Fluid Plan; Replace fluid deficit in the first hour and provide ongoing renal losses associated with Adam's native kidneys with a type of fluid low in sodium content (0.18 NaCl/4%Glucose). This fluid, Saline & Glucose mixture is recommended for dehydration in the British National Formulary (BNF) Number 29, March 1995 **(Ref BNF 29, copy enclosed)**. There is no advice on the problems associated with Anti-diuretic Hormone with this mixture of fluid until March 2003 **(Ref BNF 45, copy enclosed)**. The remainder of the fluid plan was to replace surgical losses as measured by swab weight, suction volume and estimated as the amount soaked in towels in conjunction with the patient's overall status with invasive monitoring of his vital signs.

4. **Describe in detail, including providing dates, the actions that you took to educate the medical profession on hyponatraemia in child surgical cases following Adam's death on 28th November 1995**

I worked with all those involved in the days and weeks following Adam's death to investigate all the possible reasons for that tragic event. This included multiple reviews of all aspects of the anaesthetic and pre-operative management. It also involved a detailed literature search by me for publications relevant to the case. We knew that a complete understanding of the reasons for his death would be essential before asking others to change their medical practice. During the Coroners Inquest clear recommendations were drafted. On the 19th June 1996 I worked in co-operation with Drs Murnaghan, Savage and Gaston to develop Draft Recommendations for Paediatric surgery (060-018-036). This was shared and discussed with my Paediatric Anaesthetic colleagues, Drs Crean and McKaigue (060-014-025 – redacted).

As a consultant in the Royal Belfast Hospital for Sick Children, with my colleagues, I have had the opportunity since 1995 to teach and train junior anaesthetic and paediatric trainee doctors in all aspects of fluid management in children undergoing major surgery. I have maintained my professional knowledge of all aspects of such cases by reading widely on the subject of fluid management and passed on such knowledge in formal and informal teaching sessions.

I became an active instructor on the Advanced Paediatric Life Support (APLS) course in 1997. On this course I have taught all of the many aspects of life support. In relation to the Inquiry I have taught many doctors and nurses about the type and volume of fluids to be administered to infants and children with serious life-threatening conditions eg, shock, dehydration, diabetes, trauma etc. This teaching follows national and international guidelines. In 1999 I became the APLS course

0078

Particular areas of interest (Cont'd)

director on two Belfast courses annually and was invited to initiate the APLS course in Dublin in 2001 and Jersey in 2003. I have also taught on the APLS course in Walsall, Manchester and Leicester. Overall I have assisted in the instruction of over 400 doctors and nurses, mainly in Northern Ireland.

I founded a group of Paediatric, Anaesthetic and Accident and Emergency Consultants who met 2-3 times per year at Antrim Area Hospital (**reference SCLG, copy enclosed**). This group called itself the Sick Child Liaison Group (SCLG). Its main purpose was to improve the quality of care to critically ill infants and children being transferred to the Paediatric ICU mainly by better communication. I chaired these meetings and kept my Clinical Director, Dr Hicks at the RBHSC, and Dr M. McCarthy, DHSS informed of our discussions. One of the outcomes from this SCLG was the production of an agreed "Meningococcal Guideline" to be used in all hospitals in Northern Ireland. This guideline included advice on the fluid management of children presenting with Meningococcal disease. At another meeting of the SCLG on 26th June 2001 the issue of dilutional hyponatraemia was presented by me in relation to children receiving intravenous fluids on paediatric wards (**reference SCLG2, copy enclosed**). Unfortunately these meetings became poorly attended probably because they were held in the evenings. I have recently introduced the use of Tele-medicine to link with other doctors who transfer sick children to PICU. This has been well received but at the moment has only been piloted between the PICU and Craigavon Area Hospital.

I was a founder member along with Dr Brendan O'Hare of the Paediatric Anaesthetic Travelling Society of Ireland (P.A.T.S.I.) in 1997. This is a group of paediatric anaesthetists from RBHSC, Temple Street Children's Hospital and Our Lady's Hospital for Sick Children who meet annually. We have a very close academic and social relationship. At our meetings we discuss areas of common interest and invite respected doctors from overseas to help in our education. Dr Des Bohn was invited to one of our meetings in 2000 to discuss intravenous fluids. I continue to provide leadership in the teaching of fluids and other important matters to other doctors involved in major paediatric surgery in Ireland.

From 1991 I met twice a year with other Consultants in Paediatric Intensive Care at organized conferences of the UK Paediatric Intensive Care Society (PICS) . At these conferences fluid management of critically ill children was discussed on several occasions. At a meeting in Great Ormond Street in October 1999 a whole session was devoted to the subject of the optimum fluid for such children. Dr Des Bohn who has published several papers on hyponatraemia spoke at this meeting. I had worked for Dr Bohn as a Paediatric Critical care Fellow in the Hospital for Sick Children, Toronto in 1988-1989. These PICS meetings also provided an opportunity to discuss paediatric fluid management on an informal manner. In 2002 I was asked to sit on the PICS Council as the co-opted member for Ireland.

In 2001 I was invited to be a member of the Working Party on Prevention of Hyponatraemia by Dr Darragh (007-050-099). As a member of this committee I helped to draft guidelines to be used by all hospital departments where children are given intravenous fluids. I was asked to report the death of a child to the Medicines Control Agency using the "yellow card" system (007-048-094 to 096 and **reference CSM, copy enclosed**) of adverse incident reporting. Correspondence from the MCA is available on the Inquiry

008

Particular areas of interest (Cont'd)

website (007-017-034). I provided a teaching aid for this committee in the form of a power-point presentation that included an audit of children admitted to PICU with hyponatraemia and recent publications (007-051-100 to111).

I have continued to phone and email other doctors and pharmacists in different parts of the world to gain some insight into the use or prohibition of saline/glucose fluids (007-041-082). This has led me to conclude that there is no consensus on the optimum type of fluids to use in children for major surgery. There is a wide spectrum of opinion on the use of saline/glucose mixtures with some individuals who wish to see these fluids restricted, eg Dr Stephen Playfor, Royal Manchester Children's Hospital (007-061-130).

In 2003 I was invited to edit the Fluids chapter for the second edition of the reference book "Medicines for Children". There was a deficiency in the text regarding the risks of hyponatraemia. I included a paragraph on dilutional hyponatraemia that reflected the CMO's guidance for the "Prevention of Hyponatraemia" which was accepted by the editors. **(reference MFC, copy enclosed)**

I do not believe that individual doctors like me can have any impact on the prescribing of fluids by doctors in the various hospitals in Northern Ireland. The implementation of the guideline on the Prevention of Hyponatraemia by the Chief Medical Officer in 2002 has made a major impact in NI. However it will take a determined effort by a powerful body such as the National Patient Safety Agency to introduce a change to clinical practice in all UK regions.

008

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]

In my letter to Dr Murnaghan on the 2nd February 1996 (059-053-108) I draw attention to a factual error as reported by Dr Sumner in his report (059-054-109to 120). He reports that the Human Plasma Protein Factor (HPPF) administered to Adam did not contain sodium (059-054-116 and 119). In actual fact this solution contains 130-150 mmol/l of sodium, similar to that present in blood. It is crucial to the understanding of the type and volume of fluids given to Adam to be absolutely accurate. I have outlined in Question 1 the reasons why each type and volume of fluid was given. It was the agreed intention of the transplant team to ensure that water would be given to replace water, salt to replace salt and blood to replace blood and that sufficient sugar be given to provide Adam's essential metabolic requirements.

Also I draw attention to other concerns with Dr Sumners report such as the reasons why 0.18 NaCl/4% Glucose was chosen as a fluid type are as outlined in correspondence to Mr Brangam prior to the inquest. (059-004-007, 059-009-028, 059-053-108)

Unlike drugs, intravenous fluids are not required to undergo rigorous licensing procedures such as evidence of their safety and efficacy. The product information as supplied by the BNF Number 29 in 1995 listed no specific hazards or contra-indications with saline/glucose mixtures. Also despite my request in 2001 for the regulating body for intravenous fluids and drugs, the Medicines Control Agency, to issue a warning about dilutional hyponatraemia (007-029-056) their response was that there should be "no amendments to product information"(007-017-034). In March 2003 a specific warning is supplied by the BNF, Number 45 for intravenous saline and glucose mixtures and the issue of ADH. **(reference BNF, copy enclosed)**

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

Signed: [signature] **Dated:** 18/7/05

BNF Number 29 (March 1995)

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

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 9.8.

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) [P, M]

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

First appears this edition. NOT in BNF No. 44.

BNF No. 45 (March 2003)

SCL5

ROYAL BELFAST HOSPITAL FOR SICK CHILDREN
PAEDIATRIC INTENSIVE CARE UNIT

MEMORANDUM

TO: The Undernoted **DATE:** 9 February 1999

FROM: Dr R Taylor **REF:** RT/AB

Following recent correspondence with Paediatricians and Anaesthetists in various Hospitals I would like to invite you, or a suitable deputy, to convene meetings regarding the CLINICAL IMPLICATIONS and implementation of the recent "Framework for the Future" document for Paediatric ICU. In particular I would like to consult widely on agreed guidelines for admission, initial management and transfer of critically ill infants and children.

Could you please indicate preference for the following date:-

March 2nd 1830-2000 yes
March 3rd 1830-2000 no
March 9th 1830-2000 yes

A Beh

Suggested venue is Antrim Area Hospital.

DR R TAYLOR
CONSULTANT ANAESTHETIST

CC Dr N McLeod Consultant Anaesthetist ICU Antrim Area Hospital
Dr J McAloon Consultant Paediatrician Antrim Area Hospital
Dr B Bell Consultant Paediatrician Craigavon Area Hospital
Dr C McAllister Consultant Anaesthetist ICU Craigavon Area Hospital
Dr B Morron Consultant Anaesthetist ICU Altnagelvin Area Hopsital
Dr N Corrigan Consultant Paediatrician Altnagelvin Area Hospital
Dr J Trinder Consultant Anaesthetist ICU Ulster Hospital
✓Dr T Brown Consultant Paediatrician Ulster Hospital

→ Dr. Bell, Please

Fy 11/2/99

AS - PSNI

093-035-110n

SCLG2

SICK CHILD LIAISON GROUP
Minutes
Tuesday 26th June 2001 - ANTRIM AREA HOSPITAL

IN ATTENDANCE:

Dr J McAloón
Dr R Taylor
Dr H Steen
Dr D O'Donoghue

APOLOGIES:

Dr M MCCarthy
Dr B Bell
Dr A Bell
Dr B Morrow

ACTION

Matters Arising;

1.1. BRONCHIOLITIS guidelines; BT to present guidelines for infants with severe bronchiolitis available for winter 2001 (— BB/BT

1.2. TRANSPORT OF CRITICALLY ILL CHILD guideline; This is a product of the Paediatric Benchmark nurses project and is currently running throughout Northern Ireland with good participation among Units. — BT

1.3. Seriously Injured Child guideline; SO'R to advise. — SO'R

Chairman's Business;

Long term Ventilated Patients now occupy five PICU beds. This is unacceptable as it blocks beds for acutely ill children. Much effort now taking place to educate and train other areas to take these patients. — BT

Hyponatraemia; BT 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 this subject.

Dr Taylor thanked Dr McAloon for organising the facilities and meals for all in attendance.

Next Meeting;
Tuesday 6 November 2001 at 6.30pm in Antrim Area Hospital

LSM

2a

COMMITTEE ON SAFETY OF MEDICINES

Market Towers • 1 Nine Elms Lane • London SW8 5NQ
Telephone [redacted] • *Facsimile* [redacted]

MEDICINES CONTROL AGENCY

IN CONFIDENCE

Dr B Taylor
Paediactric ICU
Royal Hosp for Sick Children
BELFAST
CO. ANTRIM
BT12 6BE

01 Oct 01

Dear Dr Taylor

RE: PATIENT: RF AGE: 9
PATIENT ID NUMBER: 476454
ADR Reg. No: 433167

Thank you for sending us a suspected adverse drug reaction report on the above patient. A copy is enclosed for your records. If additional information becomes available about this report it would be most helpful if you could send this to us, quoting the above reference number.

Your contribution to the UK's Adverse Drug Reactions Reporting Scheme is greatly appreciated. This provides an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of medicines.

Yours sincerely,

Dr J M Raine
Director - Post Licensing Division

OTHER DRUGS (including self-medication & herbal remedies)

Did the patient take any other drugs in the last 3 months prior to the reaction? (Yes) / No

If yes, please give the following information if known:

Drug (Brand, if known)	Route	Dosage	Date started	Date stopped	Prescribed for
CEFOTAXIME	2400mg	IV	07/6/01	10/6/01	MENINGITIS
METRONIDAZOLE					"

Additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed), suspected drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the date of the last menstrual period.

POST OP APPENDICECTOMY. - UREA + ELECTROLYTES NOT MONITORED FOR 48 hours
- SYMPTOMATIC — SEIZURES
NaT 118

433167

REPORTER DETAILS

Name and Professional Address: Dr Bob TAYLOR
PAEDIATRIC ICU, 180 FALLS ROAD
BELFAST

Post code: BT12 6BE Tel No: [redacted]

Speciality: PAEDIATRIC ANAESTHESIA

Signature: [signature] Date: 25/9/01

CLINICIAN (If not the reporter)

Name and Professional Address: _____

_____

Post code: _____

Tel No: Speciality:

If you would like information about other adverse reactions associated with the suspected drug, please tick this box ☑

Send to Medicines Control Agency, CSM FREEPOST, LONDON SW8 5BR or if you are in one of the following NHS regions:

to CSM Mersey, FREEPOST, Liverpool L3 3AB
or CSM Northern, FREEPOST 1085, Newcastle upon Tyne NE1 1BR
or CSM West Midlands, FREEPOST SW2991, Birmingham B18 7BR
or CSM Wales, FREEPOST, Cardiff CF4 1YZ

AS - PSNI

093-035-110q

COMMITTEE ON SAFETY OF MEDICINES

In Confidence

M.C.A.

MEDICINES CONTROL AGENCY

SUSPECTED ADVERSE DRUG REACTIONS

P2

If you are suspicious that an adverse reaction may be [illegible] drug or combination of drugs please complete this Yellow Card. Please report all adverse reactions for black triangle (▼) drugs and only [illegible] adverse reactions for established drugs. For additional reporting advice please see page 10 of the BNF or the MCA website www.open.gov.uk/[illegible].htm. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials: R.F. Sex: M / F Weight if known (kg): 25

Age (at time of reaction): 9 Identification (Your Practice / Hospital Ref.)*: 476454

SUSPECTED DRUG(S)

Give brand name of drug and batch Number if known: (FLUIDS I.V. (HYPONATRAEMIA → COMA) 133167

Route	Dosage	Date started	Date stopped	Prescribed for
0.18% NaCl/4% Gluc 5 I.V.	80mls/hour	7/6/01	9/6/01	Post-OP

SUSPECTED REACTION(S)

Please describe the reaction(s) and any treatment given:

HEADACHES → VOMITING → SEIZURES (NOT ILS) → COMA → BRAINSTEM DEATH

Date reaction(s) started: 7/6/2001 Date reaction(s) stopped: 10/6/01

Do you consider the reaction to be serious? (Yes) No

If *yes*, please indicate why the reaction is considered to be serious (please tick all that apply):

Patient died due to reaction	☒	Involved or prolonged inpatient hospitalisation	☐
Life threatening	☐	Involved persistent or significant disability or incapacity	☐
Congenital abnormality	☐	Medically significant; please give details:	

Outcome

Recovered	☐
Recovering	☐
Continuing	☐
Other	☒

COMMITTEE ON SAFETY OF MEDICINES 1 OCT 2001

* This is to enable you to identify the patient in any future correspondence concerning this report

Please attach additional pages if necessary

093-035-110r

AS - PSNI

CSM

2.

COMMITTEE ON SAFETY
OF MEDICINES

Market Towers • 1 Nine Elms Lane • London SW8 5NQ
Telephone [redacted] *• Facsimile* [redacted]

MEDICINES CONTROL
AGENCY

IN CONFIDENCE

Dr B Taylor
Paediactric ICU
Royal Hosp for Sick Children
BELFAST
CO. ANTRIM
BT12 6BE

01 Oct 01

Dear Dr Taylor

RE: PATIENT: RF AGE: 9
PATIENT ID NUMBER: 476454
ADR Reg. No: 433167

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Your contribution to the UK's Adverse Drug Reactions Reporting Scheme is greatly appreciated. This provides an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of medicines.

Yours sincerely,

Dr J M Raine
Director - Post Licensing Division

AS - PSNI

093-035-110s

OTHER DRUGS (including self-medication & herbal remedies)

Did the patient take any other drugs in the last 3 months prior to the reaction? (Yes) / No

If *yes*, please give the following information if known:

Drug (Brand, if known)	Route	Dosage	Date started	Date stopped	Prescribed for
CEFOTAXIME	240mg	IV	07/6/01	10/6/01	APPENDICITIS
METRONIDAZOLE					"

Additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed), suspected drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the date of the last menstrual period.

POST OP APPENDICECTOMY. - UREA + ELECTROLYTES NOT MONITORED FOR 48 hours
- SYMPTOMATIC — SEIZURES
Na+ 118

433167

REPORTER DETAILS

Name and Professional Address: Dr BOBS TAYLOR
PAEDIATRIC ICU, ISO FALLS ROAD
BELFAST

Post code: BT12 6BE Tel No: [redacted]

Speciality: PAEDIATRIC ANAESTHESIA

Signature: [signature] Date: 25/9/01

CLINICIAN (if not the reporter)

Name and Professional Address:

Post code:

Tel No: Speciality:

If you would like information about other adverse reactions associated with the suspected drug, please tick this box ☑

Send to Medicines Control Agency, CSM FREEPOST, LONDON SW8 5BR or if you are in one of the following NHS regions:

to CSM Mersey, FREEPOST, Liverpool L3 3AB
or CSM Northern, FREEPOST 1085, Newcastle upon Tyne NE1 1BR
or CSM West Midlands, FREEPOST SW2991, Birmingham B18 7BR
or CSM Wales, FREEPOST, Cardiff CF4 1TZ

COMMITTEE ON SAFETY OF MEDICINES

In Confidence

M.C.I.A.I

MEDICINES CONTROL AGENCY

SUSPECTED ADVERSE DRUG REACTIONS

P2

If you are suspicious that an adverse reaction may be related to a drug or combination of drugs please complete this Yellow Card. Please report all adverse reactions for black triangle (▼) drugs and only serious adverse reactions for established drugs. For additional reporting advice please see page 10 of the BNF or the MCA website www.open.gov.uk/[illegible].htm. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials: R.F. Sex: M / F Weight if known (kg): 25

Age (at time of reaction): 9 Identification (Your Practice / Hospital Ref.)*: 476454

SUSPECTED DRUG(S) 133167

Give brand name of drug and batch Number if known (FLUIDS I.V. (HYPONATRAEMIA → COMA)

	Route	Dosage	Date started	Date stopped	Prescribed for
0.18% NaCl/4% Glucose	I.V.	80mls/hour	7/6/01	9/6/01	POST-OP A

SUSPECTED REACTION(S)

Please describe the reaction(s) and any treatment given:

HEADACHES → VOMITING → SEIZURES → COMA → BRAINSTEM DEATH (NCT 118)

Date reaction(s) started: 7/6/2001 Date reaction(s) stopped: 10/6/01

Do you consider the reaction to be serious? (Yes) No

If *yes*, please indicate why the reaction is considered to be serious (please tick all that apply):

- Patient died due to reaction ☒
- Life threatening ☐
- Congenital abnormality ☐
- Involved or prolonged inpatient hospitalisation ☐
- Involved persistent or significant disability or incapacity ☐
- Medically significant; please give details:

COMMITTEE ON SAFETY OF MEDICINES 1 OCT 2001

Outcome

- Recovered ☐
- Recovering ☐
- Continuing ☐
- Other ☒

* This is to enable you to identify the patient in any future correspondence concerning this report

Please attach additional pages if necessary

AS - PSNI

093-035-110u

Intravenous fluid and electrolytes are given to maintain or restore body composition to normal when it is not possible or desirable to use the enteral route. Fluid and electrolytes are given as maintenance and/or replacement therapy.

MAINTENANCE THERAPY

For this purpose fluid and electrolytes (chiefly Na^+, Cl^- and K^+) are given together with glucose to replace usual normal losses of water and electrolytes in quantities 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 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 situation and types of losses incurred.

Fluid requirements/24 hours

Body weight <3kg	
3–10kg For each kg between 10–20 kg For each kg over 20kg	
Sodium requirement/24 hours	
Potassium requirement/24 hours	
Glucose requirement/24 hours	

REPLACEMENT THERAPY

In general, initial intravenous replacement fluid is required if >10% dehydrated or if 5–10% dehydrated and oral and enteral rehydration is not tolerated or possible. Oral rehydration is adequate if tolerated in the majority of those <10% dehydrated. Subsequent fluid and electrolyte requirements are determined by clinical assessment of fluid balance, including measurement of on going excessive renal and extra renal losses, and measurement of plasma electrolytes, bicarbonate and glucose together with calcium, phosphate and magnesium where appropriate. In the UK oral rehydration is under used and severe dehydration over diagnosed clinically.

Intravenous sodium is commonly given as a component of maintenance and replacement therapy. It may be given as saline for initial fluid bolus in acute fluid loss and to replace ongoing gastrointestinal losses from the upper gastrointestinal tract. For maintenance and continuing replacement therapy it is most usually given in combination with glucose and other electrolytes, the exact strength depending on the clinical situation. Other uses include promotion of saline diuresis in the management of some poisoning, as a vehicle for reconstitution and administration of intravenous medications and to maintain patency of arterial/CVP/other lines. It must be given with caution as sodium overload may be easily produced. Particular care is needed in those with renal insufficiency, cardiac failure, other cardio-respiratory disease, hepatic cirrhosis and those receiving glucocorticosteroids.

Solutions available

- ☐ Sodium chloride 0.45% – Na^+ 75mmol/L; Cl^- 75mmol/L; osmolarity 154mOsm/L
- ☐ Sodium chloride 0.9% – Na^+ 150mmol/L; Cl^- 150mmol/L; osmolarity 308mOsm/L
- ☐ Sodium chloride 1.8% – Na^+ 300mmol/L; Cl^- 300mmol/L; osmolarity 616mOsm/L

Other infusion fluids containing sodium – see table. Extreme care must be taken if giving sodium chloride in solutions stronger than 0.9% and there must be specific indications for their administration.

MEDICINES FOR CHILDREN

Intravenous potassium is commonly given as a component of maintenance and replacement intravenous therapy and in the correction of severe hypokalaemia where oral potassium is insufficient or not possible. For maintenance and continuing replacement therapy it is most usually given in combination with glucose and other electrolytes. Whilst it is often added to glucose/saline solutions, ready-prepared infusion fluid containing these together with potassium may be adequate in many cases and their use may decrease the number of errors in its administration. The quantity required is calculated according to usual maintenance requirements with adjustment for any deficit and ongoing loss. As in all cases, the situation must be monitored by clinical assessment and measurement of plasma potassium levels. Potassium should not be given in established hyperkalaemia and should only be given with extreme caution and close monitoring where there is renal impairment or coincidental administration of drugs which may cause hyperkalaemia. Potassium should only be given as a slow infusion and it is recommended that the concentration of the solution should not exceed 40 mmol of potassium per litre. ECG monitoring should be used where there is concern regarding hypo or hyperkalaemia, together with frequent measurement of plasma potassium.

Solutions available

- ☐ Strong potassium chloride (15%) – K^+ 2mmol/mL; Cl^- 2mmol/mL

Strong KCl should be diluted with not less than 50 times its volume of compatible intravenous fluid, mixed well and given as a slow infusion. Other infusion fluids containing potassium – see table (page G50).

Intravenous glucose is given in maintenance and replacement therapy to minimise gluconeogenesis and is also used specifically in the treatment of hypoglycaemia. For maintenance and continuing replacement therapy it is most usually given in combination with other electrolytes. In hypoglycaemia an initial bolus of 0.2g/kg of glucose given as 2mL/kg of 10% glucose over 2-3 minutes is recommended.

Solutions available

- ☐ Glucose 5 % – osmolarity 278mOsm/L
- ☐ Glucose 10 % – osmolarity 555mOsm/L
- ☐ Glucose 20 % – osmolarity 1110mOsm/L
- ☐ Glucose 40 % – osmolarity 2220mOsm/L
- ☐ Glucose 50 % – osmolarity 2775mOsm/L

Other infusion fluids containing glucose – see below. Solutions stronger than 10% glucose should NOT be used except in exceptional circumstances because of the dangers of hyperosmolality.

Intravenous bicarbonate is used in the management of metabolic acidosis. In most circumstances metabolic acidosis is secondary to hypoxia/ hypovolaemia/ hypoperfusion and treatment of any underlying condition with appropriate fluid replacement and cardiovascular support will improve or correct acidosis.

Bicarbonate may be given to correct the acid-base imbalance in severe metabolic acidosis or in specific circumstances, e.g. renal tubular acidosis. In the acute situation e.g. cardiac arrest, an initial bolus of 1mmol/kg may be given as a slow bolus if required (1mL/kg of 8.4% sodium bicarbonate or equivalent volume of 2mL/kg of 4.2% sodium bicarbonate). The volume required of 8.4% sodium bicarbonate to correct a metabolic acidosis = base deficit x body weight (kg) x 0.3. Half this volume is usually given initially by slow infusion and progress monitored by clinical assessment and measurement of plasma pH or H^+ concentration before giving the remaining half. The standard sodium bicarbonate solutions available are hypertonic. Venous damage or thrombophlebitis may occur at the site of infusion. Continued administration can lead to hypernatraemia and overdosage of sodium bicarbonate may cause diarrhoea, nausea and vomiting, hyperpnoea and convulsions.

Solutions available

- ☐ Sodium bicarbonate 1.26% – Na^+ 150mmol/L; HCO_3^- 150mmol/L; – osmolarity 300mOsm/L
- ☐ Sodium bicarbonate 4.2% – Na^+ 500mmol/L; HCO_3^- 500mmol/L; – osmolarity 1000mOsm/L
- ☐ Sodium bicarbonate 8.4% – Na^+ 1000mmol/L; HCO_3^- 1000mmol/L; – osmolarity 2000mOsm/L

Lactate was previously used in the management of metabolic acidosis but is now not recommended because of the risk of producing lactic acidosis, especially in those with hepatic impairment or poor tissue perfusion. Any solutions containing lactate should not be given to those with impairment of hepatic function.

MF. CHLDRN 2003

G54 Intravenous fluid therapy

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 neuroendocrine 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

Intravenous fluid therapy continued

REPLACEMENT THERAPY

In general, initial intravenous replacement fluid is required if >10% dehydrated or if 5-10% dehydrated and oral and enteral rehydration is not tolerated or possible. Oral rehydration is adequate if tolerated in the majority of those <10% dehydrated. Subsequent fluid and electrolyte requirements are determined by clinical assessment of fluid balance, including measurement of ongoing excessive renal and extra renal losses, and measurement of plasma electrolytes, bicarbonate and glucose together with calcium, phosphate and magnesium where appropriate. In the United Kingdom oral rehydration is underused and severe dehydration overdiagnosed clinically.

Intravenous sodium is commonly given as a component of maintenance and replacement therapy. It may be given as NaCl 0.9% for initial fluid bolus in acute fluid loss and to replace ongoing gastrointestinal losses from the upper gastrointestinal tract. For maintenance and continuing replacement therapy it is usually given in combination with other electrolytes and glucose, the exact strength depending on the clinical situation. Other uses include promotion of saline diuresis in the management of some poisoning, as a vehicle for reconstitution and administration of intravenous medications and to maintain patency of arterial/venous catheters. It must be given with caution as sodium overload may be easily produced. Particular care is needed in those with renal insufficiency, cardiac failure, other cardio-respiratory disease, hepatic cirrhosis and those receiving glucocorticoids. Conversely, hyponatraemia with serious consequences can occur if maintenance and replacement fluids do not meet sodium requirements. See cautionary note about dilutional hyponatraemia above.

Solutions available

- ☐ Sodium chloride 0.45% – Na^+ 75mmol/L; Cl^- 75mmol/L; osmolarity 154mOsm/L
- ☐ Sodium chloride 0.9% – Na^+ 150mmol/L; Cl^- 150mmol/L; osmolarity 308mOsm/L
- ☐ Sodium chloride 1.8% – Na^+ 300mmol/L; Cl^- 300mmol/L; osmolarity 616mOsm/L

Other infusion fluids containing sodium – see table.

Extreme care must be taken if giving sodium chloride in solutions stronger than 0.9% and there must be specific indications for their administration.

Intravenous potassium is commonly given as a component of maintenance and replacement intravenous therapy and in the correction of severe hypokalaemia where oral potassium is insufficient or not possible. For maintenance and continuing replacement therapy it is most usually given in combination with glucose and other electrolytes. Whilst it is often added to glucose/saline solutions, ready-prepared infusion fluid containing these together with potassium may be adequate in many cases and their use may decrease the number of errors in its administration. The quantity required is calculated according to usual maintenance requirements with adjustment for any deficit and ongoing loss. As always, the situation must be monitored by clinical assessment and measurement of plasma potassium concentration. Potassium should not be given in established hyperkalaemia and should only be given with extreme caution and close monitoring where there is renal impairment or coincidental administration of drugs which may cause hyperkalaemia. Potassium should only be given as a slow infusion and it is recommended that the concentration of the solution should not exceed 40mmol of potassium per litre. ECG monitoring should be used where there is concern regarding hypo or hyperkalaemia, together with frequent measurement of plasma potassium.

Solutions available

- ☐ Strong potassium chloride (15%)* – K^+ 2mmol/mL; Cl^- 2mmol/mL
- ☐ Strong KCl should be diluted with not less than 50 times its volume of compatible intravenous fluid, mixed well and given as a slow infusion. Where possible, compounding should be performed in a pharmacy. For other infusion fluids containing potassium – see table.

Intravenous glucose is given in maintenance and replacement therapy to minimise gluconeogenesis and is also used specifically in the treatment of hypoglycaemia. For maintenance and continuing replacement therapy it is most usually given in combination with other electrolytes. In hypoglycaemia an initial bolus of 200mg/kg of glucose given as 2mL/kg of 10% glucose over 2–5 minutes is recommended.

Solutions available

- ☐ Glucose 5 % – osmolarity 278mOsm/L
- ☐ Glucose 10 % – osmolarity 555mOsm/L
- ☐ Glucose 20 % – osmolarity 1110mOsm/L

Intravenous fluid therapy continued

☐ Glucose 40 % – osmolarity 2220mOsm/L
☐ Glucose 50 % – osmolarity 2775mOsm/L

For other infusion fluids containing glucose – see below. Solutions stronger than 10% glucose should NOT be used except in exceptional circumstances because of the dangers of hyperosmolarity.

Intravenous bicarbonate is used in the management of metabolic acidosis. In most circumstances metabolic acidosis is secondary to hypoxia/hypovolaemia/hypoperfusion and treatment of any underlying condition with appropriate fluid replacement and cardiovascular support will improve or correct acidosis.

Bicarbonate may be given to correct the acid-base imbalance in severe metabolic acidosis or in specific circumstances, e.g. renal tubular acidosis. In the acute situation e.g. cardiac arrest, an initial bolus of 1mmol/kg may be given as a slow bolus if required (1ml/kg of 8.4% sodium bicarbonate or 2ml/kg of 4.2% sodium bicarbonate). The volume required of 8.4% sodium bicarbonate to correct a metabolic acidosis = base deficit x body weight (kg) x 0.3 for children other than newborns (x 0.5-0.6 in premature neonate; x 0.4 in term neonates). Half this volume is usually given initially by slow infusion and progress monitored by clinical assessment and measurement of plasma pH or H^+ concentration before giving the remaining half. The standard sodium bicarbonate solutions available are hypertonic. Venous damage or thrombophlebitis may occur at the site of infusion, and extravasation can cause severe tissue injury. Continued administration can lead to hypernatraemia and overdosage of sodium bicarbonate may cause diarrhoea, nausea and vomiting, hyperpnoea and convulsions.

Solutions available

☐ Sodium bicarbonate 1.26% – Na^+ 150mmol/L; $HCO3^-$ 150mmol/L; – osmolarity 300mOsm/L
☐ Sodium bicarbonate 4.2% – Na^+ 500mmol/L; $HCO3^-$ 500mmol/L; – osmolarity 1000mOsm/L
☐ Sodium bicarbonate 8.4% – Na^+ 1000mmol/L; $HCO3^-$ 1000mmol/L; – osmolarity 2000mOsm/L

THAM (tris-hydroxymethyl aminomethane trometamol) is an organic buffer used for correction of metabolic acidosis. It is an alternative to sodium bicarbonate when there is concern about carbon dioxide retention, hypernatraemia or renal impairment. THAM is available as 3.6% or 7.2% solution, and should be used as 3.6% solution when given intravenously. 1mL of 7.2% solution (2mL of 3.6% solution) is equivalent to 1mmol of bicarbonate ion.

Lactate was previously used in the management of metabolic acidosis but is now not recommended because of the risk of producing lactic acidosis, especially in those with hepatic impairment or poor tissue perfusion. Any solutions containing lactate should not be given to those with impairment of hepatic function.

Solutions available

☐ Sodium lactate M/6 – Na^+ 167 mmol/L; lactate 167 mmol/L

For other infusion fluids, which contain lactate – see table.

Combined intravenous fluids

	Na^+ (mmol/L)	Cl^- (mmol/L)	K^+ (mmol/L)	Other (mmol/L)	Osmolarity †(mOsm/L)	Energy (kcal/L)
Glucose 2.5%/NaCl 0.45%	75	75	-	-	293	100
Glucose 4%/NaCl 0.18%	30	30	-	-	263	160
Glucose 5%/NaCl 0.45%	75	75	-	-	432	200
Glucose 5%/NaCl 0.9%	150	150	-	-	586	200
Glucose 10%/NaCl 0.18%	30	30	-	-	567	400
Glucose 10%/NaCl 0.45%	75	75	-	-	660	400
Glucose 5%/KCl 0.15%	-	20	20	-	318	200
Glucose 5%/KCl 0.2%	-	27	27	-	332	200
Glucose 5%/KCl 0.3%	-	40	40	-	358	200
Glucose 4%/NaCl 0.18% with KCl 0.15%	30	50	20	-	322	160
Glucose 4%/NaCl 0.18% with KCl 0.2%	30	57	27	-	336	160

Intravenous fluid therapy continued

Combined intravenous fluids continued

	Na^+ (mmol/L)	Cl^- (mmol/L)	K^+ (mmol/L)	Other (mmol/L)	Osmolarity †(mOsm/L)	Energy (kcal/L)
Glucose 4%/NaCl 0.18% with KCl 0.3%	30	70	40	-	362	160
Glucose 5%/NaCl 0.45% with KCl 0.15% (Alder Hey Special K)	75	95	20	-	426	200
NaCl 0.9%/KCl 0.15%	150	170	20	-	340	0
NaCl 0.9%/KCl 0.2%	150	177	27	-	354	0
NaCl 0.9%/KCl 0.3%	150	190	40	-	380	0
Ringer's – compound sodium chloride	147.5	156	4	Calcium – 2	310	0
Hartmann's – compound sodium lactate	131	111	5	Lactate – 29 Calcium – 2	278	0
Half Hartmann's with glucose 5%	66	56	3	Lactate – 14 Calcium – 1	418	200
Darrow's – lactated potassic saline	121	103	35	Lactate – 53	312	0

†Osmolarity may differ slightly depending on brand. The figures quoted are mainly for Baxter products

COLLOIDS

These are used for plasma replacement or expansion. They may be natural products like human albumin solution (HAS) and fresh frozen plasma (FFP), or synthetic: based on gelatin like Gelofusine® (succinylated gelatin) and Haemaccel™ (urea-linked gelatin), or hydroxyethyl starches (HES) like Pentastarch™; or dextrans. HAS and gelatins are essentially plasma substitutes, whereas hydroxyethyl starches and dextrans are true plasma expanders – they produce an increase in plasma volume greater than the volume of colloid infused. A meta-analysis of clinical trials has suggested that use of HAS may be associated with increased mortality across all age ranges; a more recent review of studies in newborns could not confirm this finding. NaCl 0.9% is often an effective crystalloid alternative for rapid volume expansion in resuscitation, sepsis and dehydration. There is no justification for use of FFP as a plasma substitute unless there is also a coagulopathy.

4.5% HAS has been the standard fluid used in neonates and infants, but it is expensive and there is a small risk of anaphylaxis or infection. More recently, there has been concern about possible variant CJD (vCJD) transmission from UK sources of HAS. A synthetic gelatin is a cheap and safe alternative to 4.5% HAS. A succinylated gelatin is preferable to a urea-linked gelatin as the reported anaphylactoid reaction rate is lower (0.05% and 0.1%, respectively). Dextrans are not routinely indicated because of increased side-effects compared to gelatins and hydroxyethyl starches.

Hydroxyethyl starches (HES) have anaphylactoid reaction rates similar to gelatins but as HES are true plasma expanders the risk of fluid overload is greater. For this reason, HES are probably best restricted to an intensive care setting.

Liver

Acute hepatitis. This is often due to hepatitis A virus infection but it may be the first presentation of serious liver disease. Serology, liver function tests and coagulation studies should be undertaken in all cases. No specific treatment is necessary in the vast majority of cases. All cases not due to hepatitis A virus or where coagulation studies are abnormal should be referred for further investigation.

Hepatitis B. Hepatitis B infection rarely causes acute hepatitis in childhood but may result in chronic carriage. Chronic infection and carriage is more likely to occur the younger the age at which the infection is acquired. It is usually asymptomatic in childhood but, if untreated, carries a high lifetime risk of progression to cirrhosis and hepatocellular carcinoma.