Supplementary statement in response to brief dated 4th July 2012 regarding Adam Strain to the Inquiry for Hyponatraemia Related Deaths in Northern Ireland

Dr Simon R Haynes

Signed: Simon R. Haynes

Date: 28th July 2012

The Inquiry would particularly welcome your comments on the following issues:

Timings of the surgery

(1) In a surgical case such as Adam's, how long would you expect the following to take:

(a) The reversal of the anaesthetic

Comment: Reversal of anaesthetic for the purpose of this discussion is taken to mean the return of spontaneous breathing and return of airway reflexes (coughing to clear saliva/mucous secretions etc). For this to occur there must be no residual effect of neuromuscular blocking drug (eg atracurium), and the partial pressure of carbon dioxide in the patient's blood must be large enough to cause the respiratory centre in the brain stem to discharge, causing spontaneous breathing to take place. At the end of an operation there will be anaesthetic agent (eg halothane) and opioid drugs present, both of which decrease the sensitivity of the respiratory centre to carbon dioxide, and there will need to be a larger partial pressure of carbon dioxide present than in the non-anaesthetised patient for spontaneous respiration to take place. Over the subsequent period, anaesthetic agent is removed from the body, mostly in exhaled breath and in the case of halothane also by metabolism, and the patient will return to an awake state.

Spontaneous breathing can be expected to return within a few minutes following cessation of artificial ventilation as carbon dioxide accumulates in the bloodstream, and airway reflexes return shortly thereafter (demonstrated by the patient coughing and gagging on the endotracheal tube, which is then removed by the anaesthetist). Following a major operation such as a renal transplant I would expect spontaneous breathing within 5 minutes or so following cessation of ventilation, but full protective airway reflexes may not be present for a further 5-10 minutes. A fully awake state (the patient obeying commands and able to hold a conversation) may well take a further hour or so to return if halothane is the anaesthetic agent used. Other factors (commonly mild hypothermia) may delay the return of a fully awake state.

(b) The preparation of the patient for transfer to PICU (including how long this would take)

Comment: This would take no more than 10 minutes.

(2) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"Dr Taylor pointed out it was very possible that this kidney could have been in place within an hour."* (Ref: 122-001-002)Comment:

Comment: This is extremely unlikely . I have obtained a snapshot from the Freeman Hospital Trans[plant database of 10 consecutive renal transplant patients carried out at the Freeman Hospital this year (2012). The average *operative* time is 3h 10 minutes, with on average a further 60 minutes taken by the

anaesthetist prior to the operation to prepare the patient. Previous abdominal or open urological surgery would increase the operative time for a kidney transplant

(b) *"In this case the kidney was in at around 9.30am. The vein was in and the arteries were being finished. At this stage Dr Taylor did a blood gas assessment and based on the results of this then started to give the blood. Once the blood was being put through the clamps were released and further blood was given at a later stage."* (Ref: 122-001-003)

(i) What may be meant by:

- *"the kidney was **in** at around 9.30am"*?

Comment: I interpret this statement as meaning that the donor kidney was placed within Adam's body, possibly with vascular anastomoses (connection of renal artery and vein) completed

- *"The vein was **in**"*?

Comment: I interpret this as meaning that the connection between the donor kidney vein and the recipient (Adam's) Iliac vein was complete

(ii) What would be the time period between the vein being *"in"* and the *"arteries [...] being finished"*?

Comment: This time would refer to the period to complete the arterial anastomosis (connecting the donor renal artery to the recipient (iliac) artery.) My experience has been that a straight forward anastomosis of a single medium sized vessel in any part of the body can usually be accomplished by an average surgeon in 20 – 30 minutes providing that the necessary dissection to expose the two vessels to be connected is completed beforehand. It was known in this case that the donor kidney was supplied by 2 arteries (058-009-027), and therefore the anastomosis would be more complicated than if a single vessel were present and as such would take longer. I cannot comment in any more detail.

(iii) What would have been the implications for Adam's fluid management when the *"kidney was in"* and the *"arteries were being finished"*?

Comment: The implication is that the door kidney vascular bed would shortly be connected with the recipient's circulation. The anaesthetist at this point in time would need to ensure that the recipient's circulating blood volume was as large as possible, the aim being to provide adequate blood flow to the donor kidney when the renal artery was opened to Adam's circulation. To accomplish this, appropriate volumes of an appropriate fluid (ie one which would remain predominantly in the intravascular fluid compartment) are given by the anaesthetist – these would include normal saline, Hartmann's solution, human albumen solution, or if necessary donor blood. A functioning CVP measurement greatly assists the anaesthetist at this point.

(c) *"this procedure was planned to last 1-1 ½ hours."* (Ref: 122-001-003)

Comment: This is incorrect. Dr Taylor should have anticipated that Adam's transplant operation ("this procedure") would have taken an hour of anaesthetic preparation and at least a further 3 hours of surgery (see 2a above).

Content of fluids

(3) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"Dr. Taylor explained that if water is in a vein, the red blood cells that water and burst. To prevent this type of occurrence they use an isotonic solution and he pointed out again that saline and dextrose together is an isotonic solution. Hartmanns solution is also isotonic."* (Ref: 122-001-001)

Comment: Dr Taylor is correct in the first part of his statement: if red blood cells are placed in water (which is hypotonic), water enters red cells until they rupture (haemolyse). The second part of his statement, taken at face value, is also correct; red cells placed in an isotonic solution will not rupture. The third part of his statement is wrong; if a solution containing dextrose and saline is given, the tonicity of the solution ultimately depends on the saline concentration. Dextrose (glucose) rapidly enters cells and is metabolised and does not effectively contribute to the solution's tonicity.

(b) *"Dr Taylor is adamant that the fluid being used was isotonic and not hypotonic. He did start to indicate that a dextrose solution which is initially isotonic can become hypotonic in the body."* (Ref: 122-001-003)

Comment: Please see 204-002-118. This is a reference for a previous report. 0.18% saline in 4% dextrose is effectively hypotonic.

(c) *"This child was used to overnight feeding and therefore produced enough insulin to keep the sugar levels under control at night. He was therefore producing high insulin levels at night and if not given food ie dextrose then his sugar levels would be severely effected by the high insulin levels and would drop very low."* (Ref: 122-001-003)

Comment: In a child of Adam's age blood sugar levels would have remained normal during the day. He ate very little and was fed very little during the day, receiving most of his nutrition overnight. (Maurice Savage witness statement 002/2 p9)There was no need to give him glucose intravenously

(d) *"Another alternative to the solution given would have been to use 5% dextrose with normal saline. However this child was not passing normal saline so the lower concentration sodium was used. At the end of the procedure the child's blood sugar was 4 which is at the low end of normal. Had he not been given large volumes of food during the procedure then his blood sugar levels would have been very low at the end of the procedure and he would have suffered brain damage as a result of this."* (Ref: 122-001-003)

Comment: Adam would not have needed extra sugar given intravenously to maintain his blood glucose concentration within normal limits. He would have had adequate fat and carbohydrate stores to allow normal glucose homeostasis (self-regulation to normal) and he would not have sustained brain damage caused by low blood sugar concentrations had none been given.

(e) *"Dr Gaston pointed out that there is very little literature on this subject. He said to provide the one-fifth normal saline solution was providing the same sodium concentration as the child had previously been receiving in the same type of fluid as the child was used to."* (Ref: 122-001-004)

Comment: It was known that Adam required sodium supplementation to compensate for sodium losses in urine. Even if 1/5 normal saline gave the same sodium concentration as his normal feed, given rapidly in large amounts, it had the effect of giving large amounts of free water to Adam. There was certainly less literature in 1996 on the subject than there is now, but certainly Arieff's work had been published by then (see refs 2 and 3 in my summary report dated 18th March 2012).

(f) *"It was briefly referred to that there is a move in North America away from providing dextrose. Dr Taylor confirmed that they would generally not use dextrose in babies over 6 months of age."* (Ref: 122-001-004)

Comment: Please see "d" and "e" above. There was no need to administer glucose to Adam. This statement is not pursued at the meeting of 14 June 1996; it is glossed over – there should logically have been discussion and subsequent investigation among the group as to *why* glucose was being used less in North America

(g) *"The other options being 10% dextrose and saline which was not appropriate as this child was not passing normal urine or Hartmanns which was not appropriate either."* (Ref: 122-001-004)

Comment: 10% dextrose in normal saline or Hartmann's would have both been appropriate solutions to use for maintainence in Adam's case. 10% dextrose in normal saline is usually reserved for neonatal use when hypoglycaemia is on occasion a aproblem

Fluid management

(4) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"Generally for surgery one would hope to replace half of the fluid deficit in the first hour, a quarter in the second hour and a quarter in the third hour."* (Ref: 122-001-001)

Comment: This is a generally accepted standard. Please see reference previously supplied (204-002-136/7). Examination of the previously prepared sheet containing both expert witnesses and Dr Taylor's fluid balance calculations shows that at 0700h Dr Taylor describes Adam as being 171 mls positive in fluid balance – ie there was no fluid deficit at that point in time which needed to be corrected.

(b) *"During this procedure judging by the CVP and BP Dr Taylor felt that he was not ahead of the fluid requirement and at 9.30am he started to give the Hartmanns. He pointed out that the Hartmanns may not have been necessary if the kidney had been in situ quickly."* (Ref: 122-001-002

Comment: The CVP as previously discussed by myself was of no meaningful value. Again referring to the fluid balance table previously provided, by 1000h, Adam was in a +ve fluid balance of 1665-1749ml (Taylor calculation) or +ve 2177 mls (Haynes calculation), or +ve 2242-2542 mls (Coulthard calculation). Unfortunately, 1500 mls of this had been given as 0.18% saline in 4% glucose ie containing 1200 mls of free water which would not have been retained in the intravascular compartment. Given Adam's previous surgery it would be predicted that the operation would take a considerable time and that the kidney would not "be in place quickly".

(c) *"Dr Taylor mentioned the analogy of a colander in that the more fluid you put in the more pours out."* (Ref: 122-001-002)

Comment: I cannot see the relevance of this comment. In a person with normally functioning kidneys, the more fluid one gives, the more fluid is lost as urine. In a patient with a systemic inflammatory response and lack of capillary (smallest blood vessel supplying tissues) wall integrity, fluid given will leak out into the extravascular space. Neither of these scenarios was applicable to Adam at the time of his transplant.

(d) *"His urine output was assumed to be fixed but was not measurable as the child was in nappies. However over a period of time the child had been receiving 2,100 mls of fluid per day and his weight was steady so therefore his fluid input and output were balanced."* (Ref: 122-001-002)

Comment: This is correct

(e) *"Usually the child received a low sodium feed ie 3 milimoles of sodium per 100 mls of feed. This is why the one-fifth normal saline was used as it had the same sodium concentration as his feed would have had. He was therefore receiving the same sodium concentration but less fluid."* (Ref: 122-001-002)

Comment: Before his transplant operation Adam received 2100 mls of fluid per day, containing a total of 67 mmols of sodium (page 9 of Professor Savage's witness statement 002/2) – equivalent to 31 mmols/litre of fluid. Urinary losses of sodium were fixed at an estimated concentration of 50 mmols/litre of urine. Adam's urinary output was also fixed. As a consequence, any further hypotonic fluid given (eg 0.18% saline/4% glucose) would inevitably lead to a decrease of blood sodium concentration. In summary, 0.18% saline/4% glucose would have been appropriate as maintenance fluid had he not been able to receive his normal enteral feed, but was inappropriate for replacement fluid administration during an operation.

(f) *"To maintain fluid one requires 4 mls per kilo of weight per hour for the first 10 kilos which would equal 40 mls per hour plus 2 mls per kilo per hour for the next 10 kilos which would equal 20 mls per hour therefore for maintenance one requires 60 mls per hour for a normal child."* (Ref: 122-001-002)

Comment: This is standard teaching for maintainence fluid requirements in children. The figure of 60 mls/hour would be correct for a normal 20 kg child. Adam's normal fluid regime (2100 mls per 24 hours) gives a value of 87 mls/hour.

(g) *"This child was passing large quantities of urine, perhaps up to 100 mls per hour of dilute urine ie low in sodium."* (Ref: 122-001-002)

Comment: Adam would have passed 2100 mls less insensible losses (approx 280 mls) of urine per 24 hours. This is 75 mls/hour. The urine would have been dilute in terms of waste products (urea and creatinine) but would have contained a fixed amount of sodium – in the region of 40 - 50 mmols/litre (witness statement 002/2, Maurice Savage).

(h) *His maintenance requirements were therefore :-* (Ref: 122-001-002)

100mls per hour	*To compensate for urinary output*
60 mls per hour	*For metabolism*
160 mls per hour	*Total requirement*
Less 10-20 mls per hour	*Urinary output of a normal child*
150 mls per hour	*Total fluid requirement*

Comment: The figures contained in this box are incorrect. His normal maintenance requirements were 2100/24 mls/hour = 87 mls/hour (daily intake/24). This assumes his fluid balance is normalised each day by peritoneal dialysis. If he were not to receive dialysis, then his maintainence requirement would be: insensible losses (approx 280 mls) plus urine output (assumed to be fixed at around 50 mls per hour (approx 1200 mls/day) Under these latter circumstances this would give a requirement of 62 mls/hour.

(i) *"The Doctors pointed out that the mother in this situation needs to understand that the child did not drown. It was also pointed out that the volume of fluids provided here was typical of the volume of fluids provided in many situations for children, for example, for sepsis they may in fact give as much as 1 litre of fluid an hour."* (Ref: 122-001-005)

Comment: I have no comment regarding the first sentence of this statement. The volume of fluid given, although generous, would not have resulted in Adam's death. It was the type of fluid given which caused his death. There are indeed many circumstances when rapid fluid administration is needed, including systemic sepsis. Under these circumstances either colloid (eg albumen solution, sodium content around 150 mmols/l, or blood), or isotonic solution (eg Hartmann's or Normal saline) is used. It is not standard practice to give hypotonic solutions (eg 0.18% saline/4% glucose) rapidly, in large volume.

(j) *"He also pointed out that there seemed to be some suggestion in the reports that the fluids had perhaps been given via the neck. He pointed out that this was not the case. All the fluids were given into the arm and there were no fluid tubes leading to the brain."* (Ref: 122-001-006)

Comment: The fact that he (Dr Taylor) makes this statement suggests that he (Dr Taylor) had doubt regarding the placement of the central line in a vein. It is perfectly acceptable practice to use a central venous line for fluid administration. Had it been necessary, the central venous line inserted into Adam, although high in the neck, and not in a standard position, could have safely been used to administer fluids with the proviso that venous blood could be freely aspirated from it. It is my opinion that the outcome would have been

identical whether the fluid had been given into a peripheral vein or the central line (assuming that it was in fact within a vein).

(5) Please explain the likely significance for the further administration of fluids to Adam in circumstances where:

(a) Replacement and maintenance fluids had been administered on the basis that the kidney would be in place in around an hour by which time there would need to be enough fluid to properly perfuse it

(b) The kidney is then not in place until a further:

(i) half hour;

(ii) hour;

(iii) hour and a half

Comment: Administration of fluids during the course of the transplant should have been guided by intraoperative events. It would have become apparent that there was some blood loss and insensible fluid loss which would have required appropriate replacement, and there is also the need to ensure that the circulation was volume replete (usually guided by a CVP measurement) at the time the implanted kidney was perfused. There should have been communication between the surgeon and anaesthetist regarding progress of the operation. If fluid had been given prematurely in anticipation of the donor kidney being perfused, then some of this would have been distributed throughout the entire extracellular space, and there may have been a need to give further fluid when the actual time for kidney reperfusion took place – again normally guided by a functioning CVP. Regardless of the timing, it was inappropriate to give large volumes of 0.18% saline/4% glucose.

Blood loss

(6) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"To replace blood one must provide 2½ times the volume of blood lost"* (Ref: 122-001-001)

Comment: This is a simple rule of thumb to allow an anaesthetist to maintain an adequate circulating blood volume in a bleeding patient. If blood or colloid solutions are used, then there is no need to give such large volumes. This formula applies only when crystalloid solutions are given. In practice, an experienced anaesthetist uses all the information available to him to manage fluid replacement eg CVP, pulse and blood pressure measurements. Please see table 10-7 in a reference previously supplied to the enquiry (204—002-137).

(b) *"The first packed cell was given after the blood gas readings had been checked. It is generally the situation that they prefer not to give blood if this is avoidable particularly with children as it may contain viruses."* (Ref: 122-001-002)

Comment: Transfusion of donor blood is avoided if possible. I suggest that the specific risk of blood borne virus transmission for the relevant era could be obtained by contacting the National Blood Transfusion Service. In the UK the risk of viral infection by donor blood in 1995 would have been very small.

(c) *"The low haematocrit level could be explained either by blood loss or over transfusion of water. If this was explained by an over transfusion of water one would have expected the haemoglobin level to be very high at the end of the procedure whereas in fact it was normal at the end of the procedure suggesting that the haematocrit low level had been due to blood loss."* (Ref: 122-001-003)

Comment: The small haematocrit level measured during the course of the operation could have resulted either from blood loss, or dilution by intravenous fluid administration, or a combination of both. I have discussed this in depth in a previous report (pp15-16 report dated 1/11/2011) and my opinion is unchanged – that although there had been some blood lost, the low haematocrit was also partly caused by dilution.

(d) *"The blood loss was measured as approximately 1,200 mls. Only 500 mls of packed cells were given but these actually are equivalent to double the amount of fluid."* (Ref: 122-001-003)

Comment: As noted in my report dated 1/11/2011, packed red cells have a hemoglobin concentration in the region of 24g/dl. Thus 500 ml of red cell concentrate will replace the haemoglobin content of 1000 mls blood (but only replacing 500 mls of intravascular volume – further fluid would require to be given to maintain the circulating blood volume

(e) *"It was also pointed out that some of what was thought to be blood loss could in fact have been a mixture of urine and blood. However, the haemoglobin at the end of the procedure was fine showing that the sums to compensate for this had been correct."* (Ref: 122-001-004)

Comment: I refer the Inquiry again to my report of 1/11/2011 in conjunction with the comparative fluid balance table prepared by the Inquiry. Adam received 500 mls of red cell concentrate, containing the haemoglobin found in approximately 1000 mls of blood. This is an appropriate volume of blood for him to have received. Much of the other fluid given will have distributed in the extravascular (including within the brain) fluid compartments

(f) *"There had also been a query raised that there was a delay in providing blood replacement. The doctors considered the following to be of guidance:- If one has lost 10% of blood volume then you could provide a drip of platelets and fluid. If 15-20% of blood volume was lost then one could give blood."* (Ref: 122-001-005)

Comment: I suggest that the timing of blood transfusion was appropriate. By the time Adam's haematocrit was 18%, he had received at least 2050mls of clear fluid (including 750 mls of 0.18% saline/4% glucose), and there would have been a significant dilutional component to the anaemia recorded

(g) *"However it was felt not to be as clear cut as to when one would start to replace the lost blood volume and it was commented that some people would*

bleed down to 30% prior to surgery. They said that the anaesthetist monitoring the situation would look at all factors and may not rush straight in to replace blood depending on the situation." (Ref: 122-001-005)

Comment: When anaesthetising a child (or any patient) for major surgery it is customary to decide in advance the threshold for blood transfusion – usually noted either mentally by the anaesthetist or in writing as a maximum acceptable blood loss before blood should be transfused. In a healthy individual with a haemoglobin of say 12g/dl, one would not consider transfusion until at least 20% of the predicted blood volume had been lost – ie when the haemoglobin would have decreased to around 9-10 g/dl. If the starting haemoglobin is lower, then less blood loss can be tolerated. Providing there is not ongoing rapid blood loss it is acceptable to wait a little longer before commencing transfusion. It would certainly be unusual to allow a haemoglobin concentration to decrease to less than 7 g/dl even in a healthy person at any point in time if at all possible. (A haemoglobin concentration of 7 g/dl is equivalent to a haematocrit of about 21%, 10g/dl equivalent to 30% etc).

Electrolyte testing

(7) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"It was asked whether there was an opportunity to do the electrolytes when the child was in theatre and it was confirmed that the opportunity was certainly there. However, this procedure was planned to last 1-1 ½ hours. A blood result taken at the start of the procedure would not have been back from the labs for perhaps 1-1 ½ hours so the procedure would have been almost complete leaving no opportunity to act on any results received."* (Ref: 122-001-003)

Comment: Please see my response to 2a above. The operation predictably took much longer than 1 ½ hours. Furthermore, there would have been a further 60 minutes or so of anaesthetic preparation time following induction of anaesthesia before the operation even commenced

(b) *"There was also no reason to expect the sodium level to need to be checked and it would not be normal to send off for electrolyte tests at this stage. In the ward the child had been "screaming and yelling" and it wasn't possible to do the test. The child has been receiving the same sodium levels and it was not anticipated that there would be any change in those so there was no reason to do the blood electrolyte tests."* (Ref: 122-001-003)

Comment: As discussed in previous reports both by others and me, it would have been desirable to obtain electrolyte assay either before or shortly after induction of anaesthesia. Even without this, had an appropriate fluid regime been utilised, then it is unlikely that there would have been such serious disorder of plasma sodium concentration as that experienced by Adam.

CVP

(8) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"The CVP readings although showing as 17 were felt to really provide a base of 12 because of the gradient between the jugular and the heart which was assessed at around 5 cms. For this procedure one would push up the CVP as high as one would dare ie around 5 cms. Therefore one would allow it to go up to 22 when starting with the base of 17."* (Ref: 122-001-003)

Comment: The first sentence in this statement is incorrect. There is not a gradient in venous pressure between the internal jugular vein and the right atrium. Secondly, as previously stated, it is my firm belief that no meaningful information could be obtained from the pressure measured in the central venous catheter inserted in Adam – there would have been obvious physical signs present had the central venous pressure really been 17 mm Hg.

(b) *"Dr Taylor pointed out that his practice would tend to be to have the CVP on a pole and to keep the transducer well away from the dialysis tube."* (Ref: 122-001-005)

Comment: I do not know why he has said this. It is standard practice to attach the pressure transducers for arterial and central venous pressure measurement to either the operating table or the patient's bed, thus if the operating table height was altered, the pressure transducers remain in a constant relationship to the patient's heart.

(c) *"Dr Taylor would have the transducers, arterial and CVP clipped onto the drip stand rather than attached to the table. In either situation when the table surface, that the patient is lying on, is tilted the CVP would have to be recalibrated and indeed in this particular case the table was moved and Dr Taylor recalibrated the settings."* (Ref: 122-001-007)

Comment: Please see 8b above

(9) In the accompanying "Notes of Inspection of Equipment" (Ref: 122-001-007), it states:

"There are default alarms on the screen with the CVP alarms at 20 and minus 5. However, the alarm had been suspended in this case so did not go off even though the CVP readings went above 20."

The monitor printout can be seen at Ref: 094-037-217, in which there is a 'mute' symbol at the top left hand corner.

(a) How do you interpret the 'mute' symbol for the alarm? For example:

(i) Does it mean that it was switched off at the very outset? Comment: To permanently silence alarms one usually has to enter through several "layers" of the controlling software depending on the make of the monitor. In my experience of working with various models of monitor, each alarm parameter can be set to appropriate values for each individual patient. Pressing the "mute" button usually silences the alarm for a

defined period – usually 1 – 2 mins according to the make of the monitor. Looking at this printout, it looks as if the monitor alarmed because an ECG lead had fallen off, presumably at the end of the operation as the surgical drapes were being removed. It would have been appropriate to temporarily silence the alarm at that point. It does not mean that all alarms on the monitor were silenced through the entire operation. Looking elsewhere on the printout (top right), there is a second, different "mute" symbol. It is not clear to me which parameter (or parameters) this refers to

(ii) Is the level at which the alarm sounds pre-set or can the anaesthetist, technician set the parameters?

Comment: Please see 9(a) I above.

(iii) Why would you switch the alarm off?

Comment: One might silence the alarm as one attends to the patient to investigate and rectify the situation. "Nuisance" alarms are common – pulse oximeter sensors or ECG electrodes being displaced from the patient being the most common causes, and can be easily rectified. Central venous pressure alerts as isolated abnormal parameters are unusual. The parameters which provide the most important useful alarms requiring immediate attention among those displayed on this tracing are oxygen saturation and heart rate

(b) The Inquiry Team would welcome any other comments you may have about anything of significance that you believe arises from the monitor printout (Ref: 094-037-217), including:

(i) The trend of the CVP readings, including the increase after 09:30, and what might have given rise to this

Comment: As previously discussed, I do not believe that any credence can be given to the CVP measurements obtained from Adam during this case, because of the previous history, the misplacement of the catheter, and the actual pressures measured which were not compatible with Adam's clinical condition at the time of insertion. It remains my opinion that the CVP reading should have been recognised as erroneous by the anaesthetist. Therefore I have no further comment to make on the trend of CVP readings.

1. The APS/APM/APD scores including the shape encountered just after 09:30, and what may have given rise to this

Comment: The systolic(APS), diastolic(APD) and mean(APM) blood pressures are displayed on the same graph. The brief peak and trough shown shortly after 0930 correlates with the time a blood sample was taken from the arterial line for blood gas analysis. During sampling, there is brief loss of continuity between the pressure transducer and the catheter tip, visible as a brief peak in pressure, accentuated when the line is flushed by the flushing device under pressure.

The printout runs from approximately 0730 (when the arterial line would have been inserted, to approximately 1140h, when one

assumes that the monitor had temporarily been disconnected for transfer to PICU.. I note that the hand written entries on the anaesthetic record (058-003-005) terminate at 1100. The admission note to PICU is timed at 12.05 hours (page 058-035-135). The availability of monitor printouts for the period 1100h – 1144h. provides haemodynamic information. Although not ideal, I think the incompleteness of the anaesthetic chart is not a deliberate omission; by this point in time I presume that concern had arisen regarding Adam's condition, and Dr Taylor's attention was diverted away from completing the anaesthetic chart, which by this time would have needed a second page.

According to the anaesthetic record, anaesthesia was induced at 0700h. The arterial pressure graph commences at approximately 0730h, when the arterial line would have been inserted and connected to the monitor. It is not clear when the surgery commenced, but it must have been some time after 0800h, which is when the CVP recording commences. Given that all that could have possibly remained to do from the anaesthetic preparation point from that time onwards would have been epidural insertion and transfer of Adam from the anaesthetic room into the operating theatre, I would suggest that the actual surgery started at around 0830h, when there is a slight upward inflection of the blood pressure trace. The blood pressure appears to have remained within normal, steady limits (allowing for some variability due to varying intensity of surgical stimulus until around about 1015h, when there was a minor downward inflection. I suggest that this might have been the time the donor kidney was re-perfused. From approximately 1025 onwards there is a steady increase in blood pressure to around 130-150/80-90, which is large for a child of Adam's age.

Why would Adam's blood pressure have steadily increased during this period to unusually large levels? This has been discussed at some length previously during the Inquiry. Possibilities include: 1:diminution of effectiveness of the epidural anaesthetic administered. It appears from the anaesthetic record (058-003-008) that only a single bolus of local anaesthetic agent was administered, presumably at the time of insertion. Its effectiveness would be diminishing by 1030, some 2 hours after administration. 2: increasing intensity of surgical stimulus – but this would give a more fluctuating pattern of blood pressure as the abdominal wound was closed, and 3: the increase in blood pressure over this time have been caused by the body's reflex response to raised intracranial pressure, the reflex is hypertension and slowing of heart rate. I cannot say with certainty which of these factors contributes to this observation of increased blood pressure. A further confounding factor may be that he might have been given dopamine to attempt to optimise renal blood flow during this time. Dr Savage notes (058-035-133) that Adam should receive dopamine in a modest dose (2 – 3 mcg/kg/min) in theatre. There is no note of this being given by Dr Taylor, but it may in fact have been given and not recorded as having been given.. Dopamine acts on the heart and peripheral circulation to increase cardiac output and to increase blood pressure.

(ii) The trend of the heart rate:

Comment: the heart rate (HR) is increased at 140/minute at 0700h when anaesthesia is induced – presumably caused by Adam being upset at the time anaesthesia was induced, and also as atropine was administered as part of the anaesthetic. The HR then remains steady at around 90 – 100 bpm until around 11.15h, when it increases again which may be coincident with the time when the administration of halothane was stopped.

Urinary catheter

(10) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"It was pointed out that one would not routinely catheterise patients going to theatre simply to measure their urinary output."* (Ref: 122-001-002)
Comment: The need to catheterise patients undergoing major surgery has been highlighted elsewhere to the Inquiry both by myself and others. The indication being to measure urine output and to assist with fluid management

(b) *"It was pointed out that it was of vital importance that one was not able to measure the urine output during the procedure as the bladder was open. Normally one would be able to measure urinary output during operation every 5 mins except for a short period when the bladder was open. However during this procedure the bladder was opened immediately and was opened for some 2 hours so it was not possible to measure the urinary output and this child was known to have high urine output."* (Ref: 122-001-004)

(i) Please explain what "*the bladder was open*" means and why it would have been opened immediately

Comment: The bladder would have been opened to allow implantation of the donor ureter into the bladder. A urinary catheter would have given Dr Taylor information regarding Adam's urine output during the period before the bladder was incised. This would have guided his fluid replacement

(ii) Please state whether the bladder being opened immediately can be ascertained from Mr. Keane's entry into Adam's medical notes and records and if not whether it should be.

No Comment: The opinion of a urologist should be sought.

(iii) Please explain why in the circumstances where the bladder was opened immediately it was nonetheless "*not possible to measure the urinary output*" and what, if any, steps could have been taken to ensure that urine output could be measured.

Comment: Any urine produced by the native kidneys would have drained into the operative field rather than passing through the urinary catheter. It is difficult to quantify urine output when this occurs.

Pulmonary oedema

(11) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"There is no evidence in other organs of oedema."* (Ref: 122-001-001)

(i) Please note that Dr Taylor in his evidence at the Inquest stated that Adam had "severe pulmonary and cerebral oedema" (011-014-098). Dr Louise Sweeney, Consultant Paediatric Radiologist at RBHSC, states at WS-242 p.2, that there was mild pulmonary oedema at 1.20pm, with a deterioration in the lungs due to increased pulmonary oedema at 9.30pm. Comment: As stated elsewhere in the Inquiry, there is no evidence that Adam had significant oedema of his lungs or organs other than his brain. He did not have severe pulmonary oedema – subsequent expert review (Dr Caren Landes) states categorically "the chest x ray does not show pulmonary oedema" (207-006-011)

Hyponatraemia

(12) Please provide, from your knowledge of Adam's case to date, your understanding of, and comments on, each of the following statements:

(a) *"Again Dr Taylor referred to the issue of overload and said if there was overload then there would be heart failure and on x-ray the child's heart was not enlarged so clearly there had been no fluid overload. "*(Ref: 122-001-005)

(i) Please note that Dr Louise Sweeney, Consultant Paediatric Radiologist at RBHSC, states at WS-242 p.2, that the 9.30pm x-ray on 27th November 1995 shows an increase in the size of the heart from the x-ray taken at 1.20pm on the same day.

Comment: As previously stated, it is my opinion that it is the type of fluid given to Adam which caused the fatal cerebral oedema to occur, not the volume given. There was no reliable CVP measurement to guide fluid replacement. Assessment of the cardio;thoracic ratio ratio in portable chest x rays is inaccurate, and unless the abnormality is very severe ie the heart is extremely dilated, no firm conclusions can be drawn from a portable chest x ray, (The Inquiry may prefer to obtain a more authoritative explanation as to why this is from an expert in radiology). In a posterior-anterior projection of the chest, taken in the x ray department, the transverse measurement of the cardiac shadow can be compared with the transverse shadow of the entire thorax. If the heart is enlarged, this ratio exceeds 0.5.This assessment cannot be properly made from a portable anterior-posterior chest x ray projection Pulmonary oedema can occur in the absence of a heart increased in size.

(b) *"What had occurred was that fluid had sequestered in the brain. There was a higher concentration in the brain of sodium than elsewhere and the child then coned. However, what had been done was reasonable. This child got no free water, every fluid used contained salt."* (Ref: 122-001-005)

Comment: This statement is incorrect. Cerebral oedema occurred as water entered the brain cells along an osmotic gradient. In effect the child (Adam) received a large volume of free water because he received 1500 mls of 0.18% saline in 4% glucose. This equates to 300 mls of isotonic saline plus 1200 mls of free water.

(i) Please explain what might be meant by *"fluid had sequestered in the brain. There was a higher concentration in the brain of sodium than elsewhere"*

Comment:: Please refer to my previous report (204-004-169/70), with the appropriate reference (204-004-293 to 299) for an explanation of the appropriate physiological principle. In particular I refer the Inquiry to figure 1-18 on page 204-004-298 of the reference. Water moved from hypotonic (because of hyponatraemia) plasma, to the isotonic interior of brain cells, causing the brain cells to swell.

Dr Joe Gaston

(13) Dr Joe Gaston was a Consultant Paediatric Anaesthetist and Clinical Director of Anaesthesia, Theatres and Intensive Care in November 1995. Please therefore comment if, having seen Adam's medical notes and the reports of Dr Armour and Dr Sumner, Dr Gaston's conclusions below were reasonable or appropriate:

(a) *"Dr Gaston felt there were two main issues to consider:-* (Ref: 122-001-004)

Firstly, the issue of volume replacement which he felt had been appropriately covered and the calculations had been reasonable, and"

(b) *"Secondly, was this the most appropriate fluid to use. However obviously the fluids provided had not been correct but one does not know why."*

Comment: I do not believe that Dr Gaston gave adequate, independent, consideration to Adam's fluid balance and as such does not make an objective assessment of the case. There is no documentary evidence that he has worked through Adam's fluid balance independently, as has been done by the Inquiry – I suggest that he merely listened to Dr Taylor talking through his (Dr Taylor's) calculations. Dr Gaston has not made an objective assessment of Adam's "normal" fluid and electrolyte balance, nor has he made his own detailed assessment of the intraoperative fluid balance. I suggest that he should have either done that for himself, or done it jointly with Dr Savage, or he should have asked an independent colleague to work through the necessary calculations from the information available. Had he done so, I believe that he may have reached conclusions similar to those reached by the various experts reporting to the Inquiry.

Prior to concluding that the fluid used was appropriate in type, he should either himself, or delegated a colleague to have searched the medical literature on the subject of hyponatraemia. **It must be remembered that in 1995, carrying out a literature search was not as simple or as rapid as it is in 2012.** My recollection is that one had to enlist the services of a

hospital/university librarian, searching for keywords, and then paper copies of the relevant journal articles would have to be ordered. The internet was not as readily or widely accessible as it is now.

Additional Comments

(14) Please provide any further points and comments that you wish to make, together with any documents.

Comment:

- The discussion is disjointed with no clear agenda and appears to ramble. There is no synopsis of the case nor list of topics arising for discussion
- Mr Keane was not in attendance. He should have been invited
- It would have been helpful if somebody had researched the medical literature and given a presentation to the group on intraoperative hyponatraemia, and also on up to date knowledge with regard to intravenous fluid therapy .
- There is no reflection on the overall outcomes of the paediatric renal transplant programme at Belfast
- Paragraph 6 on page 122-001-005 is of concern. Firstly, there is no mention in any of the other documents I have seem of the fact that blood did not flow from the transplanted renal artery when a needle was inserted. Secondly, it is appears to me that something had obviously gone far wrong by the time the operation site was closed, because "the performance of the kidney was no longer relevant at this stage" No explanation is offered for either of these statements

Expert witness declaration

I, Simon Haynes declare that:

1: I understand that my duty in providing written reports and giving evidence is to help the Court, and that this duty overrides any obligation to the party by whom I am engaged or the person who has paid or is liable to pay me. I confirm that I have complied and will continue to comply with my duty

2: I confirm that I have not entered into any arrangement where the amount or payment of my fees is in any way dependent on the outcome of the case

3: I know of no conflict of interest of any kind, other than any which I have disclosed in my report.

4: I do not consider that any interest which I have disclosed affects my suitability as an expert witness on any issues on which I have given evidence

5: I will advise the party by whom I am instructed if, between the date of my report and the trial, there is any change in circumstances which affect my answers to 3 and 4 above

6: I have shown all the sources of information I have used

7:I have exercised reasonable care and skill in order to be accurate and complete in preparing this report

8: I have endeavoured to include in my report those matters of which I have knowledge or of which I been made aware, that might adversely affect the validity of my opinion. I have clearly stated my qualifications to my opinion

9: I have not, without forming an independent view, included or excluded anything which has been suggested to me by others, including my instructing lawyers.

10: I will notofy those instructing me immediately and confirm in writing if, for any reason, my existing report requires any correction or qualification.

11: I understand that:

11.1: my report will form the evidence to be given under oath or affirmation

11.2: questions may be put to me in writing for the purposes of clarifying the report and that my answers shall be treated as part of my report and covered by the statement of truth

11.3; The court may at any stage direct a discussion to take place between experts for the purpose of identifying and discussing the expert issues in the proceedings, where possible reaching an agreed opinion on those issues and identifying what action, if any, may be taken to resolve any of the outstanding issues between the parties.

11.4: the court may direct that following a discussion between the experts that a statement should be prepared showing those issue which are agreed , and those issues which are not agreed, together with a summary of the reasons for disagreeing

11.5: I may be required to attend court to be cross-examined on my report by a cross-examiner assisted by an expert

11.6: I am likely to be the subject of public adverse criticism by the judge if the court concludes that I have not taken reasonable care in trying to meet the standards set out above

12: I have read part 35 of the Civil Procedure Rules and the accompanying practice direction including the "Protocol for Instruction of Experts to give evidence in Civil Claims" and I have complied with the requirements

13: I am aware of the practice direction on pre-action conduct. I have acted in accordance with the Code of Practice for Experts.

Statement of Truth:

I confirm that I have made clear which facts and matters referred to uin this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

Simon R. Haynes

Signed:
Dr Simon R. Haynes

28th July 2012

Dated:
28th July 2012

Dr Simon Haynes MBChB, FRCA