ADAM STRAIN

Report by Advisors (Part 1 – Clinical)

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This short report, written by the Advisors to the Inquiry, describes the main clinical issues that impacted on Adam's care during his hospital admission in November 1995 that they think require further examination by the Inquiry during the forthcoming Oral Hearings

In addition to all the relevant clinical, nursing and administrative records, the following statements and reports were used in the generation of this document:

- 1. Protocol and briefs for experts
- 2. Witness Statements and responses to questions; Dr Taylor, consultant paediatric anaesthetist.
- 3. Witness Statements and responses to questions; Dr Montague, senior registrar in anaesthesia.
- 4. Witness Statements and responses to questions; Dr Savage, consultant paediatric nephrologist.
- 5. Witness Statements and responses to questions; Mr Keane, consultant urologist.
- 6. Witness Statements and responses to questions; Mr Brown, consultant paediatric surgeon.
- 7. Witness Statements and responses to questions; Dr O'Connor, consultant paediatric nephrologist.
- 8. Witness Statement, Dr Leslie Dyer
- 9. Depositions to Inquest
- 10. Witness statements to PSNI
- 11. PSNI interviews
- 12. Expert reports to Inquest: Prof Berry, Prof Risdon and Dr Sumner.
- 13. Expert reports to PSNI: Mr Koffman, Dr Sumner, Prof Risdon
- 14. Expert reports by Dr M Coulthard, consultant nephrologist.
- 15. Expert reports by Prof Gross, professor of medicine and nephrology.
- 16. Expert reports by Messrs Forsythe and Rigg, consultant transplant surgeons.
- 17. Expert reports by Dr SR Haynes, consultant in paediatric cardiothoracic anaesthesia and intensive care.
- 18. Expert reports by Ms S. Ramsay, independent advisor on children's nursing.
- 19. Expert report by Dr B Dolan, barrister.
- 20. Expert report by Dr JW Keeling, consultant paediatric pathologist.
- 21. Expert reports by Dr W Squier, consultant neuropathologist.
- 22. Expert report by Dr C Landes, consultant paediatric radiologist.
- 23. Expert reports by Prof. Fenella Kirkham, paediatric neurologist
- 24. Expert reports by Dr Philip Anslow, consultant neuroradiologist
- 25. Standards for solid organ transplantation, British Transplantation Society, 2003.
- 26. Renal Services Review, Department of Health, 2002.
- 27. Paediatric Surgical Services in NI, Report of a Working Group, 1999.
- 28. The Report of the Working Party to Review Organ Transplantation, 1999.
- 29. Towards Standards for Organ and Tissue Transplantation in the UK, British Transplantation Society, 1998.

- The Provision of Services in the UK for Children and Adolescents with Renal Disease; Report of a Working Party of the British Association for Paediatric Nephrology, 1995.
- 31. Tertiary Services for Children and Young People, British Paediatric Association, September 1995.
- 32. Letters to the Inquiry from the DLS
- 33. Also, Harvey Marcovitch attended two experts' meetings in Newcastle; Carol Williams and Peter Booker checked the transcripts

We consider that the main issues that need to be considered by the Inquiry are as follows:

1. Consent process.

• <u>Was the consent process for Adam adequate, comprehensive and at least equal</u> to the standard expected at the time?

There are different expert opinions as to who should have gained consent for paediatric renal transplantation in the mid 1990's. Guidance on consent is much clearer today.

Consent to Adam's surgery was obtained by Dr Savage, who had known Adam and his mother, Ms Slavin for several years. No explanation of surgical or anaesthetic procedures, risks and alternatives (including the possibility of a transfer to another hospital in the UK) is evidenced. Mr Keane, consultant transplant surgeon did not visit Adam and his mother before the operation. In addition, Ms Slavin had previously expressed a view on which surgeon she did not wish to be involved but this view was not communicated, forgotten or disregarded.

Dr Savage had previously spoken to Ms Slavin about transplantation and knew her to be concerned about the risks involved; apparently he spoke to her again on the evening of the 26th November. (**WS 002/3: 22a**) Dr Savage stated that: "I would have expected the transplant surgeon and consultant anaesthetist to also talk with Ms Slavin." (**WS 002/3: 21a and 4h**) In her PSNI statement, Ms Slavin stated that she did not see a consultant on the morning prior to the transplant surgery, (**093-003-005**), though Dr Taylor told the PSNI that he spoke to Ms Slavin at 0545. (**093-035-110b**). Apparently, no one from the surgical team discussed the surgery with Ms Slavin or had been available to answer her questions prior to the operation.

Messrs Rigg and Forsythe state: "It is the role of the transplant surgeon to gain consent from a paediatric patient's parents ..." (203-004-065) Similarly, Dr Haynes opined in his reports that it would be normal practice for the anaesthetist to visit a child and parents prior to surgery to discuss proposed perioperative care. (204-004-162) In contrast, Dr Coulthard states that in 1995 it "was relatively common for ..the final written consent for a child's kidney transplant to be undertaken by the consultant paediatric nephrologist." (200-007-117)

- What was the normal practice in the RHBSC at the time for providing explanations of major elective surgical procedures, particularly transplants, to children and parents
- Whether it was reasonable that Mr Keane (and, possibly, Dr Taylor) did not speak to Ms Slavin prior to Adam's surgery.

2. Preoperative preparation

a) Long-term management

• Were adequate measurements made (in the years) before the transplant to enable proper understanding of Adam's renal status?

The instructed experts raised two issues about the monitoring of Adam's health in the year preceding surgery (when his care was supervised by Dr Savage): firstly, not measuring urinary sodium concentration and secondly, not measuring urinary creatinine concentration. However, Dr Coulthard considers that this first figure can be reasonably inferred (so not obtaining a direct measurement is of no concern) because:

- a) Adam's daily dietary sodium intake was known
- b) His urinary output can be (and was) calculated from knowledge of his fluid intake and subtracting insensible fluid losses

Using these figures, Dr Coulthard calculated that Adam's likely urinary sodium concentration was in the range expected for children with end-stage renal failure resulting from dysplastic kidneys. (1st Report, pg. 22)

Measuring urinary creatinine would have allowed his clinicians to derive the 'fractional excretion rate for water', that proportion of the water filtered through his kidneys which was excreted. Dr Savage states that it was not routine to undertake this measurement neither at RBHSC nor at other renal units and that policy remains the case today. (WS 002/3: 18)

Dr Coulthard estimated that Adam was unlikely to be able to excrete more than 65 ml of water hourly and Prof Gross considers he could not have excreted more than 60 ml/h. (**Gross Report, pp. 15, 63**) This is a highly significant issue, in that Dr Taylor appeared, at the time of surgery, to have believed that Adam was able to pass much larger volumes of water in response to a fluid load, in excess of 200 ml/h, and this informed his decisions about the appropriate infusion rate of intra-operative fluids. (**WS 008/2: 9d**)

- Whether knowledge of Adam's fractional excretion rate for water or any other measureable variables would have better informed the preoperative discussions between Drs Savage and Taylor as to fluid management during his transplant?
- Was it reasonable for Dr Savage not to have measured Adam's urinary sodium and creatinine at regular 6 12 monthly intervals whilst he was on the transplant list?

b) The pre-operative admission

• <u>Did Dr Savage communicate all necessary information to his</u> <u>anaesthetic and surgical colleagues before surgery started?</u>

When Adam was admitted on the night before his transplant, the assessment of his general condition and performance of routine investigations were the responsibility of Dr Savage's team. The paediatric staff involved failed to maintain intravenous access. This is a relatively common phenomenon in young children who have been subjected to multiple medical interventions: we do not believe this is a matter of concern.

Ms Ramsay concluded that 'record-keeping in relation to fluid and nutritional management and dialysis was inadequate'. (**202-002-021, 026**) Certainly, as did the reporting experts, we had some difficulty in determining the precise nature of the oral fluids given overnight, (whether Dioralyte or some other glucose and/or glucose-electrolyte solution). However, Dr Coulthard considers this largely irrelevant because of the ability of dialysis to normalise fluid balance. (1st Report, pg. 27) There are also inconsistencies in the recordings of body weights and pre-dialysis serum sodium concentration. Whilst none of these matters are likely to have had a significant effect on outcome, they may have hampered communication between the care professionals as good record keeping is a key component of effective communication for both nurses and doctors. (See also section 12 on this issue)

On the evening of Adam's admission Drs Savage and Taylor apparently discussed Adam's fluid requirements in relation to his renal problems and Dr Savage was satisfied that Dr Taylor had all the information he required about Adam's usual fluid regime. (**WS 002/2: 10a**) In particular, Dr Savage states: "I did inform Dr Taylor of Adam's urinary output." (**WS 002/3: 8c**) Dr Savage reported detailed discussions with the anaesthetic and surgical teams at times during the night, though no record was made of these discussions in Adam's notes.

- How important was it that Dr Taylor and Mr Keane received all relevant information about Adam's past history and present condition from Dr Savage in the hours preceding the start of surgery?
- Whether it was likely that Dr Taylor and Mr Keane had received all relevant information about Adam's past history and present condition from Dr Savage in the hours preceding the start of surgery.
- Whether the lack of pre-operative record keeping in relation to Adam's management affected Dr Taylor's ability to make an effective assessment of Adam's fluid requirements.

3. Preoperative dialysis

• <u>How adequate were the recording, monitoring and clinical assessment</u> of Adam's dialysis on the night before surgery?

Adam's dialysis treatment was normally carried out by Ms Slavin (at home) over an 11 hour period each night. She kept records of his weight and fluid loss/gain from dialysis cycles in a notebook. These showed variation in fluid loss during dialysis (from about 150 ml to 650 ml; average 290 ml). When Adam was admitted to hospital on 26th November, he was dialysed for approximately eight hours overnight, with the treatment finishing at about 0600. There was no record made of Adam's dialysis cycles, no record of pre- and post- treatment weight and no record of dialysis loss. Hence, it is impossible to calculate how much fluid Adam lost (if any) during this shortened dialysis treatment. Moreover, no member of Dr Savage's team or any other clinician appears to have made any post-dialysis assessment of Adam, for instance re-checking his heart rate, blood pressure, weight, and measured gain/loss. Ms Ramsay noted that there were no nursing or medical records relating to dialysis (202-002-026) and stated, in her report, that 'there were omissions in pre-operative observations of height, weight, blood pressure and temperature'. (202-002-021, 026) It is unclear who was responsible for recording and managing Adam's dialysis and assessing its effectiveness.

Although renal transplant surgery was a relatively unusual procedure for a patient on Musgrave Ward, it is not fundamentally different from any major abdominal surgery. Staff should have been familiar with caring for children on peritoneal dialysis and aware of the importance of assessing Adam's fluid balance prior to surgery. Nevertheless, support from a senior nurse and clear management guidelines should have been available.

- Who was responsible for measuring and recording i) the dialysis cycles; ii) dialysis fluid loss; and iii) Adam's pre- and post-dialysis weight and BP.
- How dialysis treatment in children was normally monitored and recorded while they were an in-patient in RHBSC in 1995
- Whether the effects of a shortened dialysis treatment period on total body water and serum electrolyte concentrations were entirely predictable.
- Whether it was reasonable that Adam was not re-assessed by any clinician after his dialysis treatment had finished. If he should have been re-assessed, who had the responsibility to re-assess him?
- What was the role of the Night Sister in supporting staff caring for children requiring preoperative dialysis?
- Did the contemporaneous clinical guidance outline clearly the preoperative preparation required by Adam?

4. Timing of surgery

- <u>Should the transplant have gone ahead, given the nature of the donor</u> <u>kidney?</u>
- In the event, was there undue delay in commencing the transplant?

The plan for arranging and conducting Adam's transplant was formulated by Dr Savage 'in consultation with Mr Keane and Dr Taylor'. (**WS 002/3: 2ii**) The donor kidney had been perfused with ice cold perfusate at 0142 on the 26th November and transported surrounded by cold preservation fluid. (**058-009-027**) Messrs Forsythe and Rigg stated that: "It is preferable not to perform kidney transplantation between the hours of 0000 and 0600 but if the cold ischaemia time is likely to be over 24 h (in 1995) or 20 hours (current) then consideration should be given to performing the operation overnight". (**1**st **Report, para 2.4**)

Dr Savage states that the optimal time to commence transplant surgery is within 24 h of the kidney having been donated; (WS 002/3: 2(o)) in Adam's case this was before 0200 on the 27th November, once the tissue cross-match had been completed. Dr Savage reported that the decision to delay the transplant was taken by the surgical and anaesthetic consultants: he accepted their views that getting some sleep overnight and starting fresh in the morning was a sufficient benefit to warrant a few more hours delay. (WS 002/3: 20f(i))

Similarly, Dr Taylor stated that the reason for delaying surgery was to ensure fresh operating room staff, that a PICU bed would be available and to prevent the emergency theatre being 'blocked' by a semi-elective case. (**WS 008/1: 1(ii)**) He further stated that it was a team decision, which included ward, theatre, PICU staff as well as Mr Keane, to commence surgery at 0700. (**ibid**) The precise timing of the conversations that led to this starting time was not recorded or recalled by any of the clinicians involved.

Messrs Rigg and Forsythe state that, because the kidney arrived in Belfast only at 2100, a delay until 0600 was reasonable: (1st Report, para 3.4) it appears that the longest extension of the 'cold ischaemia time' was made before the kidney arrived in Belfast. Mr Keane stated that he did not "believe that surgery of that nature should be undertaken in the early hours of the morning for reasons of patient safety". (WS 006/02: 3g)

Messrs Rigg and Forsythe add that: "neither of us would have accepted this kidney for this child either in 1995 or now", though they accept that there are likely to be other surgeons in the UK who would have accepted this organ for this child. (2nd **Report, para 4(i)**) Their reservations relate to three main factors: i) the long cold ischaemia time; ii) Adam's complex past surgical history and problems with polyuria and recurrent hyponatraemia; and iii) the donor kidney having two arteries. The decision on whether to accept the donor kidney may be a joint one between surgeon and nephrologist, but the ultimate responsibility lies with the surgeon.

- Whether it was reasonable that Adam's transplant should have proceeded, given the already prolonged 'cold ischaemia time', the relative inexperience of the operating team and Adam's risk factors.
- Whether it was reasonable to delay starting the transplant until 0700, given the already long 'cold ischaemia time'.
- Whose responsibility it was to determine the time when surgery would start.
- Whether there was any local written guidance regarding the timing of transplant surgery.
- Whether Dr Savage and/or Mr Keane ever considered not accepting the donor kidney and if not, why not?

5. Anaesthesia and intraoperative monitoring

a) Fluids and electrolytes

- What were the implications of not checking Adam's serum electrolyte concentrations until surgery was completed?
- What was the significance of the volume and content of fluids given to Adam in theatre, taking into account the somewhat differing estimates of fluid balance by Witnesses & Experts?

Relevant witness statements make it clear that Adam was anaesthetised in theatre, with his mother in attendance, at about 0700. Dr Montague, a trainee anaesthetist, was not present but was preparing drugs and equipment in the adjoining anaesthetic room. (WS 009/3: 2a) Assisting Dr Taylor, consultant paediatric anaesthetist, was Mr Shaw, an MTO, and an unnamed anaesthetic nurse (who was also part of the theatre nurse team). (WS 008/3: 70d) Induction of anaesthesia was achieved intravenously and Dr Taylor then proceeded to give Adam drugs that would keep him paralysed and anaesthetised throughout the procedure. An endotracheal tube was inserted and Adam was artificially ventilated using the ventilator on the anaesthetic machine. Another peripheral venous cannula was then inserted.

Originally, it had been planned to take a blood sample from Adam after dialysis had finished at 0600, to check his electrolyte balance, but this was not achieved because there was no longer a venous cannula in situ. (WS 002/3: 8(ii); 27(a); 30(f,g)) Adam had relatively poor veins such that the paediatric junior staff (reasonably) were unable to cannulate any, and he became increasingly distressed at their repeated attempts. The first opportunity to remedy this difficulty was when anaesthesia was induced. A blood sample could have been taken and sent to the central laboratory and/or to a nearby blood gas machine (BGM). Dr Savage states that the judgement not to measure serum electrolytes once the anaesthetic was administered was "contrary to my request". (WS 002/3: 30(h))

We consider there were sufficient staff members present to take, label and transport a sample to the laboratory/BGM: Dr Taylor had three assistants and at least two other theatre nurses, (who would not have needed >40 min to prepare their instrument trolleys, etc., so were potentially free to help). (WS 008/3: 70(c), 70(d)) However, Dr Taylor states that he chose not to take a blood sample at this time because he did not think it a high priority and he had much else to do; he assumed that following dialysis Adam's serum electrolytes would be reasonably normal and hence there was no urgency to check them. (WS 008/3: 17b, 18a, 90a, 90d)

He is supported in this view by Dr Coulthard, (1st Report, pg. 27) though in later reports, (200-007-116, 200-009-153), Dr Coulthard has made clear that he has reservations that this was a sensible approach under the circumstances.

Nevertheless, in his report of 11.11.11 he comments that [so far as fluids and electrolytes were concerned] Adam was in a safe and suitable condition to have an anaesthetic. In contrast, Prof. Gross, (Gross Report, pp. 31, 63), Dr Savage, (WS 002/3: 37, 39, 40), and Dr Haynes, (2nd report, pg. 8), state that the measurement of serum electrolyte concentrations should have been performed as soon as was practicable after induction of anaesthesia.

Dr Taylor gave Adam about 750 ml of i.v. dextrose 4% saline 0.18% between 0700 and 0800 (the start of surgery). (**058-003-005**) This intervention is based largely upon Dr Taylor's correct assumption that since 0500 Adam had received no oral or i.v. fluids; he concluded that because (of his belief that) Adam had been and was continuing to pass 200 ml of urine every hour, he would have a fluid deficit of at least 600 ml by 0800. (**WS 008/3: 52a**) We cannot find any evidence to support this estimate of Adam's urine output. In contrast, Dr Savage estimates it as 50-60 ml/h, (**WS 002/3: 9(a), 30(c)**), a figure consistent with that calculated by both Prof Gross and Dr Coulthard. In his report of 11.11.11, Dr Coulthard states that "simple mathematics indicate that the estimate of 200 ml was a large error".

In his latest WS, however, Dr Taylor has accepted that Adam's urine output was 78 ml/h. (**WS-008/5: 1(c)**)

- Was it reasonable for Dr Taylor not to take a blood sample and check Adam's serum electrolyte concentrations at the first available opportunity after induction of anaesthesia, contrary to Dr Savage's request?
- What fluid losses would Adam have experienced between 0500 and 0800? What was their likely sodium content and volume?
- Whether Adam had a significant fluid deficit when he arrived in theatre at 0700. If so, what was it? Was it predictable?
- What was Adam's serum sodium concentration likely to have been at 0700? What was it likely to have been at 0800?
- What was the basis on which Dr Taylor made his conjecture regarding Adam's likely urine output? Does Dr Taylor now wish to revise this earlier conjecture?
- What was Dr Taylor's experience in providing anaesthesia for (i) paediatric renal transplantation and (ii) polyuric patients undergoing major surgery?

One reason Dr Taylor gives for not measuring serum electrolyte concentrations at this time was that all he had done was replace Adam's supposed fluid deficit and urine output with fluid containing approximately the same amount of sodium. (WS 008/3: 48a, 80a, 110d, 105b)

Dr Savage states that he calculated Adam's fluid deficit at the start of surgery as being 500 ml and that replacing this deficit over 2 h would seem to be reasonable. (**WS 002/2: 11(e)**). He also stated that the deficit could be replaced over 1-2 h depending on the CVP. (**WS 002/3: 38(b)**)

Dr Coulthard, on the other hand, states that overnight dialysis tends to normalise a child's total body water so that it is unlikely there would have been any such deficit. (1st **Report, pg. 27, 200-009-149**) In his report of 11.11.11, he calculates that at the start of surgery (0800), Adam would have had a net positive balance of between +686 and +986 ml. (**200-009-161**) In the course of the experts' meeting he repeatedly stated that Adam was given fluid which was the equivalent of 500 mls of water over about 1 hour at the beginning of surgery.

Matters for further consideration:

- Did Dr Taylor make a reasonable decision to plan not to measure serum electrolyte concentrations in Adam until the end of the case?
- Should Dr Taylor have anticipated that Adam would experience an acute decrease in his serum sodium concentration following the rapid infusion of a large volume of dextrose saline, particularly if his contemporaneous assumption regarding Adam's urine output was incorrect and Dr Coulthard's calculation that Adam was in net positive balance at the start of surgery is correct?
- What volume of fluid was it reasonable for Dr Taylor to have given Adam after induction of anaesthesia: in the first hour until 0800; from 0800-1000?

b) Central venous pressure

• What was the significance of the misplaced central venous catheter (CVC)?

One of the procedures performed by Dr Taylor between 0700 and 0800 was the insertion of a CVC, his last intervention before surgery started at 0800. A CVC is a useful monitoring device in children undergoing major surgery because, if they have normal heart function, it can provide a valuable guide to the volume of fluid required to maintain the patient's circulating blood volume. In Adam's case, it was particularly important, as Dr Taylor (and Mr Keane, the transplant surgeon) wished to ensure that, just prior to release of the vascular clamps, Adam had a higher than normal

blood volume. (This is because they did not want Adam's blood pressure to fall secondary to the release of blood into the new kidney).

Catheters had been inserted into Adam's central veins before his renal transplant on five previous occasions: 27.11.91, percutaneous via his left subclavian vein, (right internal jugular cannulation attempted but failed) (049-028-073); 29.11.91, percutaneous left internal jugular vein (049-029-089); 08.12.91 via his right *external* jugular vein, right cervical incision (050-008-032); 28.12.91 surgical cut-down of his left antecubital fossa (050-015-047); 29.05.92 via his left common facial vein, left cervical incision. (053-015-052, 054-057-131) The line inserted in May 1992 apparently was not removed until February 1995. The post mortem examination suggests that the left internal jugular vein had been ligated (perhaps an error by the surgeons, mistaking it for the common facial vein, albeit this is denied by the DLS on their behalf) and, in any event, the longevity of the left sided line placed in 1992 made the left sided approach potentially problematic. The right internal jugular vein had never previously been cannulated.

Instead, Dr Taylor used the right subclavian vein as a route for his CVC although this approach is associated with higher malposition risk than the right internal jugular vein. (Ruesch S et al. *Crit Care Med 2002*; **30**: 454-60) Once in a neck vessel, it is difficult to redirect the catheter into the correct position without X-ray or ultrasound imaging. Dr Taylor felt the catheter in the neck, so knew it was misplaced. (**WS 008/3: 35j**) He judged that, due to time constraints, surgery ought to proceed, despite the potential unreliability of the central venous pressure (CVP) measurements obtained through the CVC. Notably, Dr Taylor knew at this time, because the CVC was misplaced in it, that the right internal jugular vein was patent.

Messrs Rigg and Forsythe state, if they had been told that the CVC as placed was not going to provide reliable or accurate readings: "We would have asked for a further attempt at placing the CVC as central venous access would have been essential to monitor fluid balance in a small child." (2nd Report, para 11(i)) They also state that 'it would have been essential" to have made further attempts at inserting a CVC, even if such attempts took 30-60 min. (2nd Report 11(ii), (iii))

Similarly, Dr Haynes states: "It would have been sensible for a discussion to take place between himself (Taylor) and the surgeon once it became apparent that difficulty was being encountered." Dr Haynes also suggests alternative strategies, such as surgical cut-down, using a femoral vein, or connecting the transducer to one of the other more proximal lumens of the triple lumen catheter. (**2**nd **Report, pp. 12/13**).

The first CVP measurement, taken at about 0800, was about 17 mmHg. (**058-008-023**). This was abnormally high (a normovolaemic patient would be expected to have a CVP of 2-6 mm Hg). In his deposition to the Coroner, Dr Taylor stated that: "There were both cardiac and respiratory patterns to the waveform confirming correct intravascular placement." (**011-014-099**) In a later statement, however, Dr Taylor stated that he ignored this initial reading as he had looked at the pressure waveform

and noted that it was non-pulsatile, so confirming in his mind that the catheter was partially obstructed and not producing accurate pressure readings. (**WS 008/3: 35(d)**) Nevertheless, he thought that the readings could provide useful and accurate information about *changes* in circulating blood volume (i.e. trend information only).

Dr Haynes states that this approach is not reliable: (2nd Report, pg.13) "If the CVC was lying against a vein wall, or kinked, the pressure measured at the transducer would not be that of the blood within the vein. If there was venous obstruction, the pressure in the internal jugular vein would not reflect the right atrial pressure."

It is difficult to ascertain the precise situation in regard to the CVC. One suggestion is that it was partially obstructed, either because it had abutted against the vessel wall and/or the vein itself was obstructed. In that circumstance the measurement could not reflect the true CVP. However, if Dr Taylor was correct in his original statement that there was a visible waveform, it suggests that the CVC was in direct communication with the right side of the heart so that the measurements were not artefactual.

The experts all agree that Adam's clinical state in the early stages of surgery was such that he could not have had a CVP as high as that recorded. This would seem to favour the 'obstructed' suggestion but does not account for the apparently observed wave form. Dr Coulthard has proposed a possible explanation, **(200-019-227)** namely that the vein was patent, the CVC was measuring CVP but that it had been incorrectly zeroed so that an artificially high reading was observed throughout. The first reading likely to have been accurate was that recorded on arrival in PICU. Dr Coulthard suggests that in the process of moving him and readjusting the equipment, it was correctly zeroed. Dr Haynes does not support this suggestion and considers it more likely that there was <u>not</u>, in fact, any wave form present. The alternative explanation for the 'normal' value recorded in PICU, favoured by Dr Haynes, is that the CVC was abutting a vessel wall, so partly obstructed and in moving Adam's head relative to his trunk when transferring him to PICU, the CVC was freed.

- Whether the facts support Dr Coulthard's hypothesis or the alternative explanations. What steps did Dr Taylor take to ensure that the CVC transducer was correctly positioned in relation to Adam's right atrium? (i.e. Was the zeroing process correct and was the positioning rechecked when the first abnormal reading was obtained?) Were there any steps not taken that would have helped ensure that the zero was correct?
- If, after rechecking the zeroing process Dr Taylor decided that the CVC was misplaced or the vein obstructed, was it a reasonable decision to proceed with the case, given the already long cold ischaemia time for the donor kidney vs. the requirement for accurate CVP measurement.

- If Dr Taylor had decided that the CVC was misplaced, should he have tried again to insert a catheter via the right internal jugular vein, as he now knew it was patent.
- Failing that, should Dr Taylor have tried to re-position his subclavian line, using X-ray or ultrasound imaging? Alternatively, should he simply have withdrawn it by a few cm while examining the waveform or attached the transducer to another lumen?
- Whether it was reasonable for Dr Taylor to have proceeded without informing Mr Keane of the misplaced/partially obstructed CVC and the likelihood that all readings from it (in his view) were likely to be unreliable.
- Whether it was reasonable for Dr Taylor to ignore the CVP measurements as being inaccurate and/or unreliable.
- Whether Dr Taylor was correct in thinking that even if the CVC was misplaced and partially obstructed it could be used to reliably determine changes in circulating blood volume.

c) Urinary catheter

One intervention that Dr Taylor did not perform in the pre-surgical phase was insertion of a urinary catheter. The decision not to insert such a catheter was taken by Mr Keane. (**WS 006/3: 24a**) Adam had a normal urethra and there was no absolute contraindication to inserting such a catheter. If one had been inserted, Dr Taylor would have been able to measure hourly urine output from Adam's native kidneys; the implications for that are obvious, given our comments above. The reason Mr Keane gives for not wanting a urinary catheter is that he wanted the bladder full, as it makes ureteric implantation that much easier. (**WS 006/3: 12a**)

This objection can be overcome by either clamping the catheter for a period prior to the ureteric implantation, or by filling the bladder with fluid using a syringe inserted into the urethral catheter. (Rigg and Forsythe, **2nd Report, para 3(xi)**) Messrs Rigg and Forsythe state that "A urethral catheter will always be placed at the beginning of the operation, unless it is not technically possible." (**1st Report, para 2.5**) However, they also state that "it was reasonable not to insert a urethral catheter at the beginning of the operation" if it was the surgeon's practice always to insert a suprapublic catheter instead. (**2nd Report, para 3(xi)**)

Dr Haynes disagrees, stating that: "If the anaesthetist believes that it is to the patient's advantage to have a urinary catheter, he should insist that one were in place unless there is a known contraindication. Monitoring of urine output during any operation is the responsibility of the anaesthetist." (**2**nd **Report, pg. 14**) He goes on to state: "To allow safe management of intravenous therapy, the anaesthetist

needed to know as best he could, the volume of urine produced, especially in a patient such as Adam where urinary losses, because of the underlying disease, may not reflect his circulatory state." (ibid) Likewise, Dr Coulthard regards the presence of a urinary catheter as an essential requirement to assess fluid therapy.

Matters for further consideration:

- The risks and benefits of inserting a urethral catheter at the start of the case.
- Whether it was a reasonable decision not to insert a urethral catheter.
- The implications of not inserting a urethral catheter, particularly in the light of unreliable CVP measurements.

6. Intraoperative fluid management

a) Blood loss and replacement

• How accurate were the blood loss calculations? What were the implications for the maintenance of circulating blood volume if these calculations were grossly inaccurate?

Once surgery started at about 0800, Dr Taylor had to think about replacing blood loss in addition to insensible and urinary losses; these latter losses were replaced using dextrose saline. He used a combination of Hartmann's solution, plasma (HPPF) and packed red blood cells to replace assumed blood loss. Dr Taylor estimated blood loss using a combination of techniques: the difference in weight between dry and blood soaked swabs (411 ml); the volume of liquid in the sucker bottle (500 ml); and a visual estimation of the amount of blood on surgical towels. (**058-007-021**) However, because Mr Keane was using ice slush around the donor kidney to keep it cool, because the bladder was full of urine when incised, together with the confounding effects of residual peritoneal fluid left by the dialysis treatment, such estimates could only offer a rough guide (which is why an accurate CVP would have been so useful). At the time, Dr Taylor estimated total blood loss as being 1128 ml, (**011-002-004**) whereas Mr Keane has subsequently calculated it as 468 ml. (**WS-006/3**, **pg. 18**)

- What was the surgical blood loss? (Calculated by comparing pre- and postoperative haematocrits, measured at times when Adam had similar blood volumes)
- Was Dr Taylor's estimate of blood loss reasonable, given the information available to him at the time?

- Whether the response to this blood loss was appropriate, (regarding content, rate and total volume of fluids given).
- Whether this blood loss was reasonable, given that Adam previously had undergone multiple abdominal operations.

b) Serum sodium

• <u>What was required for Adam to have avoided becoming hyponatraemic (if indeed it was avoidable)?</u>

At 0930, Dr Taylor sent a blood sample to be analysed at the nearby blood gas machine (BGM) because he wanted to know Adam's haematocrit (as blood loss was apparently becoming significant by this time). As he had predicted, Adam's haematocrit was abnormally low, so Dr Taylor responded (appropriately) by infusing packed red cells. However, the BGM had automatically measured other parameters besides haematocrit, such as serum sodium, which Dr Taylor chose to disregard. Dr Taylor explains this decision by giving two reasons; firstly he had been told that the BGM did not produce reliable results for serum electrolytes (**011-014-108**) and, secondly, the dilutional effect of adding liquid heparin to the syringe would tend to produce artefactually low serum electrolyte concentrations. (**WS 008/3: 39a/b, 41a**)

Dr Coulthard calculated that the serum sodium concentration reading of 123 mmol/L measured at 0932 "is likely to be correct". (1st report, pg. 30) He also states that a very abnormal result obtained from a BGM should have initiated an urgent serum sodium measurement in the central laboratory. (2nd report, pg. 18)

Dr Haynes states that the BGM used by Dr Taylor was capable of producing reliable and reasonably accurate results; "sodium assay using a BGM has been invaluable in identifying potentially lethal electrolyte abnormalities at an early stage.." (**2**nd **Report, pp. 6/7**). Similarly, "Even though ... point of care testing is helpful in guiding treatment at any early stage, it is prudent to follow up with formal laboratory assay." (**ibid**)

In his witness statement, Mr Wheeler of Instrumentation Laboratories UK Ltd states that while they do not recommend the use of sodium heparin in samples measured on their BGM, it would only *increase* the measured level of sodium by 1-3 mmol/L.

- The likely cause of Adam's acute severe hyponatraemia at 0932, (assuming the result to have been approximately correct).
- Whether it was reasonable for Dr Taylor to disregard the BGM serum sodium concentration of 123 mmol/L, measured at 0932.

- What should Dr Taylor have done in response to the serum sodium result?
- Whether Dr Taylor's assumption, (that any serum sodium concentration measured by the BGM was likely to be incorrect), was reasonable.
- Whether, even if Dr Taylor was correct to doubt the BGM result, he should in any event have sent another sample (immediately) to the central laboratory to check the result.
- Whether using liquid heparin and/or sodium heparin would significantly affect the accuracy of the results produced by the BGM. Were there any strategies that should have been known about and used to minimise any such effects on the accuracy of the results?
- Would any different action taken at 0932 have altered the outcome for Adam?

Dr Taylor sent a blood sample to the central laboratory after the end of the case, at about 1130. This revealed a serum sodium concentration of 119 mmol/L. (**057-007-008**). We consider actions taken after this time were appropriate, so not of concern.

Matters for further consideration:

- Does a serum sodium concentration of 119 mmol/L measured in the central laboratory at 1130 suggest that the earlier measurement of 123 mmol/L (produced by the BGM at 0932) was reasonably accurate, given that in 2 h between these two measurements little extra 'free water' was given to Adam?
- Given that many of the results obtained from the BGM at 0932 were very abnormal, was it reasonable to defer checking these until after the end of the case at 1130?

7. Surgery

Some aspects of the surgical approach used by Mr Keane were criticised by Messrs Rigg and Forsythe in their first report. (1st Report, para. 3.5, 4.13) One other notable issue is that there appears to have been little communication between the surgeons and Dr Taylor and vice versa.

Matters for further consideration:

• The relative experience of Mr Keane, in November 1995, compared to his peers, in performing renal transplants in children under 6 years of age.

- Whether the surgical approach used by Mr Keane made it unlikely that the transplant would have been a success even if Adam had survived.
- Whether the surgical approach used by Mr Keane had any significant impact on the chances of Adam's survival.
- Whether the apparent lack of communication between Dr Taylor and Mr Keane regarding CVP, urinary catheter, blood loss and serum electrolytes increased the peri-operative risk for Adam.
- Whether Mr Keane's leaving the operating theatre near the end of the case (to attend an emergency in another hospital) had any impact on Adam's survival.

8. Problems determined at the end of the procedure

Surgery ended at about 1100. It soon became apparent that Adam was comatose and apnoeic, despite stopping all anaesthetic drugs, and that he had fixed, dilated pupils, all features suggesting severe brain damage.

Mr Keane, who had left theatre early to attend an emergency elsewhere, had assumed and expected that Mr Brown would speak to Adam's parents after the case finished. (WS 006/3: 17b) Mr Brown did not think it was his responsibility. (WS 007/3: 10d) Hence, nobody communicated with Adam's parents about these problems until after Adam was admitted to the PICU.

Matters for further consideration:

- At what time was it likely that Adam's brain damage was so severe and irreversible that recovery thereafter was extremely unlikely, whatever had been done? In particular, was anything that was done (or not done) after 1100 going to affect Adam's chances of survival?
- Should Mr Brown have spoken to Adam's parents after the case finished? Should Mr Keane have spoken to Adam's parents when he finished his emergency later that day?
- Should Dr Taylor have spoken to Adam's parents immediately after handing over the care of Adam to the intensive care staff?

9. Transfer to ICU and ICU care

Adam was transferred the short distance from theatre to the PICU shortly after 1200. According to the trend monitor printout, the last CVP reading made in theatre at 1120 was about 18 mm Hg. (**058-008-023**) In contrast, the first CVP reading made in the PICU at about 1220 was a more normal 11 mmHg. (**058-008-022**). There is no

obvious reason, in terms of fluid losses, why such a dramatic fall in venous pressure should have occurred in that hour.

Dr Taylor states that a change in Adam's head/neck position may have changed the position of the CVC tip such that it produced a much lower reading: (**WS 008/4: 9** and **13**) this raises the possibility that a withdrawal of the catheter or connecting the transducer to another lumen, when the waveform was first seen, could have allowed a more accurate and reliable pressure reading throughout surgery.

Matter for further consideration:

• The most likely reason for the acute decrease in CVP between 1120 and 1220 and the implications of that reason, if any, on Adam's intraoperative fluid management, bearing in mind Dr Coulthard's suggestion of incorrect zeroing as opposed to Dr Haynes' opinion that the CVC was partially obstructed against the vein wall.

The nursing record makes no reference to handover from theatre staff. The PSNI and supplemental witness statements of Staff Nurse Knaggs, who admitted Adam to PICU, provide very little information as she cannot recall the events. Dr O'Connor is the only clinician who made any contemporaneous note as to Adam's condition on arrival in the PICU.

Dr O'Connor, at 1205 on 27th November, opined that Adam had 'coned' in theatre (that is, his brainstem had herniated into the foramen magnum of the skull due to raised intracranial pressure). (**058-035-137**)

Dr Squier, in her pathology report, is unable to confirm this diagnosis. (**206-002-008**) However, the CT scan (performed about 3 h after surgery had finished) does show generalised and acute brain swelling. (**206-003-018**)

We consider it likely, therefore, that subsequent PICU care is irrelevant in terms of understanding why Adam died and so is not a cause for concern. Thus, although death was not pronounced until after two formal assessments of his brainstem function, while he was still receiving full resuscitatory and supportive management, it is probable that Adam's life was unsaveable from some time before his admission to the PICU.

When Ms Slavin first saw Adam in the PICU, she noticed immediately that he was "severely bloated". (**WS-001/1: pg. 4**) However, the only nurse or doctor in attendance either at the end of surgery or in the PICU who commented on Adam's appearance was Dr O'Connor who, in a contemporaneous note, recorded that he looked 'puffy'. (**058-035-136**)

It remains unclear whether, at the time he was admitted to the PICU, Adam had generalised oedema, or swelling limited to his head and neck, or neither. However,

Dr Landes states quite unequivocally in her report that there was no evidence of pulmonary or subcutaneous oedema on the chest X-ray taken about 2 h after surgery had finished (at 1320). (**207-003-005**)

Dr Haynes opines that the combination of previous multiple CVP cannulations, Adam's facial swelling (photos), and a large catheter sitting in the right internal jugular vein meant that it was likely that "there was obstruction to venous drainage from the head". (**204-004-168, 204-006-331 and 333**)

In his report of 11.11.11, Dr Coulthard estimates that, by the time of arrival in PICU, Adam had a net fluid excess of about 1.9 litres, of which nearly 900ml was water and about 1 litre was equivalent to normal saline.

Matters for further consideration:

- Whether there is any evidence that Adam was grossly fluid overloaded by the time he was admitted to the PICU after surgery.
- Whether Adam had clinically significant obstruction to venous drainage from the head i) before, ii) during or iii) after his transplant surgery.
- How much of Adam's cerebral oedema was accounted for by the effects of hyponatraemia and how much by venous obstruction due to the presence of his CVC in combination with previous ligation of the left internal jugular vein and/or previous frequent CVC insertions

10. Communication with parents

At around 1215 (after admission to the PICU at 1205), Ms Slavin was informed about the problems with waking Adam, but not that this was considered a serious problem. Ms Slavin states she knew something was wrong when she saw Adam at 1215 and was told something was seriously wrong a short time later. (**011-009-026**) The relative counselling record contains a note from 1300 on 27th November, recorded by S/N Knaggs, that Drs Savage and Taylor informed Adam's mother and aunt that there was a 'great deal of concern' that Adam had not woken up. (**058-038-181**) After the CT scan was performed, S/N Beattie records that Dr Savage had explained to Ms Slavin that hope of recovery was remote. (**058-038-180**) Ms Slavin confirmed that after the CT scan someone spoke to her and explained the severity of the situation. (**093-003-004**). The nursing record also noted that Dr Savage spoke to Adam's parents and grandparent apparently after the first brainstem tests at 2030. (**058-038-181, 182**) The counselling record suggests Ms Slavin was told about brain swelling and fluid imbalance but not about the hyponatraemia in theatre. She confirms this in her deposition to the Coroner. (**011-009**)

• Whether clinicians informed Ms Slavin of Adam's hyponatraemia and what may have caused it and, if not, why not.

11. Post mortem examination

An autopsy was performed by Dr Armour, a senior registrar, on 29th November. She reported that Adam's cause of death was 'cerebral oedema due to dilutional hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (congenital obstructive uropathy)'. (070-002-002) Dr Armour also stated that the autopsy had revealed 'ligation of the left internal jugular vein.' She went on to postulate that the cerebral oedema caused by the hyponatraemia 'was compounded by impaired cerebral perfusion'. (070-002-009) Dr Squier has opined that Adam's brain swelling was 'moderate' and not severe. (206-002-004). She goes on to suggest that the fixed brain weight recorded by Dr Armour was inaccurate (since it is inconsistent with the stated weight after fixation as well as with known normal levels for brain weight in a child. (206-002-006) Furthermore she states the PM report is unclear in relation to the 'suture' described and whether or not it was causing venous obstruction. She is critical that the description is insufficient to estimate when any such suture was placed. She concludes: "It would have been better procedure as well as a matter of professional courtesy to give Dr Mirakhur the opportunity to express her opinion formally and produce a signed report." (206-004-025)

- Dr Armour's relevant experience in paediatric autopsies by November 1995 and whether she should have been supervised (while performing this autopsy) by a more senior pathologist and whether such a senior should have signed off her report. In this respect, we are concerned by the uncertainty about the nature, timing and effect of the suture material she described and the apparent errors in brain weighing.
- Whether, given the nature of his death and the observations she made of the brain a consultant neuropathologist should have been requested to provide a second opinion and a formal report, (as per Dr Squier's opinion)
- Whether it was likely that Dr Armour was mistaken in her identification of the ligature around the left internal jugular vein.
- Whether it was likely that Mr McCallion, Mr Stewart or Mr Brown, the surgeons who carried out the Broviac line insertion in 1992, were mistaken in their identification of the common facial vein and, in fact, ligated the left internal jugular vein by mistake.
- Whether, if the left internal jugular vein had been ligated in 1992, this would have been likely to significantly affect cerebral venous drainage in 1995.

A further matter that concerns us is that Dr Armour reported (and expert pathologists have confirmed) that the kidney was infarcted (dead). Messrs Forsythe and Rigg give as their opinion that this had occurred between donor kidney reperfusion (at about 1015) and withdrawal of life support. (1st Report, para 4.10) They further state (1st Report, para 4.14): "However, there is concern that there was discolouration of the kidney before closure which may have been relatively benign as is sometimes seen a short time after re-perfusion. On the other hand, it may have indicated an evolving ischaemia of the kidney either for positional reasons or due to reduced flow in the renal artery particularly as the smaller external iliac artery was used."

Matters for further consideration:

- When it was most likely that the donor kidney infarcted.
- Whether potential or actual ischaemic changes should have been observed intraoperatively
- The most likely cause of the donor kidney's infarction.

12. Standard of record keeping

Ms Ramsay noted that there were inadequacies in relation to record keeping in relation to a number of aspects of nursing care, including 'fluid and nutritional management', medications, pre-operative observations, care planning and records of communication with the family. (**202-002-042**) In addition, Ms Ramsay has indicated that it would have been usual for doctors to record prescription of medications, (**202-002-024**) and assessment of the effectiveness of the dialysis. (**020-002-026**) However, no records were made.

- Did the standard of record keeping meet that required by both the nursing and medical professions at that time?
- Was there any investigation of the standard of record keeping in relation to professional guidance undertaken as part of any investigation following Adam's death?

13: The dispute between the experts as to the cause of death

Dr Coulthard, Prof. Gross, Dr Haynes and Dr Squier all state that they accept as the primary reason for Adam's death is that found at his Inquest. In their reports they discuss possible exacerbating factors which might have made Adam more vulnerable to brain injury from excessive and rapid free water infusion.

However, Prof Kirkham in her reports appears not to accept the Inquest finding, suggesting that death was not primarily due to dilutional hyponatraemia (although she accepts that Adam was given too much fluid and that he did have cerebral oedema. However, she states that this was a contributory factor and that the primary cause of death was a combination of derangement of cerebral blood flow and/or cerebral oxygen delivery falling below a critical level (including the effects of anaemia); that there was some obstruction to venous outflow, particularly in relation to the posterior part of the brain (where Dr Armour and Dr Squier demonstrated a greater degree of oedema); and that he may have had the condition called posterior reversible encephalopathy syndrome.

Some support is offered in the Witness Statement by Dr Dyer, who gave cerebral hypoxia as a primary cause and hyponatraemia as a contributory cause. Dr Coulthard has mounted a robust argument against Dr Dyer's calculations in relation to cerebral perfusion pressures.

When asked to comment on these suggestions, the other experts disagree, suggesting that while these issues are all possible there is little or no supportive pathological evidence for hypoxia, venous obstruction or PRES and that her opinion as to cause of death represents speculation.

We note that the Terms of Reference do not include re-examination of the Inquest verdict. It is our opinion that there is no convincing reason given why the verdict should be revisited. We note that the consensus of the experts whose reports we have read is that the primary cause of death was the very rapid infusion of hypotonic fluid between Adam's arrival in theatre and about 0800 on the day of operation. It is not within our expertise to confirm or refute Prof. Kirkham's hypotheses.