

**REPORT OF EXPERT ON NEPHROLOGY: DR. MALCOLM COULTHARD
ADAM STRAIN**

ADDITIONAL BRIEF

Introduction

1. You have already provided three Reports on this case, the first (4th August 2010) in relation to a number of issues which for convenience are set out below, the second (4th December 2010) addressing some points of clarification, and the third (15th March 2011) commenting on the transcript of the interview of Dr. Robert Taylor under caution:

Pre-Operative Period

- (1) Requirement for pre-operative measurement of electrolytes to be carried out after dialysis and before surgery, together with the likely significance of the absence of the information that would have been provided by those tests had they been carried out as requested by Dr. Maurice Savage.
- (2) The quality of record keeping and monitoring of fluids & electrolytes, including recording of dialysis cycles.
- (3) Respective roles of Dr. Robert Taylor, Mr. Patrick Keane and Dr. Maurice Savage (and their respective teams) in the preparation of Adam for surgery.
- (4) Whether the assumptions made by Dr. Taylor regarding Adam's preoperative fluid and electrolyte balance, urine output and hydration status were reasonable under the circumstances.

What would have been the implications for Adam's subsequent management if:

- His usual overnight fluid intake was 1200 mls or 1500 mls
- He had been fed 950 mls Dioralyte overnight (47mls/kg/24h) or the same volumes of normal saline or of 0.18% saline in 4% dextrose or water (alternatives quoted because of uncertainty as to nature of fluids actually given).
- Adam had or had not received his normal saline supplements (100 mls normal saline and 50 ml 8.4% sodium bicarbonate in addition to the above.
- Accurate fluid balance charts had been kept during dialysis
- Adam had been catheterised and accurate hourly urine output measured and known preoperatively.

Operative Period

- (1) Significance of the volume and nature of IV fluids infused depending on whether he was dehydrated, properly hydrated or overhydrated at the point anaesthesia was induced; and whether these fluids were accurately documented.

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- (2) Significance, if any, of the position of the central venous catheter, the starting and subsequent central venous pressure (CVP) measured intraoperatively and the implications for fluid management.
- (3) Implications of the 'tying off' of the left internal jugular vein in relation to CVP measurements and intraoperative fluid management.
- (4) Difference in views between Dr. Taylor and Dr. Sumner on the diagnosis of Adam having developed 'dilutional hyponatraemia', including Dr. Taylor's comments on Professor Arieff's research on hyponatraemia.
- (5) The significance, if any, of Adam's history of episodes of abnormal sodium levels, including a measurement of 124 mmol/L recorded 4 months pre-operatively (8.6.95)
- (6) Significance, if any, of the transplanted kidney not functioning, including any effect this might have had on the fluids administered to Adam and otherwise as a factor in the onset or exacerbation of his hyponatraemia (with reference to the statements of Mr. Patrick Keane, Mr. Stephen Brown, Dr. Robert Taylor, Dr. Mary O' Connor and the expert reports of Professor Peter Berry, Professor Risdon and Mr. Geoff Koffman. It also would be helpful if you could comment on the quality of the material made available to Professors Risdon and Berry for their examination and reports, to the extent that there were any differences and if so, the significance of those differences.

Postoperatively Period

- (1) The significance of his 'bloated' appearance (presumably representing generalised oedema) noted by staff and mother immediately after the end of surgery and captured in photographs taken in ICU.
 - (2) Significance of the first few CVP readings taken in ICU.
 - (3) Significance of urine output measured in ICU immediately post-op.
2. The Inquiry has instructed experts to consider the role and conduct of the Anaesthetists, the Surgeons and the Nurses. The Inquiry wishes you now to focus and Report specifically upon the role and conduct of the Nephrologists, Dr. Maurice Savage¹ and Dr. Mary O'Connor.
3. Accordingly, the Inquiry would be grateful if you would address the following matters and provide your response in a fully referenced additional Report:-
- (1) Whether in November 1995 the Royal Belfast Hospital for Sick Children (RBHSC) had the facilities and resources, both in terms of clinical experience and support services, to carry out paediatric renal transplant surgery, including that with the complexities of Adam's surgery²

¹ Now Professor Maurice Savage

² Attached is information provided to the Inquiry on: (i) paediatric renal transplants carried out at the RBHSC and the Belfast City Hospital (BCH) from 1990 (when paediatric transplants started at the RBHSC) until 1995 (when Adam's transplant was performed); (ii) numbers of paediatric renal transplants in which Dr. Robert Taylor and Mr. Keane (and other clinicians at those 2 hospitals) had been involved

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- (2) Please describe and comment on the role of a Consultant Paediatric Nephrologist in relation to a paediatric renal transplant in 1995. In particular, please comment on the role of a Consultant Paediatric Nephrologist in:
- (a) Managing a child in end-stage renal failure
 - (b) Providing information and advice to the child's family including in relation to:
 - (i) Child's condition e.g. polyuria and propensity for low sodium
 - (ii) Dialysis and the length of time the child can continue to safely remain on dialysis
 - (iii) Renal transplant options and the transplant centre where such the surgery could/should be carried out e.g. the expertise of the local centre as opposed to any other
 - (iv) Likely complexities of the surgery given any previous surgery
 - (v) Likely complexities of the anaesthesia given any potential fluid management difficulties
 - (vi) The chances of success/risks of failure of the graft following transplantation
 - (vii) Risks to the child of the anaesthetic and/or surgery
 - (viii) Who else should be asked to assist in providing information and advice e.g. Anaesthetist, Surgeon
 - (c) Managing the process of getting the child on the transplant list and the plans for what should happen when an offer is received, including who else should be involved in the process e.g. anaesthetist, surgeon
 - (d) Managing the process once the offer is made, including the arrangements to be made and anyone else who should be involved
 - (e) Obtaining consent, including the requirements of 'A guide to consent for examination or treatment' circulated on 6th October 1995 by the Management Executive Office of the Chief Executive Ref: HSS(GHS)2/95³, together with the extent to which anyone else should be involved in the process e.g. Anaesthetist, Surgeon
 - (f) Being in the operating theatre during the transplant surgery
 - (g) Transferring the patient from the operating theatre to PICU

³ Copy attached

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- (h) Managing the post-operative phase
- (i) Providing information to the child's family, including where the child has died, and whether or not with others e.g. Anaesthetist, Surgeon
- (j) Participating in, should the surgery end in the child's death, any process of 'lessons learned' including:
 - (i) Morbidity and mortality meeting
 - (ii) Development of departmental recommendations
 - (iii) Revisions to clinical protocols/guidelines
 - (iv) Internal hospital enquiry
- (3) The protocols (if any) that were generally available in 1995 (and now) governing or having an impact upon the work or role of a Nephrologist before, during and after a renal transplant procedure
- (4) Please state and explain the factors that Dr. Savage as a Consultant Paediatric Nephrologist should have considered in:
 - (a) Accepting the donor kidney in principle over the phone
 - (b) Accepting the donor kidney after cross-matching was complete
 - (c) In particular, state if, in your opinion, Dr. Savage should have considered the particular risks and disadvantages of the transplant surgery whether by himself or with others, including the implications (if any) of:
 - (i) Adam's age and size
 - (ii) Adam's multiple previous operations
 - (iii) Extent of the cold ischaemic time
 - (iv) The "*widely separated arteries on 1 patch*" (as compared to a single artery or 2 that were not widely separated)
 - (v) Half match of the donor kidney
 - (vi) Size of the kidney from the 16 year old donor
 - (vii) Possibility of not proceeding with the transplant surgery
- (5) Please state, given Adam's history and his regular need for dialysis, how long you believe Adam could have continued on dialysis if the donor kidney that was offered on 26th November 1995 had not been accepted for any reason
- (6) Please describe and comment on the discussions that a Consultant Paediatric Nephrologist should have with the family of a paediatric

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patient who required renal transplant surgery. In particular, please comment on what Dr. Savage should have discussed with Adam's mother at each of the following stages:

- (a) When the need for a renal transplant for Adam was first apparent
 - (b) When Adam was placed on the renal transplant list
 - (c) When a donor kidney became available
 - (d) Upon arriving at the hospital, and pre-surgery
- (7) In addition, please state whether you would have expected Dr. Savage to have discussed the following with Adam's mother, and if so, what he should have discussed, and at what stage he should have discussed it:
- (a) The risks and disadvantages of the transplant surgery with this donor kidney
 - (b) Significance (if any) of Adam's age and size
 - (c) Implications of Adam's multiple previous operations
 - (d) Extent of the cold ischaemic time
 - (e) The "*widely separated arteries on 1 patch*" (as compared to a single artery)
 - (f) Half match of the donor kidney
 - (g) Size of the kidney from the 16 year old donor
 - (h) Possibility of not proceeding with the transplant surgery
 - (i) Composition of the Anaesthetic and Surgical teams, including the inclusion of Mr. Stephen Brown (if she had previously made clear her objection to his further involvement in Adam's care - for which see Debra Slavin's PSNI Statements and her Inquiry Witness Statements)
- (8) Please comment on whether you would have expected Dr. Savage to have discussed any of the following with Dr. Taylor, as the anaesthetist for Adam's transplant surgery, and if so, what he should have discussed, and at what stage he should have discussed it:

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- (a) Diagnosis of obstructive uropathy and a degree of renal dysplasia, together with polyuric failure, including the implications of that diagnosis for the formulation of a fluid management plan for Adam's transplant surgery
 - (b) Multiple previous anaesthetics and operations, including previous CVP lines
 - (c) Previous urological history
 - (d) Daily urine output and the rate of his urine output, and generally the capacity of his bladder
 - (e) Daily intake, including the information that he was on a high calorie Nutrison feed of 2.1 litres daily given through a gastrostomy bag, that rate of delivery of that feed, the feed supplements also administered due to his propensity for low sodium
 - (f) Peritoneal dialysis, the prescription (volume, and number of cycles etc) together with his weight before and after his dialysis
 - (g) General state of health and the results of the Renal Protocol investigations, including his weight
 - (h) Examination of Adam, explaining the anaesthetic and risks and assisting in the process of taking consent from Adam's mother
- (9) Please state whether you would have expected Dr. Taylor and Dr. Savage to have discussed and agreed Adam's pre-operative and/or intra-operative fluid management regime
- (10) If Dr. Savage should have been involved in the formulation of either of those regimes, then please comment on:
- (a) What Dr. Savage could and should have been able to contribute to their formulation
 - (b) Whether you would have expected Dr. Taylor to alert Dr. Savage to any changes that he was proposing to make to either Adam's pre-operative or his intra-operative fluid management regime and, if so, those changes, together with the reasons for them, to have been discussed and agreed between them
 - (c) Whether you would have expected Dr. Taylor to have alerted Dr. Savage to the fact that he had not sent bloods off for electrolyte testing as soon as he gained IV access if, as Dr. Savage claims he had

made it clear to Dr. Taylor such testing was important and that they had agreed it would be done (Ref: WS-002-03, pgs. 9, 13, 14, 29, 33, 34, 34 and 42 - Dr. Savage's 3rd Inquiry Witness Statement)

- (d) What you would have expected Dr. Savage to do had he learned that the electrolyte test had not been, and was not being, carried out
- (11) Please comment on whether you would have expected Dr. Savage to have discussed any of the following with Mr. Keane, as the Surgeon for Adam's transplant surgery, and if so, what he should have discussed, and at what stage he should have discussed it:
- (a) Diagnosis of obstructive uropathy and a degree of renal dysplasia
 - (b) Multiple previous anaesthetics, CVP lines and operations, the result of previous surgery being that one of his ureters was cross-connected to the other rather than to his bladder
 - (c) Retention of his native kidneys
 - (d) Previous urological history, including that his native kidneys were polyuric
 - (e) Daily urine output and his rate of urine output, and generally the capacity of his bladder
 - (f) General state of health and the results of the Renal Protocol investigations
 - (g) Examination of Adam, explaining the surgery and risks and assisting in the process of taking consent from Adam's mother
- (12) Dr. Savage makes a pre-transplant 'checklist' for Adam's surgery at Ref: 059-006-011. Please comment generally as to the adequacy of this 'checklist' including:
- (a) Whether in your opinion there were any elements missing from the checklist
 - (b) The comment that "*no mannitol*" was required in view of Adam's "*natural polyuric state*"
 - (c) Whether the checklist was in line with the renal transplantation guidelines operating at RBHSC at the time ("*Renal transplantation in small children*" - Dr. Maurice Savage, September 1990 - WS-002-03, Appendix 3)

- (13) Dr. Savage took the consent from Debra Slavin (Ref: 058-039-185 - Consent Form dated 27th November 1995). Please comment upon the issues that either he should have discussed with her and the extent to which he should have arranged for others to discuss with her (e.g. Anaesthetist, Surgeon)
- (14) You state at p.32 of your first Report for the Inquiry (4th August 2010) that *"my interpretation of the pressure traces provided in the case notes assumes that the horizontal dotted line half way between the zero mark and the 60 mm Hg line represents a value of 30 mmHg."*

If the maximum CVP on the graph is instead 40mmHg (which appears on the graph at the beginning of the CVP monitoring line just before 07.30), and the horizontal dotted line half way between the zero mark and the top of the graph therefore represents a value of 20 mmHg, how does this affect your comments in your statements regarding the management of Adam's CVP?

- (15) Please comment on the presence of Drs. Savage and O'Connor in the operating theatre on the morning of 27th November. In particular, please comment on:
- (a) The purpose for which they were there and what they should have been doing in theatre
 - (b) Whether they should have commented to the anaesthetic or surgical staff about:
 - (i) initial rate of fluid administration
 - (ii) departure from the prior fluid management plan (on the basis of which Dr. Savage had prescribed *"no mannitol as natural polyuric state"*)
 - (iii) initial CVP reading of 17mmHg
 - (iv) relative changes in the CVP readings
- (16) Please comment on what you would estimate was the maximum capacity of Adam's bladder, given his age and previous clinical history
- (17) Please comment on whether you would have expected Adam's normal urine output to increase in response to his increased fluid intake. If so, please state to what extent you would have expected it to increase. If not, explain why this would have been the case
- (18) Please comment on your impression of the CVP values during Adam's surgery, including:

- (a) Whether either nephrologist should have asked about the fluid regime as a precaution given the CVP levels
 - (b) What volume of fluid might precipitate an initial CVP value of 17mmHg
 - (c) Whether the relative changes in the CVP from 17mmHg, including the brief rise to 30mmHg, would have been a cause for alarm
- (19) Please state whether you would have expected a Nephrologist to have been trained and able to use a blood gas analyser machine in November 1995
- (20) Dr. Webb records in Adam's clinical notes that Adam's cerebral oedema "*may have occurred on the basis of unexplained fluid shifts - 'osmotic disequilibrium syndrome'*" (Ref: 058-035-140). This view is repeated further by Dr. Webb in a letter to Dr. George Murnaghan, Director of Medical Administration dated 12th December 1995 (Ref: 059-061-147) and in his Inquiry Witness Statements (WS-107-1, p.3-4, Answers 3(a)-(d) and WS-107-2, p.2-3, Answers 1(c) and 3(a)). It is also mentioned on Adam's autopsy request form (copy attached). The author of this document is currently unknown
- (a) Please explain what you believe is meant by '*osmotic disequilibrium syndrome*'
 - (b) Please comment on Dr. Webb's view that Adam's cerebral oedema "*may have occurred on the basis of unexplained fluid shifts - 'osmotic disequilibrium syndrome'*"
- (21) You noted in your second Report for the Inquiry (dated 4th December 2010) that because of the maintenance of fluid intake at a high level in renal transplants to prevent hypovolaemia:
- "[c]hildren often have a mild and controlled degree of deliberate fluid overload. Occasionally, this is extensive enough to result in pulmonary oedema, but this is rare, and because it is anticipated it is typically dealt with promptly and does not cause clinical problems. I personally have seen 2 children with overt pulmonary oedema following renal transplantation in my career of over 25 years, both of whom were treated easily and did not suffer any consequences of this, and both had successful longterm kidney transplants."*
- (a) Please find attached an article titled "*Anesthesia for pediatric renal transplantation with and without epidural analgesia - a review of 7 years experience*" (Coupe et al, Pediatric Anesthesia 2005, 15: 220-228). In a

study of 53 paediatric patients at Westmead Children's Hospital undergoing renal transplantation, 8 had pulmonary oedema as a postoperative complication. Of those who were given analgesia (18 of the 53), 5 had pulmonary oedema as a postoperative complication

- (b) Please comment on whether, in your experience, the results found regarding postoperative pulmonary oedema at Westmead Children's Hospital were expected or unusual, and explain why
 - (c) Please comment on whether this study has any effect on your assertion that pulmonary oedema is 'rare' in paediatric renal transplantation
- (22) You also stated that Adam was "*at risk of suffering from both of these types [cerebral and pulmonary] oedemas.*" Please identify any evidence that Adam was actually suffering from pulmonary oedema at any time during his care and treatment
- (23) Please find attached a blank table regarding Adam's fluid balance. We would be grateful if you could fill in the table as follows:
- (a) What you believe to have been Adam's daily fluid intake prior to his admission to RBHSC on 26th November 1995
 - (b) What you believe to have been Adam's daily fluid output prior to his admission to RBHSC on 26th November 1995
 - (c) What you believe to have been Adam's fluid losses at each of the indicated stages on 26th and 27th November 1995, including your calculations and losses due to:
 - (i) Insensible losses
 - (ii) Urine output
 - (iii) Blood loss
 - (iv) Dialysis loss
 - (d) What fluid was actually received by Adam at each of the indicated stages on 26th and 27th November 1995
 - (e) Given what you believe the fluid losses to have been and what fluid was actually received by Adam, what you believe his fluid excess/deficit was at each of the indicated stages on 26th and 27th November 1995
 - (f) Any comments and relevant information regarding the sodium content of the input fluids and losses

- (g) Any reasons why planned fluid infusion (content or infusion rate) should change due to changes in estimated loss
- (24) Please explain what you regard, from a Nephrologist's perspective, as the lessons to be learned from Adam's death and state whether you consider the changes made by Drs. Savage and O'Connor to the 1990 RBHSC Renal Protocol to be an adequate response (Ref: WS-002-03, Appendix 2)
- (25) The book '*Clinical Management of Renal Transplantation*' which was edited by Mary G. McGeown and published 1992, was, as far as the Inquiry team is aware, the only text regarding renal transplantation. Please address the following:
- (a) Your comments on the following sections:
- (i) Chapter 13 - "*Insertion of the kidney*"
 - (ii) Chapter 14 - "*Management of the recipient during the operation*"
 - (iii) Chapter 16 - "*Nursing care of the patient with a renal transplant*"
 - (iv) Chapter 20 - "*Early medical complications after renal transplantation*"
- (b) Please state whether there are any other sections of the book which you would like to see to comment further on (see contents page at Ref: 070-023i-245 to 251)
- (26) Please find attached further statements as follows:
- (a) Dr. Savage (WS-002-01 dated 22nd July 2005)
 - (b) Dr. Savage (WS-002-02 dated 14th April 2011)
 - (c) Addendum from Dr. Savage to WS-002-02 (dated 9th September 2011)
 - (d) Dr. Savage (WS-002-03 dated 28th September 2011)
 - (e) Dr. Savage (WS-002-04 dated 28th September 2011)
 - (f) Dr. O'Connor (WS-014-01 dated 19th July 2005)
 - (g) Dr. O'Connor (WS-014-02 dated 11th April 2011)
 - (h) Dr. O'Connor (WS-014-03 dated 22nd September 2011)
 - (i) Dr. O'Connor (WS-014-04 dated 22nd September 2011)

Please provide your comments on the conduct of Drs. Savage and O'Connor in the light of your view as to what could and should have happened. If those statements provoke further amendment or comment to your previous reports, please outline any such amendments or comments

Conclusion

4. It is of fundamental importance that the Inquiry receives a clear reasoned opinion on these issues.
5. Your assistance on the Inquiry's requirements should be provided in the form of a fully referenced Expert's Report.