BEFORE MR JOHN O'HARA QC

IN THE MATTER OF ADAM STRAIN (AS) DECEASED

PROVISIONAL SUBMISSIONS ON BEHALF OF PROFESSOR MAURICE SAVAGE (MS) ON CLINICAL AND GOVERNANCE ISSUES AND SUBJECT TO AMENDMENT, IF NECESSARY, ON COMPLETION OF ALL THE EVIDENCE

1.0 THE FIRST SUBMISSION

1.1 It is anticipated as the Chairman reminds himself once again that AS's death occurred back in November 1995 that he will remember to assess both clinical and governance issues in accordance with the then accepted practice of a reasonable body of healthcare professionals, drawing upon such guidance and / or protocols that were current at that time in Northern Ireland, resisting thereby the temptation to apply the practices and standards of 2012 given the many changes over the intervening years. Any failure so to do may lead to prejudice and undue / unfair criticism of MS.

1.2 The Chairman has now heard a wealth of evidence in relation to AS's management and renal transplant, the consequential Inquest and the opinions of numerous Experts as to AS's care. The evidence has been received by the Chairman in numerous ways, namely, as hospital records, reports or statements made for HM Coroner, the PSNI, the Inquiry itself and of course on oath or by affirmation.

1.3 The Chairman therefore has a very broad framework of evidence in which to operate and from that evidence to reach decisions of fact in accordance with

the civil standard of proof.

1.4 It is anticipated that the Chairman will set out clearly in his Report his approach to the evidence, the standard applied to that evidence, a well reasoned basis for his findings of fact and most particularly if such findings of fact involve the rejection of a witness's evidence, whether in whole or in part.

1.5 These Submissions are intended to address those issues mentioned in the three Salmon Letters of the 23rd March 2012, the 8th June 2012 and the 19th July 2012 relating to AS's care and the matters arising therefrom as shortly as possible, bearing in mind the volume of reading carried out already by the Chairman and his request for short Submissions. Any failure to highlight certain matters in these Submissions should be ascribed to Counsel and not to MS. Page references, unless otherwise stated, relate to the evidence given by MS.

2.0 THE BACKGROUND

2.1 It is trite to say that the death of any child is a matter of such enormous significance to his / her parents, family and friends and that when such a death occurs in surgery to the attending doctors and nurses.

2.2 AS's death has had a devastating effect on his Mother, Debbie Slavin (DS), his family, MS and all those who had cared for and knew AS. The Inquiry has revealed shortcomings in the then planning for and performance of an elective paediatric cadaver renal transplant and thereafter a failure by the RBHSC (The Trust) to investigate what had gone wrong and to learn lessons there from for the avoidance of similar deaths in the future.

2.3 What lies at the heart of AS's care and subsequent death is the arguably standard use in 1995 of N/5 Saline with 4% Dextrose (N/5 Saline), as a fluid whether for maintenance or replacement.

2.4 MS had looked after AS from a baby and over the period of almost four years MS had built up with AS and DS a very strong bond of trust **(18th April 2012, Pages 36 @ 4 – 38 @ 22) (18th April 2012, Page 173 @ 4 – 8).** It was only a matter of time before AS needed a transplant so that he (AS) could enjoy a more normal childhood **(17th April 2012, Pages 106 @ 9 – 107 @ 24).**

2.5 An audit publication of the UK Transplant and Service Authority (UKTSS) reported in 1995 that in the decade 1984 to 1993 1406 renal transplants had

been performed in children of which over 60% were still functioning after five years. Of these 1406 renal transplants only 119 had been in children under 5 and 40% of those had failed within one year, 25% of the failing kidneys had failed within seven days and the commonest cause for such failure had been vascular thrombosis. 7% of those children had died by 1993 **(WS 002/3 @ Appendix 5).**

2.6 An audit published in the Ulster Medical Journal for Belfast in the years 1984 to 1998 had identified 77 renal transplants carried out in children. 64% of those were functioning after 5 years, 13% had failed in the first 30 days and two children had died (2.6%) **(22nd June 2012, Pages 106 @ 15 – 108 @ 16), (WS 002/3 @ Appendix 4).**

2.7 Whilst these were still early days for paediatric renal transplants, the UKTSS had identified as major centres those hospitals which had performed more than fifty such procedures in a ten year period. Belfast had performed 47 renal transplants in the ten years from 1984 until 1993. MS had operated as a single Nephrologist throughout that period and thereafter until late 1995 when Mary O'Connor (MOC) had been appointed and as such MS had been responsible for the paediatric renal service and the development of a dialysis and transplant programme for children in Northern Ireland **(WS 002/3 @ Appendix 5).**

2.8 MS accepted that the Renal Transplant Protocol (RTP), drawn up in September 1990, used as the basis for AS's transplant, required significant revision after AS's death. Although the RTP 1990 was supposed to be available to all members of the renal team **(17th April 2012, Pages 25 @ 14 – 27 @ 8)**, some of the evidence called during the Inquiry demonstrated a lack of awareness or recollection of the RTP's existence **(17th April 2012, Pages 45 @ 6 – 46 @ 23).**

2.9 AS's medical records were numerous and cumbersome and they lacked a short but concise typed front sheet setting out for any inquiring clinician the relevant diagnostic and surgical landmarks, his clinical needs and any findings in AS's complex medical history **[See MOC (25th April 2012, Pages 31 @ 25 – 34 @ 10)] [See John Forsythe (JF) & Keith Rigg (KR) (3rd May 2012, Pages 150 @ 25 – 156 @ 21)].** Although MOC had summarised AS's clinical status

on 9th November 1995, a typed version acting as a front sheet would no doubt have been of considerable benefit to Dr Robert Taylor (RT) who was to be AS's Anaesthetist during the transplant and responsible for AS's fluid management. There is little doubt that some of the entries in AS's medical records could and should have been fuller. However these medical records need to be judged by the standards of that time when auditing of such records was not as common or as strict as the practice has now become.

2.10 MS believed that DS had received a copy of the Nottingham Children Hospital's Booklet on Renal Transplants and like other carers with children approaching dialysis or going on call DS had been drip fed by him and his experienced team of renal nurses and social workers all the relevant information over many months, **(17th April 2012, Page 52 @ 8 – 15), (17th April 2012, Pages 80 @ 4 - 83 @ 20).** MS had effectively ruled out for altruistic reasons a live donor transplant with DS as the donor as DS was a single Mother, who needed in his judgment to be able to care for AS in recovery **(17th April 2012, Pages 68 @ 25 – 72 @ 12) [See JF & KR (3rd May 2012, Pages 171 @ 4 – 178 @ 21)] [See Malcolm Coulthard (MC) (8th May 2012, Pages 110 @ 5 – 111 @ 24)] [See Geoff Koffman (GK) (16th May 2012, Pages 38 @ 10 – 49 @ 15)].**

2.11 MS accepted that it would have been better for AS and DS to have met a Transplant Surgeon, in reality then an Adult Consultant Urologist, much earlier whilst on call so that the benefits and risks of such surgery and any questions arising about the actual surgery could be more appropriately addressed. Such a meeting should have been and is now part of the Multi – Disciplinary Team (MDT) approach to such procedures. MS accepted that he had not discussed in advance with DS the experience of the team due to carry out AS's renal transplant and that included the role of Mr Stephen Brown (SB) if he (MS) was then aware **(17th April 2012, Page 171 @ 20 - 25)** that SB was to act as Mr Patrick Keene (PK)'s Assistant. MS probably thought that given SB's knowledge of AS as a patient SB's assistance would be of benefit to PK **(18th April 2012, Pages 127 @ 24 – 129 @ 12).** MS assumed that both RT and PK were suitably experienced to carry out the surgery.

2.12 MS's duty of care to AS meant that it was his (MS's) responsibility to ensure that AS was fit to undergo surgery and that his fluids were balanced or at least

to identify any significant deficit. MS accepted that there had been no regular measurements of AS's urinary sodium or urinary creatinine. MS had managed AS's sodium requirements from his (MS's) knowledge of and manipulation of the sodium content of AS's feeds in relation to the variations in AS's serum sodium. MS accepted with hindsight that such measurements would have been beneficial to assist in the choice of intravenous fluids. MS added those measurements as a requirement in the RTP 1996 **(17th April 2012, Pages 120 @ 5 – 122 @ 6).**

2.13 MS's conversations with PK about the surgery **(17th April 2012, Page137 @ 6 – 22) (18th April 2012, Pages 7 @ 22 – 9 @ 3)** and RT about AS's fluids **(18th April 2012, Pages 105 @ 5 – 108 @ 6)** on that Sunday evening led him (MS) to expect not only that both Clinicians understood what was required professionally of them and further that each was capable and competent of discharging that professional duty but also that at least one of them if not both would see AS and DS before surgery took place. MS anticipated that such a meeting could and would address any last minute anxieties or questions in DS's mind **(18th April 2012, Pages 22 @ 10 – 24 @ 11).** MS's expectations were not realised.

2.14 The Chairman will have to decide based on all the evidence that he has heard relating to those conversations whether MS had given both PK and RT sufficient information upon which to decide whether the kidney should have been accepted and whether the transplant should have gone ahead and if so at what time. Furthermore that PK and RT had put themselves into positions to carry out safely such a procedure **[see RT (20th April 2012, Pages 15 @ 6 – 16 @ 12)] and [see PK (24th April 2012, Pages 14 @ 25 – 19 @ 2)].** PK did not consider abandoning the procedure. None of these conversations were noted by anyone at the time and such a failure obviously calls into question the reliability of the individual memories of MS, PK and RT. MS did not anticipate that RT would have any difficulty in managing AS's fluids or PK in carrying out the surgery **(18th April 2012, Pages 53 @ 12 – 54 @ 11).** MC would not at that time have noted such conversations **[See MC (8th May 2012, Pages 147 @ 15 – 152 @ 8)].** MS remained available both pre-operatively and during the early part of the operation until MOC took over AS's care to answer any queries from either PK or RT and of course to be available to AS and DS.

2.15 There is common ground amongst

the Experts as to then who was to obtain DS's informed consent to the transplant proceeding. MS has accepted that his then practice of obtaining consent, as recognised by MC and subject to MC's local caveat that a surgeon will have been previously involved, **(18th April 2012, Pages 55 @ 18 – 58 @ 22) [See (GK) (16th May 2012, Pages 9 @ 7 – 10 @ 10)]** is no longer tenable.

2.16 There has been close scrutiny of AS's medical records, not least RT's anaesthetic record, **058-003-005**, which sets out what fluids were administered to AS and their timings. There can be on the face of that record no doubt and indeed MS was in no doubt when he first saw the anaesthetic record with MOC in intensive care **(18th April 2012, Page 151 @ 1 - 20)** that RT had administered an excessive volume of fluid including 1.5 litres of hypotonic N/5 Saline within two and a half hours, a quantity so large in volume and at such a rate of administration that AS had suffered cerebral oedema leading to coning due to dilutional hyponatraemia.

2.17 Whilst many aspects of the procedure for and management of AS's transplant have been addressed in the succeeding years, nothing can possibly explain RT's failure to manage appropriately AS's fluid balance and his (RT's) longstanding reluctance to acknowledge that failure and to recognise his responsibility for causing AS's death.

2.18 RT's failure and reluctance have dominated so much of all the evidence put in front of the Chairman, whether the route has been clinical, educational or by way of governance.

2.19 MS has accepted that he (MS) did not insist at the time on a more effective investigation by the Trust as to how and what had happened **(22nd June 2012, Pages 26 @ 10 – 27 @ 2)** and what steps thereafter had been needed and should have been taken to maintain public confidence in such procedures.

2.20 MS did not report to QUB RT's failure to manage appropriately AS's fluid balance and his (RT's) longstanding reluctance to acknowledge that failure and to recognise his responsibility for causing AS's death for two reasons. Firstly, RT did not teach fluid management to undergraduates at QUB and secondly QUB had no responsibility for post registration teaching.

3.0 THE SURGERY

3.1 There has been much discussion amongst the witnesses about when and indeed if the transplant should have proceeded taking into account the cold ischaemia time and the then accepted practice to transplant a kidney within twenty four hours. However the decision to proceed rested ultimately with PK, taking all relevant factors into account and of course the views of the team then assisting him. Once the decision had been taken by PK that the surgery would proceed not around 2.00 am or 3.00 am on that Monday morning but sometime from 7.00 am onwards, significant preparation was required in ensuring that a suitable theatre fully equipped and staffed was available.

3.2 Whilst it may not come completely as a surprise that the recollections of the nurses in theatre are based primarily on entries made in AS's medical records as the nurses were first asked about the procedure some ten years later, the Chairman has been confronted with conflicting accounts from the clinicians actually involved in theatre throughout as to the atmosphere in which and indeed how the procedure was conducted.

3.3 MS was available initially to give any advice before he left at about 9.30 am to undertake his teaching duties at QUB, leaving MOC to be available in his place. Both MS and MOC informed the Chairman that it was individually their usual practice to be available, either in or close to theatre, during such procedures to advise as or when necessary **[See MOC (25th April 2012, Pages 9 @ 9 – 10 @ 5)].** It was MOC who summoned MS back to PICU when AS failed to start breathing spontaneously after the surgery had ended.

3.4 Both MS and MOC appreciated immediately on examining the anaesthetic record what had happened to AS **(22nd June 2012, Page 19 @ 6 – 8).** However RT could not and he apparently maintained this position for some sixteen years until confronted by an overwhelming volume of expert evidence. This was despite RT's participation in a DHPSS Working Party which had led to the withdrawal of N/5 Saline in Dextrose from use in Northern Ireland in 2002.

3.5 MS and RT saw DS shortly after the discovery of AS's failure to breathe spontaneously. MS explained that he believed AS had been given an excessive quantity of fluid leading to the swelling of his brain albeit he conceded that he had not used the term hyponatraemia **(18th April 2012,**

Pages 152 @ 9 – 155 @ 15) (22nd June 2012 Pages 15 @ 14 – 16 @ 23). MS did not think that PK would see DS immediately as he (MS) had assumed that responsibility **(18th April 2012, Pages 157 @ 7 – 158 @ 15) (22nd June 2012, Pages 14 @ 2 – 17 @ 21).**

4.0 THE CLINICAL AFTERMATH

4.1 MS and MOC reviewed the RTP 1990 to prevent any recurrence and in so doing examined protocols from five or six other major UK Paediatric Transplant Centres **(17th April 2012, Page 86 @ 13 – 17)** to identify best practice for incorporation into a revised protocol which was finalised in September 1996. Additions in the RTP 1996 included not only the early involvement of a transplant surgeon which was facilitated by the appointment of a dedicated transplant surgeon within the Trust but also agreement in advance as to the acceptable size and tissue match of a donor kidney and a discussion as to the possibility of live donation from a relative or the referral to Great Ormond Street Hospital if a complex medical issue was identified. The final decision to proceed with surgery when a kidney is offered continues to be made by the transplant surgeon taking into account specific donor kidney information including the cold ischaemia time and the vascular anatomy.

4.2 The RTP 1996 has been identified as representing a significant improvement by the Inquiry's Experts. Key changes that have been identified to the Chairman include:

- Pre-operative urine electrolyte including sodium measurement is required and the average daily urine output is recorded.
- Immediate pre-operative and two hourly intra-operative blood urea and electrolyte estimates are recommended.
- Fluid for volume expansion is now recommended to be Normal saline, plasma or blood.
- Specific parameters for CVP have been defined.
- N/2 saline in dextrose is identified as the default intravenous maintenance fluid.

5.0 PREPARATION FOR THE INQUEST

5.1 Dr Alison Armour (AA) carried out the Autopsy, which was attended by MS as AS had been his patient and further that he wanted confirmation of the medical cause of death **(18th April 2012, Page 156 @ 12 - 20).**

5.2 HM Coroner for Greater Belfast (HMC) asked for and received numerous reports and statements from amongst others, MS, PK and RT to assist him to answer the fourth Question as to 'How' meaning 'By What Means' AS came by his death.

5.3 Those clinicians summoned as witnesses to attend the Inquest could expect to receive competent professional advice and assistance from George Brangam (GB), now deceased, as the Trust's Solicitor in the preparation of such reports and statements and as how to give evidence **(22nd June 2012, Pages 90 @ 17 – 92 @ 6).** It was also obvious to all the clinicians and it must have been blindingly obvious to GB that there was not just a marked difference of medical opinion between MS and RT as to how AS came by his death but more particularly an actual conflict of interest between those two clinicians and the Trust, whose interests GB was supposed to represent. GB failed to give appropriate advice to the Trust and to both MS and RT that he could not properly represent all three Parties and that it was in the best interests of RT that he be advised to seek independent legal advice as he was after all a Member of the Medical Protection Society (MPS). GB's failure to give that advice to all three Parties was at best a demonstration of incompetence or at worst a demonstration of negligence.

5.4 Consequently, Consultations took place in which attempts were made by GB, assisted by George Murnaghan (GM), the Trust's then Director of Medical Administration, and based on RT's very detailed instructions to address issues raised by MS and the Experts instructed by HMC, namely, Dr Edward Sumner (ES) and Dr John Alexander (JA) all supporting AA's Autopsy and her conclusions.. MS remained in contact with DS both supporting her in the early stages of her grieving and assisting her to understand what the Experts were saying.

5.5 It is little wonder that concerns have been raised about the contents of such Consultations. One such Consultation took place on Friday 14th June 1996 just days before the Inquest. The Note for the Consultation **(122-001-001)**

written by Helen Neill (HN) is not verbatim and cannot be described as a transcript. HN tried to put all the issues together by theme rather than chronology **[See HN (6th September 2012, Page 8 @ 8 – 14 and Page 12 @ 3)].** The Notes purports to record what was discussed and agreed by the doctors attending including a reference on Page 5 **(005)** thereof to the placing of a needle into the renal artery, something not mentioned previously by any clinician or attending nurse. PK made it very clear that any placing of a needle into the renal artery could not have gone unnoticed by the other clinicians and the attending nurses **[See PK (7th September 2012, Pages 132 @ 5 – 135 @ 9)].** The reference purports to assert as a fact that a needle was placed into the renal artery. The reference therefore appears to exclude as a possibility the proposition advanced by MS **(10th September 2012, Pages 61 @ 1 – 64 @ 21 and Page 70 @ 7 – 20)** in evidence whether someone merely queried if it was possible to test the perfusion of the kidney by placing a needle into the renal artery. As it written there does not appear to be any rebuttal to such an assertion.

5.6 The Chairman must first decide whether and / or how far the Note, either in part or as a whole, represents an accurate and complete account of what was discussed at a time when those said to include MS were present before deciding what weight can be attached to its contents. Should the Chairman determine that the Note is a collage of topics covered but assembled by HN in a thematic way as to make a sensible / credible read, then little weight should be attached to that Paragraph in particular. The Chairman is invited to recall that the Note had not been seen and agreed by those attending including GB and most particularly by MS.

6.0 AFTER THE INQUEST

6.1 HMC had been given by GB on behalf of the Trust an assurance in the form of a Statement prepared by the Consultant Paediatric Anaesthetists **(011-014-107A)** that lessons would be learned from AS's death. RT was one of the draftsmen of the Statement **[See RT (20th April 2012, Pages 140 @ 15 – 145 @ 6)].** As RT conceded in that passage, the Statement referred to the Arieff Paper published in the BMJ in May 1992. The Arieff Paper itself had alerted clinicians to the dangers of hyponatraemia, largely due to the extensive extra

renal loss of electrolyte containing fluids and their replacement by hypotonic fluids in the presence of antidiurectic hormone activity. The Arieff Paper was not restricted to and did not involve children undergoing major paediatric surgery.

6.2 Nevertheless RT et al had decided to alert only other anaesthetists to the risks of dilutional hyponatraemia and limited its dissemination to the anaesthetic department within the Trust. Such a limitation was to prove both unduly narrow and short-sighted as further deaths occurred within the Trust involving cerebral oedema due to hyponatraemia. These deaths are also now covered by the terms of the Inquiry.

6.3 There should have been held a Mortality Meeting attended by all the various disciplines involved at which AS's case should have been examined comprehensively. Such a meeting did not take place as GM, who was responsible for organising it went on leave. A possible consequence of the failure to hold such a meeting was the loss of an opportunity to alert paediatricians in general to the potential danger of prescribing N/5 Saline in Dextrose. The death of Claire Roberts, albeit in a different clinical situation, occurred just four months after AS's Inquest. GK alone would have stopped the transplant programme instantly pending an urgent independent review **[See GK(16th May 2012, Pages 141 @ 14 – 145 @ 20)].**

7.0 GOVERNANCE

7.1 Governance or clinical governance was very much in an embryonic state in 1995. Clinical audit was to become a cornerstone by which standards could be measured and improvements made. Guidance at that time was not as prolific as it has become in recent years. The resolution of any clinical issues within a particular directorate would depend upon the enthusiasm or willingness of the clinical director to address them **[See Simon Haynes (SH) (2nd May 2012, Pages 5 @ 1 – 9 @ 15)].**

7.2 Nevertheless the Chairman may conclude on the evidence called that the Trust failed to carry out any effective Inquiry of its own into AS's death or indeed into whether RT was then safe to continue in practice as a Consultant Paediatric Anaesthetist. It was of course also open to the Trust to refer RT to the General Medical Council (GMC) for the Registrar to investigate RT's

Fitness to Practise.

7.3 Such failures, which included a statement of regret by MS as well that he did not press the Trust hard enough to hold such an Inquiry, can have done nothing to maintain public confidence but more importantly may have led to allegations of a cover up of the kind suggested in the Ulster TV documentary 'When Hospitals Kill'.

7.4 MS acknowledged that mistakes had been made but he hoped that lessons had been and were being learned **(18th April 2012, Pages 175 @ 19 – 176 @ 21).** MS and MOC did however review and revise the RTP leading to the 1996 Edition. MS's paramount concern at that time was for the safety of patients undergoing renal transplant surgery. MS therefore also wrote to the British Association for Paediatric Nephrology to request a national audit through UKTSS to evaluate the risks of dilutional hyponatraemia when undergoing renal transplantation **(22nd June 2012, Pages 103 @ 7 – 105 @ 15).**

8.0 THE PRESENT TIME

8.1 MS has now retired leaving MOC as the Senior Nephrologist to manage those patients who require dialysis or renal transplants. It is submitted that MS gave his evidence, making concessions where appropriate but in a caring, reflective and at times a forthright manner, retaining throughout the faith and the trust placed in him by DS but subsequently let down badly by Senior Managers within the Trust and by the now deceased Trust Solicitor.

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16th October 2012

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