STATEMENT OF WITNESS

STATEMENT OF: MAURICE SAVAGE
Name *Rank*

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

To be completed when the statement has been written

I declare that this statement consisting of 9 pages, each signed by me is true to the best of my knowledge and belief and I make it knowing that, if it is tendered in evidence at a preliminary enquiry or at the trial of any person, I shall be liable to prosecution if I have wilfully stated in it anything which I know to be false or do not believe to be true.

Dated this 8th day of May 2006

Lilli R. Cross

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

William R. Cross

PRINT NAME IN CAPS

SIGNATURE OF WITNESS

J Maurice Savage

I am a Consultant Paediatric Nephrologist in the Royal Belfast Hospital for Sick Children (RBHSC). I was in that position in November 1995 when Adam Strain was admitted to the RBHSC for a renal transplant. I am also now Professor of Paediatrics at Queens University, Belfast. I was involved in the general medical care of Adam Strain from early infancy when he was referred by Dr Angela Bell from the Ulster Hospital, Dundonald where he had been born with cystic, dysplastic kidneys. There were associated problems with the drainage of his kidneys related to obstruction and vesico ureteric reflux. He required multiple operations to the urinary tract and from that point of view was under the care of the Consultant Paediatric Surgeon, Mr Stephen Brown. To optimise drainage of the urinary tract he had a suprapubic catheter inserted. He had re-implantation of his ureters on two occasions and had nephrostomies performed during the early months of his life. On several occasions he became critically ill and required care in our Intensive Care Unit and a brief period of dialysis because of acute renal failure. My medical

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management was aimed at optimising Adam's nutrition and preserving his residual renal function for as long as possible. Maintaining nutrition was a major problem because of persistent vomiting and a fundoplication operation to stop gastro-oesophageal reflux was carrjed out in 1992. However he continued to have major feeding problems and required supplemental tube feeding and eventually required all his nutrition via a gastrostomy tube. He was subject to recurrent urinary tract infections and his renal function gradually deteriorated until he required dialysis support. Home peritoneal dialysis was chosen. His mother was trained in the home peritoneal dialysis technique by our dialysis nurses. I co-ordinated Adam's care, prescribed and monitored his dialysis treatment with support from a dietician, psychologist, social worker, the renal nursing team and of course his mother. Although he had many hospital admissions and was seen regularly as an out-patient, a lot of his complicated management, including his medication, tube feeds and home dialysis, was carried out meticulously with great skill by his mother, Debra Strain, with whom we worked closely. Despite the fact that his kidneys were unable to excrete waste products adequately so that he required dialysis for uraemia his urine output was quite large but of poor quality. His tube feeds in the months prior to transplantation, were slightly over 2 litres per day and although his night time dialysis removed some fluid he continued to pass in excess of 1 litre of urine each day. Once he was on dialysis he was put on call for a kidney transplant. Adam required multiple medications with Calcium Carbonate, Keflex, Iron, One-Alpha Vitamin D, Erythropoietin and Sodium Bicarbonate and nighttime gastrostomy tube feeding. The medications and tube feeds were to ensure good nutrition and to prevent renal anaemia and bone disease. He was a well-nourished, well-grown boy

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with height near the 50th centile and weight at the 90th centile for his age. Prior to his admission for renal transplant Adam's most recent acute illness was with a gastrostomy exit site infection in July 1995. On the 26th November 1995 we had an offer of a kidney from the UK Transplant Service that was a reasonable match for Adam. He was therefore admitted to Musgrave Ward under my care in the Royal Belfast Hospital for Sick Children for pre-operative assessment and so that a tissue crossmatch could be carried out. Standard pre-transplant checks were performed including assessment of hydration, temperature, blood pressure, chest examination, blood crossmatch, biochemistry screen, a full blood picture, coagulation screen and a virological check of his blood. His urine and some peritoneal dialysis fluid were cultured and consent obtained for a transplant. I contacted our operating theatre, the consultant anaesthetist on call and the transplant surgeon on call to alert them to the possibility of a transplant operation and the nature of Adam's medical condition. Adam's mother had previously been given information about transplantation. In discussion she was apprehensive in relation to such major surgery but of course Adam had experienced quite a long and stormy medical history with many operations so this procedure did seem to offer him the best chance of a more normal life. As it takes approximately six hours for a transplant crossmatch process to be completed it was 1.00 am before we knew that the transplant crossmatch was favourable. After detailed telephone discussion of the complexity of Adam's case the surgical and anaesthetic team decided that rather than commence major surgery in the middle of the night a planned transplant operation should commence at 7.00 am, 16 hours after the kidney had been donated. His serum electrolytes, haemoglobin and coagulation were satisfactory.

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H.B.10.5g/dl, Na 139, K 3.6, Urea 16.8, Ca.2.54, Albumin 40, Prothrombin time 12.3. His chest was clear on examination. B.P. 108/56. He was apyrexial. There were no signs of infection. Usually Adam was given a high calorie tube feed, Nutrison, and had 1500 mls each night. This contains 43 mmol of sodium/L. In consultation with Dr Taylor it was decided that he should have clear fluids overnight by gastrostomy tube rather than his normal Nutrison feeds. The gastrostomy fluids were to stop two hours before going to theatre. On the night of his transplant he instead had a glucose and electrolyte solution known as Dioralyte which contains 60 mmol of sodium chloride/L so that his stomach would be empty by 7.00 am. He had 900 mls of Dioralyte. . His peritoneal dialysis was performed as usual, although the duration of the dialysis was, of necessity, shorter than usual – using a 750 ml fluid volume 1.36% Dianeal solution. He was given 8 cycles before going to theatre at 7.00 am. I discussed Adam's underlying diagnosis, his past medical history and the current management of his condition in terms of dialysis and fluids with Dr Taylor so that he was aware that Adam normally received 2.1 litres of fluid each day, 1500 ml of which were usually given overnight and that I estimated that his urine output each day was 1200-1500 mls. It was planned that Adam should receive intravenous fluid (75 ml/hr) after the tube feeds were discontinued and have his blood chemistry checked before theatre but it proved impossible to achieve venous access. I arranged to return to the hospital early the following morning to be available for consultation if required. I noted in the clinical chart the anti-rejection and antibiotic drugs which I recommended for Adam and a request for a double or triple lumen long intravenous central line to be placed for ease of blood sampling, drug administration and monitoring of his CVP. On the morning of the 27th November I

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made myself available in theatre for consultation and understood there were no early problems during the transplantation procedure with cardiovascular status or anaesthesia. . I reassured Ms Strain of this before undertaking some university duties and my colleague, Dr Mary O'Connor, then made herself available for consultation. Neither of us, of course, take part in the transplant surgery itself but are responsible for the immunosuppressive treatment and usually take over the care of the patient again once they have returned from theatre. Surgery was complex, but successful organ transplantation was achieved with acceptably matched kidney from a 16-year-old donor. Post-operatively Adam failed to breathe spontaneously. On examination he had dilated pupils and bilateral papilloedema. I was contacted and came immediately to the Intensive Care Unit. Post-operative electrolyte analysis indicated a sodium of 119 compared to 139 the previous evening. We were concerned that Adam had developed cerebral oedema. A chest x-ray showed pulmonary oedema and an emergency CAT brain scan confirmed cerebral oedema and herniation and compression of the brain stem. As soon as this situation was clear I sat down with Adam's mother and the family and told them we were in a grave situation. I explained that Adam had cerebral oedema with a swollen brain causing pressure on his vital centres and indicated that I thought the hope of recovery was remote. Despite this devastating news Ms Strain subsequently wanted to discuss the possibility of organ donation with me. Neurological testing by Dr David Webb on the evening of 27.11.95 and the morning of the 28.11.95 confirmed brain death. Debra Strain, the mother and the immediate family were informed of the complications and prognosis regularly throughout these events. Death was certified shortly after 9.00 am on 28th November. With the consent and

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in the presence of the family ventilatory support was withdrawn at 11.30 am while Adam was being nursed by his mother. In the succeeding months I kept in contact with Debra Strain and her parents as they struggled to cope with their tragic loss. I tried at all times to be open and honest in talking with them and shared their grief. Following the events surrounding Adam's death Dr O'Connor and I revised the Renal Transplant Protocol to state that normal saline, plasma or blood should be used in theatre to raise central venous pressure prior to releasing vascular clamps to perfuse the kidney. After ten years it is difficult to remember the detail of the answers I gave to questions at the Inquest but I have reviewed the transcription of my deposition at that time which points out the meticulous care which Debra Strain gave to her son Adam. In response to questions then, I stated that he needed sodium supplements in his feeds but that the sodium levels were well controlled. (The sodium supplements were in the form of sodium bicarbonate to help control acidosis). I stated I believed that the speed of change in electrolytes is very significant in that the body copes with rapid change less well. I stated in response to questions by Miss Higgins that Adam did have a potential for a low sodium which was being managed. I explained that because Adam was fed by gastrostomy tube he did not have normal thirst symptoms as a result of his illness and treatment. The majority of children with renal failure have problems concerning electrolyte levels. The transcript states that since Adam's death these would be measured more frequently. I believe I meant during surgical procedures. I explained that a serum sodium level below 135 would be considered low but there is a lower figure at which hyponatraemia becomes dangerous. A level below 120 needs urgent action and at 128 action needs to be taken to redress the balance. I pointed out that at certain

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levels of low sodium a patient could appear to be perfectly well. It is standard practice to test electrolyte levels near the start of surgery but electrolytes could not be checked, first thing on the morning of Adam's surgery as planned because venous access could not be obtained. I was not aware of the 9.32 am reading. I believe a child in renal failure is at greater risk of developing sodium imbalance. I accepted the cause of death given by the pathologist.

In response to questions by Mr Brangham I said I had known Adam since he was a baby. He needed to have the transplant operation in order to live any length of time and to have a normal life. I discussed the operation in detail with his mother on the day before surgery. I also discussed it with Dr Taylor, the Anaesthetist. The operation had been put back to the following morning. His overnight feeding was discussed in detail and Dr Taylor would have been aware of his normal feeding regime (as described earlier in this statement). The overnight volume given, of 900 ml, arose as he had to switch from tube feeding to intravenous feeding two hours before the operation (this was so that his stomach would be empty). I was satisfied the anaesthetic staff had all the relevant information. I agreed that all the fluids given to Adam during the operation contained sodium. One cannot simply pick a figure for determining (dangerous) hyponatraemia. It is a matter for clinical judgement which would influenced by the speed of change. Again in response to questions I stated that the lab would take approximately one hour to carry out an electrolyte analysis. In response to further questions by Miss Higgins I said: With the benefit of hindsight Adam's sodium became too low. A lab analysis is more accurate than that given by the blood gas machine. I personally never used that machine as I have no reason to do so.

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I have been asked specific questions by Detective Sergeant Cross and reply as follows: The pre-operative electrolyte tests were directed by me. I discussed Adam's situation with Dr Taylor before the operation and explained how his fluids were managed daily, explaining the type and quantity of fluids given, with the calculated urine losses. It was in this discussion with Dr Taylor that clear fluids were ordered overnight rather than his usual high calorie feed. The gastrostomy fluids were to be stopped two hours before Theatre. These clear fluids were given by gastrostomy tube as were all his feeds and then Adam was to change to intravenous fluids for two hours but this proved not to be possible as the junior doctor was unable to obtain a vein. I would have told Dr Taylor that Adam, unlike some other patients with advanced renal failure, was still passing large amounts of urine over 1 litre per day, all be it urine which did not remove waste products so that he required dialysis to remain well. My estimation of urine output, in excess of 1 litre per day and his usual fluid intake at 2.1 litres per day, were discussed to enable the anaesthetic team to be aware of his normal fluid requirements and build this into the calculation of his fluid needs during surgery. I am not aware of anyone conducting enquiries into the performance of the paired donor kidney. I agreed that I expected that the electrolytes would have been checked prior to, or at the commencement of surgery. I explained during transplant surgery one of the two Nephrologists make themselves available for consultation, so that although I remained on the RVH site during the operation I was undertaking university commitments in the Medical School. I handed over to my colleague, Dr O'Connor so that she was available if the surgical or anaesthetic team wished to consult with one of us. I am not sure of the time at which I left for my office but at that time, around 9 am, there were no

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concerns I was aware of in Theatre. I had no direct contact with the Operating Theatre and next became directly involved when Dr O'Connor telephoned me at lunchtime when Adam had returned to the Intensive Care Unit. I was therefore not party to any discussions on CVP, fluid balance or electrolytes during surgery. It is my practice to specify that if possible a triple lumen intravenous catheter should be placed as small patients like Adam will require multiple intravenous drug therapy, intravenous fluids, monitoring – including blood sample. A triple lumen line facilitates all these with the least upset to the patient.