Witness Statement Ref. No. 100/3

NAME OF CHILD: Adam Strain

Name: Eleanor Donaghy

Title: Ms

Present position and institution:

NI Organ Donor Services Team, Team Manager

NHS Blood & Transplant

Previous position and institution:
[Since your Witness Statement of 28th July 2011]

Membership of Advisory Panels and Committees:
[Identify by date and title all of those since your Witness Statement of 28th July 2011]

Previous Statements, Depositions and Reports:
[Identify by date and title all those since your Witness Statement of 28th July 2011]

OFFICIAL USE:
List of previous statements, depositions and reports:

Ref:	Date:	
093-015	28.04.2006	PSNI Witness Statement
093-016	21.06.2006	Second PSNI Witness Statement
100/1	14.04.2011	Inquiry Witness Statement
100/2	28-07-2011	Second Inquiry Witness Statement

IMPORTANT INSTRUCTIONS FOR ANSWERING:
Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number. If the document does not have such a number then please provide a copy of the document.

I QUERIES ARISING OUT OF YOUR INITIAL WITNESS STATEMENT

With reference to your witness statement dated 14th April 2011, please provide clarification and/or further information in respect of the following:

(1) Answer to Question 6(a) at p. 6:

"I had thought 'why are they continuing to transplant this kidney when the child is brain stem dead'. However I did not know what part of the procedure they were at."

(a) Explain exactly what you saw Mr. Keane, the other surgeon, the anaesthetists and other theatre staff doing in theatre in order for you to have perceived that "*... they [were] continuing to transplant this kidney*".

I remember two surgeons standing at opposite sides of the operating table. There was an anaesthetist and nursing staff in theatre. I cannot remember what they were doing.

(b) State whether the wound had been closed at the time when you first went into the operating theatre and "*thought 'why are they continuing to transplant this kidney when the child is brain stem dead'.*"

I cannot remember what I saw.

II ADDITIONAL INFORMATION

(2) Please provide a detailed description of the paediatric kidney donation 'offering process' and the 'recipient assessment' in 1995, starting from the time at the 'donor centre' when the major vessels are cross clamped and the kidney perfused with cold preservation fluids up until the time at the 'recipient centre' when the donor kidney is removed from its 'ice-bag' and re-perfused for transplant. Please include in your description of the process:

(a) Removal of the kidney from the donor and its inspection

This is not within my area of expertise it should be answered by a surgeon experienced in the retrieval process.

(b) Packing the kidney on ice prior to transportation to the recipient renal transplant centre

Once the kidney has been placed into plastic bags surrounded by preservation fluid it is handed, by the Scrub Nurse, to the Donor Transplant Co-ordinator (DTC). Occasionally it might be handed to a perfusionist who has travelled with the retrieving surgical team. Not all centres had a DTC who was on duty for donor surgery. The DTC would have already prepared the kidney transport box to receive the kidney. This was a self closing cardboard box, lined with polystyrene and two plastic bags, one inside the other. A 'bed' of ice would be placed in the bottom of the box, inside the plastic bags, the kidney placed on top of the ice and more ice put into the box to completely cover the kidney. Two pots,

one containing lymph nodes, the other spleen would also be placed into the ice for the purpose of the cross match at the retrieving centre. Both bags would be sealed separately with plastic ties and the top of the box closed. The Kidney Donor Information Form would be placed in the box between the polystyrene and the lid. The Box was addressed by the DTC using an address given to them by the duty office and a label with the Human Organ Transplant Act, Form A number , was stuck to the outside of the box

(c) Completion of the UKTSSA at the 'donor centre', an explanation of the details that are recorded and the person responsible for completing that form

Completion of the UKTSSA, Kidney Donor Information Form, Section I, would be completed in theatre at the donating centre. Who completed it was dependent upon the professional composition of the visiting retrieval team and if there was a local DTC present for the donation.
If present, the local DTC would have completed Section I. In the absence of a local DTC and, if the retrieval team had brought their own DTC or a perfusionist they would have completed Section I. If none of those personel were present the retrieving surgeon would have completed the form.
Points 1. to 20. relate to clinical details about the donor and would have been completed by the local DTC prior to theatre or, by the visiting DTC, perfusionist, or surgeon in theatre.
Points 21. to 29. would be completed after surgery with details about the anatomy of the kidney and any damage (points 26 & 27) being completed either by the retrieving surgeon or by the DTC/Perfusionist under the direction of the retrieving surgeon.
I now have some knowledge about the meaning of the details which are recorded, developed over many years, but would not have had in 1995.

(d) Offering process, including details of the national allocation scheme that was in operation in November 1995

The 'offering process' and National Allocation Scheme are the remit of Organ Donation and Transplantation, NHS Blood and Transplant (formally UK Transplant/UKTSSA)

(e) Discussion of the offer between the 'donor centre' and the 'recipient centre', identifying the likely 'donor factors' and the likely 'recipient factors' for discussion and identifying who would have been involved in it on both 'sides'

Discussion would be between the Duty Office, ODT (UKTSSA), Consultant Nephrologist for the recipient and possibly the transplant surgeon.

(f) Decision to accept the offer, including who would have made it and what investigations and arrangements are likely to have been made to enable a decision to be made on whether to accept the offer

The decision to accept the offer would have been made by the Consultant Nephrologist for the patient and possibly the transplanting surgeon. In 1995 the Urological surgeons who performed transplants were not involved in the medical management of the transplant patients - they would have been included in the decision to transplant if there were specific, anticipated, surgical problems in the recipient or the donor kidney. If the potential transplant was deemed, by the accepting nephrologist, to be uncomplicated the surgeons were not involved in the decision to transplant - only consulted about their availability.
I do not know what level of discussion took place between the paediatric consultants and Urology surgeons when a paediatric renal transplant was being planned.
It is difficult to give a general answer to this question as every renal transplant unit operated independently - some had dedicated renal surgeons - others did not. From 1997 when a dedicated

renal transplant surgeon was appointed in BCH the surgical input into the decision increased.

(g) Transportation arrangements, including whose responsibility it was to make them and what they would be for getting a donor kidney from a hospital in Glasgow to the RBHSC

Transport arrangements would have been made through the Duty Office, ODT (UKTSSA).

(h) When the child's family would have been called into hospital and by whom

My only knowledge of this process relates to calling patients in for transplant in Belfast.
In the adult unit (BCH), if I was on-call/on duty I would have telephoned the patient to call them into hospital. If I was not there, nursing staff on the ward would have undertaken this task.
If the patient was a child, either medical or nursing staff involved with the renal children would have called them in for transplant, generally as soon as the kidney offer had been accepted.

(i) The cross-matching and any other tests that are carried out once the donor kidney arrives in Belfast and where those tests are done

Cross matching is performed in Tissue Typing lab, BCH

(j) The receipt of the results of the tests and the decision to proceed with the transplant, including the person that is responsible for making that decision

This would have involved a discussion between Tissue Typing lab and the Cons Nephrologist looking after prospective transplant recipient

(k) Assessing the child and taking consent

This is the remit of medical staff caring for the prospective recipient

(l) Booking of the operating theatre and finalising the nursing and operating team arrangements, including the person responsible for doing so

My knowledge is limited to the process in Belfast. For adult patients in the BCH, I would have made all of the arrangements for the transplant when I was on duty. This involved speaking to anaesthetists, surgeons, nursing staff on the transplant ward and in theatres, the patient's Nephrologist and the Nephrologist looking after the transplant ward (if they were different) to set a suitable time for transplant. Communication would have been in person or by telephone. In my absence this would have been done by the Consultant Nephrologist and possibly the nursing staff on the transplant ward
Staff caring for children in RBHSC would have made these arrangements.

(m)Transportation of the donor kidney to the operating theatre.

My knowledge is limited to the process in Belfast. In BCH the kidney was taken to theatre generally by me or the Consultant Nephrologist.
When the transplant was in RBHSC the surgeon would have brought the kidney with him from the BCH

(n) Completion of the UKTSSA at the 'recipient centre', an explanation of the details that are recorded and the person responsible for completing that form

The transplanting surgeon is responsible for completion of the form and should explain the recorded details.

(o) Removal of the donor kidney from its 'ice-bath' and re-perfusing it

This is the role of Transplant Surgeon

(p) Please also include in your description the likely time that would have been taken in 1995 with the various stages

Timings varied in every case. It is possible that ODT/UKTSSA could provide an 'average' time.

(3) Please identify any documents setting out or guiding the process that you have described.
Every Renal Transplant unit in the UK would have had their own procedures for arranging kidney transplants.
There was a protocol drawn up July/August 1992 by me and a Senior Sister in the BCH Transplant ward, setting out agreed roles between nursing staff on the Transplant Ward and myself when a transplant was being arranged in BCH. It covered procedure for when I was on and off duty. This Protocol is out of date and no longer exists.
No protocol existed for RBHSC.
The first National guidance was issued in 1998 - Cadaveric Donor Assurances and Damage Reporting, although this mainly dealt with responsibilities around the donor kidney rather than the transplant.
Link given below and PDF copy attached.
http://www.uktransplant.org.uk/ukt/about_transplants/organ_allocation/pdf/annexe/cadaveric_donor_assurances_&_damage_reporting_12-2002.pdf (Ref 1)

(4) Explain your knowledge and involvement in the process you describe above as it related to Adam.
The only involvement I had in this process in Adam Strain's case was to complete some parts of the Kidney Donor Information Form (Ref: 058-009-025) – See witness statement (100/2)

(5) Explain in so far as you can, what happened to the donor kidney between the time perfusion commenced at 01.42 in the morning of 26th November 1995 and the offer of a kidney for Adam made by UK Transplant Service to Dr. Savage by telephone on the evening of 26th November 1995, and in particular the reasons why it took that length of time before that kidney was offered to Adam.
I had no involvement in this process.

(6) State whether you were involved in a 'clinical audit' of Adam's case. If so describe your role.
I was not involved

(7) State whether there has been any audit or assessment of renal transplant surgery at the RBHSC or of Belfast as a renal transplant centre. If so:

(a) State when such audits or assessments occurred (in both cases)

(b) Identify who conducted them

(c) Describe your role, if any, in them

(d) Identify any report resulting from such audits and assessments, and if available, provide a copy

I am only aware of one assessment of Renal Surgical services at Belfast City Hospital which was conducted by Members of the British Transplantation Society in early 2011. I gave evidence to the panel. I have not seen the report.

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: Eleanor Boyce (Nee Donaghy) Dated: 22/09/11

ANNEX B

CADAVERIC DONOR ASSURANCES AND DAMAGE REPORTING

A PROTOCOL PREPARED BY:

BRITISH TRANSPLANTATION SOCIETY

UK TRANSPLANT CO-ORDINATORS' ASSOCIATION

UK TRANSPLANT

May 1998
Updated April and December 2002

CONTENTS

CADAVERIC DONOR ASSURANCES AND DAMAGE REPORTING

INTRODUCTION

1 This protocol identifies clear lines of responsibility for the collection of information about the medical and social history of potential organ donors. It remains the responsibility of the transplant surgeon to discuss with potential recipients the risks associated with transplantation, including those of transmission of infectious agents.

2 Extant guidance from the Health Departments, including 'Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation' issued in August 2000 by the Department of Health, defines two main categories of absolute exclusion from organ donation: known HIV and known or suspected CJD. In addition two relative contraindications to solid organ donation are identified, although organs may be considered in life-saving situations (after discussing all implications with organ recipient or those close to the patient) if the patient is already infected with or immune to:

i Hepatitis B – HbsAg(3)(4)

ii Hepatitis C – HCV antibody.

3 The Department of Health guidance also makes recommendations on the selection of donors. It is the responsibility of donor transplant co-ordinators to ensure that a full social and medical history is obtained and recorded in each case. This may be by means of reference to medical notes, and if possible to the clinician caring for the patient prior to their death, interview with the most relevant life partner or close family member and where possible the GP.

4 No organs may be offered either through UK Transplant or to transplant centres until these enquiries are complete. If any doubt exists then the donor transplant co-ordinator should seek further medical advice from transplant clinicians.

5 Once donation has been confirmed and the necessary consent/lack of objection obtained, the donor should be examined and an accurate record made of any tattoos, signs of intravenous drug use, skin malignancies or evidence of surgical procedures.

6 The UK Transplant Core Donor Data form must be completed and signed by the donor transplant co-ordinator.

7 The mechanism for the safe transfer and tracking of information about the condition of any organ considered for transplant operates through the use of the UK Transplant organ donor information forms and the routines agreed from time to time with representatives of the UK Transplant Duty Office and representatives of the transplant community. The use of this channel ensures that the information is fully logged but it is nevertheless the responsibility of the retrieving and transplanting unit(s) to ensure that adequate records are maintained for their own purposes.

8 It is the responsibility of the transplant surgeon to be satisfied as to the safety of the donor material prior to the transplant operation, and to make any checks that they feel are appropriate to ascertain the full facts.

RESPONSIBILITY OF DONOR TRANSPLANT CO-ORDINATOR

9 The donor transplant co-ordinator will assess the eligibility of all potential organ donors with regard to medical and social/behavioural history and current status by completing the following actions:

i contact the most relevant life partner or close family member

ii review the medical notes and discuss eligibility with the clinician caring for the patient

iii contact the potential donor's General Practitioner within three working days

iv complete national lack of objection form, leaving one copy in the donor's medical notes.

10 Where there is obvious evidence of tattoos, previous surgical procedures or a history of intravenous drug abuse, these must be reported. In a few exceptional circumstances the family interview may need to be conducted over the telephone. This is not recommended but if it does occur it must be recorded as such. The donor transplant co-ordinator should document their findings in the medical notes. Having satisfied themselves of the eligibility of the potential donor, the donor transplant co-ordinator will contact the UK Transplant Duty Office to confirm the donation and they will also complete and sign the Core Donor Data form. If in doubt they must discuss the case with a transplant clinician.

RESPONSIBILITIES OF UK TRANSPLANT

11 The UK Transplant Duty Office will ensure that for every potential donor, they receive confirmation of eligibility to donate from the donor transplant co-ordinator; and will pass on to the eventual recipient unit(s) any information they receive either from the donor transplant co-ordinator or subsequently from the retrieving surgeon.

12 The Duty Office will ask the donor transplant co-ordinator:

Are you aware of any medical or social contraindications with this donor?

If so, what are they (and these will be passed on to the recipient unit)?

RESPONSIBILITY OF RETRIEVING SURGEON

13 The retrieving surgeon(s) will review the eligibility of the potential donor and satisfy themselves that all donation criteria are met prior to removal of organs(s). They will also ensure clear and legible documentation of any damage or relevant factor found on explantation and record the procedure and findings on the medical notes. The donor transplant co-ordinator must be informed of any such damage.

14 The retrieving surgeon will review the medical notes and if necessary discuss with the donor transplant co-ordinator if there are any areas of difficulty. If further contact with the donor family is needed this should be made by the donor transplant co-ordinator who will usually have interviewed the family previously. If further clarification is needed then contact should be made with the GP or clinician caring for the patient immediately prior to referral for donation. The retrieving surgeon(s) will sign the UK Transplant Organ Specific Donation form to confirm absence of contraindications to donation and to report any relevant damage or physical features.

15 It is the responsibility of the retrieving surgeon(s) to ensure that full information regarding any possible contraindications for the use of any organ(s) reaches the recipient transplant surgeon(s) so that the fullest possible risk assessment can be made in each case.

RESPONSIBILITY OF TRANSPLANT SURGEON

16 The transplant surgeon must ensure that all potential recipients are aware of the risks involved in transplantation. They must also satisfy themselves that adequate checks have been made to discover any contraindications to transplantation in relation to a specific organ donor for an organ for which they will be taking responsibility. In doing so, the transplanting surgeon must have regard to the current published guidance [**CMO(87)5**, 2 March 1987; **PL/CMO(90)2**, 26 April 1990; **PL/CMO(93)11**, 31 August 1993; **PL/CMO(96)5**, 1 July 1996; the MSBT Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation, August 2000].

17 The transplanting surgeon will review the Organ Specific Donor form and contact the retrieving surgeon or donor transplant co-ordinator to obtain any clarification they require. It is the responsibility of the clinician to ensure that full information regarding any possible contraindications for the use of any organ has been considered and the risks assessed. The transplant surgeon may request further specific tests to be carried out before transplanting the organ. Final responsibility for the condition of the transplanted organ rests with the transplant surgeon.

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