REPORT OF EXPERT ON NHS HOSPITAL MANAGEMENT & GOVERNANCE: STEPHEN RAMSDEN ADAM STRAIN

SUPPLEMENTARY BRIEF

There are some specific queries arising out of your Report and we would be grateful if you would address the following matters and provide your response in a fully referenced Supplemental Report.

Please note that the Inquiry has formatted your report for ease of use. Please find a copy attached. You will note that the paragraphs are now numbered, the font changed and a header and footer have been added. In addition, the references have been incorporated into the text as footnotes. The substance of the report is unchanged. The references below are references to the formatted report.

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1. para.5, line 6:

   "the author has ... for the purposes of this Report, made the assumption that hospitals in Northern Ireland, especially in 1995, were subjected to the same guidance and expectations ... as were hospitals in England at the time. Certainly, the KFOA [Kings Fund Organisational Audit] Programme was marketed to hospitals in Northern Ireland as well as England and Wales at the same time and the standards contained were generic to the NHS throughout the UK."

   The Inquiry understands that both the RBHSC and the Belfast City Hospital subscribed to the KFOA and were accredited in 1995. We refer you to 'Clinical Management of Renal Transplantation', a textbook compiled by Dr Mary McGeown with assistance from Northern Ireland clinicians (amongst others Mr Keane) which was a current text in Northern Ireland at the time of Adam Strain's surgery. Please state what difference, if any, that information and the textbook makes to the comments in your Report.

2. para.12, line 6:

   "The 'Risk Management in the NHS' manual devotes a chapter to consent quoting from HC (90)22 'A guide to consent for examination and treatment'"

   Please state whether or not those publications were available in and/or applicable to Northern Ireland?

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3. para.17(a), line 1:

"Mr. Keane as the Transplant Surgeon undertaking the procedure should have formally consented Ms. Slavin."

Professor Koffman states in the report that he provided to the PSNI [Ref: 094-007-031] that: *"It appears from the records that consent for the operation was not performed by the surgeons but probably by the paediatric nephrologist Dr. Savage and this would be normal acceptable practice for the mid 1990s."*

It would be helpful if you could comment upon that statement in the light of the view that you express in your report.

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4. para.18, line 1:

*"The answer to Question (1) above begins to address this question. Additionally, in the author's experience, it would be very rare for managers to get involved in such a decision to change the location of significant surgery. Indeed 'Risk management in the NHS suggests that '**Obtaining consent to treatment** is an area almost entirely under the control of professional health care staff and not one in which managers are generally involved."* (Emphasis added)

The reference to *"obtaining consent to treatment"* suggests that the issue - *"how a decision would be made and evaluated to change the location of significant surgery in the mid 1990s, and whether this would have been predominantly a decision by clinicians or management"* - has been largely addressed from the particular perspective of changing the location of Adam's surgery from the RBHSC to a different Transplant Centre. It would be helpful if you would now also consider the issue more generally, as to the circumstances in which in 1995 (and now):

(i) A particular hospital might/should assess the extent to which it continues to offer certain types of significant surgery, including the:
   (a) particular circumstances that might prompt such an assessment
   (b) factors likely to be considered in carrying out the assessment
   (c) personnel likely to be involved in such an assessment and the relative weight likely to be afforded the views of clinicians, management, Trust/Departmental personnel
   (d) process by which such an assessment would be undertaken
   (e) factors that would be likely to prove determinative/persuasive

(ii) A Trust/Department might/should carry out such an assessment of a

hospital.

Please support your analysis by reference to any available literature.

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5. para.33, line 1:

"Preservation and storage of health records have been the subject of DH guidance for many years and at the time of Adam's death HC (89)20 would have been the most recent guidance. This requires the retention of children's records for 25 years irrespective of any untoward event."

Please clarify what constitutes *"health records"* for the purpose of the 25-year retention period.

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6. para.35, line 1:

"For the Medical staff ... there have been a number of guidelines and recommendations, but all from professional organisations such as AFPP (formerly NATN) and RCA. None of these was mandated by the NHS in England. However, it has been regarded as good practice to have as a minimum ..."

(i) Please identify actual guidelines and recommendations on the composition of the medical team for a paediatric renal transplant that were current at the time of Adam's surgery.

(ii) Please provide the basis for your/Hugh Rogers statement that the details set out have *"been regarded as good practice to have as a minimum"*.

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7. para.38, line 1:

*"the grade mix of the scrub roles and the circulating is more complex but **she knows that Northern Ireland** had not/has not gone far with innovative/new ways of working/new roles so this should have been a combination of Registered Nurse (RN), Enrolled Nurse (EN) or Healthcare Assistant (HCA). The **minimum standard** was an RN in the theatre, with a combination of others in support of him/her."* (Emphasis added)

(i) Please identify clearly the source of Jane Reid's 'knowledge' that

"Northern Ireland had not/has not gone far with innovative/new ways of working/new roles"

(ii) Please explain in detail the basis of Jane Reid's view that *"this should have been a combination of Registered Nurse (RN), Enrolled Nurse (EN) or Healthcare Assistant (HCA)"*, identifying any relevant documents

(iii) Please identify and explain in detail the basis of Jane Reid's view that the *"minimum standard was an RN in the theatre, with a combination of others in support of him/her"*, identifying any relevant documents

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8. para.51, line 1:

"In 1989, a Hazard notice HC(Hazard)(89)31 'Blood Gas measuring: The need for reliability of results produced in extra laboratory areas' was released. It warned, following a recent incident, that the use of blood gas analysers by untrained staff and ***proper*** *operating procedures and quality control methods can produce misleading results and potentially adversely affect the treatment of patients. It called for action to formalise the management arrangements of such equipment and also independent quality control processes. It also asked that it be brought to the attention of pathology laboratory staff, and all medical, nursing and operating department staff with direct access to blood gas analysers."* (Emphasis added)

(i) Please confirm that *"proper"* is a typographical error and that it should read 'improper'.

(ii) Please state whether or not the Hazard Notice applied to Northern Ireland at the time of Adam's transplant surgery.

(iii) If the Hazard Notice did apply to Northern Ireland, then please describe and explain the steps that you consider should have been undertaken by the RBHSC to adequately respond to it.[1]

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9. para. 63, line 6:

"It is questionable whether Dr. McLaughlin made the seriousness of this adverse event and the potential malfunction of the equipment absolutely clear."

As you have identified earlier in your paragraph 63, Brian McLaughlin is a

[1] A copy of it is attached for your convenience

Medical Technician and not a doctor, whereas George Murnaghan is a doctor and the Director of Administration who arranged for the equipment check and report. See his Inquiry Witness Statement [Ref: WS-015-01]. Please reconsider your comment in the light of that.

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10. para. 65, line 4 (from top of the page):

"A further source of learning has been through the litigation route with the Clinical Negligence scheme for Trusts, though that did not start until 1995."

(i) Please explain what you mean by: *"the Clinical Negligence scheme for Trusts".*

(ii) Please state when in 1995 the 'scheme' started and whether it applied to or was operated in Northern Ireland.

(iii) Is the 'scheme' is set out or discussed in any document? If so, please provide a copy of it.

11. para. 68, line 1:

"There seems to have been some attempts to learn from Adam's death and the risk of hyponatraemia in paediatric surgery ***within the Royal*** *– e.g. drafting Recommendations for Paediatric Surgery; internal risk management seminar; awareness raising with all internal consultant anaesthetists about the monitoring of electrolyte balance; internal paediatric nephrologists modifying their guidelines; further sharing of the lessons from this case especially with the Anaesthetists on good record keeping etc."*

(i) Please comment upon the RBHSC's process of identifying: (a) what the lessons were that arose out of Adam's death and the Inquest into it; and (b) how those lessons should be disseminated.

(ii) lease provide your view on what that process should have involved, including the extent to which it would have been appropriate/prudent for the RBHSC to look for broader lessons on fluid management and the prevention of hyponatraemia in addition to those concerning the narrower areas of paediatric surgery and paediatric renal surgery.

(iii) In the light of the outcome of Adam's Inquest and the provision of paediatric services in Northern Ireland hospitals (including paediatric surgery), please explain what factors the RBHSC should have considered in deciding whether or not to disseminate the lessons learned

from Adam's death to other hospitals in Northern Ireland.

(iv) In addition, state what factors, if present, would have made it incumbent on the RBHSC to disseminate the lessons learned more widely than through internal learning alone.

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12. para.70, line 1:

"The view of some of the Clinicians is that the Royal was the only paediatric transplant centre in Northern Ireland and so the emphasis on ***internal learning****, especially in view of the lack of national learning culture, may have been justified."*

Please explain the extent to which the RBHSC should have realised that the issues arising in Adam's case had a broader application rather than being confined to the area of 'major paediatric surgery'.

Other queries

13. Question 1 at page 2 of your Report seeks your view of the extent to which Adam's family was kept informed about the risks to him in the proposed transplant surgery and their options *"including having the surgery conducted outside the jurisdiction – for example at a hospital in England"*. Question 2 at page 8, seeks your knowledge of how a decision is made and evaluated *"to change the location of significant surgery in the mid 1990s, and whether this would have been predominantly a decision by clinicians or management."*

A related, but broader and perhaps more policy-related issue, is the extent to which a hospital should continue to carry out certain types of surgery (in this case paediatric renal transplantation) having regard to: (a) the volume and frequency of such procedures being carried out; (b) the extent of suitably skilled and experienced medical, nursing and technical personnel; and (c) the availability of appropriate support services (laboratory testing etc) and equipment. Please consider the following:

(a) 6 reports[2] dealing with the provision of surgical services in Northern Ireland and organ transplantation in the UK:
- British Association for Paediatric Nephrology, 'The provision of services in the UK for children and adolescents with renal disease'; Report of a working party (March 1995);
- Towards Standards for Organ and Tissue Transplantation in the United Kingdom; British Transplantation Society (November 1998);

[2] These are attached

- The Report of the Working Party to Review Organ Transplantation; The Royal College of Surgeons (January 1999);
- Paediatric Surgical Services in Northern Ireland; Report of a Working Group (1999);
- 2002 Review of Renal Services commissioned by the Northern Ireland Minister for Health, Social Services and Public Safety
- Improving Services for General Paediatric Surgery - Policy and Standards of Care for General Paediatric Surgery in Northern Ireland; Department of Health, Social Services and Public Safety (May 2010)

(b) 2 tables provided by the NHS Blood and Transplant Agency showing for Belfast and other Transplant Centres the figures for: (a) 1990 - 2010 paediatric renal transplants by year and age group; and (b) 1998 - 2010 median cold ischaemic time by years and age group

(c) Information received through Freedom of Information requests and from the Directorate of Legal Services, in respect of the number of transplant procedures that have been carried out by surgeons and anaesthetists at the RBHSC and the Belfast City Hospital (including Adam's Anaesthetist Dr. Taylor and his Surgeon Mr. Keane):[3]

- Letter from the Liaison Officer of Belfast City Hospital Trust to Dr. Burton dated 29th July 2005, with the enclosed schedule showing the number of paediatric transplants carried out by identified surgeons at the Belfast City Hospital site (BCH) over the period 1st January 1990 to 31st December 2004 [Ref: 094-013k-082 & Ref: 094-013k-083]
- Letter from the Publications Manager of the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust to Dr. Burton dated 17th May 2005, with the enclosed 2 schedules showing the dates of paediatric renal transplants for children under 14 years at both the RBHSC and BCH for the period January 1990 to December 2004 [Ref: 094-163-766 to Ref: 094-163-768]
- Email from the Publications Manager of the Royal Group of Hospitals and Dental Hospital Health and Social Services Trust to Dr. Burton of 11th July May 2005 stating the numbers of renal transplants carried out by identified surgeons at the RBHSC over the period 1st January 1990 to 31st December 2004 [Ref: 094-163-769]
- Letter dated 16th December 2010 from the Directorate of Legal Services to the Inquiry

(d) PSNI and Inquiry Witness Statements of the medical, nursing and technical staff involved in Adam's transplant surgery deal with their respective qualifications and experience in relation to paediatric renal transplants and the associated equipment:[4]

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[3] These are attached

[4] You should have a set of these but please advise if there are any that you require

- Dr. Savage (Consultant Paediatric Nephrologist [Ref: WS-002-02]), who was Adam's Consultant Nephorologist and who left the operating theatre for other duties at about 09.00. He had experience of 22 paediatric renal transplants prior to Adam, largely in the 1980s, the most recent of which was on 17th July 1993
- Dr. O'Connor (Consultant Paediatric Nephrologist [Ref: WS-014-02]), who replaced Dr. Savage at around 09.00. She had joined the RBHSC on 1st November 1995 and had been involved in 13 paediatric renal transplants before Adam, almost all of them were in 1995 with the most recent - and the only previous one in Belfast - being on 17th November 1995[5]
- Dr. Taylor (Consultant Paediatric Anaesthetist [Ref: WS-008-02]) who was the on-call Anaesthetist. According to correspondence from the Department of Legal Services[6] he had not been involved in a paediatric renal transplant between 1st April 1993 and Adam's transplant, has no recollection of how many if any he had been involved with prior to then and had never anaesthetised a polyuric child before Adam
- Dr. Montague (Senior Anaesthetic Registrar [Ref: WS-009-01]), who assisted Dr. Taylor. He had not previously been involved in a renal transplant, in November 1995 he was in his first month of training in the RBHSC and he went off duty at about 08.30 following the completion of a 24 hour shift
- An unidentified trainee anaesthetic registrar[7] (referred to by Dr. Taylor in his Inquiry Witness Statement [Ref: WS-008-02] as assisting him after Dr. Montague left at about 08.30)
- Mr. Keane (Consultant Urologist [Ref: WS-006-02]) who may have been the on-call transplant surgeon. According to him, he *"was the only appropriately trained surgeon available and capable of performing the [renal transplant] procedure"* on Adam on 27th November 1995 [Ref: WS-006-02, p.8]. According to correspondence from the RBHSC, BCH and the Directorate of Legal Services:
  - between 1st January 1990 and 31st December 2004, Mr. Keane was involved in 4 paediatric renal transplants at Belfast City Hospital (it is unclear if he was the lead surgeon or assisted in these operations) [Ref: 094-013-082 & Ref: 094-013-083]
  - prior to Adam's transplant, Mr. Keane had performed 3 renal transplants involving children aged less than 6 years old (whilst assisting in others), the most recent of which prior to Adam was at the RBHSC on 17th November 1995 involving a 3 year old child and with Mr. Victor Boston (Consultant Paediatric Surgeon) [Ref: WS-006-02, p12, Ref: 094-163-769 and letter from the Directorate of Legal Services to the Inquiry dated 2nd August 2011]

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5 She also provides details of the numbers of renal transplants

6 Letter of 2nd August 2011

7 The Inquiry has been advised by the Directorate of Legal Services that the staff rotas have been destroyed in accordance with hospital policy. See attached letter dated 2nd August 2011

- Mr. Keane has performed no paediatric transplants since Adam's surgery [Ref: WS-006-02, p.13]
- Mr. Brown (Consultant Paediatric Surgeon [Ref: WS-007-02]) who assisted Mr. Keane. He states in his PSNI and Inquiry Witness Statements that he:
  - had not performed nor been involved in any transplant operation prior to Adam's renal transplant [Ref: 093-011-031]
  - does not recall if he was involved in any other transplant operation after Adam's death [Ref: WS-007-02, p.5] but believes that if he had, they would have been very few [Ref: 093-011-031]
  - does not recall ever having previously assisted Mr. Keane [Ref: WS-007-02, p.5]
- SN Conway (Paediatric Staff Nurse [Ref: WS-060-03]) who acted as scrub nurse, went off duty at 08.00 and was not present during the transplant operation. She claims that at the time of Adam's transplant she did not know how to use a blood gas machine and that *"It was not within the remit of a staff nurse"* [Ref: WS-060-03, p.4]
- SN Popplestone (Registered Sick Children's Nurse [Ref: 093-012-039]) who was on duty that day and took over from SN Conway as scrub nurse
- SN Mathewson (Registered Sick Children's Nurse [Ref: WS-101-01]) who was on duty on the day of Adam's transplant and acted as circulating nurse assisting SN Popplestone. She claims in her Inquiry Witness Statement that in November 1995 her duties ranged from *"being anaesthetic nurse, to scrub nurse to being runner and also working in recovery"* and that she cannot recall how many renal transplant cases she was in. She also states that at the time of Adam's transplant she did not know how to use a blood gas machine, had not been trained and was not authorised to do so [Ref: WS-101-01, p.2 and p.4]
- Peter Shaw (Medical Technical Officer [Ref: WS-106-01], whose pre-operative role was to check all the operating equipment and, during the operation, to assist the anaesthetists together with (if need be) acting as a second runner
- Tommy Ryan (Senior Technician [Ref: WS-125-01 and WS-125-02) who was Mr. Shaw's line manager and was trained to use the blood gas analyser and authorised to do so

In the light of that information, please comment on:

(i) What consideration the RBHSC, the Trust and the Department should have given in 1995 (and now) to assessing the risks (if any) of the RBHSC continuing to offer paediatric renal transplants.

(ii) What consideration the RBHSC, the Trust and the Department should have given in 1995 (and now) to the competency of the unit at the RBHSC when deciding whether to continue to offer paediatric renal transplants.

(iii) What consideration the RBHSC, the Trust and the Department should have given to the implementation of programmes to manage any risks identified and the feasibility of the RBHSC being able to effect material changes having regard to the size of the Northern Ireland population (approximately 1.5million), the likely incidence of chronic kidney failure amongst its child population and the volume of the likely demand for paediatric renal transplants.

(iv) What advice/options should have been given to families by the medical transplant personnel at the RBHSC in 1995 (and now).

(v) The literature (if any) that was available in 1995 (and now) which discusses such issues.