

**REPORT OF EXPERT ON NHS HOSPITAL MANAGEMENT & GOVERNANCE:
STEPHEN RAMSDEN - DR. DANIELLE FREEDMAN**

ADAM STRAIN

SUPPLEMENTARY BRIEF

There are some specific queries arising out of the 'General Statement' from Dr. Freedman that included as Appendix 3 of your Report and we would be grateful if you would have Dr. Freedman address the following matters and for you to provide her response within your fully referenced Supplemental Report.

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Question 1

1. 1st para.

"This [the standards expected at the time for the laboratory and equipment support] all hinges on whether the laboratory had CPA Accreditation and/or gone through the King's Fund OA process."

- (i) Please identify the different accreditation bodies operating in the UK as at 26th November 1995 for laboratories and laboratory equipment and describe the process of accreditation for each
- (ii) Please describe the implications for 'standards' of accreditation with any of those bodies, generally and in particular:
 - accuracy and reliability of results of blood tests especially those for electrolytes
 - turn-around times for the results of blood tests during normal working hours, out of hours and in urgent cases (whether or not they arise within working hours)
- (iii) The Inquiry has been informed that the Belfast City Hospital Trust and the Royal Group of Hospitals Trust (which incorporates the RBHSC) separately applied to the King's Fund Organisational Audit in 1995/96 but neither became accredited in 1995 or 1996. The Belfast City Hospital Trust received accreditation in June 1997 and the Royal Group of Hospitals Trust after that. The Inquiry has sought the following further information in relation to accreditation:
 - (a) the dates that each hospital applied
 - (b) the applications for each hospital

- (c) correspondence relating to the applications and their results
- (d) the certificates of successful accreditation

Ahead of any response to that request, and on the basis of the information that has been provided to you (including the application for accreditation to the KFOA), please provide:

- your view of the standards in November 1995 that might be expected of the laboratory and equipment support in the Royal Group of Hospitals in general and in the RBHSC in particular
 - the reasons for your view
- (iv) Please state the significance/importance of a hospital's laboratory being accredited and explain the:
- (a) process of applying for and being granted accreditation
 - (b) means of ensuring that standards are being maintained, including whether through periodic audits and External Quality Assurance etc

2. Point C:

"This is not the case [the laboratory taking an hour] for an 'urgent' sample. From the time a sample is booked-in to the time a result is produced, nowadays would be 40 minutes. In fact during the mid-90s and certainly from our own lab (and many others I have visited as a CPA Assessor), they had specific, dedicated, what we call 'STAT' machines measuring sodium, potassium, urea and creatine. In fact, measuring sodium, potassium and urea on a STAT machine would only take 20 minutes"

- (i) Please provide the basis for your statements in relation to 'turn-around' times, ie 40 minutes nowadays for a laboratory result and 20 minutes from a STAT machine.
- (ii) Please explain what you think the 'turn-around' time in November 1995 (as opposed to "nowadays") was from "*the time a sample is booked-in to the time a result is produced*".
- (iii) Please explain what you mean by a STAT machine and:
 - (a) whether it includes a 'portable i-STAT machine'
 - (b) how reliable the results of the STAT machine were as compared to laboratory tests

3. The Inquiry has received layout plans for the RBHSC and the main Royal Victoria Hospital,¹ showing the location of: the operating theatre, PICU and the Clinical Biochemistry Laboratory in the RBHSC, together with the main

¹ These are attached

Royal Victoria Hospital Laboratory in the Kelvin Building. The Inquiry has also received correspondence from the Directorate of Legal Services ("DLS") dated 24th August 2010 and 3rd November 2010,² which provides details of the operation of the laboratories, together with the location, use and accuracy of the blood gas analyser machine that was used during Adam's transplant surgery. The blood gas machine in use during Adam's transplant surgery (and to which Dr. Taylor refers) was an IL 1400 series blood gas analyser manufactured by Instrumentation Laboratory (part of the Werfen Group)

- (i) Please comment upon the statements made about the blood gas machine in the correspondence from the DLS.
- (ii) Please also consider the comments about the laboratories and their proximity to the operating theatre in relation to 'turn-around' times for blood electrolyte tests.

Question 2

4. Point A:

"In fact, during the mid-90s, one could measure sodium on a blood gas analyser, ie it was feasible."

Your statement was provided in response to: *"Dr. Taylor claimed that he would not rely on the blood gas machine to accurately analyse sodium levels and it was common practice in the RBHSC":*

- (i) Please comment upon Dr. Taylor's claim that at that time (ie the mid-1990s) the blood gas machine could not be relied upon to accurately analyse sodium levels when using heparin syringes as the sodium content was likely to be altered by the addition of heparin to the sample syringe.
- (ii) It would be helpful if you would describe and explain the levels of accuracy and reliability of such a machine (including whether or not a heparin syringe is used) by comparison with laboratory results.

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5. final para:

"I would be happy to send you are present day POCT Policy together with our policy from the mid-90's if you so require."

² These are attached

EXPERTS

Please provide a copy of your current POCT Policy together with your policy from the mid-90's.

³ A copy of it is attached for your convenience

⁴ These are attached

⁵ These are attached

⁶ You should have a set of these but please advise if there are any that you require

⁷ She also provides details of the numbers of renal transplants

⁸ Letter of 2nd August 2011

⁹ 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