HSC Business Services Organisation

Directorate of Legal Services
PRACTITIONERS IN LAW TO THE HEALTH & SOCIAL CARE SECTOR

2 Franklin Street, Belfast, BT2 8DQ
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Your Ref:
AD-0652-13
AD-0629-13

Our Ref:
HYPS071/01

Date:
15th October 2013

Ms A Dillon
Solicitor to the Inquiry
Arthur House
41 Arthur Street
Belfast
BT1 4GB

Dear Madam,

RE: INQUIRY INTO HYPONATRAEMIA RELATED DEATHS – CONOR MITCHELL

I refer to the above matter and to your letter of 24th September 2013.

With regard to your letter of 4th September 2013 (AD-0629-13), it was initially anticipated that the Trust would be in a position to respond to this correspondence by the 18th September 2013. When it became apparent that this would not be possible I telephoned the Inquiry offices at approximately 4:45 pm on 18th September to speak with Mrs Conlon. Mrs Conlon was not available and so I asked to speak with you, you were also not available. I subsequently left a message for Mrs Conlon indicating that the Trust had provided instructions to me regarding your letter (AD-0629-13) but given the time of day I would not be in a position to draft the response and have this approved by the Trust and submitted to you by close of business. I indicated that I would hope to have this response with you the next day.

Mrs Conlon telephoned me on Thursday 19th September 2013 at approximately 10.00 am and I confirmed that I was in the process of finalising the draft letter and would be shortly sending it to the Trust for approval. Mrs Conlon asked me whether the response was "a full response" and I advised her of the difficulties experienced by the Trust regarding Dr Humphrey's letter to the CMO and Dr Humphrey's witness statement. I also spoke to Mrs Colon later that day and confirmed that the response was with the Trust for approval and I awaited hearing from them. The response was approved and sent to Mrs Conlon via email on 20th September 2013. I accept that I did not make a formal extension request; however, you will note that I did speak with Inquiry staff on a number of occasions providing a full explanation for the delay and kept Mrs Conlon updated regarding the situation. Given that it was initially anticipated that the response would be submitted the following morning I did not feel that a formal extension would be necessary. Certainly had I anticipated that there would be a significant delay in responding to your correspondence or had I been advised that a formal application was expected despite my various discussions with Inquiry staff I would, as we have done in the past, have made a

formal extension application. Please accept my apologies for any inconvenience caused by the fact that I did not make a formal application in this instance.

The Trust has noted your comments in relation to the letter of 4th July 2013 (BC-0204-13) and in particular those regarding Dr Humphrey. The Trust wishes to apologise unreservedly for any delay in providing a full response to Mrs Conlon's letter of 4th July 2013. However it is important to note that this letter was received by the Trust on Friday 4th July 2013, immediately prior to the July holiday period, a time of the year during which, I am sure you will appreciate, a high volume of Trust staff were on annual leave. Due to the timing of this request, the Trust experienced considerable difficulty in making contact with individuals within the Trust in order to take instructions. A number of individuals who were key to the provision of information/documentation regarding this request were on leave during this period, on occasion that leave overlapped making it difficult to verify information. These difficulties were further exacerbated by issues relating to the retrieval of historical documentation. The Trust provided initial instructions to us on 16th August 2013 and the final correspondence was approved by the Trust and sent to the Inquiry on 28th August 2013. The Trust fully appreciates that the Inquiry requested a response to this correspondence by the 29th July 2013 and apologises that it was not in a position to provide a response within that timescale.

The Trust instructs that it did not in any way intend to submit inaccurate or incomplete information to the inquiry and the Trust is fully committed to working with the inquiry and its timescales. I am instructed that the information provided to the Inquiry in the letter of 28th August 2013 (BC-0204-13) regarding the implementation and dissemination of the 2002 Fluid Guidelines was based on the limited information retrieved from historical records. Due to the limited documentation which the Trust was able to source much of the Trust's response was based on the recollections of individual trust employees. The Trust is presently carrying out a second search of historical records. Details of this search will follow in response to your letter of 2nd October 2013 (AD- 0658-13).

I am instructed that because the information provided to the Inquiry was in part based on information provided to the Trust by various employees there have been two occasions when the information initially provided required amendment as the individual's recollection of events was further informed by emerging information. This was the case in relation to the information provided by the Trust in the letter dated 28th August 2013 (BC-0204-13) regarding Dr Sharpe's involvement in the informal working group which was in place in 2001 working to develop internal guidance. I am instructed that having reflected upon the information previously given to the Inquiry Dr Sharpe realised that his initial recollection had been incorrect and the Trust subsequently sought to correct this in the letter dated 20th September 2013 (AD-0629-13).

The Trust did not deliberately provide erroneous or misleading information to the Inquiry. With regard to the identity of the Nursing Director as you are aware the Trust sought to confirm the

name of the Nursing Director was accurate prior to providing that information to the Inquiry. You will be aware that the individual holding the post of Nursing Director changed in 2002. Please note that this information was clarified and provided to you on 26th September with further information being provided later on that date.

The Trust did not approach Dr Humphrey on its initial receipt of the letter of the 4th July as its objective at that point had been to provide the Inquiry with the information it sought regarding the group of clinicians referred to in this communication as specifically requested. The Trust was very much focused at that time on sourcing the information/documentation sought directly from those individuals who were noted to have taken the guidance forward within the Trust. You will appreciate that due to the difficulties referred to above, the information provided to the Inquiry took a considerable length of time to obtain and the Trust experienced some difficultly in verifying the information within the letter in order to respond to your letter of 4th July 2013 (BC-0204-13).

We have noted your comments in relation to the service of the witness statement on Dr Humphrey. However your letter of 28th August 2013 (AD-0625-13) specifically states that *"witnesses should not discuss the contents of their witness statements with anyone other than their legal advisers".* The information sought in Dr Humphrey's statement is the same information sought from the Trust. The Trust was both mindful of the direction in your aforementioned letter and cognisant of the fact that the individual's evidence should be their own independent account or recollection. The Trust did want to take any steps which might potentially undermine the integrity of that evidence.

The witness statement issued by the Inquiry in respect of Dr Humphrey was sent to us on the 28th August 2013 with a submission deadline of 20th September 2013. You will be aware that the Inquiry was advised in an email dated 4th September 2013 that Dr Humphrey was no longer employed by the Trust and that we had made a request to the GMC for her current contact details. I would also refer you to my emails of 24th September 2013 (11:59 and 13:41) to separately setting out the difficulties experienced by the Trust in contacting Dr Humphrey and seeking an extension in respect Dr Humphrey's witness statement. Please also see Mrs Conlon's email to me on 24th September 2013 confirming that an extension had been granted. Please note that the extension had been applied for and granted prior to our receiving your correspondence on 24th September 2013. It would appear that my various emails have crossed with your letter of 24th September but I trust that this clarifies matters. In any event you will be aware that Dr Humphrey's completed witness statement was submitted to the Inquiry on 8th October 2013.

With regard to the specific numbered points set out in your letter I am instructed as follows: -

1) Please see my emails of 24th September 2013 referred to above. I would ask that you note that this information was provided prior to our receiving your letter of 24th September (AD-0652-13).

2) Dr Sharpe had indicated in his witness statement (under membership of Advisory Panels and Committees) that from 2002 he has been Chair of the Trusts Point of Care Testing Committee. Please find attached a document which sets out the function and remit of this committee.

3) I can confirm that we have fully advised the Inquiry as regards the progress of all the various witness statements issued in your letter. The relevant Directors of Nursing have been identified to the Inquiry and statements have been issued to them. As you are aware the statements of Dr Hogan, Dr Davis, Dr Bell, Mrs O'Rourke, Dr McCaughey, Mr Mone were all submitted to the Inquiry on or before the submission deadline. Furthermore we have kept the Inquiry fully advised regarding the position regarding Dr Chillingworth and Mr Templeton and Ms Foy, appropriate applications have been made to the Inquiry regarding same, and those statements have also been provided to the Inquiry.

4) The Trust can confirm that the clinical services manager referred to was Mrs O'Rourke. Mrs O'Rourke's witness statement was submitted to you on 3rd October 2013, prior to the 4th October deadline. The Trust believes that Mr O'Rourke has addressed the below questions in her witness statement.

5) The information in point 1 of my letter of 28th August 2013 was provided by Margaret Marshall, Interim Assistant Director of Clinical and Social Care Governance, who has confirmed that that it was reflective of the information available to her at that point in time.

6) I am instructed that Mrs Marshall spoke to Dr Sharpe on the week being 5th August 2013 and during this conversation Dr Sharpe confirmed that he was the Consultant Biochemist cited in Dr Humphrey's letter. Dr Sharpe was and is the sole Consultant Biochemist within both the legacy CAH Trust and the present. Dr Sharpe then went on a period of annual leave during which the Trust's response was submitted to the Inquiry. Upon his return on the week being the 26th August I am instructed that Dr Sharpe gave further consideration to Dr Humphrey's letter and subsequently advised Mrs Marshall that it was clear to him that his involvement in the context of Hyponatraemia guidelines was in respect of Adults. The Trust accepts that it would have been appropriate to have Dr Sharpe approve the Trust's response prior to it being submitted to the Inquiry. However, as indicated above, Dr Sharpe was on annual leave at this stage and the Trust did not wish to further delay the provision of information to

the Inquiry and therefore submitted the information. The Trust apologises that the information given to the Inquiry was not accurate in this respect.

7) I am instructed that the Trust has been unable to locate any document which formally withdraws Dr Lowry's and Dr Smith's guidance following the publication of Regional Fluid Management Guidelines in 2002.

8) I am instructed that the Trust has been unable to locate any teaching materials relating to Table A of the correspondence of the 20th September 2013.

9) I am instructed that a search was carried out by the Trust's IT department in the hope of locating any electronic information presently on the Trust's system. The Southern Health and Social Care Trust was created in 2007 and as part of this merger the legacy infrastructures merged to create a single IT Infrastructure. All data that existed in the legacy Trusts (PCs, laptops and Servers) including the legacy CAH Group Trust was migrated into the new Southern IT Infrastructure and no data was lost. In 2002, 5 years before the creation of the SHSCT, the IT Infrastructure in CAH Group Trust was very immature. There was limited central data backup which was mainly limited to application backup. Word processing and general documents would have been either saved to local PC hard disks or onto floppy disks. As no data was lost during the migration process if the electronic version of the document exists then it should be available. In view of this information a search was undertaken the results of which produced no documents on electronic file. The Head of Informatics is Mr Stephen Hylands.

10) The Trust confirms that this document was provided to Dr Lowry, at his request, by Dr Taylor. Please also refer to Dr Smith's second witness statement, question 1b, which indicates that he and Dr Lowry received some written material from Dr Bob Taylor which was incorporated into local guidelines. The Trust apologises that that it did not clarify this information at an earlier stage.

11) I am instructed that Appendix 12, attached to my letter of 20th September 2013, is the only document located by the Trust to date which shows that steps were taken to check that the poster was displayed.

12) A) I am instructed that the information to which you refer in my letter of 20th September 2013 was provided to the Trust by the Effectiveness and Evaluation Manager and the Lead Clinician in Paediatrics, Craigavon Area Hospital.

B) Please find enclosed herewith.

C) I am instructed that the Trust is not in possession of any documentation demonstrating that the audits 'specifically and directly' examined compliance with the 2002 guidelines. The Trust believes the documentation submitted demonstrates where the management of IV fluids in Paediatrics had been considered by the clinical body during the time period of these initiatives.

The Trust wishes to take this opportunity to apologise again to the Inquiry Team for any inconvenience caused as result of any delay in the provision of information and/or documentation to it and trust that the inquiry will accept the very genuine reasons for this. I am instructed that the Trust have found it challenging to respond within the timescales set by the Inquiry as on occasions locating former employees has required a considerable amount of time in particular in respect of those residing outside this jurisdiction.

The Chief Executive of the Trust wishes to reassure you that the Trust is fully committed to cooperating with the Inquiry and that staff within the Trust have been consistently making every effort to respond to the Inquiry's information requests by working to process information requests, search for documentation and disseminate witness statement requests within the deadlines set by the Inquiry. Furthermore, in order to ensure that witness statements have been provided to witnesses, no longer employed by the Trust, staff have personally and on more than one occasion attended at the addresses of witnesses in order to make contact with them, made numerous telephone calls to individuals outside working hours, sometimes in difficult circumstances, and provided administrative support to witnesses. The Trust has actively tried to ensure that witness statements have been submitted within the timescales set by the Inquiry wherever possible. I am instructed that the Trust has in no way intended to inconvenience or delay the Inquiry's investigations and deeply regrets that it has been unable to satisfy the Inquiry with the information and/or documentation which has been provided to date.

Yours faithfully

JRBo

Joanna Bolton
Solicitor Consultant

Craigavon Area Hospital Group Trust

POINT OF CARE TESTING (POCT)

POLICY

1. INTRODUCTION

Point of Care Testing, POCT, is the testing of patients' samples by non-laboratory staff - mainly medical and nursing staff - outside the main laboratory. POCT is currently used in the Trust and is likely to increase because of advancing technology and changing clinical practice.

A formal Policy specifying the involvement of the laboratory, and where appropriate, other disciplines, at every stage of POCT, is essential to ensure that the whole process is conducted in accordance with the principles of Clinical Governance. Joint planning will incorporate laboratory advice about equipment purchase, agreement on support, consumable costs and user training and accreditation. This will ensure:

- high quality and cost-effective patient care
- effective risk management, including control of infection
- coherent and informed service planning, and Trust-wide equipment standardisation
- optimum financial arrangements, including discount agreements with suppliers for equipment and consumables
- fully trained users of POCT, resulting in efficient use of ward and laboratory staff time

2. BACKGROUND:

Guidelines on POCT have been published by a number of organisations[1-7] and most recently by the Medical Devices Agency (now known as MHRA, Medicines and Healthcare Products Regulatory Agency)[1]. It is essential that POCT applications are subject to clinical effectiveness studies and the associated risks managed to the standards published.

The Clinical Biochemistry laboratory has actively supported POCT throughout the Trust, particularly with regard to user training and quality assurance in the use of blood glucose meters and blood gas analysers in clinical areas.

A new multi-disciplinary POCT committee has been established in the Trust in 2002 with the aim of advising, investigating, supervising and auditing POCT throughout the Trust.

This policy is designed to ensure that POCT in CAHGT complies with all such advice and guidance. It applies to all Pathology POCT (biochemistry, haematology and microbiology).

3. AIM:

A Trust-wide Policy on POCT will ensure that consistent procedures are in place throughout the Trust and that a high quality and cost-effective service is provided.

(a) **Strategic Planning:** Joint planning of diagnostic services with the laboratory and POCT committee is essential, taking the existing service into account. Advances in analytical technology mean that POCT will continue to develop so that the repertoire of tests available will expand. This, together with the growing emphasis on Primary Care, may change the profile of the provision of diagnostic testing in the future.

(b) **Service Planning**: Establishment of new POCT within the hospitals must be discussed, from the earliest stage, with the laboratory and POCT committee. Careful consideration of the whole clinical context, including the level of existing services and the cost implications of implementing POCT, is essential, as it may be possible to meet the clinical needs by adapting the current service. It is important that similar arrangements are in place in the community and the laboratory will work towards achieving this. Replacement of existing equipment will be discussed in the context of any likely changes in service requirements or increase in costs.

(c) **Equipment standardisation and procurement:** Trust-wide standardisation of POCT equipment, where possible, will minimise costs and facilitate staff training. Replacement can then be discussed in the context of any likely changes in service requirements; the laboratory's advice on type of equipment and supplier is of paramount importance for the best clinical and cost-effective decision. If a clinical department proposes to purchase non-standard POCT equipment, support from the POCT committee cannot be guaranteed. It is essential that all potential users submit a request for the POCT device to the POCT committee using the Trust application form (attached)

(d) **Service Level Agreements:** Agreements between POCT committee and users at each POCT site before equipment is commissioned will cover:

- equipment procurement and capital / leasing & consumable costs
- risk management, including control of infection / equipment cleanliness/decontamination
- compliance with Standard Operating Procedures for equipment, as specified by the laboratory
- equipment maintenance and support by the laboratory
- quality control and external quality assurance
- user training; untrained users must not use equipment
- clinical liaison

(e) **Operating costs:** POCT is generally more expensive than central laboratory testing. Users, who are responsible for the revenue consequences of every purchase, including the manufacturer's maintenance contract and repair costs, own POCT equipment. Operating costs include consumables, QC/EQA, the manufacturers maintenance contract and repair costs. How these will be met must be agreed with the POCT committee before equipment is commissioned.

(f) **Remote monitoring and Patient Data Capture:** Remote IT monitoring of POCT equipment, particularly blood gas analysers, allows faster trouble-shooting, storage of QC data and also, with input of patient ID, patient data capture. Interfacing with the Laboratory Information System (LIS) is then possible, and in due course with PAS and the electronic patient record. It is essential that all replacement/new POCT equipment can be interfaced with the LIS.

4. COMPLIANCE:

Compliance with the Policy is important to minimise clinical risk and to ensure clinical and cost-effectiveness. Supported equipment found to be operating outside quality limits, or otherwise unsafely, will be taken out of service, after discussion with the clinical area concerned. Discussion will take place incrementally with the following people, until the matter is resolved.

1. Local Clinician
2. Lead Clinician/Clinical Director/Divisional Nurse
3. Trust Medical Director/Director of Nursing

For reasons of quality and clinical risk, it is desirable that POCT which is currently not supported by POCT committee is brought under supervision. Arrangement to accomplish this will be negotiated

5 REVIEW:

This Policy will be reviewed annually by the POCT Committee, in consultation with users and the Medical Director. This will ensure that our practice is in accordance with the most up to date professional standards and that POCT in CAHGT is of the highest possible quality and operates cost-effectively.

References

1. MDA DB2002(03) Management of IVD Point of Care Test Devices, Medical devices Agency, March 2002.
2. Joint Working Group on Quality Assurance. Near to Patient or Point of Care Testing Guidelines. Secretary, Dr Dennis Kilshaw, Diagnostic Services Ltd, Liverpool. January 1999.
3. Association of Clinical biochemists. Guidelines for the Implementation of Near Patient Testing, 1993.

4. Welsh Scientific Advisory Committee. Near Patient Testing: The Use of Diagnostic Equipment and Procedures Outside the Diagnostic Laboratory. Cardiff: Welsh Scientific Advisory committee, 1995.
5. Scottish Office Department of Health. Near Patient Testing: A Statement of Best Practice for Scotland. Edinburgh: Scottish Office Department of Health.
6. Freedman, D.B. Guidelines for the Implementation of POCT. International Federation of Clinical Chemistry (IFCC), 1999.
7. Institute of Biomedical Science. Near Patient Testing, 1996.

Updated June 2006

CAHGT POCT COMMITTEE

Terms of Reference

1. The POCT committee has been established to meet the needs of clinical governance.

2. The CAHGT POCT committee is currently chaired by Dr Peter Sharpe, Consultant Chemical Pathologist. It is multidisciplinary and consists of representatives from all interests (laboratory, clinical users, finance, business and planning).

3. The Chairperson of the POCT committee will report directly to the Clinical and Social Care Governance Committee of the Trust.

4. The POCT committee will oversee the planning, implementation, co-ordination and regulation of all POCT activities in the Trust. Any final decision by the committee will be binding.

5. At the outset the POCT committee should establish that the perceived need is valid and that a POCT solution will be clinically and operationally effective.

6. The Pathology laboratory will advise the POCT committee on the suitability of equipment and co-ordinate the assessment and evaluation of candidate devices.

7. Any decision to proceed with a POCT application should be subject to a business case detailing the clinical and operational benefits to be gained and the likely economic impact. It must represent Value For Money for the Trust. The cost/benefit analysis should include clinical risk management and involvement of the laboratory is mandatory.

8. The Chairperson of the POCT committee will advise clinical managers and make them aware of their responsibility for clinical governance and of the medico-legal implications of using POCT; in particular the implications of an erroneous result.

9. The POCT committee will ensure that the procedures and polices regarding POCT as set out by regulatory bodies are adhered to.

   This includes the following:
   (a) Accreditation
   (b) Training
   (c) Standard Operating Procedure (SOP)
   (d) Maintenance
   (e) Health & Safety
   (f) Quality Assurance
   (g) Record Keeping
   (h) Adverse Incident Reporting
   (i) Audit
   (j) Budgeting Arrangements
   (k) Agreement
   (l) Assurance to Clinical & Social Care Governance Committee

Craigavon Area Hospital Group (HSS) Trust

Point of Care Testing Committee

Constitution

The Point of Care Testing Committee is a formally constituted Sub-Committee of the Medical Executive Committee.

Membership of the Committee

- Lead Consultant – Chemical Pathology (Chair)
- Lead Consultant - Haematology
- Pathology and Laboratory Services Manager
- Principal Biomedical Scientist – Chemical Pathology
- Principal Biomedical Scientist - Haematology
- Director of Finance
- Planning Manager – Pathology and Laboratory Services
- Clinical Users – A&E, ICU, General Medicine, Paediatrics, Purchasing Pharmacist, Diabetes Specialist Nurse

Authority

This Committee is authorised by the Medical Executive Committee to oversee the planning, implementation, coordination and regulation of all POCT activities in the Trust.

Role and Responsibilities of the Committee

The POCT Committee will establish that the need for POCT is valid and that a POCT solution will be clinically and operationally effective. The POCT committee will take into account assurances that are necessary within their

responsibility for clinical governance, including any medico-legal implications of using POCT.

Internal Arrangements

- The Pathology laboratory will advise the POCT Committee on the suitability of equipment and coordinate the assessment and evaluation of candidate devices.

- POCT applications will be subject to a business case detailing the clinical and operational benefits to be gained and the likely economic impact, including the value for money assessment. The cost/benefit analysis will include the assessment of clinical risk. Involvement of the laboratory is mandatory. The POCT committee will have the remit to recommend the withdrawal of equipment, if necessary.

- The Committee will provide to Medical Executive, an annual report on POCT activity, including specific assurances in regard to POCT applications.

Policies & Procedures

The POCT Committee will ensure that the procedures and policies regarding POCT as set out by regulatory bodies are adhered to. This includes the following:

(i)	Accreditation	(vii)	Record Keeping
(ii)	Training	(viii)	Adverse Incident Reporting
(iii)	Standard Operating Procedure	(ix)	Audit
(iv)	Maintenance	(x)	Budgeting Arrangements
(v)	Health and Safety	(xi)	Agreement
(vi)	Quality Assurance	(xii)	Assurance to Clinical & Social Care Governance Committee

Links to Committees

The Committee will work closely with the Medical Executive Committee to ensure that Clinical Directors are aware of POCT Committee recommendations.

Reporting

The minutes of meetings of the Committee shall be formally recorded and made available on request to the Medical Executive Committee and Clinical and Social Care Governance Committee.

Frequency of Meetings

Quarterly, with no fewer than 3 meetings per year.

Quorum

A Quorum shall be 50% of the Committee Membership (including the Chair and/or Vice-Chair). There should be at least one medically qualified individual present