

The Inquiry into Hyponatraemia-related Deaths

Chairman: Mr John O'Hara QC

Ms Wendy Beggs
Directorate of Legal Services
2 Franklin Street
BELFAST
BT2 8DQ

Our Ref: BC-0226-16

Date: 22nd June 2016

Dear Ms Beggs,

**Re: Your Client(s): Health & Social Care Board
 Belfast Health & Social Care Trust**

I attach for your attention two schedules of questions which the Chairman would like a response to on or before 22nd July 2016. He would be grateful for concise responses specifically tailored to the questions asked and reflecting the numbers used in the schedules.

If you have any queries regarding this matter, please do not hesitate to contact me.

Yours sincerely,



Bernie Conlon
Secretary to the Inquiry

Secretary: Bernie Conlon

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Questions Belfast Health & Social Care Trust

No	Context	Question
1	<p><i>"Belfast Trust 'Policy and Procedure for the Management of Complaints and Compliments' (2010)".</i></p> <p><i>The Concern which I wish to look at ... is that this policy, at least on paper, provides for very little input on the part of a patient or family into the complaint beyond making the complaint in the first place.</i></p> <p>Transcript 11th November 2013 p.6 L.1-6 AVMA/PCC</p>	<p>i. Please provide a copy of the current policy.</p>
2	<p>Policy and Procedure for the Management of Complaints and Compliments April 2010.</p> <p>Chairman: <i>Review date was April 2013 – it is currently under review"</i></p> <p>Transcript 11th November 2013 p.7 L.10-11 AVMA/PCC</p>	<p>i. When was the review completed?</p> <p>ii. Please provide a copy</p>
3	<p><i>"A complaint cannot properly be investigated in any way by somebody who's provided the care to the patient in question".</i></p> <p>Transcript 11th November 2013 p.66</p>	<p>i. To what extent does this still happen during the 'local resolution' phase?</p>
4	<p>Transcript 11 November p 74 L 17-19</p> <p>Chairman: <i>"Is there any way in Northern Ireland ... of measuring the outcome of complaints ... or has any thought been given to developing such a system".</i></p> <p>Transcript 11th November 2013 p.74 L.17-19 AVMA/PCC</p>	<p>i. Are the outcomes of complaints measured by the Trust now?</p>

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5	The BH&SCT refers to the “discussion/sharing of the final report with the family”. 348-002	i. Is their provision for sharing a ‘draft report’ or providing an ‘update on the investigation’ where the process of achieving a final report is protracted?
6	RQIA Review of Advocacy Services for Children and Adults in Northern Ireland (January 2016), which states: <i>“The provision of advocacy services continues [since the Department’s ‘Developing Advocacy Services: Policy Guide for Commissioners’] to be predominantly for mental health, learning disability and children’s service. There have been some developments for other programmes of care”.</i> (page20)	i. In what circumstances and how many times have advocacy services been offered in past 3 years?
7	Chairman “in what sort of scenario are lay reviewers engaged to assist?” Transcript 12th November 2013 p.17 L.10-14 Trust Evidence	i. In what circumstances and how many times have lay reviewers been used in past 3 years?
8	BHSCT SAI Procedure April 2014 – <i>“The Co-Director responsible for the SAI <u>should ensure</u> the appropriate level of involvement of ... family ... throughout the investigation including discussion/ <u>sharing of the final report</u> with the ... family ... and this <u>should be agreed</u> with the investigation team at the outset”.</i> 348-002	i. In what circumstances would you not involve the family? ii. If the family are not involved would they still be informed that a SAI investigation was underway? iii. Are the decisions not to inform a family recorded and monitored?

No	Context	Question
9	Draft BHSCT Serious Adverse Incident (SAI) Procedures – April 2014 348-002a	i. Please provide a copy of final version?
10	<p>Donaldson Report</p> <p>4.6, p.38: <i>“The system is too often falling down to level two [open but poor communication] because:</i></p> <ul style="list-style-type: none"> <i>• Staff who communicate with patients and families during the Serious Adverse Incident investigation process have variable communication skills ... Little formal effort has been made to train staff to manage these difficult interactions well.</i> <i>• Patients and families are often not offered the opportunity to meet with those who they would like to – the staff directly involved in the incident. Instead they tend to meet with managers and with clinicians who were not involved.</i> <i>• There are frequently delays in the process of investigating a Serious Adverse Incident.</i> <p><i>Patients and families are too often sent letters filled with technical jargon and legalese</i></p>	<p>i. Is training currently being made available to help staff develop the communication skills to “manage these difficult interactions well”?</p> <p>ii. What is the current procedure in relation to the family being able to meet (if they wish to) with those directly involved in their children’s care?</p>
11	<p>Joint Guidance from GMC and NMC (15 June 2015):</p> <p><i>“Your organisation should support you to report adverse incidents and near misses routinely. If you do not feel supported to report, and in particular if you are discouraged or prevented from reporting, you should raise a concern in line with our guidance.”</i></p>	<p>i. In light of concerns that there is lack of support for doctors and nurses who want to report adverse incidents and near misses. What steps are being taken to provide that support?</p>

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12	<p><i>"In the Children's Hospital, all deaths are now reviewed irrespective of whether there have been any concern about the quality of care. These meetings are recorded and a culture of openness and candour is being actively encouraged."</i></p> <p>Transcript 12th November 2013 p.9 L.9-13 BHSCT Evidence</p>	<p>i. Where is this done and how is the result measured and assessed?</p>
13	<p><i>"I suppose I expected that some planning would take place into the formation of a protocol, but what I know happened was that it had been tried -- that is a police officer taking statements -- but it didn't seem to work."</i></p> <p>Transcript 26th June 2013 p.88 L.24 Coroners Evidence</p> <p>Chairman: <i>"There was a point at which the coroner had raised the possibility that the statements should no longer be forwarded to him through the hospital, as had been the practice. In fact, he had suggested, but effectively he let it drop, that it should be the police who take the statements. I presume that is not happening?"</i></p> <p>Transcript 12th November 2013 p.56 L.15-24 BHSCT</p>	<p>i. Who currently takes statements for Inquests?</p>
14	<p><i>"We have learned from the events of this inquiry and are updating our arrangements to ensure a proper separation of coronial and medico legal functions".</i></p> <p>Transcript 12th November 2013 p.10 L.16-18 BHSCT Evidence</p>	<p>i. What "updated" arrangements are currently in place?</p>

No	Context	Question
15	<p>Department's position paper to the Inquiry (333-304): <i>"Teaching about the requirement to refer death to the Coroner, and how to complete a MCCD has been a long standing part of the undergraduate training for medical students at Queen's University."</i></p> <p><i>"In 2005 a review of induction processes for junior doctors recommended that first day induction should include Coroner's issues. In recent years a presentation on death certification and referral to the Coroner has been included in the induction for foundation doctors, and they are also required to complete an e-learning module. Knowledge of death certification and referral to the Coroner is also included in the foundation curriculum."</i></p>	<ul style="list-style-type: none"> i. What continued professional development is doctors receiving on this, particularly at consultant-level? ii. If death certification and referral to the Coroner is not being audited, how is doctors' training monitored in this area? iii. In what way are student doctors and nurses learning in their training lessons which have been learnt from unexpected deaths in hospitals and from Coroners Inquests? Please give specific examples.
16	<p>Department Position Paper (333-303): A pilot scheme has also been developed within the Belfast HSC Trust to review all deaths that occur in their hospitals and discussions are ongoing on implementing this process across Northern Ireland. Essentially the process will record, review, monitor and analyse all hospital deaths.</p>	<ul style="list-style-type: none"> i. What was the outcome of the pilot scheme? ii. What system has now been implemented?

No	Context	Question
17	<p>CMO Annual Report for 2015 (published 18 May 2016) p38: <i>"It is anticipated that the RM&MRs will begin a phased roll-out in August 2016, with the system being fully functional in all Trusts by March 2017."</i></p> <p>Also: <i>"effective use of the RM&MRS will help front line staff, working together on a multi-disciplinary basis, to identify learning which will improve the quality of care they can provide and to share this learning with others. It will also provide means for additional scrutiny of the death certification process ... the main benefits for improving quality of care derive from the opportunity for health and care professionals to learn from any cases where the quality of care could have been better and to promulgate learning."</i></p>	<p>i. Please provide any documents available explaining the full procedure for the implementation of the RM & MRs?</p> <p>ii. What training will staff be provided with for these RM & MRs reviews?</p> <p>iii. Will the consultant reviewing the death be the consultant involved in the care?</p> <p>iv. Will the M&M Review Meetings be minuted?</p>
16	<p>Chairman: <i>"she [Staff Nurse McRandal] then said: "It is still not normal to measure urine output on the Allen Ward, but it is on other wards" ... Can you help with that?"</i></p> <p>Brenda Creaney: <i>"Yes. That is a matter of concern ... Subsequent to the evidence given last year, it became apparent to us that our policy wasn't explicit enough in that regard ... we have revised the policy"</i></p> <p>Transcript 12th November 2013 p.50 L.9 et seq BHSCT Evidence</p>	<p>i. What is the revised policy?</p> <p>ii. When did the revised policy come into effect?</p> <p>iii. How is compliance with the revised policy being monitored and evaluated?</p> <p>iv. What procedures does BH&SCT currently have in place to identify any similar non-compliance through 'ambiguity'/'lack of clarity'?</p>
17	<p>Colm Donaghy <i>"In relation to serious adverse incidents ... We have recently strengthened our corporate arrangements by establishing a learning from experience steering group chaired ... by the deputy chief executive"</i></p> <p><i>"We have the HSCB Procedure for the Reporting and follow up of Serious</i></p>	<p>i. Please provide the current version of 2013 Health & Social Care Board procedure for reporting and following up serious adverse incidents.</p> <p>ii. What are the 'strengthened corporate arrangements'</p>

No	Context	Question
	<p><i>Adverse Incidents (Oct 2013)</i>".</p> <p>Transcript 12th November 2013 p.11 L.2-9 BHSCT Evidence</p>	<p>referred to?</p> <p>iii. Does the 'learning from experience steering group' issue reports and/or make recommendations?</p> <p>iv. If so to whom?</p> <p>v. What benefits has it brought and how are they measured and assessed?</p>
18	<p>Colm Donaghy "... there have been one or two instances that have arisen where we believe applying the serious adverse incident process could potentially cause further hurt or trauma"</p> <p>p.33, L.17-20 12th November 2013</p> <p>"... we're in discussion with the Health & Social Care Board for example around those sorts of areas and there may be another way".</p> <p>Transcript 12th November 2013 p.34 L.5-7 BHSCT Evidence</p>	<p>i. What was the result of those discussions in terms of 'another way'?</p>
19	<p>"... our SAI board ... brings together all of the SAIs within the organisation – and other incidents as well – and looks to see if there's any trend or any issues that we need to learn from"</p> <p>"Annual Report for BH&SCT (2014/2015) sets out an 'Assurance Sub-Committee Structure' (p.80), starting with the Board and going on to an 'Assurance Group', on to a 'Learning from Experience Steering Group' and finally to an SAI Group."</p> <p>Transcript 12th November 2013 p.38 L.15-19 BHSCT Evidence</p>	<p>i. How does the 4 tier structure operate in practice and over what time frame does it consider incidents?</p>

No	Context	Question
20	Chairman's letter to BH&SCT (27.03.14) – re June 2013 'Learning Report' (348-001): <i>"it does not address a more fundamental and worrying point, namely, whether there is any consistency in identifying and categorising adverse incidents".</i>	i. How is the Trust addressing this given it makes the largest number of SAI reports and has the premier Children's Hospital?
21	<i>BH&SCT reports (348-002) that the "4 week timeframe for investigation ... is insufficient to involve family in the review at such a difficult and traumatic time".</i>	i. How this being managed by the Trust?
22	<i>RQIA's report of December 2014 of SAIs refers draft guidance "currently at the final stages of consultation" for HSC organisations on "engagement with patients, clients and families as part of the SAI process" (para.2.2, pgs.3-4)</i>	i. What action has been taken by the Trust regarding engagement with families?
23	HSCB: A Guide for Health and Social Care Staff – Engagement/Communication with the Service User/Family/Carers following a Serious Adverse Incident (January 2015), provides guidance on apologies (p.9, 3.3) and on the involvement and services of the Patient Client Council (Appendix 2, p.27)	i. How is the implementation and effectiveness of this guidance being monitored?

Questions for Health & Social Care Board

No	Context	Question
1	<p>HSCB - Policy for HSCB Staff on the Management of Complaints (April 2016) provides: <i>"The use of an independent expert in the resolution of a complaint may be by the complainant ..."</i></p> <p>Chairman: <i>"is there a way in Northern Ireland of getting specialist support to help you with a complaint".</i></p> <p>Transcript 11th November 2013 p.19 L.6-8 AVMA/PCC</p>	<p>i. To what extent are Independent experts used?</p> <p>ii. How successful has this been?</p>
2	<p>Recommendation 10 [from the May 2013 workshop]: (344-001) <i>"There should be a regionally agreed method of disseminating learning from complaints, that should be developed by the Health & Social Care Board and by the Public Health Agency".</i></p> <p>Transcript 11th November 2013 p.69 L.12-19 AVMA/PCC</p>	<p>i. Has recommendation 10 been implemented?</p> <p>ii. If so, from what date?</p>
3	<p>On 31 March 2014 the Permanent Secretary wrote to HSCB and PHA concerning the complaints systems coming to a halt if there is litigation referring to the need for further guidance: <i>"In particular such guidance needs to make clear that litigation or legal proceedings should not be an obstacle to engaging with patients, clients and families".</i></p> <p>348-010d</p>	<p>i. Was this guidance issued?</p> <p>ii. If so, what steps have been taken to ensure that the guidance is followed?</p>
4	<p>HSCB/PHA Annual Quality Report 2014/2015 includes a section on 'Measuring improvement from complaints' (p.64), which refers to the monthly meetings of the Regional Complaints Sub-Group and "examples of changes implemented as a result of complaints".</p>	<p>i. How is learning from complaints actually analysed and evaluated?</p>
5	<p>HSC Board – The sixth Annual Complaints report of the Health and Social Care Board - 1 April 2015 – 31 March 2016.</p>	<p>i. Please provide a copy?</p>

No	Context	Question
6	<p>Joint Guidance from GMC and NMC (15 June 2015):</p> <p><i>"b. You must report suspected adverse drug reactions to the UK-wide Yellow Card Scheme run by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines.</i></p> <p><i>c. You must report adverse incidents involving medical devices to the UK-wide MHRA reporting system."</i></p>	<p>i. Is any consideration being given to the professions being required to report adverse incidents and near misses?</p>
7	<p>John Compton <i>"we have recently written to the coroner to formally request that all coroner's reports that may have learning for health and social care will be sent to us routinely so we can review those and take any necessary action"</i></p> <p>Transcript 14th November 2013 p.21 L.1-5 HSCB and PHA Evidence</p>	<p>i. Please provide copies of the correspondence with the Coroner on this issue and any response received?</p> <p>ii. How many reports referred to have been received subsequently?</p>
8	<p><i>"in March of this year [2013] the HSC board announced that, by 2015, plans would be implemented for all paediatric services to admit children up to their 16th birthday"</i></p> <p>Transcript 13th November 2013 p.56 L.12-17 RQIA Evidence</p>	<p>i. Have the plans referred to been implemented?</p> <p>ii. If not, why not?</p>
9	<p>HSCB/PHA 'Competency Framework for Reducing the Risk of Hyponatraemia when Administering Intravenous Infusions to Children and Young People' (2 February 2015): <i>"This Framework applies to all HSC Trust registered nurses ... midwives, dentists, operating department assistants, medical practitioners and pharmacists, who may be involved in the prescription, administration, monitoring and review of intravenous infusions to children aged over 4 weeks and up to 16th birthday. This framework will be formally reviewed by the PHA in January 2016".</i></p>	<p>i. Did the Review by PHA in January 2016 take place? If so please provide a copy.</p> <p>ii. If not, when will it happen?</p>

No	Context	Question
10	HSCB/PHA 'Guidelines for use of Child Regional Fluid Balance & Prescription (RFB&P) chart' (June 2015)	i. How (if at all) does the 'Regional Fluid Balance & Prescription chart' equate or relate to the Daily Fluid Balance Chart as a " <i>single daily chart</i> " that was recommended by GAIN in its audit of Parenteral Fluid Therapy for Children and Young Persons (8 August 2014)?
11	HSCB: Learning Matters (issue 5, April 2016), p.4: " <i>Prescription of IV Fluids. There have been a number of incidents where intravenous fluids have ... not [been] documented on the Medicine Kardex ... This has ... the potential to result in harm</i> ".	i. How many incidents were there and what were the circumstances? ii. What monitoring is done of learning/compliance with the safety issues identified in 'Learning Matters' – particularly given the e-learning issued in May 2014
12	Mr John Compton SAIs: " <i>In total, 966 serious adverse incidents have been reported to the board since 1 May 2010. In the most recent year of 2012/2013, 320 serious adverse incidents were reported to the board. This represents an increase from the previous year when 262 were reported</i> ". Transcript 14 th November 2013 p.15 L.7-11 HSCB Evidence	i. Please provide the latest Learning Report Serious Adverse Incidents (October 2015 – March 2016)
13	BH&SCT report (348-002): " <i>There is no regional consistency in the timeframe for a report to be completed and deemed final, which can result in only draft reports being provided to the Coroner & others.</i> "	i. Is the HSCB aware of this? ii. If so how is it being addressed? iii. If not why not?
14	October 2013 as part of a review of the SAI system and recommending that " <i>Deaths of children from natural causes should not be classified as Serious Adverse Incidents</i> ". The letter seeks " <i>to discuss this recommendation</i> " Reply from Chairman (11.09.15): " <i>I have some concerns. Exempting such deaths... should not become a way of avoiding the reporting of deaths such as</i>	i. Has the new notification been issued? ii. Have the revised SAI criteria been issued? If not, when is it expected they will be issued? iii. Please provide copies of anything that has been issued

No	Context	Question
	<p><i>those with which the Inquiry has been concerned. The wording and interpretation of 'natural causes' would have to be very narrow to avoid this"</i></p> <p><i>"Learning Report Serious Adverse Incidents (November 2015), 'Child Death Notifications', referring to the requirement to notify as an SAI all deaths of children receiving HSC services and the comments of Donaldson: This was an issue the HSCB/PHA had already identified and work had commenced on an alternative arrangement for child death notification.</i></p> <p><i>DHSSPS intend to issue the new child death notification process to the HSC in November 2015 for implementation on 1 December 2015. In conjunction with this new process, the HSCB will issue a revised set of SAI criteria"</i></p>	<p>in relation to this.</p>
15	<p><i>NI Policy Response to the report, 'Why children die death in infants, children and young people in the UK Part A': "Recommendation 2 - The DHSSPS should enact the legislation in Northern Ireland to allow the creation of a Child Deaths Review Panel managed by the Safeguarding Board for Northern Ireland (SBNI)" (p.6)</i></p> <p><i>Minutes of the BH&SCT Board (03.09.15)- item 37/15(b): Dr Johnston (Death Certification Policy Certification Policy and Legislation Unit): commencing August 2016, the Regional Mortality and Morbidity Review system (RM&MRs) will be introduced throughout hospitals in NI"</i></p> <p><i>Learning Report Serious Adverse Incidents (November 2015), 'Child Death Notifications': "DHSSPS ... with HSCB/PHA and Trusts, have agreed a new process for recording, reviewing and reporting of all child deaths as part of a new Regional Mortality and Morbidity Review (MMR) System. This process will be introduced and regarded as a pilot with a review being performed after one year"</i></p>	<p>i. What procedures and guidelines had been issued to ensure regional consistency and effectiveness?</p> <p>ii. Has the 12 month pilot commenced?</p>

No	Context	Question
16	<p>PHA response (14.04.14) (348-003) setting out the 'circulars' and the 'alerts' that remain 'open':</p> <ul style="list-style-type: none"> • RQIA follow up Review Reducing the Risk of Hyponatraemia when Administering Intravenous Infusions to Children, which was re-opened on 3 June 2013 (348-008c-004) • RQIA Review of Under 18s Accommodation in Adult Hospital Wards, which was left open following a Review by the Safety, Quality and Alerts Team (SQAT) during 1 April – 30 September 2013 (348-008c-005) • MOU on Investigating Patient or Client Safety Incidents – HSS(MD) 8/2013, which was also left open following the same Review (348-008c-005) • RQIA Review on NICE Guidance Implementation Process in HSC Organisations in 2013/2014 (348-008c-006). 	<p>i. What is the current position in relation to each of these?</p>
17	<p>NI Policy Response to the report, 'Why children die death in infants, children and young people in the UK Part A': "Recommendation 21 – "The HSCB, Health and Social Care Trusts and relevant professional associations should ensure that all frontline professionals involved in the acute assessment of infants, children and young people utilise resources such as 'Spotting the sick child' web resource and complete relevant professional development so they are competent and confident to recognise a sick child" (p.15)</p>	<p>i. What if anything has happened about the recommendation for training in relation to competently and confidently recognising the sick child?</p>
18	<p>H&SCB and PHA Annual Quality Report (2014/2015) Learning Report Serious Adverse Incidents (November 2015), p.102: "Paediatric early warning score systems have been established for use in acutely unwell children in order to identify the physiological and behavioural signs of deterioration prior to collapse ... it was agreed that as part of the HSC Safety Forum Paediatric Collaborative, a subgroup would develop and agree a single chart(s) for use in all units to standardise the process and facilitate the moment of patients and staff between HSCTs"</p>	<p>i. Please provide the document that explains this Paediatric Early Warning Score System?</p> <p>ii. Are standard charts in use now and if not when are they to be introduced?</p>

No	Context	Question
19	<p><i>"Regional adverse incident review group, all SAIs are reviewed for regional learning."</i></p> <p>Transcript 14th November 2013 p.40 L.8-10 HSCB Evidence</p>	<p>i. How often do the RAIRG meetings take place?</p> <p>ii. Are there any records of those meetings?</p>
20	<p><i>Chairman's letter (27.03.14) – re table received on 11 November 2013 of incidents across the 5 Trusts: "how reliable is the adverse incident reporting system when there are such gross variations in categorisation?"</i></p> <p><i>Response: There is no consistent method of coding used across all NI Trusts despite all using the same software system.</i></p>	<p>i. How (if at all) is the HSCB addressing this?</p>