Ms Catherine Rodgers
Departmental Solicitors Office
2nd Floor
Centre House
Chichester Street
BELFAST
BT1 4JE

Our Ref: BC-0227-16

Date: 22nd June 2016

Dear Ms Rodgers,

Re: Your Client(s): DoH

I attach for your attention a schedule 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,

B. Conlon

Bernie Conlon
Secretary to the Inquiry

Questions for Department of Health

No	Context	Question
1	Recommendations from Report of Sir Liam Donaldson	i. What steps have been taken to implement the recommendations in the Donaldson report in relation to complaints and SAIs? ii. What progress has been made to date?
2	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: *"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"*. **348-010d**	i. Was this guidance issued? ii. If so, what steps have been taken to ensure that the guidance is followed?
3	Minister of Health's statement on 27 January 2015: *"I want more work to be done to measure and report patient and client experience ... I have asked my officials to review the current arrangements for measuring patient/client experience to ensure we take the best available worldwide experience and design a framework to strengthen the voice of patients at every level from the front line up to the Department"*. **Hansard, 27 January 2015, vol.101, no.4.**	i. What is the current position in relation to this Review of 'measuring and monitoring patient and client experience'?
4	Dr Woods: *"The expectation with the RAIL process is that all adverse incidents will be drawn together and analysed and that the lessons learned from the totality of adverse incidents will be drawn together and disseminated for learning across the piece. The expectation is also that, in addition, there will be learning from issues that arise from clinical negligence cases and complaints. As the Venn diagram in the report shows, they are separate but interrelated: they overlap in some respects, but they all present the opportunity for learning and the avoidance of repetition."* **PAC – Hansard 14 November 2012, p.24:**	i. What is the current position with the development of a system to 'draw all AIs together across Northern Ireland' for purposes of assessing trends and lessons learned?

No	Context	Question
5	**Joint Guidance from GMC and NMC (15 June 2015):** *"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.* *c. You must report adverse incidents involving medical devices to the UK-wide MHRA reporting system."*	**i.** Is any consideration being given to the professions being required to report adverse incidents and near misses?
6	**Information from DOH in response to FOI request from the Detail.** *"Over the past 3 years, confidentiality clauses have been used in some 2% of all clinical negligence settlements. The Department has recently issued guidance reinforcing the principle that confidentiality agreements should not be used".*	**i.** Please provide the relevant statistics since November 2013 to date. **ii.** Please provide a copy of the guidance. **iii.** When was the guidance issued? **iv.** How is adherence to the guidance being monitored?
7	**Minister of Health's statement on 27 January 2015:** *"The effectiveness of whistle blowing arrangements within the Health and Care system continues to be a cause for concern. As part of the 2015/18 RQIA Review Programme, I have directed that RQIA should undertake a review of the operation of whistle blowing in health and social care bodies and make recommendations on how we can improve its effectiveness".* **Hansard 27th January 2015 vol 101 No 4**	**i.** What is the position in relation to the RQIA review of the operation of Whistle blowing?
8	**PAC Report on General Report on the Health and Social Care Sector 2012-13 and 2013-14 (25 November 2015)** **Recommendation 8:** *"The Department must take steps to ensure that its policy on whistleblowers is matched by arrangements which work in practice"* (p.15).	**i.** What actions are being taken by the Department to ensure that the Trusts are adhering to its policy in whistle-blowers?

No	Context	Question
9	*"I know there was some discussion about coroner's service, after Northern Ireland became a single coroner's district, should produce an annual report, and that would be a document that would allow for rule 23 referrals and responses to be published. But also, I think I should advise you that there is some suggestion of rule 23 in our legislation being amended, and that is under consideration at the present time."* **Transcript 26th June 2013 p.57 L.14-21 Coroners Evidence**	**i.** What liaison has there been between Department of Health and Department of Justice about improving the Health Service through the issue of Rule 23 reports following Inquests and the sharing of SAI reports for Inquests? **ii.** Is any further liaison under active consideration? **iii.** Are there any plans to bring the NI legislation in line with England and Wales or for amendments in any way?
10	**Opinion of Nicholas Hanna QC for the Coroner (12 December 2013):** Managers of Trusts have no legal obligation to provide the Coroner with documents, such as in a general duty of discovery. Practitioners do under s.7 of the Act to provide the *"facts and circumstances of which they were aware. Documents can only be compelled through the cumbersome use of subpoena duces tecum".*	**i.** Has the Department issued any guidance or direction to Trusts about circumstance when it should not exercise its right to claim privilege on expert reports in the context of Coroners Inquests?
11	An audit report of clinical coding performed by 3M Health Information Systems in the Belfast Health and Social Trust published in August 2011 showed that 27.4% of episodes audited involved coding errors. In the RBHSC, this figure was 10.9%, which is close to the English national average of 11%.	**i.** In light of this report what steps has Department taken to monitor accuracy of coding?
12	**Inquiry List of Issues Departmental** *(iv). "Are there now more reports to the Coronial service than before?"*	**i.** Please provide information on number of reports to the Coronial service from all Trusts over past 10 years.
13	On 2nd April 2014 the Coroner wrote to the CMO expressing concern about deaths reported to him that may be linked to SAI reports.	**i.** Please provide copy of that letter. **ii.** The response to the Coroner. **iii.** Any subsequent correspondence issued to the Trusts by the CMO?

No	Context	Question
14	A letter dated 25th February 2015 from the Minister for Health providing information on the SAI look-back exercise. According to Hansard (4/3/15) the letter sets out the initiatives the Dept intends to take to *"strengthen and enhance public assurance and the process on the scrutiny of the death certification"*	**i.** Please provide a copy of the letter dated 25th February 2015?
15	**Departmental Position Paper (333-303):** A Death Certification Implementation Working Group has been established to review the current position on death certification and take forward the implementation of Option 1. The first meeting was arranged to have taken place on 4th October 2013.	**i.** Has this Working Group reported? **ii.** If so, is the report available?
16	**Departmental 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.	**i.** What was the outcome of the pilot scheme? **ii.** What system has now been implemented?
17	**CNO:** *"we will be auditing this in February [2014] both in terms of quantitative audit ... and also a qualitative audit"* **Transcript 15th November 2013 p.52 L.1-6 Department Evidence**	**i.** Is this 'audit' the audit carried out by GAIN and published on 8 August 2014?
18	**CMO Annual Report for 2015 (published 18 May 2016) p38:** *"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."* Also: *"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.** Please provide any documents available explaining the full procedure for the implementation of the RM & MRs? **ii.** What training will staff be provided with for these RM & MRs reviews? **iii.** Will the consultant reviewing the death be the consultant involved in the care? **iv.** Will the M&M Review Meetings be minuted?

No	Context	Question
19	**GAIN (8 August 2014) – Audit of Parenteral Fluid Therapy for Children and Young Persons of 170 children categorised at <u>high risk of hyponatraemia</u>:** *"Additional safety in the management of intravenous fluids comes from appropriate and timely monitoring, the clear recording of results and prompt intervention when necessary. The audit found that performance in these areas rated from moderate to very good but that all can be further improved. A view was taken that for many of these performance criteria, the aim must be for <u>**100% compliance**</u>"*	i. Can the Department confirm that these figures show that the Hyponatraemia guidelines were not being followed adequately?
20	**<u>GAIN (8 August 2014) – Audit of Parenteral Fluid Therapy for Children and Young Persons of 170 children categorised at high risk of hyponatraemia:</u>** *"Primary recommendations* *1. Health and Social Care Trusts (HSCTs) must ensure that **patients are identified** on fluid balance charts, using at least their name, date of birth and hospital identification number.* *6. HSCTs must ensure that **cumulative totalling** of fluid input and output, with the calculation of a 24 hour balance figure, is performed daily. ..."* *"Further recommendations* *2. Every child on intravenous fluids should have a DFBC [Daily Fluid Balance Sheet], preferably a single daily chart which moves with them on their patient's journey. All fluids administered must be both prescribed and their administration recorded on the DFBCs.* *3. Fluid calculations for bolus, maintenance, deficit and on-going loss replacement must be made and documented, preferably on the DFBC and with a coded indication for the fluid administration.* *... 7. An Electrolyte and Urea (E&U) must be taken for every 24 hour period while receiving IV fluids, including the last day of an infusion – as per*	i. What (if anything) has been done or is proposed to be done to implement any of these recommendations particularly for a single daily chart for a DFBC?

No	Context	Question
	Paediatric Wallchart. *8. E&U monitoring must be more frequent if there is hyponatraemia and if the child is ill – as per Paediatric*	
21	**On 29 September 2014 CMO wrote to Chief Executives of the HSC Trusts** referring to the *"revision of the wall chart guidance: Parenteral Fluid Therapy for Children and Adults (aged over 4 weeks and under 16 years). These in turn have necessitated a review of the fluid balance and prescription charts"* *"There should be no local modification to the agreed format of the charts without prior agreement with the Department that appropriate steps have been taken to mitigate any risks arising from deviating from what has been regionally agreed. Risks should be managed on the risk register of the organisation and reviewed as appropriate"* *"We would be grateful if you would now take the necessary steps to distribute the revised charts and make resources available for the training to be delivered in order to facilitate their introduction across the HSC".*	**i.** Why is a facility provided for local modification *"from what has been regionally agreed"?* **ii.** What did the development of the regionally agreed position disclose as the likely requirement for such modification? **iii.** How will the Department monitor and/or keep under review any risk from the 'deviation'? **iv.** What steps were taken to ensure that the revised charts were distributed and the training delivered *"to facilitate their introduction across the HSC"?* **v.** What procedures are in place for the Department to know what has been done since 2014 and is currently being done about adherence to the revised wall chart guidance?
22	**CNO:** *"That training and education [fluid management] has now been brought into the undergraduate programmes of both professional groups, and I have asked for assurances through my Central Nursing and Midwifery Advisory Committee to provide assurances that the universities confirm that they have actually done that and that is in place so that when the students come out into practice for their clinical placements, they're familiar with and see that new chart working well in practice.* *And as a bolt-on to that I have asked that NIPEC [Northern Ireland Practice & Education Council for Nursing & Midwifery] in their quality assurance role, take forward their review of the fluid management course for children*	**i.** Please provide a copy of the review referred to

No	Context	Question
	next year [2014]". **Transcript 15th November 2013 p.52 L.13-25 Departments Evidence**	
23	**CNO:** *"...establishment of the nursing as a degree programme, which means that nursing is on a par with all other professions and the nurses on the ground feel and believe that they're competent practitioners, they're able to analyse and interpret information, they use critical enquiry, they're trained in research and they have the skills to challenge a practice when it needs to be challenged and that they have the ability to raise hose concerns.* *Particularly in relation to paediatric nursing and in recognition of this inquiry and the work that it has done and answers that it has sought to gain, nursing as a profession has already learnt lessons from it, and I wanted to point to a small number of things that we have taken forward: recognising the sick child, record keeping, which was identified as an issue in this inquiry. There has been a very big piece of work done on record keeping in Northern Ireland and that work will continue through the auspices of my office [CNO] and NIPEC".* **Transcript 15th November 2013 p.96 L.2-20 Departments Evidence**	**i.** Please provide a copy of *'piece of work'* referred to and evidence of the continuing work being done by the CNO & NIPEC.
24	**Andrew McCormick** Permanent Secretary would expect a *"phone call from the Chief Executive if"* or an 'early alert' if there was a serious SAI. **Transcript 15th November 2013 p.16 L.1-2 & p.18 L.11 Department Evidence**	**i.** How often has that actually happened since November 2013? **ii.** How do they define a 'serious' SAI as distinct from simply an SAI?
25	**Letter from the CMO to HSC Trusts, HSCB, PHA etc dated 6 October 2014 re 'early alerts'**: *"The [Early Alert] system is designed to ensure that the Department receives prompt and timely details of events which fulfil criteria... Some of these events (but not all) may become serious adverse incidents and may be notified separately to the HSCB. This does not negate the need for them to be reports as Early Alerts...* *You are reminded that it is not sufficient to share details via a telephone*	**i.** Are these early alerts assessed for trends, if so who does it and where is that reported?

No	Context	Question
	conversation with a senior official ... you must notify the Department formally using the pro forma as part of the Early Alert system within 24 hours."	
26	*Chairman's letter to BH&SCT (27.03.14)* **(348-001)** *– re 'consistency in identifying adverse incidents' and response:* *i. Dealt with internally and any learning retained - no report to HSCB* *i. Around 80,000 – 90,000 per year overall* **i.** *Department is seeking to establish means to identify learning from adverse incidents and disseminate it across the HSCs (with involvement of the HSCB and PHA)*	**i.** What has happened about this? Are there any reports from the Regional Leaning Project Team on it? **ii.** How will the differences between the Trusts be managed?
27	*Response of BH&SCT* ***(348-002)****: There is no consistent method of coding used across all NI Trusts despite all using the same software system.* *Chairman's letter to Department (27.03.14)* ***(348-009)*** *– re 'inconsistency in adverse incident recording'. Response of the Department (15.04.14)* ***(348-010)*** *acknowledges "variations in categorisation and recording" which are being addressed by a Regional Learning System Project Team.*	**i.** Have the milestones for the work of the Regional Learning System Project Team (set out at 348-010-005) been met? **ii.** Have recommendations for the future development of a Regional Learning System that were due at the end of September 2015 been made? **iii.** If so, where are they? If not, when will they be issued?
28	Evidence received by the House of Commons Public Administration Select Committee: 'Investigating clinical incidents in the NHS' 6th report (24.03.15) includes criticism of Datix by the Royal College of Anaesthetists including that the software design means: *"It is very difficult to search Datix for clinically related incidents, without specific training on how to use the system, making all the information recorded in the database largely inaccessible"* (para.16)	**i.** How (if at all) is this criticism by the Royal College of Anaesthetists being addressed?
29	OECD Review recommendations for Northern Ireland include *'strengthening the central leadership role of the Department in quality and safety governance for the system'* In November 2015 the Minister announced his vision for reform, arising out of *"the work of Donaldson and the Department's Review of Commissioning"*	**i.** Is the OECD's assessment to be factored into this 'reform'?

No	Context	Question
30	Children's Services Co-operation Act (Northern Ireland) 2015 requires the Department, Trusts and HSCB to co-operate in exercise their functions for the well-being of children, including their *"physical and mental health"*.	**i.** How is cooperation under that legislation in respect of SAIs and children being addressed, given the requirement at s.2 on arrangements and s.3 on the adoption of a strategy