THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Issues for Health and Social Care Board – Paper 1

1 (a) Explain your understanding of the respective responsibilities of the Board and Department for ensuring that Trusts provide healthcare of an acceptable standard.

The Health and Social Care (Reform) Act (NI) 2009 (Appendix 1) sets out the respective responsibilities of all Health and Social Care (HSC) organisations

The roles and functions of all HSC organisations are further described in the Department's Framework Document, which states that all HSC bodies are ultimately accountable to the Department for the discharge of the functions set out in their founding legislation. HSC Trusts are directly accountable to the Health and Social Care Board (HSCB) for operational and financial performance, and directly to the Department for all other areas.

The Department retains the normal authority and responsibilities of a parent Department as regards direction and control of an arm's length body.

While HSC Trusts are accountable to the Department, the HSCB expects that they have in place effective governance arrangements which would ensure any issues impacting on the safety and quality of services are identified and notified to the HSCB/PHA. Each HSC Trust also has a statutory obligation to put, and keep in place arrangements for monitoring and improving the quality of health and social care which it provides to individuals and the environment in which it provides them (Health and

Personal Social Services (Quality, Improvement and Regulation) (NI) Order 2003).

The HSCB has a range of functions that can be summarised under three broad headings:-

Commissioning – including monitoring delivery to ensure that health and social care meets established safety and quality standards. The PHA work with the HSCB with the aim of providing professional input to the commissioning of health and social care services that meet established safety and quality standards.

Performance Management and Service Improvement – by monitoring health and social care performance against relevant objectives, targets and standards.

Resources Management – to ensure the best possible use of the resources of the health and social care system, both in terms of quality, accessible services for users and value for money for the taxpayer.

(b) How does the Board discharge any such responsibility? Specifically how does the Board ensure that the healthcare provided in the RBHSC is of the standard required?

The HSCB has an Assurance Framework which sets out the range of elements to provide assurance to the Board of Directors on the achievement of corporate objectives and the commissioning and delivery of high quality health and social care.

The Framework provides a clear, concise structure for reporting key information to the Board, Committees of the Board, Senior Management Team and other groups/forums. It also identifies any of the organisation's objectives which are at risk because of any inadequacies in the operation of controls, or where the Board has insufficient assurance about them. In conjunction with the HSCB's Corporate Risk Register, it provides assurance about how risks are managed effectively to deliver agreed objectives.

The Framework provides assurance on the effectiveness of controls, under the four domains of: Corporate Control, Safety and Quality, Finance and Operational Performance and Service Improvement.

In respect to Safety and Quality, this includes a wide range of areas including:-

- Monitoring of Serious Adverse Incidents (SAIs) and the identification and dissemination of learning resulting from these;
- Monitoring of complaints and the identification and dissemination of learning resulting from these;
- Monitoring the implementation of NICE Guidance;
- Monitoring the implementation of Safety and Quality Alerts, including HSCB/PHA Learning Letters;
- Monitoring of Hospital Standardised Mortality Rates;
- Monitoring of Patient Experience Standards;
- Monitoring rates of healthcare associated infections;
- Monitoring the full range of Ministerial performance targets and standards.

The above monitoring arrangements apply to all provider organisations including Belfast Trust (RBHSC).

2 (a) What arrangements are now in place for the reporting and investigation of a serious adverse incident such as the unexpected death of a child, the learning of lessons (if any) from the incident and dissemination of that learning?

On 1 May 2010 the responsibility for the management and follow up of SAIs transferred from DHSSPS to the HSCB working in partnership with PHA and collaboratively with RQIA. At the same time the Procedure for the Reporting and Follow up of SAIs (Appendix II), was issued to all HSC organisations and Special

Agencies, which set out the process to be followed when a SAI occurred during the course of their normal business or commissioned service.

The criteria and timescales for reporting and investigating SAIs are outlined in sections 4.0 and 5.0 of the attached procedure (Appendix II).

The arrangements for managing SAIs reported to the HSCB/PHA include:

- Regional reporting system to the HSCB for all SAIs
- The nomination of an HSCB/PHA Designated Review Officer (DRO) to review and scrutinise reports in liaison with other relevant professionals
- A Regional SAI Review Group meeting held on a bi-monthly basis to consider reports, identify learning and agree actions to disseminate learning regionally
- The HSCB SMT receives and considers all SAIs on a weekly basis and the HSCB Governance Committee receive a summary SAI report at each of its meetings.

Since 2011, the HSCB in collaboration with the PHA has issued bi-annual SAI Learning Reports across the wider HSC.

(b) How do these arrangements work in practice

The arrangements are described in the Procedure for the Reporting and Follow up of Serious Adverse Incidents 2010. In addition to the above procedure, the HSCB and PHA issued an internal administrative protocol (revised in September 2011) to support Designated Review Officers in carrying out their role throughout the SAI process (Appendix III)

(c) How robust are these arrangements

Immediately an SAI is notified to the HSCB, a lead officer from within the HSCB/PHA will assign a (DRO) to every individual SAI.

(A DRO is a senior professional adviser in the HSCB or PHA). Once assigned, the DRO will consider the SAI notification and if necessary, will contact the reporting organisation to confirm all immediate actions following the incident have been implemented.

On receipt of a completed investigation report, the DRO will consider the adequacy of the investigation report and liaise with relevant colleagues and other organisations, including RQIA, to ensure that the reporting organisation has taken reasonable action to reduce the risk of recurrence and determine if the SAI can be closed. If the DRO is not satisfied that the report reflects a robust and timely investigation s/he will continue to liaise with the reporting organisation and/or other professionals /officers, including RQIA until a satisfactory response is received.

When the DRO is satisfied that the investigation has been robust and recommendations are appropriate, they will complete the necessary documentation stating their reason for closure of the SAI. This will indicate that, based on the investigation report received and any other information provided, the DRO is satisfied to close the SAI. It will acknowledge that any recommendations and further actions required will be monitored through the reporting organisation's internal governance arrangements.

On some occasions, for example, when dealing with particularly complex SAIs, a DRO may close an SAI, but request that the reporting organisation provides an additional assurance mechanism by advising within a stipulated period of time, that action following an SAI has been implemented.

The DRO will also identify any regional learning arising from the SAI. That is then considered by the HSCB/PHA Regional SAI Review Group to ensure that themes and learning from SAIs is identified, disseminated and implemented in a timely manner.

The HSCB/PHA has undertaken a review of the SAI procedure during 2013, and a revised procedure was approved by the HSCB Board at its meeting on 12 September 2013, for implementation from October 2013 (Appendix IV). The revised procedure includes inter alia, a new criterion for a SAI that any death of a child (up to their 18th birthday) in a hospital setting must be reported as an SAI.

(d) In what circumstances will the Department be notified of such an incident

Circular HSC (SQSC) 08/2010, issued in April 2010, provided guidance on the transfer of SAI reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency. In May 2010, the Department issued Circular HSC (SQSD) 10/10 which provided guidance on the introduction of an Early Alert System.

This system provides a channel which enables Chief Executives and other senior staff in HSC organisations to notify the Department, HSCB and PHA in a prompt and timely way, of events or incidents which have occurred in the services provided or commissioned by their organisations, and which may require immediate attention by Minister, Chief Professional Officers or policy leads, and/or require urgent action by the Department.

3 (a) Where the investigation of a serious adverse incident finds that poor quality healthcare played a part in the incident, what options are now available to address that finding?

For HSC Trusts

- A protocol, policy or procedure can be developed or revised to incorporate the learning identified through the serious adverse incident (SAI) investigation.
- Training may be provided for the individual member(s) of staff involved and/or other relevant staff.
- Audit can be conducted to assess the extent to which staff are adhering to protocols, policies or procedures.
- Other relevant authorities can be alerted, including those responsible for health and safety at work, and safety of medical devices and equipment.
- Disciplinary action may be instigated against individual staff, including if necessary, referral to the appropriate professional regulator.

- By exception, a service may need to be reconfigured if it does not meet Departmental endorsed standards for good practice. This can be a complex and lengthy process and is typically high profile politically and publicly. HSCB/PHA and Department would be involved in agreeing reconfiguration.

For HSCB/PHA

- For issues within an individual Trust, the DRO in HSCB/PHA will ask for assurance from the Trust that the issues identified through the investigation of the SAI have been addressed.

- The HSCB/PHA Regional SAI Review Group review the learning and themes arising from SAI investigations and determine if further action is required:

  - For issues that are relevant to more than one HSC Trust, or where there is a pattern of incidents of a similar type, a Learning Letter can be issued by HSCB/PHA to all HSC Trusts and other relevant providers. The Learning Letter describes the circumstances of the incident, the learning identified in the investigation, and the actions that need to be taken. HSC Trusts are asked to confirm that the required actions have been implemented and the process is monitored until the assurance is secured.

  - Alternatively, or in addition, a specific project may be initiated to address the learning. For example, HSCB/PHA may convene a regional group with HSC Trusts to develop standard documentation and/or training, undertake quality improvement work, and/or change information systems, and/or explore the potential to redesign a medical device or piece of equipment, and/or reconfigure or develop services through commissioning.

- By exception, HSCB/PHA may need to work with the HSC Trust and Department to reconfigure services so that they meet Departmental endorsed standards.

For Department

- May issue a letter to the HSC advising them of a particular situation.
- May commission the Regional Quality Improvement Authority (RQIA) to undertake an independent review and will set the Terms of Reference for the review.
- May commission an Independent Inquiry to investigate the incident further, identify learning and make recommendations.

For RQIA

- RQIA may use their regulatory powers to enforce a provider to stop or adjust the service they provide.

4 (a) How do new guidelines, practices and recommendations which are developed in Northern Ireland become embedded in practice?

The Department

- Issues guidance, practices and recommendations that they have endorsed for implementation in NI. Examples include Departmental strategies, standards for services, NICE guidance, and letters from professional officers in the Department.

The RQIA

- RQIA issues its independent reports to the HSC, including recommendations for action.
- RQIA inspect regulatory providers against standards set by the Department.

HSCB/PHA

- HSCB/PHA commission services in line with guidelines, practices and recommendations issued by DHSSPS and/or RQIA. Each Commissioning team takes account of documents issued by DHSSPS and RQIA in determining the investments required in a service to ensure they meet the standards set. On occasion, services need to be reconfigured ie provided in a different way, to enable them to meet standards. Services are developed within available resources, with priority given to key safety risks.

- HSCB Service Level Agreements with Trusts and independent providers, require provider organisations to adhere to guidelines and standards endorsed by DHSSPS for implementation in NI.

- HSCB/PHA also support quality improvement work in HSC organisations through:
  - The Safety Forum annual work programme
  - Monitoring of Trust quality improvement plans, and
  - A range of other specific projects.

HSC Trusts

- Specific actions that HSC Trusts might take to embed guidelines, practices and recommendations, include:

  - Identification of a local lead for implementation

- Development or revisions to policies and procedures, and dissemination of those to staff
- Training for relevant staff
- Team/service level reviews, audits or quality improvement activities to assess and improve performance against recommended practice
- Peer review, for example, peer review of cancer services
- Seeking evidence of adherence to guidelines, practices and recommendations in annual appraisal of medical staff
- Inclusion of training and development needs in the Personal Development Plans of staff.

(b) How is adherence to them enforced/confirmed?

Assurance that HSC Trusts adhere to guidelines, practices and recommendations issued by the Department and/or RQIA is based firstly on HSC Trust level monitoring, then HSCB/PHA monitoring as the commissioner of services, then Departmental monitoring, with RQIA available to provide independent assurance.

HSC Trust level

- Assurance that guidelines, practices and recommendations are embedded in Trusts is based on each Trust's governance framework and the structures and processes that underpin each framework. Trusts report relevant activity and progress to their Boards.

- Trusts are also required to provide positive assurance to the HSCB on implementation of guidance and specific other safety and quality related guidance, practices and recommendations, and to DHSSPS at 6-monthly accountability meetings and through the Chief Executive's

Annual Governance Statement and Mid Year Assurance Statement.

HSCB/PHA level

- Assurance that services commissioned by the HSCB/PHA adhere to guidelines, practices and recommendations, are based on the HSCB Governance Framework and the structures and processes that underpin that Framework.

- As part of the overall HSCB Governance Framework, there are specific processes within HSCB/PHA to log each piece of guidance, practices and recommendations issued by the Department or RQIA; and oversee implementation through existing group structures or through bespoke groups. For example, HSCB/PHA may convene a regional group with HSC Trusts to develop standard documentation and/or training, undertake quality improvement work, change information systems, and/or reconfigure or develop services through commissioning, with available resources.

- In addition, HSCB/PHA seeks positive assurance from HSC Trusts that guidance, practices and recommendations issued by the Department or RQIA, have been implemented. HSCB/PHA considers each individually, and where necessary, will seek explicit assurance from HSC Trusts on implementation. HSCB/PHA follow up with each HSC Trust until content that each HSC Trust has completed the required actions.

- If a service does not and/or cannot meet Departmental required standards, HSCB will advise the Department and/or need for service change.

- In line with the HSCB Governance Framework, HSCB/PHA report to the HSCB Board on adherence to guidance,

practice and recommendations, and on other work to assure or improve the safety and quality of services.

- HSCB/PHA also provide positive assurance to the Department at 6-monthly accountability meetings and through the Chief Executive's Annual Governance Statement and Mid Year Assurance Statement.

Department level

- The Department can commission ;

  - GAIN (Guidelines Audit and Implementation Network) to undertake audits to assess adherence to guidelines, practices and recommendations, or to produce guidelines for use by the HSC

  - RQIA to do more extensive reviews of the degree to which guidelines, practices and recommendations have been implemented, and/or the overall governance arrangements in HSC Trusts.

RQIA level

- RQIA undertake independent reviews of the governance framework in HSC organisations. In addition, they undertake independent reviews of the degree to which practice adheres to guidelines, practices and recommendations. The RQIA annual work programme is approved by the Department and in addition, the Department may ask RQIA to undertake specific pieces of work that arise unexpectedly in-year.

- As the HSC regulator, RQIA conduct on-site inspections and other reviews of regulated providers against standards set by the Department. RQIA therefore provide an additional level of independent assurance.

5(a) How are guidelines, practices and guidelines developed elsewhere considered and if appropriate adapted for use in Northern Ireland?

Department level

- The Department assesses Guidelines developed by NICE and determines whether or not they should be adopted for use in NI. The Department informs HSC organisations of its determination. Details of the process are provided below.
- The Department also produces standards and strategies to be applied in NI. These are based on available evidence and good practice elsewhere. The Department issues these strategies to HSC organisations.
- The Department also allocates resources to the HSC. HSC organisations then commission or provide services in line with Departmental-endorsed guidelines, strategies and standards, but within available resources and subject to Ministerial approval.

NICE Guidance

- The HSCB/PHA is required to work under the direction of Departmental Circular HSC (SQSD) 04/11: NICE Technology Appraisals and Clinical Guidelines – New Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland which provides the framework for the implementation all NICE Guidance. It should be noted that the circular is currently being reviewed and that a revised version is expected to be issued in the coming months.

- NICE is tasked with providing guidance on current best practice in health and social care, including public health, health technologies and clinical practice, to the NHS in England. The Department has a formal link with the Institute

under which NICE Technology Appraisals and Clinical Guidelines, published from 1 July 2006, are reviewed locally for their applicability to NI and, where found to be applicable, are endorsed by the Department for implementation within HSC.

- *NICE Technology Appraisals (TAs)*

TAs endorsed for application in NI are forwarded to the HSCB/PHA. The relevant service leads within the HSCB/PHA review each TA to produce a draft service notification which details the commissioning arrangements for that TA. The service notification is developed by the HSCB/PHA within 15 weeks and forwarded to the Department for approval. Following approval of the service notification by the Department, the service notification is issued externally to HSC Trusts and other relevant stakeholders, typically within 10 days. On receipt of a Service Notification, the expectation is that proportionate implementation arrangements are established in all relevant HSC organisations. HSC Trusts should ensure that within three months: targeted dissemination takes place; a clinical/management change leader has been agreed; and an implementation plan is in place. HSC Trusts are expected to have fully implemented a Technology Appraisal within nine months of the Service Notification being issued in most cases, with longer timescales being specified in the Service Notification if appropriate.

- *NICE Clinical Guidelines (CGs)*

The process for CGs is currently under review but there is a clear expectation that within 3 months of issue HSC Trusts should ensure that within three months: targeted dissemination takes place; a clinical/management change leader has been agreed; and an implementation plan is in place. The process to date has been that the timescale for implementation of a CG would be specified within the service notification (typically 3-5 years). CGs can cover broad aspects of clinical practice and

service delivery and by their nature, can be complex. They can require investment and as such need to be considered as part of the ongoing commissioning process alongside other commissioning priorities and often require incremental implementation over time.

Where guidelines have resource implications they are often formally commissioned through the commissioning plan. Also each service team has an agreed commissioner specification which is evidence based. This specification forms the basis for commissioning decisions and sets standards against which investment proposals are judged and approved.

- *Assurance*

The HSCB routinely monitors the progress of the implementation of NICE guidelines through bi-monthly HSCB/HSC Trust Director level meetings. Positive assurance is provided by HSC Trusts after the 3 month planning period confirming:

- targeted dissemination takes place;
- a clinical/management change leader has been agreed;
- and an implementation plan is in place.

HSC Trusts are required to provide further assurance once the expected implementation date has passed. Any material issues which could delay implementation are raised, addressed and monitored through the bi-monthly meetings.

The HSCB is required to report annually on the commissioning and implementation of NICE Guidance to the Department.