Belfast Health and Social Care Trust

Submission to the Inquiry into hyponatraemia-related Deaths

Quality and Safety Initiatives in the Belfast Health and Social Care Trust

April 2007 to August 2013

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Quality and Safety Journey

Introduction

Strategic Context

The HPSS (Quality, Improvement and Regulation) Order (NI) 2003[1] established the legislative framework for a Statutory Duty of Quality on a par with the statutory duty in relation to financial stewardship. The DHSSPS defined Clinical and Social Care Governance as a 'framework through which HPSS bodies are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical and social care will flourish'. [2]

In the period from 2003/04 there have been a number of key policies, strategies, guidance and legislation that have been produced by the DHSSPS on clinical and social care governance, risk identification, assessment and management, appraisal and revalidation, the management of underperformance, adverse incident investigation and reporting, complaints management and patient and public involvement. This guidance has influenced the development of much of the governance and assurance arrangements in the former Royal Hospitals Trust and subsequently by the Belfast Health and Social care Trust from its inception in April 2007. The guidance will be referenced and a description of its implementation within the Belfast Health and Social Care Trust will be detailed below.

Much of the existing policy, strategy and guidance relating to quality and safety are available on the DHSSPS website at www.dhsspsni.gov.uk. This paper submitted by the Belfast Health and Social Care Trust to the Inquiry into Hyponatraemia Related Deaths highlights a small number of the policy documents and guidance which are pertinent to describing the Trust's journey in improving safety and quality.

These include:-

- *Confidence in Care Programme;* - ongoing since 2008;
- *Quality 2020 – A 10-Year Strategy to Protect and Improve Quality in Health and Social Care in Northern Ireland* - published by DHSSPS in November 2011;

[1] Health and Personal Social Services (Quality, Improvement and Regulation) Order (Northern Ireland) at www.dhsspsni.gov.uk/hpss_qi_regulations

[2] Governance in the HPSS – DHSSPS www.dhsspsni.gov.uk/governance.ppt

- *Escalation of Risks within and Between Health and Social care organisations;* guidance cascaded by DHSSPS in November 2011;

- *Assurance and Accountability Framework for Arms' Length Bodies* - DHSSPS 2012[3]

The following sections outline the Trust's response to these and other extant guidance and strategic documents relating to Safety and Quality and will address the issues raised by the Inquiry into Hyponatraemia Related Deaths in the letter dated 5th August 2013.

Belfast HSC Trust Governance and Accountability Arrangements (Issue 1a &b)

Introduction

The Belfast HSC Trust has developed a system of internal control built on the principles of governance and accountability. The following sections outline these systems and provide a description of how they work in practice. The Board of Directors of the Belfast HSC Trust (The Board) has a responsibility to provide high quality care, which is safe for patients, clients, young people, visitors and staff, and which is underpinned by the public service values of accountability, probity and openness.

The Board is responsible for ensuring it has effective systems in place for governance, essential for the achievements of its organisational objectives. The Assurance Framework provides the structure by which the Board's responsibilities are fulfilled. The Assurance Framework is an integral part of the governance arrangements for the Belfast HSC Trust.

The Directors of the Belfast HSC Trust have:

- Defined Corporate objectives[4];
- Identified principal risks that may threaten the achievement of those objectives;
- Controls in place to manage these risks, underpinned by core Controls Assurance Standards;
- Explicit arrangements for obtaining assurance on the effectiveness of existing controls across all areas.

On an ongoing basis the Board:

[3] Supersedes the 'Assurance and Accountability Framework for Arms' Length Bodies – a practical guide. DHSSPSNI March 2009

[4] Belfast Health and Social Care Trust – Corporate, Management & Trust Delivery Plans

- Assess the assurances given;
- Identify where there are gaps in controls and/or assurances;
- Take corrective action where gaps have been identified, and;
- Maintain dynamic risk management arrangements including, crucially, a regularly reviewed Principal Risk Document.

Assurance Framework

From its inception, 1 April 2007 the Belfast Health and Social Care Trust (the Trust) developed an Assurance Framework in line with DHSSPS (NI) guidance[5]. The Assurance Framework describes the relationship between organisational objectives, identified potential risks to their achievement and the key controls through which these risks will be managed, as well as the sources of assurance surrounding the effectiveness of these controls.

The Assurance Framework (and Principal Risk Document) describes the organisational objectives, identifies potential risks to their achievement, the key controls through which these risks will be managed and the sources of assurance about the effectiveness of these controls. It lays out the sources of evidence which the Board will use to be assured of the soundness and effectiveness of the systems and processes in place to meet objectives and deliver appropriate outcomes.

The Assurance Framework incorporates the Risk Management Policy and establishes the context in which the Trust Management Plan is developed, as well as determining the mechanism through which assurances are provided to the Trust Board. This framework should provide the Board with confidence that the systems, policies, and people are operating effectively, are subject to appropriate scrutiny and that the Board is able to demonstrate that they have been informed about key risks affecting the organisation.

The Assurance Framework has been revised on a number of occasions to take account of changing organisational and committee structures. The current version which was approved by Trust Board in June 2013 has taken account of the recommendations of the Francis Report[6] and the need to strengthen the arrangements for learning from significant events (see Appendix 1).

[5] DHSSPS (2009) *op.cit*

[6] The Final Report of the Independent Inquiry into Care provided by the Mid Staffordshire NHS Trust: January 2005 – March 2009 chaired by Sir Robert Francis www.midstaffsinquiry.com.

Governance arrangements in the Children's Hospital

The Children's Hospital (Royal Belfast Hospital for Sick Children) is managed within the Directorate of Specialist Hospitals and Women's Health, one of four service directorates in the Belfast HSC Trust. The Directorate has established governance arrangements in line with the Trust's Assurance Framework (see Appendix 2a and 2b). The Directorate has an Assurance Committee which is chaired by the Director with a subcommittee for each functional area including one for the Children's Hospital. The Assurance Committee has agreed terms of reference and standing agenda items which cover a range of governance issues (see Appendix 2c and d). The Children's Hospital Governance group reviews serious adverse incidents, complaints, risk registers, new policies, audit, quality improvement measures, specialty issues and morbidity and mortality (see Appendix 3a and b).

Annual Governance Statement (formerly Statement on Internal Control)

The Belfast HSC Trust formally submits an annual Governance Statement to the DHSSPS[7]. The Governance Statement came into effect for the year ended 31 March 2013 and was previously referred to as the Statement on Internal Control[8]. The Governance Statement is the means by which the Accounting Officer provides a comprehensive explanation on the Trust's approach to governance, risk management, internal control and how they operate in practice. The Statement also provides an account of the Trust's Board and Committees, including reference to the board's performance and effectiveness. In addition, it represents a medium for the Accounting Officer to highlight significant control issues which have been identified during the reporting period and those previously reported control issues which are continuing within the Trust. The Governance Statement forms an integral component of the Annual Report and Accounts.

Risk Management Strategy

The Belfast HSC Trust has had in place since June 2007 a Risk Management Strategy. The Strategy has been reviewed every three years since that date and the latest version was approved by the Assurance Committee of Trust Board in June 2013 (see Appendix 4). The latest version has adopted the most recent regional guidance.[9] The Strategy sets out the approach to risk management, including the

[7] DHSSPS Circular HSC(F) 15-2013 HSC Manual of Accounts 2012-13 Section E Governance Statement

[8] DHSSPS Circular HSC(F) 12-2012 HSC Manual of Accounts 2011-12 Section E Statement on Internal Control

[9] How to classify incidents and risk. DHSSPS April 2006

escalation of risk[10] , in the Trust and builds on work which was underway in relation to risk management within the previous organisations which came to form the Belfast Trust following the Review of Public Administration (RPA), including the Royal Group of Hospitals.

The Risk Management Strategy is closely linked to the Trust's strategic themes. It informs the management planning process and assists the Trust in achieving corporate and Directorate objectives. In endorsing this strategy the Board of Directors recognises the importance of risk management in ensuring that the Trust does its reasonable best to protect patients and service users, staff, the public, other stakeholders and the organisation's assets and reputation, from the risks arising from its undertakings.

The management of risk is the responsibility of staff at all levels within the Trust. Patients, service users and the public also have an important part to play in improving the risk management processes of the Trust by supporting staff in adhering to local, regional and national policy guidance and by proactively participating in their care. The Strategy is explicit in defining a number of key objectives in relation to risk which include:

- raise staff awareness of the principles and practice of risk management;
- establish an "open and fair culture" encouraging lessons to be learned and good practice to be maintained;
- achieve improved patient outcomes and experience through the implementation of effective governance arrangements;
- protect the health and safety of patients, clients, staff, visitors and others who may be affected by the Belfast HSC Trust activities;
- establish priorities for the control of risks, based on a suitable assessment process;
- minimise financial liability through effective Controls Assurance;

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[10] Belfast HSC Trust Risk Management Strategy 2013-16: Escalation of risk s. 7.1.3

- minimise potential loss or damage to the assets and reputation of the Belfast HSC Trust;

- involve the public and users of our services in the application of risk management and assurance to the Trust's undertakings.

Principal Risk Document

The purpose of a Principal Risk Document is to provide the Trust with a simple but comprehensive method for the effective and focused management of the principal risks that arise in meeting its objectives. A Principal Risk Document differs from a risk register in that it is a high level assessment of risks that may adversely impact on the delivery of key objectives. The Principal Risk Document focuses on evidence of action to control or mitigate risk. The Belfast HSC Trust has developed and maintained a Principal Risk Register since February 2008. The Principal Risk Document is reviewed by the Assurance Committee of Trust Board on a quarterly basis. It is also forwarded to the Performance Management Unit at DHSSPS on a quarterly basis.

Risk Registers

In addition to the Principal Risk Register the Belfast HSC Trust has a Corporate Risk Register which is populated from Directorate Risk Registers. The identification of risk within the Trust is addressed in a proactive, as well as, a reactive way. The proactive approach to the identification of risk relies upon robust risk assessment and comprehensive dynamic risk registers at all levels of the organisation. This enables the Board of Directors to prioritise risk and allocate funding accordingly.

Directorates are required to: develop and maintain a register of all identified risks specific to their own activities and circumstances. Directorates are expected to review their risk registers at least four times a year. Risk registers are submitted to the corporate governance team and reviewed by Risk Register Review Group which is a sub group of the Assurance Group of the Senior Executive Team.

Controls Assurance Standards

The DHSSPS introduced Controls Assurance Standards into NI during 2003/04 as part of their continuing development of risk management and controls assurance in the HPSS[11]. Initially the focus was on 21 areas for which the NHS in England had already developed standards.[12] These included clinically orientated standards such

[11] DHSSPSNI HSS (PPM) 5/2003

[12] *Loc. cit*

as medicines management, infection prevention and control and records management and corporate standards such as building, land and plant and finance, risk management, governance finance, records management, medical devices and equipment, emergency planning and medicines management. The DHSSPS identified a policy lead within the Department to be responsible for drawing up the first draft of a standard, in conjunction with key stakeholders. The wider Department and the HPSS then had the opportunity to comment on the draft standards before they were formally launched. The standards have been reviewed and revised in subsequent years as legislation and/or best practice guidance emerged. HSC Trusts are currently requested to complete self-assessments against 22 standards across a range of clinical and non clinical areas[13]. The three core standards are governance, risk management and finance.

Compliance with the controls assurance standards is measured largely by a system of self assessment however annually a number of standards (including the core standards of finance, governance and risk management) require independent verification by Internal Audit. Compliance scores are submitted annually to the DHSSPS and HSC Trusts are required to implement action plans to deal with any gaps in control or assurance. The Belfast HSC Trust has incorporated controls assurance standards into the system for the management of risk registers. Risks and action plans are incorporated into directorate and corporate risk registers and where applicable into the Principal Risk Register. Compliance with controls assurance standards is an integral part of the Annual Governance Statement.

At 31 March 2013 the Belfast HSC Trust met the required compliance level for all 22 standards (see Appendix 5). This reflects a year on year improvement in process and practices.

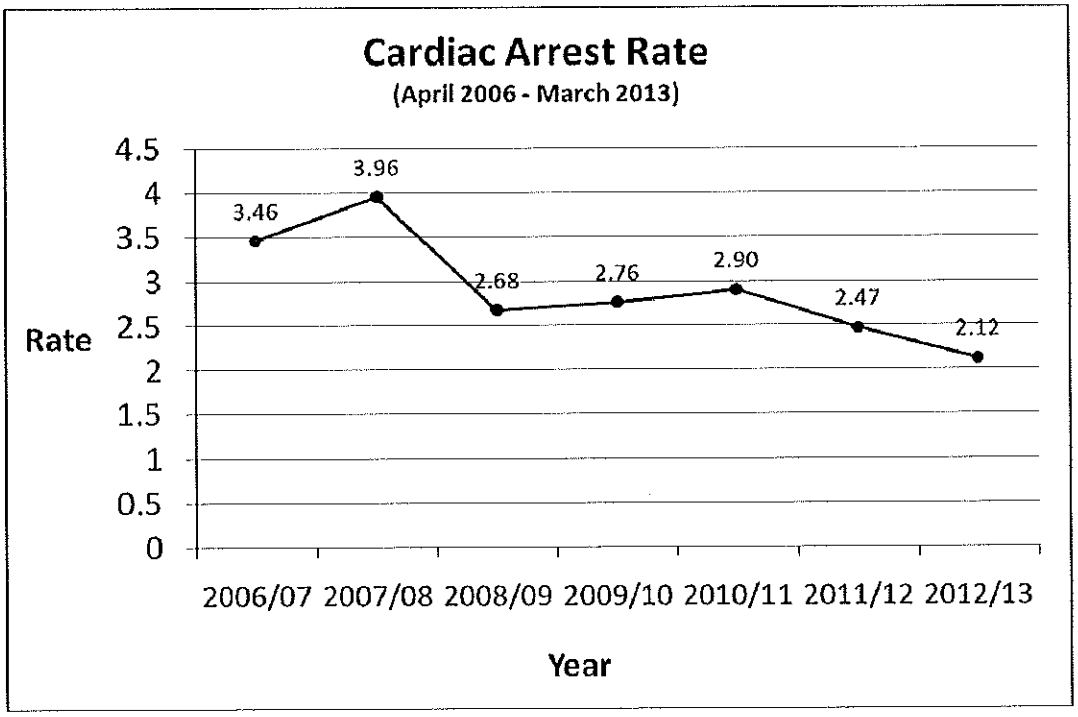
Quality 2020 – A 10 Year Strategy to Protect and Improve Quality in Health and Social Care in Northern Ireland

The Quality Strategy was published by the DHSSPS in November 2011 following a period of consultation. The document acknowledges the work of the HSC Trusts in quality and safety work which has been underway since 2004 when the former Down and Lisburn Trust were involved in the first phase of the national Safer Patient Initiative (SPI)[14] which was facilitated in the UK by the Health Foundation[15] in

[13] Current and archived standards can be viewed at www.dhsspsni.gov.uk/index/hss/governance/governance-controls. I

[14] SPI UK – the Safer Patient Initiative UK ran for four years from 2004 – 2008. It was set up to test practical ways of improving hospital safety and to demonstrate what can be achieved through an organisation-wide approach to patient safety. It was the first major improvement programme to start to address the issue of patient safety in the UK. It was complex and large-scale in its approach to improvement, recognising that

conjunction with the Institute for Healthcare Improvement (IHI)[16], Boston, USA. In 2006 the former Royal Hospitals' Trust and the Mater Hospital Trust as a 'couplet' were accepted onto and successfully completed the second SPI programme which ran for 20 months. As part of the programme the Trusts were required to develop Quality Improvement Plans to deliver a number of patient safety goals or targets. This work has been the foundation for the current Belfast HSC Quality and Safety Improvement Plan described below. The benefit of ongoing work in these areas is demonstrated, for example, by a progressive reduction in cardiac arrests for the period from 2006/07 Royal Group and Mater Hospital only until 2007/08 when the data was captured for the entire Trust:



change needed to take place across whole organisations and systems rather than focusing on individual incidents.

[15] Health Foundation is an independent charity working to continuously improve the quality of healthcare in the UK. It was formed was founded in 1983 as the PPP Medical Trust with a donation of £350,000 a year from Private Patients Plan Limited (PPP). In 1998, the organisation, then named the PPP Healthcare Medical Trust, became fully independent with an endowment of approximately £540 million resulting from the sale of the PPP Healthcare group. It became the Health Foundation in 2003 and today the Foundation awards in the region of £17 million each year through programmes to projects across the UK further information at www.health.org.uk.

[16] IHI is an independent not-for-profit organisation based in Cambridge, Massachusetts, it is a leading innovator in health and health care improvement worldwide. Healthcare practitioners can register for free and many publications and guidance documentation are also free of charge. Their extensive website can be viewed at www.ihi.org.

Trust Quality and Safety Improvement Plan

The Trust has an annual Quality and Safety Improvement Plan which is approved by the Assurance Committee of Trust Board and is monitored and reviewed externally by the HSCB/PHA. A patient safety improvement plan was being developed from 2008/09 and was first approved in 2010. The Quality and Safety Plan for 2013/14 was approved by the Assurance Committee of Trust Board in June 2013 (see Appendix 6). The plan provides the focus during the current year for driving further and sustained improvement in quality and safety for all the users of our services. It builds on the previous and ongoing work using recognised international improvement methods. The objectives are to reduce, as far as practically possible, avoidable or unintentional harm to patients/clients and, to learn from patients', clients' experience and to continually improve the healthcare we provide to patients and clients.

A high level dashboard report will be included in the monthly Trust Board performance reports. Within the Assurance Framework a Safety and Quality Steering Group will maintain oversight of progress against each outcome measure and supporting action plan.[17] It will report to the Senior Executive Team and Assurance Committee of the Trust.

Delivery of the Quality and Safety Improvement Plan will continue to rely on quality improvement methodology in particular the use of small cycles of change and the technique of test and spread, based on best practice evidence.[18] This plan recognises the key role of directorates in driving change and the need for clinical champions at local level.

In particular, the Belfast HSC Trust recognises the importance of patient experience in driving change and assuring quality is recognised. The Trust is engaged in regular activity to measure patient experience and recognises the effective involvement of patients and carers is central to the delivery of quality care and can lead to improvements in the experience of using services (see Appendix 7).

Belfast HSC Quality Forum

The Trust has recently developed a quality forum under the leadership of the Assistant Medical Director. The aim of the Forum is to:

- build capacity and capability in quality improvement
- raise awareness of safety agenda and the Quality and Safety Improvement Plan
- involve people who use our services.

[17] Assurance Framework (2013/14) *op cit* Appendix 1

[18] IHI improvement methodology at www.ihi.org

The Forum will offer mentoring and support, facilitate access to relevant training and development and be available to all staff. Meetings will be delivered in a cafe culture style to stimulate debate.

Belfast Risk and Audit Tool (BRAAT)

In February 2011 the Trust introduced a new tool across all clinical and non-clinical Directorates. The tool is being rolled out across the all directorates in a systematic way. The tool consists of 31 standards designed to establish compliance with legislative standards, Trust policies and best practice standards (see Appendix 6). The tool assists managers at ward and departmental level to prioritise risk and provide a safer working environment. The tool is divided into 5 sections:-

- Risk Management
- Management of Health & Safety
- Management of Medical Gases/Devices
- Organisational Issues e.g. complaint procedure and incident reporting
- Health & Social Care of Patients & Clients.

This tool resulted from a comprehensive review of previous documents used in legacy hospital sites, including the Royal Hospital site and in consultation with key individuals from acute, community, clinical and non-clinical environments throughout the Trust. This process ensured that a robust audit tool was produced which provides the Trust with assurance that there is continuity of approach across all Service Areas.

The audit is primarily a self-assessment tool completed by Service Area Managers to highlight gaps in their current level of compliance. The resultant action plan is linked with the Trust's Risk Register process and is used to assist Service Areas address any outstanding issues within a specific timescale.

Advice and guidance on completion of the self-assessment tool continues to be provided by Corporate Governance team in partnership with the Directorate Governance Managers. Upon completion the scoring sheets are submitted to the Corporate Governance Department. A quarterly progress report is forwarded to each Directorate to provide Senior Management with a summary of their current level of compliance and overall response rate. This process is now monitored through the Trust's Performance Management/Accountability arrangements.

Post Francis Governance Action Plan

The Trust has undertaken a gap analysis against the findings of both Francis Reports into the Mid Staffordshire Trust.[19] [20] The findings of the Report have been

[19] The report into the Mid Staffordshire NHS Foundation Trust. Sir Robert Francis published 24th February 2010.

considered by the Assurance Committee of Trust Board and have also been shared regionally at a Workshop led by the Chief Medical Officer in July 2013. The Trust is developing an action plan to address gaps across a number of themes including incident reporting, complaints management, leadership and innovation and medical/nursing training and education.

Complaints Management (Issue 2a-c)

In April 2009, the DHSSPS (NI) issued a new complaints management procedure[21]. This procedure offers a streamlined process that applies to all HSC organisations. It is a simple, consistent approach for staff who manage complaints and for those people raising complaints who use or who are waiting to use services. The guidance reflects the changing structure of Health and Social Care. It is intended that there is an increased emphasis on learning in order to ensure patient safety and quality while promoting a culture of openness and transparency across the organisation. Based on this guidance the Trust developed and implemented a complaints management policy which superseded the legacy hospital/trust policies which were extant on the 1 April 2007(see Appendix 8). This policy has been extant since April 2010. The purpose of the policy is to provide staff with a greater understanding and guidance on complaints management in order to ensure all complaints are managed in a positive and open manner, services improved, lessons learnt and shared as appropriate.

As part of the implementation of the new procedure the Trust engaged in various levels of Complaints training for staff. This training consists of a number of training packages developed by the Regional Complaints Forum. The Trust further developed specific training packages for senior clinical and managerial staff, relevant to their Service Directorates in relation to Investigation and Response Writing. This training is based on the Ishikawa model[22] and is delivered by a Non- Executive Director and Senior Manager for Complaints. The Trust would expect that the investigations carried out and the subsequent responses to complaints would be thorough, in both the investigation and response writing and would also be sensitive to the needs of the individual. More recently the Trust has worked proactively with the Health and Social Care Board (HSCB) to appoint a number of lay reviewers who can be called upon to assist the organisation with the investigation of cases that

[20] Francis (2009) *op. cit*

[21] DHSSPS (NI) "Complaints in Health and Social Care (HSC)" -.(Standards and Guidelines for Resolution and Learning). April 2009.

[22] Kaoru Ishikawa a quality pioneer introduced cause and effect models such as the 'fishbone' and 5 Whys to facilitate teams reach the root cause(s) of a problem.

require independent input. To date Belfast HSC Trust has used lay reviewers to chair two complaints investigations to the satisfaction of the complainant.

The Belfast HSC Trust has assimilated all the staff from the legacy Trusts into one team and co located them and invested in IT systems to support their work. These systems interlink with adverse incidents, claims and risk registers.[23]

A considerable amount of work has been completed in relation to the interface of complaints and serious adverse incidents (SAIs). When a complaint is received it is graded in line with regional guidance[24] and the Trust's Risk Management Strategy. The Trust developed this grading system in line with Controls Assurance Standards but ahead of any regional direction. If a complaint is graded as moderate to high, the complaints staff will consider if the complaint meets the SAI reporting criteria described below. In conjunction with the Corporate Risk and the Service Directorate, a decision will be taken on the level of investigation that needs to be carried out. If the issues raised in the complaint meet the SAI reporting criteria the complaint investigation is suspended and the SAI investigation is commenced. The complainant is made aware of this change.

The Complaints team are aligned to and work closely with the Service Directorates. This encourages good working relationships and communication throughout the Trust. The complaints team are in a strong position to monitor trends and highlight areas of concerns to senior management. They are also in a position to identify concerns around performance in relation to a clinicians practice and report accordingly.

The Trust has a quarterly Complaints Review Committee with an agreed Terms of Reference (see Appendix 9). These meeting are chaired by a Non- Executive Director with representation from the Service Directorates. Quarterly complaints and performance reports are presented and discussed. Analysis and trends in relation to complaints are identified, discussed and reviewed. Recommendations arising from complaints are tracked and monitored. Learning arising from the complaint is discussed and shared. On a monthly basis all complaints are reviewed and monitored by two Non Executive Directors. These monthly reports are also monitored by the HSC Board. Both the HSC Board and the Trusts Non Executive Directors will challenge the content of these reports or raise any concerns when

[23] The Trust purchased Datix in 2007/08 to replace and harmonise legacy Trust information systems. Datix is a supplier of patient safety incidents healthcare software and risk management software systems for incident reporting and adverse events. Datix is currently used by all the HSC Trusts and the HSCB.

[24] DHSSPS (2006) *op.cit*

identified. An annual report on complaints management is submitted to the Assurance Committee of Trust Board (see Appendix 10).

Management of Adverse Incidents including Serious Adverse Incidents incorporating the sharing of learning at local, national and regional level. (Issues 3, 4, 10, 11 and 12).

The Belfast HSC Trust has developed systems to facilitate staff to raise concerns and report adverse incidents both internally in line with the Assurance Framework and externally with other HSC bodies. These systems described below will address issues 3, 4, 10, 11 and 12. The Trust believes that Dr Carson was referring in evidence to a fear of reporting incidents generally and not to reporting concerns to the GMC (Issue 8e). Therefore the Trust has described potential barriers to reporting in this section of the document.

The Belfast HSC Trust has an Adverse Incident Policy which was first approved in February 2008. The first policy was an amalgamation of best practice from the former legacy arrangements including the Royal Group of Hospitals. The policy has been revised since that date and the extant policy was approved in April 2010 (see Appendix 11). The policy is due for renewal however the Trust is awaiting new guidance from the Health and Social Care Board due to be published in October 2013 in relation to the management of serious adverse incidents.

The Trust recognises that adverse incidents will occur and that it is important to identify causes to ensure lessons are learned to prevent reoccurrence. It is therefore essential that a responsive and effective adverse incident reporting and analysis system is in place to achieve this aim. This policy and its linked procedures[25] will ensure that staff have access to a comprehensive, clear and user-friendly adverse incident reporting system that will encourage the reporting of adverse incidents so that real opportunities for improvement and risk reduction are taken.

All staff must report and manage adverse incidents according to this policy and related procedures for adverse incident reporting (see page 9). Staff who make a prompt and honest report in relation to an adverse incident or near miss will not be disciplined except under the following circumstances:

- A breach of law
- Wilful or gross carelessness or professional misconduct
- Repeated breaches of Trust policy and procedure

[25] Adverse Incident related procedures; Reporting and Managing an Adverse Incident, Grading an Incident, Investigation an Adverse Incident, Reporting a Serious Adverse Incident and Guidance on Writing a Statement.

- Where, in the view of the Trust, and/or any professional registration body, the action causing the adverse incident is far removed from acceptable practice
- Where there is failure to report a major or catastrophic adverse incident in which a member of staff was involved or about which they were aware.

The Trust recognises that the completion of an Adverse Incident Reporting form or web form does not discharge staff of the duty of care and their risk management responsibility. Service Group Managers should ensure timely and appropriate follow-up of adverse incidents and to identify contributing factors to these events. Investigation officers should ensure preventative measures or procedural changes are identified to minimise risk.

The Trust has defined an adverse incident as '*Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation.*[26]
As is common across the Trust, Directorates have established local procedures to manage adverse incidents in line with Regional and Trust policies. The Children's Hospital has established a Child Health Incident Panel (CHIP) which reviews all incidents (See Appendix 12). The Directorate has also established an incident reporting flow chart available at local level to assist staff in reporting incidents (see Appendix 13).

Adverse Incident Rates

The Trust recognises that adverse incidents can and do occur. Research has shown that around 10% of hospital in-patient admissions may result in some kind of adverse event.[27] A study in the United Kingdom, suggested that, up to 425,000 patients a year, over 1,000 patients a day, suffer an adverse event that is avoidable. Similar studies in other countries indicate that there is a similar rate of error or mishap occurring elsewhere. [28] [29]

The Trust believes that it has improved incident reporting by developing an open and honest culture and through specific induction and training programmes. The following graph shows the total adverse incidents reported per annum from April

[26] Loc Cit HPSS April 2006

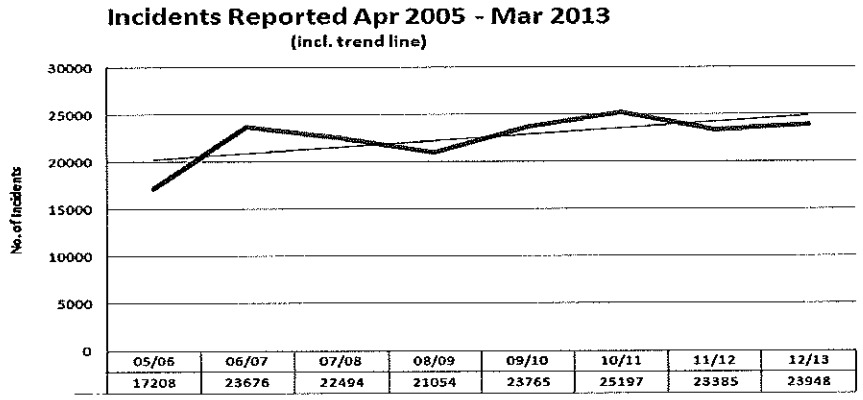
[27] Vincent, Neale, Woloshynowych, *Adverse Events in British Hospitals: Preliminary Retrospective Record Review*, BMJ 2001, 322, 517-19

[28] Brennan et al, *Incidence of Adverse events and Negligence in Hospitalised Patients,. Results of the Harvard Medical Practice Study I,* New England Journal of Medicine, 11991, 324: 370-6

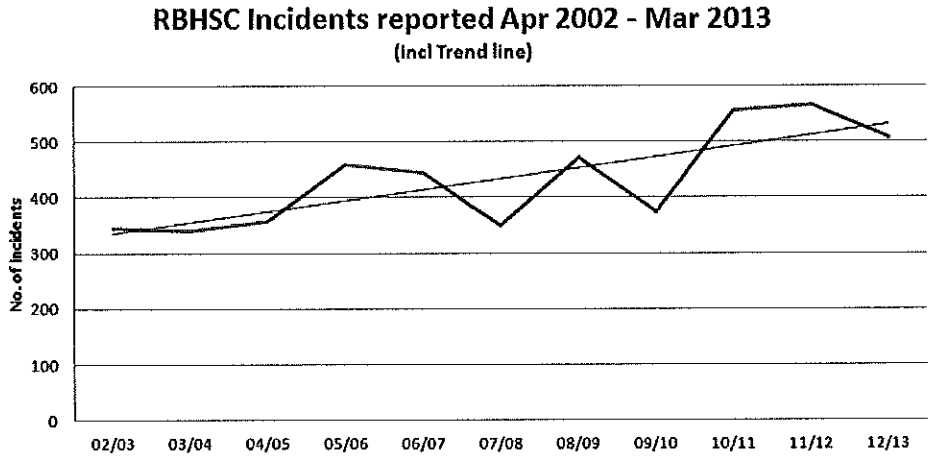
[29] Wilson, et al, *The Quality in Australia Healthcare Study*, Med J August, 1995; 163; 458-71

2005 to end March 2013. The data was prepared using incidents recorded on legacy Trust incident reporting systems. The Belfast HSC Trust purchased Datix, an incident information management system which became operational from January 2009 allowing trend data to be provided by Directorate. The graph represents absolute numbers and includes staff, property, services and clinical and social care adverse incidents.

Belfast HSC Trust Adverse Incidents



The Children's Hospital has also shown a positive increase in reporting trends. As the previous Royal Group had established an information management system during 2000/01, which remained operational until Datix replaced the legacy system in 2009, we are able to demonstrate trends since April 2002 in the graph below.

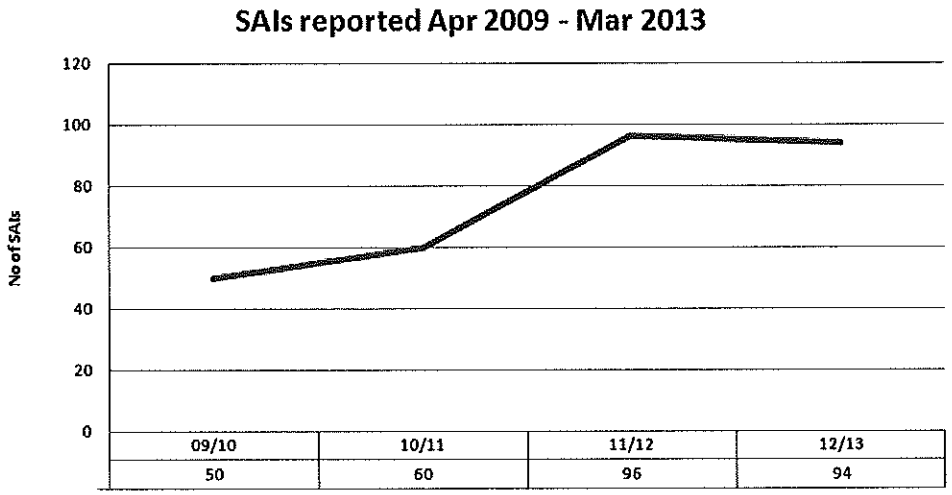


Reporting Serious Adverse Incidents (SAIs)

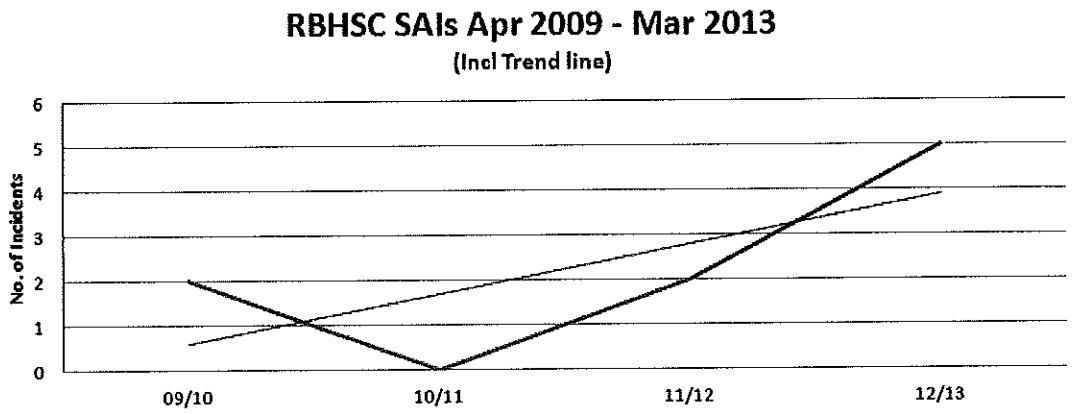
The Trust has a procedure for the reporting of adverse incidents which was approved in May 2010 (see Appendix 14). The procedure defines the criterion for escalating an adverse incident to a serious adverse incident that is reportable to the HSCB and other external agencies including the RQIA.

The Executive Lead Director for the management of the SAI process is the Medical Director. Ensuring learning from SAIs is a responsibility of all Directors. To facilitate learning and provide assurance the Trust established an SAI Review Board in line with the Assurance Framework. This is currently chaired by the Executive Director of Nursing and User Experience. The Terms of Reference were approved by the Assurance Committee of Trust Board (see Appendix 15). The Committee structure will shortly be reviewed as described above under Governance and Accountability arrangements to take account of a new Learning from Experience Steering Group. The Assurance Committee of the Trust Board reviews a quarterly and annual report on serious adverse incidents. In addition, SAIs are reported on a timely basis to full Trust Board at both confidential and public Trust Board meetings.

The Belfast HSC Trust has a positive approach to SAI reporting and can demonstrate through improved reporting trends openness to report and share lessons. The following graph demonstrates incident reporting trends since April 2009.



The Children's Hospital has fewer unexpected or unexplained deaths in comparison with other specialty areas. However, the Trust proactively reports deaths which may not strictly fit the regional criterion but where senior management believe that a high level investigation may lead to regional learning and these events are therefore reported to the HSCB. The following graph demonstrates the trend in SAI reporting by the Children's Hospital (RBHSC) from April 2009.



Investigating adverse Incidents

When an incident occurs in another facility but is recognised within the Belfast HSC Trust a number of options are now available. If the incident meets the SAI criteria Belfast Trust will contact the other facility to inform them that an incident has occurred. Belfast Trust will report the SAI to the HSCB who will decide who will lead the investigation, frequently the Trust where the incident occurred. If the incident relates to more than one organisation for example another Trust and the NI Ambulance Service the HSCB advice an independent chair to investigate. If the incident does not meet the SAI criteria Belfast HSC will contact the other Trust by telephone and/or email and share the incident form to allow the other organisation to investigate internally. This communication will tend to be from one Assistant Director of Risk/Governance to another although on occasion it will be escalated to the Medical Director's within the organisations. In addition, incidents may also be shared informally within clinical networks. The Children's Hospital has established a communication strategy to share information internally and externally. This communication strategy applies to both issues relating to care management and the dissemination of standards and guidelines which will be described more fully below (see Appendix 16).

The Trust has developed a procedure for the investigation of adverse incidents. The extant version was approved in May 2010 (see Appendix 17). This procedure can be applied to all adverse incidents and complaints; it details how to decide the level of investigation required and the action to be taken by the investigation team or individual investigating. The process aims to identify and record the direct, contributory and root causes of the adverse incident. The information obtained can then be analysed and common causes and trends highlighted and appropriate preventative action can then be taken to avoid a recurrence.

More serious adverse incidents will be investigated using root cause analysis (RCA) methodology in line with National Patient Safety Agency (NPSA) guidance.[30] A number of senior staff have undertaken specialist training in this field. More recently the Trust has implemented the use of Significant Event Audit (SEA) as a form of investigation of clinical incidents.[31]

In circumstances of unexpected death or serious untoward harm requiring investigation by the police, Coroners or HSENI separately or jointly, the Memorandum of Understanding may be applied.[32] This may be the case when an incident has arisen from or involved criminal intent, recklessness and/or gross negligence, or in the context of health and safety, a work-related death. The memorandum of understanding is supported by other operational guidelines produced by the respective organisations. The Memorandum sets out the general principles for the HPSS, police, coroners and HSENI to observe when liaising with one another. It applies to people receiving care and treatment from the HPSS in Northern Ireland.

Families and carers are involved in the management of adverse incidents in a number of ways depending upon the complexities and seriousness of the event. Families are informed that an adverse incident has occurred and is being investigated in line with the Trust's Adverse Incident Reporting Policy and Being Open Policy (see below). Staff need to be mindful of any additional support the family may require. In the circumstance of a serious adverse incident a meeting is arranged as soon as possible after the incident and the Trust usually finds it useful to agree a key named contact for the family if relevant to ensure that they are updated appropriately. On many occasions the family can add to the investigation in terms of factual accuracy and sharing their experiences with the service. If the family are agreeable to being interviewed this has to be handled with great sensitivity. They will be interviewed usually by 2 members of the RCA team. Upon completion of the investigation the family will then get a copy of the report. The Trust would prefer to meet the family to share and discuss the report. This meeting will be chaired by a senior officer of the Trust who will invite one or two members of the RCA panel to be

[30] NPSA Guide to Root Cause Analysis at www.npsa.nhs.uk/rca

[31] NPSA National Reporting and Learning Service. Significant Event Audit – Guidance for Primary Care Teams October 2008 at www.npsa.nhs.uk/nrls

[32] Memorandum of Understanding; investigating patient or client safety incidents (Unexpected death or serious untoward harm) DHSSPSNI, PSNI, Coroner's Service and HSENI, February 2006 amended

present to facilitate the sharing of information. On occasion families will also request feedback on the implementation of any remedial action plans.

Investigation reports are compiled in line with DHSSPS guidance.[33]

Barriers to adverse incident reporting

The health service has long acknowledged that there is an under reporting of adverse events.[34] [35] [36] [37] The Kennedy Report [38] following an independent inquiry into the deaths of 29 out of 53 babies and young children undergoing cardiac surgery at the Bristol Royal Infirmary between 1988 and 1995 recognised that a key factor in improving patient safety is learning from these adverse events. However, if an organisation is to learn from its errors and accidents, then these must be reported in the first instance. The Report recommended that every effort should be made to create an open, learning culture and a non-punitive environment in which it is safe to report and admit when things go wrong.

The Report considered the often-made distinctions derived from law between an error and mistake on one hand, and accidents on the other. In a patient-centred healthcare system it is the effect of events on the patient (and their families) that is paramount. Therefore there is a need not to distinguish between an error and

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[33] DHSSPSNI HSC Regional Guidance for Investigation/Review Report September 2007.

[34] Shekelle PG. *Why don't physicians enthusiastically support quality improvement programmes?* Downloaded from qualitysafety.bmj.com on August 19, 2011

[35] Firth-Cozens J. *Barriers to incident reporting.* Downloaded from qualitysafety.bmj.com on August 19, 2011

[36] Ferner RE . *Criminal proceedings will hamper calls for open culture.* Letter to BMJ 2005; 331:1272 (26 November)

[37] Cantor MD. *Telling patients the truth: a systems approach to disclosing adverse events.* Downloaded from qualitysafety.bmj.com on August 19, 2011

[38] Department of Health. *Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995. In: Learning from Bristol.* HMSO July 2001

accident but to group them together as adverse incidents, meaning "an unplanned event which results in harm to the patient". Traditionally, hospitals willingly disclosed and discussed accidents but where much less willing to be open in the case of an error or mistake. The Report indicated that this would have to change and that the health service would have to accept that even if the mistake could have legal repercussions there was a duty to disclose this mistake, "a duty of candour".[39] This duty was defined as an integral part of the open and honest culture that was to be at the heart of the drive to improve patient safety.

If an organisation is to reduce the rate of harm then it needs to identify how, when and why adverse events occur – and how system defects contribute. A fundamental feature of a culture of safety is the need for the organisation to create an open and non- punitive environment in which it is safe for clinicians to report adverse incidents, "safe to admit error, safe to admit when things have almost gone wrong and safe to explore the reasons why".[40] A recent study showed the types of errors that are likely to be reported and by whom. [41] Nurses and to a lesser extent midwives are more likely to report than doctors; reporting is more likely to take place where protocols are in place and not adhered to and reporting is more likely to occur when patients are harmed by error. In 2000 the under reporting of adverse incidents was estimated to range from 50% to 90% annually.[42]

The Kennedy Report[43] acknowledged that many incidents go unreported because of fear. There is a fear of being blamed and perhaps even more fundamentally a fear of what it will mean for clinicians to acknowledge that because of their conduct a patient has been harmed.[44]

Following the Kennedy Report the publication *'An organisation with a memory'* (OWAM)[45] became an important milestone in the NHS's patient safety agenda and marked the drive to improve reporting and learning. OWAM offered some key messages and one of these messages was that when things go wrong the roots of the failure are usually systematic and may reveal failings in the following areas; the

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[39] *Ibid.*, Chapter 23 p51

[40] Department of Health (2001) *Op.Cit.*, Chapter 26 p 17

[41] Lawton R, Parker . *Barriers to incident reporting in a healthcare system.* QSHC 2002; 11:15-18.

[42] Barach P & Small SD, *Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems.* BMJ 2000; 320: 759 -763

[43] Department of Health (2001) *Op.Cit.*

[44] *Loc.Cit.*

[45] Department of Health (2000) *Op.Cit.*

team, the work environment, the organisation and the organisation's culture. *Organisation with a memory* sought to highlight that adverse events are common in healthcare systems across the world, and that most adverse events are not caused by "bad individuals". The Report emphasised the importance of establishing a reporting and questioning culture. It sought to see the NHS develop a "safety culture" and not a "blame culture". The Belfast HSC Trust has sought to further develop the initiatives that were present in the Royal Hospitals Trust and endeavoured to create a culture of "openness and transparency" and "fair blame" and this is clearly identified in the Assurance Framework, the Risk Management Strategy and the Adverse Incident Reporting Policy and Procedures.

In England, following the publication of OWAM the NHS Litigation Authority (NHSLA) identified a number of barriers to incident reporting.[46] These included staff awareness of incident reporting systems, understanding of what constitutes an adverse incident/near miss, poorly designed forms and time pressure on staff. The Belfast Trust has attempted to deal with these barriers through induction and training, the introduction of web based reporting and improved feedback on reporting. Despite the work that many Trusts had undertaken to establish an 'open and fair blame' culture, in their 2004 Report the NHSLA also identified that staff perceived that a blame culture still prevailed leading to under reporting of clinical adverse incidents.

The Kennedy Report[47] found that blame and fault "find their expression most strongly in the system of clinical negligence litigation". The report recognised that the impact of litigation was so strong that it warranted scrutiny in its investigation. In its conclusion it held that "we believe that both the threat and the reality of litigation to claim damages for clinical negligence serve as barriers and disincentives to openness within the NHS". [48] Although it has historically been stated that fear of litigation is a barrier to incident reporting, anecdotal evidence would suggest that it is the potentially public nature of legal proceedings/public inquiries with the potential damage to reputation and standing with peers that is more significant. This is despite the very clear duties laid out by the regulators and the personal support and encouragement that is given to individuals in the Trust when they find themselves in such a situation. This topic is addressed by the Medical Director when he presents to new consultants during their induction programme 'Clinicians Leading, Improving and Managing Effectively' (CLIME) described below.

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[46] NHS Litigation Authority. *A Review of the NHSLA Incident Reporting and Management and Learning from Experience Standards* September 2004

[47] Department of Health (2002) *Op.Cit*

[48] Department of Health (2001) *Op.Cit.*, Chapter 26 p 25

Despite the barriers to reporting the Belfast Trust though its policies and behaviours has seen an acceptance among staff of the concept of openness and fairness. This can be evidenced subjectively in discussion with staff. More objectively the Belfast HSC Trust's staff survey 2012 [49] indicates that 9 out of 10 respondents (93%) know how to report errors, near misses and incidents. In the month prior to the survey 28% of those who responded had seen an error, near miss or incident that could have hurt a patient/service user with 91% saying that they or a colleague had reported it.

Learning from adverse incidents and other significant events

Where learning from adverse incidents is identified the necessary changes need to be put in place to improve practice. Learning and sharing from adverse incidents can only take place when they are reported and investigated in a positive, open, honest and structured way.

Crucial to the effectiveness of adverse incident reporting is the Trust's wish to promote an open, honest and just culture where all staff can participate in reporting adverse incidents. Ultimately the Trust wants to encourage staff to report areas of concern and to foster a positive ethos around reporting. This level of an open and learning culture has been greatly facilitated by the adoption of internationally recognised processes, in particular the Safer Patient Initiative and subsequent development of Safety and Quality Improvement plans described above.

The Assurance Framework demonstrates a strong commitment to learning from patient experience and sharing that learning within the Trust or at regional or national levels where applicable. Many of the Committees within the Assurance Framework focus on learning as has been evidenced by the Terms of Reference provided as appendices to this document. The sharing of learning within the Directorate governance arrangements is also clearly demonstrated by the Children's Hospital communication strategy (see Appendix 16).

The development of a new Learning from Patient Experience Steering Group as a high level subcommittee of Trust Board will enhance existing arrangements for the sharing of learning. The purpose of the Steering Group is to provide assurance to the Assurance Committee around the effectiveness of structures and processes established to support learning from the events and experiences of our service users and staff. The Learning from Experience Steering Group will bring together aspects of the assurance framework agenda in order to realise continuous improvement in safety and quality.

[49] BHSCT Staff Survey 2012 facilities by the HSC Leadership Centre

This Steering Group will be supported by a number of sub committees including; SAI, Complaints, Claims, External Reports and Outcomes Review (including mortality).[50]

The Trust also posts 'news' stories on new policies or learning from events on the Trust's intranet 'The Hub' (see Appendix 18). The Trust has a Risk and Governance newsletter which is widely disseminated which is published 4 times a year (see Appendix 19) and Learning from SAIs newsletter which has been produced annually to date (see Appendix 20). The Trust plans to amalgamate these two newsletters during 2013/14 as a result of staff evaluation.

The Belfast HSC Trust is committed to learn from experience whether the learning has come from staff/patient surveys, incident/complaints/claims investigations or external reports. During the course of the Inquiry the Trust has identified learning which senior management has addressed in advance of any published recommendations. In relation to information governance, training programmes were reviewed to ensure that the circumstances in which patient records are correctly accessed is made clear ie that they are only accessed in relation to clinical management including clinical audit.

Within the Children's Hospital each child death is assessed to establish if there were any circumstances that suggest the events leading up to the death require further investigation. As had been standard practice since the implementation of the HSCB SAI guidance where a death was not anticipated, and SAI report is developed and a formal investigation is initiated.

Where an SAI is initiated, families are advised at the earliest opportunity. They are also invited to provide information to the SAI investigation team and the feedback from the investigation or review is discussed with the family. All deaths are discussed at the monthly Morbidity and Mortality meeting. The Trust is also in discussion with the HSCB regarding the possible investigation of all children who die in hospital under the SAI process.

A more structured process for reviewing child deaths is being developed by the directorate to review both the clinical and non-clinical care provided to a child prior to their death. One aspect of this review will be the communication with parents and family. Parents are routinely offered the opportunity to meet with staff following the death of their child to discuss any aspect of care that they either wish for further clarity on or to discuss concerns they may have. Parents are also put in contact with the Trust's Bereavement Co-ordinator who is able to guide them through the grieving process. Where appropriate, the clinical psychology department in the Trust is able

[50] Assurance Framework (2013/14) *op.cit*

to offer support to parents and the wider family (e.g. siblings) prior to an anticipated death and also after.

The policy in relation to fluid management/recording is being reviewed and is due for submission to the Trust's Standards and Guidelines Committee by end September 2013. The weighing of nappies was reviewed and is in line with Trust policy ie nappies are weighed when clinically indicated. An audit of low sodium in the Children's Hospital was completed which showed that fluid balance chart completion was an area requiring some improvement. In response to this a weekly fluid balance chart audit is being undertaken and the results of this audit will be presented to the Trust's Hyponatraemia Task Group.

Being Open Policy

The Trust recognises that harming a patient can have devastating emotional and physical consequences on the individuals, their families and carers, and can be distressing for the professionals involved. *'Being open'* is a set of principles that healthcare staff should use when offering an explanation and apologising to patients and/or their carers when harm has resulted from an incident. Therefore the Trust developed a 'Being Open' Policy which has been in place since November 2011 and supersedes the policies of the legacy organisations (see Appendix 21). The policy is currently being revised to take account of recommendations from the Francis Report[51] in relation to establishing a duty of candour. This policy defines the Belfast HSC Trust's commitment to *'Being open'* by establishing a culture where there is a commitment to provide open and honest communication between healthcare staff and a patient (and/or their family and carers) when they have suffered harm as a result of their treatment.

The policy reiterates the Trust's commitment to have a culture that is open and fair and the purpose of the policy is to ensure that rapid and open disclosure and emotional support is available to patients and families who experience incidents leading to harm. The policy also addresses ways to support and educate staff involved in such incidents. In line with the National Patient Safety Agency (NPSA) guidance[52] the policy deals with patient safety incidents, which have caused moderate, major or catastrophic harm.

In order to further embed the purpose and objective of the 'Being Open' policy the Trust has agreed the following actions:

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[51] Francis (2013) *Op cit*

[52] NPSA Seven steps to patient safety: full reference guide – July 2004. Being open: communicating patient safety incidents with patients, their families and carers. 'Being open' Framework – November 2009.

1. Progress with developing a full e-learning module (Phase 1 training) based on the NPSA tool to deliver training to identified staff groups that are key to introducing the "Being Open" culture to the organisation (see list below):

    a. Assistant Service Managers
    b. Ward managers
    c. Clinical Directors / Associate Medical Directors
    d. Associate Directors of Nursing

2. Identify appropriate training plan for Phase 2 training which should reach all medical and nursing staff.

Whistleblowing Policy

The Trust has a Whistleblowing policy which has been in place since 12 August 2008. The most recent version was approved by the Senior Executive Team in May 2013 (see Appendix 22). Within the context of health care the term "whistleblowing" refers to the disclosure by employees, of wrong doing including fraud, financial irregularity, serious maladministration arising out of improper conduct, unethical activities which may be of a criminal nature or acts or omissions which create a risk to the health and safety within the organisation. The policy was developed in recognition of the fact that individual members of staff have a right and a duty to raise with the Trust any matter of concern that they may have.

The aim of the Policy is to promote a culture of openness, transparency and dialogue which at the same time: -

- reassures staff that they will not be penalised for raising a genuine concern and gives them a process to follow
- upholds patient confidentiality
- does not unreasonably undermine confidence in the service
- meets the obligations of staff to their employer
- contributes towards improving services provided by the Trust.

All matters are investigated in line with Trust procedure. If the complaint is in relation to care management issues when the investigation is finished the complainant receives a letter outlining the findings and recommendations of the investigating team. The final report is also shared with the Director(s) involved for action. A database of matters raised through the whistleblow policy is maintained by the Head of Office for the Chief Executive for matters pertaining to care management and by the Head of Financial Governance when the issue is in relation to financial matters.

In 2012, the Trust Chief Executive forwarded a letter from the Health Minister to remind all staff about their rights and responsibilities around whistle blowing. The Chief Executive highlighted the Whistleblowing Policy (see Appendix 22), which was developed in recognition of the fact that all members of staff have a right and a duty to raise any matter of concern that they may have. A summary of concerns brought forward by staff is reviewed by the DHSSPS on an annual basis.

Legal Services Management incorporating Coroner's cases (Issues 6 and 7)

The Trust has a Claims Management policy and associated procedures which are designed to ensure the systematic identification, analysis and control of risk relating to claims. The effective management of clinical, professional, and general, (i.e. employer's and public/occupier's liability claims) against the Trust represents important sources of risk identification and is an integral element of the Trust's risk management systems and processes.

The current version of the policy was approved by the Trust's Policy Committee on the 12 August 2013 (see Appendix 23). The policy, including associated procedures, details the Trust's arrangements for the management of such claims, as primarily directed by Circular HSC (SQSD) 5/10 as issued by the Department of Health, Social Services and Public Safety, as either arising from incidents which occurred within the Trust Since its establishment on 1 April 2007, or within the former legacy Trusts.

Excluded from this policy are arrangements in respect of Employment Law claims which are managed by the Director of Human Resources and also claims where causation is an insurable matter against which risk the Trust has purchased commercial insurance, for example, third party motor insurance and legal expenses cover for Foster Carers.

The Trust has a legal services department which is managed by a Legal Services Manager. This is a new post created as part of the Belfast Trust's Medical Director's Group in recognition of the workload in this area and need for modernisation and reform of the service in the light of Pre Action Protocols – add reference etc. The Manager has a clinical background and has also legal qualifications and was appointed in November 2010. In addition the Trust has invested in an Associate Medical Director to provide professional support and guidance in this field and in particular in relation to working collaboratively with the Coroner's Officer to establish learning.

On conclusion/ settlement of litigation cases the Legal Services Manager completes a closed case summary in which any lessons to be learned from the case are identified and disseminated to the relevant clinicians and the Governance Manager for that specific Directorate/ Specialty. It is also recognised that any learning to be

derived may not be specific to one specialty, in which case the case summary will be shared with all of the Trust`s Governance managers to ensure the widest dissemination of learning possible. It should, however, be noted that clinical negligence cases often take several years to reach settlement: if, during the course of investigation of a claim, a deficit in care is identified which could lead to harm in other patients, immediate steps are taken to ensure that this is highlighted to relevant staff and actions implemented to ensure that the alleged harmful circumstance is addressed and any appropriate learning immediately implemented. Such cases are rare - it is more frequently the case that individual specialties will have implemented updated guidelines long before the trial date or that practice will have substantially changed in the interim period.

A quarterly Trust Claims Review meeting is held at which there is opportunity for further discussion of closed case summaries and suggestions made as to additional learning or a means of improving upon this process. There is a wide range of attendees including Governance Managers, the Assistant Medical Director with responsibility for Legal Services, Senior Managers and the Co-Director for Risk and Governance. Other relevant persons, including representatives from the Directorate of Legal Services, may be invited to attend where appropriate. (Estates and other personnel are also in attendance; however this is to facilitate discussion of EL/OL rather than Clinical Negligence matters).

Claims brought against the Trust are recorded on a Claims database which allows for trends to be identified in relation to individual specialties and clinicians: where such exist, they can then be brought to attention of any relevant personnel for implementation of further investigation/ action.

Counsel will occasionally compile a brief summary of any learning to be gleaned from the case.

Quarterly and annual reports are published and disseminated for discussion at the Trust`s Claims Review meetings.

The Legal Services Manager and Assistant Medical Director, Litigation meet approximately eight times per year with Senior DLS Solicitors to discuss a cohort of selected cases which require decisions taken as to liability/ defence/ causation and quantum and general case progression. Whilst such meetings are primarily directed at case management, they nevertheless afford additional opportunity to identify areas of vulnerability for the Trust which may require immediate remedial action to prevent a reoccurrence of similar cases.

Coroner's Cases (Issues 6 and 7)

Whilst the focus of Coroners` Inquests is not for the purpose of attributing blame, there is nevertheless frequently learning to be derived from such cases, many of which may also have been the subject of an internal Trust Serious Adverse Incident investigation. Where the Trust has been legally represented in such cases, individual Counsel will occasionally compile a brief summary of any learning to be gleaned from the case which is disseminated to appropriate clinical teams or across the service as is appropriate. The Trust now has regular meetings with the Medical Examiner from the Coroner's Office to facilitate the sharing of learning.

The Belfast HSC Trust has developed a Morbidity and Mortality policy to set out clear roles and responsibilities and procedures to ensure that all deaths occurring throughout the Trust will be recorded, reviewed, monitored and analysed. This policy will be described below when addressing Issue 15.

The Trust's Coroner Liaison office work closely with the Bereavement Coordinator to support families involved in inquests. The Trust has recently issued a new Bereavement Pack for use across the organisation.

Currently the advice given to staff preparing statements for inquests is that they should provide fact. Staff will not be advised against reflecting upon their own practice within written statements but would be advised not to comment upon the practice of other members of staff.

The Belfast HSC Trust continues to believe that it is entitled to and in certain circumstances it will be appropriate and indeed necessary for it to obtain the benefit of independent expert medical advice for the purpose of ensuring that its interests are adequately and properly protected at the hearing of an Inquest. Such advice may involve obtaining a formal report from the independent expert. Such a report may require revision in the light of further information being provided before being finalised. An Inquest is by its nature an Inquisitorial procedure conducted by the Coroner. Subject to any possible Article 2 considerations, the Trust is under no legal duty to furnish any such independent expert report that it has obtained to the Coroner. The Trust is under no legal duty to request the Coroner to add any such expert to the list of witnesses scheduled to give evidence at the Inquest. Nor is the Coroner under any duty to accede to the request of a Trust to hear evidence from any expert retained on behalf of a Trust. An independent expert retained on behalf of a Trust may form an opinion on a matter of professional practice which is at odds with the sincerely held opinions of senior clinicians involved in the management of the Deceased patient. The fact that such a divergence of opinion exists is obviously a matter to which a Trust must give serious consideration. But the mere fact that such a divergence of opinion exists does not create a duty on the part of the Trust to reveal the contents of any such independent expert report to the Coroner if the Trust is satisfied as to the validity of the professional opinions expressed by the senior

clinicians involved in the treatment of the Deceased patient. The Trust would be entitled to seek a second independent expert opinion. If such an opinion was supportive, the Trust would be at liberty to submit the report to the Coroner but it would be under no duty to submit the earlier unsupportive report. The Trust believes that this is an accurate analysis of Coronial law and practice in Northern Ireland. Any duty of candour is a duty relating to the facts. It does not and cannot be interpreted as extending to a duty to share expressions of professional opinion which run contrary to the reasonably held professional opinions of the senior clinicians in the employment of the Trust involved in the treatment of the Deceased patient.

Managing Doctors and Nurses in Difficulty (Issue 8)

The Belfast HSC Trust has furthered developed systems to manage doctors and nurse in difficulty. The policies, procedures and practices in relation to these 2 professions are described below.

Confidence in Care

In December 2008, the DHSSPS established the 'Confidence in Care' programme to deliver on the recommendations of the UK White Paper 'Trust, Assurance and Safety'[53] and the outstanding actions of the DHSSPS report 'Improving Patient Safety: - Building Public Confidence'[54]. The programme is taking forward the reform of professional regulation and aspects of this work are relevant to the governance arrangements of the Trust, notably the development of systems for appraisal and for intervention when concerns arise over the performance of an individual practitioner.

A robust system of appraisal, together with the submission of a range of supporting information is contributing to the revalidation of doctors by the General Medical Council (GMC). In preparation for revalidation, every HSC organisation in Northern Ireland has now nominated a Responsible Officer (RO). They are lead doctors, who have a statutory duty to ensure that their organisation has the necessary processes in place to support medical revalidation and who will be required to make revalidation recommendations to the GMC about the fitness to practice of individual doctors who work there. The Medical Director is the RO for the Belfast HSC Trust. Revalidation commenced for doctors in December 2012 and the vast majority of practicing doctors in Northern Ireland are scheduled to revalidate by 2016. For doctors in training the Post Graduate Dean is the RO. The Trust cooperates closely with the Post Graduate Dean and the NI Medical and Dental Training Agency (NIMDTA).

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[53] UK White Paper 'Trust, Assurance and Safety – the Regulation of Professionals in the 21st Century February 2007' HMSO

[54] DHSSPSNI 'Improving Patient Safety: - Building Public Confidence' December 2006 at www.dhsspsni.gov.uk

Medical Revalidation and Appraisal in BHSCT

The purpose of revalidation is to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and are practising to the appropriate professional standards. Within the Trust medical appraisal is currently in place for consultants and specialty doctors (and equivalent grades). Doctors in training are appraised and revalidated directly by NIMDTA. The revalidation process for dental practitioners will be developed by the General Dental Counsel (GDC) at a later date.

The following arrangements have been implemented by the Belfast HSC Trust to date:-

- Revalidation process commenced on 3 December 2012.

- Belfast Trust Revalidation Recommendation Protocol developed and implemented (see Appendix 24).

- New appraisal documentation and guidance has been developed regionally and now implemented within the Trust.

- The Medical Director in his role as RO has responsibility for approximately 840 doctors. An active process of communicating with medical staff, making recommendations, and the management of prescribed connections is in place with medical staff and the GMC.

- Almost all our doctors are voluntarily participating in regular appraisal and any doctors who have found this difficult are being directly managed.

- A total of 116 appraisers were recruited during 2012. One hundred and twelve attended a one day training programme in 2012 which was positively evaluated. A further half day update sessions delivered during March / April 2013 were well attended, with most appraisers in attendance.

- Fourteen 'Appraisee' Revalidation & Appraisal update sessions were delivered during April and May 2013. A total of 383 Consultants & Specialty Doctors attended these sessions which were very positively evaluated.

- Colleague Feedback process was fully implemented in September 2012 supported by the Trust's Service Level Agreement (SLA) with the HSC Leadership Centre. This process is being rolled out based on timing of

revalidation dates. There have been 274 participants, with 218 surveys completed to date. A further 62 Doctors' surveys will commence soon.

- Patient Feedback process implemented in November 2012 supported within Trust SLA by HSC Leadership Centre. This process is being rolled out based on timing of revalidation dates. There have been 184 participants, with 83 surveys complete. A further 72 Doctors' surveys will commence soon.

- Trust processes were developed to assist medical staff in meeting other GMC supporting information requirements including significant events, complaints, clinical activity data and outcome information.

- A new Trust database has been developed in relation to revalidation, appraisal and related processes.

- The Trust's intranet site 'The Hub' resource site has been fully developed to support medical staff (see Appendix 25).

Future developments will include; implementation of a Quality Evaluation Framework, which includes appraisee / appraiser feedback, folder audit and quality assurance of appraiser roles, development of appraisee E Learning and participation in the regional development and implementation of an on-line appraisal system.

Maintaining High Professional Standards

The DHSSPS guidance on 'Maintaining High Professional Standards'[55] (MHPS) is also part of the 'Confidence in Care' programme. This guidance relates to procedures for the management of underperformance in employed doctors and dentists, e.g. by a HSC Trust. The Belfast HSC Trust has developed Doctors and Dentists case review group and a case review process (see Appendix 26). This review group is chaired by the Medical Director (or his deputy) and has membership from service directorates, Human Resource services and corporate governance services. The review group has a deputy Director of the Directorate of Legal Services (DLS) in attendance to provide the necessary legal support and guidance.

[55] http://www.dhsspsni.gov.uk/hrd_suspensions_framework.pdf

The Trust's existing policy and procedures for the general management and support of staff must always be followed and sit alongside the specific support provided through MHPS. The line management of doctors and dentists is the responsibility of the Service Director (ordinarily delegated to the relevant Co Director) in whose specialty the doctor or dentist works. Within the Directorate, doctors and dentists are professionally responsible to their Clinical Director and Associate Medical Director, and through them they are accountable to the Medical Director, as an executive director and in his role as RO.

Concerns about a doctor or dentist may arise from a number of sources for example complaints, incident reports, reports from whistleblowers, appraisal, audit, morbidity and mortality review, patient/colleague feedback and litigation. On occasion concerns may also be raised by external bodies for example the Ombudsman for Complaints, the PSNI, the Deanery, HSCB, PHA, DHSSPS and GMC. Where there is a single significant issue that causes concerns in relation to the performance of a doctor, or where there is an accumulation of issues or concerns, these are considered in line with the protocol.

Referring medical staff to GDC/GMC

Referral to the General Medical Council (and/or to the General Dental Council (GDC) in the case of those staff registered with the GDC) is considered within the MHPS framework.[56] This framework also outlines the access which the Trust has to the National Clinical Assessment Service advisers who are available to provide advice on all aspects of the management of concerns, inclusive of the appropriateness of referral to the regulators. Notably the General Medical Council have recently appointed an Employer Liaison Adviser for Northern Ireland ; the Trust is therefore able to engage with the General Medical Council in considering if and when to make formal referral to the regulator.

The Trust has made the following referrals to the GDC/GMC in the period from 2007 to July 2013:

- There are 6 concluded Fitness To Practice Hearings for doctors relating to Belfast HSC Trust between 2007 - 2012.

Management of Nurses/Midwives in Difficulty

[56] *Loc. cit*

Belfast HSC Trust has a number of policies and processes to deal with nurses/midwives' capability issues and nurses/midwives in difficulty. In May 2011, the Trust issued a policy entitled 'Managing performance within BHSCT capability procedure – guidance to support nursing and midwifery staff' (see Appendix 27). Subsequently, a 'Frequently Asked Questions' leaflet was issued as an aide-memoir for staff responsible for managing performance (see Appendix 28). The purpose of the Policy and leaflet is to provide staff with step-by-step guidance and templates for those instances when the Trust's Capability Procedure (see Appendix 29) is invoked in order to deal with a nurse or midwife's capability. This Policy, and all other Trust policies, is available on the Trust Intranet.

On page 5 of the Policy, under the section entitled 'capability', it states

> '*managers have a responsibility to ... take steps to identify and deal with poor performance by offering the necessary support to those who may be experiencing difficulty*'.

Examples of poor performance, taken from the Department of Health (DoH) document 'Handling concerns about the performance of health care professionals: principles of good practice' (2006) are listed in the Policy, and references are made to other related Trust policies, including the Disciplinary Procedure (see Appendix 30) and Attendance Management Policy (see Appendix 31). The process for the management of poor performance is detailed from page 7 of the Policy. Actions to be taken during the informal and formal processes of the Trust's Capability Procedure are listed, and there is guidance on when managers should seek support from their line manager and professional nursing/midwifery lead. Templates of letters, records of meetings, and action plans are included in the Appendices of the Policy.

Since coming into post in January 2010, the Executive Director of Nursing and User Experience has established a series of regular meetings known as 'Nurses/Midwifes in Difficulty'. The purpose of these meetings is to:

- Guide nurses/midwives and managers in the Nursing and Midwifery (NMC) referral process.
- Support fair and equitable treatment of staff where there are concerns about fitness to practise.
- To fulfil the requirements of NMC in relation to fitness to practise.

There are some instances during the formal processes of the Trust's Capability Procedure when a nurse/midwife's performance necessitates a case management meeting with the Co-Director responsible for Nursing Governance, Standards and Performance. In these instances, a 'Nurse/Midwife in Difficulty meeting' is arranged, and the manager presents the case and actions undertaken to the Co-Director and

senior staff from the Human Resources Department. At this meeting, further actions and timeframes are agreed. Updates from these meetings are reported regularly to the Executive Director of Nursing and User Experience and discussed formally at a quarterly meeting with the Senior Nursing and Midwifery Team.

There are some instances when a nurse/midwife's lack of competence is such that he/she is unfit to practise safely and effectively and is referred by the Trust to the NMC. In July 2011, BHSCT issued a policy entitled 'Making a referral to the Nursing and Midwifery Council' (see Appendix 32). The purpose of this Policy is to provide staff with guidance on how to make a referral. In Belfast HSC Trust, the final decision regarding a referral to the NMC is made by the Executive Director of Nursing and User Experience. Each of the referrals made are screened by the NMC to determine if there is a case to answer, and in those instances where particular risk factors are identified, such as lack of competence, the nurse/midwife is referred to a hearing. The range of sanctions available to the NMC includes Caution order (1 to 5 years); Conditions of practice order; Suspension order; and Striking-off order. The Trust has developed close partnerships with NMC colleagues, and seeks advice and updates on referrals regularly.

The role of the NMC is to safeguard the health and wellbeing of the Public from Nurses and Midwives whose fitness to practice is impaired and whose situation cannot be managed locally. In 2002, the NMC published guidance for employers and managers that listed two reasons why a nurse/midwife could be referred to the NMC. These were; unfitness to practise (poor health) and misconduct.

In 2004 two further guidelines were produced by the NMC, 'Reporting unfitness to practise: A guide for employers and managers' and 'Reporting lack of competence: A guide for employers and managers'.

In 2010, the NMC re-issued this guidance advising employers and managers that the Fitness to Practise directorate of the NMC were to investigate all allegations made against nurses and midwives questioning their fitness to practise, including allegations of:

- Misconduct
- Lack of competence
- Bad character, and
- Poor health

Further advice and information on the responsibilities of employers of nurses and midwives was published in April 2012. This focused on

- Registration of nurses and midwives
- Recruitment processes of nurses and midwives
- Definition of fitness to practise
- Procedures to go through when making a fitness to practise issues including:
    - Urgent referrals and interim orders
    - Misconduct
    - Lack of competence
    - Bad character
    - Serious ill health

Prior to 01 April 2007, the Royal Group of Hospitals Trust comprised the Royal Victoria Hospital, the Royal Jubilee Maternity Services, the Royal Belfast Hospital for Sick Children, and the School of Dentistry. A review of legacy records on NMC referrals revealed that during the period 01 April 2003 and 31 March 2007, 5 nurses/midwives were referred to the NMC. Of these staff, 3 were referred on to a hearing. This data was confirmed by NMC colleagues in the preparation of this report.

Since 1 April 2007, there have been 56 nurses /midwives referred to the Nursing and Midwifery Council (NMC). Of these referrals:

35 have been made by the Trust

10 by the NMC

9 by members of the public, and

2 by the registrant themselves.

Dissemination of External Standards and Guidelines (Issue 9)

In the period up to 2006 external guidance was received largely from the DHSSPSNI for implementation / action within the Trusts. Within Belfast HSC Trust these were

received into the Chief Executive's Office and then distributed as advised by the Department.

In 2006, a number of changes took place in Northern Ireland which contributed to an increase in the volume of external guidance and the actions required (DHSSPSNI set up systems to endorse guidance/alerts from both the National Institute for Clinical Excellence (NICE) and the National Patient Safety Agency (NPSA)).

Given this increase in volume of external guidance, many of the former Trusts including the Royal Group of Hospitals Trust (RGH) recognised the need to put in place a trust wide system for assuring that any actions outlined in guidance were completed. An RGH Standards & Guidelines Committee was set up with the remit of ensuring that all external clinical guidance was directed to the appropriate areas and that any action was completed within specified timeframes, progress being monitored through the committee. On the formation of Belfast Trust in 2007, this model was adopted and a Belfast HSC Trust Standards & Guidelines Committee formed (See Appendix 33). This is a clinically orientated Committee, co chaired by an Assistant MD and a nursing Co Director.

As the amount and variety of guidance increased, the Standards & Guideline Committee continued in its remit, but it was recognised that the Trust needed to introduce a more timely system to insure the rapid dissemination / action of guidance as appropriate. In 2010, Executive team approved a process for the dissemination and action of external guidance. This process identifies the key areas for guidance and provides a follow up that insures all actions are completed and reported to the HSC Board (see Appendix 34).

Training required to implement new guidelines may be provided at local level if the guidance is more specialised in nature. If the guidance is more generic then Trust wide training programmes (face to face) or e training may be required. The Trust has a Statutory and Mandatory Training Policy (see Appendix 35) and any guidance will be reviewed in light of this policy to decide who will require the training and how often. The Trust has also recently approved an Induction Training Policy (see Appendix 36). An example of how the Trust has dealt with training in relation to new guidance is described under the section on the current management of hyponatraemia.

The Belfast HSC Trust set up a regional intra hospital policy collaborative which was chaired by one of the senior clinicians and supported by the Trust's Standards and Guidelines department. This collaborative was stood down in 2013 when more mature regional arrangements developed by the HSCB.

Current Management of Hyponatraemia (Issue 13)

The Belfast HSC Trust received the DHSSPS Circular NPSA Safety Alert 2: Reducing the Risk of Hyponatraemia when Administering Intravenous Infusions to Children on the 27 April 2007.[57] The Trust manages children up to the age of 18 years in a number of clinical settings across the organisation and not just within the Children's Hospital.

The five actions points highlighted in the NPSA alert were taken forward immediately across the Trust under the direction of the Medical Director, and the summary below outlines the key improvements made.

1. *Remove sodium chloride 0.18% with glucose 4% intravenous infusions from stock and general use in areas that treat children. Suitable alternatives must be available. Restrict availability of these intravenous infusions to critical care and specialist wards.*

Following audit and consultation with medical staff, No.18 solution was removed from all clinical areas with the exception of those which demonstrated a clear requirement for stocking No.18. All of these areas were included within the exception list on the NPSA 22 Alert. Currently the only areas allowed to stock No. 18 solution are Barbour ward (surgical paediatric ward) and PICU both within the Children's Hospital as defined in Trust policy (see below).

A Consultant only prescribing system for all other areas with checks at Pharmacy was instigated. Six monthly audits of stock reports and consultant only prescribing were put in place and are currently ongoing. These restrictions are embedded in Trust policy. This work has been managed primarily through the Trust's Drugs and Therapeutics Committee and Pharmacy Department.

2. *Produce and disseminate clinical guidelines for the fluid management of paediatric patients.*

The Trust's Standards & Guidelines Committee co-ordinated legacy guidelines / practices to produce a Belfast Trust "Policy for the administration of intravenous fluids to children aged from 1 month until the 16th birthday: reducing the risk of hyponatraemia" (see Appendix 37a). This policy was written in consultation with staff throughout the Trust and is subject to periodic review. This policy document includes the regional wall chart produced by the DHSSPSNI. Wall charts issued by the DHSSPSNI were issued and are displayed in all clinical areas. Annual audits are carried out to ensure compliance.

[57] DHSSPS Circular HSC (SQS) 20/2007 NPSA Safety Alert 2: Reducing the Risk of Hyponatraemia when Administering Intravenous Infusions to Children at www.dhsspsni.go.uk/hsc

3. *Provide adequate staff training and supervision.*

An e-learning BMJ module was made available nationally and incorporated into Belfast HSC Trust Policy. This training is mandatory for the following groups:

- All RBHSC Nursing and Medical staff
- All Junior doctors entering the trust

Both the e-learning module and awareness training is available to Medical and Nursing staff in all other areas. The concern of maintaining competency following training (due to potentially low number of cases is some clinical areas) has been addressed through making clinical guidelines available and providing a "Sources of Advice" protocol for doctors in these areas. The Medical Director has recently written to all Consultants and Career Grade staff requesting confirmation that they have either completed mandatory training or that they are not required to administer intravenous fluids to children aged from 1 month until the 16th birthday (see Appendix 37b).

4. *Review and improve the design of existing intravenous fluid prescriptions and fluid balance charts for children.*

A Paediatric Fluid Balance chart was designed, piloted, audited and rolled out in the Children's Hospital and any other clinical areas where children may be cared for. This work highlighted the need for a review of the adult chart, which subsequently took place with a revised chart (which is similar in style so as to avoid error) being rolled out for adult patients.

A regional working group was set up with leadership to develop fluid balance charts for the region; these are being rolled out from July 2013.

5. *Promote the reporting of hospital-acquired hyponatraemia incidents via local risk management reporting systems. Implement an audit programme.*

The Trust had an established incident reporting system at the time of this alert. Work was undertaken to devise a "trigger list" highlighting to staff what should be reported as an "incident" (e.g. poor monitoring / drop in sodium levels to <130mmol/l) to facilitate learning through the normal incident review process. This trigger list forms part of the policy mentioned under point 2.

The trust undertakes regular 6 monthly audits of episodes of hyponatraemia as identified by the laboratories. These audits are led by Consultants and involve review of notes to insure that the following key standards are met in relation to the management of hyponatraemia:

- Fluid management including choice of fluid and monitoring is in line with policy
- Advice / support from senior colleague is sought if appropriate
- Any incidents (as identified by the Trigger list in policy) are recorded on the trusts incident reporting system.

Continued performance against these 5 key areas has been monitored over the last 6 years through inspection by the Regulatory & Quality Improvement Authority (RQIA) and these reviews have recognised the achievements in relation to this Alert. Where further work in implementing good practice has been identified by the RQIA, this work has also been progressed.

Internally the Trust monitors performance through a Hyponatraemia Task Force with multiprofessional membership chaired by Professor Ian Young. The Task Force reports performance through the Assurance Framework to the Medical Advisory Committee under the leadership of the Medical Director.

Morbidity and Mortality Policy (Issue 15)

The Belfast HSC Trust undertakes mortality review in two ways:

1. Mortality Ratios and comparisons with peer sites are provided by national benchmarking services[58] and these are reviewed by the Medical Director and other Senior Medical Colleagues to identify any areas of concern. Any concerns are investigated through discussion with relevant speciality / audit if appropriate. Under the current governance arrangements in Belfast Trust, this work is carried out by the Trust's Mortality Review Group

2. Clinical specialties can review individual cases during the morbidity and mortality section of their monthly rolling audit calendar meetings. The Trust ensures that all clinics / non-emergency work is cancelled on the rolling audit calendar dates (set regionally) to allow clinical staff to participate in these meetings which also encompass audit.

In 2011, the Trust audited clinical records to identify cases where *Clostridium Difficile* was the primary / secondary cause of death. This audit identified that there was both a lack of documentation around cause of death and a lack of assurance that all deaths were been reviewed appropriately. A need for a Trust wide system for the recording and reviewing of deaths was identified.

[58] CHKS is a provider of healthcare intelligence and quality improvement services including the provision of on line performance monitoring and benchmarking combined with expert analysis at www.chks.co.uk

In response to this and under some direction from the Public Health Agency (PHA), the Trust developed a Morbidity and Mortality Policy (see Appendix 38 and 39) which outlined a requirement for all deaths to be part of a "Review Process". The implementation of this policy was supported by the development and launch of an IT system which facilitates the recording and reviewing of all deaths through a four stage process:

- Recording of death / details
- Review of details by Consultant in charge of patient, including identification of any potential contributory factors
- Discussion of case at Speciality Morbidity & Mortality meeting.
- Identification and taking forward of any lessons / actions

This system was piloted in August 2012 on one site is being rolled out to all areas, since May 2013. It is set up to assign each death to an identified specialty team for review and track the completion of review.

Undertaking this process also enabled the Trust to:

- clarify team memberships, so all medical staff belong to a team
- identify Morbidity & Mortality leads in areas where they were not in place
- improve communication between speciality teams in relation to mortality review
- insure mortality review takes place in all specialities
- review cause of death / incidents related to death on a trust wide basis.

Medical Engagement

Since inception of the Belfast Trust there has been a programme entitled "Clinical Engagement and Leadership designed to involve doctors in the operational business and leadership of the Trust. The Trust developed a cadre of senior medical managers at associate medical director and clinical director level. The Associate Medical Directors all took part in a development programme.

Over a period of two years the Chief Executive has engaged in a programme of specialty meetings, a means by which he and other senior managers talk to medical teams about key strategic and operational issues including patient safety issues.

The Trust has recognised the central importance of clinical directors to driving both the service and quality agendas within the Trust. A clinical director's forum has been established and a varied programme of events has already been delivered (sample agendas are attached Appendix 40 and 41). Forum meetings are evaluated to ensure that the programme continues to meet the needs and expectations of clinicians (see Appendix 42).

The Trust also developed the CLIME programme of management induction for new consultants. The overall objective of this induction programme is to:

- To increase participant awareness of the key external/internal issues facing Clinicians, their services and the organisation over the next few years;
- To provide opportunities for participants to become more familiar with the Trust's strategic direction and priorities for the future;
- To gain insight into how the Trust functions, including its structures, funding arrangements and programmes for change and to explore the leadership role of Doctors within it;
- To identify the nature of the Clinical Governance agenda facing the Trust and its implications for roles, responsibilities and team working into the future;
- To explore ways of improving the current structures in management to enhance the organisation and delivery of services.

The programme is delivered in 2 modules (see Appendix 43 and 44). Presentations are delivered by both internal senior managers/clinicians and external key stakeholders including the Chief Executive of the HSCB.