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Northern Ireland Audit Office

The Safety of Services Provided by Health and Social Care Trusts

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL
23 October 2012

Northern Ireland Audit Office

Report by the Comptroller and Auditor General for Northern Ireland

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K J Donnelly
Comptroller and Auditor General

Northern Ireland Audit Office
23 October 2012

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Contents

1 First Annual Complaints Report of the HSC Board (1 April 2009 to 31 March 2010) and Second Annual Complaints Report of the HSC Board (April 2010-March 2011).

2 HSC Board "*Report on the Process Evaluation of the Complaints in HSC: Standards and Guidelines for Resolution and Learning*" November 2011.

Contents

3 Cases categorised as obstetrics and gynaecology include cases relating to birthing injury and are therefore related to paediatrics.

Abbreviations

BSO	Business Services Organisation
DHSSPS	Department of Health, Social Services and Public Safety (the Department)
DLS	Directorate of Legal Services
FPS	Family Practitioner Service
GB	Great Britain
HSC	Health and Social Care
HPSS	Health and Personal Social Services
HSS(PPM)	Health and Social Services (Planning and Performance Management)
NIA	Northern Ireland Assembly
NIAIC	Northern Ireland Adverse Incident Centre
NIAO	Northern Ireland Audit Office
NAO	National Audit Office
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
PCC	Patient and Client Council
PHA	Public Health Agency
RCA	Root Cause Analysis
RCN	Royal College of Nursing
RQIA	Regulation and Quality Improvement Authority
SAI	Serious Adverse Incident
SCIE	Social Care Institute for Excellence
UK	United Kingdom

List of figures

Executive Summary

Executive Summary

Introduction

1. The safety of health and social care (HSC) is crucially important. Overall, we enjoy high standards of care from Northern Ireland Health and Social Care Trusts (Trusts). However, adverse incidents, which can and do harm patients or clients, do occur. A small proportion of these incidents will have serious consequences for healthcare patients and social care clients (patients and clients), their families and HSC staff. How Trusts respond to adverse events, learn from them and prevent them happening again is a fundamental aspect of organisational culture. It requires robust reporting systems and a strong safety culture across all HSC services, based on a constant awareness of the potential risk in every action, and a determination to learn from experience.

2. Existing incident reporting systems are already stimulating varying degrees of improvements in patient and client safety and these systems have the potential to form a sound basis for further development and improvement. Also, there is work being carried out to improve the culture within the HSC services, by moving from a traditional blame culture to a just culture, recognising that the origins of most errors are systemic and within the power of the organisation to influence. It is important to balance the need for non-punitive learning with the need to hold staff accountable for their actions.

3. Accurately determining the number of adverse incidents which occur in Trusts is difficult. Not all incidents are reported and currently there is no system to aggregate their number and type. Although studies into healthcare systems outside Northern Ireland also struggle to provide accurate figures on the extent of harm, such evidence as there is strongly suggests that adverse events are a serious problem both in the other NHS regions of the United Kingdom and HSC Trusts in Northern Ireland.

4. Adverse incidents have consequential costs to the HSC system. In the past five years, settlement of HSC negligence claims has cost the Department of Health, Social Services and Public Safety (the Department) almost £116 million. Moreover, the Department estimates that it could cost almost £136 million to meet the compensation costs of all the active negligence claims currently in the system. These figures do not provide a complete picture of the true cost of adverse incidents since they omit many of the costs relating to avoidable harm – not least the cost of providing additional care and medical treatment.

5. This report examines patient and client safety arrangements across Trusts, with a specific focus on the system for managing clinical and social care negligence cases. While the incidence of clinical negligence actions and the cost to the public purse was the initial focus of our review, necessarily the report also considers the wider issue of adverse incidents and the implications they have for quality management. With the language and culture of quality and risk management

permeating the Department's latest *Quality 2020* policy document, we were keen to look more widely at the structures and systems in place to ensure that lessons are learnt from all possible sources: adverse incidents, whistleblowing allegations, complaints and negligence claims.

Main Findings

6. Improving patient and client safety is about ensuring that the HSC system can effectively monitor adverse incidents, anticipate them and minimise harm to patients and clients. However, arrangements to ensure the competency of HSC workers are also central to a comprehensive safety programme. It is particularly important, therefore, that the skills and knowledge of all HSC professionals are assessed regularly to ensure that they are fit to practice. A 2010 survey of HSC staff identified considerable variation in the extent of appraisal across staff groups.

7. Levels of incident reporting are increasing, however, these still fall short of what is expected, particularly within hospitals. More needs to be done to ensure an open culture and to encourage the reporting of adverse incidents or near-misses as a mechanism for learning lessons and driving improvements. In this regard, it is important that staff raising concerns receive feedback on what is being done as a result or, at the very least, why action has not yet been taken.

8. The public expects and deserves safe care. Improved information and data systems are needed to allow HSC bodies to demonstrate the level of patient and client safety of care they offer. Currently, there is no incident monitoring system which collates patient and client safety data across the entire HSC sector. While some regional data is collected on serious adverse incidents and healthcare associated infections, these represent only a proportion of the available patient and client safety data. There is no cohesive management information reporting system capable of delivering, at a regional level, high-quality, routinely available information on patterns, trends and underlying causes of harm to patients and clients. This limits the ability of HSC services to monitor performance and improve patient safety. As a result, there are no high-level performance indicators relating to incident reporting levels or lessons learned and no agreed datasets. Trusts have been unable to benchmark against other Trusts and regional sharing of "lessons learned" has not been as structured and comprehensive as it could be.

9. The publication of *Quality 2020* and the planned development of a Northern Ireland wide, centralised database to record, analyse and report on all adverse incidents across the HSC sector (including Trusts) are important initial steps by the Department to reduce the level of patients and clients who experience harm while in a clinical or social care setting. More effective reporting of patient safety will enable improved accountability.

Executive Summary

10. We note the efforts across the sector to simplify and publicise the complaints process and acknowledge the work undertaken to ensure that individual complaints are dealt with appropriately. Given that it is the outcome of complaints that counts for patients and clients, we consider that, in addition to quantifying the level of complaints, consideration is given to the actual outcome of individual complaints; the extent to which complainants were satisfied with the investigation and the response to their concerns; and the learning generated from complaints.

11. The legal and other costs of settling clinical negligence cases, account for a significant proportion of the overall cost. Over the five year period to March 2012, the Department paid compensation of £77 million to successful claimants. Legal and other costs incurred by both plaintiff and defence over the same period were also paid out of the HSC budget and amounted to just over £39 million.

12. Under current arrangements, patients and clients and their families face considerable distress and pressure when they take legal action to prove negligence against a HSC body. In our view, the introduction of formal dispute resolution procedures which offer a viable alternative to litigation should be addressed so that eligible patients and clients receive compensation in a predictable, timely and fair manner through a system which encourages openness and learning.

13. We acknowledge the efforts of the Directorate of Legal Services in reducing the legal costs of settling compensation cases which have led to financial savings. While we acknowledge that in some smaller cases it may still be appropriate to develop a robust legal defence, we consider that work is required to develop a means through which smaller cases can be settled without the need to incur substantial litigation costs which, on occasion, exceed the level of compensation paid.

Part One:
Introduction and Scope

Part One:
Introduction and Scope

1.1 The Department of Health, Social Services and Public Safety (the Department) estimates that each year, in health and social care (HSC), there are in excess of 15 million key interactions between HSC staff and healthcare patients and social care clients (patients and clients) in the form of appointments, admissions and other interventions. There are over 78,000 people employed in commissioning and delivering the full range of HSC services to Northern Ireland's population of 1.8 million. Attendances at hospitals each year include over 1.5 million outpatient attendances, over 700,000 treatments at Accident and Emergency departments and around 500,000 inpatient or day case admissions. The complexity and scale of the HSC, brought about by advances in technology and treatment regimes alongside a rapid turnover of patients and clients, presents its own challenges for safety in HSC delivery. Appendix 1 sets out details of the organisations responsible for planning, delivering and monitoring HSC across Northern Ireland.

1.2 The Health and Social Care Board (HSC Board) in conjunction with the Public Health Agency commissions HSC services for the public. The main providers of these services are the six HSC Trusts (the Trusts). Each Trust has a statutory obligation to "*put, and keep in place, arrangements for monitoring and improving the quality of the health and social care services it provides to individuals and the environment in which it provides them*"[4]. More recent legislation[5] places a specific duty on each Trust to exercise its functions with the aim of improving the health and well-being of, and reducing the health inequalities between, those for whom it provides, or may provide, health and social care.

The vast majority of those who access HSC services do so without incident

1.3 The vast majority of HSC patients and clients access services without incident. However, no HSC system is risk or error free, and in some cases, things do go wrong. Incidents which could have, or do, result in harm to patients and clients can be categorised according to the degree of harm, or potential harm, they cause.

1.4 In the HSC "*any event or circumstance that could have, or did, lead to harm, loss or damage to people, property, environment or reputation*" is defined as an adverse incident (AI)[6]. This definition acknowledges that not all incidents result in harm, but some do. Where an incident is prevented or avoided, resulting in no harm, this is called a '*near miss*'. AIs can be, but are not always, related to individual human error. Often they are linked to system faults, work environments, technological failures or the complex characteristics of the individual patient's or client's condition or circumstance.

The number and nature of adverse incidents

1.5 Collectively approximately 83,000 AIs are reported each year by HSC organisations in Northern Ireland[7]. This information is retained within individual Trusts, unless the incident is so serious that

4 Health and Personal Social Services (Quality, Improvement and Regulation) (NI) Order 2003
5 Health and Social Care (Reform) Act (NI) 2009, Section 21
6 Procedures for Reporting and Follow-up of Serious Adverse Incidents, HSC Board 2010
7 Figure provided by the Department

it meets the criteria set out in paragraph 1.9 and is, therefore, sub-categorised as a Serious Adverse Incident (SAI). Medicines incidents are amongst the most frequently reported AIs in all Trusts and occur in all stages of the medicines management process e.g. prescribing, administration and dispensing.

1.6 Slips, trips and falls also account for a large number of reported AIs. Only a minority of these result in actual physical injury to the service user. The most common of these types of reported AIs are suspected falls, falls on level ground or falls from a height, for example from a bed or chair.

1.7 Incidents involving violence and abuse are also among the most frequently reported AIs and are sub-categorised to identify, for example, disruptive/ aggressive behaviour, physical abuse or assault, sexual assault and verbal abuse.

1.8 A large numbers of AIs are also reported in other categories such as:

- estates problems, e.g. leaking roof in a facility; security breaches e.g. unauthorised access to Trust premises;
- failure of medical devices to work;
- laboratory investigations, e.g. incomplete blood test request forms;
- information technology problems affecting business continuity e.g. server failure or computer virus;
- issues with patient or client notes e.g. notes unavailable when patient attends a clinic, notes incorrectly filed or illegible entries; or
- patients or clients who abscond from Trust care - including patients who leave hospital without informing staff.

AIs involving medical devices, non-medical equipment and plant and buildings are recorded and investigated by the Northern Ireland Adverse Incident Centre within the Department (see paragraphs 2.8 and 2.9 below).

The number and nature of reported Serious Adverse Incidents (SAIs)

1.9 SAIs are a subset of AIs. Over the period from May 2010 to March 2012, a total of 528 SAIs were reported to the HSC Board. Its procedures[8] advise that an SAI, rather than an AI, has occurred where there is:

- serious injury to, or the unexpected/ unexplained death (including suspected suicides and serious self–harm) of: a service user; a service user known to Mental Health Services (including Child and Adolescent Mental Health Services or Learning Disability) within the last two years; a staff member in the course of their work; or a member of the public whilst visiting a HSC facility;
- unexpected serious risk to a service user and/or staff member and/or member of the public;

8 Procedure for Reporting and Follow-up of Serious Adverse Incidents, HSC Board, 2010

Part One:
Introduction and Scope

- unexpected or significant threat to the provision of services and/or the maintenance of business continuity;
- serious assault (including homicide and sexual assaults) by a service user on other users/staff/members of the public occurring within a healthcare facility or in the community care setting; or
- serious incidents of public interest or concern involving theft, fraud, information breaches or data losses.

Paragraph 3.19 provides details of actual incidents in these categories.

The Department has set the strategic policy context within which a programme for improving the safety and quality of HSC services can be taken forward

1.10 The Department is responsible for setting the strategic policy context within which a programme for improving the safety and quality of HSC services can be taken forward. In 2011, it launched *Quality 2020*[9] which sets out its plans for protecting and improving the quality of HSC over the next 10 years. This is the most recent in a series of key Departmental policy initiatives which have focussed on patient/client safety. Previously, the Department's publication *Best Practice – Best Care, 2001* set out proposals for a framework to improve the quality of services delivered by the Health and Personal Social Services (HPSS) by setting standards (and linking with national standard setting bodies, such as the Social Care Institute for Excellence (SCIE)[10] and the National Institute for Clinical Excellence (NICE)[11]); improving clinical and social care governance; improving regulation of the HSC workforce; introducing a '*duty of quality*'; and establishing the Regulation and Quality Improvement Authority (RQIA) (see paragraph 2.3).

1.11 In 2006, the Department issued *Safety First: A framework for sustainable improvement in the HPSS*, as part of the wider quality agenda. The philosophy and ideas it set out provided an important set of underlying concepts to inform the continued development of the patient safety programme. Its focus was in creating an informed safety culture, raising awareness of risk and promoting timely reporting of AIs, sharing learning, implementing change and investigating SAIs. It identified the four main components of an informed safety culture as: a reporting culture, a just culture, a flexible culture and a learning culture.

1.12 Safety First described an '*open and fair*' organisation as one where staff are not blamed, criticised or disciplined as a result of a genuine slip or mistake that might have lead to an incident. Disciplinary action would, however, follow an incident that occurred as a result of misconduct, gross negligence or an act of deliberate harm. In determining '*blameworthiness*',

9 Quality 2020: A 10-year Strategy to Protect and Improve Quality in Health and Social Care in Northern Ireland, DHSSPS 2011

10 The Social Care Institute for Excellence (SCIE) is an independent charity which gathers and analyses knowledge about what works in care services and translates that knowledge into practical resources, learning materials and services (such as training and consultancy).

11 The National Institute for Clinical Excellence (NICE) provides independent, authoritative and evidence-based guidance on the most cost-effective ways to prevent, diagnose and treat illness and ill health, reducing inequalities and variation.

a fair approach is one that separates the actions of individuals involved from the patient/client outcomes. A '*fair*' culture advocates the systems approach, recognising that incidents may occur as a result of a series of system failures and not a deliberate malicious act on the part of an individual. Rather than blaming individuals, the systems approach seeks to identify the underlying causes of incidents, learn from them and take action to put things right. This approach promotes a culture of openness and transparency and encourages staff to acknowledge errors, investigate the events leading to errors and disseminate any learning gained as a result of investigation.

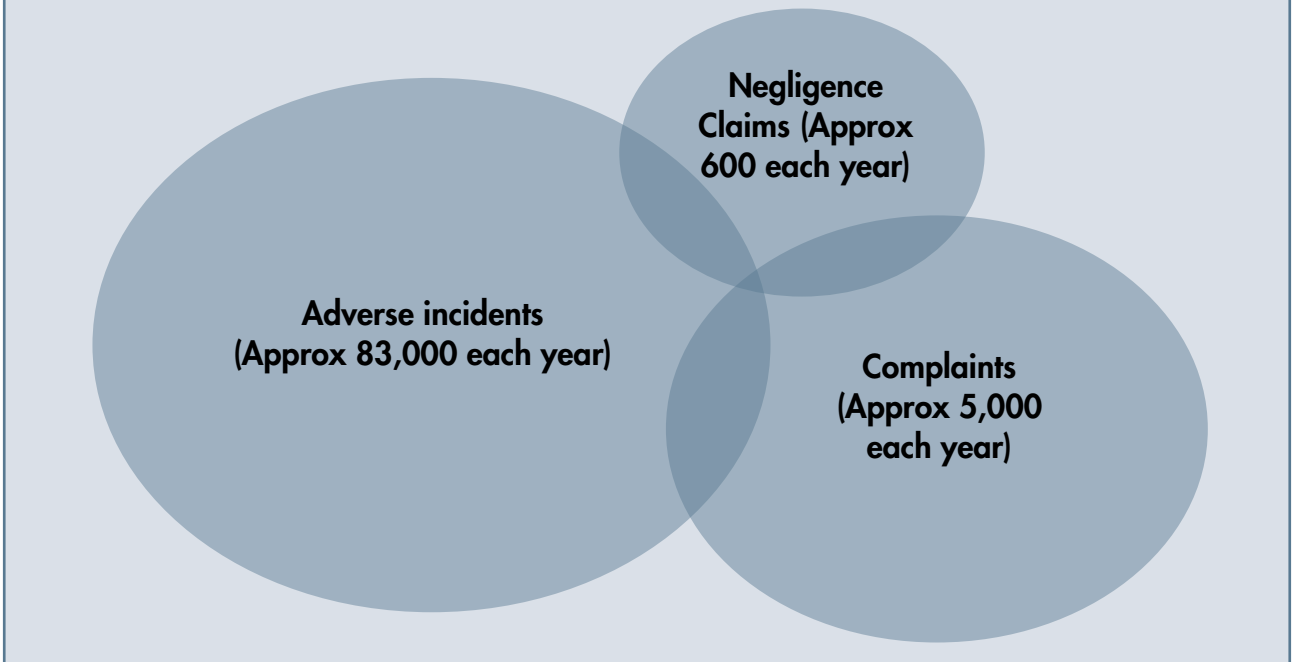
The relationship between complaints, adverse incidence and clinical negligence claims is not straightforward

1.13 The relationship between complaints, AIs and clinical negligence claims, as illustrated in Figure 1, is complicated.

1.14 Figure 1 shows that clinical and social care negligence claims, AIs and complaints are distinct but, in some instances, related concepts. In considering the relationship, it is important to note that:

- whilst the occurrence of an AI may lead to a complaint, the vast majority do not;

Figure 1: Relationship between clinical and social care negligence claims, adverse incidents and complaints



Source: The Department provided the annual numbers in each category.

Note: Figure 1 is purely illustrative. The dimensions used are not representative of the relative numbers and do not accurately reflect the extent of overlap between each of the categories.

Part One:
Introduction and Scope

- not all clinical and social care negligence claims arise as a result of AIs and/or complaints. Some may arise for other reasons, such as, misdiagnosis, missed results, communication issues;

- conversely, complaints and clinical and social care negligence claims may arise where no AI has occurred. This is because complaints and clinical and social care negligence claims are perceptions of treatment from the perspective of claimants and may subsequently be shown to be erroneous; and

- even when an AI has occurred it may not have come about as a result of negligence. Adverse outcomes which are consistent with '*normal*' risk must be borne by the patient.

Where adverse incidents occur, they have the potential to harm patients and clients and to generate additional costs

1.15 By recognising what is going wrong and learning from AIs, many safety issues can be (and are) prevented and the associated costs curtailed. This requires the use of robust reporting systems and the promotion of an informed safety culture across Trusts. Such a culture recognises the potential risk in every action, and instils a determination to learn from a variety of sources, such as:

- AIs (including SAIs and "near misses");

- complaints;

- clinical and social care negligence cases; and

- the experience of others, both nationally and internationally.

1.16 There is no authoritative measurement of the scale of avoidable harm anywhere in the world. In England a retrospective study[12] of patient records in two hospitals, carried out a decade ago, found that 10.8 per cent of patients experienced an AI; of which around half (5.2 per cent) were judged to have been preventable. The authors stated that they could not extrapolate the results with any precision but the findings strongly suggested that adverse events were a serious problem in the NHS. More recently, in 2009, a review[13] of patient notes in one surgical emergency department in England found an AI rate of 11.9 per cent, with potential AIs or "near misses" making up another 13.8 per cent of admissions.

1.17 In terms of the financial outcome of harm to patients and clients, the only actual figure available is the cost of compensation paid out in clinical and social care negligence cases. Figure 2 shows that in the five years to 31 March 2012, the cost of settling negligence claims (i.e. the cost of compensation paid to claimants together with the associated legal and other costs) totalled more than £116 million.

12 Adverse events in British hospitals: preliminary retrospective record review, C. Vincent et al, March 2001, British Medical Journal, 322 (7285): 517-519

13 Quality and safety on an acute surgical ward: an exploratory cohort study of process and outcome, S. Krecher et al, December 2009; 250 (6): 1035-40

Figure 2: The number and cost of Clinical and Social Care Negligence Cases in the period 2007 to 2012

	2007-08	2008-09	2009-10	2010-11	2011-12	Total
Number of Cases at the Year End	2,131	2,868	2,839	2,670	2,640	-
Number of new Cases in year	372	1,124	568	607	633	3,304
Number of Cases Closed in year	354	438	596	778	671	2,837
Number of Cases closed in year with a settlement	129	147	151	184	193	804
Total Cost of Cases	**£18.4m**	**£21.0m**	**£17.0m**	**£31.5m**	**£28.5m**	**£116.4m**

Source: Directorate of Legal Services[14]

Note: 2009-10 was the first full year when all negligence cases were represented by the Directorate of Legal Services (DLS). Prior to July 2008 around 30% of negligence cases were put to private sector solicitors by Trusts.
The figures for 2008-09 include cases managed by private sector solicitors and DLS. In a number of cases, where two or more Trusts were Defendants, each Trust had a separate representation, which accounts for any disparity in balances for those years. The figures for 2007-08 only include cases managed by DLS.

We reported on Clinical Negligence Payments in 2002

1.18 In 2002, our review of clinical negligence payments[15] identified that at 31 March 2001, there were 3,532 clinical negligence compensation cases awaiting resolution. Our report was critical of the absence of a central database of clinical negligence cases; of the time taken to progress negligence claims; and of the extent to which information and experience was shared across the sector. A summary of our recommendations and the actions taken by the Department and HSC organisations is set out in Appendix 2. All our recommendations were accepted by the Department and action has been taken to address each of the points that we raised.

The National Audit Office (NAO) reported on Patient Safety in 2005

1.19 The National Audit Office reported[16] on Patient Safety in 2005 and reinforced the need to learn lessons from previous incidents to avoid reoccurrence. NAO found that, whilst reporting had improved at the local level, progress on developing a national reporting and learning system had been slower than envisaged. Overall, NAO reported that there remained a need to improve evaluation and share lessons or solutions across those organisations involved in patient safety. NAO also identified the need to develop a system to monitor the extent to which lessons are actually learned.

14 The Directorate of Legal Services is the sole provider of legal services for the Health and Social Care Sector (HSC) in Northern Ireland.
15 Compensation Payments for Clinical Negligence, NIAO, July 2002, NIA112/02
16 NAO Report, 3 November 2005, *A Safer Place for Patients: Learning to Improve Patient Safety*

Part One:
Introduction and Scope

Our review examines the safety of services provided by HSC Trusts

1.20 The aim of this review is to examine the extent to which Trusts have been successful in improving patient and client safety by reducing the risk of AIs, especially those resulting in harm. Part 2 assesses the effectiveness of organisational arrangements in place to support the delivery of safer services; Part 3 examines the action taken by Trusts and the Department to improve patient safety, particularly through the use of information, and to reduce the cost burden of patient harm; Part 4 reviews the effectiveness of the specific arrangements in place for dealing with complaints and clinical and social care negligence cases. The methodology used in the review is set out in Appendix 3.

Part Two:
Arrangements for Ensuring Safer Services

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Effective clinical and social care governance and risk management arrangements minimise the risk of harm to patients and clients

2.1 HSC provision is complex and the risk that patients and clients may be harmed can never be mitigated entirely. The major challenge continually faced by Trusts is in identifying and minimising the risk of harm. Effective use of clinical and social care governance and risk management systems, within the wider sphere of corporate governance[17], enables Trusts to monitor, support, evaluate and improve practices.

2.2 Clinical and social care governance, underpinned by the Trusts' statutory duty of quality, is the framework through which HSC organisations (including Trusts) are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment. It is designed to bring together all the components relating to the delivery of high quality care and treatment, such as, risk management, complaints management and AI management for the purpose of improving patient and client safety.

The Regulation and Quality Improvement Authority (RQIA) found that Trusts have prioritised risk management and patient safety

2.3 RQIA is an independent non-departmental public body which was established in 2005[18]. It is charged with overall responsibility for regulating, inspecting and monitoring the standard and quality of HSC services provided by independent and statutory bodies in Northern Ireland. "*Safe and effective care*" is one of the five key quality themes[19] which are the basis for the reviews of HSC services undertaken by RQIA. This theme is sub-divided into three areas: ensuring safe practice and the appropriate management of risk; preventing, detecting, communicating and learning from AIs; and promoting effective care.

2.4 In 2010, as part of a wider review[20], RQIA examined how robust systems of clinical risk management and patient safety were within Trusts. Accountability for patient safety rests with the Chair and Board of each Trust. The review found that, in general, Trusts have prioritised risk management and patient safety and that there is active leadership at Trust Board and senior management level. More specifically RQIA reported that:

- all Trusts have risk management strategies and/or policies. Risks are assessed using standardised approaches and considered at appropriate levels in the organisation. Risk registers are in place at corporate and operational levels;

- all Trusts have established systems for incident reporting and recording. Trusts have put in place a range of

17 Corporate governance systems define the way in which organisations are directed, controlled and led.
18 RQIA was established under The Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003.
19 The Quality Standards for Health and Social Care, DHSSPS 2006
20 In 2010, RQIA worked with the General Medical Council, the NHS Revalidation Support Team, Quality Improvement Scotland and the Healthcare Inspectorate Wales to pilot an approach for independently reviewing medical revalidation procedures within Trusts.

local mechanisms to disseminate learning from incidents, for example through newsletters, or establishment of patient safety working groups to lead and coordinate action in specific areas;

- all Trusts have taken forward specific patient safety initiatives (both local and regional); and

- systems have been established to track progress on implementation of patient safety alerts and ensure action is taken.

The work of the HSC Safety Forum and the Northern Ireland Adverse Incident Centre is integral to the Department's approach to patient and client safety

HSC Safety Forum

2.5 The HSC Safety Forum, funded by the Department, was launched in 2007 and is now part of the Public Health Agency[21] (PHA). It aims to:

- work collaboratively with stakeholders to assist the drive for improvement in safety and quality in the HSC;

- help service providers build and develop their quality improvement capability in line with internationally recognised theory and practice; and

- facilitate engagement between patients and clients, commissioners and service providers in order to promote safety and quality.

The HSC Safety Forum uses a variety of facilitative approaches, which include:

- enhancement of knowledge on safety, quality and improvement science within the HSC system;

- providing exposure to nationally and internationally recognised experts in the field;

- acting as a conduit for the sharing of best practice;

- hosting collaborative working; and

- directly supporting improvement initiatives within HSC organisations.

2.6 To date, the HSC Safety Forum has supported HSC organisations in implementing evidence-based interventions known to save lives and reduce harm. In addition, it works with individuals and organisations who continuously strive to make a difference for patients and clients. The HSC Safety Forum has played a role in:

- implementing the World Health Organisation Surgical Site Checklist[22] in all Trusts;

- regionally reducing ventilator associated pneumonia rates, central line infections and crash calls for cardio-respiratory arrest; and

21 The Public Health Agency was established in 2009 as part of the major reform of health and social care structures in Northern Ireland.

22 The Surgical Site Checklist was designed by the World Health Organisation as part of its Safer Services Save Lives campaign.

Part Two:
Arrangements for Ensuring Safer Services

- encouraging progress on mental health measures.

2.7 The HSC Safety Forum has explored patient safety ideas and themes with the Trusts and patient and client representatives, to ensure that its priorities focus on what is important to patients, clients and the staff who care for them. This work not only supports Trusts in providing safer, more effective, care but saves distress and injury to patients and clients and their families and, in addition, saves on scarce resources. The Department told us that, in aggregate, the Forum has secured savings of £2 million across the HSC sector in the period since 2008. Initiatives have included, reducing the incidence of central line related blood stream infections (securing savings of £240,000 across all Trusts during 2011-12) and reducing the incidence of Ventilator Acquired Pneumonia (generating savings of £270,000 in 2011-12).

Northern Ireland Adverse Incident Centre (NIAIC)

2.8 The Northern Ireland Adverse Incident Centre (NIAIC) records and investigates reported AIs involving medical devices, non-medical equipment, plant and building items used in HSC services, and issues warning notices and guidance to help prevent recurrence and avert injury. In the two years to 31 March 2011, a total of almost 900 AIs were reported by HSC Trusts to NIAIC.

2.9 NIAIC has direct links with the Medicines and Healthcare products Regulatory Agency (MHRA) which collates information on medical device safety across the United Kingdom (UK). It also has links with the Estates and Facilities Division within the UK Department of Health and with several other safety bodies.

The Patient and Client Council was established to provide a powerful, independent voice for service users

2.10 The Patient and Client Council (PCC) was established in April 2009. It offers an independent voice for users of HSC services. It collects user views, encourages users to interact with service providers, provides advice and information and provides assistance (by way of representation or otherwise) to individuals making, or intending to make, a complaint relating to the HSC. Assistance can take the form of helping to write letters of complaint, making telephone calls and attending meetings with complainants. In addition, the PCC works with HSC providers to improve services by providing patient and client input and perspective on quality improvement measures.

The competence of staff providing HSC services impacts on the quality of care provided to patients and clients

2.11 Ensuring the continuing competency of HSC staff is an important step towards creating a safe HSC system. The Department's Quality 2020 document (see paragraph 1.10) states that:

"…increasing levels of competence among HSC professionals will be evidenced through professional revalidation and appraisal."

2.12 Revalidation is a regulatory system designed to ensure that doctors' skills and competence remain at a high standard once they have qualified. Under this system, doctors will be required to produce a portfolio to show how they are actively developing their skills to meet General Medical Council (GMC) standards. Responsible Officers will be appointed and will report to the GMC on individual doctor's fitness to practice, based on a five year revalidation cycle. The Department told us it plans to introduce a new revalidation process in December 2012 to assess whether doctors remain competent and fit to practice.

2.13 The doctor's portfolio of supporting evidence will include patient/client and colleague feedback, compliments, complaints, clinical data and details of training and education courses taken to maintain skills. Doctors will use their portfolio during the appraisal cycle to demonstrate how they meet GMC standards. The Department told us that serious concerns about doctors will be highlighted before the appraisal cycle, through good clinical governance systems. If this happens, the doctor may be required to go through a remediation process[23].

2.14 In 2010, RQIA undertook a review of Trusts' readiness for the introduction of revalidation. The review found that there is a strong commitment in all Trusts to ensuring they have effective systems of appraisal, and Trusts have made good progress towards preparing for revalidation. In those Trusts where appraisal rates had previously been identified by RQIA[24] as low, RQIA found there has been a significant increase in the number of doctors who have undertaken an annual appraisal. In addition, RQIA reported that Trusts have introduced a number of innovative developments to enhance the management and delivery of their appraisal systems.

2.15 In terms of the overall appraisal of staff, the HSC Staff Survey, issued by the Department in 2010, reported that over half of those who responded[25] had received no annual appraisal or review during the preceding twelve months and did not have a personal development plan in place. The survey indicated significant variance in the extent of appraisal across staff groups. For example, 70 per cent of medical and dental staff who responded said that their performance had been appraised, while only 7 per cent of paramedics and 5 per cent of ambulance technicians who responded stated that their performance had been appraised.

2.16 The Department told us that work is progressing across all staff groups to ensure that appraisals are carried out. It also told us that, under current appraisal arrangements, all HSC staff are required to assess their specific development

23 Remediation is the act or process of correcting a fault or deficiency.
24 RQIA, Review of Consultant Medical Appraisal Across HSC Trusts, August 2008.
25 The Survey was issued to 17,500 HSC employees. The overall response rate was 39 per cent, with 6,737 staff participating.

Part Two:
Arrangements for Ensuring Safer Services

needs. For staff under Agenda for Change[26] terms and conditions, use of the Knowledge and Skills Framework will help determine development needs. For staff under medical and dental terms and conditions, development needs will be identified through the Continuous Professional Development (CPD) scheme, appraisal and revalidation.

2.17 All HSC staff must be assessed on a regular basis. In the absence of such assessment, poor performance may remain unchallenged and training and development opportunities may be missed. We recommend that further steps are taken to ensure that the performance of all HSC staff is regularly assessed.

2.18 The Department has told us that it accepts the recommendation and that it will write to HSC organisations asking them to ensure that the performance of all staff is regularly assessed.

26 The Agenda for Change system uses a Job Evaluation Scheme to allocate individual posts to set pay bands. It aims to deliver fair pay for non-medical staff, based on the principle of 'equal pay for work of equal value', provide better links between pay and career progression (by using the Knowledge and Skills Framework); and harmonise terms and conditions of service such as annual leave, hours and sick pay, and work done in 'unsocial hours'.

Part Three:
Building Trusts' Capacity to use Safety-Related Information to Drive Improvement

Part Three:
Building Trusts' Capacity to use Safety-Related Information to Drive Improvement

Identifying patterns, trends and underlying causes of harm is crucial to learning from adverse incidents

3.1 Effective AI reporting contributes to the identification, management and minimisation of risk and ensures that all possible lessons are learnt and shared. Collating and analysing all available information on AIs helps identify safety risks which may result in clusters or trends over time.

Trusts' AI management information systems

3.2 Individually, Trusts maintain an AI reporting database to record and analyse HSC incidents. Trusts' internal systems aggregate the number and type of reported AIs. Data from these databases are used to report performance to Trust Boards as part of their clinical and social care governance arrangements. While Trusts gather AI data in this way, only data on SAIs (a small subset of AIs) are reported and analysed regionally. Data on the wider category of AIs are currently not collected or analysed on a regional basis.

HSC-wide SAI reporting system

3.3 The SAI reporting system was first introduced by the Department in July 2004[27]. In May 2010, responsibility for managing the system transferred to the HSC Board. To coincide with the transfer, the Department issued guidance[28] on a new Early Alert System which ensures that the Department receives prompt and timely notifications of actual and potential events which may require urgent attention or action. The Department told us that the SAI reporting system was designed to complement existing local and national reporting systems. It is not a performance management tool but raises awareness of, and actively encourages, reporting and learning so that the quality of services improves.

3.4 Since its introduction, HSC bodies have been required to formally report details of each SAI which occurs. This requirement does not eliminate the requirement for bodies to report SAIs to other statutory agencies and external bodies[29].

3.5 SAI information submitted to the HSC Board (and previously to the Department) is collated and learning points are identified and disseminated across the sector. During the period from July 2004 and April 2010, when the Department was responsible for managing the SAI system, it produced three Supporting Safer Services reports relating to reported SAIs. Since responsibility for the system transferred to the HSC Board, it has produced two "*Learning*" reports. Both types of reports are produced to support and promote the implementation of regional learning identified from SAIs. Figure 3 shows that between July 2004 and March 2012, 2,084 SAIs were reported.

27 DHSSPS Circular HSS (PPM) 06/04 introduced the serious adverse incident reporting system.
28 DHSSPS Circular HSC (SQSD) 10/2010, effective from 1 June 2010.
29 Serious adverse incidents must be notified to the HSC Board but requirements are also in place to ensure notification (as appropriate) to other statutory agencies and external bodies, such as, the Health and Safety Executive Northern Ireland (HSENI), the Pharmaceutical Society Northern Ireland, the Northern Ireland Adverse Incident Centre, Regulation & Quality Improvement Authority and/or the National Confidential Enquiries into Patient Outcomes and Death.

Figure 3: Reported Serious Adverse Incidents (SAIs)

Year	Number of Reported SAIs
July 2004 to December 2005	235
January 2006 to March 2007	306
April 2007 to December 2007	263
January 2008 to December 2008	397
January 2009 to December 2009	287[1]
January 2010 to March 2011	301
April 2011 to March 2012	295
TOTAL	**2,084**

Source: Supporting Safer Services Reports June 2006, December 2007 & September 2011 and the HSC Board
Note1: There was a decrease in reported SAIs as a result of the removal of certain categories of incident from the Department's SAI reporting system[30].

Root Cause Analysis is used by Trusts to investigate the circumstances surrounding SAIs

3.6 Intelligent data analysis requires a sound incident classification scheme. If useful information is to be elicited from SAI reports (which will tend to contain principally narrative information), then the data will need to be converted. Such data conversions require a certain level of sophistication. Root Cause Analysis (RCA)[31] is often the key to unlocking learning from adverse incidents. The Department told us that Trusts have been using this tool to undertake in-depth analysis of SAIs to learn lessons and we note that the Department has issued guidance in this area[32].

3.7 In our view the guidance on use of RCA could be more explicit, advising, for example, on the need to consider the proportionality of individual cases. In addition, we noted that the results of completed RCAs are not collated regionally. In our view, consolidation would facilitate the identification of regional patterns and trends.

3.8 We recommend that the Department reviews the guidance issued to Trusts advising on the proportionate use of incident investigative techniques, such as RCA. In addition, the Department should advise Trusts of the need to ensure that appropriate training is made available to those carrying out RCAs. Further, we recommend that the Department

30 DHSSPS Circular HSC (SQSD) 9/2009 advised health and social care bodies that from 1 April 2009, suspected suicides were not to be reported through the Serious Adverse Incidents reporting system but were to be formally notified to RQIA. From May 2010 SAIs involving suspected suicides are to be reported to both the HSC Board and RQIA. Also, HSC bodies were advised that, in order to avoid duplication, the admission of under 18 year olds to adult mental health/learning disability facilities was to be notified to the HSC Board through systems other than the SAI reporting system.

31 Root Cause Analysis is a method used to examine the circumstances of a given situation in order to identify the "root cause" of the outcome.

32 HSS(MD)12/06 How to Classify Incidents and Risk; HSS(SQSD) 18/07 Conducting Patient Safety Reviews/ Lookback Exercise' HSC(SQSD) 34/07 HSC Regional Template & Guidance for Incident Review Reports (includes reference to Seven Steps to Patient Safety: A Guide for NHS staff - NPSA, 2004 (including the RCA tool kit)).

Part Three:
Building Trusts' Capacity to use Safety-Related Information to Drive Improvement

develops a methodology for aggregating the results of all RCAs so that, at a regional level, patterns and themes can be identified.

3.9 The Department told us that it has already commenced a review of the relevant guidance.

There is likely to be significant under-reporting of SAIs

3.10 The Department's 2007 SAI Report[33] (see paragraph 3.5) noted that, of the 306 SAIs reported during 1 January 2006 to 31 March 2007, just over 20 per cent were reported from an acute HSC setting (and almost half of which were from the acute mental health services). This had increased to 35 per cent by 2011[34]. Data available on SAIs reported in England and Wales in 2009[35], showed almost three quarters of SAIs reported were from an acute/general hospital setting. The Department has acknowledged[36] that comparing this with the reporting pattern locally suggests that "*there continues to be under-reporting of incidents from this setting in Northern Ireland*". Nevertheless, the Department considers that the year-on-year increase in local SAI reporting suggests an increased awareness of, and commitment to, SAI reporting on the part of HSC organisations.

3.11 According to the National Audit Office in 2005 (see paragraph 1.19), Trusts in England estimated that, on average, around 22 per cent of AIs and a further 39 per cent of near misses go un-reported. The subsequent Westminster PAC report[37] found that incidents leading to serious harm (SAIs) were among the least likely to be reported and that doctors are less likely to report an incident than other staff groups.

3.12 An informed safety culture which encourages the reporting of incidents and is '*open and fair*' (paragraph 1.12) is essential to the success of data collection and subsequent improvement in activity, systems and care. In our view, the Department and Trusts are working to improve their safety culture however, the fact that there is under-reporting suggests that HSC bodies need to better promote timely and open reporting at an organisational and individual level. Quality 2020 includes *Transforming the Culture* as one of five key strategic goals. Through this, the Department intends to make achieving high quality a priority at all levels in the HSC sector and to promote and encourage partnerships between staff, patients, clients and carers to support decision making.

3.13 There are a number of reasons why under-reporting arises. The persistence of a perceived "*blame culture*", for example, can undermine staff's willingness to report. The most recent HSC Staff Survey (2010) showed that 41 per cent of staff responding to the survey did not agree that their organisation blamed or punished people who are involved in errors, near misses or incidents. However, 12 per cent

33 DHSSPS, Supporting Safer Services Report 2007.
34 DHSSPS, Supporting Safer Services Report 2011.
35 Quarterly National Reporting & Learning System data summary, Issue 14: July 2009 to November 2009.
36 Supporting Safer Services Report, DHSSPS September 2011.
37 Committee of Public Accounts – "A safer place for patients, learning to improve patient safety". Fifty-first Report of Session 2005-06, HC 831.

of staff took the contrary view while 44 per cent neither agreed nor disagreed that staff would be blamed for reporting an AI.

3.14 Across the UK, over 410,000 nurses, student nurses and healthcare assistants are registered as Royal College of Nursing (RCN) members. The RCN's mission is to represent nurses and nursing, promote excellence in practice and shape health policies. As part of our audit, we asked the RCN in Northern Ireland whether it considered that nurses felt comfortable raising concerns about patient safety. While it assured us that Northern Ireland nurses are fully aware of their professional responsibility to raise concerns about patient safety and standards of care, it told us that, in its view, there remains a certain level of reluctance about raising concerns among nursing staff. However, the Department told us that, in accordance with HSC Terms and Conditions (which in turn reflect those applicable to the NHS elsewhere in the United Kingdom), all employees working in the HSC have a contractual right and duty to raise genuine concerns they have with their employer about patient safety, malpractice, financial impropriety or any other serious risks they consider to be in the public interest. Recent guidance issued by the Department to all HSC staff has reinforced the point that all HSC organisations should promote a culture which encourages staff to raise concerns openly on the basis that such issues will be addressed properly and fairly.

3.15 The increased willingness of HSC staff to report SAIs is welcomed and represents a positive step towards developing an informed safety culture across the sector. However, the Department accepts that the under-reporting of incidents is a matter of concern. We recommend that the Department gives further consideration as to how best to encourage the reporting of all incidents. In our view, Trusts need to stress the importance of reporting and training to all groups of staff and encourage a culture of openness so that reporting levels increase. Staff should be regularly informed about changes that are made as a result of incidents they report. Factors which might improve reporting include: providing prompts for staff on areas to consider when filling out reports; encouraging a broader range of staff groups to report; and informing staff about changes to practice that have been made because of the incidents they report.

3.16 The Department has told us that it accepts this recommendation and reported that it is taking this forward through the Regional Adverse Incident and Learning (RAIL) project (see paragraph 3.24).

3.17 In order to demonstrate improvements in the safety culture over time, we recommend that the Department makes use of available tools[38] to regularly assess the safety culture of organisations and periodically publishes the results of such an approach.

38 *Measuring Safety Culture*, The Health Foundation, February 2011 provides details of a range of tools including: the Safety Attitudes Questionnaire; Patient Safety Culture in Healthcare Organisations; Hospital Survey on Patient Safety Culture; Safety Climate Survey; and Manchester Patient Safety Assessment Framework. In addition, the European Union Network for Patient Safety has produced a "Patient Safety Culture Report – focusing on indicators".

Part Three:
Building Trusts' Capacity to use Safety-Related Information to Drive Improvement

3.18 The Department has told us it accepts this recommendation and reported that planning for this commenced as part of Quality 2020 in April 2012.

Regularly reporting on SAIs facilitates learning and has the potential to improve patient safety

3.19 Since May 2010, a total of 528 SAIs have been reported to the HSC Board; the most common of which fall under the following categories:

- **Suicide (suspected or proven)**
  The most common category of SAI relates to the suspected or actual suicide of a patient or service user and this accounts for 34 per cent of the total SAIs reported. In most circumstances these will be suspected or actual suicides of patients/ service users who are living within the community but who have been in contact with mental health services within two years of the incident occurring.

- **Unexpected/Unexplained Death**
  Unexpected/unexplained deaths account for eight per cent of total SAIs reported. An example of this type of incident would be the death of a patient/service user living in the community who may be known to HSC services for drug and alcohol addiction but at the time of notification, cause of death could not be determined.

- **Information Governance**
  SAIs in this category may relate to corruption of patient records or data due to an IT problem, the loss or theft of patient records or confidential information from a healthcare facility or member of healthcare staff. These account for five per cent of the total of SAIs reported. For example:

  - in February 2011, an independent inquiry at Belfast School of Dentistry in the Royal Hospital within the Belfast HSC Trust concluded that, inter alia, there was a significant problem with the availability and completeness of patient records. It considered that the deficiencies had the potential to have a significant adverse impact on the quality of patient care.

- **Violence and Abuse**
  Violence and Abuse accounts for 13 per cent of all reported SAIs and occurs most commonly within mental health, childcare and learning disability facilities. These SAIs include serious assaults (including homicide and sexual assault) by service users on other service users, staff or members of the public.

- **Other Categories**
  Other categorises of SAIs account for 35 per cent of the total and include, for example, incidents from acute services, maternity services, family and childcare and infection control. Recent examples include:

- in March 2011, a public inquiry concluded that the handling of an outbreak of clostridrium difficile was linked to 31 deaths during 2007-08. The Department was alerted to the possibility of an increase in cases in October 2007, following normal surveillance procedures. The report identified management weaknesses and communications problems within the Northern HSC Trust at the time of the outbreak.

- between November 2011 and January 2012, an increase in cases of pseudomonas aeruginosa resulted in the death of one baby in the neo-natal unit of Altnaglevin Hospital (Western HSC Trust) and three babies in the neo-natal unit of the Royal Victoria Hospital (Belfast HSC Trust). This was reported as an early alert to the Department on the 17 January 2012 by the Belfast HSC Trust.

- **Family Practitioner Services**
  Four per cent of reported SAIs originate from within the Family Practitioner Services, including the General Medical Service, Pharmacy, Optometry and Dentistry. Examples include the loss or theft of prescriptions or drugs.

3.20 We recognise the benefits in highlighting risks and identifying good practice through the regular reporting of SAIs. Given their value to learning and improving patient and client care and safety, we recommend that the reports on SAIs, in their current form, are produced on a consistent and more timely basis and are made publicly available.

3.21 The Department told us it accepts this recommendation and will ensure that in future all learning reports are made publicly available.

The recording and monitoring of adverse incidents could be improved

3.22 We recognise that a regional process for reporting, managing, analysing and learning from **serious** AIs is in place. However, there is, currently no cohesive management information reporting system capable of delivering, at a regional level, high-quality, routinely available information on patterns, trends and underlying causes of harm to patients and clients from the wider category of AIs.

3.23 Since 2003, the Department of Health in England has operated a National Reporting and Learning System (NRLS)[39] - a central database of patient safety incident reports from across England and Wales - to support the development of improved patient safety solutions at a national level. The Department told us that patient safety alerts are cascaded by NRLS to all relevant organisations and clinical specialties, including NIAIC, for consideration and dissemination as appropriate.

3.24 The Department also told us that the Public Health Agency (PHA) is currently

39 In June 2012, the key functions of the National Patient Safety Agency (NPSA) transferred to the NHS Commissioning Board Special Health Authority. As an interim measure, the Imperial College Healthcare Foundation Trust has taken on temporary responsibility for operational management of the NRLS for a two year period from April 2012.

Part Three:
Building Trusts' Capacity to use Safety-Related Information to Drive Improvement

preparing a business case to develop a Northern Ireland wide, centralised database (the Regional Adverse Incident Learning (RAIL) system) to store, analyse and report on aggregated data emanating from all AIs (including SAIs and near misses) from across all HSC organisations so that the causal and contributory factors in patient and client safety can be assessed. RAIL will aim to address the gap in regional patient and client safety data by:

- maximising the reporting of AIs (including near misses);
- ensuring that learning from all incidents and near misses, where relevant, is identified across the HSC;
- providing a mechanism to share learning from AIs in a meaningful way within the HSC; and
- ensuring that learning from AIs is put into practice in a timely manner.

3.25 The Department's plans to improve the AI reporting systems across the HSC are encouraging but, in the interim, the absence of comprehensive information limits the ability of Trusts to monitor and improve patient and client safety. The inability to aggregate this type of data at a regional level means that there are no high-level performance indicators relating to incident reporting levels or lessons learned and no agreed datasets. Trusts have, therefore, been unable to benchmark against other Trusts and regional sharing of "lessons learned" has not been as structured and comprehensive as it could be.

3.26 An undertaking has been given in Quality 2020 that the HSC Board, the PHA and Trusts will work with the PCC, RQIA and others to "….*devise a set of outcome measures, with quality indicators focused on* ***safety****, effectiveness and patient/ client experience*". In order to secure the progress planned for in *Quality 2020*, it is crucial that the Department ensures that patient safety goals, priorities and targets are supported, as soon as possible, by a robust data collection and reporting system.

3.27 Identifying suitable information to evaluate performance against safety goals will, to some extent, vary in nature by the type of services being provided. For example, the types of issues facing a mental health unit will be very different to those faced by the ambulance service or district nursing service. However, there are some generic measures that, with some adaptation, are suitable for measurement in most types of HSC setting or service.

3.28 Appendix 4 provides some general pointers on the types of system-wide and driver-level information and tools that Trusts can and, in some instances already do, incorporate within their governance model for safety. Some of the proposed indicators rely on data that is already collected regionally, others are not yet part of a regional dataset. This information can be used to measure improvement over time within an organisation.

3.29 Despite the volume of incident reporting, the HSC Board and Trusts are not yet producing high quality, routinely available information on patterns, trends and underlying causes of harm to healthcare patients and social care clients. Whatever regional reporting option the Department eventually decides on (based on the outcomes of the PHA business case), we recommend that it identifies the sources of risk and harm to patients at a local and regional level. It must simplify and encourage reporting and have an ability to analyse risk-prone situations and anticipate AIs. Moreover, as a medium-term aim, the issues emerging from patient safety data should be more directly linked to establishing regional reduction goals and targets. Towards these ends, we recommend that the system:

- captures accurate and complete information about all potential and actual patient harm which has occurred. Of particular importance is the inclusion of contributory or contextual factors such as where and when the incident occurred, what happened, the likely severity of avoided or actual outcomes, contributory factors, as well as reporters' narratives that will reveal the underlying system failure. This approach will yield the most powerful information relating to causality and future prevention;
- is used to provide analysis and feedback to the HSC (including Trusts) in order to ensure that lessons are learned and models of best practice are implemented effectively;
- is accepted by all HSC staff as an effective reporting system; and
- has controls in place to ensure that, at organisation level, reporting, investigating, monitoring, feedback, learning and management of all AIs is discharged effectively and is a priority of Management Boards.

3.30 In addition, it is also important that this system interfaces with other bodies and activities that gather different sources of data, such as complaints, negligence cases (see Part 4), whistleblowing allegations, RCA and coroners' reports and to ensure that all serious harm and deaths associated with AIs are identified. As a result, information on AIs will become an invaluable source of information and feedback on the standard of care being provided across the HSC sector.

3.31 The Department has told us it accepts this recommendation and reported that it has been working to achieve these outcomes through the development of the Regional Adverse Incident and Learning (RAIL) project since 2010.

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

Patients or clients dissatisfied with the quality of treatment or care received, may submit a complaint

4.1 Effective complaints handling is an important aspect of clinical and social care governance arrangements and, as such, helps HSC organisations to continue to improve the quality of their services and safeguard high standards of care and treatment. Complaints are seen as a significant source of learning within the HSC and provide opportunities to improve outcomes for patients and clients, the quality of services and the patient and client experience.

4.2 The HSC Complaints Procedure[40] defines a complaint as "an expression of dissatisfaction that requires a response". Under these arrangements Trusts are required to:

- promote access to and raise awareness of the HSC Complaints Procedure (by issuing posters, leaflets etc);
- support complainants and staff;
- investigate, and respond to, all complaints received;
- collate and record complaints centrally;
- monitor and learn from complaints; and
- report internally to senior management and externally to the public (e.g. through the Trust annual complaints reports) and the HSC Board.

Since the introduction of the revised complaints procedures in 2009, the HSC Board has published two annual reports[41] on complaints handling by HSC bodies

4.3 The HSC Board is required to monitor how it, or those providing care on its behalf, deal with and respond to complaints. This involves regularly reporting on complaints and monitoring complaints processes, outcomes and service improvements. The HSC Board is required to produce an Annual Report on complaints outlining the number of complaints received, the categories to which complaints relate and the response times.

4.4 The HSC Board has published two annual complaints reports since the launch of the new guidelines in 2009. These reports show that each year, around 5,000 complaints are raised against Trusts by those who have accessed HSC services. Trust complaints statistics are recorded against the individual Programmes of Care to which they refer, for example, acute services, maternity and child health and elderly services.

4.5 The HSC Board's Second Annual Report (2010-11) shows the highest number of complaints received are attributable to acute services (60 per cent), maternal and child health (6 per cent) and primary health and adult community (6 per cent). Complaints statistics are

40 Guidance is contained in Complaints in HSC: Standards and Guidelines for Resolution and Learning (2009); HSC Complaints Procedure Directions (2009).

41 First Annual Complaints Report of the HSC Board (1 April 2009 to 31 March 2010) and Second Annual Complaints Report of the HSC Board (April 2010 to March 2011).

further categorised under 26 subject areas, for example, clinical diagnosis, confidentiality, delayed admissions, and so on. Figures show the top three subject areas for complaints against Trusts as the quality of treatment and care, staff attitude or behaviour and communication/ information to patients.

An evaluation of the complaints procedure published in February 2012[42] raised several concerns relating to complaints handling

4.6 In February 2012, the HSC Board published the findings of its process evaluation of the HSC Complaints Procedure. The evaluation, commissioned by the Department, sought to measure the extent to which the new complaints procedure had been implemented and to identify any weaknesses in the arrangements. The HSC Board found that HSC bodies had taken significant steps to implement the principles of the guidance, that there is a high level of awareness of the complaints procedures among staff and service users, and confirmed that there is evidence of learning from complaints across the HSC.

4.7 However, the evaluation revealed that:

- there appeared to be uncertainty (among staff and service users) with regard to the roles and responsibilities of the various HSC organisations in relation to complaints;
- effort is still required to efficiently achieve more robust local resolution arrangements, including the adoption of alternative methods of complaints resolution;
- complainants felt that they are not always informed of improvements to services or changes in policy or procedure as a result of their complaints; and
- some service users felt reluctant to complain for fear of reprisal[43] and had issues with the time taken to respond and the quality of responses.

4.8 The Report, approved by the Department, contained 14 recommendations for improvement which are set out at Appendix 5. The HSC Board is currently finalising an Action Plan to take these forward across the HSC.

4.9 We note the efforts made across the sector to simplify and publicise the complaints process and acknowledge the work undertaken to ensure that individual complaints are dealt with appropriately. We acknowledge the Department's commitment, through its evaluation process, to ensuring a fully functioning and effective procedure and recommend that it works with the HSC Board towards the implementation of the recommendations arising from the HSC Board's Evaluation Report (2011) especially those focussing on the measurement of outcomes. Given that it is the outcome of complaints that counts for patients and clients, we consider that, in addition to quantifying the level of complaints, consideration

42 HSC Board "*Report on the Process Evaluation of the Complaints in HSC: Standards and Guidelines for Resolution and Learning*" November 2011.

43 Similar reprisal concerns were identified in England. The House of Commons Health Committee reported in 2010 that only 5 per cent of those who are dissatisfied with the treatment or care they receive complain about the health and social care body.

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

should be given to the actual outcome of individual complaints; the extent to which complainants were satisfied with the investigation and the response to their concerns; and the learning generated from complaints.

4.10 The Department told us that it accepts this recommendation and is working closely with the HSC Board and other HSC organisations to address these issues.

There has been long-running interest and concern surrounding the incidence, cost and time taken to resolve negligence cases against the HSC

4.11 The existing clinical negligence framework in Northern Ireland is based on tort, which is fault-based i.e. a breach of a civil duty to a person or persons must be established. In order to successfully bring a case against the HSC, a claimant must prove that the practitioner or organisation failed to adhere to accepted standards of care and treatment. That is, the claimant must prove that no competent practitioner from the same specialty would support or endorse the care or treatment provided.

Northern Ireland Audit Office Report 2002

4.12 In 2002 we reported[44] on the financial cost and management of clinical and social care negligence cases and concluded that:

- the potential financial burden of negligence cases was increasing;
- the Department needed to compare compensation costs in Northern Ireland against those in Great Britain;
- litigation (legal proceedings through the courts) may be an inefficient way of addressing critical medical mishaps; and
- the average time taken to settle claims should be capable of being shortened.

The cost of defending and settling clinical and social care negligence claims is substantial

4.13 Figure 4 shows that over the 5-year period to March 2012, the cost of defending and settling clinical and social care negligence cases amounted to £116 million. In 2011-12 alone, the cost of clinical and social care negligence cases amounted to £28.5 million. Of this, £18.1 million was paid in compensation to plaintiffs while the remaining £10.4 million related to legal and other costs. In the past five years, over one third of the total costs of settling clinical and social care negligence cases, related to legal (both plaintiff and defence) and other costs.

44 Compensation Payments for Clinical Negligence, NIAO July 2002, NIA 112/02

Figure 4: Costs of cases over the period 2007-08 to 2011-12[1]

	2007-08 £ (%)	2008-09 £ (%)	2009-10 £ (%)	2010-11 £ (%)	2011-12 £ (%)	TOTAL £ (%)
Compensation Paid	11,995,199 (65%)	13,773,533 (65%)	9,608,533[2] (56%)	23,491,112 (75%)	18,146,021 (63%)	77,014,398 (66%)
Plaintiff costs	3,755,031 (20%)	4,168,686 (20%)	4,416,508 (26%)	3,989,247 (13%)	7,120,397 (25%)	23,449,869 (20%)
Defence cost (excl DLS)	1,956,797 (11%)	2,250,730 (11%)	1,859,775 (11%)	2,975,553 (9%)	2,157,743 (8%)	11,200,598 (10%)
DLS	666,967 (4%)	814,870 (4%)	1,123,184 (7%)	1,064,198 (3%)	1,106,031 (4%)	4,775,250 (4%)
TOTAL	**18,373,994**	**21,007,819**	**17,008,000**	**31,520,110**	**28,530,192**	**116,440,115**

Source: DLS

Note 1 2009-10 was the first full year when all negligence cases were represented by the Directorate of Legal Services (DLS). Prior to July 2008 around 30% of negligence cases were put to private sector solicitors by Trusts.

Note 2 DLS explained that in 2009-10, there were fewer large settlements and, as a result, the compensation paid in that year is significantly lower than in other years. Further, since 2010, a larger number of cases have been listed for Hearing (as a consequence of tighter judicial management).

Estimates of the potential total cost of settling outstanding clinical and social care negligence cases increased by almost 20 per cent in the five year period to 31 March 2012

4.14 Estimates of the likely cost of settling outstanding claims are included in the Trusts' and Department's annual accounts. These estimations (shown in Figure 5) are based on the number of claims which might succeed, the circumstances of each claim and how much would be paid out to plaintiffs as a result. The estimated cost of settling all outstanding cases increased by 18 per cent from £114.7 million to £135.9 million over the five years to 2011-12. The actual cost of settling claims increased by 50 per cent over the same period.

Figure 5: The actual cost of settling cases each year and the potential cost of settling all outstanding cases

Year	Actual Cost of Cases Settled in the Year £m	Estimated Cost of Settling those Cases Outstanding at 31 March £m
2007-08	18	114.7
2008-09	21	105.5
2009-10	17	115.1
2010-11	32	140.6
2011-12	29	135.9

Source: Trusts' and Department's Accounts

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

4.15 If patients or clients are harmed during the process of receiving care, it is right that they are entitled to recompense. However, it is important to strike the proper balance between access to compensation claims and ensuring costs are proportionate, sustainable and affordable. The increase in provision for clinical negligence claims and the compensation paid out annually demonstrates that this is a key risk to HSC expenditure. In a time when services are so financially constrained, any escalation in these costs can mean that less money is available for the HSC. The actions the Department and Trusts have been taking to address the risk posed by clinical error are covered in Part 2 of this report.

The number of outstanding negligence cases has decreased substantially over the last 10 years

4.16 Figure 6 shows that, in recent years, more negligence claims have been closed than opened – evidence of the success of the concerted effort which has been made to progress cases as quickly as possible. As a result, the overall active caseload has decreased. In April 2011, there were 2,670 active clinical and social care negligence cases. Ten years earlier, in April 2001, there were 3,532 active cases – a reduction of just under 25 per cent. A breakdown of the caseload by Trust shows that one-third of the cases relate to the Belfast Trust (Appendix 6), which is one of the largest Trusts in the UK. The closure of a claim does not necessarily imply a cost to the Department, as many negligence claims which have little chance of succeeding in court are closed without payment to the plaintiff. The number of paid claims is substantially lower than the number of closed claims: of the 1,374 claims closed between 2009 and 2011 (Figure 6), only 326 (24 per cent) resulted in compensation being paid (Figure 7).

4.17 The level of compensation paid in settled cases varies considerably depending on the individual circumstances of each case. In the two years to 31 March 2011, clinical and social care negligence compensation (excluding legal costs) cost just over £33 million. Figure 7 below sets out details of the range of payments made in settled cases and shows that the majority of claims result in compensation

Figure 6: Comparison of active caseload at 30 April 2011 against active caseload 10 years earlier at 30 April 2001

	1999-00[1]	2000-01[1]	2009-10[2]	2010-11[2]
Number of cases at year end	3,303	3,532	2,839	2,670
Annual number of new cases	555	708	568	607
Annual number of closed cases	422	479	596	778

Sources: 1 NIAO 2002 report; 2 DLS

Figure 7: Level of clinical and social care negligence compensation paid in the two years to 31 March 2011

Amount of Compensation (excluding legal costs)	Number of Claims[1]
£5,000 or less	87
£5,001 - £10,000	45
£10,001 - £50,000	136
£50,001 - £500,000	48
Greater than £500,000	10
TOTAL	**326**

Source: DLS

Note 1: The number of "claims" quoted above does not match the total number of "cases" (335) recorded in Figure 2. This is because an individual claim may cover care provided by a number of Trusts and therefore result in DLS recording multiple cases.

of £50,000 or less, with relatively few claims resulting in high compensation settlements.

Some specialties, for example obstetrics and gynaecology[45], tend to result in the highest settlement costs, reflecting the relative risks involved in these specialties

4.18 Figure 8 provides a breakdown of clinical and social care negligence claims categorised by medical specialty. Claims outstanding at 31 March 2011 related to over 40 specialties. The largest proportion of claims (25 per cent) related to Obstetrics and Gynaecology. A further 17 per cent of claims arose from Accident and Emergency.

Figure 8: Clinical and Social Care Negligence claims by specialty

Specialty	% and (number) at 31 March 1999[1]	% and (number) at 31 March 2011[2]
Obstetrics and Gynaecology	27% (856)	25% (634)
Accident and Emergency	17% (539)	17% (425)
General Surgery[3]	13% (412)	12% (302)
Trauma[3] and Orthopaedics	6% (190)	10% (246)
General Medicine	5% (159)	6% (147)
Paediatrics	4% (127)	3% (83)
Other	15% (475)	24% (624)
Unclassified/Not Known	13% (412)	3% (83)
TOTAL	**3,170**	**2,544[4]**

Source: [1]NIAO 2002 report; [2]DHSSPS

Note: 3 General Surgery is now classified as Surgical, and Trauma is now classified as Emergency Medicine
Note: 4 The Department's figure at 31 March 2011 does not agree with the figure provided by DLS (2,670 – see Figures 2 and 6) due to timing and definitional differences.

45 Cases categorised as obstetrics and gynaecology include cases relating to birthing injury and are therefore related to paediatrics.

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

4.19 The higher relative risk of certain specialties is reflected in the cost of settlements. Figure 9 shows the cost (including compensation, legal and expert costs) of claims settled in the two year period to 2011.

It took us a considerable length of time to compile comprehensive information on negligence cases across the HSC sector

4.20 In our 2002 report, we identified that although Trusts had been required to maintain a comprehensive database on negligence cases since 1998, not all Trusts could provide such information. The Department undertook to ensure that detailed information on outstanding claims would be held by the individual HSC bodies and held centrally. Despite this, we found it difficult to obtain comprehensive information on the total cost and the nature of clinical and social care negligence cases over the period from 1 April 2007 to 31 March 2009.

4.21 Since 2009-10 and later, comprehensive information on all negligence cases is available from the HSC Business Services Organisation (through DLS)[46]. DLS does not have comprehensive information where, prior to that date, cases were handled by private sector legal practices. The Department holds information on 2004-05 and 2005-06 cases and on cases opened since 1 April 2010 but does not have information for the intervening periods. Individual Trusts have some information on claims relating to care they provided but were unable to provide us with complete information on:

Figure 9: Summary of the numbers and costs of case settlements for 2009-11 by Specialty

Specialty	Numbers of cases (%)[1]		Costs (%)[2] £'000s	
Obstetrics & Gynaecology	64	(18%)	£16,406	(36%)
Paediatrics	10	(3%)	£5,271	(11%)
A&E	52	(14%)	£4,102	(9%)
Paediatric Cardiology	1	(<1%)	£3,901	(9%)
Paediatric Surgery	1	(<1%)	£3,610	(8%)
General Surgery	36	(10%)	£2,245	(5%)
Other Specialties	196	(54%)	£9,921	(22%)
TOTAL	**360**	**(100%)**	**£45,456**	**(100%)**

Source: DLS

Note: 1 The number of cases shown here is greater than that in Figure 7 because the Directorate of Legal Services (DLS's) database records cases where two or more specialties are cited against each of the named specialties; in these cases the costs have been split equally across each of the named specialties to avoid double counting.

Note: 2 The costs of the DLS are excluded from these figures.

46 In July 2008 the Minister for Health directed that the Directorate of Legal Services would be the HSC's legal services providers for all professional [medical] and social care negligence cases (and other areas). This followed the discovery of fraudulent activity, perpetrated on several HSC bodies by George Brangam, principal partner in the partnership of solicitors operating under the name of Brangam Bagnall & Company – see *Contracting for Legal Services in the Health & Social Care Sector* – Memorandum to the Public Accounts Committee of the Northern Ireland Assembly, NIAO December 2008.

- cases where treatment of care was provided by legacy Trusts[47];
- the length of time taken to settle individual claims;
- the age and status of on-going claims; or
- the specialism and incident types involved in current cases.

4.22 Despite an undertaking in response to our 2002 report, comprehensive information relating to clinical and social care negligence cases is not available for all periods prior to 2009-10. We note the improvements and the availability of comprehensive information from databases since 2009-10 (by the Department and DLS) but in our view, individual Trusts also need to hold the information listed above if they are to manage clinical and social care negligence cases and improve the quality of services.

4.23 The Department told us that it is satisfied that the work programme of the HSC Safety Forum and the Regional Adverse Incident and Learning (RAIL) project will ensure that Trusts are able to make sound risk assessments.

Based on our examination of a sample of cases, we consider that DLS takes reasonable steps to progress clinical negligence cases

4.24 The UK's fault-based approach to compensation (see paragraph 4.11) has received significant criticism for a number of years and has been accused of failing either to provide fair compensation or to create incentives for deterrence. The National Audit Office[48], a major public inquiry[49] and the House of Commons Public Accounts Committee[50] have each proposed radical reform. The principal charges are that the system is costly to the health service, imposes long delays on patients seeking redress, is administratively inefficient (in that the legal and administrative costs of cases regularly exceed the value of the compensation at stake), and engenders a culture of secrecy and cover-up in which colleagues are unwilling to 'blow the whistle' on bad practice. It is, therefore, at odds with improved standards of care.

4.25 In 2010[51], the Northern Ireland Assembly (NIA) expressed: "*…its deep concern at the delay in resolving some medical negligence cases, with one case ongoing for 27 years, and a total of 55 cases lasting over 15 years*". It called on the Department to: "*…commission a review of all medical negligence cases outstanding for 10 years or more, to ensure that they*

47 In April 2007, the 18 Health and Social Services Trusts were merged into five Health and Social Care Trusts - Western, Northern, Southern, South Eastern and Belfast HSC Trusts as part of the Review of Public Administration. The 18 Trusts are now referred to as legacy Trusts.
48 Handling Clinical Negligence Claims in England, National Audit Office Report HC 403 2000–2001, 2 May 2001, London.
49 The Report of the Inquiry into the Care and Management of Children Receiving Complex Heart Treatment between 1984 and 1995, Kennedy, 18 July, London: HMSO.
50 Handling Clinical Negligence Claims in England, House of Commons Public Accounts Committee, 37th Report of Session 2001–02, HC 280.
51 NI Assembly private members' business – Medical Negligence Cases, 21st September 2010.

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

are being dealt with expeditiously, and to report on how cases, generally, can be handled in a more efficient, timely and compassionate manner."

4.26 In response, DLS reviewed all live cases which had been on-going for periods in excess of 10 years. The review resulted in the closure of a total of 35 cases. In 23 of these closures, after initially lodging a claim, the plaintiff did not pursue the case. In the remaining 12 cases, settlement was reached and compensation payments were made.

4.27 On-going review of cases by DLS has resulted in a 46 per cent reduction in the number of cases running for over five years (from 769 to 414) (Figure 10).

4.28 In order to assess the adequacy of arrangements for handling negligence claims, we selected a sample of 30 cases. Our sample included:

- 20 recently settled cases in which liability was accepted by Trusts and, as a result, compensation and costs were paid by the Department; and
- 10 recently closed cases where, despite an original claim, action did not progress to its conclusion. In these cases, no compensation payment was made and there was no acceptance of liability.

4.29 For each of the cases we selected, we reviewed the case files to identify how individual cases were progressed, the process of gathering evidence, the factors affecting settlement and the costs involved in progressing cases.

4.30 The length of time taken to settle individual claims can vary considerably, due to a wide range of factors. Key factors affecting our sample of 20 cases included:

- delays in cases involving legal aid because of the need to :
  - undertake a means test of the applicant's financial eligibility against set criteria;
  - conduct a series of "merits tests" to demonstrate that individual claims are reasonable; and
  - obtain approval from the legal aid providers to engage experts, gather medical records and obtain statements;

Figure 10: Comparison of the age profile of long-running live cases at September 2010 and September 2011

Age of Cases	5-10 years	11-15 years	15+ years	TOTAL
September 2010	562	142	65	769
September 2011	302	76	36	414

Source: DLS

- the timescales allowed for lodging negligence claims. Generally, the plaintiff has three years from the date of the incident or date of knowledge of the incident to pursue a claim, by serving a writ;

- delays by the plaintiff's solicitor pursuing cases (progress on clinical and social care negligence cases is regularly reviewed by the High Court (Senior Queen's Bench Judge) and the High Court Master);

- in seven of the sample cases we examined, Trusts were unable to produce the patient's medical records or took a considerable time to produce the required records which delayed the progress of the case; and

- in two of the sample cases, progress was delayed because of the time taken by Trusts to obtain statements from the clinical staff involved in the treatment giving rise to the claim, or from other experts.

4.31 Delays in progressing cases are often a result of factors outside the control of DLS or Trusts. We noted that in several of the cases we examined, DLS took steps to follow-up on outstanding correspondence. However, we also found cases were progress was delayed because of the unavailability of complete medical records or because of delays by Trusts in providing requested information. DLS has told us that the situation is improving, largely as a consequence of tighter judicial management.

4.32 Given the distress suffered by those who have sustained injury through their treatment or care and to curtail unnecessary costs due to delay, we recommend that the Department reinforces to Trusts the need to engage promptly with DLS in all compensation cases.

4.33 The Department told us that it accepts this recommendation and will be writing to Trusts regarding the need for prompt engagement with DLS.

Contrary to arrangements in GB, the compensation cost of negligence claims falls to the Department in Northern Ireland

4.34 In order to provide an incentive to take care, it seems appropriate that a person who causes injury to another person should face at least some of the costs. In the HSC, this issue is complicated by the fact that patients and clients may suffer injury due to the interaction of multiple factors leading to organisational, rather than individual, failures.

4.35 In England and Wales, the Government has created a centrally-funded pool of resources to meet the costs of clinical and social care negligence claims brought against the NHS. Contributions are extracted from NHS Trusts on the basis of assessments of their risk management procedures. In Northern Ireland, Trusts are only required to meet DLS's costs but do not contribute towards the compensation awarded. The Department meets compensation costs, the plaintiff's legal

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

costs, the costs of the defence counsel and the costs incurred by any experts involved in the case.

The rates of financial compensation in Northern Ireland tend to be higher than those in England and Wales

4.36 As demonstrated in Figure 2 at paragraph 1.17, clinical negligence settlements are substantial in terms of the costs to the public purse. In addition, there are physical and emotional impacts on the individuals involved and their families. Almost all settlements are negotiated between defence and plaintiff counsel, and are informed by their assessment of the personal injuries as well as experts' evaluations of past and future care costs, loss of earnings etc. When considering the valuation of personal injury, counsel are aided by The Judicial Studies Board for Northern Ireland guidelines (the Green Book)[52] which puts a monetary value on a wide range of personal injuries and conditions.

4.37 The format of the Northern Ireland Green Book has remained unchanged since the first edition in 1996. Valuation bands have been increased over time to reflect inflation. The decision to discontinue use of the GB guidelines and develop Northern Ireland specific guidelines (the Green Book)[52] was justified on the basis that:

- the levels of compensation in Northern Ireland are significantly higher than in England and Wales - in large measure due to the fact that in Northern Ireland the assessment of compensation was in the hands of juries until 1987;
- practitioners (when valuing cases) and judges (when assessing compensation levels) have regard to the level of compensation paid prior to 1987; and
- the perception that it would be "…. *irrational and unjust*" to rely on the English guidelines simply because no Northern Ireland-specific version was developed.

4.38 The issue of synchronising compensation payments across the United Kingdom was raised in 2010 by the Public Accounts Committee[53] in relation to compensation paid out by the Department for Regional Development in respect of personal injury claims. In response the Department of Finance and Personnel[54] pointed out that the Court of Appeal in Northern Ireland held that "*Northern Ireland need not conform to standards observed in other jurisdictions since Northern Ireland constitutes a separate jurisdiction with its own judicial and social outlook.*" The Public Accounts Committee's report has been provided to the Judicial Studies Board for Northern Ireland and this remains the position.

52 Guidelines for the Assessment of General Damages in Personal Injury Cases in Northern Ireland (third edition) 2008 The Judicial Studies Board for Northern Ireland.
53 The management of personal injury claims, Public Accounts Committee, NIA 48/09/10/R Session 2009-10,
54 The management of personal injury claims, Memorandum on the 13th Report from PAC, 22nd June 2010

The legal costs of settling compensation claims are significant and for some smaller settlements, costs exceed the level of compensation paid

4.39 The legal costs of settlements, comprising defence and plaintiff's solicitors and counsel, are substantial and on occasions account for a significant proportion of the overall costs (see Figure 4). DLS checks and confirms that bills of costs are properly payable and it told us that it routinely challenges the professional fees of the plaintiff's solicitors.

4.40 In addition, in the last two years, DLS has established a new panel of counsel who specialise in negligence claims and operate on a substantially lower scale of fees. It told us that, as a consequence of these new arrangements, it has made savings of £2.1 million and £1.9 million in solicitors' and counsel's fees respectively over the two years to 31 December 2011.

4.41 We welcome the work done by DLS to reduce the legal and other costs of settling compensation cases and agree that, as a result, financial savings have been realised. It is important that DLS continues to challenge costs in all negligence claims. In our view, however, given that in some smaller cases, the legal and other costs exceed the level of compensation paid, more needs to be done to assess the possibilities for resolving such cases without incurring the full costs associated with litigation.

The Department recognises the value of alternative dispute resolution action and alternatives to the legal process are under consideration

4.42 In recognition of the concerns expressed about the fault-based approach to compensation (paragraph 4.24), the Department of Health in England conducted a review of arrangements in 2003[55]. The paper emphasised the importance of negligence prevention through reducing risks, preventing harm and promoting best practice, rather than remedial cure through compensation. Where remedial action was required, a better co-ordinated response and the development of a more predictable and affordable system of redress was proposed. Enabling legislation (the NHS Redress Act) was passed in 2006, providing the legislative framework to allow the Secretary of State to establish the NHS Redress Scheme. It was expected that the Scheme would begin operating in 2008, but this has not happened. In 2009, the Health Committee at Westminster commented[56]:

"By dragging its heels over implementing the NHS Redress Scheme, the Department of Health is forcing harmed patients and their families or carers to endure often lengthy and distressing litigation to obtain justice and compensation. It is also obliging the NHS to spend considerable sums on legal costs, and encouraging defensiveness by NHS organisations. In addition, it is hindering the development of a safety culture in the NHS, which cannot flourish in the midst

55 Making Amends – clinical negligence reform, Chief Medical Officer , July 2003.
56 House of Commons Health Committee, Sixth Report of Session 2008-09, 18 June 2009, HC 151-1.

Part Four:
The Adequacy of Arrangements for Resolving Complaints and Clinical and Social Care Negligence Cases

of powerful tensions between the desire to be open and medico-legal concerns. We recommend that the Redress Scheme be implemented immediately."

4.43 The lack of alternatives to legal redress makes it difficult for those who suffer as a result of medical accidents or negligence to obtain explanations of what happened to them, and in particular to extract apologies. The Department considers that effective redress can include offering an apology, providing reassurance and speedy remedial treatment, in addition to offering compensation, if appropriate, when harm has been caused to a patient or client[57]. In its guidance[58], the Department encourages (but does not compel) HSC organisations to comply with a 2009 GB protocol designed to resolve disputes about healthcare or medical treatment. The protocol governs how clinical negligence claims are handled and the timeframe within which each element must be addressed, for example, the sharing of medical records between HSC organisations and the claimant or their representatives. It also aims to find less adversarial, and more cost-effective ways, of resolving disputes about health care and treatment, such as negotiation, mediation, arbitration and adjudication.

4.44 We recommend that the Department takes steps to develop formal dispute resolution procedures which offer a viable alternative to litigation. We recommend that any revised arrangements should:

- channel compensation to eligible patients and clients in a manner that is timely and fair;
- be compatible with a system that generates detailed information for learning purposes;
- provide incentives for HSC staff and organisations to work towards improving the quality of care; and
- recognise that most preventable injuries in HSC settings are due to the imperfect systems within which professionals work rather than the result of incompetence.

4.45 The Department told us that it accepts this recommendation and is keen to take steps to review and test the feasibility of formal dispute resolution procedures which may offer available alternatives to litigation.

57 Safety First : A Framework for Sustainable Improvement in the HPSS, DHSSPS March 2006.
58 Guidance on Claims Handling in HSCC Organisations (March 2010).

Appendices

Appendix 1: (Paragraph 1.1)

Organisations responsible for planning, delivering and monitoring Health and Social Care across Northern Ireland

- **Department of Health, Social Services and Public Safety (the Department)** is one of 12 Northern Ireland Departments. It is the Department's mission to improve the health and social well-being of the people of Northern Ireland. The Department has responsibilities devising policy and legislation for :

  - **Health and Social Care (HSC) services** (hospitals, family practitioner services and community health and personal social services);

  - **Public Health** (promoting and protecting the health and well-being of the population); and

  - **Public Safety** (fire and rescue services).

- **Health and Social Care Board (HSC Board)** is responsible for commissioning services, resource management and performance management and service improvement. It works to identify and meet the needs of the Northern Ireland population through its five Local Commissioning Groups which cover the same geographical areas as the Trusts. The HSC Board is jointly responsible (with the PHA) for the development of a fully integrated commissioning plan for HSC in Northern Ireland.

- **Public Health Agency (PHA)** has responsibility for health and wellbeing protection and improvement, screening, undertaking HSC research and development and providing leadership in ensuring the safety and quality of services. In addition, it provides advice to public health, nursing and allied health professionals.

  In delivering its core objectives, the PHA:

  - works in partnership with communities, groups and organisations to address the major causes of poor health and wellbeing;

  - targets resources to those who need it most; and

  - generates, disseminates and supplies information to help us better understand the health status and needs of our population.

- **Health and Social Care Trusts (Trusts)**. There are six Trusts in Northern Ireland.

  Five Trusts provide integrated HSC services across Northern Ireland: Belfast Trust, South Eastern Trust, Western Trust, Southern Trust and Northern Trust. Trusts manage and administer hospitals, health centres, residential homes, day centres and other HSC facilities and they provide a wide range of HSC services to the community.

  The sixth Trust is the Northern Ireland Ambulance Service, which operates a single Northern Ireland wide service to people in need and aims to improve the health and well-being of the community through the delivery of high quality ambulance services.

- **Regulation and Quality Improvement Authority (RQIA)** is the independent HSC care regulator in Northern Ireland. In its work, RQIA

encourages continuous improvement in the quality of HSC services through a programme of inspections and reviews.

- **Patient and Client Council (PCC)** is a regional body with local offices covering the geographical areas of the five integrated Health and Care Trusts.

  The overarching objective of the PCC is to provide a powerful, independent voice for patients, clients, carers, and communities on HSC issues.

- **The Business Services Organisation** is responsible for the provision of a range of business support and specialist professional services to the whole of the HSC sector including HR, finance, legal services, procurement, ICT and other services. This will be taken forward in a phased approach.

- **Other HSC organisations:**

  - **NI Guardian Ad Litem Agency (NIGALA)**. Its functions are:

    - to safeguard and promote the interests of children by providing independent social work investigation and advice in specified proceedings under the Children (Northern Ireland) Order 1995 and in Adoption (Northern Ireland) Order 1987; and

    - to provide effective representation of children's views and interests.

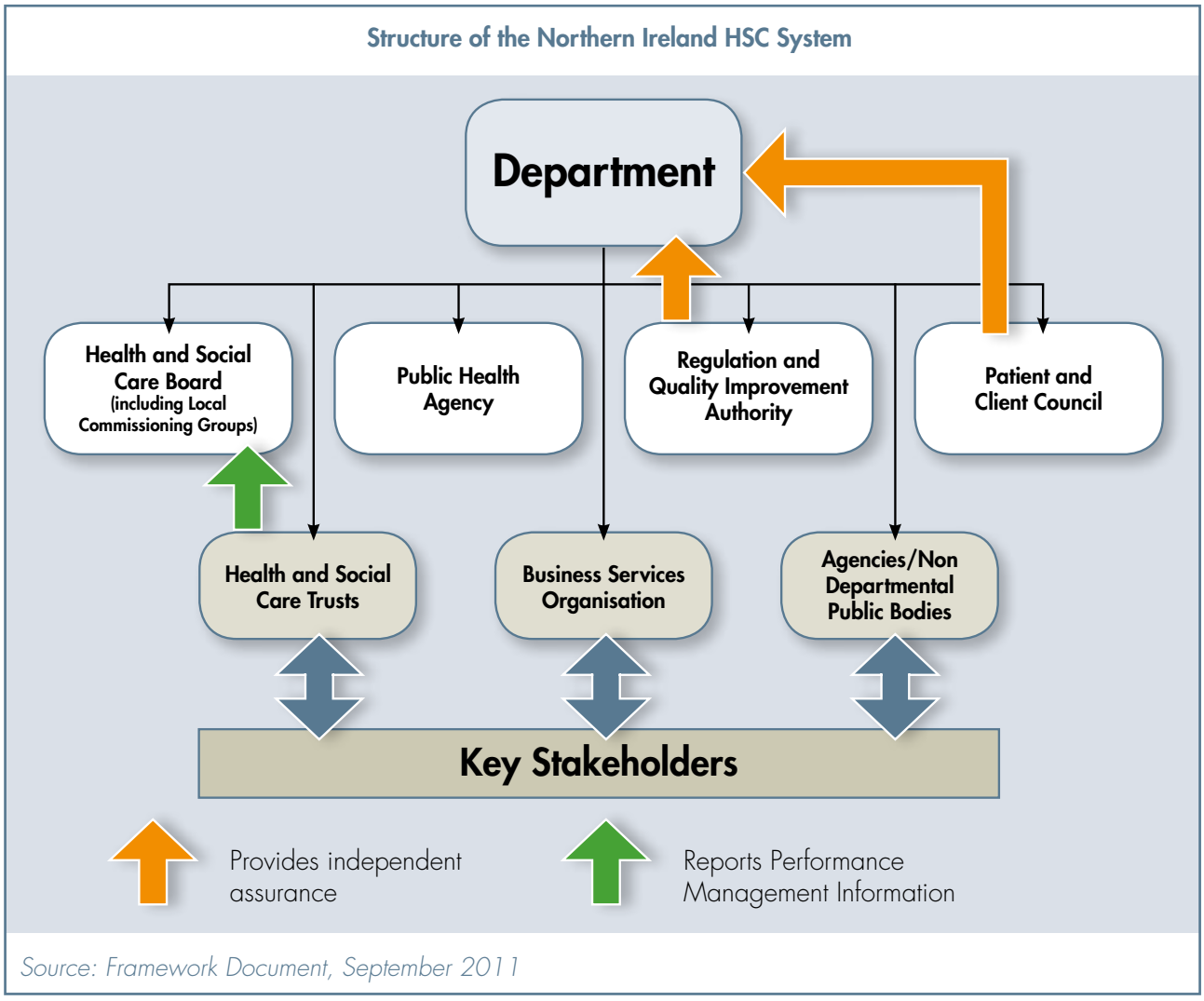
  - **NI Blood Transfusion Service (NIBTS)** exists to supply the needs of all hospitals and clinical units in the province with safe and effective blood and blood products and other related services. The discharge of this function includes a commitment to the care and welfare of voluntary donors.

  - **NI Social Care Council (NISCC)** is the regulatory body for the social care workforce in Northern Ireland. Its aim is to increase the protection of those using social care services, their carers and the public.

  - **NI Practice and Education Council for Nursing and Midwifery (NIPEC)** aims to improve the quality of HSC by supporting the practice, education and professional development of nurses and midwives.

  - **NI Medical and Dental Training Agency (NIMDTA)** is responsible for funding, managing and supporting postgraduate medical and dental education within the Northern Ireland Deanery. It provides a wide range of functions in the organisation, development and quality assurance of Postgraduate Medical and Dental Education and in the delivery and quality assurance of Continuing Professional Development for general, medical and dental practitioners.

Appendix 1: (Paragraph 1.1)



Source: Framework Document, September 2011

Appendix 2: (Paragraph 1.18)

Summary of recommendations from NIAO's report '*Compensation payments for Clinical Negligence*' 2002 (NIA 112/02) and action taken by the Department and health and social care bodies

Summary of Recommendation	Action Taken
The need to establish a central database of clinical negligence cases;	Since 2009-10, the Directorate of Legal Services (DLS) has maintained a central database for negligence cases. Comprehensive information for periods prior to 2009-10 is not easily accessible. The Department is also currently considering the feasibility of developing a Northern Ireland Regional Adverse Incident Learning System (RAIL) to facilitate assessment of the causal and contributory factors of patient safety.
The need for better information on, and control over, the cost of cases;	The DLS database provides better information on cases. DLS has been taking steps to ensure more timely resolution of cases and therefore reduce costs.
The need for more regular and consistent review of live cases, with a view to closure;	DLS actively reviews all live cases. In 2010, in response to concerns from Northern Ireland Assembly members, DLS reviewed all live cases which had been on-going for periods in excess of 10 years. The review resulted in the closure of 35 cases.
The need for the Department and health bodies to be more proactive in attempting to reduce the projected costs of future negligence cases;	In September 2002, the Department issued guidance (HSS(F) 20/2002) which advised health bodies that there was some evidence to suggest that patients who suffer an AI may be diverted from making a claim for compensation where they are provided with an expression of sympathy, a full and factual explanation and, if appropriate, are offered early corrective treatment. The guidance recommended that individual HSC bodies consider how to adopt this policy.
The need for mechanisms to be introduced to facilitate learning, and sharing of lessons learnt, from adverse clinical incidents;	Since 2004, three Supporting Safer Services Reports and two Learning Reports have been issued to support and promote learning from SAIs. The Department considers that the introduction of the proposed RAIL system will facilitate improved learning and sharing of lessons from all AIs (including near misses).

Appendix 2: (Paragraph 1.18)

Summary of Recommendation	Action Taken
The need to promote earlier resolution of claims;	In 2010, DLS completed a review of all live cases which were active for more than 10 years. As a result of the exercise, 35 cases were closed. DLS is now proactive in monitoring the progression of cases.
The need for a review to identify the extent of problems in relation to medical record keeping;	HSS(F) 20/2002 reminded HSC bodies that, in line with the pre-action protocol, medical records should be provided within 40 days from the date they are requested.
The need to eliminate the use of confidentiality clauses in settlements;	DLS assures us that confidentiality clauses are only used in cases where they are specifically requested by the plaintiff (i.e. the injured party).
The need for strong case management;	DLS procedures now ensure that cases are actively managed.
The need to implement a pre-action protocol for the resolution of clinical disputes;	HSC bodies are encouraged to use a pre-action protocol to resolve disputes.
The need for further improvement in risk management; and	Risk management procedures have been enhanced, and continue to be developed, across the HSC sector.
The need to emphasise the importance of clinical audit and clinical governance, and their contribution to enhancing quality of care.	Various strategies and guidance issued have addressed this, including: Best Practice Best Care – Next Steps (July 2002) HSS (PPM) 10/02 Governance in the HPSS – Clinical and Social Care Governance Guidelines for Implementation The HPSS (Quality Improvement & Regulations) (NI) Order 2003 introduced the duty of quality & established RQIA Safety First: A Framework for Sustainable Improvement in the HPSS (2006) The Quality Standards for Health and Social Care (2006)

Appendix 3: (Paragraph 1.20)

Study Methodology

Our methodology was designed to provide an insight into patient safety and the quality of care in the HSC sector from the perspective of the HSC oversight arrangements and the extent of adverse incidence and negligence. We obtained information from each of the six Trusts as well as the Department, the RQIA and commissioning bodies, and healthcare professional organisations.

Methods	Purpose
Discussions with DHSSPS officials We had face-to-face discussions with senior departmental officials responsible for safety, quality and standards.	To understand: • the Department's arrangements for ensuring the HSC sector delivers quality care; and • its views on the extent of under reporting of AIs and the cost of poor quality care. In addition, we discussed progress and the emerging findings during our fieldwork.
Visits to Trusts We carried out face-to-face semi-structured interviews with officials on: • complaints and incidents management; and • DATIX (the Trusts' Risk Management database for complaints, incidents and negligence cases).	To understand: • the governance arrangements for complaints and AIs; and • the information held by Trusts on complaints, AIs and negligence cases.
Negligence cases We carried out face-to-face semi-structured meetings with the Director of Legal Services and his staff. We covered: • the provision of legal services to Trusts; • the legal processing and management of negligence cases; and • the database of negligence cases.	To understand: • the legal process and role of the various parties in negligence cases; • the trends in the type and quantum of negligence cases; and • the progress, outcomes and costs involved in specific negligence cases reviewed by NIAO.

Appendix 3: (Paragraph 1.20)

Methods	Purpose
We also undertook a review of a sample of settled and closed negligence cases (a detailed methodology is provided below).	
Consultations with other HSC stakeholders We discussed the issues with officials at: • HSC Board (the Department's commissioning body); • RQIA (the HSC regulator); and • the Patient and Client Council (the patient/ client's voice in the HSC).	To understand: • the nature and quantum of SAIs; • the assessments of quality of care; and • the patients and clients recourse to independent advice and review of complaints.
Consultation with academic and professional bodies We sought the comments of a number of bodies on specific issues • General Medical Council (NI Council) • QUB Medical School • QUB Dental School • Royal College of Nursing (NI branch) • NI Social Care Council • NI Practice and Educational Council for Nursing and Midwifery	To understand: • arrangements for ensuring the training and development of HSC staff; and • the extent to which HSC staff are willing to report AIs.
We undertook a review of clinical and social care negligence cases We selected two groups of negligence cases for review from the Directorate for Legal Services – settled cases (with payments) and cases closed without payments. The methodology for selecting settled negligence cases for review was: • a sample drawn from the 326 negligence cases settled in 2009-10 and 2010-11 - totalling £33.1 million payment to plaintiffs; • a judgemental sample of 20 cases comprising: - the 10 cases with the largest compensation payments (from £300,000 to £3.3 million);	To understand: • the decision making process around liability; • the progress of claims; • the basis for settlement amounts; • the management of legal and other costs; and • the background to the closure of cases (without settlement).

Methods	Purpose
- 5 cases drawn at random from the remaining 32 cases with compensation payments greater than £100,000 (and less than £300,000); and - 5 cases drawn at random from the 284 cases with compensation less than £100,000. The 20 cases comprised 6% by number and 66% (£22 million) by value. A separate judgemental sample of 10 closed negligence cases (without any payments by the HSC sector) was selected from DLS lists of recently closed cases.	

Appendix 4: (Paragraph 3.26)

Methodology for establishing a set of Patient safety indicators

System-wide or outcome measures

These measures tend to be fairly crude – that is, not necessarily risk adjusted – but should be as close to real time as possible. They align closely to the strategic aims of an organisation and should consider things such as:

- Incident rates and levels of harm[59];
- Mortality;
- Healthcare-associated infection numbers and rates;
- Re-admissions;
- Adverse drug events;
- Pressure ulcers;
- Falls in hospitals and homes for older people;
- Experience of patients and clients; and
- Safety in the workplace.

Drivers

This information will contain a mixture of both quantitative and qualitative data relating to issues such as:

- Organisational culture;
- Team work;
- Clinical engagement;
- Resources, for example proportions of bank and agency staff;
- Facilities and environment;
- Training; and
- Staff views and attitudes.

N.B. The European Society for Quality in Healthcare has produced a range of guidance on this issue, as recently as 2012 (http://www.esqh-office-arhus.dk/files/Subsites/ESQH/S%20Kristensen.pdf). In addition, the Agency for Healthcare Research and Quality has also produced a series of patient safety indicators: for example, http://www.qualityindicators.ahrq.gov/Modules/psi_overview.aspx

59 As measured by incident reporting systems or other tools such as observational techniques. It should be noted that incidents involving near-misses or failure to provide effective care provide just as much learning opportunity to prevent errors in the future as do adverse incidents of commission that actually lead to harm.

Appendix 5: (Paragraph 4.8)

Recommendations from the HSC Board's 'Report on the Process Evaluation of the Complaints in HSC: Standards and Guidelines for Resolution and Learning' February 2012

The evaluation identified a total of 14 recommendations which may assist in the further implementation of the Guidance as follows:

1. The Department should review the Guidance in order to provide greater clarity in respect of achieving more robust local resolution arrangements in order to ensure a better understanding by staff and service users;

2. The HSC Board should consider co-ordinating training for HSC/Family Practitioner Service (FPS) staff on a regional basis, as a method to improve the understanding of how more robust local resolution arrangements may be delivered, and improve recognition as to how and when to apply alternative techniques in the resolution of complaints;

3. The Department should review the Guidance to provide a better understanding and provide clarification to HSC organisations and service users, as to the responsibilities of the various organisations in relation to complaints and more specifically the provision of support and advice to service users wishing to raise a complaint and regarding the sequencing of the complaints process;

4. The HSC Board should with HSC organisations seek to develop further definition and clarification with respect to the role of the Complaints Manager in order to provide a greater understanding and appreciation by staff and service users of the role in terms of providing support and advice;

5. The HSC Board should remind FPS Practitioners of their requirements under the Guidance and should make tangible efforts to ensure that FPS Practices are aware of and have access to the support and advice that can be provided by the Board in respect of complaints resolution and implementation of the Guidance;

6. The HSC Board should further develop and promote the role of "honest broker" as a means to resolution of complaints within FPS, in order to provide greater clarity and understanding within HSC organisations, FPS and services users;

7. HSC organisations should ensure that they comply with the Guidance to improve their communications with service users who make a complaint by developing processes to maintain regular, proactive contact with users. This system should include the ability to provide users with a rationale for not being able to respond within the agreed timescales, detail of progress, a projected timescale for completion of investigation and/or timescales for issue of the response;

8. Recognising the practical difficulties in ensuring all staff received mandatory training and in an attempt to increase the staff uptake in this requirement, HSC organisations should explore the further rollout of the current e-learning complaints

Appendix 5: (Paragraph 4.8)

training package. The HSC Board should ensure that this includes FPS Practices;

9. HSC organisations and Family Practitioner Services should ensure that where changes to policy, procedure, or improvements to services have occurred as a result of a complaint being raised, the service user is informed of this within the response to them, including details regarding implementation of associated action plans, etc. where appropriate;

10. A regionally-agreed method of disseminating learning from complaints should be developed by the HSC Board and Public Health Agency (PHA). This should include co-ordination of an Annual Regional Complaints Workshop event and agreed ad hoc/scheduled communications, such as newsletters etc;

11. A regional mechanism for receiving user satisfaction feedback in relation to complaint resolution should be developed by HSC organisations, recognising the sensitivities involved in such an area. The HSC Board/PHA should lead on this with input from the Patient Client Council, Trusts and service users. Consideration should be given to engaging with key stakeholders in this regard through focus groups across the Trust/ Local Commissioning Group areas;

12. Recognising that communication, staff attitude and behaviour are among the highest categories of complaints received across the HSC, innovative methods in attempting to address this at the core of staff/service user interactions should be explored led by the PHA and the HSC Board;

13. There may be merit in further regional discussions, led by the Department, regarding the 20 working day response timescale. Any discussions and agreements should include clarification of the timescales associated with honest broker complaints; and

14. HSC organisations should review their Complaints Policies and Procedures to reflect any clarification/amendment to the Guidance.

Appendix 6: (Paragraph 4.16)

Numbers of Active Clinical and Social Care Negligence cases by Trust at September 2012

Trust	'Live' Negligence Cases	
Belfast[1]	949	(35.1%)
Western	423	(15.6%)
South Eastern	414	(15.3%)
Northern	382	(14.1%)
Southern	367	(13.6%)
HSC Board[2]	157	(5.8%)
NI Ambulance Service	9	(<1%)
NI Blood Transfusion Service	2	(<1%)
TOTAL	**2,703**	**(100%)**

Source: DLS

Notes:
1 The Belfast Trust is one of the largest Trusts in the UK and provides various regional treatments.
2 The HSC Board assumed management responsibility for the negligence claims against the Health and Social Services Boards on its formation on 1 April 2009.

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