Witness Statement Ref. No 068/1

INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Name: Jonathan Bill

Title: Mr

Present position and department/employer:

Deputy Director, Quality & Performance Improvement Unit,

Department of Health, Social Services & Public Safety

Length of time in post: 17 months

Previous position and department/employer in 1995:

Departmental Private Secretary Department of Health and Social Services (September 1994 to February 1999) (including September – December 1995 on "Young Leaders Programme" in Boston USA)

Previous position and department/employer in 2000:

Deputy Principal, Trusts & Human Resources Directorate, Department of Health and Social Services

Previous position and department/employer in 2001:

Deputy Principal, Planning & Priorities Unit, Department of Health, Social Services and Public Safety

Membership of Professionals Bodies:

None

Particular areas of interest
[Please attach additional sheets if more space is required]

(i) Explain in detail when you first became aware of the deaths of Adam, Lucy and Raychel to include how you were so informed and by whom.

Adam: media report of establishment of the Inquiry into Hyponatraemia-related deaths around November 2004.

Lucy: media reports on coroner's case (probably Belfast Telegraph) around February 2004.

Raychel: media reports linking case to Lucy (probably Belfast Telegraph) – not sure when.

(ii) Describe your role in the period following notification to the DHSSPS of the deaths, to include the actions taken by your division to deal with the deaths of the three children and to put measures in place to prevent such deaths happening again.

My Unit is responsible for policy matters involving quality and safety in the Health and Personal Social Services (HPSS). This means taking forward a suite of issues that are designed to improve the quality of care provided by the HPSS and beyond, and ensure the safety of users and staff. Much of the work finds its genesis in ***Best Practice Best Care: A Consultation Paper 2001*** **[Copy attached]**.

My Unit had responsibility for the establishment of the HPSS Regulation and Improvement Authority. The Authority commenced its work on a phased basis on 1 April 2005. The Authority will be responsible for monitoring the quality of care provided by the HPSS. One of the ways it will do this is by carrying out reviews of the clinical and social care governance arrangements of HPSS organisations. The Authority will promote a culture of continuous improvement and best practice, and play a key role in the investigation of serious and/or persistent clinical and social care governance problems. It will have a duty to report to the Department on the provision, availability and quality of care.

My Unit also had responsibility for the establishment of a HPSS Clinical and Social Care Governance Support Team. The aim of the Department when establishing this multi-disciplinary team in April 2004 was to promote the longer-term cultural change and organisational development that it considered necessary to ensure that the statutory duty of quality, introduced the previous year, could be implemented successfully. The Support Team provides leadership, guidance, advice and support on clinical and social care governance issues to HPSS organisations; assists organisations in building and developing capacity; and shares the learning from its work with the HPSS.

On taking up my current post in February 2004 I became a member of the Safety in Health and Social Care Group (a Departmental committee, though with some HPSS membership) that had commissioned Deloitte in 2003 to carry out a review of the reporting of adverse incidents and near misses in the Health & Personal Social Services (HPSS). In summary, the Deloitte report ***Safety in Health & Social Care Project – Clinical and Social Care Governance Final Report 31 March 2004*** **[copy attached]** noted that whilst there was a widespread understanding of the importance of adverse incident reporting within the HPSS, there was a lack of consistency in organisations' reporting arrangements. Following receipt and consideration of the Deloitte report in April 2004, the Safety in Health and Social Care Group recommended 3 major actions:

- One was to commission the HPSS Regional Governance and Risk Management Adviser to carry out a project to create HPSS-agreed standard incident definitions, a suite of standard reporting forms and regional coding of incidents. This work was commenced in late 2004.

- The second was for guidance to be produced on the reporting to the DHSSPS by HPSS organisations of serious adverse incidents. I was involved in the drafting of that guidance. The

resultant guidance ***Reporting and Follow-Up on Serious Adverse Incidents: Interim Guidance – HSS(PPM) 06/04*** **[copy attached]** was issued on July 2004. The guidance instructs HPSS organisations to report serious adverse incidents that they consider are likely to be: serious enough to warrant regional action; of public concern; or require an independent review. The guidance also states that organisations should: have in place systems that facilitate the collection, analysis and reporting of adverse incidents and near misses; nominate a senior manager at board level who will have overall responsibility for the reporting and management of adverse incidents within the organisation; and where they consider an independent review to be appropriate it should be seen as completely independent. The reason for the guidance being issued was twofold: To ensure that the Department was made aware in a timely fashion about serious adverse incidents, and to enable the Department to consider the adequacy of the HPSS organisation's response to the serious adverse incident reported. A small group (including myself) within the Department considers the appropriateness of the organisations' response to the incident and whether any subsequent Departmental action is required. The administration of the serious adverse reporting process is carried out by my Unit.

I was also involved in the drafting of a follow up circular to that issued in July 2004. ***Reporting of Serious Adverse Incidents within the HPSS – HSS(PPM) 05/05*** **[copy attached]** was issued in June 2005. This circular re-stated the importance of adverse incident reporting, requested organisations provide the Department with the names of the senior manager at board level with overall responsibility for the reporting and management of adverse incidents within the organisation and outlined the key findings of the Deloitte report on adverse incidents reporting (referred to above).

In addition the Department held a briefing session for the HPSS also in June 2005 to give feedback on the interim reporting arrangements thus far. I was involved in this event.

- The third was that the Department should formalise its links with the National Patients Safety Agency (NPSA). I have subsequently been involved in discussions with the National Patients Safety Agency on the establishment of a service level agreement and it is hoped that such an agreement can be concluded over the summer 2005. The agreement will enable Northern Ireland to share the benefits of learning from the research and analysis of incidents and the solutions work being undertaken by NPSA and in due course be part of the NPSA's National Reporting and Learning System.

In October 2004 a service level agreement between the DHSSPS and National Clinical Assessment Authority (now known as the National Clinical Assessment Service - NCAS) came into force. The NCAS provides advice, information and support for organisations dealing with under-performing doctors and dentists. I had some peripheral input to the development of that agreement and my Unit has responsibility for the funding of the agreement.

I was also on the project team that between November 2004 and March 2005 developed and drafted, and is currently consulting upon (consultation closes in July 2005), the ***Best Practice Best Care Quality Standards for Health and Social Care*** **[copy attached]**. These Standards will enable the public to be aware of the standard of care they should expect from the service and are expected to be used in due course by the HPSS Regulation & Improvement Authority in its consideration of the quality of services provided by the HPSS.

Recently two further project teams have been established within the Department to take forward work on a safety framework for the HPSS; and the Northern Ireland response to the Shipman Enquiry recommendations. I am on both these teams. Both these pieces of work are designed to provide for better outcomes for HPSS users and staff.

My only involvement regarding Departmental work specifically around the deaths of Adam, Lucy and Raychel was when I was asked to contribute briefing for an interview the then Minister, Angela Smith, was due to have with the Impartial Reporter newspaper concerning the death of Lucy Crawford. I provided input

to the briefing on the quality agenda generally (010-039-234), the reporting of adverse incidents (010-023-149) and Sperrin Lakeland Trust's proposed analysis of aspects of its handling of Lucy's case (010-011-025). In connection with this briefing exercise I attended briefing meetings with other Departmental officials and a video-conference meeting involving other Departmental officials and the Minister. This activity was concentrated in a two week period (late May/early June 2004).

Particular areas of interest (Cont'd)

(iii) What was the system in place in Northern Ireland at the time of Adam Strain's death in 1995 for reporting untoward deaths to the DHSSPS and disseminating information on the outcomes of Coroners' Inquests within the Health Service?

As I understand it, in 1995 the only formal requirement for the HPSS to report adverse incidents to the DHSS was through the terms of a guidance circular issued in 1973 ***HSS4(CS) 1/73 "Notification of Untoward Deaths in Psychiatric and Special Care Hospitals"*** **[copy attached]**, subsequently amended by ***THRD 1/97 "Notification of Untoward Events in Psychiatric and Specialist Hospitals for People with Learning Disability"*** **[copy attached]** issued in 1997, but this applied only to psychiatric or special care hospitals. Under the 1973 guidance, notification to the DHSS was to be by the Health & Social Services Boards and under the 1997 guidance, notification was to be by Health & Social Services Trusts.

There was no specific formal procedure for reporting, for example, acute medical adverse incidents, to the Department in 1995. I understand that serious untoward incidents were reported informally by Trusts to the Department either through telephone calls or through personal contact.

I am unaware of any process for the dissemination of information on the outcomes of Coroners' Inquests within the HPSS.

(iv) What was the role of the DHSSPS in reporting, analysing and disseminating the information referred to at (iii) above and in ensuring that lessons learned would be fed into teaching/training and the care of patients?

I am unaware of the Department's role.

Particular areas of interest (Cont'd)

(v) What procedures existed in 1995 to ensure the fulfilling of roles relating to the reporting, analysing, disseminating of information from a Coroner's Inquest or untoward death and to ensure that lessons would be learned.

I am unaware of the procedures, if any, for ensuring these roles.

(v) With reference to issues (iii) to (v) above, what was the situation in 2000 and 2001 respectively?

As I understand it, the position as outlined in my response to (iii) remained extant.

With regards to (iv) and (v) my response is the same, in that I am unaware of the Department's role in the former or the procedure in the latter.

Particular areas of interest (Cont'd)

(vii) With reference to issues (iii) to (v) above, what is the situation now?

Since 2002 the Department has introduced a series of circulars on various aspects of controls assurance including the phased introduction of HPSS controls assurance standards. The ***Risk Management Controls Assurance Standard*** **[copy attached]** includes a criterion on adverse incidents: "An agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with HPSS guidance". I understand that compliance with the standard is fundamentally self-assessment. For 2004/05 I understand that the DHSSPS required that the Risk Management Controls Standard was independently verified by internal auditors.

As I outlined in my answer to question (ii) the Department receives reports of serious adverse incidents from the HPSS in line with the guidance in ***Reporting and Follow-Up on Serious Adverse Incidents: Interim Guidance – HSS(PPM) 06/04*** issued in July 2004. The Department considers the appropriateness of the organisations' response to the incident and whether any subsequent Departmental action is required.

I am unaware of the arrangements, if any, on the dissemination of the outcome of Coroners' Inquests within the health service.

(viii) Describe in detail the procedures that the DHSSPS, Hospital Trusts and Health Boards are required to have in place to handle allegations relating to the running of hospitals or work related activities of members of the medical or nursing profession following a complaint by any person or persons within the hospitals, Boards and Trusts.

I have no knowledge of such procedures.

Other points you wish to make including additions to any previous Statements, Depositions and or Reports
[Please attach additional sheets if more space is required]

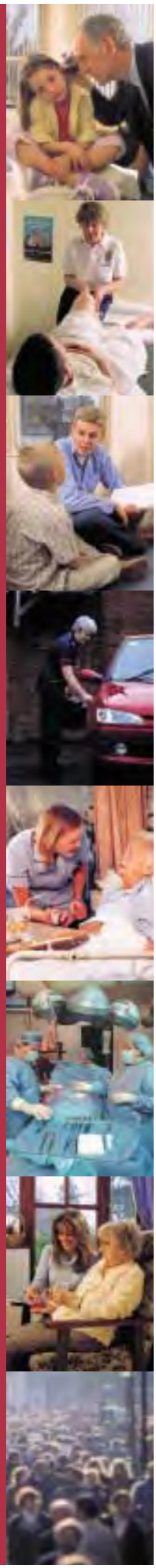
THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: Jonathan P Bell **Dated:** 30 | 6 | 2005

Best Practice - Best Care

A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS

A Consultation Paper
April 2001



Department of Health, Social Services and Public Safety
An Roinn Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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Réamhrá

Thug an Coiste Feidhmiúcháin gealltanas i gClár um Rialtas chun creatlach a chur i bhfeidhm a thógfaidh caighdeán na seirbhísí a sholáthar don phobal agus go rachadh sé i ngleic le lag-ghníomhú fud fad na SSSP. Cuireann sé áthas orm an doiciméad a chur os bhur gcomhair ina bhfuil moltaí leagtar amach chun seo a chur i gcrích. Is é an aidhmn atá agam córas cúraim shóisialta agus sláinte ardcaighdeánaí a sholáthar a bhíonn áisiúil agus furasta a úsáid, a fhreastalaíonn ar riachtanais daoine agus a chuireann muinín iontu siúd a úsáideann é.

Molann an doiciméad coras le dul i ngleic le lag-ghníomhú, nuair a tharlaíonn sin, chun cinntiú gur lú na héagsúlachtaí i gcaighdeán an chúraim agus an cóireála a thugtar. Ina theannta seo tógann sé ar a bhfuil déanta go maith sna SSSP agus san am céanna ag aithint go bhfuil gá ann le freagracht agus trédhearcacht agus fócas nua ar ghníomhú.

Rachaidh an chreatlach sa doiciméad seo i bhfeidhm ar gach duine i soláthar seirbhísí sláinte agus sóisialta. Is buneochair páirteachas an úsáideora.

Cuireann na moltaí atá leagtha amach sa doiciméad síos ar an dóigh ar féidir caighdeán na seirbhísí a ardú. Tá sé riachtanach go dtuigeann gach duine a bhfuil páirt aige nó aici an gá le seirbhísí ardchaighdeánacha a sholáthar. Caithfidh an fhoireann barúlacha agus dea-chleachtadh a roinnt agus a bheith freagracht as caighdeán na seirbhísí a sholátharaíonn siad. Léiríonn scileanna na foirne cheana infheistíocht shunstach agus mar sin de is gá le heagraíochtaí an infheistíocht a chothabháil agus an deis a thabhairt dá bhfoireann a scileanna agus a gcleachtadh a fhorbairt.

Tá sé costasach cúram ardcaighdeánach a sholáthar ach tá sé costasach cúram d'ísealchaighdeán a sholáthar chomh maith. Is cur amú airgead é gach punt a chaitear ar athsrúduithe nó ar fhiosrúcháin nó ar mheancóga a cheartú, airgead nach bhfuil ar fáil chun cóireáil ná cúram a sholáthar.

Fáiltím roimh bhur mbarúil ar na moltaí sa doiciméad seo air sin atá mar dhúshraith do thodhchaí ár seirbhísí cúraim.

An Aire Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

Foreword

In the Programme for Government the Executive has given a commitment to put in place a framework to raise the quality of services provided to the community and tackle issues of poor performance across the HPSS. I am pleased to present this consultation paper which sets out proposals to deliver this. My aim is to provide a high quality system of health and social care which is easy and convenient to use, which is responsive to people's needs and which provides a service that instills confidence in those who use it.

This paper proposes systems to deal with under-performance, when that occurs, to ensure there are fewer variations in the standard of care and treatment delivered. In addition it builds on what is already being done well in the HPSS while recognising that there is a need for increased accountability and transparency with a new focus on performance.

The framework proposed in this paper will apply to everyone involved in the provision of health and social care services. User involvement will be a key requirement.

The proposals set out in this paper describe how the quality of services can be improved. It is essential that everyone involved recognises the need to deliver high quality services. Staff need to share ideas and good practice and take responsibility for the quality of services they provide. The skills of the staff represent already a significant investment, therefore organisations need to maintain that investment and provide staff with the opportunity to develop their skills and practice.

Providing high quality care is expensive but poor quality also costs money. Every pound wasted on repeated examinations or investigations, or on correcting mistakes is money that is not available for providing treatment and care.

I welcome your views on the proposals in this paper on what is fundamental for the future of our caring services.

Edwin Poots

Minister for Health, Social Services and Public Safety

Executive Summary

Introduction

1. This paper sets out proposals for new arrangements aimed at providing high quality services in the HPSS. The many medical, professional and technological advances and increased public expectation of the standards of services delivered, make it vital that the HPSS is modernised and improved in the future to enable it to provide a fast, effective high quality service. The proposals in this paper aim to put in place new arrangements which will do just that. These proposals are for public consultation.

Proposals

2. The proposals in this document centre on:
   - setting standards - improving services and practice;
   - delivering services - ensuring local accountability; and
   - improving monitoring and regulation of the services.

Setting standards - improving services

3. In order to ensure that standards are applied in a consistent manner throughout the HPSS and to reduce unacceptable variations in care provided, it is considered essential that a single more focussed approach is taken on the development and dissemination of standards and guidelines for the HPSS. Three options are offered for consideration.

   - **Option One:** establish an independent body to research and appraise the evidence of new drugs and technologies or existing procedures based on priorities within the HPSS.
   - **Option Two:** establish an internal body within the Department to carry out research and appraise the evidence on new drugs and technologies or on existing procedures in line with identified priorities for the HPSS.
   - **Option Three:** the Department would make arrangements with other standard setting bodies e.g. NICE and SCIE, whereby the Department would have early warning of the standards and guidelines to be produced. In addition the Department would act as a filter for the standards and guidelines emanating from NICE and SCIE.

Executive Summary

Setting Standards - improving practice

4. Investing in the workforce is crucial to the provision of high quality services. Many initiatives are ongoing at present to promote continuous professional development through lifelong learning and through strengthening professional regulation. The framework proposed in this paper will bring together these various initiatives so that they can be managed and monitored within one framework for improving the quality of services.

Delivering Services - ensuring local accountability

5. It is proposed to introduce a system of clinical and social care governance, backed by a statutory duty of quality and supported by continuous professional development.

6. The introduction of clinical and social care governance will mark a major change for the HPSS. Governance arrangements are already in place to ensure overall probity, transparency and adherence to public service values. Clinical and social care governance, backed by a statutory duty of quality will mean that for the first time Health and Social Services Boards and HSS Trusts will have to place the provision of high quality services to the forefront of their statutory duties in the same way they must currently adhere to statutory financial duties.

7. A system of clinical and social care governance will bring together all the existing activity relating to the delivery of high quality services for example, education and research; audit; risk management and complaints management.

Improving monitoring and regulation of services

8. This paper proposes that an independent means of monitoring the delivery of services should be introduced. In addition, it is proposed to extend and improve the range of social care services currently regulated. It is also proposed to improve current regulation of private and voluntary healthcare services and to extend that regulation to cover a wider range of services delivered by that sector.

Proposals to monitor the delivery of services

9. It is proposed to monitor the delivery of services through the introduction of a new independent body - a Health and Social Services Improvement Authority. This body would carry out independent reviews of clinical and social care governance arrangements in Health and Social Services Boards and HSS Trusts and would also carry out investigations where significant or persistent problems occur.

Proposals to extend and improve the regulation of services

10. It is proposed to extend and improve the regulation of services to cover: statutory homes, homes covered by Charters and Acts of Parliament, small residential homes for adults, day care for adults, supported accommodation, nursing agencies, schools with boarding departments, the private and voluntary healthcare sector and agencies providing domiciliary care, fostering, adoption, services for Under 12s and nursing home care.

11. To discharge this more comprehensive regulation of services it is proposed that a Northern Ireland Commission for Care Services be established. This body would take over responsibility for the work currently carried out by the Registration and Inspection Units within the four Health and Social Services Boards; register and inspect a wider range of care services including the private and voluntary healthcare sector and where necessary take appropriate enforcement action to ensure standards are improved.

Equality Issues

12. During the consultation process, the Department will pay particular attention to the equality aspects of its proposals. It will make a special effort to obtain views from representatives of the nine categories specifically identified in the equality legislation.

About this paper

1

1.1 Securing more responsive, caring public services which strive towards excellence is at the heart of the commitment in the Programme for Government. Raising the quality of health and social services and tackling under-performance within the HPSS will require a concerted effort on the part of everyone involved in the HPSS.

1.2 Quality means the provision of high standards of care and treatment, given by the right person at the right time and in the appropriate setting. This paper sets out the Department's proposals for a framework designed to modernise and continuously improve the delivery of health and social care services. The paper suggests a framework consisting of three strands:

- setting standards - improving services & practice;
- delivery of services - through increased accountability at local levels; and
- monitoring performance, and improved regulation of services.

How to Respond

1.3 Comments on the proposals in this paper can be sent by e-mail or in writing to the address shown at the end of this Section. Unless otherwise requested, it will be assumed that responses are not intended to be confidential.

Timescale for Response

1.4 The closing date for receiving comments on this paper is 18th July 2001.

Additional Copies and Accessible Versions

1.5 The consultation paper is being widely circulated to key interest groups and will be available in libraries and on the Department's website. The Department will make the document available in audio tape, Braille, Irish and Cantonese. The Department will also consider requests for translations into other minority ethnic languages.

1 About this paper

What Happens Next?

1.6 Following the consultation period all the responses to the paper will be analysed. A separate report summarising the views expressed during the consultation will be published for information. The Minister for Health, Social Services and Public Safety will take decisions on the issues raised in this paper, taking account of the views expressed during the consultation exercise.

Contact Address

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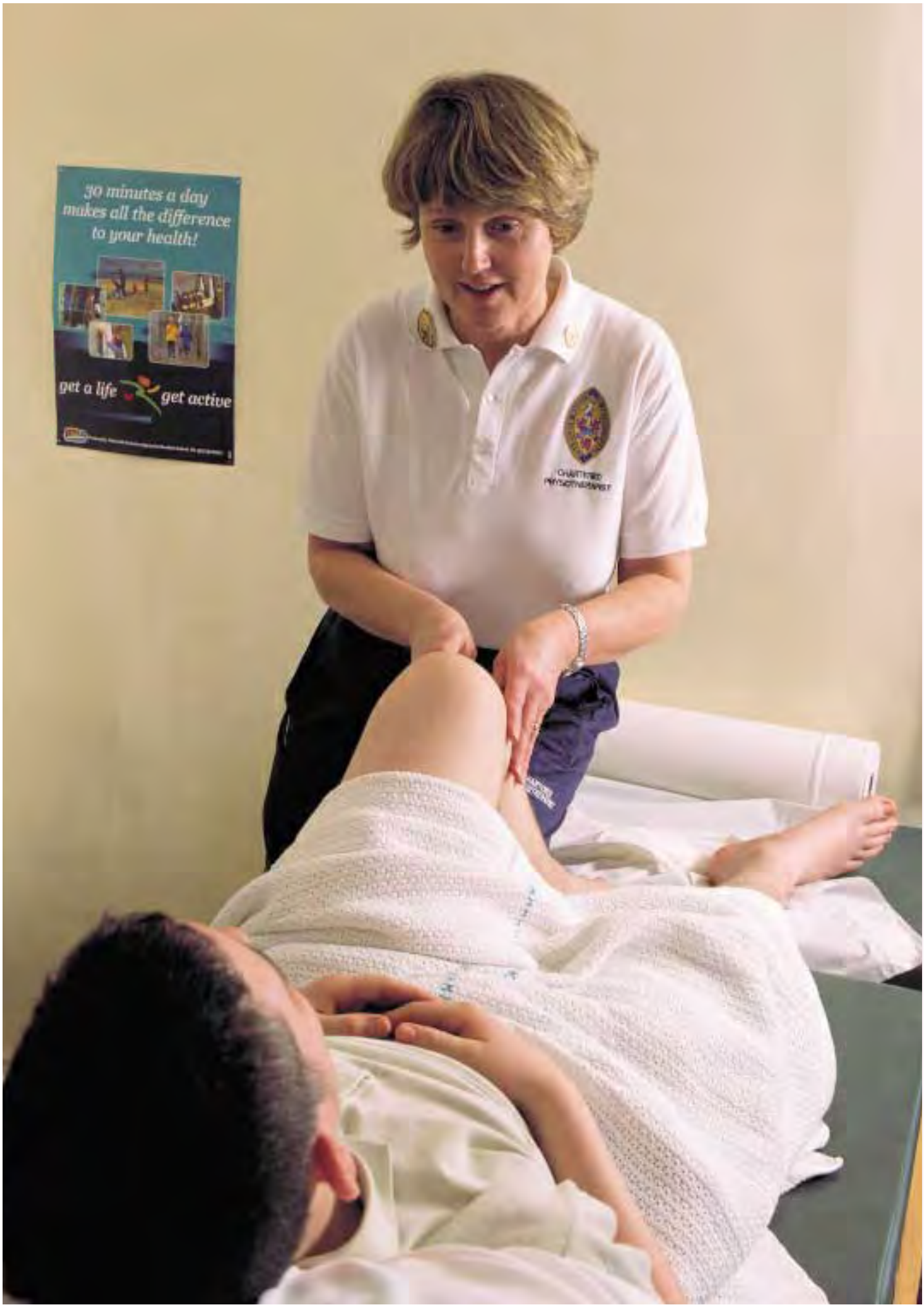

30 minutes a day
makes all the difference
to your health!
get a life
get active

2

Focusing on quality

2.1 Every year our hospitals provide over a million outpatient treatments. There are half a million admissions to hospital or day procedure clinics every year. Every day, 30,000 people see a doctor or a practice nurse. Every working day 120,000 people will visit a community pharmacy. In an average year, over 180,000 people will have contacted social services and more than 24,000 older people will be supported in their own homes.

2.2 The vast majority of people who need health or social care services are dealt with quickly and effectively. However some are dissatisfied with the way the service deals with them. Higher public expectation in the HPSS along with rapid advances in medicine, technology and in professional practice along with changing demography, mean that the HPSS has to modernise and improve in the future to enable it to provide a fast, effective high quality service.

2.3 Added to this is the new environment of local democratic control within which all public services now operate. The Programme for Government contains a clear commitment to raise the standard of public services. The Executive will be held to account for the commitments given in the Programme for Government. In parallel with the political changes, major developments have taken place in the NHS in England, Wales and Scotland which are aimed at raising the standard of services provided. There are now expectations in the HPSS that no less emphasis will be placed on the drive to raise the quality of services here.

2.4 As well as a need to modernise the HPSS there is also a need to ensure that unacceptable variations in the standards of care and treatment delivered are addressed. Recent events have shaken the public's confidence in our services. The revelations about organ retention and the Bristol enquiry[1] into the deaths of babies following heart surgery have highlighted shortcomings in hospital services, while the Shipman case[2] has underlined the need for closer scrutiny of general practice.

1 Public inquiry into Paediatric Cardiac Surgery Services at Bristol Royal Infirmary

2 Harold Shipman's Clinical Practice 1974-1993 - A Clinical Audit, CMO, DoH(L) ("The Baker Report") in addition an independent inquiry into the Shipman Case commenced on 31st January 2001.

2 Focusing on quality

2.5 There is no room for complacency in the HPSS. Similar incidents can happen here. The McLernon case[3] drew attention to the need to enhance and improve professional practice in assessment and care management arrangements to secure the continuity of care within and between primary, secondary and community sectors. In addition many people have to wait too long for their treatment or care. The experience of many is still of a disjointed and impersonal service which puts the needs of the organisation before the needs of individuals.

2.6 The challenge now facing the HPSS is to guarantee a standard of service that the public can expect no matter where they go for treatment or care. This challenge must be met head on with a co-ordinated approach to the raising of standards and robust accountability arrangements to ensure that those standards are met.

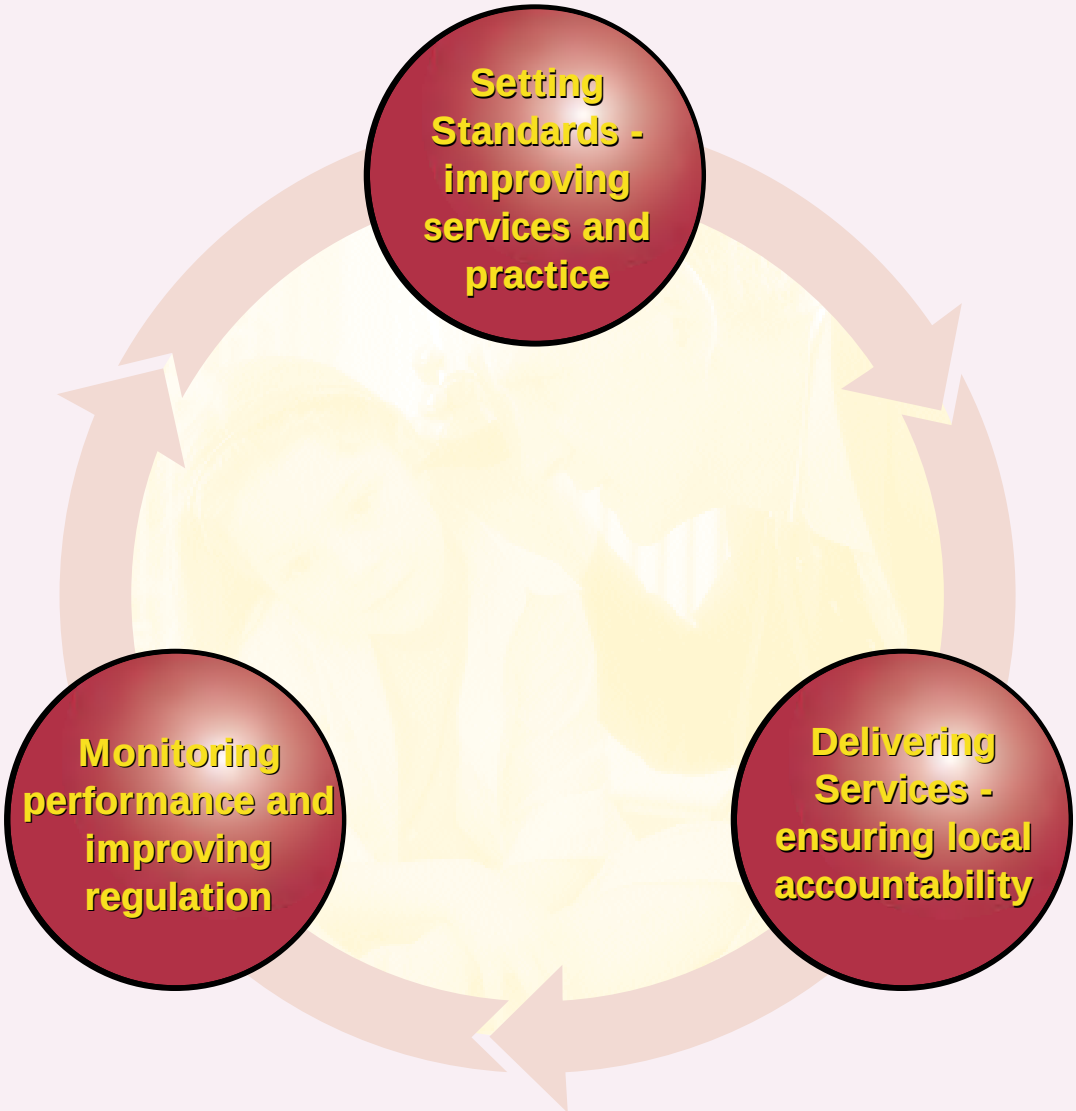
2.7 The starting point must be the development of staff who provide the services. A highly trained, competent and confident workforce is fundamental to securing the delivery of high quality services. The HPSS is one of the largest employers here with a total workforce of approximately 60,000. The skills of the staff represent already a significant investment for the benefit of the community. The great majority of these staff are highly motivated and continually strive for higher standards, despite the fact that demands and pressures on services have been rising inexorably. It is crucial therefore that we continue to invest in staff and enable them to develop their skills and expertise.

2.8 As well as supporting staff to continually develop their skills and knowledge it is essential that there are in place systems to monitor how the organisation and individuals are performing. It is only by establishing a full picture of what is being done well, and what falls short of this, that changes can be made and services improved.

2.9 This document proposes a framework which aims to improve quality in order to provide reassurance to those

3 "Community Care From Policy to Practice" - the Case of Mr Frederick Joseph McLernon (deceased), SSI, September 1998

Focusing on quality



who use the services that they will receive high standards of care and treatment wherever or however they are treated. The framework applies to everyone who works in, commissions and delivers services. Everyone must become involved in developing and nurturing a culture and environment where quality always comes first.

2.10 Those who use the service can bring valuable knowledge of how their local services are actually performing and how they would like to see services shaped in their local area. Through the greater involvement of the community in the planning, delivery and monitoring of services, the HPSS should aim to improve the quality of the services it provides.

2.11 The framework proposed in this paper centres on three interlocking strands. Each strand, while easily identified in its own right can only work to maximum effect if the other two strands are fully implemented. They are:

- setting standards - improving services and practice;
- delivering services - ensuring local accountability; and
- monitoring performance and improving regulation.

2.12 The delivery of high quality services using consistent standards, based on sound research and best practice, delivered by a competent and confident workforce will go some way in providing the public with access to a uniform standard of high quality health and social care. It is recognised that many HPSS organisations have been putting in place arrangements to raise the quality of services they deliver. These organisations are to be commended for their attempts to raise standards and provides further proof of the commitment of staff within the HPSS. It is important, however, that there is a comprehensive and uniform approach to raising the standard of services delivered. The proposals within this document should now build on the arrangements already in place in some organisations and enable all HPSS organisations to work within a single consistent framework for raising standards.

3

Setting Standards - Improving Services

3.1 Much work is underway to ensure high standards of care in the HPSS, through continuous professional development and strengthened professional regulation. There are still, however, many gaps and inconsistencies in the way standards and guidelines for services are produced and applied here. A more co-ordinated and structured approach is needed. Providing the HPSS with clear, consistent, evidence based guidelines and standards, which can be incorporated into standards for service delivery will improve outcomes for users. A structured approach to these developments would include for example, consideration of HPSS priorities, clinical and social care governance implications and the views of local professionals and lay people here in addition to the standards set by professionals.

3.2 This means identifying and reducing unacceptable variations in the delivery of services and ensuring the best use of resources to achieve the greatest benefit for all. To accomplish this, standards and guidelines must be based on:

- robust research and evidence of good practice;
- the effectiveness of care and treatment (including cost effectiveness);
- the experience of HPSS professionals and managers;
- the values and experience of the people receiving and using the services; and
- the requirements of legislation.

3.3 It is proposed therefore that standards and guidelines for the HPSS should be provided through:

- the introduction of service development frameworks; and
- the provision of a single, easily accessible source for producing and disseminating standards and guidelines for services.

Service Development Frameworks

3.4 Consideration is being given to the introduction of service development frameworks. Service development

frameworks would cover the whole system of care for a particular service and provide a holistic approach to planning, delivery and monitoring of services. Service development frameworks would spell out where care is best provided e.g. in a primary care setting, in hospital or in a specialist unit. They would set the standard of care that people should be offered in each setting and establish performance measures against which progress within agreed timescales will be measured.

3.5 Service development frameworks will take time to develop and will focus on the main priorities flowing from the Programme for Government. The framework for cancer services[4] here is an example of how a service has been remodelled using a service framework approach.

Questions for consultation

? Do you consider the service development framework approach should be introduced for the HPSS?

? How can user involvement be best secured in the development of service development frameworks?

? What services could be considered for development using a service framework approach?

A single, easily accessible source for the production and dissemination of guidelines and standards for services

3.6 Currently there is no single focus for the production and dissemination of service guidelines or standards for health and social services. Up until recently guidelines and standards for clinical and social care were developed by a range of bodies across Great Britain and here. These include professional and regulatory organisations and Social Services Inspectorates. Locally, the Clinical

4 Cancer Services - Investing for the Future. Report of the Cancer Working Group. DHSS 1996.

Resource Efficiency Support Team (CREST) and the Regional Multi-professional Audit Group (RMAG) contribute to this work.

3.7 These guidelines related to areas such as standards for good practice and cost effectiveness in health and social care services. Areas covered included guidelines from particular conditions or circumstances as well as guidelines on new health technologies such as new medicines, devices and products. Many of these guidelines were produced on a reactive basis rather than on a planned agenda flowing from the priorities within the HPSS, knowledge of forthcoming new health technologies and a systematic approach to the identification of gaps.

3.8 In England and Wales, recognising that guidelines and standards emanating from so many different sources can lead to variations in care, the National Institute for Clinical Excellence (NICE) was established on 1st April 1999. A similar body - the Social Care Institute for Excellence (SCIE) - for social care services is being established later this year for England and Wales.

National Institute for Clinical Excellence (NICE)

NICE covers the NHS in England and Wales. Its functions are to:

* promote clinical and cost effectiveness and audit through guidance to support front line staff;
* advise on best practice in the use of existing treatment options;
* appraise new health interventions such as newly developed drugs, devices and procedures and advise the NHS on how they can be implemented and how best they might sit alongside existing treatments.

NICE involves professionals, patients, carers and NHS service interests. It works to a programme agreed and funded by the Department of Health, in conjunction with the National Assembly for Wales. NICE brings together work such as the National Prescribing Centre appraisals and bulletins; the effectiveness bulletins produced by the NHS Centre for Reviews and Dissemination at York University; The National Centre for Clinical Audit has also come under the umbrella of NICE.

Setting Standards - Improving Services

Social Care Institute for Excellence (SCIE)

SCIE will cover social care services in England and Wales. Its functions will be to:

* pull together information about good practice in social care;
* assess social work practice through service reviews or research;
* issue guidance on good practice for the services.

SCIE will work closely with NICE, taking account of the views of users and carers, research evidence, findings from inspections, joint reviews and other sources of good practice.

Proposals

3.9 The absence of a single focus here for the production and dissemination of clear consistent guidelines for the HPSS is already leading to uncertainty. As a result it is likely to lead to variations in the standards of services. Added to this is the need to ensure that the HPSS knows how to handle guidelines and standards emanating from NICE, SCIE and other standard setting bodies.

3.10 It is proposed that the HPSS should receive clear consistent guidelines from a single source. In judging what is the most appropriate way to produce guidelines and standards it is considered that any local arrangements should:

- minimise bureaucracy and not involve the establishment of new public bodies unless absolutely necessary;
- avoid “re-inventing the wheel”;
- provide for a single, easily accessible source of guidelines and standards;
- utilise the range of expertise within the HPSS and elsewhere;
- promote a multi-disciplinary approach to the production and dissemination of standards and guidelines;
- ensure standards and guidelines are endorsed and promulgated in a timely manner;
- be sensitive to issues specific to the HPSS e.g. integration of health and social care services and challenges to viability of specialist services;
- be aware of local views of users;

- be able to respond rapidly to any emergency need for guidance and
- provide the mechanism to produce standards which will form part of service development frameworks.

3.11 The following options are offered for consideration:

- **OPTION ONE:** establish an independent body to research and appraise the evidence of new drugs and technologies or existing procedures and services based on priorities for the HPSS - to replicate much of what NICE and SCIE and other standard setting bodies are producing;
- **OPTION TWO:** establish an internal body within the Department to carry out research and appraise the evidence on new drugs and technologies or on existing procedures in line with identified priorities for the HPSS - replicate much of what NICE and SCIE and other standard setting bodies are producing;
- **OPTION THREE:** the Department would make arrangements with the standard setting bodies e.g. NICE, SCIE whereby the Department would have early warning of the standards and guidelines being produced. In addition the Department would act as a filter for the standards and guidelines emanating from NICE, SCIE and other standard setting bodies.

OPTION ONE

3.12 Option One would entail the establishment of a new independent body with its own staff, budget and a board of directors, drawn from the HPSS (including Research & Development Office), lay and user fields. This body would be seen to be operationally more independent than either Option Two or Three and this model would ensure that the focus remains on producing and disseminating standards and guidelines.

3.13 It is clear that this option would involve substantial costs. It is also doubtful if the HPSS, due to its size would have the relevant expertise and access to the relevant interests that would need to be represented on such a body, to replicate the research and production work involved in producing standards and guidelines. There is a danger, that under this Option the HPSS would lose access to the wide range of expertise available in England, Scotland and Wales. There is also the possibility that the production and dissemination of standards and guidelines would be considerably delayed under this Option. It is considered a waste of resources to seek to replicate the research and appraisal of evidence that will have already been undertaken by a much larger body such as NICE or SCIE.

OPTION TWO

3.14 Under this Option an internal body within the Department would replicate many of the standards and guidelines emanating from both NICE and SCIE. The research and appraisal of the evidence on new drugs, technologies and existing procedures would be undertaken by the internal body. The independence of this body would not be as apparent as for Option One, however the focus would remain as for Option One on producing and disseminating standards and guidelines.

3.15 A considerable number of experts and lay interests would need to be represented on the board of such an internal body. As for Option One this would involve substantial costs and again it is doubtful if the HPSS would have the relevant expertise and access to the relevant interests that would need to be represented on the internal body. As for Option One there is a danger of losing access to the wide range of expertise available in the other three countries and there is a possibility of delays in producing and disseminating the standards and guidelines to the HPSS under this Option.

OPTION THREE

3.16 Under Option Three it is proposed that the Department would seek to secure arrangements with NICE, SCIE and other agenda setting bodies to ensure early access to and indications of the programme of work for these bodies. In this way the Department would be in a position to filter the standards and guidelines through to the HPSS, having had an opportunity to consider their applicability to the HPSS. To provide for an easily recognisable source for these guidelines it is suggested that the Department would provide the vehicle for filtering the guidelines and standards to the HPSS through an internal mechanism known as the HPSS Standards Board.

3.17 It is envisaged that the majority of guidelines and standards emanating from NICE, SCIE and other standard setting bodies would generally be applicable for use within the HPSS. However, the HPSS Standards Board would as the need arises, be able to produce or commission specific guidelines for the HPSS, or adapt NICE, SCIE or other guidelines for use in the HPSS, as appropriate. When commissioning specific guidelines for the HPSS or adapting NICE or SCIE guidelines, the HPSS Standards Board would constitute a group of relevant expertise, including user representatives to develop the required standards and guidelines.

3.18 Under this Option the costs involved would be kept to a minimum. Any arrangements with bodies such as NICE and SCIE would involve costs and there would be administrative costs within the Department. In addition, if a group of experts were commissioned to produce specific guidelines and standards, funding would be required. Guidelines and standards would be disseminated quickly to the HPSS as the early indication of the standards and guidelines to be produced by NICE, SCIE and other bodies would allow the Department to consider the applicability of such standards and guidelines for the HPSS in advance of them being disseminated from NICE or SCIE etc.

Preferred Option

3.19 The preferred option for the production and dissemination of guidelines and standards for the HPSS is Option Three. Taking account of the parameters set at paragraph 3.10, it is considered that this Option best reflects what would be required of any local arrangements.

3.20 Clearly any arrangements introduced for the HPSS will have an impact on the current role of the Clinical Resource Efficiency Support Team (CREST) and the Regional Multi-professional Audit Group (RMAG). Obviously the provision of a single source for the production and dissemination of standards and guidelines will reflect some of the work currently undertaken by these groups. Your views are sought on how the work of these groups can best be progressed under any new local arrangements.

Questions for consultation

? Does there need to be a local focus to disseminate and produce guidelines and standards for the HPSS?

? Do you agree with the parameters set out at paragraph 3.11? Are there any others which have not been included?

? What are your views on the options - are there any other options which should be considered?

? Do you agree that Option Three best reflects the parameters set for a local arrangement?

? How can users best be represented on any group set up to produce specific standards and guidelines for the HPSS?

? Any option considered will have an impact on the current role of the Clinical Resource Efficiency Support Team (CREST) and Regional Multi-Professional Audit Group (RMAG). Should the work of these bodies be linked to the local arrangements or should they be retained as self-standing groups? Taking account of the parameters set for the local arrangements what future role do you see for CREST and RMAG?

Setting Standards - Improving Practice

4

4.1 It is essential that the workforce has the opportunity to keep up to date with best practice and develop their skills. This can only happen in a culture where sharing information and best practice is a normal part of everyday life.

Continuous Professional Development

4.2 The concept of Continuous Professional Development (CPD) or lifelong learning is not new. CPD is already providing opportunities for staff to develop their skills and improve the quality of services they deliver. The aim of CPD is to promote lifelong learning and development in individuals and teams and ensure that they remain up to date and competent to practice. It applies to all those who work in the HPSS, both professionals and non-professionals. For professionals it may also be a requirement to maintain registration. CPD is a key building block to supporting quality improvements in practice. The Department, employers, professional bodies and service users all have interests in the provision and promotion of CPD.

4.3 The Department wants to see the same standards of practice applied to everyone who uses the HPSS no matter where they live. Employers have a substantial investment in the skills of their staff which they would seek to maintain and improve. Professional bodies want to assist their members in retaining the necessary skills required for the job and service users need to be assured that their care and treatment is up to date and effective and that it is provided by those whose skills have been kept up to date.

What does CPD mean?

4.4 CPD is the systematic maintenance, improvement and broadening of knowledge and skill and the development of personal qualities necessary for the execution of professional, technical or other duties throughout the individuals working life. This means that for an individual

to work properly, the systematic acquisition of knowledge, skills and personal qualities is essential. In addition, once acquired, the same knowledge, skills and personal qualities must be methodically kept up to date to maintain them at an adequate level. They must then be developed and broadened.

CPD and the Individual

4.5 CPD is essentially about individuals, their development needs and what they are doing to achieve them. Individuals are ultimately responsible for managing their own CPD, although most people have obligations to employers and professional bodies. The CPD cycle places responsibility on the individual to identify their own learning needs and decide on how best to meet these needs. They should then identify how learning might take place to meet these needs, record these activities and evaluate the effectiveness of the CPD intervention. Following evaluation they must then identify any additional training needs, thus commencing the CPD cycle again.

4.6 CPD is not just about courses or qualifications. CPD includes a wide variety of activities which lead to learning and development. These include open learning, private study, work experience and many more.

CPD within Organisations

4.7 For organisations, CPD is about the identification of staff needs, taking account of organisational development and facilitating achieving those personal and professional needs and development of all the organisation's staff. Employers should provide support to individuals by developing procedures which support CPD; providing development opportunities (particularly those that can be experienced in-house); assisting with resources and expertise and by giving positive encouragement and recognition. This does not need highly formal and inflexible systems. It can happen in other ways. It can

result from shared experiences between members of staff or the development of an individual's leadership skills following a well considered delegation of authority and responsibility. It might even result from undertaking a challenging new task. A successful CPD system is a reflection of the enthusiasm of those operating, participating in and supporting it.

Strengthening Professional Regulation

4.8 CPD will help develop staff to enable them to deliver higher quality services. In addition to CPD a number of initiatives are currently taking place with the aim of improving standards of professional practice. These initiatives will further support the concept of staff development and learning through strengthening professional regulation. Current initiatives are detailed below.

General Medical Council Proposals

4.9 The vast majority of doctors are competent and conscientious. However the current systems of medical regulation do not give the public sufficient confidence that poorly performing doctors are being identified and early action is being taken to protect patients.

4.10 The proposals for revalidation - the regular demonstration by doctors that they remain fit to practice, are part of the response to concerns raised. Proposals for a comprehensive revalidation model are being drawn up at present and legislation will then be required to make participation in revalidation mandatory. Legislation will apply here as well.

Confidence in the Future - a consultation document on the prevention, recognition and management of poor performance of doctors in Northern Ireland

4.11 In October 2000 the Department issued the consultation document "Confidence in the Future - for patients and for

doctors". The overall aim of the proposals in this document is to create a supportive environment within which all doctors are able to practice, and one in which the vast majority of doctors will be able to explicitly demonstrate their high level of clinical practice.

4.12 This will be achieved through such things as:

- the introduction of a compulsory and comprehensive system of professional appraisal;
- the participation of all doctors in clinical audit;
- participation of all doctors in programmes of continuing medical education (CME), and continuing professional development (CPD);
- comprehensive induction programmes for all new staff;
- clear guidance and appropriate supervision from senior doctors for all doctors in training;
- proposals to review and strengthen occupational health services for all doctors; and
- by recording adverse events from which doctors can learn to prevent similar occurrences in future.

Strengthened regulation of Nursing, Midwifery and Health Visitors

4.13 The recommendations made following an independent review of the UK wide legislation regulating the nursing, midwifery and health visiting professions resulted in the proposal to establish a new Nursing and Midwifery Council to replace the United Kingdom Central Council (UKCC) and the four National Boards.

4.14 The new Council will have increased lay and user involvement and will be responsible for setting and monitoring standards of professional training, performance and conduct. It will also have wide powers to deal with nurses and midwives who present unacceptable risk to patients.

Proposals aimed at supporting the education, practice and performance of Nurses, Midwives and Health Visitors within the HPSS

4.15 A Project Board chaired by the Chief Nursing Officer has been established to consider the needs and opportunities for improved structures to develop nurse, midwife and health visiting education, practice and performance.

4.16 The Project Board carried out a three month consultation exercise proposing the creation of a new local body to support the initial and ongoing education, practice and performance of nurses, midwives and health visitors with the primary purpose of enhancing the quality of care provided to patients and users. Following the consultation process, work is now underway to implement the proposals.

Strengthened Regulation of the Professions Allied to Medicine

4.17 Following an independent review of the UK wide legislation regulating the Professions Allied to Medicine, proposals were formulated on the establishment of a new Health Professions Council. The proposals, which have been the subject of extensive consultation, will strengthen professional regulation to make public protection paramount, by increasing lay involvement to balance professional interest.

4.18 The new Council will have powers to tackle poor professional conduct and performance and will have streamlined procedures to ensure fitness for practice including quality assurance of professional training. The proposed new Health Professions Council will have scope to regulate professions which are not regulated now.

The Northern Ireland Social Care Council

4.19 The Northern Ireland Social Care Council (NISCC) is being established from 1st October 2001. It will have two key

responsibilities - to register and regulate the social care workforce and draw up codes of practice both for social care workers and their employers; and to ensure that staff are properly trained and qualified to do their jobs. The functions of Central Council for the Education and Training in Social Work (CCETSW) will be transferred to the Northern Ireland Social Care Council as will the functions of the Training Organisation for Personal Social Services (TOPSS). This should ensure that education, training and qualifications are to a high standard, fit for their purpose and meet the needs of the social care workforce.

4.20 A recent review of the professional training within social work has recommended improvements for the reform of social work professional training. The Department issued "Reforming Professional Social Work Training" for consultation on 24th November 2000. The document is consulting on seven key areas for reform.

Strengthened Regulation of the Pharmaceutical Profession

4.21 The practice of pharmacy and, in particular, the control of medicines is highly regulated. Nevertheless, to provide added assurance to the public in regard to professional competency to practise, further regulatory powers are envisaged to maintain and enhance the quality and safety of pharmaceutical services.

4.22 The scope of the provision made in the HPSS Act (Northern Ireland) 2001 allows for further legislative powers to be made pertaining to for example:

- the education and training requirements before and after admission to practice;
- standards of conduct and performance;
- discipline and fitness to practice; and
- investigation and enforcement.

Strengthened Regulation of the Dental Profession

4.23 The General Dental Council (GDC) has a statutory responsibility to promote high standards of dental education and has long favoured mandatory continuing

education. A preparatory scheme was introduced on 1st October 2000 and a statutory scheme commences on 1st January 2002. It will be phased in over a three year period according to the date of registration of the dentist. Legislation which will apply equally here is being prepared presently.

Summary

4.24 These regulatory mechanisms provide important and powerful assurance controls at practitioner level and will help to improve professional standards and ultimately the quality of care that people get. Continuous professional development and strengthened professional regulation will help to assure the public that those who are providing the services on which they depend are competent and reliable.

4.25 Building on the current developments in CPD and professional regulation and placing them within this framework will ensure a consistent approach to quality which can be managed and monitored within one single framework. CPD and professional regulation will be key building blocks in raising standards of services.

Delivering Services - Local Accountability

5

5.1 Governance arrangements are already in place in HPSS bodies to ensure overall probity, transparency and adherence to public service values. It is vital that comparable arrangements are in place to guarantee the delivery of high quality services. The production and dissemination of guidelines and standards for services, revising and strengthening standards for professional practice and the workforce and ensuring that staff are appropriately educated, trained and supported to help them deliver to the required standards will help to ensure higher quality services.

5.2 Placing responsibility for the standard of services delivered on local organisations will provide a guarantee that standards are being applied consistently throughout the HPSS. A system of local accountability will help the HPSS to continuously improve the quality of their services and safeguard high standards of delivery.

Proposals

5.3 It is therefore proposed to introduce a system of clinical and social care governance, underpinned by a statutory duty of quality and backed by continuous professional development and other training programmes.

What does clinical and social care governance mean?

5.4 Clinical and social care governance is about organisations taking corporate responsibility for performance and will provide guarantees for the standards of clinical and social care. It is the framework within which HPSS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment.

5.5 Clinical and social care governance will help those planning and delivering services to identify and build on good practice; to assess and minimise risk of untoward

events; to investigate problems as they arise and to ensure that lessons are learnt. It will also help professionals by ensuring that lifelong learning through continuous professional development is addressed by and within their organisation.

5.6 A system of clinical and social care governance which is simple to use and easily understood will help to identify areas where improvements can be made and where there are risks, that these can be easily identified and reduced. In addition such a system should set in place procedures to identify and rectify poor practice e.g. through increased awareness of proper procedures or additional training. Such a system will also offer reassurance to the public that checks are in place to ensure that they receive the highest standards of care and treatment.

5.7 A system of clinical and social care governance will build on and strengthen existing activity relating to the delivery of high quality care and treatment. This includes activity on:

- education and research;
- continuing professional and personal development;
- professional regulation and learning lessons from poor performance;
- quality standards;
- audit;
- risk management;
- complaints management;
- clinical effectiveness;
- effectiveness in social care services in meeting identified needs; and
- evidence-based practice.

5.8 The system of clinical and social care governance is designed to bring all of these components together and to secure a co-ordinated approach to the provision of high quality care and treatment, while ensuring a greater focus on the standard of clinical and social care practice.

Duty of Quality

5.9 To strengthen the clinical and social care governance systems it is proposed to introduce a statutory duty of quality on Health and Social Services Boards, HSS Trusts and those Special Agencies which provide services directly to users e.g. The Northern Ireland Blood Transfusion Agency. The duty of quality will place a statutory requirement on these bodies *to put and keep in place arrangements for improving and monitoring the quality of health and social care services* ***they provide directly*** *to individuals.* That is, they will have to put and keep in place a system of clinical and social care governance.

5.10 Clinical and social care governance systems backed by a statutory duty of quality will mean that each Health and Social Services Board, HSS Trust and where appropriate, Special Agency will have to establish clear lines of responsibility and accountability for the overall quality of care and treatment provided. Health and Social Services Boards, HSS Trusts and Special Agencies will be required to prepare regular reports for their boards and report annually on quality. This will mean that for the first time, Health and Social Services Boards, HSS Trusts and Special Agencies will have to place the provision of quality services at the forefront of their statutory duties in the same way they must adhere currently to statutory financial duties.

5.11 While the duty of quality will not extend to services which a Health and Social Services Board, HSS Trust or Special Agency commissions from individual practitioners, or Family Health Services under service agreements or contractual arrangements, these Family Health Services practitioners will be expected to implement clinical and social care governance systems. Commissioners will ensure their duty to the quality of services delivered is met through their contractual arrangements with the organisations concerned.

5 Delivering Services - Local Accountability

Questions for Consultation

? Do you consider the duty of quality should be placed on those services ***commissioned*** by an HSS Trust?

Family Health Services

5.12 While clinical and social care governance is an organisational concept, the principles of clinical and social care governance apply to all Family Health Services, such as general medical and dental practitioners, community pharmacists and opticians. Health and Social Services Boards, HSS Trusts and Special Agencies will be expected to actively promote clinical and social care governance principles with all those to whom they look to deliver services.

5.13 Practice teams and organised groups can identify areas for development and ways to make necessary quality improvements e.g. through:

- working together to determine practice and local health and social care priorities;
- encouraging development of personal and practice development plans aligned with identified priorities; and
- engaging in a range of quality activities such as audit, risk management, significant event analysis and seeking and incorporating patient views.

5.14 Proposals for new arrangements in primary care have already been set out in the consultation paper "Building the Way Forward in Primary Care"[5]. That paper proposed the creation of Local Health and Social Care Groups, which envisages groups of primary care professionals working together at local level to improve the delivery of primary care services and to become involved in the commissioning of services.

5 Building the Way Forward in Primary Care - A Consultation document, DHSSPS, December 2000

5.15 Subject to the outcome of the consultation on those proposals, it is considered that the creation of such groups would provide an organisational platform around which a model of clinical and social care governance could be developed in primary care.

Questions for Consultation

? In view of the Independent contractor status of Family Health Services Practitioners, how best can clinical and social care governance be applied in primary care?

? Do the proposals for Local Health and Social Care Groups set out in "Building the Way Forward in Primary Care" provide a possible structure to support clinical and social care governance in this area of primary care?

Clinical & social care governance in practice

5.16 For clinical & social care governance to be successful all HPSS organisations, in tackling issues of performance or poor quality must move away from a culture of blame to one of learning. They will need to adopt a partnership and collaborative approach within health and social care teams and between health and social care professionals and managers.

5.17 In an organisation where good clinical and social care governance systems are working, multi-disciplinary teams will be working at all levels, professional staff will be contributing to the improvement of standards, ideas and good practice will be shared and education and research will be prized. Staff will feel valued and supported and those using the services will be confident of receiving high quality services and their views will be central to the design and delivery of services. Information will be used to full advantage to plan and assess progress.

5.18 These values will be the key to good clinical and social care governance within organisations, family health services and at individual practice level.

5 Delivering Services - Local Accountability

Developing staff

5.19 While the system of clinical and social care governance is an organisational concept, the development of staff through continuous professional development (CPD) will be crucial to the success of clinical and social care governance and the organisations' ability to guarantee that quality services are being delivered within their organisation.

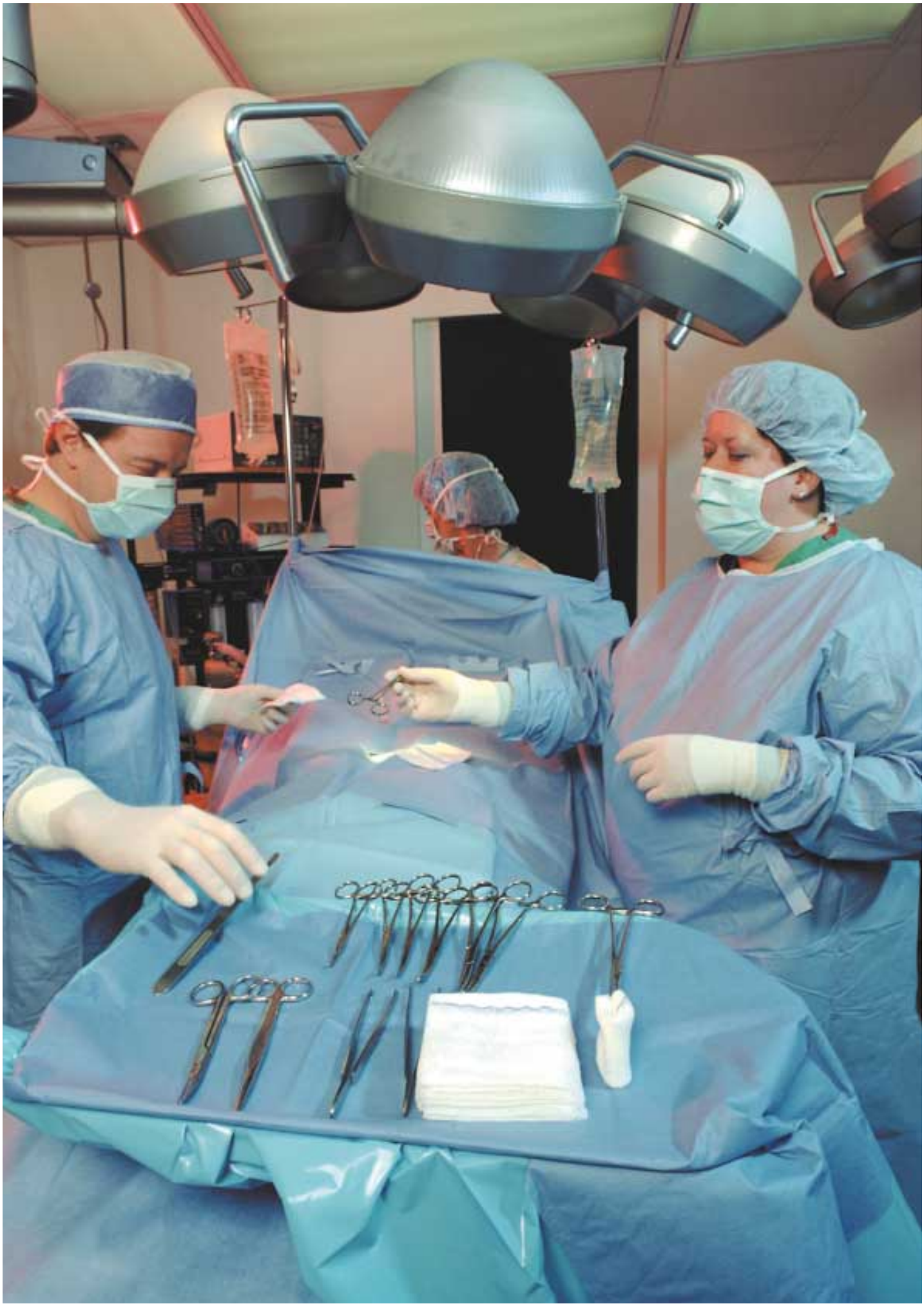
5.20 CPD is not new. CPD is being actively promoted throughout the HPSS and many developments have taken place to ensure that all organisations will be able to support their workforce by providing opportunities for education and training through CPD programmes.

Questions for Consultation

? Do you consider that this system of clinical and social care governance will help to improve the quality of services?

? Should the statutory duty of quality be placed on an HSS Trust for the services it commissions as well as those services it provides?

? How best do you think clinical and social care governance principles can be applied in primary care?



6

Monitoring Performance

6.1 It is crucial that the Minister, the HPSS Committee and the Assembly can be assured that the resources allocated to the HPSS are used effectively to develop and deliver high quality services in line with the objectives set out in the Programme for Government. There must also be a clear line of accountability from front line delivery back to the Executive. Nowhere is this more relevant than in the HPSS. People must have assurances that services are being delivered to the highest standards by a competent and confident workforce. They need to know that they will receive a high standard of service no matter who they are or where they live.

6.2 Setting standards for the workforce, putting in place a mechanism to produce and disseminate standards and guidelines for the services, putting in place local accountability arrangements to assure the delivery of high quality services to the standards set are very important elements of this framework. Standards, the way in which services are delivered and clinical and social care practice must be continually reviewed, challenged and where necessary changed. More robust monitoring arrangements will help to ensure that this happens.

Current monitoring arrangements

6.3 Standards and service performance are currently monitored at Departmental, HSS Board and HSS Trust levels. Groups including the Social Services Inspectorate (SSI), Pharmaceutical Inspectorate, Registration and Inspection Units, the Regional Multi-professional Audit Group (RMAG) and the Clinical Resource Efficiency Support Team (CREST) all make a significant contribution to support monitoring in the HPSS.

Proposals

6.4 More needs to be done. Robust performance management arrangements of individuals and of services must be in place throughout the HPSS to provide service users, the

6 Monitoring Performance

Department, those who commission and those who provide services with a clear picture of what is being done well in the service and what needs to be changed.

6.5 Improving clinical and social care practice will be supported through the clinical and social care governance framework, together with continuous professional development and professional regulation. It is proposed that improvements in the assessment of service performance should be addressed by:

- a new Performance Management Framework; and
- the establishment of a new independent body to monitor and report on clinical and social care governance arrangements within Health and Social Services Boards, HSS Trusts, Special Agencies and where appropriate, Family Health Services.

A new Performance Management Framework

6.6 The Department is currently working on proposals to develop a Performance Management Framework, which it is envisaged will provide an overall template to judge performance of the HPSS at all levels. The Performance Management Framework will focus on measuring performance against six key areas:

- improved health and social well-being;
- fair access to health and social care services;
- effectiveness in the delivery of appropriate health and social care services;
- the experience of service users and their contribution to the planning and delivery of services;
- efficiency in the delivery of health and social care services; and
- health and social care outcomes.

6.7 Indicators will need to be identified and/or developed which will enable the Department to assess how well the HPSS is performing in each of the six key areas above. The

Monitoring Performance

Performance Management Framework will continue to be developed to provide the mechanism of measuring performance against key planning priorities.

6.8 Health and Social Services Boards should be able to use the Performance Management Framework to help identify areas for Health and Wellbeing Investment Programmes. HSS Trusts should be able to use the Performance Management Framework to help them continuously improve and benchmark against other similar organisations and to demonstrate that they are delivering services to the agreed standards. Ultimately the Performance Management Framework will provide a vehicle for the Assembly to assess progress against the priorities set in the Programme for Government and will help inform future Programmes.

6.9 Work is progressing on the development of the Performance Management Framework and proposals will be brought forward at a later date.

Independent monitoring of services

6.10. Independent scrutiny of clinical and social services is currently limited. Valuable work is carried out by professional groups and bodies to promote and support improvements in clinical practice. Bodies such as the Mental Health Commission and the Northern Ireland Hospital Advisory Service (NIHAS) and groups such as CREST and RMAG all contribute to this work. Independent scrutiny of social services is carried out through the Social Services Inspectorate. Registration and inspection of pharmacies is carried out by the Pharmaceutical Inspectorate, which also has wider inspection and enforcement powers under legislation.

Proposals

6.11. To further strengthen monitoring and accountability systems it is proposed that a more independent system of monitoring services should be introduced in the HPSS. An

6 Monitoring Performance

independent examination of the governance and delivery of all services should provide the public with assurances that the HPSS is fulfilling its responsibilities for quality and should afford greater protection for service users. When things are going wrong in the HPSS, people need to know that failures are identified quickly, openly investigated and put right. Indeed the establishment of the Commission for Health Improvement for England and Wales has already raised expectations that similar independent assurances about the quality of services will be given here.

The Commission for Health Improvement (CHI) was established in April 2000 with the aim of improving the quality of patient care in the NHS across England and Wales. Working to a programme which aims to reduce unacceptable variation in care and ensuring every NHS patient receives a high level of care, the core functions of CHI are:

- to provide national leadership to develop and disseminate clinical governance principles;
- independently scrutinise local clinical governance arrangements to support, promote and deliver high quality services. CHI will conduct a rolling programme of reviews of clinical governance arrangements visiting every NHS Trust, Primary Care Trust and Health Authority every four years and will make its findings public;
- review and monitor local and national implementation of national guidelines in the form of National Service Frameworks (NSFs) and National Institute for Clinical Excellence (NICE) guidance;
- help the NHS identify and tackle serious or persistent clinical problems. CHI has the capacity for rapid investigation and intervention to help put these right;
- increasingly take on responsibility for overseeing and assisting with external NHS incident enquiries in England and Wales; and
- seek to identify excellence and celebrate and share good practice, thus producing bench marks.

CHI does not have the powers to remove or replace any member of staff, management teams or board members. However it will report any serious finding to the Secretary of State for Health in England or the National Assembly for Wales.

Monitoring Performance

6.12. In considering how best to secure independent monitoring in the HPSS, it is regarded as essential that any new arrangements here would need to be truly independent, reflect the integrated services and should add as little as possible to bureaucracy.

The Health and Social Services Improvement Authority

6.13. Taking account of the stipulations above it is proposed to establish an independent body, called the Health and Social Services Improvement Authority. This body would be required to:

- monitor, assure and provide advice and information on clinical and social care governance arrangements;
- review the clinical and social care governance arrangements as part of rolling three or four year visits to every Health and Social Services Board, HSS Trust, Special Agency and Family Health Services where appropriate;
- investigate incidents where significant or persistent clinical or social care problems occur; and
- work closely with the Health Services Audit; the Northern Ireland Audit Office; the Health and Safety Inspectorate; the Commission for Health Improvement; professional regulatory bodies and the Northern Ireland Commission for Care Services.

6.14. The Health and Social Services Improvement Authority would be established as a non-departmental public body to carry out the functions detailed in paragraph 6.13 above. The Health and Social Services Improvement Authority would be directly accountable to the Minister and would carry out investigations at the request of the Minister reporting back to the Minister on the findings.

6.15. The Health and Social Services Improvement Authority would have a chair, board of directors and full administrative support. In addition the Health and Social Services Improvement Authority would have an executive team responsible for carrying out the review visits and

investigations. A pool of experts from within the HPSS would be established, from which the executive team would draw when carrying out review visits.

6.16. Where in exceptional cases it is considered that expertise from elsewhere is required to assist in investigations, the Department has secured provision in the Health Act 1999 to allow it, subject to the Minister's approval to approach the Commission for Health Improvement in England, to provide the relevant expertise in clinical issues.

Questions for Consultation

? Do you consider there is a need for independent scrutiny of clinical and social care services?

? Are there any other options which should be considered to secure independent monitoring?

? What representation would need to be included on this body?

? How could user representation be secured - on the board of the Health and Social Services Improvement Authority and when carrying out reviews and investigations?

7

Improving and Extending the Regulation of Services

7.1 Another vital link in seeking improvements in the standard of services delivered is the need to improve and extend the range of social care services that are currently regulated. Regulation is based on legislation and involves the whole process of registration, inspection and enforcement, distinct sets of activities which ensure compliance with statutory requirements.

7.2 The Registered Homes (Northern Ireland) Order 1992, the Children (Northern Ireland) Order 1995 and their accompanying regulations govern the current arrangements for regulating nursing, residential and children's services and schools with boarding departments.

7.3 The current system of regulation has developed over a number of years in a fragmented and piecemeal fashion and has led to numerous problems, including inconsistency in the standards set and applied across the sectors.

7.4 An earlier consultation exercise carried out by the Department in 1998, indicated a need to improve the current system of regulation of social care services and to extend regulation to cover a wider range of social care services. For example residential care homes run by Trusts and homes provided under Royal Charters or Acts of Parliament are not subject to regulation, nor is support to people in their own homes and day care centres. Extending regulation to cover these services will offer better protection to vulnerable people using these services. Improving and extending regulation will ensure that services are regulated and monitored against agreed minimum standards.

Private and Voluntary Healthcare

7.5 The private and voluntary healthcare sector is currently subject to regulation under the Registered Homes (Northern Ireland) Order 1992. Under this Order, private and voluntary hospitals are classed as nursing homes. This is inappropriate given the range of work they do.

7 Improving and Extending the Regulation of Services

7.6 The current regulatory arrangements have a number of shortcomings. In particular Registration and Inspection Units have few powers other than to decline to register a new establishment or to de-register an existing one and cannot for example require an establishment to cease undertaking particular treatments even if the inspectors are concerned about the safety of patients. This undermines the effectiveness of current regulatory work.

Proposals

7.7 The current system of regulation is carried out by the Registration and Inspection Units within the four Health and Social Services Boards in relation to residential and nursing home care and by eleven HSS Trusts in relation to Under 12's services. This makes it more difficult to set and enforce standards in a consistent and independent manner here. It is proposed therefore to extend regulation of social care services to include a wider range of services and to establish a Northern Ireland Commission for Care Services to carry out the regulation of the current and extended range of services.

7.8 It is proposed to extend and improve the regulation of services to cover: statutory homes, homes covered by Charters and Acts of Parliament, small residential homes for adults, day care for adults, supported accommodation, nursing agencies, schools with boarding departments, the private and voluntary healthcare sector and agencies providing:

- domiciliary care;
- fostering;
- adoption;
- services for children under 12; and
- nursing home care.

Northern Ireland Commission for Care Services

7.9 To discharge this more comprehensive regulation of services it is proposed that a Northern Ireland Commission

for Care Services be established. The Northern Ireland Commission for Care Services would carry out the regulation of the current and extended range of services and would mirror the National Care Standards Commission established for England and Wales.

The National Care Standards Commission (NCSC) is a new independent regulatory body for social care services and private and voluntary health care. The NCSC will be responsible for the regulation of the whole range of care services from care homes for the elderly, children's homes, domiciliary care, fostering and adoption agencies through to private hospitals and clinics. The Secretary of State for England and the National Assembly for Wales have powers to make regulations governing the conduct of services regulated and to issue minimum national standards applicable to all the services to which the registration authorities and providers must have regard. The NCSC will ensure all regulated care services are provided to national minimum standards laid down by the Secretary of State in England and the National Assembly for Wales, through regulation and inspection. It will investigate complaints against registered services and report to the Secretary of State (or National Assembly for Wales) on the range and quality of regulated services. The NCSC will encourage improvement in the quality of services (through e.g. disseminating examples of good practice and giving advice to providers on how to meet the national minimum standards) and make information available to the public about the quality of services. This might include information about the location and types of services available, as well as the results of its inspections of individual providers. The NCSC will advise the Secretary of State or provide information about any aspect of the provision of services and about changes to the national minimum standards with a view to seeking improvement in the quality of services.

Functions of the Northern Ireland Commission for Care Services (NICCS)

7.10 The Northern Ireland Commission for Care Services (NICCS) would be established as an independent non-departmental public body. The functions of the NICCS would be to:

- take over responsibility for the work currently carried out by the Registration & Inspection Units within the four HSS Boards;
- register and inspect a wider range of care services;
- investigate complaints against registered services;
- where necessary take appropriate enforcement action to ensure standards are improved;
- serve improvement notices, prosecute and where necessary de-register services;
- regulate the private and voluntary healthcare sector;
- monitor and enforce the adherence to the Codes of Practice for employers as laid down by the Northern Ireland Social Care Council; and
- work in collaboration with other bodies including the Health and Social Services Improvement Authority and the Mental Health Commission on issues pertaining to that area of work.

7.11 Standards for care services will be developed through a process of consultation between the Department and a range of interested parties. The NICCS will be expected to apply these standards and will introduce a consistent and thorough approach to the conduct of registration and inspection and the application of standards and recommend changes where necessary. The NICCS would be expected to work in collaboration with the Northern Ireland Social Care Council and The Health and Social Services Improvement Authority. The NICCS would have its own management board comprising of chair and members drawn from the wide range of key stakeholders in the health and social services field including user and provider representation.

Social Care Tribunal (Enforcement and Appeals)

7.12 All regulated services including statutory services will be subject to appropriate enforcement action. This action includes the power to serve improvement notices, prosecute and where necessary de-register. Providers will have rights of appeal against de-registration decisions.

Improving and Extending the Regulation of Services

7.13 The Social Care Tribunal as established under the HPSS (Northern Ireland) Act 2001, will replace the existing Registered Homes Tribunal and will consider appeals for the extended range of services.

Questions for Consultation

? What other social care services do you consider should be subject to regulation?

? What health and social care services currently delivered by the private and voluntary healthcare sector do you consider should be regulated under these proposals?

? How could user/lay input be best represented on the new Northern Ireland Commission for Care Services?

? What other representatives should be on the board of the new Northern Ireland Commission for Care Services?

? Given the current and extended range of services to be regulated and the specialist nature of those services should the new Northern Ireland Commission for Care Services be structured on a specialist or on a generic basis with specialist oversight?

? What powers should the Northern Ireland Commission for Care Services have in addition to those already mentioned?

8

Equality Issues

8.1 Section 75 of and Schedule 9 to the Northern Ireland Act 1998 place new statutory obligations on Departments and other public authorities in carrying out their functions. Such bodies are to have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between persons with a disability and persons without; and
- between persons with dependants and persons without.

8.2 Without prejudice to the above, they are also to have regard, in carrying out their functions, to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group.

8.3 As part of this consultation process, the Department wishes to pay particular attention to the equality aspects of its proposals. The purpose of this framework is to improve the quality of the services delivered by the HPSS, thereby raising standards and ensuring a consistency in the standards applied. It should result in providing assurance to everyone who uses the services that they will be provided with the highest standard of care, no matter where they live or what HPSS facility they use.

8.4 The proposals to provide a single focus for the production and dissemination of standards and guidelines for the HPSS should result in a consistent approach to the provision of services across the HPSS, thereby removing inequalities and inequities in service provision.

8.5 Subject to the outcome of this consultation, should the two new non-departmental public bodies - the Health and Social Services Improvement Authority and the Northern Ireland Commission for Care Services be established, they will be subject to statutory equality obligations under Section 75 of the Northern Ireland Act 1998 and as such will be required to produce their own equality schemes.

8 Equality Issues

Questions for Consultation

? Comments are invited on whether the proposals in this paper have any particular implications for equality of opportunity between the nine categories specified in the equality legislation in the Northern Ireland Act; or for promoting good relations between persons of different religious belief, political opinion or racial group.

? If so, can you state where and to what extent you think this might be the case?

? Do you consider that these proposals will have a differential impact on any of the categories specified in the equality legislation in the Northern Ireland Act 1998?

? Is there a better way of meeting the objectives set out in this document, which will better promote equality of opportunity? If yes, how?

THE QUALITY CIRCLE

Notes

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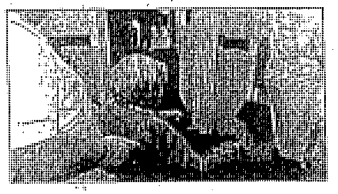

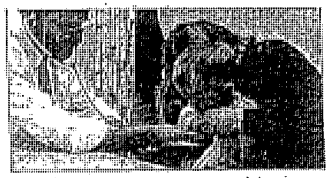

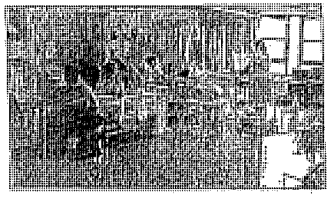

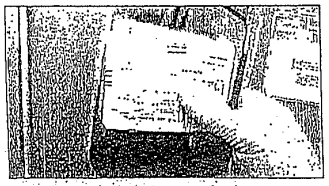

Department of Health, Social Services and Public Safety

Safety in Health and Social Care Project – Clinical and Social Care Governance

Final Report

31st March 2004

Deloitte.

Department of Health, Social Services and Public Safety

An Roinn Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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1 EXECUTIVE SUMMARY

1.1 Introduction & Background

The DHSSPS has established a Safety in Health & Social Care Steering Group whose terms of reference include the development of a strategic approach to the recording, reporting and investigation of adverse incidents and near misses. As part of this work the Steering Group have commissioned Deloitte to:

- carry out a scoping exercise on adverse incidents and near miss reporting in the HPSS; and
- carry out an evaluation of the NI Adverse Incident Centre.

1.2 Our Approach

We performed the assignment based on the Terms of Reference detailed in the Engagement Letter dated 11th November 2003. This broadly involved review and research of the area, discussion with key individuals in the DHSSPS and NIAIC and the issuance of a questionnaire and subsequent site visit to all relevant areas within the HPSS and wider health & social care community. The detailed terms of reference are included in Section 2 of the report.

The report has been prepared on the basis of the information gathered from desktop review of the relevant areas of incident reporting, the returned questionnaires and the discussions undertaken with key individuals in the relevant organisations. The report has presented the findings of each HPSS organisation based on the key areas detailed within the terms of reference. The information detailed by each organisation has been presented in tables indicating whether the organisation has meet key indicators associated with incident reporting. These have been scored as follows:

Key:			
✓	in place	X	not in place
✓	partially in place/in development	N	not applicable

The information supplied in Appendices V, VI and VII provides narrative detail to complement the information supplied in these tables. The findings presented and the subsequent recommendations are a summarised assessment of the position of each area of incident reporting. This summarised assessment is based on the common themes identified across the organisations and does not agree to the findings of each organisation.

It should be noted that the scorings provided for each organisation are based on assessment of what organisations presented to us through the questionnaire and the site visits. We have verified this information were possible, however significant levels were based on opinion of the individuals we met. Frequently differing views were provided from within the same organisation, and when this has occurred we have made an assessment of the overall status. It is also important to note that these scores are at a point in time and will change as organisations continue to address their CSCG and incident and near miss reporting systems.

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1.3 Context of Incident Reporting in Northern Ireland

The following key organisations and documents significantly affect incident reporting within Northern Ireland:

- *Department of Health, Social Services and Public Safety (DHSSPS)* - the Department's mission is to improve the health and social well being of the people of Northern Ireland.
- *Health and Personal Social Services (HPSS)* - are provided as an integrated service in Northern Ireland. The four health and social services boards (Eastern, Northern, Southern and Western) are agents of the DHSSPS in planning and commissioning and purchasing services for the residents in their areas. The 19 HSS Trusts are the providers of health and social services.
- *Health Estate's* task is to provide professional and technical advice, guidance and support on estate maters at both strategic and operational levels to the various bodies charged with the responsibility for the Health and Social Services estate in Northern Ireland. Health Estates includes the "Northern Ireland Adverse Incident Centre (NIAIC)" as a business area.
- *NIAIC's* objective is "to improve the quality of service provided to the community by improving safety and effectiveness in using medical devices and equipment." NIAIC's role in incident reporting in fully discussed in Section 5 of this report.
- *Best Practice - Best Care* is a consultation paper setting out proposals to deliver a framework to raise the quality of services provided to the community and tackle issues of poor performance across the HPSS detailed in the Programme for Government by the former Northern Ireland Executive.
- *Controls Assurance* - the standards discussed below are those considered to have particular relevance to Safety in Health & Social Care:
  - Governance
  - Risk Management
  - Medical Devices and Equipment Management
  - Medicines Management Standard (Safe and Secure Handling of Medicines)
- *Medicines Governance Project* - was designed to minimise the occurrence of medication-related adverse events in hospitals through a systems-based approach to risk management.
- *Other Incident Reporting Regulations and Agencies and Groups* include:
  - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)
  - Defective Medicinal Products reporting in conjunction with the Pharmaceutical Branch of DHSSPS
  - Regional Pharmaceutical Laboratory Service

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- Environment Health Officer/Foods Standard Agency

1.4 Incident Reporting in Great Britain

The following main observations were made in relation to incident reporting in Great Britain:

- The structure for incident and near miss reporting in Great Britain has changed significantly in recent years with increased focus on patient safety following significant research and subsequent reports.
- The reports "An Organisation with a Memory[1]", and its follow-up "Building a Safer NHS for Patients[2]" highlighted research suggesting that around 10% of patients admitted to UK acute hospitals suffer some kind of incident that affect their safety, up to half of which may be preventable. Findings in the US, Australia, New Zealand and Denmark have suggested similar levels. The reports were instrumental in establishing that the NHS had to improve its capacity to learn when things go wrong.
- The National Patient Safety Agency (NPSA) is a Special Health Authority created in July 2001 following the publication of two reports on patient safety in the NHS and aims to co-ordinate the efforts of all those involved in healthcare, and more importantly to learn from, patient safety incidents occurring in the NHS.
- The NPSA have recently undertaken a scoping exercise of the incident reporting systems utilised in the NHS. They have established that there are currently 36 different reporting systems for Trusts.
- Wales have recently bought into NPSA, however indications are currently that Scotland won't be following suit. Northern Ireland are currently not formally linked to NPSA, however informal linkages do exist.
- NPSA are developing a National Reporting and Learning System (NRLS), which is being rolled out during 2004. It will be the first healthcare incident data collection system on this scale in the world and will collate information on incidents that affect patient safety and identify any emerging patterns that may not be apparent at a local level.
- NRLS will enable NHS staff, patients and their carers in England and Wales to report any incident or prevented incident (near miss) that they are involved in or witness. The information they provide to NPSA will be stored in an anonymous form and analysed to identify the key underlying factors that affect patient safety. This data, alongside a number of other information sources, will help NPSA determine where it should concentrate its efforts and allow it to establish patient safety priorities.
- The Medicines and Healthcare products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) in April 2003. The Agency is committed to safeguarding public health by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely. Medicines, as distinct from devices,

[1] Department of Health, 2000.
[2] Department of Health, 2001.

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are licenced products and are subject to significant regulatory control, with MHRA being the lead regulatory body in the UK. The MHRA have recently developed a Memorandum of Understanding with HSE and NPSA.

- The Defective Medicines Report Centre (DMRC) receives and assesses complaints and reports of actual or suspected defects in medicinal products for human use and co-ordinates the necessary actions.
- Whilst MHRA works closely with NPSA the two organisations operate differently in that MHRA will investigate all incidents whereas NPSA are specifically interested in trend analysis. MHRA tend to inform NPSA of 'User Error' Incidents.
- NPSA has been slow to get up and running and significant criticisms are still levied at it in terms of its effectiveness and remit. Despite these criticisms the potential value of NPSA to Northern Ireland HSS organisations is considered as high, however Northern Ireland would need to have a level of consistency in approach to incident reporting to fully benefit from this linkage.
- The Scottish Healthcare service currently utilises the Incident Reporting & Investigation Centre (part of Scottish Healthcare Supplies) which co-ordinates the investigation of Adverse Incidents on behalf of the Scottish Executive Health Department. Working exclusively in the NHS in Scotland it pursues investigations involving medical devices and estates equipment.
- "Building a safer NHS for Patients – Improving Medication Safety" was published in January 2004 and follows on from the original "Building a Safer NHS for Patients" report published in July 2002. The new report specifically deals with the issue of medication errors that occur in the NHS.
- The Safety Alert Broadcast System (a new electronic system developed by the Department of Health, with the MHRA) has been piloted and is due for roll out in April 2004. At present Northern Ireland has no linkage with SABS and there appears to be no prospect of this occurring in the near future.
- The Commission for Health Improvement (CHI) is the independent authoritative voice on the state of the NHS in England and Wales. CHI aims to improve the quality of patient care in the NHS (Scotland has its own regulatory body, the NHS Quality Improvement Scotland).

1.5 Review of Incident Reporting in the HPSS

Detailed review of the systems used to report and record incident and near miss reporting in Northern Ireland revealed one overwhelmingly obvious finding: inconsistency of approach. This inconsistency existed in nearly every aspect of incident and near miss reporting, from defining an incident or near miss within each organisation to the procedures for reporting and collating the information and how the information is analysed and used within each organisation. The only consistent element within each organisation was the drive to improve incident reporting based on a common belief and understanding of the benefits it accrues to patient safety and care. On the back of these high-level observations, the HPSS incident reporting systems could be summarised as having:

"Inconsistencies in Process – Consistency in Spirit"

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Whilst significant variations existed in how organisations undertake the reporting of incidents and near misses, common practice did exist in many areas. Overall, most organisations use the same basic structure to report, record and analysis incident and near miss information, although it was noted that the incident reporting system in each organisation had evolved at different levels and in different ways.

The review demonstrated that a significant level of the organisations involved have put considerable effort and resource into their incident reporting system recently, but that most policies and procedures reviewed are still considered as evolving or in development. No organisation stated that it has fully developed its system and 100% incident reporting is considered unattainable by all organisations.

A detailed narrative review of each organisation involved in the Safety in Health & Social Care project has been produced and is attached in Appendices V, VI and VII. Based on the scope of the project, the pre-site questionnaire completed by each HPSS organisation and the subsequent observations made at the site visits, seven categories relating to incident and near miss reporting have been developed:

1.5.1 Incident Reporting Policies

The Incident Reporting Policies section considers the policies that each organisation has developed in relation to incident and near miss reporting. The following major observations were made in relation to incident and near miss reporting policies:

- *Policies* - major inconsistencies were observed in the level and existence of policies relating to Clinical and Social Care Governance (CSCG), risk management and incident reporting within the various organisations.
- *Definitions* - major inconsistencies were observed in the definitions for incidents and near misses within each organisation and across the region. The majority of organisations would consider the development of regional incident reporting definitions as a very positive step forward.
- *Reporting Culture* - all organisations promote an open reporting culture, but differences exist in treatment of anonymous reporting. No organisation was assessed as having a fully open culture with 100% reporting, however significant differences were noted between individual organisations.

1.5.2 Incident Reporting Procedures

The Incident Reporting Procedures section considers the operational procedures in place within each organisation to capture incidents and near misses. Although the organisations observed a common high-level approach to incident and near miss reporting the detailed procedures in each organisation differ significantly. The following major observations were made in relation to incident and near miss reporting procedures:

- *Reporting Process* - very few organisations demonstrated a fully consistent procedure for dealing with all aspects of incident reporting across all areas. Differences existed in whether organisations co-ordinated incident reporting in one area or had fragmented reporting at Directorate level.
- *Reporting Forms* - only one organisation currently uses a single electronic reporting form, although it has not replaced the paper form completely at this stage. Nine organisations have a single paper reporting form. A significant number of organisations have two or three forms based on the need to separate different incident reporting information.

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- *Risk Assessment* - All organisations undertake some form of risk assessment and management, but this ranges from very informal and ad hoc to highly formalised and structured risk management processes.

1.5.3 Incident Reporting Systems

The Incident Reporting Systems section considers the systems and support utilised to record incidents and near misses within each organisation. The following major observations were made in relation to incident and near miss reporting systems:

- *System Type* - Out of the 26 HSS organisations, 11 use Datix to record incidents and near misses, with another 10 currently implementing it or planning to implement it. The other systems that are used by organisations to record incidents and near misses are Ulysses, Safecode, CASS, Excel, Word, Access and SHE.
- *System Coding* - most organisations had tailored an existing coding system for reported incident data (including those organisations using Datix).
- *System Resources* - the majority of organisations have dedicated staff to input data onto the incident reporting system, however the circumstances of these individuals in relation to where in the organisation they sit, how much training they have received and their level of responsibility differ significantly between each organisation.

1.5.4 Review of Incidents Reported

The Review of Incidents Reported section considers how each organisation investigates incidents and near misses and reviews trends relating to incidents and near misses. The following major observations were made in relation to incident and near miss reporting systems:

- *Investigations* - most organisations have a systematic process to decide what to investigate, however the formalisation and complexity of processes varied greatly within different organisations.
- *Analysis of Incident Reporting Data* - most organisations have a systematic approach to reviewing reported incidents, however this varied greatly in its complexity. Trend analysis is undertaken by most organisations at some level, however the level and type of analysis differs significantly between the organisations (not least as the organisations are basing the analysis on differing quality of data and information). A significant number of organisations do not undertake root cause analysis due to lack of understanding/training or resource issues.
- *Continual Audit/Monitoring of Outcomes* - most organisations link incident reporting to internal audit programmes (including clinical audit), however the majority of organisations saw this as an area where improved links and development is required. Most organisations have a process for monitoring how recommendations/actions plans are implemented, however in most cases this is a very informal process with no policy or procedure in place.
- *Feedback to Staff* - feedback to staff is ad hoc and inconsistent in the majority of organisations.

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1.5.5 Training/Staff Awareness

The Training/Staff Awareness section considers the training received by staff of all levels within each organisation and assesses staff awareness of incident reporting within each organisation. The following major observations were made in relation to incident and near miss reporting systems:

- *Staff Training* - most organisations have undertaken a process of training staff in incident reporting policies, procedures and systems however this has not consistently reached those on the lower levels of the organisations.
- *Awareness of Incident Reporting* - the vast majority of staff interviewed were aware of the relevant incident and near miss reporting policy and procedures in their organisation and specific area. Whilst staff were often aware of the requirement to report incidents and near misses, a considerable level of confusion exists in terms of policies, definitions of incidents and near misses and the procedures to be used e.g. which form to use when. No organisation believes it has 100% incident reporting.

1.5.6 Third Party Relations

The Third Party Relations section considers how each organisation interacts with all external groups in relation to incident and near miss reporting. The following major observations were made in relation to incident and near miss reporting systems:

- *Contractors/Agencies* - The majority of organisations stated that contracts with contractors and agencies covered incident reporting requirements, however most organisations identified this as an area for further development.
- *Sharing Knowledge* - All organisations recognised a need to improve knowledge share and lessons learnt between organisations.

1.5.7 HSS Acute Trusts

The following key observations were made for HSS Acute Trusts:

- Acute Trusts generally had higher levels of incident reporting internally due to groups of reporting staff being located together and receiving more communication regarding incident reporting through feedback.
- Acute Trusts are less likely to report information to Boards than Community Trusts due to the perceived sensitivities of the clinical information.
- Consultants and Junior Doctors are generally considered to be the worst at reporting incidents and near misses, with nurses considered to be the best at reporting.

1.5.8 HSS Community Trusts

The following key observations were made for HSS Community Trusts:

- Community Trusts generally had lower levels of incident reporting internally due to issues such as lone workers, reporting culture and types of incidents occurring.

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- Community Trusts are more likely to report incident and near miss information to Boards than Acute Trusts.
- Some Community Trusts feel that Northern Ireland incident reporting tends to be based on NHS systems which can largely ignore social care elements.
- Some Community Trusts feel that social care incident reporting needs to be considered on a regional basis to ensure its full inclusion within any regional developments or guidance.

1.5.9 HSS Combined Trusts

The Combined Trusts displayed the same characteristics in the Health and Social Services areas of service as described in the Acute and Community Trusts above.

1.5.10 Health and Social Services Boards

There are four Health and Social Services Boards, the Western, Northern, Eastern and Southern Health and Social Services Boards, which act as agents for the Department. The following comments for each organisation should be noted:

- The Boards are all currently reviewing their incident and near reporting procedures to some extent.
- The Boards have three main areas of interest in relation to incident reporting. Firstly, there is internal incident reporting which tends to be low in volume and risk. Secondly there are incidents occurring in care homes which are recorded, monitored and reported on by each Board's R&I Unit. Thirdly, and possibly most significantly, there is the monitoring of incidents and near misses occurring within the Trusts that the Board have commissioned work from.
- Internal incident reporting systems procedures are simplistic based on the volume and seriousness of the incidents involved. Most incidents in this category relate to theft/security, personal injury or IT incidents. The Boards do not believe there are serious internal incidents occurring that they are not aware of.
- Accountability issues between Boards and Trusts currently exist and have affected the level of information being provided from the Trusts to the Boards on a periodic and one-off basis.
- The Boards are all in the process of trying to agree the level of information to be provided by the Trusts. This is occurring at different levels in each Board area, however the perceived method to resolve this issue appears to be on a four Board basis with consultation with the Trusts.
- The Boards have developed Untoward Incident Policies to detail the level of incident reporting required from the Trusts, however these are not being adhered to by the majority of Trusts.
- The Boards are experiencing notification of approximately 50 incidents per year from the Trusts, however one Board is only receiving one or two per year.

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- The Boards generally consider the Community Trusts as better at reporting to them than the Acute Trusts.

1.5.11 Health and Social Services Special Agencies

The following key observations were noted in relation to the HSS Special Agencies:

- The special agencies are all addressing incident reporting to reflect the unique circumstances that exist in each organisation.
- The NI Regional Medical Physics Agency combines its incident reporting systems with the Trusts that it is working with to ensure a robust process exists. It currently does not use IT to record incidents and near misses, however it has ordered Datix.
- A quinquennial review indicated that overlaps exist between the NI Regional Medical Physics Agency and NIAIC, however these are not considered to be significant and the Agency believes its role to be quite clear within the health service.
- The Northern Ireland Blood Transfusion Service has a structured approach to incident reporting including the use of the Q-Pulse and Safecode IT systems.
- The Central Services Agency has a low level of internal incidents occurring which largely relate to security/theft incidents, personal injury incidents and IT incidents.
- Regional Supplies Service (part of CSA) also receive incident reports from Trusts in relation to medical products, which impacts on the incident reporting process from Trusts to NIAIC.

1.5.12 Wider Health and Social Care Community

The review preformed some investigation in assessing incident reporting in the wider health and social care community. This consisted of discussion with HPSS organisations in relation to the information received from the wider health and social care community and their perceptions of incident reporting in these areas. Furthermore a questionnaire was sent to a small sample of health centres (refer to Appendix 1) and social service agencies to ascertain the systems and approach undertaken with respect to incident and near miss reporting. The information received came from GPs and the NI Guardian Ad Litem Agency and indicated similar patterns to those displayed by the HPSS organisations in terms of inconsistency of approach. The following key observations were made in relation to General Practitioners:

- GPs appear to be very inconsistent in their approach to recording and reporting incidents and near misses.
- The majority of GPs have a policy on recording incidents, however a significant number do not.
- The majority of GPs have a form for recording incidents, however a significant number do not.
- The most common incidents relate to medication incidents.

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- Significant inconsistencies appear in the level of understanding and usage of risk management and risk assessment by GPs. Some GPs appear to be very clear about the need for risk management and the usage of risk assessment, whilst others have no appreciation of the issues and do not use risk assessment.
- Significant inconsistencies appear to exist in the level of root cause analysis being used by GPs in relation to incident and near miss reporting. No significant pattern was observed, with some GPs using root cause analysis and trend analysis and some not.
- All GPs questioned had received NIAIC alerts, however few of them found them relevant to their specific area.
- GPs are under no obligation to report to the Boards, however they will report very serious incidents.

The following key observations were made in relation to the Northern Ireland Guardian Ad Litem Agency:

- Use Microsoft to record incidents and near misses.
- Has policies and definitions for incident and near miss reporting and does not allow anonymous reporting.
- Does not currently undertake trend analysis or root cause analysis in relation to incident and near miss reporting.
- The Agency provides staff with feedback on a regular basis.
- Staff are trained in incident and near miss reporting at induction. Training also occurred when the Adverse Incident Policy was developed.
- The Agency does not have any medical devices or equipment and thus did not respond to the NIAIC questionnaire.

The following key observations were made in relation to the wider health and social care community and indicate that a centralised and co-ordinated approach is needed in all areas:

- Major inconsistencies in approach to incident reporting exist.
- Limited existence of policy on recording incidents.
- Inconsistencies in relation to forms used for recording incidents.
- Significant inconsistencies in the level of understanding and usage of risk management and risk assessment.
- Significant inconsistencies exist in the level of root cause analysis and trend analysis being used in relation to incident and near miss reporting.
- Awareness of NIAIC alerts is reasonable, however understanding of NIAIC is low.

1.6 Review of the Northern Ireland Adverse Incident Centre (NIAIC)

The following key observations were made in relation to NIAIC:

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- *Awareness of NIAIC* - all HPSS organisations are aware of NIAIC's roles and responsibility at a senior level. All HPSS organisations have a NIAIC Liaison Officer. Majority of HPSS staff were aware of the NIAIC alerts, but not did not necessarily know about NIAIC or understand its role. All GPs questioned are aware of NIAIC.
- *NIAIC System* - the system for disseminating alerts and bulletins on Medical Devices and Equipment is used in all HPSS 26 organisations questioned. Trusts stated that NIAIC does not usually investigate incidents reported – manufacturers or Trusts will investigate (issue of independence).
- *Coverage* - varying degrees of reporting coverage were noted between organisations, however no organisation felt that all incidents were being reported.
- *Training* - training appears to be inadequate in the majority of organisations for staff on the ground, resulting in confusion over the role of NIAIC and what the process is to report to them.
- *Dissemination of Device Bulletins* – twenty-three (out of 26) organisations had a specific policy in place relating to the dissemination of Medical Device and Equipment Alerts (MDEAs). Twenty (out of 26) organisations disseminate MDEAs designated as urgent within 24 hours.
- *Data Quality, Accuracy and Completeness* - the systems used to collate and report on medical device and equipment incidents differ significantly across the HPSS and wider health & social care community.
- *Strengths and Weaknesses of the System* - all organisations believe that the system for dealing with medical devices and equipment has improved significantly over recent years, primarily due to NIAIC's involvement. Most organisations consider NIAIC as slow to investigate and feedback results after having been alerted of a medical device or equipment incident, however NIAIC are considered as a good central point for advice and guidance relating to medical devices and equipment.
- *Operation of Systems* - the systems used to collate and report on medical device and equipment incidents differ significantly across the HPSS and wider health & social care community.
- *Validation of Information* - Validation of information reported to NIAIC for investigation follows a robust and complete set of processes and procedures, however due to resource constraints, NIAIC are not always able to validate and investigate the information in a timely manner.
- *Induction and Training* - some organisations believe that NIAIC should promote and market itself better, in order to focus all concerned on its roles and responsibilities and to further promote the area of medical device and equipment incident reporting. Nine (out of 26) organisations have a process for highlighting NIAIC during induction training for staff.
- *Effectiveness of NIAIC* - NIAIC is considered by most organisations as a good central reference point for seeking guidance and advice on medical devices and equipment. Some organisations referred to NIAIC as a "post-box" i.e. its only function is sending and receiving information, with little analysis or investigative work being undertaken. A significant number of organisations stated that they were dissatisfied with NIAIC's investigation system, especially in relation to time taken and type of investigation undertaken. The majority of organisations felt that NIAIC was

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under-resourced to undertake its full remit in relation to Medical Devices and Equipment. The majority of organisations stated that feedback from NIAIC was poor in relation to investigations and regional medical and equipment incidents. All organisations stated that NIAIC was a very useful contact point from which further investigation can occur.

1.7 Conclusions

The following key conclusions provide a summary of the findings from the review of incident reporting within the HPSS and wider health & social care community in Northern Ireland.

- *Regional Approach to Incident Reporting* - The most significant finding of this review has been that no single regional approach exists for all incident reporting in Northern Ireland.
- *Linkages to GB Incident Reporting Systems* – Linkages were observed with GB incident reporting systems between MHRA and NIAIC in relation to medical devices and equipment. It was also noted that linkages do exist with other national incident reporting systems such as the Confidential Investigation into deaths of Mothers and Children (CEMACH), the Confidential Investigation into Suicide and Homicide by People with Mental Illness. These linkages tend to be linked to statutory reporting requirements in specific areas and do not consider general incident reporting across the service. Northern Ireland has not made any formalised links with the National Patient Safety Agency (NPSA) although discussions about future linkage have been undertaken.
- *Investigations and Trend Analysis* - Inconsistency in approach to investigation and trend analysis across the region has been a key observation during this review.
- *Sharing of Knowledge* - Currently there is limited sharing of knowledge between the healthcare organisations and bodies within Northern Ireland. Whilst groups such as the Risk Management Forum exist for organisations to discuss key issues, they tend not to concentrate on incident reporting and thus do not allow a complete and robust knowledge sharing experience. Whilst some organisations are starting to utilise such tools as the Datix messageboard, not all organisations have access to it and those that do are using it at different levels.
- *Countering the Blame Culture* - Currently organisations are dealing with the reporting culture issue in differing ways. Whilst most organisations advocate an open culture, different terms are used, including "no-blame", "fair-blame", "just-blame" or simply "open and honest culture". The Medicines Governance Project has also had an impact on the issue of reporting culture as it is often implemented using anonymous reporting within Trusts, however this is in contrast to most Trusts' position on anonymous reporting. This issue will need to be addressed if a regionally consistent approach to incident reporting is to occur.
- *Data Definitions and Quality* - Significant differences have been noted in relation to the data recorded, analysed and reported across the HPSS organisations. This is due to the use of different incident reporting procedures (including different definitions) and ultimately the use of different incident reporting systems. A single incident reporting system across all organisations would therefore be a key development in Northern Ireland.
- *Evaluation of NIAIC* - It is clear that NIAIC's role within incident reporting is considered as necessary by all those involved with incident and near miss reporting in Northern Ireland. However, it is equally clear that NIAIC have significant resource constraints, which are impacting on its ability

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to perform its roles and responsibilities. This is most noticeable in the area of investigation, whereby NIAIC are considered to be slow in following up on reported incidents within Trusts. NIAIC's ability to market itself and better communicate key issues and themes (e.g. by means of an annual seminar) have also been observed as key issues.

- *Linkages to Clinical and Social Care Governance, Risk Management and Other Activities* - Clinical and social care governance is about organisations providing the highest standards of clinical and social care and taking corporate responsibility for performance. Most organisations consider incident reporting as a key element of the CSCG agenda, but not all organisations have made this link and guidance, support and training will be required. Risk Management is a key component of CSCG, however as evidenced by the findings presented above is undertaken inconsistently throughout the HPSS and wider health and social care environment.
- *Roles and Responsibilities* - As in other facets of clinical and social care governance it is important that there is clear accountability for incident reporting systems in the HPSS organisations. It has been observed that a differing level of structure and formalised process is evident across the organisations. It will be necessary for this to be addressed before consistency of approach of incident reporting can occur in Northern Ireland.

1.8 Recommendations

The following key recommendations have been made:

1.8.1 Incident Reporting Policy

- DHSSPS to facilitate a network of organisations to promote consistency of approach in incident reporting definitions.
- Network of organisations to develop consistent Northern Ireland regional definitions for incident reporting.
- DHSSPS to provide training and support for Network and individual organisations.
- Linkage between the Medicines Governance Project and the wider incident reporting systems in Northern Ireland need to be strengthened to ensure that inconsistencies that may occur can be resolved.

1.8.2 Incident Reporting Procedures

- The Safety in Health & Social Care Steering Group should promote the development of a single incident reporting form, or set of reporting forms across the region to promote consistency of approach.
- A consistent risk assessment model should be developed for use across all organisations in Northern Ireland and should be linked to each organisations risk register and risk management process.
- The DHSSPS should consider providing guidance to organisations on structure and process of incident reporting internally and with other organisations e.g. between Trusts and Boards.

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- The potential for utilising electronic reporting forms in all areas following the Patient Client Information System (PCIS) should be considered by the DHSSPS.
- The Risk Management Forum and CSCG Network should consider the issue of sharing knowledge between organisations. This would also require assessment of whether the Northern Ireland organisations would benefit from a formal linkage with the NPSA.
- The DHSSPS should provide guidance to all organisations on document and information retention periods pertaining to incident and near miss reporting data.

1.8.3 Incident Reporting Systems

- The Safety in Health & Social Care Steering Group should further consider the potential of all Trusts providing consistent electronic incident reporting to a centralised group for sharing of knowledge/lessons learnt.
- The DHSSPS should consider what training and support can be provided to those organisations that are currently developing their systems, which essentially means all HSS organisations.
- The Safety in Health & Social Care Steering Group should promote the development of common incident and near miss codes across Northern Ireland (as is occurring within medication incident reporting).
- The Safety in Health & Social Care Steering Group should consult further with the Medicines Governance Project to ensure that a consistent approach occurs in relation to all incident reporting in Northern Ireland.
- The DHSSPS should provide improved guidance on the linkages of statutory and confidential reporting with incident reporting generally.
- The DHSSPS should consider what financial resource it can provide to organisations to undertake a full incident reporting system.

1.8.4 Review of Incidents Reported

- The Safety in Health & Social Care Steering Group should consider how training and support could be provided to the HSS organisations to improve investigation and analysis techniques, including trend analysis and root cause analysis.
- The DHSSPS should consider what formal investigation and audit procedures are required (on a regional basis) for serious incidents occurring within the Northern Ireland HSS.
- The Safety in Health & Social Care Steering Group should aim to develop a culture of feedback within all of the HSS organisations to ensure all members of staff can fully understand the benefits of a robust incident reporting systems, but more importantly can be advised of lessons learnt and knowledge from other areas within the wider health & social care community.

1.8.5 Training/Staff Awareness

- The Safety in Health & Social Care Steering Group should consider how improved training in areas such as root cause analysis can be provided.

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- The Safety in Health & Social Care Steering Group should consider how it could improve the profile of incident reporting and the benefits for patients/clients safety across the HSS.

1.8.6 Third Party Relations

- The Safety in Health & Social Care Steering Group and DHSSPS need to promote improved incident reporting arrangements between contractors/agencies and HSS organisations.
- The Safety in Health & Social Care Steering Group and DHSSPS need to consider how improved sharing of knowledge can be achieved. It is suggested that this would occur through several forums. Firstly the combined Risk Management Forum and CSCG Network should be consulted to ascertain whether that forum could be used to discuss lessons learnt. Whilst it is recognised that these groups do address this issue to some extent, it is considered as limited and open to improvement. Secondly the development or utilisation of an IT system with the same capacity as the Datix messageboard should be established for all Trusts (the Datix messageboard could be used if all Trusts had access to it). Thirdly, the production of periodic regional incident and near miss reporting reports detailing trends and lessons learnt should be a key objective of all concerned within the Northern Ireland HSS.

1.8.7 NIAIC

- NIAIC needs improved resources to allow it to perform its independent investigation function fully. The recruiting of an Operational Manager for NIAIC (as is presently being undertaken) will be a positive step in that direction, however additional resource may be required to fully undertake NIAIC's role in a robust and complete manner.
- Increased resources in NIAIC would allow NIAIC to market itself more effectively and better inform the HPSS and wider health & social care community of both its activities and information on medical devices and equipment.
- NIAIC should investigate the potential for running an annual or bi-annual workshop for all relevant organisations, in order to promote incident reporting and focus organisations and individuals on NIAIC's role within that area.
- NIAIC should investigate the possibility of gaining control of its website, in order that it be updated on a more frequent basis.

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2 INTRODUCTION & BACKGROUND

2.1 Background

The DHSSPS has established a Safety in Health & Social Care Steering Group whose terms of reference include the development of a strategic approach to the recording, reporting and investigation of adverse incidents and near misses. As part of this work the Steering Group commissioned Deloitte to:

- carry out a scoping exercise on adverse incidents and near miss reporting in the HPSS; and
- carry out an evaluation of NI Adverse Incident Centre.

The following key points were identified:

- the Steering Group for this project is chaired by Dr Ian Carson and includes representatives from professional groups, Health Estates and Trust representatives;
- NIAIC currently consists of one individual, Brian Godfrey, who is an HEA member of staff, and is relatively resource constrained;
- NIAIC picks up relevant guidance from England & Wales and disseminates it through specific nominated individuals in the Trusts; and
- there are a number of different systems of adverse incident and near miss reporting in the HPSS, and their scope and data sets differ.

2.2 Scope

The project is divided into two distinct parts as follows:

2.2.1 Scoping Exercise on Adverse Incidents/Near Misses

The consultants are required to:

- determine what Clinical and Social Care Governance Systems are in place to detect, monitor and manage adverse incidents and near misses;
- identify whether or not the organisation has policies in place covering the reporting of adverse incidents and near misses;
- identify whether or not the organisation's policies on adverse incidents and near misses deals with the issues of blame, anonymous reporting and whistle blowing;
- evaluate the strengths and weaknesses of the organisation's policies on adverse incidents and near misses;
- compile a list of adverse incident and near miss systems. The information for each system should identify:

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- coverage: Which parts of the organisation the system covers
- purpose: Whether the system is for general use or used to cover particular type of incidents or particular services;
- contacts: Details of a relevant contact within each organisation who can provide further information about the system;
- open reporting: Whether or not the system involves anonymous reporting;
- data lists: A list of relevant data items, data classifications and definitions;
- collection: Methods of collection (e.g. paper, spreadsheet or database);
- access: Who can report incidents and near misses to the system;
- historical data: The time period for which data is available;
- IT systems: Identify bespoke IT systems/software and licensing details;
- management: Details of how the system is managed/updated;
- analyses: Details of routine and ad hoc analysis;
- communication: What information, emerging from the system is shared with internally and externally to e.g. HSS Boards, the Central Services Agency (CSA) and the Department etc.

• provide an initial assessment of the scope and effectiveness of each system based on the following questions:

- does risk assessment and risk management take place?
- is information about individual incidents and summary information about incidents in general shared with senior professionals and senior managers who need to consider and act upon the information?
- does the organisation routinely, sometimes or never use information emerging from the system to inform changes to practice, services, culture, etc?
- are staff working at locations and in services covered by the system aware of the reporting system, have they been trained, and do they routinely use the system?

Based on your terms of reference we have visited all HSS Boards and Trusts as well as the CSA and two Special Agencies (NI Blood Transfusion Service and the Regional Medical Physics Laboratory) including a sample of organisations/individuals in the wider health and social care community. The terms of reference also required us to provide an outline comparative evaluation of the working arrangements in and between equivalent NIAIC organisations in GB, such as the National Patient Safety Agency (NPSA), the Medicines and Healthcare Products Regulatory Agency (MHRA), Scottish Healthcare Supplies and the National Assembly for Wales.

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2.2.2 Evaluation of NIAIC

The Department also wishes to undertake an independent assessment of the effectiveness of NIAIC including an assessment of:

- the level of awareness of NIAIC, how to report adverse incidents, action to be taken on receipt of an MDEA etc amongst HPSS and the wider health and social care community;
- the extent to which the system is in use across the HPSS and the independent section;
- coverage i.e. to what extent incidents which should be reported are reported;
- whether information and professional staff have been given adequate instruction regarding provision and collation of the information, adequate information on definitions etc in order to utilise the system;
- the appropriateness of the dissemination of Medical Device/Equipment ALERTS within the HPSS and wider health and social care community, including coverage, timeliness, format etc;
- the appropriateness of the dissemination of Device Bulletins and other guidance material within the HPSS and wider health and social care community, including coverage, format, usefulness, responses etc;
- data quality, accuracy and completeness;
- strengths and weaknesses of the system;
- the operation of systems (whether computer or manual) in place in each HPSS organisation to support provision of the information in the form required;
- appropriateness of procedures in place for validation of the information;
- the quality of induction and training available to staff in the HPSS and the wider health and social care community;
- the overall effectiveness of NIAIC advice to the DHSSPS and the independent sector on the safety, quality and performance of medical devices and equipment in terms of the objectives of NIAIC.

This element of the project was undertaken through separate review of NIAIC and during the visits to all the HSS Boards and Trusts as well as the CSA and two Special Agencies (NI Blood Transfusion Service and the Regional Medical Physics Laboratory).

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3 OUR APPROACH

3.1 Overview

This section outlines our approach to the assignment based on the agreed terms of reference discussed in Section 2. The key phases of the approach and methodology are summarised in Figure 3.1 and the following paragraphs.

3.2 Phase I – Project Initiation

In this phase, we finalised the project plan for the review including:

- Final review of our planned approach with you for any required refinements as appropriate.
- Agreeing the nominated liaison officer within DHSSPS for this review and key contacts in the organisations for adverse incident reporting.
- Getting access to relevant information already held by Quality and Performance Improvement Unit on NIAIC or adverse incident recording and reporting systems.
- Agreeing required project reporting arrangements (including timing of Steering Group meetings, day to day liaison points and checkpoint meetings).
- Agreeing the quality assurance mechanisms to be used during this assignment.

Completion of this phase enabled us to finalise the project plan and commence the project fieldwork in a planned and controlled manner taking account of your specific requirements and timetable. It was agreed that Brian Godfrey (NIAIC) would be our main point of contact during the review and that a review group containing key individuals from the Trusts would be formed to consult on the detailed scoping exercise. This group consisted of Patricia Beresford (Clinical & Social Care Governance Network), Irene Low (Risk Management Forum), Janet Taylor (Clinical & Social Care Governance Network), Brian Godfrey (NIAIC), Heather Shepherd (Risk Management Forum) and Jackie Kingsmill (Claims & Litigation Steering Group).

3.3 Phase II – Planning and Initial Analysis

The objectives of this phase of the project were:

- To analyse readily available information on adverse incident reporting in the NIHPSS and NIAIC through desk top review and structured interviews.
- To plan in more detail visits to the relevant HPSS organisations, refining the checklist to be covered so that we could efficiently cover both the NIAIC evaluation and the review of adverse incident reporting systems at one visit per organisation.

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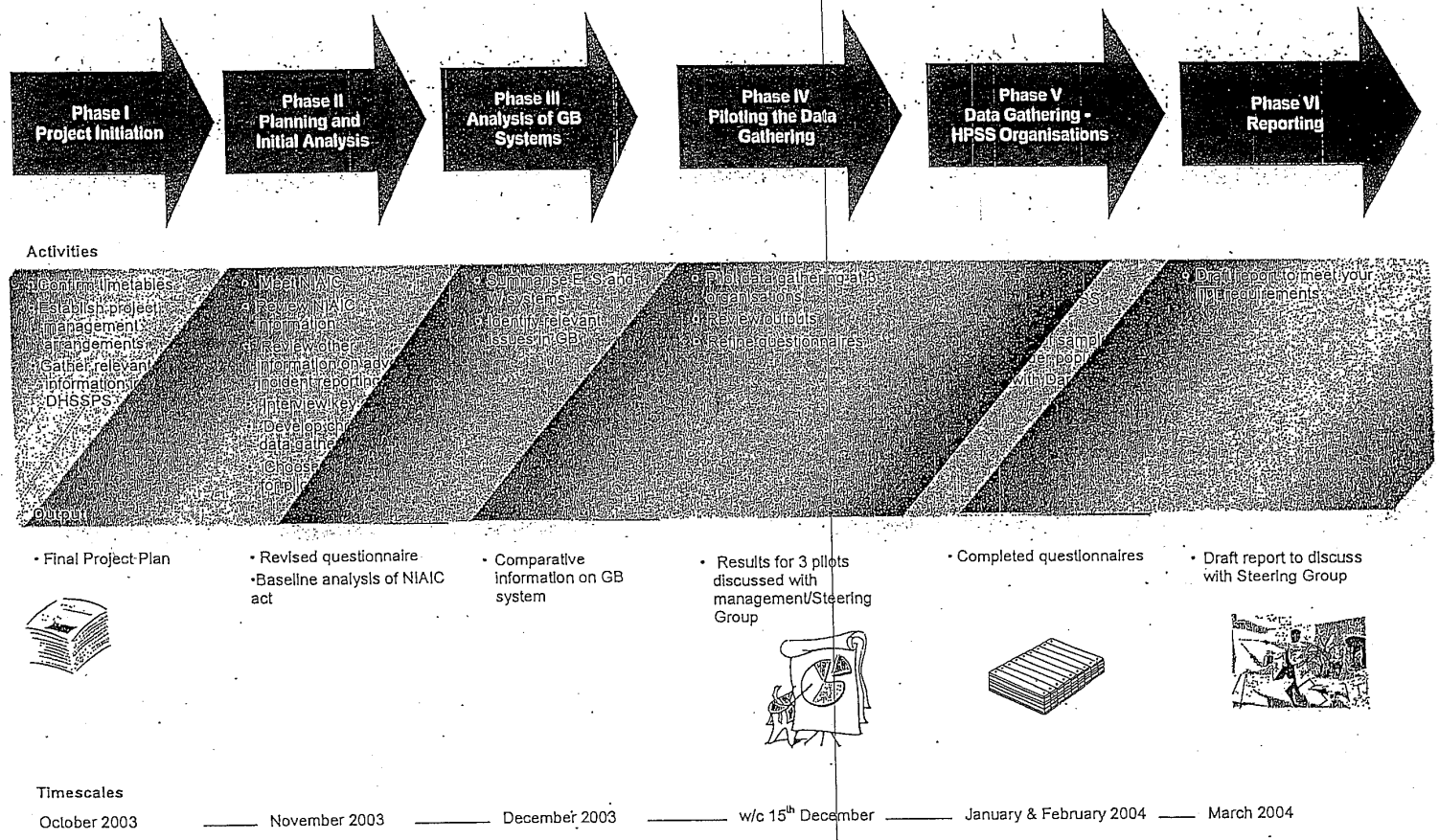
Figure 3.1
Summary of Our Approach



Source: Deloitte

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We carried out structured interviews with a number of key people at this stage, including Brian Godfrey, Ray Martin and the Chair of the Steering Committee, Dr. Ian Carson. It was also agreed that we should meet Liz Qua (Principal Nurse, Health Estates), Tracy Boyce (Medicines Governance Project), Pat Newe (SSI) and Robert Thompson (GP Advisor).

Key activities in this phase included:

- Reviewing NIAIC's business plan, objectives and resources (staff, financial, etc).
- Understanding how the Department currently measures their performance (for example, through the SLA).
- Understanding their key processes, including issuance of guidance, recording and reporting and advice on medical device safety clarifying whether their scope includes investigating adverse incidents.
- Reviewing any information DHSSPS already holds on adverse reporting, for example through Trust Monitoring, Professional Offices (e.g. CMO); and Quality & Performance Improvement Unit.
- Developing/refining a checklist to use in data collection at the Trusts/other bodies which covers the key questions that are included in the terms of reference.

3.4 Phase III – Analysis of GB Systems

In parallel to Phase II we summarised the key features of the adverse incident reporting systems in GB including England, Wales and Scotland. We have utilised members of our national team to summarise the working arrangements in MHRA, SHS, NPSA and IRIC amongst others. This phase also included desk review, supplemented by contact with the relevant agencies to fill any gaps.

3.5 Phase IV – Piloting the Questionnaire

We piloted the questionnaire over a week period in late October 2003 with 3 HPSS organisations, the Royal Group of Hospitals Trust, Craigavon and Banbridge Community Trust and Ulster Community and Hospitals Trust. A copy of the final questionnaire is attached as Appendix I.

We utilised the first section of the questionnaire developed to gather initial previsit information from the organisations. This included details of their adverse incident policies, relevant IT systems and reporting protocols amongst others at a relatively high level.

We directed the questionnaire initially at the Risk Manager or CSCG Co-ordinator, the Chair of the Risk Management/Clinical & Social Governance Committee and the Lead Professional (e.g. Clinical Director) and asked them to complete it and identify key contacts. We utilised the questionnaire to guide structured interviews with key personnel in each organisation at the time of our visits.

For each organisation we asked the lead contact to organise a day (approximately) of interviews, which included:

- a business manager (in a speciality or programme of care);

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- the local contact for NI Adverse Incident Centre;
- professionals (e.g. medics, social workers, nurses, pharmacists);
- a member of the Risk Management Committee;
- the Clinical Director or Director of Programme;
- medical records staff;
- clinical/social care audit staff.

It was noted that each organisation had different structures in place to deal with incident and near miss reporting and thus the job descriptions of those interviewed in each organisation differed slightly. We completed the questionnaire and site visits for the three organisations and reviewed the results with the Project Group, with an aim of refining the questionnaire if appropriate. No significant changes were made to the pilot questionnaire and the pilot site visits were assessed as successful, resulting in these organisations not requiring a second questionnaire or site visit.

3.6 Phase V – Data Gathering

Having refined the questionnaire/approach in Phase III we moved into data gathering across the remaining organisations. The refined questionnaire and covering letter explaining the process was sent on the 19th December 2003 to all HSS Boards and Trusts, as well as the CSA and two Special Agencies (NI Blood Transfusion Service and the Regional Medical Physics Laboratory). During early January 2004, arrangements were made with each organisation for the return of the completed questionnaire and a date set for the site visit. Table 3.1 indicates the site visit dates for each organisation over the period January to March 2004.

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Table 3.1
Summary of Organisational Visits

Trust	Key Contact	Job Title	Site Visit Date
Craigavon & Banbridge Community HSS Trust	Janet Taylor	Health & Safety Manager	09/12/2003
Ulster Community and Hospitals HSS Trust	Irene Lowe	Risk Manager	10/12/2003
Royal Group of Hospitals and Dental HSS Trust	June Champion	Risk Manager	11/12/2003
Causeway HSS Trust	Peter Crook	Assistant Director Corporate Support	30/01/2004
Altnagelvin Hospitals HSS Trust	Caroline Kyle	Clinical Governance Co-ordinator	03/02/2004
Sperrin Lakeland HSS Trust	Eileen Quinlivan	CSCG Project Officer	10/02/2004
Southern Health and Social Services Board	Anne Madill	Risk Manager	11/02/2004
NI Regional Medical Physics Agency	Prof. Peter Jarritt	Chief Executive	11/02/2004
Green Park HSS Trust	Patricia O'Callaghan	Dir. of Nursing & Clinical Effectiveness	13/02/2004
N&W Belfast HSS Trust	Ian Jamieson	Assistant Director of Corporate Affairs	16/02/2004
Foyle HSS Trust	Joe Lusby	Director of Business Services	17/02/2004
Belfast City Hospital HSS Trust	Eleanor Hayes	Director of Nursing	18/02/2004
NI Blood Transfusion Service Agency	Geoff Geddis	Quality Assurance Manager	19/02/2004
United Hospitals HSS Trust	Yvonne Kirkpatrick	Clinical Governance Officer	20/02/2004
Newry & Mourne HSS Trust	Roberta Wilson	CSCG Co-ordinator	23/02/2004
Craigavon Area Hospital Group HSS Trust	Beatrice Moonan	Project Manager (Medical Directorate)	26/02/2004
The Central Services Agency for the HPSS	Greg Irwin	Equality Manager	27/02/2004
Down Lisburn HSS Trust	James Livingstone	Deputy Director of Corporate Affairs	27/02/2004
Mater Infirmorum Hospital HSS Trust	Diane Irwin	Risk Mgt Co-ordinator	01/03/2004
S&E Belfast HSS Trust	Adrienne McKimm	Risk Manager	02/03/2004
Armagh & Dungannon HSS Trust	Heather Ellis	Director of Personnel Services	03/03/2004
Northern Health and Social Services Board	Carol Reynolds	Business Services Manager	05/03/2004
Eastern Health and Social Services Board	Steven Adams	Head of Corporate Services	05/03/2004
Western Health and Social Services Board	Michael Gormley	Head of Consumer Services	09/03/2004
Homefirst Community HSS Trust	Alex Lynch	Head of Governance	11/03/2004
NI Ambulance Service HSS Trust	Dr David McManus	Medical Director	N/a*
Health Promotion Agency	Fiona Campbell	HR Manager	N/a
NI Guardian Ad Litem Agency	Declan McAllister	Business Manager	N/a

Source: Deloitte

**Review undertaken by questionnaire only*

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3.7 Phase VI – Reporting of Findings

The final phase required summarising the outputs from the initial evaluation of NIAIC, the visits to HPSS organisations and a sample of others into a draft report. The draft report has been discussed with the Liaison Individual prior to finalisation and presentation to the Steering Group.

The report has been prepared on the basis of the information gathered from desktop review of the relevant areas of incident reporting, the returned questionnaires and the discussions undertaken with key individuals in the relevant organisations. The report has presented the findings of each HPSS organisation based on the key areas detailed within the terms of reference. The information detailed by each organisation has been presented in tables indicating whether the organisation has meet key indicators associated with incident reporting. These have been scored as follows:

Key:			
✓	in place	X	not in place
✓	partially in place/in development	N	not applicable

The information supplied in Appendices V, VI and VII provides narrative detail to complement the information supplied in these tables. The findings presented and the subsequent recommendations are a summarised assessment of the position of each area of incident reporting. This summarised assessment is based on the common themes identified across the organisations and does not agree to the findings of each organisation.

It should be noted that the scorings provided for each organisation are based on assessment of what organisations presented to us through the questionnaire and the site visits. We have verified this information were possible, however significant levels were based on opinion of the individuals we met. Frequently differing views were provided from within the same organisation, and when this has occurred we have made an assessment of the overall status. It is also important to note that these scores are at a point in time and will change as organisations continue to address their CSCG and incident and near miss reporting systems.

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4 REVIEW OF INCIDENT REPORTING IN THE HPSS

4.1 Introduction

In order to perform a scoping exercise of incident and near miss reporting in the HPSS we reviewed the activities undertaken in the 19 HPSS Trusts, 4 Health and Social Services Boards, 3 Special Agencies and the wider health & social care community in Northern Ireland (using the methodology discussed in Section 3). This section describes the findings of that process.

4.2 Overview of Incident Reporting in the HPSS

Detailed review of the systems used to report and record incident and near miss reporting in Northern Ireland revealed one overwhelmingly obvious finding: inconsistency of approach. This inconsistency existed in nearly every aspect of incident and near miss reporting, from defining an incident or near miss within each organisation to the procedures for reporting and collating the information and how the information is analysed and used within each organisation. The only consistent element within each organisation was the drive to improve incident reporting based on a common belief and understanding of the benefits it accrues to patients/clients safety and care. On the back of these high-level observations, the HPSS incident reporting systems could be summarised as having:

"Inconsistencies in Process – Consistency in Spirit"

Whilst significant variations existed in *how* organisations undertake the reporting of incidents and near misses, common practice did exist in many areas. Overall, most organisations use the same basic structure to report, record and analysis incident and near miss information, although it was noted that the incident reporting system in each organisation had evolved at different levels and in different ways. Nonetheless, the common structure used in incident reporting is shown in Figure 4.1 overleaf. This diagram illustrates the high-level structure that most organisations attempt to utilise to report incidents and near misses from the occurrence of the incident with staff and patients/clients involvement to the high-level review of reported incidents/near misses by the organisation's Board.

The review demonstrated that a significant level of the organisations involved have put considerable effort and resource into their incident reporting system recently, but that most policies and procedures reviewed are still considered as evolving or in development. No organisation stated that it has fully developed its system and 100% incident reporting is considered unattainable by all organisations we met.

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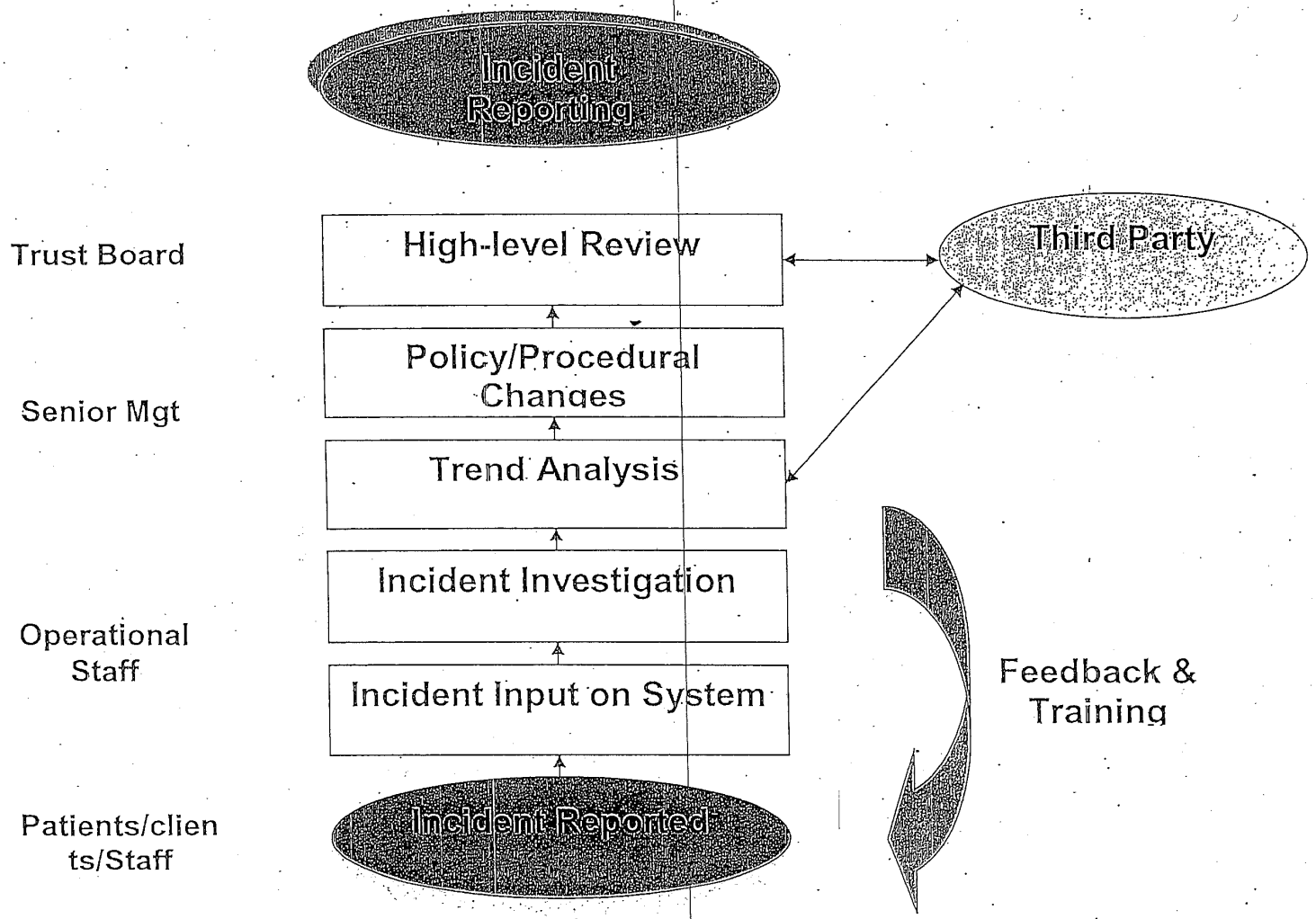
Figure 4.1 Incident Reporting in HPSS Organisations



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In order to fully scope the incident and near miss reporting systems that exist within the HPSS in Northern Ireland, a detailed review has been performed in accordance with our approach detailed in Section 3 of the report.

4.3 Detailed Review of Incident reporting in HPSS

A detailed narrative review of each organisation involved in the Safety in Health & Social Care project has been produced and is attached in Appendices V, VI and VII. Based on the scope of the project, the pre-site questionnaire completed by each HPSS organisation and the subsequent observations made at the site visits, seven categories relating to incident and near miss reporting have been developed. The seven categories cover the elements involved in incident and near miss reporting and allow for comparisons to be made between organisations at a detailed level. The seven categories are described as follows:

- *Incident Reporting Policies* – considers the policies that each organisation has developed in relation to incident and near miss reporting;
- *Incident Reporting Procedures* – considers the operational procedures in place within each organisation to capture incidents and near misses;
- *Incident Reporting Systems* – considers the systems and support utilised to record incidents and near misses within each organisation;
- *Review of Incidents Reported* – considers how each organisation investigates incidents and near misses and reviews trends relating to incidents and near misses;
- *Training/Staff Awareness* – considers the training received by staff of all levels within each organisation and assesses staff's awareness of incident reporting within each organisation;
- *Third Party Relations* – considers how each organisation interacts with all external groups in relation to incident and near miss reporting;
- *NIAIC* – considers how each organisation deals with the requirements of the Northern Ireland Adverse Incident Centre.

The findings of each of these areas are discussed below, including a review of the specific observations made for each of the HPSS groups (i.e. the Trusts, Boards, Special Agencies and wider health & social care community). The NIAIC element of the review has been discussed within Section 5 of the report, under the context of the NIAIC evaluation.

4.4 Incident Reporting Policies

The Incident Reporting Policies section considers the policies that each organisation has developed in relation to incident and near miss reporting. Table 4.1 below details the observations made at each of the HPSS organisations during the site visits undertaken.

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Table 4.1
Summary of Incident Reporting Policy Findings

INCIDENT REPORTING POLICIES	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Altnagelvin Hospital Trust	Sperrin & Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	Homefirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
The Organisation:																										
- has a CSCG policy in place	✓	✓	✓	✓	✓	✓	✓	X	✓	X	X	✓	X	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	X	X	X
- has a Risk Management policy/strategy in place	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has an adverse incident policy in place	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a near miss policy in place	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a whistle-blowing policy in place	✓	✓	✓	✓	X	✓	✓	✓	✓	X	✓	X	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X
- allows anonymous reporting	✓	✓	✓	✓	X	✓	✓	X	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
- encourages an open culture for reporting incidents	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a definition for incidents/near misses	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a definition for serious/critical incidents	✓	✓	✓	X	✓	X	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X

Source: Deloitte

Key:			
✓	in place	X	not in place
✓	partially in place/in development	N	not applicable

The following major observations were made in relation to incident and near miss reporting policies:

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4.4.1 Policies

Major inconsistencies were observed in the level and existence of policies relating to Clinical and Social Care Governance (CSCG), risk management and incident reporting within the various organisations. Whilst most organisations have some form of incident reporting policy in place, the level of detail differed greatly. It was noted that different organisations also emphasised different areas i.e. some organisations focused largely on risk management, while other organisations emphasised CSCG.

This was also observed in which area or department within each organisation was responsible for driving incident and near miss reporting. In most organisations the Risk Management department is responsible, however in other organisations either no Risk Management department exists, or a different department was responsible for this function. Whilst different titles and job descriptions existed within organisations e.g. Clinical Governance Department, the Corporate Affairs Department, the Risk Management Department, it was noted that the roles performed by these groups or individuals was often very similar. A small number of organisations do not have a centralised department for incident reporting, and individual Directorates perform this function.

4.4.2 Definitions

Major inconsistencies were observed in the definitions for incidents and near misses within each organisation, and the following points were noted:

- Organisations varied in terminology used e.g. incidents, clinical incidents, adverse incidents, untoward events, near misses, accidents etc.
- Similar terms or phrases mean different things between most organisations, however we also observed these differences existing between directorates within some Trusts i.e. what is considered as an incident or near miss in one organisation has a different meaning in another;
- Organisations are keen to co-ordinate incident reporting definitions and terminology internally and regionally;
- No common regional definitions exist in Northern Ireland, but this was considered as potentially very useful by those we spoke to.

4.4.3 Reporting Culture

All organisations promote an open reporting culture, but differences exist in treatment of anonymous reporting:

- Most organisations require a signature on incident reporting forms, but will accept anonymous reports if provided.
- The Medicines Governance Project has had an impact on anonymous reporting in Trusts. It was observed that most Trusts require all incidents to be signed off by the relevant staff member when they are reported, however the Medicines Governance Project can be implemented using anonymous reporting (as an option for each organisation). This has caused some issue in Trusts and has resulted in different forms being produced within these organisations.

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- Most organisations have a whistle-blowing policy, however the line between open reporting and whistle-blowing/disciplinary action is unclear in most organisations.

4.5 Incident Reporting Procedures

The Incident Reporting Procedures section considers the operational procedures in place within each organisation to capture incidents and near misses. Although the organisations observed a common high-level approach to incident and near miss reporting (as described in Figure 4.1) the detailed procedures in each organisation differ significantly. As a result this area provided the most variation of approach from one organisation to the next. Two extremes were noted in this area, with either a very co-ordinated/centralised, structured and formalised approach existing or a fragmented, unstructured and informal process existing. These two extremes are demonstrated by Figures 4.2 and 4.3 below. It was noted that most organisations have procedures that are somewhere in the middle of these two examples.

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Figure 4.2 Fragmented Incident Reporting Procedure

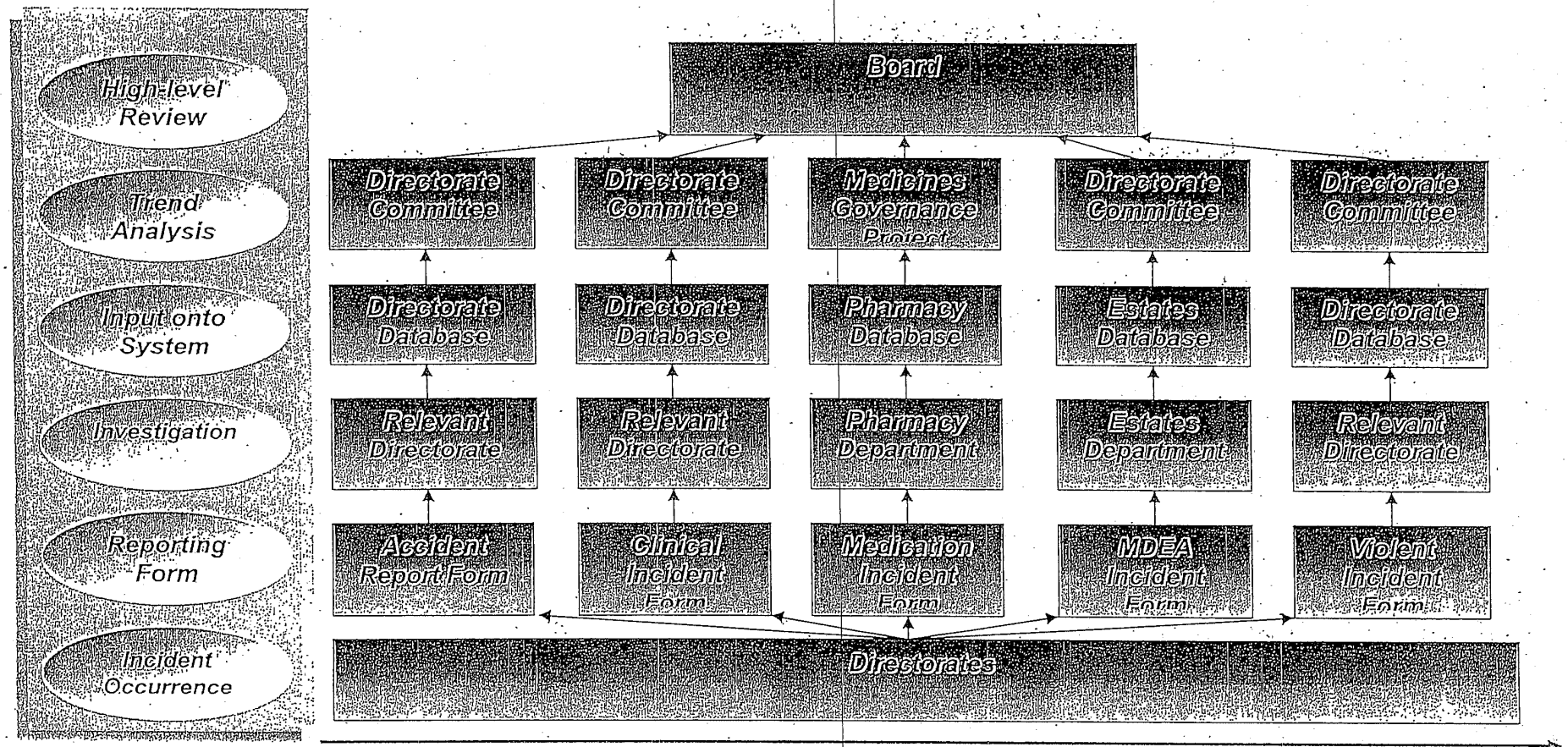

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Figure 4.3 Centralised Incident Reporting Procedures

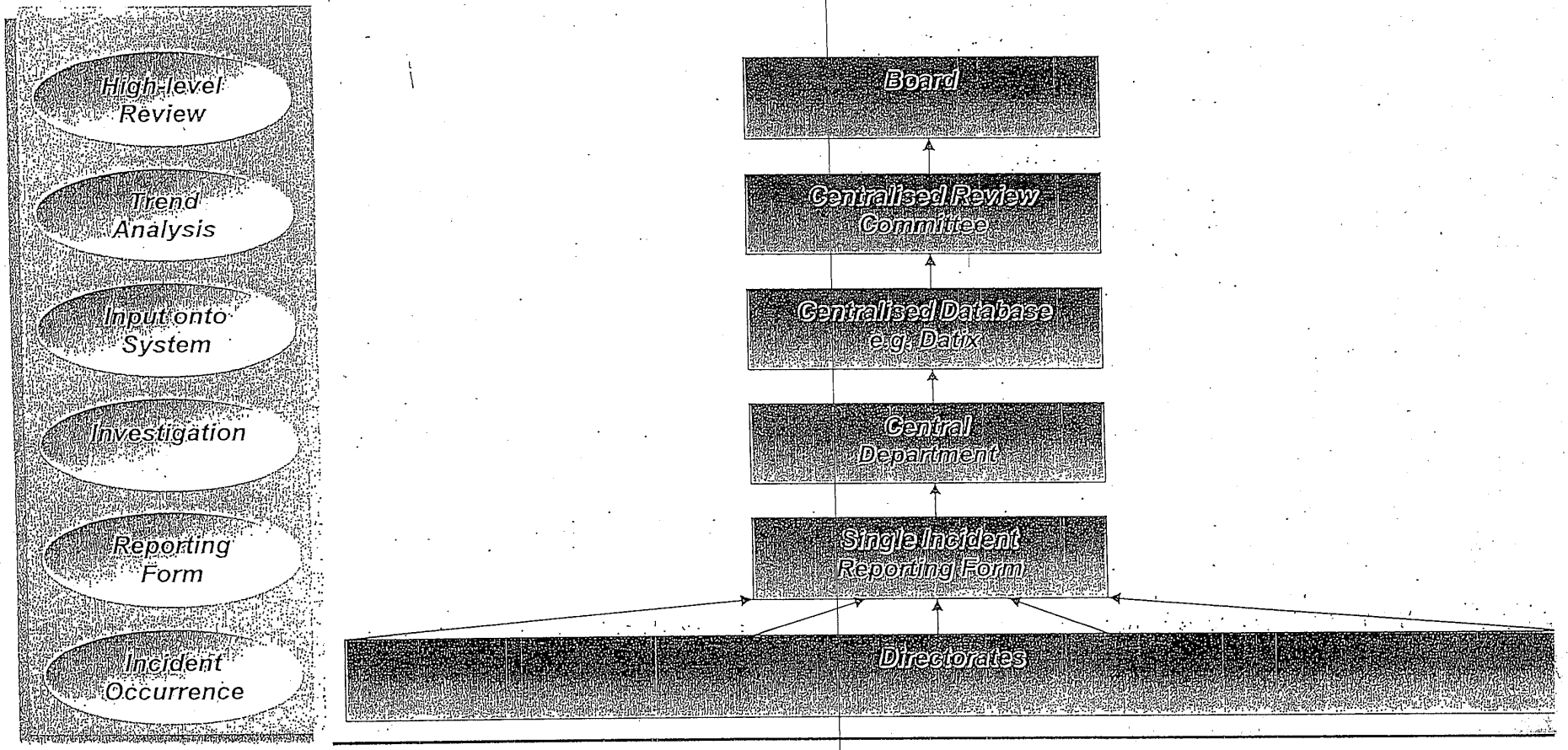

Table 4.2 overleaf details the observations made at each of the HPSS organisations during the site visits undertaken.

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Table 4.2
Summary of Incident Reporting Procedures Findings

INCIDENT REPORTING PROCEDURES	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Almagelvin Hospital Trust	Sperrin & Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	Homefirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
The Organisation:																										
- has formal structures and procedures in place for Incident and Near Miss Reporting	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a consistent procedure to IR throughout the organisation	✓	✓	✓	X	✓	X	✓	✓	X	X	X	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a single electronic reporting form	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	✓	X	X	X	X	X	X	X	X	X	X
- has a single paper incident reporting form	✓	✓	✓	X	✓	✓	✓	✓	X	X	X	✓	X	✓	X	✓	✓	X	✓	✓	X	✓	✓	X	✓	X	X
- has specific personnel roles identified for IR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- allows all staff to report incidents/near misses	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a defined period for retaining IR documents	X	✓	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
- undertakes risk assessment and risk mgt for incidents	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
- acknowledges incident reports from staff	X	X	X	X	✓	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Source: Deloitte

The following major observations were made in relation to incident and near miss reporting procedures:

4.5.1 Reporting Process

- Very few organisations demonstrated a fully consistent procedure for dealing with all aspects of incident reporting across all areas.
- Differences existed in whether organisations co-ordinated incident reporting in one area, or had fragmented reporting at Directorate level (as demonstrated by Figures 4.1 and 4.2 above).

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- A significant number of organisations are currently reviewing their incident and near miss reporting procedures, in addition to a review of related policies and IT systems.
- Centralised incident reporting occurred in a number of areas e.g. risk management department, clinical governance department or a specific directorate.
- Individuals responsible for operational incident reporting included Risk Managers, Directors, CSCG Facilitators, Clinical Governance Managers and Project Managers.
- All organisations allow all staff to report in incidents in theory, but not all staff have access to reporting tools in some organisations.
- Very few organisations have a defined period for retaining incident reporting documentation.
- Only one Trust formally acknowledges every incident reported by staff (by means of a letter).

4.5.2 Reporting Forms

- Only one organisation currently uses a single electronic reporting form, although it has not replaced the paper form completely at this stage.
- Nine organisations have a single paper reporting form.
- A significant number of organisations have two or three forms based on the need to separate different incident reporting information. This may relate to medication incidents requiring separate identification, or an organisation requiring separate reporting of clinical incidents from all other types of incidents.
- Whilst most organisations feel that one form is the best method to collect all incident reporting information, this is not the case in all areas. It was also observed that the format and content of single incident reporting forms differed significantly between organisations.
- The majority of organisations have specific personnel roles identified for incident reporting, although significant inconsistencies exist in terms of job title and grade of involvement in each organisation.

4.5.3 Risk Management

- All organisations undertake some form of risk assessment and management, but this ranges from very informal and ad hoc to highly formalised and structured risk management processes.
- Informal and ad hoc risk assessment processes do not grade or rank the individual incidents and thus no formal and consistent system is in place for deciding which incidents to investigate or for undertaking detailed trend analysis. This also impacts on the organisations ability to utilise this information for risk registers and risk management processes.

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- The organisations with formal and structured risk assessment processes, require staff to grade each incident using a risk matrix (rating likelihood against impact). which is reviewed by their line manager and possibly the centralised incident reporting department for consistency. This produces a colour coding which will trigger different processes in relation to investigation and review. The risk assessment also allows improved trend analysis across the organisation and allows the organisation to link incident reporting with the risk registers and risk management process.

4.6 Incident Reporting Systems

The Incident Reporting Systems section considers the systems and support utilised to record incidents and near misses within each organisation. Table 4.3 overleaf details the observations made at each of the HPSS organisations during the site visits undertaken.

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Table 4.3
Summary of Incident Reporting Systems Findings

INCIDENT REPORTING SYSTEMS	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Altnagelvin Hospital Trust	Sperrin & Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	Homefirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
The Organisation:																										
- utilises Datix as its IR system	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	X	✓	✓	✓	✓	X
- use an IT system other than Datix for IR	X	X	✓	X	✓	X	X	X	X	✓	✓	X	✓	X	X	✓	✓	X	X	X	✓	X	X	X	✓	✓
- has arrangements in place for systems mgt	✓	✓	✓	X	✓	✓	✓	✓	✓	X	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	✓	✓
- has IR system integrated with other IT modules	✓	✓	X	X	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	X	X	X	X	X	X	✓
- uses the same IR system in all areas	✓	✓	✓	X	✓	✓	✓	✓	✓	X	X	✓	X	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	X	✓	X
- has tailored coding classifications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	X	X	X	X	X
- grades specific incidents in relation to seriousness	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
- captures IR info through confidential enquiries	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	✓
- captures IR info through statutory reporting	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	✓
- has dedicated staff to update the IR system	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	✓	✓

Source: Deloitte

The following major observations were made in relation to incident and near miss reporting systems:

4.6.1 System Type

- Out of the 26 HSS organisations, 11 use Datix to record incidents and near misses, with another 10 currently implementing it or planning to implement it.

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- The other systems that are used by organisations to record incidents and near misses are Ulysses, Safecode, CASS, Excel, Word, Access and SHE.
- All organisations with Datix have systems management procedures in place, however those with other systems varied in this area.
- Most organisations with Datix had linked the incident reporting module to other Datix modules e.g. claims and litigation, complaints, risk management. Some organisations also have their risk registers on the Datix system, although this has proved to be more challenging than some of the other modules. The majority of Trusts stated that they will be implementing the new Knowledge and Skill module on version 7 of Datix to be launched in April 2004 and some have already investigated the possibility of implementing the Data Protection module that will available on Datix from August 2004.
- Those organisations with Datix are able to access the Datix Users Group for technical support and use the Datix Messageboard for sharing knowledge and lessons learnt.

4.6.2 System Coding

- Most organisations had tailored an existing coding system for reported incident data (including those organisations using Datix).
- The Medicines Governance Project has provided consistent coding of medication incidents across significant areas of the region.
- Coding for non-medication incidents varied greatly between organisations. Organisations that have implemented Datix largely use the core Datix coding list, but have tailored it to suit there own circumstances. This has resulted in a wide range of inconsistent codes being used across those organisations. However, whilst the codes have been tailored differently in each organisation, a common set of core codes was observed in many organisations, which a regional coding system could be based on.
- Grading of incidents occurred at some level in all organisations, however this ranged from ad hoc inconsistent grading of only serious incidents to robust and highly procedural systems of risk assessment to grade all incidents occurring within the organisation.
- Most organisations captured incidents reporting information through confidential enquiries and statutory reporting, however the level that this was achieved and how it is undertaken differs greatly between organisations.

4.6.3 System Resources

- The majority of organisations have dedicated staff to input data onto the incident reporting system, however the circumstances of these individuals in relation to where in the organisation they sit, how much training they have received and there level of responsibility differ significantly between each organisation.

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4.7 Review of Incidents Reported

The Review of Incidents Reported section considers how each organisation investigates incidents and near misses and reviews trends relating to incidents and near misses. Table 4.4 overleaf details the observations made at each of the HPSS organisations during the site visits undertaken.

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Table 4.4
Summary of Review of Incidents Reported Findings

	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Altnagelvin Hospital Trust	Sperrin & Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	HomeFirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
REVIEW OF INCIDENTS REPORTED																										
The Organisation:																										
- has a systematic approach to reviewing all incidents	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a systematic process to decide what to investigate	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a process to ensure consistent approach in investigations	✓	✓	X	✓	X	✓	✓	✓	✓	X	X	✓	X	✓	X	✓	X	✓	✓	X	✓	✓	X	✓	✓	X
- analyses the information on a periodic basis	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- undertakes investigation on serious incidents	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- undertakes root cause analysis were appropriate	✓	✓	X	✓	X	✓	✓	✓	✓	X	X	✓	✓	X	X	X	X	✓	✓	X	X	X	X	X	X	✓
- has a process for monitoring recommendations	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	X	✓	X	✓	✓	✓	✓	✓	X	✓	✓	✓
- links internal audit programmes to IR findings	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	X	✓
- requires senior staff/Trust Board to review IR information	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- communicate IR outcomes with senior staff/Trust Board	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- routinely provides reports to directorates on IR activity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a process to feedback lessons learnt to all staff	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- uses IR info. to change practice and services	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- undertakes trend analysis	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Source: Deloitte

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The following major observations were made in relation to incident and near miss reporting systems:

4.7.1 Investigations

- Most organisations had a systematic process to decide what to investigate, however the formalisation and complexity of processes varied greatly within different organisations;
- As with the incident reporting procedures, the organisations with formal and structured investigation processes have clear lines of responsibility and procedure. This often requires staff to grade each incident using a risk matrix (rating likelihood against impact) which is reviewed by their line manager and possibly the centralised incident-reporting department for consistency. This produces a colour coding which will trigger different processes in relation to investigation and review, however most of all it will provide a consistent approach to the investigation of incidents across the organisation. The most structured organisations have Serious Incident Review groups, with clear lines of accountability and terms of reference. The investigations that result produce clear action and development plans, which are subsequently communicated to the relevant committees and the organisation's Board. These formalised processes usually also include feedback procedures to ensure lessons learnt are communicated.
- The organisations with an informal and fragmented investigation process undertake investigation on an ad hoc basis. This process is often inconsistent between Directorates within the organisation as no formal policy exists to guide individuals on what should be investigated and how the investigation should be undertaken. This often results in local investigation occurring in order to solve the problem, with no process for investigation in order to learn lessons and share knowledge across the organisation or with other organisations.
- A significant number of organisations stated that they wished to review or improve their current investigation processes, perhaps in line with a review of the incident and near miss reporting policy and procedures overall.

4.7.2 Analysis of Incident Reporting Data

- Most organisations have a systematic approach to reviewing reported incidents, however this varied greatly in its complexity.
- Trend analysis is undertaken by most organisations at some level, however the level and type of analysis differs significantly between the organisations (not least as the organisations are basing the analysis on differing quality of data and information).
- The report producing capability of the organisations also differs significantly, with most producing periodic reports, but of differing quality and with different review arrangements.
- Some organisations only produce reports on an ad hoc basis e.g. when requested by a specific individual. In these cases formal periodic review of trends in order to affect patients/clients safety and care does not occur.

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- A significant number of organisations have a structured process for producing trend analysis reports and a formalised structure for their periodic review. These organisations tend to be the organisations with the formalised and structured procedures, which utilise a central department.
- The organisations that centralise the collation of incident and near miss reporting information and the production of reports have a more consistent approach to reviewing both investigations and trend analysis.
- A significant number of organisations do not undertake root cause analysis due to lack of understanding/training or resource issues.

4.7.3 Continual Audit/Monitoring of Outcomes

- Most organisations link incident reporting to internal audit programmes (including clinical audit), however the majority of organisations saw this as an area where improved links and development is required.
- Most organisations have a process for monitoring how recommendations/actions plans are implemented, however in most cases this is a very informal process with no policy or procedure in place.

4.7.4 Feedback to Staff

- Feedback to staff is ad hoc and inconsistent in the majority of organisations.
- Feedback is usually only given to managers (or equivalents), with the expectation that it will be cascaded down the organisation from there.
- Feedback is rarely provided in a consistent, detailed and structured format on a periodic basis across the organisation at all levels.

4.8 Training/Staff Awareness

The Training/Staff Awareness section considers the training received by staff of all levels within each organisation and assesses staff's awareness of incident reporting within each organisation. Table 4.5 overleaf details the observations made at each of the HPSS organisations during the site visits undertaken.

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Table 4.5
Summary of Training/Staff Awareness Findings

	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Altnagelvin Hospital Trust	Sperrin & Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	Homefirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
TRAINING/STAFF AWARENESS																										
The Organisation:																										
- has provided training to all staff on IR	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓
- highlights the IR process at staff induction	✓	✓	✓	X	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓
- has a process for training those responsible for investigation incidents	✓	✓	✓	X	✓	X	✓	✓	X	X	X	✓	X	X	X	X	X	X	X	X	X	X	X	X	X	X
- staff are aware of the reporting system	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- staff report all incidents occurring in the organisation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- provides root cause analysis training	✓	✓	✓	X	✓	X	✓	✓	✓	✓	X	✓	✓	X	X	X	X	X	X	X	X	X	X	X	X	X

Source: Deloitte

The following major observations were made in relation to incident and near miss reporting systems:

4.8.1 Staff Training

- Most organisations have undertaken a process of training staff in incident reporting policies, procedures and systems however this has not consistently reached those on the lower levels of the organisations. The majority of organisations have trained key staff with the expectation that the information will be cascaded down the organisation. Whilst in most cases this has occurred through on-the-job training, a small number of staff members stated that they had never been given any instruction on how to complete an incident form or what the process involved.

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- The majority of organisations include incident reporting in their induction processes, however the level of detail differs significantly between the organisations. It was noted that incident reporting could be given at corporate induction training and/or department/ward induction training.
- Specific training for those involved in investigations is less frequent, with general incident reporting training covering the investigation process generally.

4.8.2 Awareness of Incident Reporting

- The vast majority of staff interviewed were aware of the relevant incident and near miss reporting policy and procedures in their organisation and specific area.
- Whilst staff were often aware of the requirement to report incidents and near misses, a considerable level of confusion exists in terms of policies, definitions of incidents and near misses and the procedures to be used e.g. which form to use when.
- No organisation believes it is reporting 100% of incidents.

4.9 Third Party Relations

The Third Party Relations section considers how each organisation interacts with all external groups in relation to incident and near miss reporting. Table 4.6 overleaf details the observations made at each of the HPSS organisations during the site visits undertaken.

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Table 4.6
Summary of Third Party Relations Findings

THIRD PARTY RELATIONS	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Altnagelvin Hospital Trust	Sperrin Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	Homefirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
The Organisation:																										
- includes IR in contracts with contractors/agencies	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- includes IR requirements in SLAs with external orgns	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- participates in sharing lessons learnt with other Trusts	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a process to inform agency staff of IR process	✓	✓	✓	✓	N	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	N	N	N	N	N	N	N	N

Source: Deloitte

The following major observations were made in relation to incident and near miss reporting systems:

4.9.1 Contractors/Agencies

- The majority of organisations stated that contracts with contractors and agencies covered incident reporting requirements, however most organisations identified this as an area for further development.
- Where applicable, organisations with agency staff considered that those staff members would receive training from permanent staff members and that senior staff would always be in charge, thus reducing the risk of an incident occurring without it being reported. However, the majority of organisations did recognise that this area would need to be reviewed with current incident reporting policy and procedures.

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4.9.2 Sharing Knowledge

- All organisations recognised a need to improve knowledge share and lessons learnt between organisations.
- All organisations stated that they currently communicate with other organisations in a variety of different ways, including the Risk Management Forum, the CSCG Network, Professional Groups and the Datix Users Group. Organisations also have informal links with other Trusts that provide a method for sharing knowledge and communicating about current issues. It was however noted that limited sharing of knowledge and lessons learnt from incident reporting occurs within these forums.
- Despite the current communication that exists the majority of organisations felt that improved communication between the organisations was the biggest issue facing patients/clients safety generally and incident reporting in particular.
- The majority of organisations felt that the current forums are not sufficient to discuss lessons learnt from incident reporting and that the sharing of information is limited at best.

4.10 Organisational Differences

The findings detailed above were the common trends identified across all HPSS organisations. There were however some key observations made for the different types of HPSS organisation, and these are discussed overleaf under the categories identified in Table 4.7.

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Table 4.7
Summary of HPSS Organisations

Organisation	Category	Organisation	Category
Altnagelvin Hospitals HSS Trust	HSS Acute Trust	Newry & Mourne HSS Trust	HSS Combined Trust
Armagh & Dungannon HSS Trust	HSS Combined Trust	North & West Belfast HSS Trust	HSS Community Trust
Belfast City Hospital HSS Trust	HSS Acute Trust	Northern HSS Board	HSS Board
Causeway HSS Trust	HSS Combined Trust	Northern Ireland Ambulance Service HSS Trust	HSS Ambulance Trust
Central Services Agency	HSS Agency	Northern Ireland Blood Transfusion Service	HSS Special Agency
Craigavon & Banbridge Community HSS Trust	HSS Community Trust	Northern Ireland Regional Medical Physics Agency	HSS Special Agency
Craigavon Area Hospital Group HSS Trust	HSS Acute Trust	Royal Group of Hospitals and Dental Hospital HSS Trust	HSS Acute Trust
Down Lisburn HSS Trust	HSS Combined Trust	South & East Belfast HSS Trust	HSS Community Trust
Eastern HSS Board	HSS Board	Southern HSS Board	HSS Board
Foyle HSS Trust	HSS Community Trust	Sperrin Lakeland HSS Trust	HSS Combined Trust
Green Park HSS Trust	HSS Acute Trust	Ulster Community and Hospitals HSS Trust	HSS Combined Trust
Homefirst Community HSS Trust	HSS Community Trust	United Hospitals HSS Trust	HSS Acute Trust
Mater Infirmorum Hospital HSS Trust	HSS Acute Trust	Western HSS Board	HSS Board

Source: Deloitte

4.10.1 HSS Trusts

Health Boards purchase healthcare services from Northern Ireland's Trusts, of which there are 19 of varying sizes. These 19 Trusts have been categorised as Acute, Community or Combined for the purposes of this report. Table 4.7 above categorises the HSS organisations that have been involved in the project.

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4.10.2 HSS Acute Trusts

The following key observations were made for HSS Acute Trusts:

- Acute Trusts generally had higher levels of incident reporting internally due to groups of reporting staff being located together and receiving more communication regarding incident reporting through feedback.
- Acute Trusts are less likely to report information to Boards than Community Trusts due to the perceived sensitivities of the clinical information.
- Consultants and Junior Doctors are generally considered to be the worst at reporting incidents and near misses, with nurses considered to be the best at reporting.

4.10.3 HSS Community Trusts

The following key observations were made for HSS Community Trusts:

- Community Trusts generally had lower levels of incident reporting internally due to issues such as lone workers, reporting culture and types of incidents occurring.
- Community Trusts are more likely to report incident and near miss information to Boards than Acute Trusts.
- Some Community Trusts feel that Northern Ireland incident reporting tends to be based on NHS systems which can largely ignore social care elements.
- Some Community Trusts feel that social care incident reporting needs to be considered on a regional basis to ensure its full inclusion within any regional developments or guidance.

4.10.4 HSS Combined Trusts

The Combined Trusts displayed the same characteristics in the Health and Social Services areas of service as described in the Acute and Community Trusts above.

4.11 Health and Social Services Boards

There are four Health and Social Services Boards, the Western, Northern, Eastern and Southern Health and Social Services Boards, which act as agents for the Department. The following comments for each organisation should be noted:

- The Boards are all currently reviewing their incident and near reporting procedures to some extent.
- The Boards have three main areas of interest in relation to incident reporting. Firstly, there is internal incident reporting which tends to be low in volume and risk. Secondly there are incidents occurring in care homes which are recorded, monitored and reported on by each

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Board's R&I Unit. Thirdly, and possibly most significantly, there is the monitoring of incidents and near misses occurring within the Trusts that the Board have commissioned work from.

- Internal incident reporting systems procedures are simplistic based on the volume and seriousness of the incidents involved. Most incidents in this category relate to theft/security, personal injury or IT incidents. The Boards do not believe there are serious internal incidents occurring that they are not aware of.
- Accountability issues between Boards and Trusts currently exist and have affected the level of information being provided from the Trusts to the Boards on a periodic and one-off basis.
- The Boards are all in the process of trying to agree the level of information to be provided by the Trusts. This is occurring at different levels in each Board area, however the perceived method to resolve this issue appears to be on a four Board basis with consultation with the Trusts.
- The Boards have developed Untoward Incident Policies to detail the level of incident reporting required from the Trusts, however these are not being adhered to by the majority of Trusts.
- The Boards are experiencing notification of approximately 50 incidents per year from the Trusts, however one Board is only receiving one or two per year.
- The Boards generally consider the Community Trusts as better at reporting to them than the Acute Trusts.

4.12 Health and Social Services Special Agencies

The following key observations were noted in relation to the HSS Special Agencies:

- The special agencies are all addressing incident reporting to reflect the unique circumstances that exist in each organisation.
- The NI Regional Medical Physics Agency combines its incident reporting systems with the Trusts that it is working with to ensure a robust process exists. It currently does not use IT to record incidents and near misses, however it has ordered Datix.
- A quinquennial review indicated that overlaps exist between the NI Regional Medical Physics Agency and NIAIC, however these are not considered to be significant and the Agency believes its role to be quite clear within the health service.
- The Northern Ireland Blood Transfusion Service has a structured approach to incident reporting including the use of the Q-Pulse and Safecode IT systems.
- The Central Services Agency has a low level of internal incidents occurring which largely relate to security/theft incidents, personal injury incidents and IT incidents.
- Regional Supplies Service (part of CSA) also receive incident reports from Trusts in relation to medical products, which impacts on the incident reporting process from Trusts to NIAIC.

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4.13 Wider Health and Social Care Community

The following key observations were made in relation to General Practitioners:

- GPs appear to be very inconsistent in their approach to recording and reporting incidents and near misses.
- The majority of GPs have a policy on recording incidents, however a significant number do not.
- The majority of GPs have a form for recording incidents, however a significant number do not.
- The most common incidents relate to medication incidents.
- Significant inconsistencies appear in the level of understanding and usage of risk management and risk assessment by GPs. Some GPs appear to be very clear about the need for risk management and the usage of risk assessment, whilst others have no appreciation of the issues and do not use risk assessment.
- Significant inconsistencies appear to exist in the level of root cause analysis being used by GPs in relation to incident and near miss reporting. No significant pattern was observed, with some GPs using root cause analysis and trend analysis and some not.
- All GPs questioned had received NIAIC alerts, however few of them found them relevant to their specific area.

The following key observations were made in relation to the Northern Ireland Guardian Ad Litem Agency:

- Use Microsoft to record incidents and near misses.
- Has policies and definitions for incident and near miss reporting and does not allow anonymous reporting.
- Does not currently undertake trend analysis or root cause analysis in relation to incident and near miss reporting.
- The Agency provides staff with feedback on a regular basis.
- Staff are trained in incident and near miss reporting at induction. Training also occurred when the Adverse Incident Policy was developed.
- The Agency does not have any medical devices or equipment and thus did not respond to the NIAIC questionnaire.

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5 REVIEW OF NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)

5.1 Introduction

We have undertaken an independent assessment of the effectiveness of NIAIC as described in Section 2 of the report. The review of NIAIC was carried out using information gathered from the following activities:

- Review of NIAIC's role and responsibilities.
- Review of existing NIAIC structure and system.
- Review of information gathered specifically relating to NIAIC from the questionnaire and subsequent site visit to HPSS organisations.
- Review of information gathered specifically relating to NIAIC from the questionnaires returned from other healthcare providers in Northern Ireland e.g. General Practitioners.
- Consideration of NIAIC's role in Northern Ireland in comparison with the role of the MHRA in England and Wales and SHS in Scotland.

Each of these elements is now considered in full.

5.2 Northern Ireland Adverse Incident Centre (NIAIC)

Our review of NIAIC included a contextual assessment of NIAIC, including background review of its current position within the Northern Ireland Incident Reporting Process. The details of this element of the review are discussed below.

5.2.1 Objectives of NIAIC

The key objective of the Northern Ireland Adverse Incident Centre (NIAIC) is "to improve the quality of service provided to the community by improving safety and effectiveness in using medical devices in the HPSS and wider health & social care community". The NIAIC fulfils this objective through the following key activities:

- Operation of a voluntary system for reporting and investigating adverse incidents for Northern Ireland.
- Issuance of warning notices and guidance publications to the HPSS and the wider health and social care community.
- Advise the Department of Health, Social Services and Public Safety on the safety, quality and performance of medical devices, equipment and associated procedures.

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NIAIC issues advice to warn health and social care providers and other uses of medical devices, non-medical equipment, buildings and plant about particular problems and risks and to recommend appropriate actions to minimise such problems and risks. Following consultation with the customer and stakeholders of the Northern Ireland Adverse Incident Centre (NIAIC), it revised the format of its advice with Medical Device/Equipment ALERTS (MDEAs) replacing Hazard Notices, Advice Notices and Safety Notices.

Device Bulletins are issued when guidance and information is needed over an extended area, for example, decontaminating endoscopes. They deal effectively with problems which keep recurring and which can be solved by good training and practice, rather than by modifying or withdrawing a particular product. It is vital that they are issued to all staff with responsibility for training, staff responsible for setting organisational policies for equipment management and any other relevant staff.

Historic Hazard Notices, Advice Notices and Safety Notices issued are still available on the NIAIC website for review. Medical Device/Equipment ALERTS are distributed to HSS Boards, Trusts, and Agencies for direct action and for onward transmission were appropriate in accordance with local procedures. NIAIC arranges for the distribution to Primary Care Professionals. Professional Estates Letters (PELs) are issued by Health Estates, Estates Policy Directorate on behalf of the DHSSPS. They set-out Departmental policy in relation to Estates issues, including medical devices, non-medical equipment, buildings and plant.

5.2.2 NIAIC Incident Definition

NIAIC define an adverse incident as "an event which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, staff, users and other people." Any adverse incident involving a medical device, non-medical equipment, plant or building should be reported to NIAIC. NIAIC publishes specific advice for incidents involving medical devices and equipment.

5.2.3 NIAIC Investigations

The method of investigation depends on the risk associated with the incident. Incidents where there has been a death or serious deterioration in health (or the potential for such) are subjected to an in-depth investigation by NIAIC investigation officers. Such investigations may involve contact with the device user and manufacturer, a visit to the site of the incident and testing of the device involved (either by the manufacturer, or an independent test house). It is these investigations which typically result in NIAIC issuing safety advice.

Incidents where there has been a minor injury or no injury, and the potential for a more serious incident is low, are generally most effectively investigated by the device manufacturer. Details of the incident report is forwarded to the manufacturer and NIAIC monitors the progress of the investigation. The manufacturer's final conclusions are passed to the reporter for information or comment.

At all stages of an investigation, the information available is subject to review in order to enable NIAIC to reassess the level of investigation and to determine what, if any, action it needs to take. During the reviews NIAIC involve all investigation team members, including Clinical and Nursing Professionals to advise on clinical or nursing aspects of the incident and the way the device had been used.

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5.2.4 MHRA and NIAIC Interface

NIAIC has direct links with the Medicines and Healthcare products Regulatory Agency (MHRA) who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland for issues concerning medical device safety. NIAIC also has links with NHS Estates and other bodies for safety issues concerning non-medical equipment, plant and building items.

The MHRA operates the adverse incident centre for the UK. All reports received in Northern Ireland are reported to MHRA for registering on the MHRA database. NIAIC undertake the investigation, with the outcome passed on to MHRA for information. With certain devices such as pacemakers, because of their expertise in these areas, MHRA are asked to undertake the investigation on our behalf. As a result of adverse incident investigation and other supporting work, this enables MHRA to build up a national picture of events concerning medical devices. MHRA can review trends and where necessary take early action by the issue of warning notices to the NHS. NIAIC are consulted by MHRA on draft warning notices to allow us to take parallel action here if needed.

5.2.5 Trends in Medical Device and Equipment Incident Reports

NIAIC received 220 reports of adverse incidents during 2001, a 40% rise on 2000. Over 240 adverse incidents were reported to NIAIC during 2003. These incidents involved medical devices and other equipment of all kinds, from simple infusion devices to highly sophisticated CT scanners. Despite the number of reported incidents continuing to grow, NIAIC believe that there is significant under-reporting of adverse incidents. This assessment is consistent with the findings detailed Section 7.4 below.

5.3 NIAIC Review 2002

Following a review of NIAIC services in 1999, the adverse incident reporting system and the distribution arrangements for warning notices and other NIAIC publications was enhanced by the development of the NIAIC website. Subsequently a report was issued to the Department of Health, Social Services and Public Safety Chief Professional Officers in March 2002 and it was proposed that NIAIC would undertake a stakeholder survey seeking views on the provision and development of NIAIC services in the following areas:

- Adverse Incident Reporting and Investigation.
- The content and relevance of Device Bulletins and other guidance material.
- Improvements in distribution and targeting of warning notices.
- Improvements and utilisation of the NIAIC website.

In order to undertake the 2002 NIAIC Review, a Professional Estates Letter (PEL (02) 07) was issued in June 2002 to all HSS Trusts, Boards, Agencies and Primary Care Professionals. It requested that:

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- Each HPSS organisation should consult with staff that receives warning notices and guidance publications to allow an organisational response to the Questionnaire.
- General Medical Practitioners, General Dental Practitioners, Optometrists and Community Pharmacists provide their views on the services outlined in the Questionnaire.

Seventy-seven responses to the questionnaire were received by the August 2002 deadline. The full findings of the report are attached as Appendix VIII, however the key findings of the review are discussed below.

5.3.1 Adverse Incident Reporting and Investigation

The majority (96%) of organisations had a management policy in place for reporting adverse incidents to NIAIC. Organisations felt it was appropriate for NIAIC to assess the level of risk on receipt of an adverse incident report to determine the most appropriate action however most felt that NIAIC should not concentrate on "high-risk" device incidents only. The majority of responses indicated that NIAIC assists in Clinical Governance issues and that clinical governance or risk management does not reduce the level of incident reporting to NIAIC. The review supported the NIAIC incident risk assessment process at that time, although it was clear that NIAIC needed to be aware that "low-risk" device incidents could actually result in "high-risk" outcomes. The review also indicated that HSS organisations felt that NIAIC has a role to play in development and support of Clinical and Social Care Governance.

Two-thirds of organisation indicated that they were completely satisfied/satisfied with the way that NIAIC investigates incidents and with the speed of the NIAIC investigation of incidents. Just over half indicated that they were completely satisfied/satisfied with the level of investigation communication from NIAIC. All organisations felt that NIAIC investigations reduce the risk of incident recurrence. NIAIC felt that the "satisfaction" indicators for NIAIC investigation are generally acceptable, but left scope for improvement.

Half the organisations felt that NIAIC should give more technical advice and two-thirds felt that NIAIC should give more training advice. Half the organisations also felt that NIAIC should do more in assessing the risks involved in incidents. One-third of organisations indicated that NIAIC should be more thorough in incident investigations and should give more advice on incident reporting procedures.

5.3.2 Content and Relevance of Device Bulletins and other Guidance material

All organisations considered that Device Bulletins are useful with the majority stating that their organisational arrangements for distribution of Device Bulletins ensures that appropriate staff receive them. The majority also felt that the format of Device Bulletins was clear.

5.3.3 Distribution and Targeting of Warning Notices

All organisations indicated that warning notices took longer than 24 hours to reach the intended recipient, with only half the organisations getting warning notices to the relevant individuals within 48 hours. One-third of organisations indicated that warning notices took longer than 48

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hours but less than a week to reach the intended recipient, with half of these responses being from Community Trusts. The remaining organisations, which included 2 Boards, 1 Mixed Trust and 2 Community Trusts took longer than one week to disseminate warning notices.

The question concerning distribution times for warning notices was specifically related to the highest level of notices, Hazard and Advice Notices. NIAIC considered this finding as particularly disappointing given that this level of notice would not reach the intended recipient within 24 hours. It was also noted that there were some logistical difficulties in distribution of warning notices from Boards R&I Units to Residential and Nursing Homes and Private Clinics, and within some mixed and community Trusts. This compared unfavourably with NHS Trusts in England and Wales where over 70% have claimed to have forwarded to relevant recipients within 24 hours of receipt from the Medical Devices Agency (MDA)[3]. As a result NIAIC reviewed this area further and now sent all information by e-mail as well as in hard copy to Chief Executives and NIAIC Liaison Officers for further dissemination to relevant areas and individuals.

The majority of organisations felt that the format of warning notices made it clear what the problem is and what to do about it and most (87%) stated that it would be acceptable to exclusively use e-mail for warning notice issue to their organisation.

5.3.4 NIAIC Website

Just over half of the organisations stated that they found the website useful. Those who found the website useful indicated that they liked the availability of a warning notice library. Regional Supplies indicated that they would like to use the warning notice facility of the website for their organisation process in alerting staff to safety issues provided the website was updated quickly. This remains an issue currently as NIAIC forward Internet material to DHSSPS information office who are then responsible for DHSSPS Internet Site maintenance.

Just under half of the organisations indicated that they had used the site to obtain documents online. Only a quarter of organisations indicated that it would be acceptable if Device Bulletins and other guidance material were only published on the website. Just under half of the organisations indicated that they found the on-line reporting facility useful.

The response on the website was generally considered as disappointing by NIAIC and was explained by the availability of Internet access within HPSS organisations. NIAIC felt that this situation would improve with time. A very low acceptability from respondents for exclusive publication using the Internet site resulted in continued hard copy publication to this day.

5.3.5 Review Recommendations

The Review presented the following recommendations based on the findings detailed above:

- Explore with HPSS organisations the development of risk assessment of incidents with incident investigation at HPSS organisational level with NIAIC support.

[3] MDA Hazard Notice Survey 2002

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- Explore areas for possible NIAIC support in the development of training at HPSS organisational level in device management.
- Explore development in HPSS systems for improvement in speed of warning notice distribution with a particular focus on mixed, community Trusts and social care providers.
- Explore the possibility for moving to e-mail issue of warning notices.
- Review in the medium term a move to exclusive publication using the Internet depending on ICT developments in this area.

5.4 Perceptions of NIAIC in HPSS and Wider Health & Social Care Community

Section B of the pre-site visit questionnaire developed for the HSS Boards, Trusts and Special Agencies specially addressed issues relating to NIAIC and the issue of Medical Devices and Equipment within the Health Service. In addition, detailed discussions were undertaken within each organisation, including the NIAIC Liaison Officer, the Lead Director responsible for incident and near miss reporting within each organisation and a selection of senior and junior staff throughout every organisation. Questionnaires were also sent to Primary Care Providers with specific questions relating to NIAIC included. Table 5.1 below indicates the results of the specific closed questions asked by HPSS organisation.

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Table 5.1
Summary of NIAIC Findings

	Craigavon & Banbridge HSS Trust	Ulster Community Hospitals Trust	RGHT	Causeway HSS Trust	Altnagelvin Hospital Trust	Spertin & Lakeland HSS Trust	Green Park HSS Trust	N&W Belfast Trust	Foyle HSS Trust	Belfast City Hospital HSS Trust	United Hospitals HSS Trust	Newry & Mourne HSS Trust	Craigavon Area Hospital Trust	Down Lisburn Trust HSS Trust	Mater Infirmorum Hospital Trust	S&E Belfast Trust	Armagh & Dungannon HSS Trust	Homefirst HSS Trust	NI Ambulance Service Trust	NHSSB	EHSSB	SHSSB	WHSSB	NI Regional Medical Physics Agency	Central Services Agency	NI Blood Transfusion Service
NIAIC																										
The Organisation:																										
- has a policy on the dissemination of MDEAs	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X
- disseminates MDEAs designated as urgent within 24 hours	✓	✓	X	✓	✓	X	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	X	✓	✓	✓	✓	✓
- has a process for monitoring staff action on an MDEA	✓	✓	✓	✓	✓	✓	✓	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	X
- has a Medical Device and Equipment Controller	X	X	✓	X	✓	X	X	X	X	✓	✓	✓	X	X	X	X	X	X	X	X	X	X	X	✓	X	X
- has a nominated NIAIC Liaison Officer	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- has a process for highlighting NIAIC during induction	✓	X	X	X	✓	X	✓	X	X	✓	X	✓	✓	X	X	X	X	X	X	X	X	X	X	✓	✓	X

Source: Deloitte

5.4.1 Awareness of NIAIC

- All HPSS organisations are aware of NIAIC's roles and responsibility at a senior level.
- All HPSS organisations have a NIAIC Liaison Officer.
- Majority of HPSS staff are aware of the NIAIC alerts, but not did not necessarily know about NIAIC or understand its role.
- All GPs questioned are aware of NIAIC.

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5.4.2 NIAIC System

- The system for disseminating alerts and bulletins on Medical Devices and Equipment is used in all HPSS 26 organisations questioned.
- Trusts stated that NIAIC does not usually investigate incidents reported – manufacturers or Trusts will investigate (issue of independence). This may be due to the perceived risk level of the incidents reported, however the majority of Trusts appeared dissatisfied with the level of investigation undertaken and the time taken to complete this exercise. It was noted that the majority of organisations commented on the lack of resources that currently exist within NIAIC.
- The majority of organisations has a process for monitoring staff action on receipt of an MDEA.

5.4.3 Coverage

- Varying degrees of reporting coverage were noted between organisations, however no organisation felt that all incidents were being reported.
- Some organisations do not report as much as required as they do not see much benefit in reporting to NIAIC as no action results; these organisations tend to contact the manufacturer directly or resolve the issue themselves.
- Some organisations appear to report everything that relates to Medical Devices and Equipment, however these organisations cannot be 100% sure that staff are reporting all relevant incidents to NIAIC Liaison Officers or other appropriate staff.
- Only seven organisations have a Medical Device and Equipment Controller.

5.4.4 Training

- Training appears to be inadequate in the majority of organisations for staff on the ground, resulting in confusion over the role of NIAIC and what the process is to report to them. Confusion also appeared to exist around the definition of Medical Devices and Equipment.
- Only eight organisations highlight the role of NIAIC at induction.

5.4.5 Dissemination of Device Bulletins

- Twenty-three (out of twenty-six) organisations had a specific policy in place relating to the dissemination of Medical Device and Equipment Alerts (MDEAs).
- Most (21 out of 26) organisations disseminate MDEAs designated as urgent within 24 hours.
- Alerts are not filtered by NIAIC but do provide a guide as to who should receive them. It was noted that this is not part of NIAIC's role and the personnel guidance is only to assist organisations to further disseminate the alerts.

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- A wide range of dissemination filtering was observed within organisations. Some NIAIC Liaison Officers simply e-mail the alerts on to all areas, or individuals in areas (e.g. Directors) and expect them to filter the alerts. Some Liaison Officers perform a review process whereby they consult with relevant individuals about the appropriateness of the alert to their area, however where this occurs alerts will take longer to reach the relevant individuals.
- A number of organisations stated that they were dissatisfied with NIAIC's alert distribution system, especially in relation to lack of filtering before it arrives at organisations, format it is sent (i.e. e-mail, fax and letter) and number of individuals that receive it in each organisation.
- Despite the issues discussed above, NIAIC alerts appear to be reaching all relevant individuals

5.4.6 Data Quality, Accuracy and Completeness

- The systems used to collate and report on medical device and equipment incidents differ significantly across the HPSS and wider health & social care community. The method of collection, collation and reporting is described in summary within Section 4 and in detail for each organisation in Appendices V, VI and VII. Most organisations currently report the incidents manually (i.e. on hard copy incident reporting forms), collate the information electronically (e.g. on an IT systems such as Datix) and report it electronically to NIAIC via e-mail. The timeliness, robustness and completeness of this system also differs significantly across the organisations.

5.4.7 Strengths and Weaknesses of the System

- All organisations believe that the system for dealing with medical devices and equipment has improved significantly over recent years, primarily due to NIAIC's involvement.
- Electronic nature of information dissemination has proved t to be very popular with all organisations.
- Most organisations consider NIAIC as slow to investigate and feedback results after having been alerted of a medical device or equipment incident.
- NIAIC are considered as a good central point for advice and guidance relating to medical devices and equipment.

5.4.8 Operation of Systems (whether computer or manual)

- The systems used to collate and report on medical device and equipment incidents differ significantly across the HPSS and wider health & social care community. The method of collection, collation and reporting is described in summary within Section 4 and in detail for each organisation in Appendices V, VI and VII. Most organisations currently report the incidents manually (i.e. on hard copy incident reporting forms), collate the information electronically (e.g. on an IT systems such as Datix) and report it electronically to NIAIC via e-mail. The timeliness, robustness and completeness of this system also differs significantly across the organisations.

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5.4.9 Validation of Information

- Validation of information reported within HSS organisations differs in line with the systems in place in each organisation – refer to Section 4 above.
- Validation of information reported to NIAIC follows a robust and complete set of processes and procedures, however due to resource constraints, NIAIC are not always able to validate and investigate this information in a timely manner.

5.4.10 Induction and Training

- Some organisations believe that NIAIC should promote and market itself better, in order to focus all concerned on its roles and responsibilities and to further promote the area of medical device and equipment incident reporting.
- Nine organisations have a process for highlighting NIAIC during induction training for staff.

5.4.11 Effectiveness of NIAIC

- NIAIC is considered by most organisations as a good central reference point for seeking guidance and advice on medical devices and equipment.
- Some organisations referred to NIAIC as a "post-box" i.e. its only function is sending and receiving information, with little analysis or investigative work being undertaken.
- A significant number of organisations stated that they were dissatisfied with NIAIC's investigation system, especially in relation to time taken and type of investigation undertaken.
- The majority of organisations felt that NIAIC was under-resourced to undertake its full remit in relation to Medical Devices and Equipment.
- The majority of organisations stated that feedback from NIAIC was poor in relation to investigations and regional medical and equipment incidents.
- All organisations stated that NIAIC was a very useful contact point from which further investigation can occur.

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6 CONCLUSIONS & RECOMMENDATIONS

6.1 Conclusions

The following key conclusions provide a summary of the findings from the review of incident reporting within the HPSS and wider health & social care community in Northern Ireland..

6.1.1 Regional Approach to Incident Reporting

The most significant finding of this review has been that no single regional approach exists for all incident reporting in Northern Ireland. Whilst there are pockets of consistent approach e.g. NIAIC, RIDDOR and other statutory reporting requirements, a high level of inconsistency has been observed across the region in relation to incident reporting.

6.1.2 Linkages to GB Incident Reporting Systems

Linkages were observed with GB incident reporting systems between MHRA and NIAIC in relation to medical devices and equipment. It was also noted that linkages do exist with other national incident reporting systems such as the Confidential Investigation into deaths of Mothers and Children (CEMACH), the Confidential Investigation into Suicide and Homicide by People with Mental Illness. These linkages tend to be linked to statutory reporting requirements in specific areas and do not consider general incident reporting across the service. Northern Ireland has not made any formalised links with the National Patient Safety Agency (NPSA) although discussions about future linkage have been undertaken. Northern Ireland is not currently involved in the SABS project and there appear to be no plans to move this position in the near future.

6.1.3 Investigations and Trend Analysis

Potentially avoidable outcomes of health care arise in a variety of ways and in different patterns. In the past, a wide range of methods - including investigations, reviews, internal and external inquiries - have been used to respond to the problems and concerns raised. Over the years, there has been little consistency in the way these responses have been made. The establishment of a new system of incident and near miss reporting for learning creates an important need to resolve these inconsistencies and clarify the role of existing and new organisations to respond effectively to service failure, both large scale and small.

6.1.4 Sharing of Knowledge

Currently there is limited sharing of knowledge between the healthcare organisations and bodies within Northern Ireland. Whilst groups such as the Risk Management Forum exist for organisations to discuss key issues; they tend not to concentrate on incident reporting and thus do not

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allow a complete and robust knowledge sharing experience. Whilst some organisations are starting to utilise such tools as the Datix messageboard, not all organisations have access to it and those that do are using it at different levels.

6.1.5 Countering the Blame Culture

One of the challenges of clinical governance is to counter the culture of blame in the HPSS and allow staff to express legitimate concerns. They should be encouraged to report problems without fear of criticism. In this way Adverse Incidents can be handled positively so that outcomes can be improved.

It is crucial that the DHSSPS and HPSS organisations encourage a shift to an open safety culture in the HPSS and beyond, where open reporting and balanced analysis are encouraged in principle and by example. This is in contrast to a blame culture, which encourages people to cover up errors for fear of retribution and act against the identification of the true causes of failure, because they focus heavily on individual actions and largely ignore the role of the underlying systems. With the introduction of Clinical and Social Care Governance there is a shared goal between the individual and the organisation to improve patients/clients safety within the HPSS and wider health & social care community.

Currently organisations are dealing with the reporting culture issue in differing ways. Whilst most organisations advocate an open culture, different terms are used, including "no-blame", "fair-blame", "just-blame" or simply "open and honest culture". The Medicines Governance Project has also had an impact on the issue of reporting culture as it provides the option of utilising anonymous reporting when medication incidents occur. This has caused some debate within Trusts as to the need or validity of anonymous reporting. This issue will need to be addressed if a regionally consistent approach to incident reporting is to occur.

6.1.6 Data Definitions and Quality

Significant differences have been noted in relation to the data recorded, analysed and reported across the HPSS organisations. This is due to the use of different incident reporting procedures (including different definitions) and ultimately the use of different incident reporting systems. Whilst the majority of organisations are currently using Datix to record and report on incidents, differences in codes used and the linkage with risk management, claims & litigation and complaints modules differs significantly. This results is inconsistent trend analysis occurring across the region, and thus this element of the process will need to be addressed if a regionalised approach to incident reporting is going to occur. A single incident reporting system across all organisations would therefore be a key development in Northern Ireland.

6.1.7 Evaluation of NIAIC

It is clear that NIAIC's role within incident reporting is considered as necessary by all those involved with incident and near miss reporting in Northern Ireland. However, it is equally clear that NIAIC have significant resource constraints which are impacting on its ability to perform its roles and responsibilities. This is most noticeable in the area of investigation, were by NIAIC are considered to be slow in following up on

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reported incidents within Trusts. NIAIC's ability to market itself and better communicate key issues and themes (e.g. by means of an annual seminar) have also been observed as key issues.

6.1.8 Linkages to Clinical and Social Care Governance, Risk Management and Other Activities

Best Practice – Best Care defined clinical and social care governance as a framework within which HPSS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment. Clinical and social care governance is about organisations providing the highest standards of clinical and social care and taking corporate responsibility for performance. Ensuring that where things do go wrong, they are quickly addressed and lessons are learnt to prevent re-occurrence is key. Risk Management is a key component of CSCG, however as evidenced by the findings presented above is undertaken inconsistently throughout the HPSS and wider health and social care environment.

6.1.9 Roles and Responsibilities

As in other facets of clinical and social care governance it is important that there is clear accountability for incident reporting systems in the HPSS organisations. It has been observed that a differing level of structure and formalised process is evident across the organisations. It will be necessary for this to be addressed before consistency of approach of incident reporting can occur in Northern Ireland.

6.2 Recommendations

We have presented our recommendations based on the incident reporting areas discussed in previous sections of the report.

6.2.1 Incident Reporting Policy

- DHSSPS to facilitate network of organisations to promote consistency of approach in incident reporting definitions. This may be through the existing groups or through the development of a sub-group.
- Network of organisations to develop consistent Northern Ireland regional definitions for incident reporting. The definition and improved reporting of near misses would be an important element in this process.
- DHSSPS to provide training and support for Network and individual organisations.
- Linkage between the Medicines Governance Project and the wider incident reporting systems in Northern Ireland need to be strengthened to ensure that inconsistencies that may occur can be resolved. This will include agreeing approach in relation to definitions, anonymous reporting, incident reporting form type, system codings, investigation procedures and reporting responsibilities.
- Organisations should provide definitive list of what is considered disciplinary incident and ensure whistle-blowing policy is consistent with incident and near miss reporting policy. This could include the combining of these two policies.

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- Organisations should ensure that staff are continually updated on incident and near miss reporting policies and definition to promote open culture.

6.2.2 Incident Reporting Procedures

- The Safety in Health & Social Care Steering Group should promote the development of a single incident reporting form, or set of reporting forms across the region to promote consistency of approach. This could be developed by the combined Risk Management Forum and CSCG Network Group and co-ordinated by the DHSSPS.
- A consistent risk assessment model should be developed for use across all organisations in Northern Ireland and should be linked to each organisations risk register and risk management process.
- The DHSSPS should consider providing guidance to organisations on structure and process of incident reporting internally and with other organisations e.g. between Trusts and Boards.
- The potential for utilising electronic reporting forms in all areas following the Patient Client Information System (PCIS) should be considered by the DHSSPS.
- The Risk Management Forum and CSCG Network should consider the issue of sharing knowledge between organisations. This would also require assessment of whether the Northern Ireland organisations would benefit from a formal linkage with the NPSA.
- The DHSSPS should provide guidance to all organisations on document and information retention periods pertaining to incident and near miss reporting data.

6.2.3 Incident Reporting Systems

- The Safety in Health & Social Care Steering Group should further consider the potential of all Trusts providing consistent electronic incident reporting to a centralised group for sharing of knowledge/lessons learnt. A single incident reporting system in all organisations would be a crucial requirement for this to occur across the region. Currently Datix is the most widely used system and may therefore become the regional choice to combine incident reporting data. The challenge will be to get agreement from the organisations as to how this system would work and what level of information is supplied and in what format it is presented. This would need to be discussed through the Datix Users Group.
- The DHSSPS should consider what training and support can be provided to those organisations that are currently developing their systems, which essentially means all HSS organisations. Training and support would be required at differing levels, but would include issues such as risk management training, IT training, investigation and trend analysis training, report training.

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- The Safety in Health & Social Care Steering Group should promote the development of common incident and near miss codes across Northern Ireland (as is occurring within medication incident reporting).
- The Safety in Health & Social Care Steering Group should consult further with the Medicines Governance Project to ensure that a consistent approach occurs in relation to all incident reporting in Northern Ireland. This would include ensuring that all issues relating to anonymous reporting and format and content of forms are resolved adequately.
- The DHSSPS should provide improved guidance on the linkages of statutory and confidential reporting with incident reporting generally. This will involve agreeing with the Trusts, Boards and primary care providers what information can and can't be shared between organisations for lesson learning.
- The DHSSPS should consider what financial resource it can provide to organisations to undertake a full incident reporting system. Currently all organisations have had to resource this area themselves with little or no guidance from the centre. As the processes and procedures become more complex and time-consuming, resources to undertake the level of recording, collation, reporting and analysis required do not appear to be capable of increasing at the same rate.

6.2.4 Review of Incidents Reported

- The Safety in Health & Social Care Steering Group should consider how training and support could be provided to the HSS organisations to improve investigation and analysis techniques, including trend analysis and root cause analysis.
- The DHSSPS should consider what formal investigation and audit procedures are required (on a regional basis) for serious incidents occurring within the Northern Ireland HSS. This should be reviewed to ensure that a robust and transparent system of accountability is in place, which will be consistent across the province.
- The Safety in Health & Social Care Steering Group should aim to develop a culture of feedback within all of the HSS organisations to ensure all members of staff can fully understand the benefits of a robust incident reporting systems, but more importantly can be advised of lessons learnt and knowledge from other areas within the wider health & social care community.

6.2.5 Training/Staff Awareness

- The Safety in Health & Social Care Steering Group should consider how improved training in areas such as root cause analysis can be provided. As previously stated this may occur through the new CSCG Group.
- The Safety in Health & Social Care Steering Group should consider how it could improve the profile of incident reporting and the benefits for patients/clients safety across the HSS.

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6.2.6 Third Party Relations

- The Safety in Health & Social Care Steering Group and DHSSPS need to promote improved incident reporting arrangements between contractors/agencies and HSS organisations.
- The Safety in Health & Social Care Steering Group and DHSSPS need to consider how improved sharing of knowledge can be achieved. It is suggested that this would occur through several forums. Firstly the combined Risk Management Forum and CSCG Network should be consulted to ascertain whether that forum could be used to discuss lessons learnt further. Whilst it is recognised that these groups do address this issue to some extent, it is considered as limited and open to improvement. Secondly the development or utilisation of an IT system with the same capacity as the Datix messageboard should be established for all Trusts (the Datix messageboard could be used if all Trusts had access to it). Thirdly, the production of periodic regional incident and near miss reporting reports detailing trends and lessons learnt should be a key objective of all concerned within the Northern Ireland HSS.

6.2.7 NIAIC

- NIAIC needs improved resources to allow it to perform its independent investigation function fully. The recruiting of an Operational Manager for NIAIC (as is presently being undertaken) will be a positive step in that direction, however additional resource may be required to fully undertake NIAIC's role in a robust and complete manner.
- Increased resources in NIAIC would allow NIAIC to market itself more effectively and better inform the HPSS and wider health & social care community of both its activities and information on medical devices and equipment.
- NIAIC should investigate the potential for running an annual or bi-annual workshop for all relevant organisations, in order to promote incident reporting and focus organisations and individuals on NIAIC's role within that area.
- NIAIC should investigate the possibility of gaining control of its website, in order that it be updated on a more frequent basis.

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APPENDICES

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Appendix I - Questionnaires

Safety in Health and Social Care Project

Trusts & Agencies

Pre-visit Questionnaire

This questionnaire should be completed and returned, with accompanying information, electronically where possible to Deloitte no later than 13th January 2004 to:

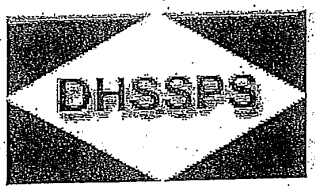
Craig Holmes

Email Cholmes [redacted]

Telephone
Mobile [redacted]

Address Deloitte & Touche LLP
19 Bedford Street
Belfast BT2 7EJ.

For advice or support whilst completing the questionnaire please contact Craig Holmes.



Deloitte.

Introduction

This questionnaire relates to *all* forms of incidents and near misses that can occur at any stage and in any part of providing health and social care and it includes incidents that involve patients and/or staff. The following list gives some examples of areas of incidents you may consider when completing the questionnaire, the list illustrative not exhaustive:

- Consent (Example: patients receiving treatment without appropriate consent being obtained);
- Medical Devices (Example: failure of a medical device);
- Diagnosis (Example: Missed or wrong diagnosis);
- Diagnostic Investigations (Example: Incorrectly reported or misinterpreted investigation results);
- Theatres (Example: Unaccounted instruments, Anaesthesia errors);
- Medicines Management (Example: Missing, incorrect administration of medication);
- Information and Security (Example: Breach of confidentiality, unauthorised use of an IT system);
- Health & Safety (Example: Fire incidents, staff accidents, slips trips & falls, violence);
- Statutory reporting (Example: Communicable diseases, Confidential Enquiries);
- Professional Report (Example: Child Protection, BNF Adverse Reactions);
- Clinical (Example: Needlestick injuries)
- Infection control (Example: MRSA, poor hygiene methods) and;
- Pathology (unexpected, significant post mortem findings).

The questionnaire is split into two main areas: Section A which relates to Adverse Incidents and Near Misses in general and Section B which specifically deals with your relationship with the Northern Ireland Adverse Incident Centre and should be completed by the NIAIC Liaison Officer.

SECTION A

1. General Information Requested

Organisation

Contact details of person completing questionnaire (Name, email address and telephone number)

List of all services provided by the Trust. (Example: General Surgery, Sexual Health, Mental Health)

Please provide copies of the following information:

Please ensure all information is clearly marked with the letter of the request it relates and clearly states the name of the organisation.

A. Copy of Risk Management Organisational and Departmental Structure.

B. Brief outline of job responsibilities detailing in particular those relating to adverse incidents, reporting, management and investigation.

C. Copies of all policies that relate to or influence incident reporting, please include details of any local definitions relating to incident reporting

D. Copies of all strategies that relate to or influence incident reporting.

E. Copy of all incident reporting forms (this include internal and external reporting forms).

F. If you use an IT package to record incidents a list of all the data fields which are populated in the package, classifications used and definitions within the software.

G. Please provide a data set of 3 months of anonymised incident reporting data (April, May and June 2003) including the following data:

- Incident Category
- Number of Incidents

This information will be used to look at trends and types of incidents recorded.

2. Information Technology

2.1 Do you use any IT software to capture information or manage incidents?

☐ Yes ☐ No

If yes, please give the following details:

- Software Package;
- Manufacturer; and
- Version you are currently using.
- Details of licensing arrangements (how many concurrent user licenses do you hold)

2.2 What arrangements does the Trust have for system maintenance? Please give details

2.3 What arrangements does the Trust have for upgrade management? Please give details.

2.4 Is the Incident reporting system/module integrated with any other IT systems or modules? Are you aware of any other organisations using it? Please give details.

3. Incident Management

3.1 Does your incident reporting system allow for anonymous reporting of incidents?

☐ Yes ☐ No

3.2 Does the organisation have a definition for adverse incidents and near misses?

☐ Yes, please give details ☐ No

If yes, is this included within the Policies and Procedures?

☐ Yes ☐ No, please give details.

3.3 If not described within policies and procedures, please describe the Incident reporting process from the incident occurring through to learning lessons from the incident.

4. Investigations

4.1 When an incident is reported are investigations undertake?

☐ Yes ☐ Sometimes ☐ No (Go to section 5)

If yes or sometimes:

4.2 How do you decide which incidents to investigate?

4.3 Who has responsibility for undertaking the investigation?

4.4 Who has responsibility for co-ordinating the investigation?

4.5 Do you use Route Cause Analysis (RCA) routinely during the process of investigation?
RCA is defined as a step by step investigation that leads to the discovery of an incidents first or root cause

☐ Yes ☐ No ☐ Occasionally

Please give details.

4.6 Who receives the report/outcome of investigation?

5. **Data Analysis**

5.1 Does the organisation analyse trends of incidents?

☐ Yes ☐ Occasionally ☐ No (Goto 5.3)

Please give an example

5.2 If yes, who is the analysis reported to?

5.3 Do you provide reports on trends to directorates/services? Please give an example.

☐ Yes, Regularly ☐ Yes, When requested ☐ No

5.4 What period of incident data do you have available?
(How long do you keep data for? When was the earliest incident you have recorded?)

6. Training & Education

6.1 Is there a process for raising the awareness on how to use the Incident Reporting process?

☐ No ☐ Yes, please give details

6.2 Is incident reporting discussed as part of the staff induction process?

☐ No ☐ Yes, please give details

6.3 Do you provide training on how to undertake Root Cause Analysis?

☐ No ☐ Yes, please give details

7. Sharing Information about Incidents

7.1 What processes are in place for you to share good practice and learning lessons from incidents within your organisation?

Please give an example

7.2 What processes are in place for you to share good practice and learning lessons from incidents with other Health and Social care organisations?

Please give an example

8. Independent Contractors

8.1 What arrangements do you have for monitoring information about incidents that occur whilst care is being delivered by an independent contractor?

Please give details

9. General Comments/Additional Information

Please provide any general comments or additional information relevant to the area of Adverse Incident/Near Miss Reporting.

SECTION B Northern Ireland Adverse Incident Centre (NIAIC)
This section should be completed by the NIAIC Liaison Officer

B1 Do you have a policy / procedure for dissemination of Medical Device/Equipment ALERTs (MDEA)?

B2 How long does is take for MDEAs with a designated urgency 'Immediate Action' to be fully cascaded?

B3 How does the Trust ensure the MDEAs are seen by those staff that need to take action?

B4 How does the organisation assure it self that appropriate action has been undertaken following the publication of an MDEA?

B5 Is the NIAIC routinely highlighted in Induction training? Please give details

B6 Are Bulletins routinely copied to Trust Executives?

B7 How could the NIAIC be of more use?

B8 Does the NIAIC Liaison Officer have clear lines of accountability within the Trust? Please give details

B9 Have you appointed a Medical Device and Equipment Co-ordinator with Clear lines of accountability with the Organisation?
Please give details

Questionnaire to Primary Care & Community Practitioners

Incidents in Primary and Community Care manifest themselves in different ways, examples include:

- Missed or wrong diagnosis
- Wrong treatment
- Loss of Medical Records
- Wrong medication dispensed or administered
- Patients misunderstanding information
- Health & Safety

Q1. Please tell us which profession you work in:

☐ General Practitioner ☐ Practice Nurse
☐ Dentist ☐ Optometrist
☐ Pharmacist ☐ Other (Please specify).....

Q2. If you were involved in an incident would you report it to anyone, if so who?

Q3. Do you have a policy on recording incidents?

☐ Yes, please attach a copy ☐ No

Q4. Do you have a form for recording incidents?

☐ Yes, please attach a copy ☐ No

Q5. If you needed advice or support following an incident where would you go?

☐ Health Board ☐ LMC ☐ BMA
☐ Defence Union ☐ Other (Please specify).....

Q6. What process do you have in place for review incidents?

Q7. Please give the categories of the last three incidents you recorded?

Q9. Where within your practice do you consider incidents most likely to occur?

☐ Practice nursing procedure ☐ Treatment room processes
☐ Medication error ☐ Staff and patient relationships
☐ Health & Safety ☐ Medical records documentation

☐ Other (please specify).....

PTO

Q10. Have you ever attended any educational event on Incident reporting?
If yes please give details

Q11. If you discovered an incident involving another professional would you report to anyone?
(If yes please give details)

Q12. Are you aware of the principles of Risk Management?

Q13. Have you undertaken a risk assessment within your practice?

☐ Yes, please give details ☐ No

Q14. Do you undertake Significant Event Audit or Root Cause Analysis within your practice?

☐ Yes, please give details ☐ No

Q15. Do you receive Medical Device Equipment Alerts from Northern Ireland Adverse Incident Centre?

☐ Yes ☐ No

Q15. Do you find they are applicable to your practice?

☐ Yes ☐ No

When you have completed the questionnaire please return it in the freepost envelope provided no later that 30th January 2004.

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Appendix II
Context of Incident Reporting in Northern Ireland

Introduction

In this section we outline the context within which incident reporting occurs within Northern Ireland. This involves review of the governmental bodies and agencies under which incident reporting has been established and operates in Northern Ireland. Furthermore we discuss the guidance relevant to incident reporting and we analysis the major projects and reviews that have been undertaken in incident reporting in Northern Ireland.

Department of Health, Social Services and Public Safety (DHSSPS)

The Department of Health, Social Services and Public Safety was established by the Departments (NI) Order 1999. The Department administers the business of:

- Health and Personal Social Services, which includes policy and legislation for hospitals, family practitioner services, community health and personal social services;
- Public Health, which covers responsibility for policy and legislation to promote and protect the health and well-being of the population of Northern Ireland; and
- Public Safety, which encompasses responsibility for the policy and legislation for the Fire Authority, food safety and emergency planning.

The Department's mission is to improve the health and social well being of the people of Northern Ireland. It endeavours to do so by ensuring the provision of appropriate health and social care services, both in clinical settings, such as hospitals and GPs' surgeries, and in the community, through nursing, social work and other professional services. It also supports programmes of health promotion and education to encourage the community to adopt activities, behaviours and attitudes that will lead to better health and well being.

The administration of the Department is organised under the Permanent Secretary, Mr Clive Gowdy CB, into several groups and one agency. These are the Planning and Resources Group, Strategic Planning and Modernisation Group and Primary, Secondary and Community Care Group and the 5 Professional Groups. The Department's Executive Agency is the Northern Ireland Health and Social Services Estates Agency (known as Health Estates or HEA).

Health and Personal Social Services (HPSS)

Health and Personal Social Services in Northern Ireland are provided as an integrated service. The four health and social services boards (Eastern, Northern, Southern and Western) are agents of the DHSSPS in planning and commissioning and purchasing services for the residents in their areas. The 19 HSS Trusts are the providers of health and social services. They manage staff and services on the ground and they control their own budgets. Monitoring the health and personal social services is the duty of the four Health and Social Service councils - one for each board area. The councils advise the public about services. They also advise on how services might be improved.

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There are five professional groups within the department, each led by a Chief Professional Officer:

- Medical and Allied Services - Dr Henrietta Campbell CB
- Social Services Inspectorate - Mr Paul Martin
- Nursing and Midwifery Advisory Group - Miss Judith Hill
- Dental Services - Mrs Doreen Wilson
- Pharmaceutical Advice and Services - Dr Norman Morrow

They provide advice to and discharge functions for the Department on medical, nursing, dental, pharmaceutical and social work matters. They also provide advice and services to the wider Northern Ireland Civil Service and the Prison Service in respect of public health, medical and dental services.

Health Estates and NIAIC

Health Estates, which became an Agency in 1995, is led by its Chief Executive John Cole. The Agency's task is to provide professional and technical advice, guidance and support on estate maters at both strategic and operational levels to the various bodies charged with the responsibility for the Health and Social Services estate in Northern Ireland. With its extensive specialist experience, the Agency is the single body in Northern Ireland with a recognised expertise in health and social care estate management, planning and design.

Health Estates includes the "Northern Ireland Adverse Incident Centre (NIAIC)" as a business area. NIAIC's key aim is "to record and investigate reported adverse incidents involving medical devices, non-medical equipment, plant and building items used in Health and Personal Social Services in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient, staff, client or user injury[4]". NIAIC's role in incident reporting in fully discussed in Section 5 of this report.

Best Practice - Best Care

In the Programme for Government the former Northern Ireland Executive a commitment to put in place a framework to raise the quality of services provided to the community and tackle issues of poor performance across the HPSS. Best Practice Best Care was presented as a consultation paper by, then Minister for Health, Social Services and Public Safety Bairbre de Brun, setting out proposals to deliver this. The paper set out proposals for new arrangements aimed at providing high quality services in the HPSS based on:

[4] Department of Health, Social Services and Public Safety Online, 2004.

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- Setting standards – improving services and practice;
- Delivering services – ensuring local accountability; and
- Improving monitoring and regulation of the services.

An integral part of delivering these objectives will be the introduction and adoption of Clinical and Social Care Governance (CSCG) within HPSS organisations. Best Practice – Best Care proposed the introduction of CSCG, underpinned by a statutory duty of quality and backed by continuous professional development and other training programmes. CSCG is "about organisations taking corporate responsibility for performance and will provide guarantees for the standards of clinical and social care[5]". It is the framework within which HPSS organisations are accountable for continuously improving quality of their services and safeguarding high standards of care and treatment.

CSCG is expected to help those planning and delivering services to identify and build on good practice; to assess and minimise risk of untoward events; to investigate problems as they arise and to ensure that lessons are learnt. A key tool in meeting these objectives is adverse incident and near miss reporting, which should run parallel with the organisation's risk management strategies and policies. A system of CSCG, which includes incident reporting, will help to identify areas where improvements can be made and identify and reduce any inherent risks in the organisation. Such a system should ultimately offer reassurance to the public that checks are in place to ensure that they receive the highest standards of care and treatment.

Controls Assurance

Since 1997/98, all Chief Executives of bodies sponsored by DHSSPS have been required, as accountable officers, to sign an assurance statement (on behalf of the board) to assure their stakeholders on internal financial controls. This responsibility has moved beyond financial assurance to the production of a wider statement covering organisational controls including risk management.

Circular HSS (PPM) 5/2003 advised that when a controls assurance standard is issued formally, HPSS bodies will be expected to conduct an initial self-assessment against the key criteria and draw up an action plan to secure compliance. Six standards have now been developed by the Department and formally issued to the HPSS. These are:

- Financial Management (core standard)
- Governance (core standard)
- Human Resources
- Medical Devices and Equipment Management
- Medicines Management

[5] Best Practice – Best Care: A Consultation Paper, April 2001.

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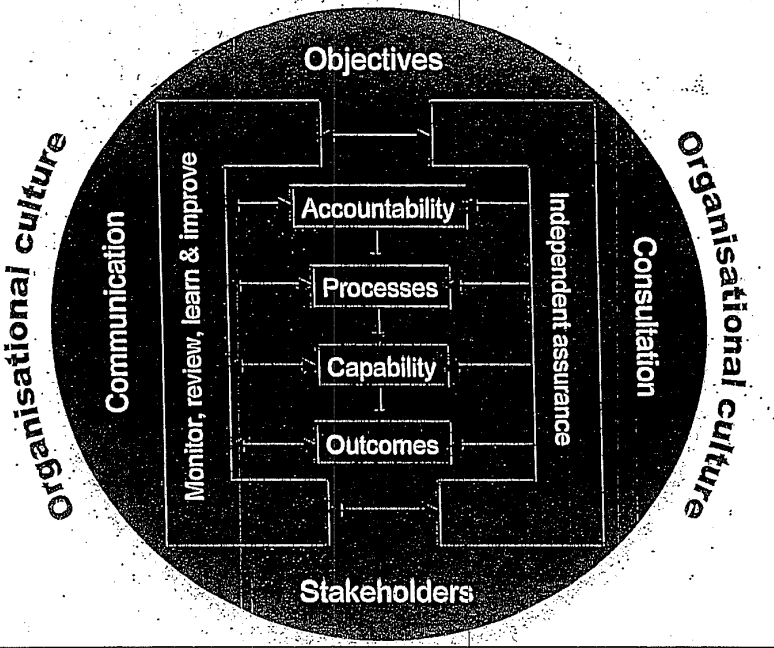
- Risk Management (core standard).

The Circular indicated that compliance with the core standards would be fundamental in underpinning individual Statements of Internal Control for 2003/04 and would provide the basis for compliance with the remaining standards. Chief Executives of bodies sponsored by DHSSPS are required in their capacity as Accountable Officers to sign a Statement on Internal Control from 2003/04 onwards.

All controls assurance standards conform to a common framework model for internal control. The framework aims to deliver assurances to stakeholders in relation to meeting an organisation's objectives. Assurance on the system can be given with reference to independent assurance processes (internal and external) and achievement of satisfactory outcomes, or results. The internal controls framework is shown in Figure 4.1 below.

Figure 4.1
Internal Controls Framework



Source: DHSSPS

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The standards discussed below are those considered to have particular relevance to Safety in Health & Social Care.

Governance

The Governance Standard is a high-level 'overarching' core controls assurance standard and is supported by two additional core standards covering Financial Management and Risk Management. Compliance with the core standards is mandatory as they are central to the whole risk management and controls assurance agenda.

The standard requires that "the board ensures that the organisation consistently follows the principles of good governance applicable to bodies sponsored by the Department of Health, Social Services & Public Safety (DHSSPS). 'Corporate governance' is the system by which an organisation is directed and controlled, at its most senior levels, in order to achieve its objectives and meet the necessary standards of accountability, probity and openness. This Standard contains key criteria and supporting introductory guidance to assist boards of bodies sponsored by DHSSPS to establish whether they have in place a sound system of governance and internal control that is based on sound corporate governance principles. This will help the organisation's board, through its Chief Executive, to sign the annual statutory Statement on Internal Control (SIC).

Whilst the Standard does address key issues and will be updated as necessary, it is to be treated as an introductory document, which does not purport to be exhaustive. The boards of HPSS bodies should satisfy themselves that all relevant governance requirements incumbent upon them, including the proposed statutory duty of quality, are properly identified and suitably addressed.

Risk Management

The standard requires that "an independently assured risk management system is in place that conforms to the principles contained in AS/NZS 4360:1999, and which meets HPSS and other requirements in respect of managing risks, hazards, incidents, complaints and claims."

This standard is principally concerned with ensuring that all HPSS bodies have the basic building blocks in place for managing risk through development and implementation of a comprehensive risk management system. Risk management should be recognised within an organisation as an integral part of good management practice and should become part of the organisation's culture. It should be integrated into its philosophy, practices and business plans rather than be viewed or practiced as a separate programme. When this is achieved, risk management becomes the business of everyone in the organisation.

The design of a risk management system will be influenced and tailored by the existing structure of the HPSS body, the services provided and the processes and specific practices employed. Employment of a specific risk management approach for all organisations is, therefore, difficult to achieve. However, common principles can be identified and these form the basis for the standard. These common principles in large part originate from the Australian/New Zealand Standard on risk management, which defines a set of generic principles for establishing a risk management system in any organisation. The standard has been licensed for the HPSS and the full standard has been made available to all HPSS bodies, who are encouraged to make good use of the information and guidance contained in AS/NZS 4360:1999.

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Medical Devices and Equipment Management

The standard requires that "there is a system in place which ensures that all risks associated with acquisition and use of Medical Devices and Equipment are minimised". The standard has 30 criteria that organisations should meet in order to be compliant with the standard. The term 'medical device' covers a broad range of products including those used every day in most health and social care settings and is defined as "any device, instrument, apparatus, implement, material substance or other article which is intended for either diagnosis, prevention, monitoring, treatment of alleviation of human disease or injury or investigation or modification of human anatomy or of physiological process.

The Medical Device and Equipment Management Controls Standard states that an Executive Director(s) should be designated as accountable officer with responsibility for medical device and equipment management. The nominated director should ensure that a liaison officer is appointed to co-ordinate the effective reporting of adverse incidents involving medical devices/equipment to NIAIC and the dissemination of advice and recommendations issued by NIAIC. A suitable medical device/equipment coordinator should take responsibility for key device and equipment management and use matters.

Medicines Management Standard (Safe and Secure Handling of Medicines)

The Standard requires that "the organisation handles medicines safely and securely, in accordance with legislative requirements and best practice." The standard states that "the safe and secure handling of medicines in both the hospital and primary care settings requires appropriate policies, procedures and quality assurance systems to be in place." This is expected to cover processes throughout the organisation, not just in pharmacy. The standard outlines legislative and best practice relating to the safe handling of medicines, including controlled drugs. The main Acts addressed within this standard include:

- The Medicines Act 1968, as amended, which regulates the manufacture, distribution, import, export, sale and supply of medicinal products
- The Misuse of Drugs Act 1971, which controls the availability of drugs liable for misuse
- The Misuse of Drugs (Northern Ireland) Regulations 2002, which enables specified health care professionals to possess, supply, prescribe and/or administer controlled drugs in the sphere of their practice.

Each HPSS body needs to ensure the safe and secure handling and storage of medicines. This will require a review of the different locations in which medicines are stored, dispensed and transported and consideration of the various staff groups responsible for this.

Within the HPSS body, attention should focus on a review of the risks and control systems covering: procurement, ordering, delivery, storage, distribution, dispensing, issue, supply, administration and disposal within and between the various locations (community hospitals, staff working in the community, in GP practices etc). Any such review should also consider continuing professional development as related to pharmacy and medicines management, along with other associated human resource issues (such as COSHH training, skill mix, training in the management of controlled drugs, handling and disposal of drugs in the community, adverse event reporting etc). The HPSS body also needs to ensure that the organisation has effective systems in place for the reporting of adverse events involving medicinal products and can demonstrate a pro-active approach to investigating any incidents locally (as well as responding to MHRA alerts).

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In addition to reviewing its own internal systems in relation to medicines management, the HPSS body should also request evidence from organisations with which the HPSS body holds service level agreements etc. as to the effectiveness of their Risk Management concerning the handling and storage of medicines (e.g. Ambulance Trusts) since risks need to be considered across organisational boundaries.

Medicines Governance Project

The Northern Ireland Medicines Governance Project was designed to minimise the occurrence of medication-related adverse events in hospitals through a systems-based approach to risk management. This is based on evidence produced by the Committee on Quality of Healthcare in America, which suggested that the root cause of adverse incidents is primarily systems-related rather than practitioner negligence. It stated that human error may be the greatest contributor to accidents in the healthcare industry but not the cause of blame as human errors are often induced by systems failures that are built into the system and present long before the active human error. They conclude that good systems design can reduce human error and thus the occurrence of medication incidents.

The project aims to promote the DHSSPS culture of openness regarding medication incidents and is consistent with the Programme for Government "Working for a Healthier People", particularly in terms of reducing preventable disease and modernising and improving care services to ensure effective care and treatment. It is also consistent with the national priorities for improving the safety of the NHS as described in "Building a safer NHS for patients". The project aims also include identifying common areas of risk, to offer new approaches and procedures to minimise or eliminate those risks, to provide an educational function and to work towards a change in the culture surrounding reporting.

The project involved the deployment of a team of six senior pharmacists and an administrative assistant dedicated to a medicines governance function. A pharmacist is located in each of six acute hospitals and has additional responsibility for other hospitals in their vicinity – giving a total of 13 Trusts involved in the project. One of the pharmacist team is designated as the project leader and reports quarterly to the multidisciplinary Project Steering Group, which provides facilitation and guidance for the project team. A patient representative is also a member of the steering group to ensure that the patients' viewpoint is considered. Within each Trust involved in the project, the project pharmacists have set up multidisciplinary groups to direct and advise on work specific to that Trust. The project commenced on the 1st August and was funded for a two-year period by executive programme funds.

Other Incident Reporting Bodies in Northern Ireland

The following organisations are also involved in incident reporting within the Northern Ireland context.

RIDDOR

Incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices, non-medical equipment, buildings or plant or not, are legally notifiable to the Health & Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 (RIDDOR), and the Ionizing Radiation Regulations (Northern Ireland) 2000. Notification to NIAIC does not count as, or substitute for, any other report, which should be sent (e.g., in respect of an employee's industrial injury).

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Defective Medicinal Products

Guidance on making reports on defective medicinal products was circulated to HSS Boards and Trusts in June 2001. The guidance focused upon medicinal products, which are, or may be defective. The guidance was intended to ensure that only hazardous or major defects were reported directly to the Department with other incidents dealt with using local schemes and in consultation with the Regional Pharmaceutical Laboratory Service.

Boards and Trusts should make arrangements whereby defects in medicinal products arising or recognised in medical, dental, pharmaceutical nursing or PAMs practice are reported to the Department (Pharmaceutical Branch) and MHRA. This procedure calls for officers making reports to do so only after prior assessment of information coming to them. Such officers should be professionally qualified and of sufficient experience to be able to act independently and outside office hours if necessary.

Boards and Trusts, in reporting a particular incident, should arrange that only one officer (or office) should make contact with the Department. Without such an arrangement, the impression can be given that several incidents have occurred concurrently. In general, reports should always be made to the Department in the first instance. However, where it is suspected that a hazardous or major defect is involved and it proves impossible to contact a Departmental officer the MCA should be informed by telephone without delay.

Regional Pharmaceutical Laboratory Service

The Regional Pharmaceutical Laboratory Service RPLS was established in 1975 as part of the application of the Medicines Act (1968) to the hospital service in Northern Ireland. It was necessary to set up a system for the quality control of hospital supplies of drugs and dressings. The service is based in Belfast City Hospital Trust.

The RPLS makes available a range of tests, audits and controls and carries out comprehensive analytical and microbiological monitoring of products using pharmacopoeial and other validated methods. It provides expert guidance on pharmaceutical quality assurance and quality control matters in the hospital service. It promotes and encourages the development of current best practice. All this is with the aim of ensuring that pharmaceutical products purchased by or prepared by the hospital service in Northern Ireland are of high quality and meet the appropriate standard.

The responsibilities of the service can be divided into several categories depending on the type of work involved. The staff in the service - 3 pharmacists, 2 technicians, 1 assistant and 1 secretary - are associated with these sections in varying degrees.

Service level agreements (SLAs) are in place with main users of the service. These are the HPSS Trusts in Northern Ireland and the Medical Physics Agency. A Steering Group, with representatives from both the RPLS and the major users, was established in 1998 to ensure that the service develops in line with changing needs and that SLAs function as necessary.

A procedure for handling substandard pharmaceutical preparations has been in existence in Northern Ireland for more than a decade, co-ordinated by the RPLS. The scheme ensures that minor defects are not ignored and that these are not unnecessarily reported to the Department and MCA. As part of its operation the following actions are usually implemented:-

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- reporting to companies
- reporting to the Analytical Information Centre
- collating and circulating of reports in Northern Ireland
- analysis of samples where necessary

Environment Health Officer/Foods Standard Agency

Incidents relating to foods involving contamination or potential contamination should be reported to the local Environment Health Officer (EHO) who will decide on what, if any, further action will be taken. The EHO will also report the incident to the Food Standards Agency as necessary.

Summary

The following key organisations and documents significantly affect incident reporting within Northern Ireland:

- *Department of Health, Social Services and Public Safety (DHSSPS)* - the Department's mission is to improve the health and social well being of the people of Northern Ireland.
- *Health and Personal Social Services (HPSS)* - are provided as an integrated service in Northern Ireland. The four health and social services boards (Eastern, Northern, Southern and Western) are agents of the DHSSPS in planning and commissioning and purchasing services for the residents in their areas. The 19 HSS Trusts are the providers of health and social services.
- *Health Estate's* task is to provide professional and technical advice, guidance and support on estate maters at both strategic and operational levels to the various bodies charged with the responsibility for the Health and Social Services estate in Northern Ireland. Health Estates includes the "Northern Ireland Adverse Incident Centre (NIAIC)" as a business area.
- *NIAIC's* objective is "to improve the quality of service provided to the community by improving safety and effectiveness in using medical devices and equipment." NIAIC's role in incident reporting in fully discussed in Section 5 of this report.
- *Best Practice - Best Care* is a consultation paper setting out proposals to deliver a framework to raise the quality of services provided to the community and tackle issues of poor performance across the HPSS detailed in the Programme for Government by the former Northern Ireland Executive.
- *Controls Assurance* - the standards discussed below are those considered to have particular relevance to Safety in Health & Social Care:
  - Governance
  - Risk Management
  - Medical Devices and Equipment Management

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- Medicines Management Standard (Safe and Secure Handling of Medicines)

- *Medicines Governance Project* - was designed to minimise the occurrence of medication-related adverse events in hospitals through a systems-based approach to risk management.
- *Other Incident Reporting Agencies* include:
  - RIDDOR
  - Defective Medicinal Products
  - Regional Pharmaceutical Laboratory Service
  - Environment Health Officer/Foods Standard Agency

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Appendix III

Incident Reporting in Great Britain

Department of Health (DoH)

The Department of Health's role is to support the government to improve the health and well being of the population. The organisation is in the middle of an 18-month programme to radically change the way it works, so that it can provide more effective leadership to the NHS and social care, and a better service to Ministers and the public. The Change Programme will reduce the size of the core Department by 1,400 - from over 3,600 posts to 2,200 - by October 2004. This represents a 38 per cent reduction at the centre. Half of those posts will not be replaced and will be achieved by efficiency savings, while the rest of the reduction will result from transferring posts to other national bodies.

The organisation is changing to reflect changes in the environment in which it works, particularly:

- The reform of the NHS and local government to meet the public's expectations for better health and social care services.
- The government's drive to shift the balance of power from Whitehall to staff in frontline hospitals, GP surgeries, care homes, social services and the community. and
- The creation of new independent bodies to inspect NHS and social care services, such as the Commission for Healthcare Audit and Improvement (CHAI).

Its new role will focus on providing strategic leadership to NHS and social care organisations, concentrating on:

- Setting overall direction.
- Ensuring national standards are set.
- Securing resources.
- Making major investment decisions; and
- Driving choice for patients and users.

The Department will be working closely with a number of partners to deliver better health and social care services and will enable the 28 Strategic Health Authorities to operate as the local headquarters for the NHS. The organisation intends to operate at arm's length from successful

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NHS organisations, intervening only where most needed. The Department will also work with CHAI and the Commission for Social Care Inspection (CSCI), who will independently inspect NHS and social care services respectively.

At the end of October, the Department followed its Board's decisions on the new structure and improvements to the way it will work. The shape of the Department has changed from a complex interaction of 14 Directorates to a streamlined structure of three Business Groups. Some of the main changes to working arrangements include:

- Introducing new flexible teams to help it respond better to changing priorities.
- Centralising how it handles enquiries and correspondence from the public and Parliament.
- Forming a new Strategy team to ensure better long-term planning.
- Introducing a new process to ensure every policy idea is properly considered at the outset and those agreed for action are then well resourced.
- Establishing a new Customer Intelligence Team to better understand the needs of patients, users and the public; and
- Appointing a new National Director for Social Care and, in time, non-executives on its Board from local government and the private sector.

The Business Groups are split into Delivery, Standards and Quality and Strategy and Business Development. The Delivery group is responsible for supporting the delivery of the targets set out in the NHS Plan. These include reducing waiting times, increasing choice for NHS patients, securing resources for NHS and local government organisations, ensuring the NHS has the capacity to deliver services to patients, and integrating NHS IT systems to deliver modernised patient services.

The Standards and Quality group is responsible for the majority of our policy-making responsibilities, ranging from leading-edge scientific developments and medical innovations, such as stem cell research, to lifestyle issues, such as obesity. The Group will set standards and define quality in health and social care services, maintain and promote health and well-being, ensure safety of patients and service users, and deliver some of the Government's key programmes, such as Coronary Heart Disease and Cancer. The Strategy and Business Development group is responsible for important corporate services (such as communications, corporate HR and IT), ensuring the Department is run effectively and efficiently. The Group also leads important programmes and policies, such as system reform, equality, medicine and pharmacy, user experience and involvement and professional leadership.

The first phase of the Change Programme is focused largely on the core Department. Following on from this the Department intends to examine the range and scope of the organisation's national health and social care bodies in the same detail. A programme of review of its arm's length bodies - which employ over 19,000 people - will begin shortly, looking in detail at their role, how efficiently they are operating and how they can reduce demands on frontline services.

This review is important - as it meets our aim to devolve more and more responsibility to those working in the NHS and local government. Those who provide local services will be given more freedom to innovate and flexibility to respond to patient and user needs. Speaking at the Select Committee in October 2003, Secretary of State John Reid said: 'Politicians and civil servants should focus on strategic issues rather than

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on day to day management of the NHS. But the process of devolving power to the front-line has to start from the top. We cannot tell others to act efficiently if we're not prepared to do so ourselves so we have to lead by example from the centre. We are not just talking about decentralisation - we are doing it.'

An Organisation with a Memory

In June 2000, the Government accepted all recommendations made in a report entitled "An Organisation with a Memory" which was written by an expert group, led by Dr Liam Donaldson, Chief Medical Officer. The report acknowledged that there has been little systematic learning from patient safety incidents and service failure in the NHS in the past and drew attention to the scale of the problem of potentially avoidable events that result in unintended harm to patients. It proposed solutions based on developing a culture of openness, reporting and safety consciousness within NHS organisations. It proposed the introduction of a new national system for identifying patient safety incidents in healthcare to gather information on causes and to learn and act to reduce risk and prevent similar events occurring in future.

The report stated that the introduction of clinical governance provided NHS organisations with a powerful imperative to focus on tackling adverse health care events. This was deemed especially important given that, at that time, NHS reporting and information systems provided an incomplete picture of the scale and nature of the problem of serious failures in health care. Statistics provided in June 2000 indicated that:

- 400 people die or are seriously injured in adverse events involving medical devices.
- Nearly 10,000 people are reported to have experienced serious adverse reactions to drugs.
- Around 1,150 people who have been in recent contact with mental health services commit suicide.
- Nearly 28,000 written complaints are made about aspects of clinical treatment in hospitals.
- The NHS pays out around £400 million a year settlement of clinical negligence claims, and has a potential liability of around £2.4 billion for existing and expected claims.
- Hospital acquired infections - around 15% of which may be avoidable - are estimated to cost the NHS nearly £1 billion.
- Adverse events in which harm is caused to patients occur in around 10% of admissions - or at a rate in excess of 850,000 a year.
- Adverse incidents in which harm is caused to patients cost the service an estimated £2 billion a year in additional hospital stays alone, without taking any account of human or wider economic costs.

The report recognised that while the issue had been the subject of major pieces of academic research in Australia and the USA, work in the UK is in its infancy. Furthermore, the report identified two areas in particular where the NHS could draw valuable lessons from the experience of other sectors:

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- Organisational culture is central to every stage of the learning process - from ensuring that incidents are identified and reported through to embedding the necessary changes deeply into practice;
- Reporting systems are vital in providing a core of sound, representative information on which to base analysis and recommendations.

The report discussed the current NHS systems for learning from failure and concluded that they had serious limitations. The report noted that guidance on the reporting of adverse incidents in the NHS stretches back over 40 years, but there was still no standardised reporting system, nor indeed a standard definition of what should be reported. The report stated that the renewed focus on quality as a core component of the Government's NHS modernisation programme provided an opportunity to address some of these shortcomings. It recommended that the reporting and analysis of adverse health care events should be a specific focus for action, over and above the general drive for improved risk management and better risk reporting.

The report identified four key areas that must be developed by the NHS to allow to embrace a modern and effective approach to learning from failures, and ultimately improve patient safety:

- Unified mechanisms for reporting and analysis when things go wrong.
- A more open culture, in which errors or service failures can be reported and discussed.
- Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice.
- A much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

Building A Safer NHS For Patients

Building A Safer NHS For Patients set out the Government's plans for promoting patient safety following the publication of the report "AN Organisation with a Memory" and the commitment to implement it in the NHS Plan. It places patient safety in the context of the Government's NHS quality programme and highlights key linkages to other Government initiatives. Central to the plan was a new mandatory, national reporting scheme for adverse health care events and near misses within the NHS. This was due to enhance existing mechanisms for improving quality of care and promoting patient safety by harnessing learning throughout the NHS when something goes wrong.

The report advocated a new national system for learning from error and adverse events. The report focused on action, both nationally and locally, necessary to establish a system which ensures that lessons from adverse events in one locality are learnt across the NHS as a whole. The system will enable reporting from local to national level. It will introduce a new integrated approach to learning from medical error, adverse events and near misses, and it will capture adverse event information from a wide variety of sources. Local reporting of adverse events and action to reduce risk within the organisation concerned is essential. On a selected basis reports to national level will enable service-wide action where patterns, clusters or trends reveal the scope to reduce risk or prevent recurrence for future patients in other parts of the country. The report described the necessary steps to be taken to set up the linked components of the new system, including:

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- Establishing agreed definitions of adverse events and near misses for the purposes of logging and reporting them within the NHS (moving gradually to agreed international standards); detailed guidance for organisations, staff and patients will be issued and pilot sites activated.
- Formalising a minimum data set for adverse events and near misses.
- Producing a standardised format for reporting (initially on paper as well as electronically but gradually moving towards the latter exclusively).
- Building expertise within the NHS in root cause analysis (the more in-depth approach to identifying causal or systems factors in more serious adverse events or near misses).
- Ensuring that information from all other major existing adverse event reporting systems (e.g. medical devices, reactions to medicines, complaints to the Health Service Commissioner, serious accidents reported to the Health and Safety Executive) are fed into the new system.
- Promoting a culture of reporting and patient safety within NHS organisations, building on the transformation already under way as part of the clinical governance initiative.

The report recommended that a new independent body, the National Patient Safety Agency, should be established within the NHS, in order to implement and operate the system with one core purpose - to improve patient safety by reducing the risk of harm through error. The report also recommended that an improved system for handling investigations and inquiries across the NHS should be adopted.

Finally, the report set out actions to reach national targets for four key categories of serious recurring adverse events identified for action in response to the recommendations in "An Organisation with a Memory":

- Reduce to zero the number of patients dying or being paralysed by mal-administered spinal injections by the end of 2001.
- Reduce by 25% the number of instances of harm in the field of obstetrics and gynaecology, which result in litigation by 2005.
- Reduce by 40% the number of serious errors in the use of prescribed drugs by 2005.
- Reduce to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails on wards by 2002.

In addition to the four targets, other areas were identified where action could provide some early gains in risk reduction. These included:

- Review of care environment to identify environmental changes and changes in care practices that could reduce risk and improve patient safety.
- Reviewing clinical practice with Royal Colleges, professional organisations and specialist associations to identify high risk procedures.
- Building safety into purchasing policy within the NHS.

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- Seeking input from the world of design to identify new opportunities for improved safety.
- Examining across the board the potential for computers to reduce the occurrence and impact of error.
- Identifying the scope for formal pre-procedure safety briefings in very high risk situations.
- Enhancing the role of simulation laboratories to expose staff to risk situations with no actual patients involved.
- Creating a clear role for patients in helping to promote and achieve safety goals.

National Patient Safety Agency (NPSA)

The National Patient Safety Agency (NPSA) is a Special Health Authority created in July 2001 following the publication of two reports on patient safety in the NHS, "An Organisation with a Memory[6]", and its follow-up "Building a Safer NHS for Patients[7]". The reports highlighted research suggesting that around 10% of patients admitted to UK acute hospitals suffer some kind of incident that affect their safety, up to half of which may be preventable. Findings in the US, Australia, New Zealand and Denmark have suggested similar levels. The reports were instrumental in establishing that the NHS had to improve its capacity to learn when things go wrong.

The NPSA aims to co-ordinate the efforts of all those involved in healthcare, and more importantly to learn from, patient safety incidents occurring in the NHS. The NPSA's aims are to:

- To set up and operate a national reporting and learning system for averse incidents.
- To develop practical solutions that improves patient safety.
- To develop and support a culture in healthcare that is open and fair, where risks are assessed and patient safety has a high priority.
- To encourage patients and the public in their work.
- To work in partnership with others.
- To be a leader and learn from others in the international field of patient safety.
- To promote an active research and development programme to inform our work.
- To be a highly respected and influential organisation; and
- To be cost effective and deliver value for money.

[6] Department of Health, 2000.
[7] Department of Health, 2001.

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As well as making sure that incidents are reported in the first place, NPSA is aiming to promote an open and fair culture in the NHS, encouraging all healthcare staff to report incidents and "near misses", when things almost go wrong. A key aim is to encourage staff to report incidents without fear of personal reprimand and know that by sharing their experiences others will be able to learn lessons and improve patient safety. The change of emphasis is more about the "how" than the "who".

NPSA collects reports from across England and Wales and initiates preventative measures, in order that the whole country can learn from each case, and so that patient safety throughout the NHS can be improved every time. The NPSA aims to play a key role in bringing patient safety to a national level, enabling the entire NHS to learn from incidents and make itself safer and more stress free for patients. With an estimated 850,000 incidents either harming or nearly harming an NHS hospital inpatient in the UK each year, reducing medical errors and improving patient safety are critical issues in healthcare today. The costs in human tragedy and suffering to patients, the effects on healthcare staff involved and the financial costs mean there has never been a greater need to improve patient safety and the patient environment.

NPSA aim to improve patient safety by:

- Collecting and analysing information on patient safety incidents from local NHS organisations, NHS staff, patients and carers.
- Taking into account other safety-related information from a variety of existing reporting systems.
- Learning lessons and ensuring that they are fed back into health care and treatment is organised and delivered. and
- By ensuring that where risks are identified, work is undertaken on producing solutions to prevent harm, and to specify national goals and establish mechanisms to track progress.

The NPSA is working at the forefront of the international effort to improve patient safety in healthcare systems across the world. NPSA have and are working with the American organisation, Veterans' Health Administration, and sharing information on patient safety experience. This has included collaborative on the experience of patients who fall in hospitals, and how technology is being used in the United States to reduce the risk of mismatching patients with aspects of their care. NPSA have also worked with the Agency for Healthcare Research and Quality in America for their adverse event reporting system integration project (see 5.3 for NRLS system) and have established links with the Australian Patient Safety Foundation and the Australian Council for Safety and Quality in Health Care.

On a European level NPSA has worked on a project in the area of Medication Safety which has led to the adoption of an Expert Consensus Document on Medication Safety. NPSA has also made a joint commitment with the World Health Organisation toward establishing the NPSA as a WHO collaborating centre. In 2002-03 the NPSA agreed to support the patient safety domain on the respected QualityHealthCare.org website in order to develop an electronic library; it offers healthcare professionals a world-class online resource for improving healthcare and patient safety.

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UK Developments

The NPSA have recently undertaken a scoping exercise of the incident reporting systems utilised in the NHS. They have established that there are currently 36 different reporting systems for Trusts. Currently there is no formalised linkage with Northern Ireland.

National Reporting and Learning System (NRLS)

To order to achieve the objectives they have been set, NPSA are developing a National Reporting and Learning System (NRLS), the first healthcare incident data collection system on this scale in the world. It is a system that collates information on incidents that affect patient safety and then identifies any emerging patterns that may not be apparent at a local level.

NRLS will be rolled out across the NHS during 2004. Over time, the NRLS will enable NHS staff, patients and their carers in England and Wales to report any incident or prevented incident (near miss) that they are involved in or witness. The information they provide to NPSA will be stored in an anonymous form and analysed to identify the key underlying factors that affect patient safety. This data, alongside a number of other information sources, will help NPSA determine where it should concentrate its efforts and allow it to establish patient safety priorities.

NPSA states that it will research and develop practical national solutions to the problems it identifies and will work with a wide range of NHS staff, whilst giving equal weight to the views of patients and the public. These solutions will then be fed back to staff and organisations across the NHS to implement locally. The NPSA will work in partnership with NHS organisations to achieve this, and the NRLS has been designed to complement the vital reporting, learning and action that also takes place within local NHS organisations.

In time, staff in every NHS organisation in England and Wales will be able to report incidents to the NRLS though a specially designed electronic reporting form (known as the e-Form) via NHS Net/HOWIS or the internet. They will also be able to do so via their organisation's local risk management system, from which incident data will be extracted and sent electronically to the NRLS. The NPSA only stores anonymous information, and does not investigate specific incidents, and this will remain the responsibility of Trusts/Local Health Boards and the appropriate NHS bodies.

The system now being evaluated by NPSA will use standard definitions of adverse events and near misses for logging and reporting. Evaluations from August 2001 have been aimed at testing the new centralised system for recording, coding, classifying, analysing and providing feedback on adverse events. The system is being tested out through selective healthcare pilots in and around the West Midlands, Yorkshire and the North, as well as other sites in London and the South. The sites are being used to test how the system records, codes information and classifies data links recording and analysis of data with other appropriate information.

The information on incidents received by the NPSA, through the national reporting system, will already have been managed by the relevant NHS trust, organisation or accountability body. However, through national reporting the NPSA will be able to develop an accurate picture of the extent of adverse incidents taking place in healthcare and have a baseline against which to measure improvements in patient safety. By working with the organisations involved NPSA will also be able to understand and tackle the "root causes" behind incidents and by sharing that learning help prevent the same incidents and errors occurring again. Through the implementation of the system they will be able to identify trends in the

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occurrence of, and reasons for, incidents and we will produce guidance and patient safety alerts where needed to improve patient safety. NPSA believe that with any improvements and changes that can be identified and communicated with colleagues across the NHS, that this will mean a better quality and ultimately safer journey for patients using medical services and ultimately save lives.

It has already been shown how it is possible for a trust to benefit from NRLS. South Manchester University Hospitals NHS trust is one of the 39 NHS organisations that have been working closely with the NPSA to test and develop the NRLS. The trust installed a fully electronic web-enabled reporting data capture system three years ago, giving all the front-line staff access to the system. This represented a significant change in the Trust's reporting culture, which enabled identification and engagement of particular areas of concern, which in turn was used to improve the quality of care for patients.

Patients, and carers, will be encouraged to report any unexpected suffering or harm that they have experience resulting from contact with NHS services for the benefit of helping others. NPSA are looking at the best way(s) of encouraging patients and carers to report this information. Everyone, including patients will have access to the annual reports produced by the new Agency and to its publicly available website. In recognising the valuable input that patients and carers have to offer, they have appointed a director of patient and public involvement who will be responsible for facilitating this interaction.

There is clear evidence that a culture of blame creates a barrier to reporting and learning from adverse events, with this in mind, a key role of the NPSA is to help develop an 'Open and Fair', more blame free culture. However, NPSA maintain that the presence of a blame free culture will not in anyway prevent the necessary disciplinary or criminal processes to combat negligent or criminal activities that lead to patient harm.

The new national reporting system will help provide the evidence to change practice or behaviour in ways that reduce the likelihood of adverse event or events recurring. NPSA have identified that this will require the search for new approaches to old problems. This insight is said to arise from every adverse event that occurs in the NHS, and every health organisation should broadcast that insight. Historically, the NPSA have never had the infrastructure to spread knowledge. NRLS involves building that infrastructure and inspire sharing to foster innovations in safety.

NPSA aids organisations that have implemented NRLS by providing feedback on national trends, patterns and contributing factors and through work on solutions to identified problems. NPSA state that becoming part of the NRLS will be a visible statement of an organisation's commitment to improving patient safety. Patient safety is critically important because it will help an organisation to:

- Increase patient confidence with the quality of care they receive.
- Help to build a culture of learning not blame,
- . Support staff and reduce stress and anxiety associated with things going wrong.

Over time, as solutions are introduced and systems improved, this may contribute to a reduction in serious complaints and claims. It will also help to make the best use of available resources and reduce waste.

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Developing solutions for improving patient safety it NPSA's prime motivation for capturing information about things that go wrong and those incidents that were prevented from occurring by some form of intervention. During the last 2 years, NPSA focused on the development of solutions. This resulted in a process for developing and issuing Patient Safety Alerts. In July 2002 the first alert was issued on the prevention of accidental overdose with intravenous Potassium solutions. A subsequent evaluation showed that this was an effective way to communicate patient safety controls. Another area where reports have identified safety issues is in infusion devices.

An integral element to NRLS is the support of an open and fair culture across the NHS. Information from patient groups has shown that they believe that an open and fair culture should encourage NHS staff to be open with patients who have been harmed as a result of accidents and errors. Along with this is has been the development of induction programmes on patient safety that aims to ensure that staff are aware of their role and that of the organisation in improving patient safety.

NPSA have also developed a 'root-cause analysis toolkit' and web-based learning programme to introduce across the NHS a consistent approach to investigating incidents that affect patient safety. It looks beyond the staff beyond the incident to the underlying causes and environmental context in which the incident occurred. This will be introduced across the NHS in 2004, supported by a training programme.

NPSA are committed to involving patients and the public in their work and have been exploring the best ways of enabling these parties to raise issues with them. They have identified three main areas to focus on in respect of any reporting system; patients and the public reporting incidents to them, developing solutions and prioritising their work. The focus is on transparency and equity in involving patients and the public. They give equal weight to professionals and the public and try to avoid being dominated by any single interest group.

All information supplied to the NPSA, through the national reporting system, will be anonymous. Reports made to the NPSA outside of the national reporting system, by patients or by staff for example will be confidential. Past experience of reporting in health care and other industries points towards the importance of confidentiality in gaining the maximum number of reports to gain a national picture. Evidence suggests that people will report incidents if they have confidence in the reporting system and if they can actually see information being used to improve services, but will similarly be reluctant to report if confidences are broken. During 2002-03, the ethical and legal issues surrounding NRLS were explored with a view to creating policies that NPSA should adopt to build trust in NRLS and maximise reporting. This is still ongoing.

NRLS Sub-Groups

The NRLS project has the objective of developing and implementing a national patient safety incident reporting system and comprises a total of 18 sub-projects. Having established the project, the NPSA was approached by a number of organisations expressing an interest in establishing reporting links to the NRLS or information sharing protocols and it became increasingly clear that a range of other NHS organisations either had existing incident reporting systems in place, or were considering options for the introduction of reporting mechanisms.

Consequently two of the 18 sub-projects of the NRLS Project are concerned with developing an understanding of the relationships, similarities and differences between the NPSA's NRLS solution and other established NHS reporting systems. They are:

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- Sub-project 7: The focus of this subproject is to produce an option appraisal report setting out options for the future integration of the MHRA reporting system for Medical Devices with the NRLS to reduce the burden of reporting for Trusts.
- Sub-project 13: The objective of this sub-project is produce an analysis of the scope, function and information content of a range of other reporting systems in the NHS, leading to the identification of similarities and/or differences with NRLS.

A third sub-project, Sub-project 16, is due to explore issues associated with working with the NPfIT, NHSIA and the DH to ensure that the issue of populating NRLS in the future from ICRS is addressed.

More recently two Cabinet Office reports *"Making a Difference – Reducing Burdens in Hospitals"* (September 2002) and *"Making a Difference – Reducing Burdens in Healthcare Inspection and Monitoring"* (July 2003) have been published which consider practical changes that would reduce or remove unnecessary or bureaucratic burdens of procedures and paperwork upon frontline NHS staff. These reports concluded that there is frequently duplication and inconsistency in requests for data and information.

Sub-Project 13 - Progress to Date and Initial Findings

The focus of Sub-project 13 has been to produce a compendium of known organisations and systems where, in due course, there may be scope for either the integration of reporting systems or the introduction of joint working arrangements.

A working version of the compendium has now been produced for use within the NPSA, this documents the range of organisations with an interest in incident reporting and provides background information regarding their function, reporting mechanisms, data handling and information production processes. This has provided an information base for 31 organisations and/or information systems.

The main objective in producing the information compendium has been to help the NPSA's NRLS Project make informed judgements about the reporting similarities and/or differences of other NHS reporting systems and to come to an initial consideration over the potential for systems integration across the NHS – as an input to the wider debate with the DH and CMO on where joint working on reporting flows might be appropriate.

To arrive at a manageable number of potential system integration options and joint working opportunities, a set of agreed evaluation criteria have been applied to the organisations and systems included in the compendium to assess, in a structured way, the degree of fit of each organisation and/or system to the NPSA's NRLS Reporting system. The evaluation criteria that have been used are:

For Organisations with a Reporting System

- The anonymity of patient information, reporter and staff details held within the system;
- The degree to which data is held at a patient specific level or in aggregated form;
- The ease with which source reporting processes operate;
- The patient safety focus of the organisation and reporting system;

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- The extent to which reporting outputs seek to reduce future risks through the lessons learnt from the incident.

For Organisations without a Reporting System

- The fit of the organisational role and function;
- The patient safety focus of the organisation;
- The learning focus of the organisation;
- The benefits likely to be gained by both the NPSA and organisation through collaboration and information sharing arrangements.

A report outlining the work undertaken, the evaluation criteria and listing those organisations and systems offering the "best fit" to the reporting and learning aims of the NPSA has been produced. A schedule showing the ranking of organisations and systems (applying the criteria set out above) is included as Appendix X.

Defining Integration and Joint Working

In moving forward with any further integration proposals for incident reporting systems it will be necessary to define the extent of integration proposed with each organisation and system. This is likely to vary and could range from:

- Introduction of an integrated source data collection process within NHS Trusts, either through local risk management systems or other protocols which feed both the NRLS and other reporting system;
- Joint data collection through a shared e-form which is either routed to each system or "cleared" through the NRLS (or the other organisation's system) to ensure that both the NPSA and host organisation receive their required data – this is the option currently being developed by the NPSA and MHRA for medical devices reporting;
- Full integration of the systems and business processes of both organisations.

For organisations not currently operating incident reporting systems the range of joint working arrangements with the NPSA would include:

- Sharing the emerging themes and trends from the NRLS regarding patient safety issues;
- Agreeing collaborative working and information sharing protocols within a memorandum of understanding;
- Hosting the reporting requirements of the organisation through the NRLS.

Next Steps – Proposals for a Strategic Review

The work from sub-project 13 has indicated that scope does appear to exist for further potential integration of incident reporting systems and collaborative working between organisations in a number of areas. The next stage might be for an NHS led appraisal to consider integrated

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reporting across all, or a subset, of the highest ranked organisations and systems emerging from the NPSA evaluation. This will need to consider a range of issues including:

- Implications for the current market of local risk management systems;
- Impact of integration upon the individual business requirements of each organisation and reporting system;
- Reporting and information cultures of the organisations;
- Balancing potential benefits and dis-benefits of systems integration e.g. reducing the burden of duplicated reporting processes against the specific ownership and culture of different reporting streams;
- Pace of change and organisational maturity;
- Identification of specific roles and responsibilities in progressing the integration process;
- Differing workflow and reporting processes within NHS Trusts;
- Relationships with the National Project for IT (NPfIT).

The work to date in this area has been undertaken as an element of the NPSA's NRLS Project. Should the proposal for an NHS-wide review of incident reporting systems be adopted then it will be important that any related study has the engagement and support of all the potential stakeholders, as well as having in place the appropriate project management and funding arrangements.

Medicines and Healthcare products Regulatory Agency (MHRA)

From 1 April 2003, the Medicines and Healthcare products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA). The MHRA is an Executive Agency of the Department of Health with trading fund status and is the Competent Authority for medical devices and the Licensing Authority for pharmaceuticals. The Agency is committed to safeguarding public health by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely. This is a merger of strengths between two leading regulatory agencies, the MDA and the MCA. With the increasing convergence of medicines and medical devices, the Agency will provide a seamless service to healthcare professionals, industry, patients and the public. The MHRA's key activities area:

- Regulating medical devices;
- Licensing of medicines before marketing and subsequent variations;
- Regulation of clinical trials;
- Operating adverse incident reporting system for medical devices;
- Issuing safety warnings;
- Responsibility for reporting, assessment and communications of defective medicines;

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- Monitoring of medicines and acting on safety concerns after marketing;
- Ensuring compliance to standards of pharmaceutical manufacture and wholesaling;
- Enforcement of requirements;
- Evaluating medical devices to inform purchasing and encourage safe use;
- Managing the General Practice Research Database (GPRD);
- Setting quality standards for drug substances through the "British Pharmacopoeia"; and
- Providing advice and guidance on medicines and medical devices.

Medicines, as distinct from devices, are licenced products and are subject to significant regulatory control, with MHRA being the lead regulatory body in the UK. MHRA covers the whole of the UK, with Wales reporting directly into the MHRA and Scotland reporting to the Common Services Agency which is part of the Healthcare Supplies Agency. The MHRA employees 60-70 Medical Device Specialists to investigate incidents (this includes support staff). The employees are split into 3 distinct units:

- Biomedical sciences/ Implants
- Imaging and acute care
- Primary and Community Care (equipment loan and single use devices)

Approximately 9,000 incidents are reported every year, with each one receiving some level of investigation based on severity. The MHRA has a register of experts, which it calls upon from time to time (in addition to the Medical Device Specialists). Each Trust has a Liaison Officer which is a locally appointed responsibility (similar to NIAIC) and all newly appointed liaison officers receive an induction pack. There is an annual conference targeted at Liaison officers, which informs of new developments and facilitates the sharing of good practice.

Whilst MHRA works closely with NPSA the two organisations operate differently in that MHRA will investigate all incidents whereas NPSA are specifically interested in trend analysis. MHRA tend to inform NPSA of 'User Error' Incidents. Wales have recently bought into NPSA, however indications are currently that Scotland won't be following suit. The MHRA have recently developed a Memorandum of Understanding with HSE and NPSA.

The MHRA aims to prevent adverse incidents happening and, where they have already happened, to prevent them happening again. No device should ever be considered 100% safe and constant effort is therefore required to reduce both the rate at which adverse incidents occur and the severity of the outcome. Reporting incidents to the Agency provides information that may be directly responsible for preventing similar incidents from happening again.

The information provided to the Agency by users, helps to build up a national picture of what is happening with medical devices across the UK. This is supplemented by reports from around the world. All this information is reviewed to identify trends and, where appropriate, early action is taken on specific problems.

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Experience suggests that although *user error* will be the cause, or may contribute to the cause, of many incidents, there are often underlying reasons. These may relate to device management and maintenance or to the adequacy of training for users.

The Agency welcomes receipt of all incident reports even where user error has been identified as the likely cause. A one-off incident in one healthcare establishment, when combined with information of several others, may identify the need for focussed awareness training or for the amendment of manufacturer's usage instructions.

The MHRA does not look to assign blame. The Department of Health document "An Organisation with a Memory" highlighted the dangers of a blame culture within healthcare organisations. The Agency's aim is to investigate incidents carefully, objectively and in an open manner, and, through this, to prevent similar incidents occurring elsewhere.

This 'prevention' is achieved through:

- Enforcement measures.
- Monitoring of action taken by manufacturers to make devices safe or to remove them from the market.
- The issue of national warnings and recommendations for action to health and social care professionals.
- Informing the relevant authorities in other EU member states and Global Harmonisation Task Force members so that they can consider their own need for action.

A total of 8,756 Adverse Incidents were reported in 2002. Receipt of an Adverse Incident Report will prompt the initiation of a number of immediate procedures within the Agency. The first step is the creation of a database entry and formal acknowledgement of receipt. The acknowledgement letter is accompanied by a short information note summarising and explained the Agency's procedures. An initial assessment of the report will determine the next appropriate action:

- Referral to another agency - A small number of the total reports received (65 in 2002) do not involve medical devices. These are referred, as appropriate, to other bodies such as NHS Estates. The incident reporter is informed accordingly.
- Recording as 'Information Only' - In 2002 there were 1,776 incident reports where no immediate action beyond the creation of the database record and acknowledgement of receipt were considered necessary. These were cases where the situation had already been resolved, either locally or by the manufacturer.
- Linking to existing investigations - 915 of the reports received in 2002 were linked to ongoing investigations and were categorised as *'known'*.

The database of information gleaned from the *Information Only* and *known* categories helps the Agency to maintain an up-to-date picture of the various device types and failure modes. This database is used increasingly to review incident data and to identify significant patterns and trends. All other reports submitted to the MHRA are investigated. The method of investigation depends upon the risk associated with the incident. Death and serious deterioration in health (or potential for such) are subject to an in-depth investigation led by one of the Agency's Medical Device Specialists. Such investigations (1,552 in 2002) may involve:

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- Contact with the device user and manufacturer.
- A visit to the site of the incident.
- Testing of the device involved (either by the MHRA's own test facilities, an independent test house, or the manufacturer).

It is these investigations, formerly referred to as Section Investigations, which typically lead to the issue of safety advice by the Agency. Minor injury and no injury (with low potential for more serious injury) are generally most effectively investigated by the relevant manufacturer. In 2002 the Agency investigated 3,989 incidents in this way, passing details from the incident report to the manufacturer and monitoring the progress of their investigation. The incident reporter is kept informed of progress through routing copies of the Agency's correspondence. In particular, and subject to the manufacturer's permission, the reporter will be provided with a copy of the manufacturer's final report conclusions for their information and/or comment. These are usually referred to as AIC Investigations.

At all stages of all investigations, the information available is subject to review. This process enables the Agency to reassess the level of the investigation and to determine what, if any, action is required. These reviews may require the involvement of the Agency's expert clinical team (on clinical aspects of the incident, including the way the device was used); the Committee on Safety of Devices; or the Agency's Register of Experts.

The MHRA issues safety warnings (Medical Device Alerts) to health and social care providers and other users of medical devices. These warn of particular problems and risks and recommend appropriate action to minimise them. These notices are distributed to NHS Trusts and Social Services for direct action and for onward transmission to relevant healthcare professionals including, where the device is used in primary care, to General Practitioners.

Almost 9,000 incidents were reported to the Agency during 2002, a rise of 11% over the previous year. These incidents involved medical devices of all kinds, from simple laboratory equipment to highly sophisticated MR and CT scanners.

One of the key functions of the MHRA, with advice from the Committee on Safety of Medicines (CSM), is monitoring the safety of marketed medicines and taking effective action when safety hazards are identified. As well as monitoring the safety of medicines, the MHRA (Inspection and Enforcement Division) also monitors the quality of medicines available on the UK market and assesses reports of suspected defective products.

Defective Medicines Report Centre (DMRC)

The Defective Medicines Report Centre (DMRC) receives and assesses complaints and reports of actual or suspected defects in medicinal products for human use and co-ordinates the necessary actions. The Centre provides an assessment and communication system between suppliers (manufacturers and distributors), users of medicines and other regulatory authorities. Manufacturers and importers are obliged to report to the MHRA any quality defect in a medicinal product which could result in a recall or restriction on supply. Other users and distributors of medicinal products are encouraged to do this.

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Where a defect is considered to be a risk to public health, the marketing authorisation holder withdraws the affected product from use and the MHRA issues a 'Drug Alert' letter. This Alert is classified from 1 to 4 depending upon the risk presented to the public health by the defective product. Class 1 is the most critical, for example serious mislabelling, microbial contamination or incorrect ingredients, and requires immediate recall; Class 4 is the least critical and advises 'caution in use'. Details of drug alerts issued since 29 October 2001 are available on this website.

The DMRC is also part of the European Rapid Alert System which disseminates information on drug quality issues within EU Member States. Patients or members of the public who have concerns about the quality of a medicine should in the first instance refer the matter to their pharmacist or doctor, who may then decide to contact the MHRA. Should this not be possible, patients and members of the public may contact the DMRC directly.

Safety Alert Broadcast System (SABS)

The Safety Alert Broadcast System is a new electronic system developed by the Department of Health, with the Medicines and Healthcare products Regulatory Agency (MHRA), NHS Estates and the National Patient Safety Agency (NPSA). It will email new safety alerts to nominated leads in Trust and PCTs, who will be asked to disseminate the message to those who need to take action. This role will be similar to the current MHRA device liaison officer role, but with the additional responsibility of completing a short feedback form to confirm that action has been taken in response to the alert. These completed feedback forms will be available on the safety alert broadcast system website, along with copies of all new alerts.

Safety alerts and other notices are issued by a number of agencies including the Department of Health, the National Patient Safety Agency, Medicines and Healthcare products Regulatory Agency and NHS Estates. These bodies issue alerts by a number of different methods and may have a number of methods in place to gain feedback on whether they have been implemented, some of which may be ad hoc in response to specific concerns.

The aim of the safety alert broadcast system project is to bring all alerts together into one electronic system and improve the way in which they are issued to the service. The aim is also to improve the Department's, SHAs' and Trusts' own systems for assuring that they have been received and implemented. We want to minimise the administrative burden for all concerned, while collecting information which is useful to Trusts (for example, in demonstrating they can meet controls assurance risk management standards) and to performance managers in SHAs.

The Safety Alert Broadcast System (SABS) has been piloted and is due for roll out in April 2004. At present Northern Ireland has no linkage with SABS and there appears to be no prospect of this occurring in the near future.

Building a safer NHS for Patients – Improving Medication Safety

"Building a safer NHS for Patients – Improving Medication Safety" was published in January 2004 and follows on from the original "Building a Safer NHS for Patients" report published in July 2002. The new report specifically deals with the issue of medication errors that occur in the NHS. It explores the causes and frequency of medication errors, highlights drugs and clinical settings that carry particular risks, and identifies

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models of good practice to reduce risks. The report is intended to help NHS organisations and professionals examine current practice to make medication safer for patients.

Commission for Health Improvement (CHI)

The Commission for Health Improvement (CHI) is the independent authoritative voice on the state of the NHS in England and Wales. CHI aims to improve the quality of patient care in the NHS (Scotland has its own regulatory body, the NHS Quality Improvement Scotland). CHI aims to address unacceptable variations in NHS patient care by identifying both notable practice, and areas where care could be improved. CHI has six operating principles that underpin all of its work:

- The patient's experience is at the heart of CHI's work
- CHI is independent, rigorous and fair
- CHI's approach is developmental and supports the NHS to continuously improve
- CHI's work is based on the best available evidence and focus on improvement
- CHI is open and accessible
- CHI applies the same standards of continuous improvement to itself that it expects of others.

National Institute for Clinical Excellence (NICE)

NICE (The National Institute for Clinical Excellence) was set up as a Special Health Authority for England and Wales on 1 April 1999. It is part of the National Health Service (NHS), and its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current "best practice". The guidance will cover both individual health technologies (including medicines, medical devices, diagnostic techniques, and procedures) and the clinical management of specific conditions. NICE offers the NHS and its patients a new service, which we intend shall earn, and retain, the confidence and respect of the community as a whole.

Scottish Healthcare Supplies (SHS)

A division of the Common Services Agency, Scottish Healthcare Supplies (SHS) provides procurement and technical services to the NHS in Scotland and to many other private sector organisations whose needs can be just as complex and regulations just as critical. SHS also includes the Incident Reporting & Investigation Centre (IRIC).

Incident Reporting & Investigation Centre (IRIC)

IRIC co-ordinates the investigation of Adverse Incidents on behalf of the Scottish Executive Health Department. Working exclusively in the NHS in Scotland it pursues investigations involving medical devices and estates equipment. Where necessary, it issues safety warnings including Hazard Notices and Safety Action Notices. IRIC maintains close links with the Medicines & Healthcare products Regulatory Agency and the

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Scottish Executive Health Department. It also provides an investigation service to the Police and Procurators Fiscal in cases where medical equipment was involved in a fatal accident. Where estates matters are involved, IRIC manages the investigation on behalf of the Property & Environment Forum Executive (PEFE) the executive arm of the NHS in Scotland Property & Environment Forum, and maintains contact with NHS Estates at the Department of Health.

Summary

- The structure for incident and near miss reporting in Great Britain has changed significantly in recent years with increased focus on patient safety following significant research and subsequent reports.
- The reports "An Organisation with a Memory[8]", and its follow-up "Building a Safer NHS for Patients[9]" highlighted research suggesting that around 10% of patients admitted to UK acute hospitals suffer some kind of incident that affect their safety, up to half of which may be preventable. Findings in the US, Australia, New Zealand and Denmark have suggested similar levels. The reports were instrumental in establishing that the NHS had to improve its capacity to learn when things go wrong.
- The National Patient Safety Agency (NPSA) is a Special Health Authority created in July 2001 following the publication of two reports on patient safety in the NHS and aims to co-ordinate the efforts of all those involved in healthcare, and more importantly to learn from, patient safety incidents occurring in the NHS.
- The NPSA have recently undertaken a scoping exercise of the incident reporting systems utilised in the NHS. They have established that there are currently 36 different reporting systems for Trusts.
- Wales have recently bought into NPSA, however indications are currently that Scotland won't be following suit. Northern Ireland are currently not formally linked to NPSA, however informal linkages do exist.
- NPSA are developing a National Reporting and Learning System (NRLS), which is being rolled out during 2004. It will be the first healthcare incident data collection system on this scale in the world and will collate information on incidents that affect patient safety and identify any emerging patterns that may not be apparent at a local level.
- NRLS will enable NHS staff, patients and their carers in England and Wales to report any incident or prevented incident (near miss) that they are involved in or witness. The information they provide to NPSA will be stored in an anonymous form and analysed to identify the key underlying factors that affect patient safety. This data, alongside a number of other information sources, will help NPSA determine where it should concentrate its efforts and allow it to establish patient safety priorities.
- The Medicines and Healthcare products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) in April 2003. The Agency is committed to safeguarding public health by ensuring that medicines, healthcare

[8] Department of Health, 2000.
[9] Department of Health, 2001.

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products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely. Medicines, as distinct from devices, are licenced products and are subject to significant regulatory control, with MHRA being the lead regulatory body in the UK. The MHRA have recently developed a Memorandum of Understanding with HSE and NPSA.

- The Defective Medicines Report Centre (DMRC) receives and assesses complaints and reports of actual or suspected defects in medicinal products for human use and co-ordinates the necessary actions.
- Whilst MHRA works closely with NPSA the two organisations operate differently in that MHRA will investigate all incidents whereas NPSA are specifically interested in trend analysis. MHRA tend to inform NPSA of 'User Error' Incidents.
- NPSA has been slow to get up and running and significant criticisms are still levied at it in terms of its effectiveness and remit. Despite these criticisms the potential value of NPSA to Northern Ireland HSS organisations is considered as high, however Northern Ireland would need to have a level of consistency in approach to incident reporting to fully benefit from this linkage.
- The Scottish Healthcare service currently utilises the Incident Reporting & Investigation Centre (part of Scottish Healthcare Supplies) which co-ordinates the investigation of Adverse Incidents on behalf of the Scottish Executive Health Department. Working exclusively in the NHS in Scotland it pursues investigations involving medical devices and estates equipment.
- "Building a safer NHS for Patients – Improving Medication Safety" was published in January 2004 and follows on from the original "Building a Safer NHS for Patients" report published in July 2002. The new report specifically deals with the issue of medication errors that occur in the NHS.
- The Safety Alert Broadcast System (a new electronic system developed by the Department of Health, with the MHRA) has been piloted and is due for roll out in April 2004. At present Northern Ireland has no linkage with SABS and there appears to be no prospect of this occurring in the near future.
- The Commission for Health Improvement (CHI) is the independent authoritative voice on the state of the NHS in England and Wales. CHI aims to improve the quality of patient care in the NHS (Scotland has its own regulatory body, the NHS Quality Improvement Scotland).

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Appendix IV
MHRA Definition of a Medical Device

The MHRA defines the term 'medical device' as covering all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap. The range of products is very wide: it includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames - many thousands of items used each and every day by healthcare providers and patients.

The list of items here is not comprehensive but shows the wide range of products that are considered to be medical devices.

Anaesthetic machines and monitors	Apnoea monitors	Hydrocephalus shunt
Artificial limbs	Artificial eyes	Infant incubators and warmers
Blood transfusion and filtration devices	Breast implants	Intra-uterine devices
Cardiac monitors	Cardiopulmonary bypass devices	Laboratory equipment covered by IVD directive
Clinical thermometers	Condoms	Medical textiles, hosiery and surgical supports
Contact lenses and prescribable spectacles	CT scanners	Operating tables
Defibrillators	Dental equipment and dentures	Ostomy and incontinence appliances
Dental material and restoratives	Diagnostic X-ray equipment	Physiotherapy equipment
Dialysers	Dressing and wound healing devices	Pressure sore relief devices
Electrosurgery devices	Endoscopes	Resuscitators
Enteral and parenteral feeding systems	Equipment for disabled people	Special support seating
Examination gloves	Fetal monitors	Suction devices
Hearing aids and inserts	Heart valves	Medical lasers
Hospital beds	Sphygmomanometers	Orthopaedic implants
Incontinence pads	Surgical instruments and gloves	Pacemakers
Infusion pumps and controllers	Syringes and needles	Sutures, clips and staples
Intravascular catheters and cannulae	Urinary catheters, vaginal speculae and drainage bags	Ultrasound imagers
Lithotripters	Walking aids	Ventilators
Prescribable footwear	Scalpels	Wheelchairs
Radiotherapy machines		

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Appendix V
Health Boards Detailed Information

Southern Health and Social Services Board (SHSSB)

Incident Reporting Policy

The Board has a Risk Management Strategy and an Untoward Events Policy in place, which provides definitions and guidelines for the reporting of incidents, untoward events and near misses. The Board indicated that the Risk Management Strategy is due to be reviewed to ensure it is robust. It was also noted that the Board wishes to further clarify the definition of near misses with the Trusts in its area as some ambiguity has arisen.

Incident Reporting Procedures

The Board has internal incident reporting i.e. reporting of any incident occurring within the Board and it has external incident reporting i.e. incident reporting information supplied by the Trusts. Internally, the Board has a single reporting form, which is used across the organisation, however the incidents occurring are very low in volume and are not perceived as high risk.

Externally, there is currently some ambiguity over the reporting requirements of Trusts to the Board, and it was noted that this is based on a larger accountability issue that currently exist between these organisations. Currently only significant untoward events and near misses are reported to the Board by the Trusts, however the organisations are discussing what further information should or could be supplied. The Board stated that improved information was required (e.g. trend analysis) to ensure them that the services provided by the Trusts are safe, effective and efficient. The Trusts have not necessarily agreed with this view based on their perception of the Board's remit i.e. to monitor the services provided by the Trusts as the commissioning body.

The Board also stated that it has no power to require Trusts to provide further incident reporting information, as they are legally accountable to the DHSSPS and only act in a monitoring role as commissioners of health and social services in that area. However, following on from the Lewis case, the Boards now have the ability to audit Trusts to ascertain of level of service is satisfactory, although ambiguity still exists in relation to this process.

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Incident Reporting Systems

The Board has Datix available but it is not currently being used for any module (including incident reporting). Currently little investigation occurs due to the low level and low volume of incidents within the Board. Trend analysis and root cause analysis is also not considered necessary due to the nature and number of internal incidents occurring.

Review of Incidents Reported

The Executive Directors of the Board meet every week to discuss Untoward Events.

Training/Staff Awareness

Staff within the Board are trained in risk management and incident reporting at induction.

Third Party Relations

The SHSSB has established an Untoward Events Group within the Southern Board area, which includes the Director of Social Services, representatives from each Directorate within the Board and representatives from the four Trusts in the area. The Board reports directly to the DHSSPS on untoward events and any incident involving child abuse (following on from the Lewis Report). The Board also reports directly to the DHSSPS on case management review i.e. cross agency review. The Board provides copies of their Board papers to the DHSSPS, however this is the only periodic information provided. The Board has received no guidance or instruction from the DHSSPS in relation to incident reporting.

NIAIC

NIAIC send the Medical Device and Equipment alerts to the Board, which are then distributed to the relevant individuals specified on the distribution list.

Western Health and Social Services Board (WHSSB)

Incident Reporting Policy

The Board has a Governance and Risk Management Policy and an Untoward Event and Near Miss Reporting Procedure in place, which provide definitions and guidelines for the reporting of incidents and near misses internally and externally. The Board indicated that the Risk Management

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Strategy and the Untoward Event Reporting policy are in the process of being reviewed. It was also noted that the Board wishes to further clarify the definition of near misses with the Trusts in its area as some ambiguity has arisen. The Board has a whistle-blowing policy in place, which will also be reviewed. The Board stated that it does not promote anonymous reporting but will review anonymous reports if they are submitted internally.

The Board stated that formalised procedures need to be developed between itself and the Trusts in relation to what incident reporting information is supplied for monitoring purposes; although the Untoward Event and Near Miss Reporting Policy provides a template for this area. The Board is committed to discussing this at the 4 Board Governance Group and consulting with the Trusts to further this debate and agree a way forward. Until this occurs, there is no agreed process for sharing this information between the Board and the Trusts.

Incident Reporting Procedures

The Board has internal incident reporting i.e. reporting of any incident occurring within the Board and it has external incident reporting i.e. incident reporting information supplied by the Trusts. Internally, the Board has a single reporting form, which is used across the organisation, however the incidents occurring are very low in volume and are not perceived as high risk.

Externally, there is currently some ambiguity over the reporting requirements of Trusts to the Board, and it was noted that this is based on a larger accountability issue that currently exist between these organisations. Currently only significant untoward events and near misses are reported to the Board by the Trusts, however the organisations are discussing what further information should or could be supplied. It was noted that only one or two incidents were reported by the three trusts in the WHSSB area during 2003, with some of the Trusts not reporting any during that period. The Board stated that improved information was required (e.g. trend analysis) from the Trusts, but stated that a good relationship currently exists with the Trusts and they do not envisage a major issue developing in this area.

Incident Reporting Systems

The Board currently has no system to report internal or external incidents due to the low volume occurring within the organisation. Currently little investigation occurs due to the low level and low volume of incidents within the Board. Trend analysis and root cause analysis is also not considered necessary due to the nature and number of incidents occurring. The Trust is intending to purchase Datix this year.

Review of Incidents Reported

The Directors of the Board will review the information supplied by the Trust when information is provided. The Directors will also review any significant incidents occurring within the Board. The Monitoring meetings with the Trusts provide a forum for the external incidents reported to the Board to formally discussed and reviewed. The R&I Unit of the Board review significant issues that occur in care homes.

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Training/Staff Awareness

Staff within the Board have received limited training in risk management and incident reporting. The Board plan to role out full training to all staff when the policies and procedures have been full y reviewed and developed.

Third Party Relations

The Board reports directly to the DHSSPS on untoward events and any incident involving child abuse (following on from the Lewis Report). The Board also reports directly to the DHSSPS on case management review i.e. cross agency review. The Board provides copies of their Board papers to the DHSSPS, however this is the only periodic information provided. The Board has received no guidance or instruction from the DHSSPS in relation to incident reporting.

NIAIC

NIAIC send the Medical Device and Equipment alerts to the Board, which are then distributed to the relevant individuals specified on the distribution list.

Northern Health and Social Services Board (NHSSB)

Incident Reporting Policy

The Board has a Risk Management Strategy and an Untoward Events Policy in place, which provides definitions and guidelines for the reporting of incidents, untoward events and near misses. The Board also has a whistle-blowing policy, and a CSCG strategy. It was noted that the Board wishes to further clarify the definition of incidents and near misses with the Trusts in its area as some ambiguity has arisen.

Incident Reporting Procedures

The Board has internal incident reporting i.e. reporting of any incident occurring within the Board and it has external incident reporting i.e. incident reporting information supplied by the Trusts. Internally, the Board has a single reporting form, which is used across the organisation, however the incidents occurring are very low in volume and are not perceived as high risk. It was noted that the IR form is very Health and Safety focused and that the Board wish to develop a single form that covers all internal incidents.

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Externally, there is currently some ambiguity over the reporting requirements of Trusts to the Board, and it was noted that this is based on a larger accountability issue that currently exist between these organisations. Currently only significant untoward events and near misses are reported to the Board by the Trusts, however the organisations are discussing what further information should or could be supplied. The Board stated that improved information was required (e.g. trend analysis) to ensure them that the services provided by the Trusts are safe, effective and efficient. The Trusts have not necessarily agreed with this view based on their perception of the Board's remit i.e. to monitor the services provided by the Trusts as the commissioning body.

The Board also stated that it has no power to require Trusts to provide further incident reporting information, as they are legally accountable to the DHSSPS and only act in a monitoring role as commissioners of health and social services in that area. However, following on from the Lewis case, the Boards now have the ability to audit Trusts to ascertain of level of service is satisfactory, although ambiguity still exists in relation to this process.

Incident Reporting Systems

The Board does not currently use any form of IT to capture incident reporting information of any type.

Review of Incidents Reported

Untoward Events are reviewed by senior management as and when they occur.

Training/Staff Awareness

Staff within the Board are trained in risk management and incident reporting at induction.

Third Party Relations

The Board reports directly to the DHSSPS on untoward events and any incident involving child abuse (following on from the Lewis Report). The Board also reports directly to the DHSSPS on case management review i.e. cross agency review. The Board provides copies of their Board papers to the DHSSPS, however this is the only periodic information provided. The Board has received no guidance or instruction from the DHSSPS in relation to incident reporting.

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NIAIC

NIAIC send the Medical Device and Equipment alerts to the Board, which are then distributed to the relevant individuals specified on the distribution list. No specific issues with the NIAIC system were noted.

Eastern Health and Social Services Board (EHSSB)

Incident Reporting Policy

The Board has a Risk Management Policy and an internal Accidents/Incident Policy in place, which provide definitions and guidelines for the reporting of incidents, accidents and near misses. The Board does not currently have a Clinical & Social Care Governance policy in place. The Board indicated that the Risk Management Strategy and the internal incident reporting policy are in the process of being reviewed, with a particular emphasis on addressing near miss reporting. It was also noted that the Board wishes to further clarify the definition of near misses with the Trusts in its area as some ambiguity has arisen. The Board has a whistle-blowing policy in place, which will also be reviewed in line with the new incident reporting policy. The Board stated that it does not promote anonymous reporting but will review anonymous reports if they are submitted internally. These reports are not retained after they have been addressed.

The Board stated that formalised procedures need to be developed between itself and the Trusts in relation to what incident reporting information is supplied for monitoring purposes. The Board is committed to holding a workshop with the Trusts to further this debate and agree a way forward. Until this occurs, there is no agreed process for sharing this information between the Board and the Trusts.

Incident Reporting Procedures

The Board has internal incident reporting i.e. reporting of any incident occurring within the Board and it has external incident reporting i.e. incident reporting information supplied by the Trusts. Internally, the Board has a single reporting form, which is used across the organisation, however the incidents occurring are very low in volume and are not perceived as high risk.

Externally, there is currently some ambiguity over the reporting requirements of Trusts to the Board, and it was noted that this is based on a larger accountability issue that currently exist between these organisations. Currently only significant untoward events and near misses are reported to the Board by the Trusts, however the organisations are discussing what further information should or could be supplied. It was noted that only fifty incidents were reported by the ten trusts in the EHSSB area during 2003, with some of the Trusts not reporting any during that period. Furthermore, it was noted that the Acute Trusts in the Board area do not tend to report, whereas the Community Trusts do.

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The Board stated that improved information was required (e.g. trend analysis) to ensure them that the services provided by the Trusts addressed the reputation, creditability, sustainability, moral responsibility and high-risk interest of the organisation. The Trusts have not necessarily agreed with this view based on their perception of the Board's remit i.e. to monitor the services provided by the Trusts as the commissioning body. The Board stated that it has no power to require Trusts to provide further incident reporting information, as they are legally accountable to the DHSSPS and only act in a monitoring role as commissioners of health and social services in that area. The planned workshop is expected to address and resolve these issues.

Incident Reporting Systems

The Board currently uses Excel to capture external incidents, but has no system to report internal incidents due to the low volume occurring within the organisation. Currently little investigation occurs due to the low level and low volume of incidents within the Board. Trend analysis and root cause analysis is also not considered necessary due to the nature and number of internal incidents occurring.

Review of Incidents Reported

The Directors of the Board will review the information supplied by the Trust on a periodic basis. The Monitoring meetings with the Trusts provide a forum for the external incidents reported to the Board to formally discussed and reviewed.

Training/Staff Awareness

Staff within the Board are trained in risk management and incident reporting at induction. The Board plan to role out full training to all staff when the policies and procedures have been full y reviewed and developed.

Third Party Relations

The Board reports directly to the DHSSPS on untoward events and any incident involving child abuse (following on from the Lewis Report). The Board also reports directly to the DHSSPS on case management review i.e. cross agency review. The Board provides copies of their Board papers to the DHSSPS, however this is the only periodic information provided. The Board has received no guidance or instruction from the DHSSPS in relation to incident reporting.

The Board stated that GPs and Dentists currently have no obligation to report to the Board on incidents. Requirements are currently in place for monitoring prescriptions, under-performing Doctors and mortality rates, however the new GMS to be implemented on 1st April 2004 could place the responsibility of incident reporting on GPs. The Board stressed that it would want to develop this in consultation with the GPs and on a four Board basis.

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NIAIC

NIAIC send the Medical Device and Equipment alerts to the Board, which are then distributed to the relevant individuals specified on the distribution list.

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Appendix VI
Trusts Detailed Information

Acute Hospital Service Trusts

Altnagelvin Hospitals HSS Trust

Incident Reporting Policies

The Trust has a "Policy for the Reporting of Clinical Incidents" in place, supported by guidelines for completing adverse incident reports. The Trust also has a "Critical Incident Protocol" to deal with those incidents assessed as serious and requiring further investigation. The Trust does not have a whistle-blowing policy, but does have a Risk Management Strategy and a Clinical Governance Strategy. The Trust advocates a "fair-blame" culture and as a result does not encourage anonymous reporting, as this is not considered compatible with an open culture. Some Trust employees felt that there is an issue regarding the terminology and definitions used for incident and near miss reporting, for example is a "near miss" not a hit?

Incident Reporting Procedures

The Trust has one form (the "Adverse Incident Report) for reporting all incidents within the organisation. When an incident occurs the report must be completed resulting in four coloured copies (yellow and white copies go to the Risk Management Department, the Blue copy goes to the Clinical Services Manager, the Head of Department or the relevant Director and the green copy stays in the book). The Adverse incident report contains four sections (i.e. Personal Details, Details of Incident, Factual Description of Incident and Reporting Details) and categorises the incident as either Accident, Clinical, Non-Clinical or Equipment. It was noted that on receipt of an incident report, the Trust sends a personal letter to the individual who completed the form to acknowledge the report and to communicate the benefits of the incident reporting system. This is viewed as extremely positive for staff morale and culture building with respect to incident reporting within the Trust.

When the yellow and white copies of the Adverse Incident Report are sent to Risk Management, each category of incident is dealt with differently. Accidents go to the Risk Management Assistant who reviews the incidents with the Risk Management Director and assesses which incidents require further investigation. These incidents are then coded and input onto the Datix system by a temporary clerical officer (who has been trained in incident reporting and coding).

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Incident Reporting Systems

The Risk Management Director receives all Clinical Incident reports and assesses whether they need to take immediate action or not. All medication incidents (which are also categorised as clinical incidents) are sent to the Medicines Governance Pharmacist, who codes and grades these incidents based on the common set of codes developed, by the Medicines Governance Project. All other clinical incidents are coded and graded by the Risk Management Director. Grading of clinical incidents has only occurred within the past three months and is based on a common matrix approach. It was noted that all IT incidents within the Trust are considered as Clinical Incidents.

Non-clinical incidents are also sent to the Risk Management Director initially, but are redirected to Site Management (who are responsible for security etc.) Site Management will code and input all these incidents on to Datix. Equipment incidents are viewed in two ways: if the incident affects the patient then it is automatically considered as a Clinical Incident and the report must go through that process. If it has not affected a patient, the report is sent to the Technical Equipment Manager who decides which incidents must be reported to NIAIC. It was noted that some confusion exists among staff regarding what should be categorised as an equipment incident, however the process for re-categorising some equipment incidents as clinical incidents alleviates this issue.

The Trust utilises the Datix system for incident reporting, which is linked to Datix modules for claims, complaints, risks, assessments and contacts. The risk management department is responsible for all of the areas and modules with the exception of complaints, which is controlled by Patients Advocates Department. The Risk Management Director sits on the Northern Ireland Datix Users Group. This group provides a forum for Trusts within the region to discuss incident-reporting issues generally and specifically address Datix issues.

Review of Incidents Reported

A quarterly incident report is produced by the Risk Management department and presents statistics on patient and staff accidents, clinical incidents and equipment incidents. The report also provides narrative on the trends of reported incidents within the Trust, but does not discuss planned actions or outcomes. This report is presented to the Risk Management and Standards Committee, the CSCG Committee, the Hospital Executive and the Hospital Management Team for review. The information is also supplied to the Directorates, however all the information is kept anonymous at this level. Risk Management also produces an annual incident report, which summarises the year's incidents and discusses actions undertaken and outcomes.

A Clinical Incident meeting is held once a month with the Risk Management Director, the Clinical Governance Co-ordinator, the Director of Nursing, the Medical Director, the Medicines Governance Pharmacist and the Clinical Effectiveness Co-ordinator. The meeting considers all aspects of those clinical incidents that are reported, but specifically concentrates on the categorisation and coding of each incident. Before an incident can be closed off from Datix, a suitable action plan must be agreed at the Clinical Incident Meetings. If an incident has not been closed off within Datix at the end of a month, its status must be investigated and explained.

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If an incident is assessed as serious it must undertake the "Critical Incident Protocol" with involves a clinical incident review meeting and a full investigation of the circumstances of the incident. The investigations are the responsibility of the Clinical Services Manager (CSM) in the appropriate Directorate and they will be responsible for undertaking a root cause analysis as part of the process. The investigation process will result in a critical incident report being drafted that includes an action plan, which may involve elements of policy review, training and communication of issue. The Trust is keen to identify were lessons can be learnt from incidents and proactively change process and procedure as a result. The critical incident report is presented to the Risk Management and Standards Committee and to the Clinical Governance Committee for review. Any major issues resulting from a critical incident review will automatically be included on the appropriate risk register.

Training/Staff Awareness

Training has not occurred for all staff within the Trust in relation to incident reporting, however it is now included in all induction training for new staff members. Some Trust employees felt that further training for existing staff members would be beneficial. Voluntary training for all staff was provided in relation to equipment incidents, and indeed was compulsory foe Ward Managers and voluntary training was provided on Health & Safety when the incident policy was introduced. Incidents books are held on all wards and a large amount of training of staff is considered to be 'on-the-job' training. The Trust feels that all staff should be aware of the incident reporting policy and required procedures.

Each Directorate must complete a Risk Management Assessment Form annually, which includes a section on incident reporting, and is feed into the Directorate and ultimately Corporate Risk Registers. This provides a secondary mechanism (in addition to the incident reporting data) for the Trust to establish, monitor and report on risks within the organisation. Currently the Women and Children's' Department is considered as the champion of incident reporting and risk management within the Trust. This is demonstrated by the existence of its own risk management committee which reviews and communicates details of incidents occurring with in the Directorate and the Trust overall.

Discussions with staff confirmed that the Incident reporting policy is widely known about and that an open culture exists within the organisation. Strengths included the open-door policy of the risk management department and the clear policies and procedures in place for reporting, review and communication of incident reporting. Weaknesses were noted that knowledge share does not occur formally with other organisations and that incident and near miss definitions and terminology are not always clear. It was noted that this was not an issue in areas that had developed a list of reportable incidents for clarification of what should and should not be reported on the Adverse Incident Report. It was also noted that the Women and Children's' Directorate was considered to be the most advanced area within the Trust and that other areas were keen to follow in their footsteps.

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Third Party Relations

The Trust undertakes four types of audit work within the organisation directed by the Clinical Audit Steering Committee (i.e. Individual Audit, Team Audit, Regional Audit and National Audit). Directorates are also responsible for undertaking audit work in areas that specifically affect them. The Trust undertakes both reactive and proactive audit work. Proactive audits are directed by the Clinical Audit Steering Committee or individual Directorates, whereas reactive audits are undertaken on the request of other organisations or on the back of incident reporting trends. Audit can occur from any incident, however it usually occurs on the occurrence of a critical incident report. Audit meetings are held to present the findings of individual reviews and an annual multi-discipline audit report is produced to discuss key findings and progress.

The Trust did not identify any formal links with the Western Health and Social Services Board and the DHSSPS in relation to incident reporting, however the WHSSB are supplied with a copy of the Annual Governance Report and monthly contract meetings do occur with them. The Datix Users Group provides the only forum for formal discussions concerning incident reporting currently, however this tends to concentrate on the technical issues of reporting as opposed to the lessons learnt from incidents.

Whilst knowledge share is often disseminated to other Trust informally via regional professional groups e.g. the Medical Directors Forum, there is currently no group to co-ordinate this approach and/or process. The Trust also believes that better communication between Healthcare organisations generally in Northern Ireland would be beneficial to all in relation to knowledge share of incident reporting processes and outcomes. The Trust does not utilise agency staff at any time. Where independent contractors are used, the contract will specifically detail the responsibility of all concerned to fully report any incidents occurring.

NIAIC

The Technical Equipment Manager acts as the NIAIC Liaison Officer within the Trust. He receives and disseminates NIAIC Alerts and reports any serious equipment incidents to NIAIC. All equipment failings are tested by the Trust and sent to the manufacturer for checking; NIAIC do not undertake any testing in the Trust. The Trust feels that NIAIC should be testing all items instead of the Trust, but they appreciate the resource limitations that currently exist. The Technical Equipment Manager is also responsible for undertaking the risk assessments for equipment incidents. The Trust stated that the NIAIC website is not updated on a regular basis, resulting in alerts links not being in an electronically communicable form quickly.

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Belfast City Hospitals HSS Trust

Incident Reporting Policy

The Trust has an Incident Reporting policy and procedure document in place, including definitions of incidents and near misses, however this has not been reviewed since August 2001. The Trust has a Clinical Governance Committee in place to report to Trust Board on incident reporting matters, however it was noted that this group has not met since March 2003. With the exception of this committee, the Trust does not currently have any sub-groups other than the Financial Audit Committee and the Health & Safety Committee. The Trust does not currently have a Clinical Audit Committee, a Complaints Committee or a Claims and Litigation Committee. Furthermore, it was noted that no Risk Management policy or Risk Management Committee currently exists within the organisation, and whilst a draft Risk Management policy has recently been developed, it has not yet been approved by Trust Board. Whilst the Trust has informal arrangements to cover these elements, no formal structure is in place and Directorate Governance Committees are largely responsible for implementing procedure in these areas.

The Trust does not have a whistle-blowing policy in place, and whilst the Risk Management department has developed a draft policy there are currently no plans to implement it within the organisation. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it will accept anonymous reports if they are provided. The Trust has indicated that a full review of management structure, policies and procedures is due to be undertaken when a new Governance Manager takes post in April 2004.

Incident Reporting Procedures

Incidents occurring within the organisation are reported on three different forms. All incidents must be either recorded on a clinical incident reporting (IR Clinical) form or a non-clinical incident reporting (IR1) at the time of the incident. In addition the A&E Department in the Surgery Directorate also complete a violent incident report (IR2) form for violent incidents only, however it was noted that this form is to be phased out. The Trust believes its incident reporting systems and processes are still at an early stage of development, but feel the organisation is developing an open culture with continually improving reporting. The Trust stated that feedback is not currently adequate and that lessons learnt were not being shared fully across the Trust. This has been identified as a key development point within the organisation. The Trust is due to undertake a full review of procedures related to incident reporting later in 2004. This will incorporate the implementation of Datix in the organisation.

Incident Reporting Systems

The Trust currently utilises the Ulysses system to record incident reporting, however it is due to implement Datix later in 2004. The Trust has stated that Ulysses is cumbersome to operate and is inconsistent with other Trusts within the region. The Trust has also indicated that they intend to implement the complaints, claims, litigation and risk management modules available on Datix. The Trust stated that it will develop the Datix coding system and the incident grading/risk assessment process for incidents once it has been fully implemented. The Trust currently has two

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dedicated incident data inputters, who are split for clinical and non-clinical incidents. It was noted that reported incidents within the organisation have increased from 1.5% of admissions in 2002 to over 6% of admissions in 2003. This is comparable with an expected national average of c10%.

Review of Incidents Reported

Line managers in each Directorate review all incidents occurring in their area and report issues/outcomes to the Directorate Governance Group. There is no formal policy for undertaking investigations of incidents in the Trust generally; however each individual Director is responsible for reviewing incidents in that area and deciding on further action and investigation. The Risk Management Department also reviews all incident forms (clinical and non-clinical) and investigations can be initiated at this level if deemed necessary. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted that managers must inform the Risk Management Department immediately if a significant incident occurs. The Trust does not currently use Root Cause Analysis to investigate recorded incidents, however training in this area is due to occur after which the organisation intends to include it within incident reporting policy and procedure.

The Trust Governance Committee and individual Directors are provided with Quarterly Incident Reports (by the Risk Management Department) detailing the number and types of incidents occurring. It was noted that due to the lack of a risk management committee or the regular meeting of the Governance Committee, the Trust has no forum to discuss trend analysis, serious incidents or associated risks at a corporate level. Furthermore, the level of information provided within the current quarterly report does not provide a high level of detailed trends analysis or significant information for full review to be undertaken. It was noted that the format and content of this report is to be reviewed in line with the implementation of Datix and the overall review of incident reporting procedures. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was also noted that the multi-discipline audit programme is also affected by incident reporting however the Trust would like to develop this area further.

Training/Staff Awareness

Training on the completion of the IR forms has been provided on a voluntary basis within the Trust and incident reporting training is included as part of its induction training. Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur as no standard feedback policy exists for incident reporting across the Trust.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to

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ensure quality care is delivered. The Trust have good links with the Eastern Health and Social Services Board, however no formal procedures or arrangements are currently in place regarding incident reporting requirements. The Trust did state that the role of the Boards in this area is somewhat ambiguous. The Trust advocated the use of regional specialist networks across Northern Ireland e.g. the Northern Ireland Cancer Network to improve knowledge share and discussion of lessons learnt from incident reporting in the province. The Trust will also seek informal guidance and advice from the Chief Medical Officer in relation to specific issues.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that the Trust was dissatisfied with the reviews/investigations undertaken by NIAIC in relation to medical device/equipment incidents reported. The Trust considered the reviews as inadequate and slow, resulting in the organisation having to resolve the issue without any assistance or guidance. This was evidenced by the fact that pacemaker incidents are now reported directly to the MHRA with NIAIC being by-passed. The Trust did however state that it was aware of resource issues within NIAIC. The Trust currently has a Medical Device and Equipment Co-ordinator in position.

Green Park HSS Trust

Incident Reporting Policy

The Trust has policy and procedures for reporting Incidents, Accidents and Near Misses, which provides definitions of incidents and near misses and detailed operational policy for reporting. The Trust has a Strategy for Clinical & Social Care Governance and a Risk Management Strategy. The current definitions used by the Trust are based on definitions used in other UK organisations i.e. the National Patient Safety Agency and in countries such as USA and Australia. The Trust promotes an "open, honest and just culture for incident reporting in order "to encourage staff to report areas of concern and to foster a positive ethos around reporting". The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it has a whistle-blowing policy and in practice will accept anonymous reports if they are provided.

Incident Reporting Procedures

All incidents are currently reported on one Accident/Incident/Near Miss Report form within the Trust. All accidents, incidents and near misses involving patients/clients, staff, visitors or contractors must be reported immediately by the person involved or who first discovered the incident to their Head of Department. Serious incidents, as defined by Trust policy, also need to be reported immediately to the Clinical Governance Department. The Trust has noted a large increase in the number of incidents reported since the introduction of the single reporting form.

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Incident Reporting Systems

Greenpark was the first Trust to use the Datix system in Northern Ireland and currently utilises it to record all incidents, whilst linking it to Risk Management, Claims, Complaints, Controls Assurance and Litigation modules on the system. The Trust will be implementing the new Knowledge and Skill module on version 7 of Datix to be launched in April 2004 and has already investigated the possibility of implementing the Data Protection module that will available on Datix from August 2004. The Trust also aims to utilise the improved report writer on version 7 of Datix for increased trend analysis data. The Trust utilises the Datix messageboard to share knowledge and gain an understanding of what other organisations are doing. Datix is not devolved to the Directorates and the Trust inputs all data within the Clinical Governance Department. It was noted that the Trust has developed its own Datix codes.

Review of Incidents Reported

The Trust require further investigation to occur for:

- all serious incidents, as defined by Trust policy;
- incidents reportable under RIDDOR regulations;
- incidents that may subsequently develop into a medical negligence or litigation claim;
- and accident/incident/near miss as determined by the Clinical Risk Manager and/or Clinical Risk Management Committee as requiring follow-up;
- any medication incident as determined by the Pharmacy Manager as requiring follow-up; or
- any incident as directed by a relevant Director/Manager on-call who considers that follow-up is necessary.

The Trust has an Incident Review group in place, which is tasked with reviewing accident, incident and near miss forms and recommending action plans as required. The Group is also expected to advise the Trust's Risk Management Committee on emerging trends and lessons learnt. It is the responsibility of the Risk Management Committee to review reports on all serious incidents, as defined by Trust policy. The Committee will endorse reports of Serious Incident Reviews and ensure that the action contained in the report is fully implemented.

Training/Staff Awareness

Training on incident reporting and completion of the IR form has been provided to all key staff members in the Trust. Training on incident reporting also occurs during induction for all staff. Feedback to staff after an incident has been reported is the responsibility of each Senior Manager, Ward Manager and Head of Department. Feedback policy exists within the Trust's policies and procedures for incident reporting. Discussions with staff indicated a high level of awareness of incident reporting and the relevant policies and procedures. Staff did suggest that there were occasions when the definition of incidents ambiguous and that open reporting does not always occur.

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Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also have regular meetings with the four Boards and feel that all necessary information is communicated on a timely basis.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. The Trust currently has no Medical Device Co-ordinator and stated it would require additional resources to implement such a role. The Trust stated that feedback from NIAIC has been poor in the past, however they accepted that resource issues were currently an issue.

Royal Group of Hospitals and Dental Hospitals HSS Trust

Incident Reporting Policy

The Trust has an Incident Reporting Policy and a Risk Management Policy, which is currently being reviewed to focus on quality and excellence. The Trust wish to promote an "open and learning culture" and as a result the reporting system is not anonymised. The Trust has consulted with the NPSA to ensure that this approach is consistent with other regions. The Trust has also requested a definition of adverse events/incidents from NPSA, as they believe that confusion still exists over the terminology e.g. a recent review of theatres indicated that a lack of consistent definitions existed in the area. The Trust believes that this issue has an impact on the grading of incidents, including deciding which incidents to investigate and undertake root cause analysis on.

The Health Care Governance/Excellence & Governance Committee have developed a Corporate Risk Register. A Corporate Treatment Plan is to be developed by February 2004. Risk management consultants have validated the risk management approach. The Trust has developed a whistle-blowing policy and a mal-administration in care policy. The Trust also has a no-blame policy in place, however the Trust has indicated it wishes to promote a fair-blame culture instead of a no-blame culture. A culture survey undertaken by the Trust indicated that fear of disclosure often occurs due to the claims culture within the organisation. The survey indicated that nursing staff may not report as much as they should due to the perceived threat of disciplinary action, however it was noted that they are more likely to report than other professional staff. It was noted that 50% of medical staff who replied to the survey were consultants indicating high levels of interest in the subject at this level. Conversely, the responses indicated that junior doctors do not have any significant interest in the area. The Trust indicated that factors such as media coverage and intervention by local politicians often affected the culture of reporting within the organisation. Trust employees also cited lack of feedback

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as a reason for not reporting incidents on a regular basis, resulting in staff feeling that reporting incidents is not worthwhile as nothing will result from it.

Incident Reporting Procedures

The Clinical Intervention ("CI") form and the Incident Reporting 1 ("IR1") form are used to report incidents within the Trust. Officially only the IR1 form should be used, and there are plans to phase the CI form out completely to avoid confusion and to have a consistent procedure. When an incident occurs in the Trust, three copies of the IR1 form must be completed (one for risk management, one for the department and one for the second service involved if necessary). All departments in the Trust use the IR1 form, with risk management ultimately holding all the forms. The form does not include information on catastrophic incidents or frequency if incidents. Clinical statutory reporting, where relevant, is the responsibility of each directorate and is not captured IR1 form. Furthermore, there is no statutory reporting monitoring co-ordination within the Trust.

General incidents are reported on the Health & Safety Report, with clinical incidents being reported on the Patients Safety Report. The RGHT does not believe that the Health & Safety Report captures all near misses or violent incidents. Currently there are approximately 800 to 1,000 Health & Safety incidents reported per year. The introduction of a single Health & Safety form appears to have reduced violent incident reporting, which was previously very straightforward. Clinical reporting is not considered as good, however the Trust believe that it depends on type of staff reporting e.g. nurses are considered better at reporting than other professional groups. It was also noted the Trust did not believe that clinicians were good at reporting their own near misses. It was noted that c80% of incidents reported within the Trust are related to patients/clients care, c20% were related to staff and c10% were related to operational systems and incidents. Incident reporting in areas such as Medicines has improved due to the organisation's efforts to move away from the blame-culture. Medicines governance has recently been made permanent by the DHSSPS.

Complaints are reported through the Director of Nursing; litigation is reported through the Director of Medicine; Risk Management is reported through the Director of Medicine.

Incident Reporting Systems

RGHT utilise the Ulysses system for incident reporting and risk management purposes, as many users (e.g. Pharmacy) consider it to be flexible. The Trust believes that the Datix system, by comparison, does not allow codes to be designed/amended as easily as Ulysses, which currently has 500 incident codes within the Trust. However, the Ulysses system does not have a dedicated support resource in Northern Ireland (as the company is based in England) and only a couple of Trusts currently utilise it in the province. The Trust has applied for grant support to implement a new reporting system in conjunction with Belfast City Hospitals Trust, however no further details are available at this stage. The

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Trust's risk registers are still produced on excel spreadsheets and the Trust has identified IT support as a major element that needs to be addressed in this area.

Data inputters code and input IR1 forms onto Ulysses, with clinical advisors available for consultation if required. Data input is always approximately 400 forms (i.e. 2-3 weeks) behind the reporting of the incident. Ulysses automatically generates an English RIDOR form, which has to be manually altered for Northern Ireland purposes. Individual staff numbers do not go onto the system for those reporting incidents, but does if the staff member is affected by the incident e.g. verbal or physical abuse. All forms are archived after seven years.

Review of Incidents Reported

Divisional risk co-ordinators review all forms before they go to risk management, identifying where continual incidents are occurring. Risk co-ordinators chase issues up in each division, however not all divisions currently have a risk co-ordinator in post. Risk management attend the Divisional Governance meetings that monitor actions undertaken following incident reporting. Annual Health & safety reports are produced to report incidents including consideration of lessons learnt. A training programme for issues identified through incident reporting exists and a framework for investigation exists within that programme. The Trust also performs root cause analysis on incidents, although this process has only been running for approximately one year.

All non-clinical incidents are passed to the Health and Safety Advisor, where the incidents are screened for further action. This may involve sending the IR1 back to the individual with an action plan or it may involve undertaking a full investigation, which is subsequently reported back to the individual. Moderate to serious incidents become the responsibility of Risk Management in order that a serious incident review is undertaken. Investigation details are widely communicated to line managers and directorate managers. Recommendations from action plans do not necessarily affect audit programmes. Incidents will only go through either an investigation or root cause analysis, but not both.

Feedback for reported incidents can only be given if an extension number is recorded on the IR1 form, although this does not guarantee that feedback will be provided. Whilst a general risk advice telephone number exists for staff, there is no dedicated hotline for incident reporting, however the Trust has stated that this is to be implemented over the next year. The Risk Management Forum acts as a formal forum to discuss serious incidents. The Datix Users Group also acts as a formal forum for Claims, Litigation and Complaints groups within the region.

The STARR document risk management tool audits control standards in each Department annually and queries whether staff are reporting incidents and are complying with NIAIC. A compliance percentage is awarded for each area. No further monitoring at ward level occurs after completion of the IR1 form. The Trust intends to draw up an audit schedule in this area (above and beyond the STARR review).

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Training/Staff Awareness

Training courses for new consultants include elements on incident reporting and are undertaken by the Deputy Medical Director. Corporate training and training for nurses also includes incident reporting elements. The Trust is now considering making attendance on courses compulsory based on the results of the culture survey. This is demonstrated by the fact that of 40 places available on the root cause analysis training courses in 2003, twenty-three people volunteered, of which only one was a Doctor.

Discussions with staff indicated that the Trust does have an open reporting culture and that staff are aware of the necessary procedure and when it is required. Staff questioned had been involved in reporting incidents and were aware of the correct forms and what they are required to do. Staff did state that further training and communication would be beneficial, especially in relation to incident reporting investigation. It was also noted that external knowledge share does not occur under any formal structure. Staff did not show any awareness of NIAIC or its role within incident reporting.

Third Party Relations

The Chief Medical Officer will send out circulars relating to lessons learnt from England. The Trust believes that a significant level of informal knowledge share exists both within the organisation and with other organisations, but that formal forums are weak for this purpose. A newsletter for Medicines is produced for the whole province (the Trusts in Wales have indicated that they wish to use the same format) The Trust stated that an overall co-ordination of incident reporting throughout Northern Ireland would be very useful. The preferred structure would include Medicines, Medical Devices, Health & Safety and General incidents as the key elements. The Trust also feels that there is a lack of co-ordination on the issue generally in the UK, as NPSA are struggling to deal with it effectively.

Standard wording relating to reporting of incidents is included within the contracts/service level agreements for independent contractors. Whilst this wording is in place, the Trust feels that control over this area is not as strong as it would like, especially in relation to sub-contractors. Where the Trust shares services with other organisations, incident reporting requirements are put in place. QUB staff providing services at the Royal and RGHT staff working in QUB areas are required to report incidents based on the contract in place with QUB. The relationship between QUB and RGHT is currently under review, as it is not considered as positive as it may otherwise be.

NIAIC

NIAIC alerts are originally sent to the Risk Manager and the Chief Executive. The Trust has found that alerts tend to arrive late on a Friday afternoon, which has caused problems for quick dissemination throughout the Trust. The high volume of alerts sent to the Trust has also proved to be an issue in the past. Despite this, the Trust has developed procedures in relation to NIAIC and a distribution list exists for communication of alerts. The NIAIC alerts are distributed widely throughout the Trust by e-mail.

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The Trust does not consider NIAIC to be an independent investigator, as they will often refer to the manufacturer with technical issues instead of undertaking an independent review. The Trust cannot usually wait for NIAIC to come out to check equipment, as it is required as soon as possible. The Trust does not consider NIAIC to have a strong technical capability and the Biomedical Technology Department within the Trust undertakes much of this work. RGHT is the only Trust in Northern Ireland to have such a department. The Trust does complete NIAIC's "G Form" along with the IR1 form as required and sends it to NIAIC (which is always acknowledged), however resulting feedback and knowledge share are considered poor.

Craigavon Area Hospital Group HSS Trust

Incident Reporting Policy

The Trust, under the direction of a new Clinical and Social Care Governance (CSCG) Group, is currently in the process of reviewing its Governance policies and procedures, which includes review of its Corporate Governance policy (which is currently not widely circulated to staff) and its incident reporting policy and procedures. It was noted that a draft incident reporting policy exists, but has not yet been endorsed by the Trust Board. The Trust does not have a whistle-blowing policy in place. The Trust does not advocate anonymous reporting, with the exception of Medication Incidents and whilst it requires staff to sign off incident reporting forms, it will accept anonymous reports if they are provided. It was noted that the Trust considers that significant under-reporting is occurring presently and believes the new policies and procedures will assist in promoting an open reporting culture.

Incident Reporting Procedures

Incidents occurring within the organisation are reported on a series of different forms. Clinical incidents are all recorded on different forms in each Directorate, however there is a consistent form for all non-clinical incidents (Accidents and Incidents Form). In addition there is one form for all medication incidents occurring within the organisation. The Trust has stated that they intend to combine all these forms into one form across the organisation and this process will be developed by the new CSCG Group.

The Trust believes its incident reporting systems and processes are still at an early stage of development, and feel the organisation needs to improve the reporting culture within the organisation. The Trust stated that feedback is not currently adequate and that lessons learnt were not being shared fully across the Trust. This has been identified as a key development point within the organisation. The Trust is due to undertake a full review of procedures related to incident reporting later in 2004.

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Incident Reporting Systems

The Trust currently utilises a range of different incident reporting systems to record incidents occurring within the organisation. Clinical incidents are recorded differently in each Directorate, with most using Ulysses, excel or access to collate the information. Non-clinical incidents reported on the Accidents and Incidents Form are recorded on the Safecode system, however lack of resources have resulted in inputting not occurring for large periods in the past year. Medication incidents are also recorded on the Safecode system. The Trust is currently debating whether to implement the Datix system, but no decision has yet been made, however a consistent incident reporting system is considered crucial for improved analysis and investigation of all incidents in the organisation.

Review of Incidents Reported

There is no formal policy for undertaking investigations of incidents in the Trust generally and the process of investigation and review is split into clinical and non-clinical incidents. Clinical incidents are investigated at Directorate level and it was noted that no consistency of approach exists within the organisation for this type of incident investigation. It was also noted that no risk assessment occurs and the Trust does not have a serious incident review group in place. Non-clinical incidents are co-ordinated by the Health and Safety manager, but the investigation process is also inconsistent. The investigation process across the Trust is due to change following the review of incident policies and procedures, however no details were available at the time of the site visit.

It was noted that managers must inform relevant Director immediately if a significant incident occurs and this process is unlikely to change following the policy and procedures review. The Trust does not currently use Root Cause Analysis to investigate recorded incidents. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was also noted that the clinical audit programme is also affected by incident reporting however the Trust would like to develop this area further.

Training/Staff Awareness

Training on the completion of the IR forms has not been provided within the Trust generally, however incident reporting training is included as part of some Directorate's induction training. Feedback to staff after an incident has been identified as an area that needs to be developed by the Trust, as no standard feedback policy exists for incident reporting across the Trust. Communication of lessons learnt also needs to be improved within the organisation, as no staff interviewed had been involved in the sharing of knowledge. Staff also appeared to be confused about the terminology surrounding incidents and near misses and the processes required to capture it and report it.

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Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust have good links with the Southern Health and Social Services Board, however no formal procedures or arrangements are currently in place regarding incident reporting requirements. The Trust did state that the role of the Boards in this area is somewhat ambiguous.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that the Trust was satisfied with the level of input from NIAIC and found Brian Godfrey to be a good point of contact if queries arise. The Trust did state that investigations are usually performed by manufacturers or the Trust itself.

United Hospitals HSS Trust

Incident Reporting Policy

The Trust is currently in the process of reviewing its Governance policies and procedures, which includes review of its risk management policy and strategy and its incident reporting policy and procedures. In addition the Trust is reviewing its governance structure, which although final details were not available at the time of visit, is expected to combine the Clinical Governance Committee and the Risk Management Committee and produce an overarching Clinical and Social Care Governance Policy. The Trust does not have a whistle-blowing policy in place, however guidance does exist within the organisation on the process for whistle-blowing. The Trust does not advocate anonymous reporting, with the exception of Medication Incidents and whilst it requires staff to sign off incident reporting forms, it will accept anonymous reports if they are provided. It was noted that the Trust considers that significant under-reporting is occurring presently and believes the new policies and procedures will assist in promoting an open reporting culture.

Incident Reporting Procedures

Incidents occurring within the organisation are reported on three different forms. All incidents must be either recorded on a clinical incident reporting (IR Clinical) form or a non-clinical incident reporting (IR1) at the time of the incident or a Medication Incidents form. Currently all clinical incidents are recorded on a Clinical Risk Management Incident Form and is sent to the Claims Manager within the Directorate of Clinical Services for inputting and review. All medication incidents are recorded anonymously on the Medication Incident Form and are also

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sent to the Claims Manager for input, however the Pharmacist Manager is responsible for coding and review. All non-clinical incidents are recorded on an Incident Report Form and are sent to the Principal Administrative Assistant within the Directorate of Support Services for inputting and review.

The Trust is in the process of drafting a new incident reporting form to cover all incidents within the organisation. The Trust believes its incident reporting systems and processes are still at an early stage of development, and feel the organisation needs to improve the reporting culture within the organisation. The Trust stated that feedback is not currently adequate and that lessons learnt were not being shared fully across the Trust. This has been identified as a key development point within the organisation. The Trust is due to undertake a full review of procedures related to incident reporting later in 2004.

Incident Reporting Systems

The Trust currently utilises two different incident reporting systems to record different types of incidents occurring within the organisation. The Datix system is used to record all clinical and medication incidents, whereas all non-clinical incidents are recorded on the Safety and Health Environment (SHE) system. The claims, litigation and risk management modules on the Datix system are also currently used by the Trust. The Trust intends to redesign this process so that all incidents are recorded on the Datix system, although the practical details of this had not been decided on at the time of the site visit.

Review of Incidents Reported

There is no formal policy for undertaking investigations of incidents in the Trust generally and the process of investigation and review is split into clinical and non-clinical incidents. The Claims Manager will produce a quarterly report from Datix, which details the clinical and medication incidents and is sent to the Clinical Governance Group and the Medicines Management Group for review. The Principal Administrative Assistant in the Directorate of Support Services produces a six-monthly report from SHE, which details the non-clinical incidents and is sent to the Controls Assurance Committee, the Health & Safety Management Group and the Security Group for review. This process is due to change following the review of incident policies and procedures, resulting in all incident reports being reviewed by the new Risk Management Committee.

It was noted that managers must inform relevant Director immediately if a significant incident occurs and this process is unlikely to change following the policy and procedures review. The Trust does not currently use Root Cause Analysis to investigate recorded incidents, however training in this area is due to occur after which the organisation intends to include it within incident reporting policy and procedure. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was also noted that the clinical audit programme is also affected by incident reporting however the Trust would like to develop this area further.

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Training/Staff Awareness

Training on the completion of the IR forms has not been provided within the Trust generally, however incident reporting training is included as part of its induction training. Feedback to staff after an incident has been identified as an area that needs to be developed by the Trust, as no standard feedback policy exists for incident reporting across the Trust. Communication of lessons learnt also needs to be improved within the organisation, as no staff interviewed had been involved in the sharing of knowledge. Staff also appeared to be confused about the terminology surrounding incidents and near misses and the processes required to capture it and report it.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust have good links with the Eastern Health and Social Services Board, however no formal procedures or arrangements are currently in place regarding incident reporting requirements. The Trust did state that the role of the Boards in this area is somewhat ambiguous. The Trust advocated the use of regional specialist networks across Northern Ireland e.g. the Northern Ireland Cancer Network to improve knowledge share and discussion of lessons learnt from incident reporting in the province. The Trust will also seek informal guidance and advice from the Chief Medical Officer in relation to specific issues.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that the Trust was dissatisfied with the reviews/investigations undertaken by NIAIC in relation to medical device/equipment incidents reported. The Trust considered the reviews as inadequate and slow, resulting in the organisation having to resolve the issue without any assistance or guidance. The Trust did however state that it was aware of resource issues within NIAIC. The Trust currently has departmental equipment co-ordinators in position.

Mater Infirmorum Hospital HSS Trust

Incident Reporting Policy

The Trust has an Adverse Incidents Reporting (Non-Clinical) Policy and Procedure document and a Policy and Procedures for Reporting Adverse Clinical Incidents and Near Miss Incidents. These policy document provide definitions of incidents and near misses and detailed operational policy for reporting for both clinical and non-clinical incidents within the organisation. The Trust also has a Risk Management

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Strategy, which promotes a "no-blame" culture within the organisation and details the organisation's whistle-blowing policy. The Trust believes its incident reporting systems and processes are still evolving, but feel the organisation is developing an open culture with continually improving reporting, however it was stated that lessons learnt were not being shared fully across the Trust. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it has a whistle-blowing policy and in practice will accept anonymous reports if they are provided.

Incident Reporting Procedures

Incidents occurring within the organisation are reported on three different forms. All incidents must be either recorded on a clinical incident reporting (IR Clinical) form or a non-clinical incident reporting (IR1) at the time of the incident. In addition a near miss medication form exists.

Incident Reporting Systems

The Trust uses the Datix system to record all incidents, and this is linked to Claims, Complaints, Controls Assurance and Litigation modules on the system. In addition, the Trust is working on bringing the risk registers onto the system to replace the current word document arrangement. The Trust will be implementing the new Knowledge and Skill module on version 7 of Datix to be launched in April 2004 and has already investigated the possibility of implementing the Data Protection module that will available on Datix from August 2004. The Trust utilises the Datix messageboard to share knowledge and gain an understanding of what other organisations are doing. Datix is not devolved to the Directorates and the Trust inputs all the incident data in the Risk Management Department. It was noted that the Trust has developed its own Datix codes.

Review of Incidents Reported

Each staff member must complete a risk assessment when reporting an incident, using a risk assessment matrix. Line managers in each Directorate review and agree risk assessments for all incidents occurring in their area. There is no formal policy for undertaking investigations of incidents in the Trust generally, however each individual Directorate Governance Committee reviews incidents in that area and decides on further action and investigation. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted that managers must inform the Risk Management Department immediately if death or a serious injury occurs. The Trust does not use Root Cause Analysis to investigate recorded incidents.

The Trust Clinical & Social Care Governance Committee and Corporate Governance Committee are provided with Quarterly Incident Reports (by the Risk Management Department) detailing the number and types of incidents occurring and narrative of actions and outcomes. It was noted that violence to staff and falls were the two most common incidents in the Trust. It was noted that the organisation has changed policies,

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procedure and protocol as a result of incident reporting in the past and has provided additional training were necessary. The clinical audit programme is also affected by incident reporting on an ad hoc basis and the Trust has identified this as an area for development.

Training/Staff Awareness

Training on the completion of the IR form was provided when it was launched, covering key staff in all Directorates and areas in the organisation. Training on incident reporting also occurs during induction for all staff. Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur. No standard feedback policy exists for incident reporting across the Trust. Discussions with staff indicated a high level of awareness of incident reporting and the relevant policies and procedures. Staff did not identify any particular issues with the current system.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also have regular meetings with the four Boards and feel that all necessary information is communicated on a timely basis.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. The Trust stated that NIAIC has previously been very slow to investigate reported incidents. This was demonstrated by the example of an infusion pump that has been out of action for three months and is still waiting for NIAIC to conduct an investigation. It was noted that the Trust has a Medical Device Co-ordinator.

Community Health and Social Services Trusts

Craigavon and Banbridge Community HSS Trust

Incident Reporting Policies

Incident reporting originated within Health & Safety in Craigavon & Banbridge Community Trust, however the culture of the organisation has been changing to include non-Health & Safety incident reporting recently. This is largely due to the Trust's promotion of a "no-blame" culture,

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meaning that incidents are not seen as always being disciplinary offences. The Trust indicated that it was keen to provide guidance on definitions of incidents and near misses specifically related to Directorates.

Whilst the Trust feels it has promoted the culture of incident reporting across the organisation, it accepts that some professional groups e.g. nurses and occupational therapists are better at reporting incidents than others. The Trust also indicated that non-professional staff were often better at reporting incidents than professionally trained staff. The Trust also identified staff who primarily work alone as high risk for non-reporting of adverse incidents and near misses. All staff receive training in incident reporting within the Trust. Training is developed with respect to best practice policies and procedures.

The Trust accepts that the role of clinicians and managers has changed to incorporate a significant level of audit and reporting. The Trust, including the Chief Executive, did state that agenda requirements were becoming more difficult to resource and that this would need to be taken into consideration in relation to any future recommendations or guidance from the DHSSPS in relation to incident reporting.

The Trust has noted that the number of incidents reported has increased dramatically over the past two years. Currently approximately 40 incidents are reported per quarter, and whilst the Trust believes this is due to better reporting than an increase in actual incidents, they are keen to ensure over-reporting does not occur. It was noted that the whistle-blowing policy is primarily used for serious incidents, however the Trust is keen to extend this to include medium-type incidents believing that this will promote anonymous reporting. No anonymous reporting has yet occurred within the Trust despite its promotion during training. The types of incidents reported is now starting to include issues like verbal and physical abuse, which previously was not reported on a regular basis.

Incident Reporting Procedures

When an incident or near miss occurs, the member of staff involved must complete an Incident Reporting ("IR") Form with their respective manager. The Incident Reporting (IR) form is currently being developed to include all incidents in the organisation. The member of staff must also verbally report the incident to the Line Director to ensure that early intervention can occur if necessary. Two lines of reporting currently exist in the Trust – statutory and professional. Both lines will result in the information being reported to the Risk Management Group. A key issue for the Trust is the proper assessment and related action plan for identified risks. Exception reports are provided to the Corporate Governance group and can also be included in a case management review if necessary. It was noted that good practice is also identified in reporting as well as adverse incidents and near misses.

The Medicines Management Group exists for medicines reporting. Information management incidents are not recorded regularly, although the Trust believes that this in not reflective of the levels of incidents actually occurring. The Trust particularly wishes to increase the reporting of incidents involving breach of confidentiality and consent. It is expected that this will be incorporated into the risk management process at a later stage.

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Incident Reporting Systems

The Trust utilises the Datix system to record and analysis incidents occurring within the organisation. Datix is always inputted one month after incident reporting occurs. Subsequently the data is e-mailed to the relevant line Director and is analysed quarterly by the relevant Directorate and by the Trust separately. The incident information ultimately goes to Trust Board for sign-off. No further incident reporting systems are used to record incidents within the Trust. The Trust is still debating whether to utilise the Internet for incident reporting purposes.

Review of Incidents Reported

Day-to-day incident monitoring comes through the Programme of Care quality groups and is reviewed by the Executive Directors. The Medical Director takes the lead in review and analysis of adverse incidents and near misses. This process may involve Datix being left open and the incident details being returned to its origin in order to request further details if reviewers are not satisfied with the original solution or action. No database of all incidents monitored exists, however this can be analysed through Datix.

Knowledge gained from incident reporting is shared externally through the Clinical and Social Care Governance committees and groups. The Trust uses periodic bulletins to update staff within the Trust. The Trust would like to see a similar Bulletin being issued by the Clinical & Social Care Governance or Health & Safety Groups or the DHSSPS to cover all incidents across Northern Ireland. Internally, professional sub-groups meet regularly to promote best practice across Directorates. Incidents relating to each Programme of Care are discussed to ensure lessons learnt are pushed across the organisation. Benefits of incident reporting have been noticed within the organisation, including the ability to improve poor processes, systems and services. The Trust believes that sharing of knowledge and lessons learnt from incidents and near misses is key to the whole process.

Training/Staff Awareness

It was stated that the Mental Health statutory reporting requirements have helped progress the culture of reporting incidents, as the requirements have been in place for some time. Incident policy guidance in this area has assisted greatly in improving incident reporting processes across all service lines. It was also noted that the introduction of a Clinical & Social Care Governance Facilitator within the Trust had helped clinicians appreciate the practical application of CSCG on their specific field. This has been further improved by provision of training across the organisation. It is felt that the Child Act will also have an impact on the incident reporting process.

Discussions with Trust staff indicated that incident reporting is actively encouraged by the Trust and that the culture is changing to promote reporting of adverse incidents and near misses. It was noted that full reporting is not always considered to occur, especially in relation to verbal and physical abuse due to the volumes experienced. Despite this, staff appeared to have had good experiences of incident reporting, stating that the training and communication related to the area are of a high standard. Staff also felt that the process was reasonably straightforward and that

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feedback relating to individual incidents reported was good. Staff were aware of the implications of incident reporting and demonstrated knowledge of the root cause analysis process and the relevant policies. This included all staff being asked to read and sign the new whistle-blowing policy to indicate awareness and understanding of it. Staff also were made aware of incident reporting through monthly team meetings, with objectives for incident reporting being included in their annual appraisal process (which occurs for all staff).

Third Party Relations

Contracted services with nursing homes are based on the Contracts Compliance Form. The Service Level Agreement gives details on the information that is required to be reported by contractors, partnerships and external providers. The Southern Health and Social Services Board is the only Board where a Contract Consortium Group exists e.g. with preferred suppliers lists for all organisations. This helps to ensure consistency occurs across the Board area. Copies of how incidents have been dealt with are kept for record purposes, however information on incidents does not get fed into Datix from this source. Incidents are reported through the Trust for all external individuals.

A relatively low level of agency or temporary staff are used in Craigavon and Banbridge Trust. Agency staff are never in charge of wards as existing staff will always take this role. This reduces the risk of incidents not being reported due to lack of knowledge of the reporting process. No corporate induction is given to temporary staff, however rigorous checking of professional qualifications is undertaken by the Agency and this is randomly checked by the Trust.

NIAIC

The Trust's Health Estates Department is responsible for medical devices and liaison with NIAIC. Administrative staff currently screens information provided by NIAIC in relation to medical devices. Health Estates stated that they receive a lot of bulletins that are not relevant to the Trust, but that where relevant MDA incidents are reported to NIAIC. It is felt that NIAIC take considerable time to feedback on issues/incidents, but that they are aware that this is resource related. It was also stated that NIAIC are unable to confirm what information is provided by Craigavon & Banbridge Community Trust. Furthermore, the information that is returned is of poor quality; for example lack of logged incidents. NIAIC do however respond to serious incidents within 24 hours. The Trust is not aware of how information originating at Craigavon and Banbridge is provided to other organisations across the province.

The Trust is set to implement a unique numbering system for all medical devices coming from the store by 31st March 2004. This will be linked to Health Estates and will provide a full history of devices and servicing. The Trust also intends to appoint a Community Devices Co-ordinator, who will be responsible for the store and for all devices coming in and going out, by using medical device tracking records. The Trust feels that the DHSSPS and relevant policy are very acute service focused in relation to medical devices. Community Trusts experience different issues from Acute Trusts, such as logistical problems with equipment frequently being located offsite and in remote locations.

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Foyle HSS Trust

Incident Reporting Policy

The Trust has a policy and procedures for the reporting of Accidents/Untoward Incidents including definitions of untoward incidents and near misses. The Trust has recently reviewed its Risk Management policy, which now promotes a "just-blame" culture within the organisation instead of a "no-blame" culture. It was also noted that the Trust is currently developing organisational risk registers. The Trust's Risk Management is to become part of the Clinical and Social Care Governance Committee. The Trust feels that staff do not currently have a full appreciation of the CSCG agenda and this affects the perception of the need for full and committed incident reporting.

The Trust also has a whistle-blowing policy in place, however it stated that staff did not regularly use this. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it will accept anonymous reports if they are provided. It was also noted that only 2 near misses had been reported within the Trust, which is believed to be due to confusion existing among staff as to what this term covers. The Trust feel this area needs to be developed through better communication and training of staff.

Incident Reporting Procedures

All incidents are currently reported on a different form within Family & Child Care and the rest of the organisation. As part of the review to be undertaken the Trust intends to redesign one incident reporting form to cover all areas within the organisation. The Trust believes its incident reporting systems and processes are still at an early stage of development, but feel the organisation is developing an open culture with continually improving reporting. The Trust stated that feedback is not currently adequate and that lessons learnt were not being shared fully across the Trust. This has been identified as a key development point within the organisation. The Trust is due to undertake a full review of procedures related to incident reporting later in 2004. This is due to the recent implementation of Datix in the organisation and the perceived need to develop one incident reporting form.

Incident Reporting Systems

The Trust has recently implemented the Datix system to record all incidents, and has also implemented the complaints and claims modules. The Trust stated that it is still developing Datix and intends to review the incident reporting form, the Datix coding system and the incident grading/risk assessment process for incidents on the back of this development. The Trust has one dedicated Datix inputter for all incidents in the organisation. The individuals responsible for incident reporting, claims and complaints have all received training in Datix, including code amendment processes.

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Review of Incidents Reported

Line managers in each Directorate review all incident occurring in their area. There is no formal policy for undertaking investigations of incidents in the Trust generally, however each individual Programme Director reviews incidents in that area and decides on further action and investigation. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted that managers must inform the Chief Executive's Office at Trust Headquarters immediately if death or a serious injury occurs. The Trust does not currently use Root Cause Analysis to investigate recorded incidents, however training in this area is included as an action plan for the Trust's incident reporting development in lie with the current review. The Trust also aims to develop a Trust Investigation Form and related formal procedure across the organisation.

The Trust Risk Management Committee and individual Programme Directors are provided with Quarterly Incident Reports (by the Chief Executive's Office) detailing the number and types of incidents occurring. The format and content of this report is to be reviewed in line with the implementation of Datix and the overall review of incident reporting procedures. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was also noted that the multi-discipline audit programme is also affected by incident reporting however the Trust would like to develop this area further.

Training/Staff Awareness

Training on the completion of the IR form is only provided in a few ward induction programmes and does not occur consistently across the organisation. Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur. No standard feedback policy exists for incident reporting across the Trust. Discussions with staff indicated a high level of awareness of incident reporting and the relevant policies and procedures. Staff did not identify any particular issues with the current system, however it was noted that inconsistencies occur between how the Directorates undertake incident reporting.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also have regular meetings with the four Boards and feel that all necessary information is communicated on a timely basis.

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NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within one week of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that the Trust was dissatisfied with the reviews/investigations undertaken by NIAIC in relation to medical device/equipment incidents reported. The Trust considered the reviews as inadequate and slow, resulting in the organisation having to resolve the issue without any assistance or guidance. The Trust did however state that it was aware of resource issues within NIAIC. The Trust currently has no Medical Device and Equipment Co-ordinator.

South and East Belfast HSS Trust

Incident Reporting Policy

The Trust has an Incident policy and procedures which provides definitions of incidents and near misses and detailed operational policy for reporting all incidents and near misses within the organisation. The Trust has a Clinical & Social Care Governance Strategy and a Risk Management Strategy, which are due to be combined by the Trust this year. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it has a whistle-blowing policy and in practice will accept anonymous reports if they are provided.

Incident Reporting Procedures

All incidents are currently reported on one Incident Report form within the Trust. The Trust currently has manual incidents reporting books in all areas, but is also rolling out an electronic version of the IR form, which allows individuals to complete the form online and submit it for immediate collation onto the IR system (CASS). Currently the form still needs to be printed off three times, signed and sent to the Risk Management Department (as electronic signatures are not admissible in court). The electronic systems does however allow the same incident to be reported on one form by a number of different individuals, as opposed to filling in a form each, as required by the hard copy IR forms.

The IR forms are reviewed by the Health & Safety Manager, the Manual Handling Manager, and the Management Aggression Trainers separately.

Incident Reporting Systems

The Trust uses the CASS incident reporting system, which is linked to a claims and litigation module. The complaints and risk management areas in the Trust are not entered onto CASS.

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Review of Incidents Reported

Line managers in each Directorate review all incidents occurring in their area. There is no formal policy for undertaking investigations of incidents in the Trust generally, however each individual Programme Director reviews incidents in that area and decides on further action and investigation. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted that managers must inform the Risk Management Department at Trust Headquarters immediately if death or a serious injury occurs. The Trust does not currently use Root Cause Analysis to investigate recorded incidents.

It was noted that only ad hoc reports are provided to the Governance Committee or the Trust Board and that not periodic review is undertaken. Despite this the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was noted that audit programmes within the Trust are only affected by incident reporting on an ad hoc basis and this was identified as an area the Trust would like to develop further.

Training/Staff Awareness

Training on incident reporting and completion of the IR form has been provided to all key staff members in the Trust. Training on incident reporting also occurs on an ad hoc basis during induction, depending on which department staff are employed. Feedback to staff after an incident has been reported is the responsibility of each Senior Manager, Ward Manager and Head of Department. There is no formal feedback policy within the Trust, and thus it is ad hoc and inconsistent across the organisation. Discussions with staff indicated differing levels of awareness of incident reporting and the relevant policies and procedures.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 48 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. The Trust currently has no Medical Device Co-ordinator and stated it would require additional resources to implement such a role. The Trust stated that feedback from NIAIC has been poor in the past, however they accepted that resource issues were currently an issue.

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North and West Belfast HSS Trust

Incident Reporting Policy

The Trust has an Adverse Events/Incidents policy providing definitions of incidents and near misses and detailed operational policy for reporting. The Trust also has a Risk Management Strategy, which promotes a "fair-blame" culture within the organisation and details the organisation's whistle-blowing policy. The current definitions used by the Trust are based on definitions used in other organisations i.e. the National Patient Safety Agency. The Trust believes its incident reporting systems and processes are still evolving, but feel the organisation is developing an open culture with continually improving reporting, however it was stated that lessons learnt were not being shared fully across the Trust. The Trust is due to undertake a full review of policies and procedures related to incident policies and risk management later in 2004, which should allow the organisation to address any current issues with the system.

The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it has a whistle-blowing policy and in practice will accept anonymous reports if they are provided. The Trust have identified that the Health Directorates of the Trust are more familiar with reporting incidents under the current process than the Social Service Directorates, due to cultures developed under historical reporting systems. The Trust stated that it feels Northern Ireland incident reporting tends to be based on NHS systems which can largely ignore social care elements. The Trust feels that social care incident reporting needs to be considered on a regional basis to ensure its full inclusion within any regional developments or guidance.

Incident Reporting Procedures

All incidents are currently reported on one Adverse Event/Incident Report form within the Trust, which include an incident reporting element and an investigation element (requiring information to be provided for the initial stages of investigative review). As part of the policy review to be undertaken, the Trust would like to redesign the form to cover only the reporting of the incident and thus split the two elements within the organisation. This will clarify the process for staff reporting incidents and allow investigations to be undertaken separately. Currently IR forms can take considerable time to be returned from some areas due to the perceived high level of information required, whereas the Trust wish to see forms being returned within 24 hours of the incident occurring. The review will also consider implementing a new e-form for incident reporting, however the Trust feels that the Patient Client Information System (PCIS) will need to be fully rolled out before this is possible. The Trust has noted a large increase in the number of incidents reported since the introduction of the single reporting form.

Incident Reporting Systems

The Trust uses the Datix system to record all incidents, and this is linked to Claims, Complaints, Controls Assurance and Litigation modules on the system. In addition, the Trust is working on bringing the risk registers onto the system to replace the current word document arrangement.

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The Trust will be implementing the new Knowledge and Skill module on version 7 of Datix to be launched in April 2004 and has already investigated the possibility of implementing the Data Protection module that will available on Datix from August 2004. The Trust also aims to utilise the improved report writer on version 7 of Datix for increased trend analysis data. The Trust utilises the Datix messageboard to share knowledge and gain an understanding of what other organisations are doing.

Datix is not devolved to the Directorates and the Trust splits the inputting into two areas – Community and Health services. All community incident forms are coded at headquarters by one dedicated Datix inputter in the Chief Executive's Office. All health incident forms are inputted at Muckamore Hospital by a dedicated Datix inputter in Medical Records. Line managers code the IR forms according to the risk matrix before sending them to the Datix inputter. It was noted that the Trust has developed its own Datix codes.

Review of Incidents Reported

Line managers in each Directorate review and code all incident occurring in their area. There is no formal policy for undertaking investigations of incidents in the Trust generally, however each individual Directorate Clinical & Social Care Governance and Risk Management Committee reviews incidents in that area and decides on further action and investigation. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted that managers must inform the Chief Executive's Office at Trust Headquarters immediately if death or a serious injury occurs. An incident will be classified as a serious professional event/incident when one or more patients/clients suffers severe unexpected impairment of health/injury/death or disability during the course of their treatment and/or care within the Trust. The responsibility for determining when an incident becomes classified as such rests with the appropriate Director in conjunction with the relevant professional staff.

The Trust questioned the use of Root Cause Analysis to investigate recorded incidents and suggested that the 10 key driver system being developed by Datix may prove more useful to analysis the information that results from incident reporting. The Trust also aims to develop a Trust Investigation Policy and such future developments by Datix may be included.

The Trust Clinical & Social Care Governance and Risk Management Committee is provided with Quarterly Incident Reports (by the Chief Executive's Office) detailing the number and types of incidents occurring and the top five incidents occurring within the Trust. It was noted that violence to staff and falls were the two most common incidents in the Trust. Each Directorate's risk register can be affected by incident reporting and if an issue cannot be resolved at Directorate level, the issue will be promoted to the corporate risk register. It was noted that the organisation has changed policies, procedure and protocol as a result of incident reporting in the past and has provided additional training were necessary. The clinical audit programme is also affected by incident reporting on an ad hoc basis and the Trust has identified this as an area for development.

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Training/Staff Awareness

Training on the completion of the IR form was provided to 600 staff members in the Trust when it was launched, covering key staff in all Directorates and areas in the organisation. Training on incident reporting also occurs during induction for all staff. Sixty key staff have also received a full days training on incident investigation including root cause analysis training. Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur. No standard feedback policy exists for incident reporting across the Trust. Discussions with staff indicated a high level of awareness of incident reporting and the relevant policies and procedures. Staff did not identify any particular issues with the current system.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also have regular meetings with the four Boards and feel that all necessary information is communicated on a timely basis.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 48 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. The Trust currently has no Medical Device Co-ordinator, however the organisation is currently developing a job description to fill the role. The Trust considers NIAIC very competent and has had very positive experiences with the organisation.

Homefirst Community HSS Trust

Incident Reporting Policy

The Trust has a Procedure for Recording and Reporting Incidents providing definitions of incidents and near misses and detailed operational policy for reporting. The Trust also has a Clinical and Social Care Governance and Risk Management Strategy and a whistle-blowing policy. The Trust believes its incident reporting systems and processes are still evolving, but feel the organisation is developing an open culture with continually improving reporting, however it was stated that lessons learnt were not being shared fully across the Trust. The Trust also has a Notification of Serious Accidents and Untoward Events policy and a Health, Safety and Welfare Policy in place which both discuss relevant issues within Incidents Reporting.

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The Trust is due to undertake a full review of policies and procedures related to incident policies and risk management later in 2004, which should allow the organisation to address any current issues with the system. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms in practice will accept anonymous reports if they are provided. The Trust have identified that the Health Directorates of the Trust are more familiar with reporting incidents under the current process than the Social Service Directorates, due to cultures developed under historical reporting systems.

Incident Reporting Procedures

All incidents are currently reported on one Incident Report form within the Trust, although the Trust is currently piloting a medication incident report as requested by the Medicines Governance Project and the Director of Nursing in the Trust. All forms are returned to the Governance Department, where they are all checked and graded by the Head of Governance to ensure any serious incidents are captured. Investigations are instigated in this way. The grading/risk assessment that is undertaken is based on the NPSA's risk matrix.

Incident Reporting Systems

The Trust uses the Datix system to record all incidents, and this is linked to the claims modules on the system. In addition, the Trust is working on bringing the complaints, risk management and risk registers onto the system to replace the current word document arrangement. The Trust utilises the Datix messageboard to share knowledge and gain an understanding of what other organisations are doing. All community incident forms are coded at headquarters by one dedicated Datix inputter in the Governance Department.

Review of Incidents Reported

The Head of Governance reviews and codes all incidents occurring in the Trust. There is no formal policy for undertaking investigations of incidents in the Trust generally, however investigations are undertaken based on the risk assessment done by the Head of Governance. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. The Trust does not use Root Cause Analysis to investigate recorded incidents.

The Trust Clinical & Social Care Governance and Risk Management Committee is provided with Quarterly Incident Reports (by the Chief Executive's Office) detailing the number and types of incidents occurring within the Trust. It was noted that violence to staff and falls were the two most common incidents in the Trust. Each Directorate's risk register can be affected by incident reporting and if an issue cannot be resolved at Directorate level, the issue will be promoted to the corporate risk register. It was noted that the organisation has changed policies, procedure and protocol as a result of incident reporting in the past and has provided additional training were necessary. The clinical audit programme is also affected by incident reporting on an ad hoc basis and the Trust has identified this as an area for development.

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Training/Staff Awareness

Training on risk management was previously provided to all key staff members in the Trust, however no updated incident reporting training has been given recently. Training on incident reporting occurs during induction for all staff. Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur. No standard feedback policy exists for incident reporting across the Trust. Discussions with staff indicated a reasonable level of awareness of incident reporting and the relevant policies and procedures. Staff did not identify any particular issues with the current system.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also have regular meetings with the Northern Board and feel that all necessary information is communicated on a timely basis.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. The Trust currently has no Medical Device Co-ordinator. The Trust considers NIAIC competent and has had positive experiences with the organisation.

Combined Health and Social Services Trusts

Armagh and Dungannon HSS Trust

Incident Reporting Policy

The Trust is currently in the process of reviewing its Incident policies and procedures, which includes review of its risk management policy and strategy which currently contains elements of its incident reporting policy and procedures. In addition the Trust has a Management of Health and Safety at Work Policy which includes procedures on the Accident/Incident Form and a whistle-blowing policy, however both documents will be reviewed as part of the overall incident and near miss policy review process. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it will accept anonymous reports if they are provided. It was noted that the Trust considers reporting to be improving within all areas of the organisation and believes the new policies and procedures will further assist to promote an open

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reporting culture. Furthermore, the Trust believes that near misses are not appropriately captured with the current IR system, however this is to be addressed when a new IR form and policy are being developed.

Incident Reporting Procedures

Incidents occurring within the organisation are reported on two different forms. All incidents must be either recorded on a clinical incident reporting form or an accident/incident reporting at the time of the incident. Currently incidents are recorded on the form by the relevant staff member and sent to the Service Line Manager for review. Forms are subsequently sent to the Admin Services Manager centrally for review and input onto the system. The Trust is in the process of drafting a new incident reporting form to cover all incidents within the organisation. Currently the Trust does not undertake a process of risk assessment for each incident, however this will be developed along with the review of the incident reporting policy and the review of the risk registers.

The Trust believes its incident reporting systems and processes are still at an early stage of development, but feel the organisation is improving the reporting culture within the organisation on a continual basis. It was noted that feedback is not considered adequate by staff and that lessons learnt were not being shared fully across the Trust. The Trust is due to undertake a full review of procedures related to incident reporting later in 2004.

Incident Reporting Systems

The Trust currently uses the Safecode system to record all incidents occurring within the organisation. The Trust is currently investigating whether it should invest in Datix, as most other trusts in Northern Ireland currently utilise it. Currently the incident reporting system is not fully linked to claims and litigation, risk management and complaints modules, however Datix may be used to address this issue within the Trust. The Trust is currently reviewing its risk management and risk register process, and linkage with the incident reporting system is considered as crucial.

Review of Incidents Reported

There is no formal policy for undertaking investigations of incidents in the Trust. The process is due to change following the review of incident policies and procedures, resulting in all incident reports being reviewed by the Risk Management Committee. It was noted that managers must inform relevant Directors immediately if a significant incident occurs and this process is unlikely to change following the policy and procedures review. If a significant incident occurs, a multidisciplinary group will perform an investigation and report to the Risk Management Committee and the Trust Board. The Trust does not currently use Root Cause Analysis to investigate recorded incidents. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was also noted that the audit programme is also affected by incident reporting.

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Training/Staff Awareness

Training on the completion of the IR forms has not been provided within the Trust generally, however incident reporting training is included as part of its induction training. Feedback to staff after an incident has been identified as an area that needs to be developed by the Trust, as no standard feedback policy exists for incident reporting across the Trust. Staff also appeared to be confused about the terminology surrounding incidents and near misses and the processes required to capture it and report it. Staff stated that the current IR forms are inadequate and that further training would be required. Staff also stated that the Trust needed to embrace the spirit of incident reporting further and not just pay lip-service to the process. Staff generally were aware of the incident reporting system, but felt that it needed further development to increase its effect on patients/clients safety.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. The Trust did state that the role of the Boards in this area is somewhat ambiguous, however it has undertaken significant discussion with the SHSSB to agree what information should be provided and now have an Untoward Events – Service Provider Procedure document in place to cover this area.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that MDEA incidents were not always notified by use of the current incident forms and that informal notification was often used. The Trust stated that NIAIC has always been good at co-ordinating MDEAs at a regional basis and that they had very positive experiences with NIAIC. It was noted that the Trust also reported to RSS (in addition to NIAIC) if problems were identified with items they had supplied. The Trust currently has departmental equipment co-ordinators in position.

Causeway HSS Trust

The Trust has a Clinical and Social Care Governance policy in place, which covers the required incident processes and procedures in place. The Trust has accepted that this policy is outdated and has stated its intention to undertake a full review of all policies related to CSCG, risk management and incident reporting when Datix is implemented in June 2004. The Trust has recently developed a definition for adverse/reportable incidents but has not yet communicated this to staff. It was noted that this policy was developed by the Trust without any guidance form external organisations. The Trust has stated that it would be very keen to consult with other organisations in Northern Ireland (or further afield) regarding incident reporting systems and processes.

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The Trust has now developed Risk Assessment Guidance and this will be provided to all Managers within the organisation. The Risk Management Guidance includes guidance on how adverse incidents should be reported. The organisation currently has a number of different forms for incident reporting, which include a NIAIC form, an accident form, a near miss form, an incidents of violence form, a, untoward event form (for social services), a medication report and a clinical incident form. The large number of different forms has caused confusion as to which form should be used for which incident among staff. It was also noted that no formal procedure exists for reporting incidents within the Trust. The Trust has indicated its intention to bring all of these forms together onto one common incident reporting form, but has identified significant issues in terms of this process.

The Trust does not currently have any formal procedures for co-ordinating investigations of incidents reported within the organisation, and these currently occur on an ad hoc basis. Whilst trend analysis is undertaken in some areas, there is no formal policy and is only undertaken by proactive individuals or groups. The Trust has stated that it wishes to review this process as part of the implementation of Datix and the wider review of CSCG and Risk Management policies.

The NIAIC reporting form is the only incident reporting process that is formal and detailed in procedure. As a result, incidents relating to this area (i.e. medical devices and equipment) are prioritised in terms of the organisations efforts and resources. Much of the discussion with the Trust revolved around this area and did not include reporting of other incidents. It was also noted that the Trust had problems with interpreting NIAIC guidelines and cited lack of guidance from NIAIC as a recurring issue.

Down Lisburn HSS Trust

Incident Reporting Policy

The Trust has a Clinical and Social Care Governance Strategy and Procedures and an Incidents policy providing definitions of incidents and detailed operational policy for all incident reporting within the organisation. The Trust also has a Risk Management Policy in place, which has been provided to all departments within the organisation. The Trust believes its incident reporting systems and processes are still evolving, but feel the organisation is developing an open culture with continually improving reporting, however it was stated that lessons learnt are not being shared fully across the Trust. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms in practice it will accept anonymous reports if they are provided. The Trust also has a whistle-blowing policy in place.

Incident Reporting Procedures

All incidents are currently reported on one three-page long Clinical/Non-Clinical Incident form within the Trust, which include an incident reporting element and an investigation element (requiring information to be provided for the initial stages of investigative review). The Trust

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had previously piloted several versions of the form based on the information required by Datix, and feel that the current form provides the best balance. The Trust has noted a large increase in the number of incidents reported since the introduction of the single reporting form, and now has c4,000 incidents reported per year.

Incident Reporting Systems

The Trust uses the Datix system to record all incidents, and this is linked to Claims and Litigation, Complaints, Controls Assurance and Risk Management (including risk registers) modules on the system. The Trust will be implementing the new Knowledge and Skill module on version 7 of Datix to be launched in April 2004 and has already investigated the possibility of implementing the Data Protection module that will available on Datix from August 2004. The Trust utilises the Datix messageboard to share knowledge and gain an understanding of what other organisations are doing.

Datix is devolved to the Directorates for information purposes, but inputs all the incidents within the Corporate Affairs Department. It was noted that the Trust has tailored its own Datix codes.

Review of Incidents Reported

Line managers in each Directorate review all incident occurring in their area. There is no formal policy for undertaking investigations of incidents in the Trust generally, however each individual Programme Director reviews incidents in that area and decides on further action and investigation. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted that managers must inform the Corporate Affairs Department at Trust Headquarters immediately if death or a serious injury occurs. The Trust does not currently use Root Cause Analysis to investigate recorded incidents, however it feels that it uses the theory and spirit of it within the investigative process if not the exact science.

The Trust Governance Committee and individual Programme Directors are provided with Quarterly Incident Reports (by the Corporate Affairs Department) detailing the number and types of incidents occurring. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was also noted that the multi-discipline audit programme is also affected by incident reporting however the Trust would like to develop this area further.

Training/Staff Awareness

Training on the completion of the single IR form was provided to the majority of staff in the Trust when it was launched, covering all managers and senior staff in all Directorates and areas in the organisation. Training on incident reporting also occurs during induction for all staff.

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Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur and no standard feedback policy exists for incident reporting across the Trust.

Discussions with staff indicated a good awareness of incident reporting policy and procedures. Staff in some areas appear to be unsure as to the role of NIAIC and all staff felt that full reporting was not occurring due to cultural issues such as perceived disciplinary outcomes from reporting.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also has a regular meeting with the Eastern Health and Social Services Board and provide details of untoward events when they occur. The Trust did state that clarity is required in relation to the accountability issue between the Board and the Trust, especially in relation to what incident reporting information the Board require and for what purpose.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that while the Trust has not reported many incidents to NIAIC, they have never received any investigative input from NIAIC, with all investigations being undertaken by the manufacturers or the Trust themselves. The Trust also stated that it would be useful if alerts sent to the organisation could be filtered more appropriately. The Trust does not have a Medical Device Co-ordinator.

Newry and Mourne HSS Trust

Incident Reporting Policy

The Trust has a Clinical and Social Care Incident Strategy and Procedures and an Accidents/Incidents policy providing definitions of incidents and near misses and detailed operational policy for all incident reporting within the organisation. The current definitions used by the Trust are based on definitions used in other organisations i.e. the National Patient Safety Agency which have been tailored to meet the organisation's requirements. The Trust also has Clinical and Social Care Governance/Risk Management Strategy and a Risk Management Policy in place, which has been provided to all departments within the organisation.

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The Trust believes its incident reporting systems and processes are still evolving, but feel the organisation is developing an open culture with continually improving reporting, however it was stated that lessons learnt are not being shared fully across the Trust. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms in practice it will accept anonymous reports if they are provided. The Trust have identified that the Health Directorates of the Trust are more familiar with reporting incidents under the current process than the Social Service Directorates, due to differing cultures having developed.

Incident Reporting Procedures

All incidents are currently reported on one Accident/Incident Report form within the Trust, which include an incident reporting element and an investigation element (requiring information to be provided for the initial stages of investigative review). The Trust have piloted several versions of the form based on the information required by Datix, and feel that the current form provides the best balance. The Trust has noted a large increase in the number of incidents reported since the introduction of the single reporting form.

Incident Reporting Systems

The Trust uses the Datix system to record all incidents, and this is linked to Claims, Complaints, Controls Assurance and Litigation modules on the system. In addition, the Trust is working on bringing the risk registers onto the system to replace the current word document arrangement. The Trust will be implementing the new Knowledge and Skill module on version 7 of Datix to be launched in April 2004 and has already investigated the possibility of implementing the Data Protection module that will available on Datix from August 2004. The Trust also aims to utilise the improved report writer on version 7 of Datix for increased trend analysis data. The Trust utilises the Datix messageboard to share knowledge and gain an understanding of what other organisations are doing.

Datix is not devolved to the Directorates and the Trust splits the inputting into two areas – clinical/social care incidents (e.g. patients/clients service incidents) and non-clinical/social care incidents (e.g. health and safety incidents). One dedicated Datix inputter under the supervision of the CSCG Co-ordinator codes at all clinical and social care incident forms. A different dedicated Datix inputter under the supervision of the Administrative Services Manager inputs all non-clinical and social care incident forms. The CSCG Co-ordinator and the ASM code their relevant IR forms according to the risk matrix before they are input onto Datix. It was noted that the Trust has tailored its own Datix codes.

Review of Incidents Reported

Incidents are graded as green, yellow, orange or red by the individual reporting the incident (with red being the most serious) and investigated accordingly. Green and yellow incidents are investigated by department staff and the relevant manager; orange incidents are investigated by the department manager and the line manager; whilst a major incident investigation team is established for a red incident. An internal report and timebound action plan is produced for both orange and red incidents and is reviewed by the Clinical Governance and Risk Management

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Committee. The Trust have detailed procedures for this process, which all staff have access to. The organisation will utilise root cause analysis for major incidents and training has been provided to key staff to undertake this process. The Trust have identified feedback of lessons learnt and knowledge share as key elements for development within the organisation.

The Trust Clinical & Social Care Governance and Risk Management Committee is provided with Quarterly Incident Reports detailing the number and types of incidents occurring within the Trust. It was noted that abuse to staff and falls were the two most common incidents in the Trust. It was noted that the organisation has changed policies, procedure and protocol as a result of incident reporting in the past and has provided additional training were necessary. The clinical audit programme is also affected by incident reporting based on the action plans resulting from the major incident investigation teams.

Training/Staff Awareness

Training on the completion of the single IR form was provided to key staff members in the Trust when it was launched, covering all managers and senior staff in all Directorates and areas in the organisation. Training on incident reporting also occurs during induction for all staff. Key staff have also received full training on incident investigation including root cause analysis training. Feedback to staff after an incident has been reported is the responsibility of each Directorate and as a result inconsistencies occur. No standard feedback policy exists for incident reporting across the Trust, and the organisation has identified this as an area that needs to be developed.

Discussions with staff indicated differing levels of awareness of incident reporting in different areas and it was noted that social services staff did not appear to be as aware as health staff of the policies and procedures. Staff in all areas appeared unsure as to the role of NIAIC and all staff felt that full reporting was not occurring due to cultural issues such as perceived disciplinary outcomes from reporting. It was also noted that junior or new staff were less familiar with the policies and procedures than more senior staff. One new member of staff stated that she had not received any training in incident reporting, but was aware where the incident reporting book was if required.

Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is well covered by the relevant contracts and Service Level Agreements. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust also has a regular meeting with the Southern Health and Social Services Board and provide details of untoward events when they occur. The Trust did state that clarity is required in relation to the accountability issue between the Board and the Trust, especially in relation to what incident reporting information the Board require and for what purpose.

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NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. It was noted that while the Trust has not reported many incidents to NIAIC, they have never received any investigative input from NIAIC, with all investigations being undertaken by the manufacturers or the Trust themselves. The Trust also stated that it would be useful if alerts sent to the organisation could be filtered more appropriately. The Trust has a Medical Device Co-ordinator.

Sperrin Lakeland Health & Social Care Trust

Incident Reporting Policy

The Trust has a "Clinical & Social Care Governance – Strategy for Ensuring Quality" Policy in place and implemented a Risk Management Strategy in February 2004. The Trust has also produced a Corporate Report and Proposed Action Plan for implementation of CSCG and has an annual report entitled "CSCG – Delivering a Quality Service". The Trust has "Guidelines for completing the Trust Incident Reporting Form" which is used throughout the organisation for all incident reporting. In addition, the Acute Directorate has "Guidelines for Improving the Reporting and Learning from Adverse Incidents and Near Miss Events", which includes definitions of adverse clinical incidents and near misses. The Trust also has Untoward Event Policy and Procedures in place, which relate specifically to the Mental Health and Community Directorates. The Trust does not advocate anonymous reporting and whilst it requires staff to sign off incident reporting forms, it has a whistle-blowing policy and in practice will accept anonymous reports if they are provided.

Incident Reporting Procedures

The Trust introduced one "Incident Reporting Form" in June 2003 and this is now used across the organisation for all incidents. The Acute Directorate also has an "Adverse Clinical Incident and Near Miss" form, which must be completed in addition to the IR form. This form is for use only within the Directorate and does not go to Risk Management for analysis/action. NIAIC alert forms, statutory forms and Medication forms are also completed by staff within the organisation in addition to the IR form. The Trust has noted a large increase in the number of incidents reported since the introduction of the single reporting form and of Datix, however it is felt that a significant number of staff would still be reluctant to report certain incidents. The Trust does not feel there is any particular split in terms of professions or Directorates for non-reporting and stated that it was down to individual attitudes. The Trust does feel that this number is reducing as the open culture of reporting improves within the organisation.

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Incident Reporting Systems

The Trust uses the Datix system to record incidents, and this is linked to Risk Management, Claims and Litigation modules on the system. The Trust did however state that this link is not being fully exploited yet and that further development in this area would need to be undertaken. There are currently two trained Datix inputters within Risk Management who code and input all non-clinical incidents within the Trust. The Trust stated that there is currently no backlog of non-clinical IR forms needing to be input. The Trust also has four trained Datix inputters within the Acute Directorate, however it was noted that currently all these staff members are absent from work and thus a significant backlog has developed for clinical incident inputting within the Trust.

Medication-prescribing incidents are not inputted onto the Datix system, but medication administration incidents are. The Pharmacists require that a separate recording tool be used in line with the Medication Governance Project, therefore input to Datix does not occur.

Review of Incidents Reported

The Risk Management Department will review every IR form when it is received to ensure no serious issues are arising. IR forms should already be coded using the Datix Matrix and thus indicating the level of seriousness. There is no formal policy for undertaking investigations of incidents in most areas, however the Trust feels that all significant incidents are fully investigated. It was noted that formal procedures exist for major incident reviews within Mental Health (as part of their statutory reporting requirements). Otherwise, the Trust encourages the local team where the incident occurred to undertake most of the investigation and thus identify lessons learnt. It was noted that managers must inform Risk Management immediately if something serious occurs, however no formal definition of "serious" exists.

The Senior Management Team is provided with "Quarterly Incident Reports" and "Exception Reports" detailing specific serious incidents and the actions that need to be taken to resolve them. No formal feedback is provided to staff members who report the incidents or to staff generally, however some informal feedback may be given at the time an incident is reported. It was noted that the organisation has changed policies, procedure and protocol as a result of incident reporting in the past. They have also provided additional training were necessary and this was exampled by the change in protocol after a high level of falls incidents were noted on wards. The clinical audit programme is affected by incident reporting on an ad hoc basis and the Trust has identified this as an area for development.

Training/Staff Awareness

Training on the completion of the IR form was provided on an ad hoc basis to staff members in the Trust, however it was noted that this did cover a significant number of areas. A series of training sessions occurred in 2002-03 over a four-month period for medical and nursing staff in relation to clinical incidents. The Risk Management team also provided training on the Datix system when it was implemented in October 2003. Training is provided at induction at ward level only and no formal training for individuals involved in investigation has occurred. Staff generally

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appeared to be aware of incident reporting and the process, although formal training and feedback appeared to be lacking. Staff also demonstrated some general confusion concerning the definitions of incidents, untoward events and near misses. Some areas also stated that a reluctance to report arose from the culture of discipline and whilst reporting was improving, it still has significant progress to make.

Third Party Relations

The Trust feels that the area of incident reporting in relation to independent contractors requires development. Whilst areas such as Domicillary Care have a Contracts Monitoring Officer responsible for such elements, this is not consistent across the organisation. Agency staff i.e. nurses are provided with on-the-job-training regarding incident reporting and are continually supervised to ensure quality care is delivered. The Trust did feel that the area of lone workers (e.g. medical locums) needs to be reviewed for incident reporting as no formal policies or procedures currently exist.

NIAIC

NIAIC alerts are reviewed by a group including the Business Service Manager, the Nursing Manager and Risk Management individuals when they are received to identify who in the organisation they should be forwarded to. This results in alerts taking up to two weeks to be fully disseminated throughout the organisation. The Trust feels it is one of the organisations that are least likely to report incidents to NIAIC, due to perception of poor feedback and delayed investigation.

Ulster Community and Hospitals Trust

Incident Reporting Policies

The Trust defines an adverse incident as an event that has caused patients/clients harm, whereas a near miss has not caused harm, but had the potential to. The Trust feels that a strong reporting culture has developed in the organisation with most incidents now being captured by the reporting system. It was noted however that the Trust felt that under-reporting may occur for medicines incidents, despite the fact that reporting in this area has increased significantly over the last 1-2 years. The Trust believes that the disciplinary/open culture line is very clear, with suspension still occurring for serious incidents.

The organisation is keen to put ownership of incident reporting area onto the Trust Board with the Chief Executive undertaking a Champion role in the Trust. The Clinical & Social Care Governance (CSCG) Group and Risk Management Group are the main groups that incident are reported to, however the Trust Board receives full communication of significant issues. The Trust has a "Near Miss and Incident Policy" in place which promotes an open culture within the organisation regarding incident reporting. The Trust also has a whistle-blowing policy in place, which is to

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be included in the Risk Management Strategy in the future. The Trust also intends to produce a summarised leaflet version of the Risk Management Strategy for staff information.

The Trust has suggested that an overall incident reporting strategy for Northern Ireland would be beneficial. The Trust also identified lack of knowledge share between Trusts and Boards as a key weakness in incident reporting in Northern Ireland. The Trust questioned how the Boards are currently addressing the risk agenda and suggested that there has been a lack of guidance from Boards over the last 10 years. The Trust have also suggested that a review of statutory reporting to Boards be undertaken, especially in relation to child protection and the addition of incidents to the child abuse register.

Whilst the Medicines Governance Project was set up to run regionally, it is to be implemented locally. Incident reporting involving medicines gets feed through the Trust and through the region via the Medicines Governance Group. The Mediform reporting document (used only for medicines reporting) is anonymous due to professional groups (i.e. pharmacy, medical and nursing staff) objection to naming staff in such circumstances. The Pharmacy department stated that King's College and Alder Hay also use anonymous reporting in this area. A recent survey[10] in this area identified disciplinary issues as a major barrier to medicine incident reporting, however the Trust has identified that reporting has actually increased in this area. Despite the anonymity of reporting within medicines, investigations are performed without significant problems and are usually based on patients/clients details (which are included for incident reporting). An outcome paper is prepared for the Medicines Governance Steering Group (organised by the DHSSPS) giving details of all incidents involving medicine incidents in the Trust. The Director of Pharmacy has stated reservations concerning merging the two existing incident reporting systems (i.e. Mediform and IR1 forms). Risk management has an opposite opinion on this issue and this could prove to be a major source of division within the Trust in this area.

Incident Reporting Procedures

The Trust has two different forms for reporting incidents: the Mediform for all Medicine related incidents and the Incident Reporting 1 form for all non-Medicine incidents, however the Trust wishes to integrate the two forms. When an incident or near miss occurs in the Trust, three copies of the Incident Reporting 1 ("IR1") form must be completed (one for risk management, one for the ward/department and one for the second service involved if necessary). Anonymous reporting is not advocated within the Trust, however the Mediform is currently completed anonymously for medicine incidents. The Risk Manager reviews all IR1 forms and at this point a decision is made as to whether further investigation into the incident is required. An investigation will either require the completion of an Incident Reporting 2 ("IR2") form by the originating Department or the completion of a Serious Incident Review. If the incident requires a serious incident review, no IR2 form is required.

[10] "Reporting Medication Incidents Questionnaire"

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The Trust has noted that some staff do not complete the forms accurately. To counter this, the Trust has developed a policy framework, which provides guidance on completing the incident reporting forms. The Trust will also provide additional training to individuals if a need can be identified. Weekly and monthly meetings occur to discuss the incidents and provide some knowledge share. Examples of where incident reporting has affected further study include the high levels of patients/clients falls, which has resulted in a project being undertaken in this area.

The main incidents occurring within the Trust were stated as needle sick injuries, patients/clients falls and issues of consent. The syringe policy has been reviewed based on statistics from incident reporting. The Trust has identified a higher level of reporting by nurses, including healthcare assistants than by medical staff, although sharing knowledge has been identified as poor across all areas. The Trust has also identified that ICU incident reporting is lower than other departments within the organisation. The department originally had its own anonymous reporting structure, and the change in procedure is blamed for the reduction in incidents reported. Issues noted within this ward included CSSD issues and consent forms not being completed properly.

Incident Reporting Systems

Information provided through the IR1 and IR2 forms and from the serious incident review is input onto the Datix system, which was implemented in April 2003. The Datix system does not contain any information from before April 2003. The Trust has three Datix inputters who input all information within 2-3 days of receiving it and as a result there is no incident reporting backlog. All the inputters are trained internally and undergo weekly checks to encourage consistency and quality of input. A member of the Medicines Governance Project codes all medication incidents, while all other clinical incidents are coded by the Litigation Services Co-ordinator. The data inputters code all non-clinical incidents. The Trust noted that no agreed coding system is used across Northern Ireland for consistency. The resulting incident reports are reviewed and checked by the Risk Manager for accuracy. The Trust's Risk Manager currently chairs the Datix Users Group in Northern Ireland.

All areas within the Datix system require to be populated, although the individual reporting the incident does not always have to give their name. It was noted that the Datix system is not considered compatible with the HR system but that the Trust would like to address this issue. The Trust has found that IR forms do not always give the Patient ID Number, and this can cause problems when trying to link patients/clients with common names to complaints and litigation history. The Trust plans to make all fields mandatory in the future to allow cross-checking to occur. The incidents, complaints and litigation claims modules are currently linked on the Trust's IT system. Whilst the risk register and controls assurance modules are not currently linked on this system, there are plans to address this in the near future. The risk register module will eventually be used in overall risk management review including new strategy and risk policy.

Review of Incidents Reported

Serious Incident Reviews act as the main source of internal review within the Trust, especially for incidents that involve sensitive areas such as Mental Health Act requirements. The threshold used to describe an incident as "serious" is deliberately set low within the Trust due to a

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perceived lack of knowledge on the subject existing within the Trust. Serious incident reviews will commence with a review meeting (based on learning approach). Maurice Dunlop chairs the Serious Incident Review Group. This process can cover any incident occurring within the Trust and will involve review of root causes, identification of lessons learnt and will result in recommendations being made. Details of the incident and investigation findings are provided to the Clinical & Social Care Governance Group for endorsement of the recommendations made. The CSCG Risk Management Committee also receives trend analysis bi-monthly, which some individuals within the Trust consider the most useful element of incident reporting output.

Serious Incident Review findings are e-mailed to all senior staff and are sent by letter to individuals who need to complete an action to satisfy the recommendations made. The findings are also sent to the Eastern Health and Social Services Board and the Mental Health Commission (where appropriate). The Trust is unaware of any mechanism to formally provide such information to other organisations within the region, and would be keen to see a regional forum for such communications. Statutory reporting for the EHSSB and the Mental Health Commission is done through Risk Management, with all other professional and statutory reporting completed by the relevant department. The Trust does wish to consider, however, how Child Protection statutory reporting is undertaken within the organisation, as it is a controversial and sensitive area.

The Clinical & Social Care Programme is addressed through the Risk Management Group and audit of relevant areas. Clinical Audit ensures that incidents identified to the Risk Management Group are addressed appropriately, but planning audits within the areas that incidents have occurred. The CSCG Committee and the Risk Management Committee are merged into an overall Governance Committee and complaints, litigation and incident reporting are analysed together for consistency purposes.

Training/Staff Awareness

Discussions with staff indicated various levels of understanding of incident reporting within the Trust. The majority of staff interviewed considered that the Trust had an open culture in relation to incident reporting and were aware of the incident reporting policy (however, not all staff had directly been involved in reporting an incident). Staff in ICU were the exception, and appeared to be least satisfied with the incident reporting process, stating that lack of confidentiality previously during incident reporting had resulted in a reluctance to report within the department. They also stated that they had not received specific training on incident reporting and were not aware of the incident reporting policy. Furthermore, they stated that they did not receive feedback when incidents were reported.

It was noted that some Consultants had observed different terminology being used in different Directorates of the Trust in relation to incident reporting. Staff also appeared to be confused about the difference between that Mediform and the IR1 form and the levels of training appeared to have differed across the organisation. Training in incident reporting is due to occur for all new Pharmacy staff, during Junior Doctor Induction and for nursing staff. However, staff interviewed in Mental Health, ICU, Theatres or Maternity had received no formal training.

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It was noted that while the Consultants interviewed felt that feedback from incident reporting was poor, other medical staff appeared satisfied with the level of feedback. Feedback was given through critical incident meetings and monthly Directorate meetings. All staff interviewed felt that knowledge share between departments and other organisations could be improved, with most unaware of any information arriving from other areas regarding lessons learnt.

Third Party Relations

Independent providers must notify Department Heads of any incidents occurring in relation to the Trust. This information is subsequently provided to Risk Management and included within incident reporting reports and reviews. Departments are also responsible for incident reporting by temporary or agency staff working under their control. This includes providing appropriate training on incident reporting and completing a return to state that it has been undertaken.

NIAIC

The Trust has experienced problems in relation to medical devices in the past due to the technical nature of the issues. Medical device bulletins are sent from NIAIC to the Trust's NIAIC Liaison Officer, who disseminates the information to the relevant individuals within the Trust. The distribution list used by the Trust is that indicated by NIAIC. As no Medical Devices Co-ordinator exists in the Trust, information relating to this area is widely disseminated to all areas e.g. clinical areas, suppliers etc. Those sent the bulletin must reply to the NIAIC Liaison Officer to state how they have dealt with the issue; however no monitoring of non-returns is undertaken. Equipment Controllers exist in each Acute Directorate to check all equipment coming in. The Risk Management Department, not the NIAIC Liaison Officer, sends any required correspondence to NIAIC (e.g. feedback forms, incident forms).

The Trust feel that IR2 (Medical Devices) form does not work particularly well as it frequently requires technical guidance to complete. NIAIC will subsequently only investigate high-risk cases. The NIAIC systems appear to be well in place and a good working relationship exists, but NIAIC are often slow to respond due to their resource limitations. The Trust does feel that NIAIC provide a good level of technical knowledge related to medical devices, however the role is considered as limited and feedback is infrequent. The Trust would be keen to see NIAIC's role increased within the area of incident reporting, including the promotion of a NIAIC website and the co-ordination by NIAIC of inspections into all incidents (not just medical devices). The Trust also suggested that NIAIC and the Medicines Governance Group should merge to provide one group responsible for all incidents within Northern Ireland.

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Northern Ireland Ambulance Service Trust

Incident Reporting Policy

The Trust has a Health & Safety at Work Policy providing detailed operational policy for reporting. The Trust also has a Clinical Governance Implementation Plan, a Risk Management Policy and a whistle-blowing policy. The Trust believes its incident reporting systems and processes are still evolving, but feel the organisation is developing an open culture with continually improving reporting, however it was stated that lessons learnt were not being shared fully across the Trust.

Incident Reporting Procedures

The Trust is currently reviewing its incident reporting procedures in line with the implementation of Datix.

Incident Reporting Systems

The Trust has just implemented the Datix system to record all patients/clients safety incidents, non-clinical adverse events, near-misses and unexpected outcomes. In addition, the Trust is working on bringing the complaints, claims and litigation and risk management modules and risk registers onto the system to replace the current word document arrangement. Datix will assist the organisation to identify trouble spots, which will enable them to assess and prioritise the risks as part of a comprehensive governance solution.

Review of Incidents Reported

There is no formal policy for undertaking investigations of incidents in the Trust generally, however investigations are undertaken based on the risk assessment done by the Head of Governance. The Trust feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. The Trust does not use Root Cause Analysis to investigate recorded incidents. The Trust is currently looking at improving formalised system of documentation control and reporting.

Training/Staff Awareness

Training on incident reporting has been included in training of technicians and pararmedics at Regional Ambulance training centre. Training is also incorporated in the Beeches Management School training. Training is to be reviewed in light of the new Datix system and the current review of the entire incident reporting system. No standard feedback policy exists for incident reporting across the Trust.

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Third Party Relations

The Trust stated that the area of incident reporting in relation to independent contractors is not applicable.

NIAIC

The Trust has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within 24 hours of receiving them to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also receive and review IR forms and assess if any are reportable to NIAIC. The Trust currently has no Medical Device Co-ordinator. The Trust considers NIAIC competent and has had positive experiences with the organisation.

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Appendix VII
Special Agencies

Northern Ireland Regional Medical Physics Agency

The Agency has 100 staff and provides specialised scientific, technical and clinical services primarily to Trusts. The Agency will often be the first port of call if problems arise with specialised equipment and it has clinically trained technicians to address these issues. A quinquennial review indicated that overlaps exist between the Agency and NIAIC, however these are not considered to be significant and the Agency believes its role to be quite clear within the health service. Staff are based at several hospitals and work closely with individual Trusts. The Agency has policies for accidents and incidents, adverse incident reporting (equipment and supplies), whistle blowing, risk management, health & safety (risk assessment) and hazard and safety action notices.

The Agency has one incident form for all incidents, however they must also fill in the incident form of the host organisation if an incident occurs on that organisation's site. This additional responsibility has the potential to cause some confusion as the IR systems differ from Trust to Trust, however the Agency is confident that reporting is completed accurately with the guidance of staff from the host organisations. The Agency did state however that the definitions of incidents and near misses have caused confusion in the past. The Agency has a very small number of incidents and as a result conducts an investigation on each one that occurs. Whilst the organisation has no formal feedback procedures, its small size makes communication straightforward and all incidents are discussed at team meetings with all staff.

The Agency does not currently utilise any IT to record or analysis reported incidents, however it has ordered Datix so that it will be in line with the Trusts that it operates in. The Agency has a dedicated NIAIC Liaison Officer, and receives NIAIC alerts. The Agency does not have any formal communication arrangements with the Trusts, Boards or the DHSSPS and all knowledge share occurs on an informal basis.

NI Blood Transfusion Service

Incident Reporting Policy

The NIBTS's incident policies and definitions are included within the organisation's Standard Operating Procedures (SOPs), however no one document exists covering all elements of incident reporting. The NIBTS has a Risk Management policy in place and intends to review it in the next few months and combine its Risk Management Committee with its Clinical Governance Committee. The revised Risk Management Strategy should allow the organisation to improve co-ordination and collation of information arising from current incident reporting processes. The NIBTS does not currently have a whistle-blowing policy in place, however it stated that it would be keen to review this area. The NIBTS does not advocate anonymous reporting and requires staff to sign off incident reporting forms and it was noted that no anonymous reports had ever been submitted.

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Incident Reporting Procedures

The NIBTS has procedures for the reporting of Adverse Incidents within its Standard Operating Procedures (SOP). As the organisation is heavily regulated (e.g. by the MHRA) it must formalise all procedures thoroughly using this system. There are several SOPs which address incident reporting within the organisation, including one dealing with the procedure for reporting adverse events and a procedure for reporting and managing quality incidents. The NIBTS has essentially four different processes for reporting different types of incidents within the organisation (in addition to the complaints procedure):

- Quality Incidents Report Forms – used to report any internal defect that could cause harm to a donor or patients/clients;
- NHS Incident Record (Form IR1) – used for all other internal incidents including fire, security, clinical, physical or verbal abuse;
- Donation Process form – used to record every donation, but will be passed to the Medical Director if an incident has occurred;
- Defect Reporting Procedure – covers incident reporting to NIBTS by external organisations.

This results in four different potential sources of incident reporting for the organisation, however it is accepted that there are in essence two main incident reporting forms (the Quality Incident Form and the NHS Incident form). The organisation has previously been criticised by DHSSPS Internal Auditors for not having just one incident reporting form, however it believes that due to the nature of its work the current system is more appropriate. Whilst the system appears complex and potentially confusing, the NIBTS stated that all staff understand the process well.

Incident Reporting Systems

The NIBTS utilises the Q-Pulse and Safecode systems to record incidents within the organisation. Q-Pulse is part of an overall quality management system, whereas Safecode is specifically designed to log Health & Safety incidents (including security incidents). The quality incident report forms are sent to the Quality Manager for review and are input on to the Q-Pulse system. The NHS Incident Record (Form IR1) is sent to the Facilities Manager for review and input onto the Safecode system. The organisation has indicated a desire to investigate the Datix system further based on awareness that most of the HPSS Trusts are now using it, however it is content with the systems it currently has in operation.

Review of Incident Reporting

There is no formal policy for undertaking investigations of incidents in the NIBTS generally, however the Quality Manager and Facilities Manager review the incident forms they receive prior to input and decide on further action and investigation based on the relevant SOP. The organisation feels that all significant incidents are fully investigated despite the lack of consistent policy across the organisation. It was noted

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that the managers will highlight significant incidents to the Risk Management Committee if they occur. The NIBTS uses the theory of Root Cause Analysis to investigate recorded incidents, however training in this area has not been received by any individual:

The NIBTS Risk Management Committee and individual Directors/Managers are provided with Monthly and Quarterly Incident Reports (from the Q-Pulse and Safecode systems). The monthly report details the number and types of incidents occurring, while the quarterly report provides analysis of specific incidents that have occurred and actions planned. It was noted that the organisation has previously changed service procedures and protocol as a result of incident reporting in the past and has provided additional training or guidance were deemed necessary. It was noted that Blood transfusion incident reporting is in an advanced state across the UK in relation to the sharing of knowledge and lessons learnt related to transfusion practice.

Training/Staff Awareness

Training on incident reporting is provided within the staff induction programme. No further training has been provided in relation to incident reporting within the organisation. No formal process exists for feeding back information to staff after an incident has been reported, however the organisation believes that due to its size this is not a significant issue.

Third Party Relations

The NIBTS stated that while there are no formal links with Boards and Trusts regarding incident reporting, that meetings will occur with Trusts if an incident occurs. The NIBTS also holds a Users Group where any user can discuss issues such as incident reporting. The organisation did state that they are aware of different reporting cultures in different HPSS Trusts. The NIBTS also have a regular meeting with the DHSSPS to discuss individual incidents and feel that all necessary information is communicated on a timely basis.

NIAIC

The organisation has a nominated NIAIC Liaison Officer who will disseminate NIAIC alerts within one day of receiving them (after consultation with senior managers) to the individuals and groups specified on the NIAIC distribution list. The NIAIC Liaison Officer will also review IR forms with senior managers and assess if any are reportable to NIAIC. It was noted that the organisation receives a large number of irrelevant alerts from NIAIC and would be keen for these to be better filtered. The NIBTS stated that it was aware of resource issues within NIAIC, but said that it had found NIAIC to be useful in the past, especially as a contact and first port of call for medical device and equipment queries. The Trust currently has no Medical Device and Equipment Co-ordinator.

The NIBTS stated that as license holders from the Medicines and Healthcare products Regulatory Agency (MHRA) they have direct links with the agency which often duplicates its relationship with NIAIC. The organisation would be keen to address this issue if possible.

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Central Services Agency

Incident Reporting Policy

The CSA (including the Regional Supplies Service) have a Health & Safety Policy in place, which includes a section on incident reporting. The organisation also has a Risk Management Policy and Strategy aimed at compliance with controls assurance, however neither document are particularly detailed.

Incident Reporting Procedures

The CSA and RSS break incident reporting into two categories. Firstly corporate CSA incidents which include reporting theft, IT issues, personal accidents etc., however these occur in very small numbers e.g. there were only ten incidents reported during 2003. Secondly there are incidents reported to the RSS from the Trusts related to medical products. It was noted that inconsistency of approach exists in this area, as most Trusts report these incidents directly to NIAIC, with only some organisations reporting them to RSS as well. The RSS will forward the information onto NIAIC if it is reported to them, and will also undertake trend analysis on the information that they are given. This information is then shared with the manufacturers if the RSS believes a significant issue exists.

Incident Reporting Systems

The CSA, including RSS, utilise Microsoft Access to record all incidents currently, however they are in the process of procuring Datix. The main objective of implementing Datix is to utilise the risk management and risk register tools, in conjunction with the claims and litigation, complaints and incident reporting modules.

Review of Reported Incidents

All incidents reported within CSA or to CSA/RSS by other organisations are investigated. The organisation does not undertake root cause analysis or risk assessment of individual incidents.

Training/Staff Awareness

The organisation provides guidance to staff on incident reporting through the Customer Good Practice Guide within RSS. No further incident reporting training is provided, however staff are reasonably aware of how incidents should be reported due to the size of the organisation.

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Third Party Relations/NIAIC

The CSA and in particular the RSS, feels that the links between the RSS, NIAIC and individual Trusts needs to be communicated better to the Trusts as confusion appears to exist among some of the Trusts. Concerns were also raised as to whether the CSA Corporate get all the MDEAs in addition to RSS, as the Quality Manager would be keen to view all correspondence on top of the alerts sent to RSS.

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Appendix VIII
NIAIC Review 2002 – Findings

Analysis of Findings

Adverse Incident Reporting and Investigation

- 96% of responses indicated that they have a management policy in place for reporting adverse incidents to NIAIC (Q1A).
- 96% of responses indicated that it was appropriate for NIAIC to assess the level of risk on receipt of an adverse incident report to determine the most appropriate action (Q1B) however 79% of responses indicated that we should not concentrate on "high-risk" device incidents only (Q1C).
- 87% of responses indicated that NIAIC assists in Clinical Governance issues (Q1D).
- 79% of responses indicated that they did not think that clinical governance or risk management reduces the level of incident reporting to NIAIC (Q1E).
- 62% of responses indicated that they are completely satisfied/satisfied with the way that NIAIC investigates incidents with 21% indicating that they were neither satisfied nor dissatisfied and 17% indicating that they were totally dissatisfied/dissatisfied (Q1F Part 1).
- 61% of responses indicated that they are completely satisfied/satisfied with the speed of the NIAIC investigation of incidents with 29% indicating that they were neither satisfied nor dissatisfied and 10% indicating that they were totally dissatisfied (Q1F Part 2).
- 54% of responses indicated that they are completely satisfied/satisfied with the level of investigation communication from NIAIC with 32% indicating that they were neither satisfied nor dissatisfied and 14% indicating that they were totally dissatisfied/dissatisfied (Q1F Part 3).
- 100% of responses thought that the NIAIC investigation reduces the risk of incident recurrence (Q1G).
- 50% of responses indicated that NIAIC should give more technical advice (Q1H).
- 63% of responses indicated that NIAIC should give more training advice (Q1H).
- 50% of responses indicated that NIAIC should do more in assessing the risks involved in incidents (Q1H).
- 29% of responses indicated that NIAIC should be more thorough in incident investigations (Q1H).
- 29% of responses indicated that NIAIC should do give more advice on incident reporting procedures (Q1H).

Content and Relevance of Device Bulletins and other Guidance material

- 100% of responses considered that Device Bulletins are useful (Q2A).

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- 96% of responses indicated that their organisational arrangements for distribution of Device Bulletins ensures that appropriate staff receive them (Q2B)
- 96% of responses indicated that the format of Device Bulletins was clear (Q2C).

Distribution and Targeting of Warning Notices

- 100% of responses indicated that warning notices took longer than 24 hours to reach the intended recipient (Q3A Part 1).
- 50% of responses indicated that warning notices took longer than 24 hours but less than 48 hours to reach the intended recipient. Q3A Part 2).
- 29% of responses indicated that warning notices took longer than 48 hours but less than a week to reach the intended recipient. (Q3A Part 3). Half of these responses where from Community Trusts.
- 21% of responses indicated that warning notices took longer than a week to reach the intended recipient. (Q3A Part 4). Responses indicating this outcome came from 2 Boards, 1 Mixed Trust and 2 Community Trusts.
- 92% of responses indicated that the format of warning notices make it clear what the problem is and what to do about it (Q3B).
- 87% of responses indicated that it would be acceptable to exclusively use e-mail for warning notice issue to their organisation (Q4B).

NIAIC Website

- 58% of responses indicated that they found the website useful, 21% indicated that they did not find it useful and 21% did not comment (Q4A).
- Those who found the website useful indicated that they liked the availability of a warning notice library. Regional Supplies indicated that they would like to use the warning notice facility of the website for their organisation process in alerting staff to safety issues provided the website was updated quickly. At present this is not the case – NIAIC forward Internet material to DHSSPS information office who are then responsible for DHSSPS Internet Site maintenance (Q4B).
- 46% or responses indicated that they had used the site to obtain documents online, 42% indicating that they have not used this facility and 12 % did not comment (Q4C). 3.2.26. 25% of responses indicated that it would be acceptable if Device Bulletins and other guidance material were only published on the website but 63% indicated that this would not be acceptable and 12% did not comment (Q4D).
- 42% of responses indicated that they found the on-line reporting facility useful with 46% indicating that did not find it useful and 12% did not comment (Q4F).

Conclusions

Adverse Incident Reporting and Investigation

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- The responses to Q1B and Q1C would support the current NIAIC incident risk assessment process provided that we considered that "lowrisk" device incidents could actually result in "high-risk" outcomes.
- HSS organisations have indicated that NIAIC has a role to play in development and support of Clinical and Social Care Governance.
- The "satisfaction" indicators for NIAIC investigation are generally acceptable leaving scope for improvement.
- On questions concerning where NIAIC can do more, there is a clear indication that HSS organisations would welcome increased practical advice and training on device management.

Content and Relevance of Device Bulletins and other Guidance material

- A good response covering Device Bulletins and other Guidance material.

Distribution and Targeting of Warning Notices

- The question concerning distribution times for warning notices was specifically related to the highest level of notices, Hazard and Advice Notices. It is disappointing therefore that no response indicated that this level of notice would not reach the intended recipient within 24 hours. This compares unfavourably with NHS Trusts in England and Wales where over 70% have claimed to have forwarded to relevant recipients within 24 hours of receipt from the Medical Devices Agency (MDA) (source: MDA Hazard Notice survey 2002). This would warrant further study.
- There are clearly some logistical difficulties in distribution of warning notices from Boards - R&I Units to Residential and Nursing Homes and Private Clinics, and within some mixed and community Trusts, probably from the area of social care. This would also warrant further study.
- There is a clear case for exploring the move to exclusive use of e-mail for the issue of warning notices.

NIAIC Website

- A generally disappointing response concerning the use of the website. A possible reason is the availability of Internet access within HPSS organisations, a situation that can only improve with time.
- A very low acceptability from respondents for exclusive publication using the Internet site. This supports continued hard copy publication in the short to medium term at least.

Recommendations

- Explore with HPSS organisations the development of risk assessment of incidents with incident investigation at HPSS organisational level with NIAIC support.
- Explore areas for possible NIAIC support in the development of training at HPSS organisational level in device management.

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- Explore development in HPSS systems for improvement in speed of warning notice distribution with a particular focus on mixed, community Trusts and social care providers.
- Explore the possibility for moving to e-mail issue of warning notices.
- Review in the medium term a move to exclusive publication using the Internet depending on ICT developments in this area.

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Appendix IX
Safety in Health and Social Services – Further Information Sources

Agency for Healthcare Quality and Research
http://www.ahcpr.gov/qual/errorsix.htm
The AHQR is becoming a portal of sorts for patient safety policy and learning in the United States. Working with other federal agencies that collect adverse event information, the AHQR is conducting analysis from event information, and will disseminate knowledge as it's acquired. They are also supporting research related to system failures that cause events and errors.

The Institute for Healthcare Improvement
http://www.ihi.org
IHI President Don Berwick, MD, is on the Board of the NHS Modernisation Agency. His organisation, IHI, conducts extremely popular seminars around their "Breakthrough" methodology, which focuses on reducing adverse drug events and medical errors.

The Australian Patient Safety Foundation
http://www.apsf.net.au
The APSF is one of the most long-standing patient safety groups in the world. Launched by Professor Bill Runciman, an anesthetist from Adelaide Royal Infirmary, the APSF has developed a highly-advanced incident classification system that will be piloted within the NHS for the national system framework. They are also developing a web-based process for learning off the back end of adverse events.

The Joint Commission on Accreditation of Healthcare
http://www.jcaho.org
The JCAHO was one of the early resources on adverse events, through its "sentinel events" programme. All accredited organisations (90% of hospitals) must conduct a formal root cause analysis for every sentinel event (pre-specified events) and determine the root causes of systems failures related to the event. Their methodology, advice, and some data are available on certain areas of their website. In particular, users might want to go to: http://www.jcaho.org/edu_pub/sealert/se_alert.html to read through what the JCAHO has learned about real adverse events in their accredited hospitals. And even though their data covers only 1,030 events over several years, there is good data.

The Institute for Safe Medication Practices
http://www.ismp.org
The ISMP, which is in America, started talking about medication errors before anyone in the U.S. believed there was a problem. Their Medication Safety Alerts are very well-received and come with membership.

National Patient Safety Foundation
http://www.npsf.org
This website was launched by the American Medical Association. It contains many excellent references to patient safety material and resources. In particular, you might want to tap into the NPSF's discussion area of the site, which allows you to observe and participate in dialogue and sharing on patient safety.

U.S. Veterans Affairs Patient Safety Area

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http://www.patientsafety.gov/index.html
This is the U.S. Veterans Affairs patient safety area. It provides a Virtual Learning Center, where there are abstracts from real patient safety lessons learned in the VA health system.

Downloadable report on Near Miss Analysis Phase 1
http://opim.wharton.upenn.edu/risk/wp/nearmiss.pdf
Downloadable report on Near Miss Analysis Phase I, by the Wharton Risk Management and Decision Processes Center of the University of Pennsylvania. The report outlines the impacts of key issues on near-miss programs, and identifies the benchmark characteristics of successful near-miss programs.

Downloadable report of the inquiry into the Ladbroke Grove Rail crash
http://www.hse.gov.uk/railway/paddrail/lgri1.pdf
The investigation of the causes of the crash and the circumstances in which it occurred, lessons which should be drawn from what happened, and recommendations for the improvement of safety in the future.

Medicines and Healthcare products Regulatory Agency
http://www.mhra.gov.uk
The MHRA was formed from a merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA) on 1 April 2003. At present the "Medicines" and "Medical devices" links give access to the original MCA and MDA sites.

ECRI (health services research agency)
http://www.ecri.org
ECRI is an independent non-profit health services research agency. Provides independent research data that will be of use to the agency. Its mission is to improve the safety, quality, and cost-effectiveness of healthcare. They are widely recognized as one of the world's most trusted organizations for unbiased, reliable information. ECRI's focus is healthcare technology, healthcare risk and quality management, and healthcare environmental management. It has been active in the patient safety arena for many years and has databases of information and regular newsletters.

Chief Medical Officer
http://www.doh.gov.uk/cmo
The Chief Medical Officer (CMO), Sir Liam Donaldson, is the UK Government's principal medical adviser and the professional head of all medical staff in England. These pages provide up-to-date information on key public health issues and offer access to CMO reports and publications.

The Patient Safety Research Programme (PSRP)
http://www.publichealth.bham.ac.uk/psrp/
The Patient Safety Research Programme (PSRP) was set up to promote patient safety research in the wake the publication of the Chief Medical Officer's An Organisation With A Memory, a report on learning from adverse events in the NHS. PSRP is funded by the Policy Research Programme, and reports directly to Sir Liam Donaldson, the Chief Medical Officer.

Commission for Health Improvement (CHI)
http://www.chi.nhs.uk
The Commission for Health Improvement (CHI) aims to improve the quality of patient care in England and Wales. It carries out a rolling programme of clinical governance reviews across every NHS trust, health authority or primary care group or trust. CHI identifies and shares good practice and work with the trust to set objectives and bring about change in the areas where there is room for improvement.

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The Royal College of General Practitioners (RCGP)
http://www.rcgp.org.uk
The Royal College of General Practitioners (RCGP) is the academic organisation in the UK for general practitioners. Its aim is to encourage and maintain the highest standards of general medical practice and act as the 'voice' of general practitioners on education, training and standards issues. Founded in 1952, the RCGP is a relatively young organisation with an outstanding record of achievement. Milestones in its history include the establishment of vocational training in general practice, the setting up of clinical guidelines for doctors, the expansion of research into general medical practice and the promotion of primary care.

Health of Wales Information Service (HOWIS)
http://www.wales.nhs.uk/
HOWIS, the official website of NHS Wales, is a seamless service bringing together information sources about the health and lifestyle of the population of Wales into a simple, electronic-based service. HOWIS provides you with: A one-stop shop to health information; Easy and instant access to health information; Timely, accurate and complete information; The corporate website of the NHS Wales, and; Links to the wider information base for healthcare.

The National Clinical Assessment Authority (NCAA)
http://www.ncaa.nhs.uk
The National Clinical Assessment Authority (NCAA) is a special health authority set up as one of the central elements of the NHS' modernisation plans to ensure the high quality of healthcare. It began work in April at its headquarters in Vauxhall, London. The Authority's aim is to provide a support service to the NHS when concerns over the performance of an individual doctor are raised. The NCAA will take referrals from doctors' employers - NHS Health Authorities, Hospital Trusts, Primary Care Groups and Trusts.

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Appendix X

Incident Reporting Systems

Ranking of Organisations and Systems

National Patient Safety Agency

Organisation Name	System Name	Category	Rank
Organisations with an Incident Reporting System			
National Patient Safety Agency	National reporting and Learning System	Learning	n/a
Serious Hazards of Transfusion - SHOT	SHOT Incident Database	Learning	1
National Institute for Clinical Excellence	Confidential Investigation into Perioperative Deaths - NCEPOD	Investigatory & Learning	1
Royal College of Anaesthetists	Royal College of Anaesthetists Critical Incident Reporting System	Learning & Professional	2
National Institute for Clinical Excellence	Confidential Investigation into Suicide & Homicide by People with Mental Illness - CISH	Investigatory & Learning	2
National Institute for Clinical Excellence	Confidential Investigation into Deaths of Mothers & Children - CEMACH	Investigatory & Learning	2
Medicines & Healthcare products Regulatory Agency	Suspected Adverse Drug Reaction (ADR) Reporting	Regulatory & Investigatory	3
Medicines & Healthcare products Regulatory Agency	Medical Devices Database	Regulatory & Investigatory	4
Health and Safety Executive	RIDDOR	Statutory and Regulatory	5
Strategic Health Authorities	STEIS & SUI	Investigatory & Performance Management	6
NHS Litigation Authority	Clinical Negligence Scheme for Trusts (CNST)	Investigatory & Performance Management	7
Organisations with Other Type of Reporting System			
Food Standards Agency	Food Hazard Warning System	Statutory ,Regulatory & Public Health	1
CMO - Safety Alert Bulletins	Public Health Link Alerts	Public Health & Performance Management	1
National Clinical Assessment Agency	NCAA Case Database	Performance Management	2
NHS Information Authority	NHSIA Incident Log	Investigatory & Performance Management	3
Prison Health Service	Performance Monitoring - Traffic Lights	Performance Management	3
Organisations with no Incident Reporting System			
Chief Medical Officer	Patient Safety Research Programme	Learning	1
Great Ormond Street Hospital	UK Newborn Screening Programme	Public Health & Learning	2
NHS Modernisation Agency	No Specific System	Performance Management	3
Coroner	No Specific System	Investigatory	3
Royal College of Nursing	No Specific System	Learning & Professional	4
Health Protection Agency	Health Protection Information	Public Health	4
Pesticides Safety Directorate	No specific System	Regulatory & Public Health	5
Commission for Health Improvement	Investigating Service Failures	Investigatory & Performance Management	6
Human Fertilisation & Embryology Authority	No Specific System	Statutory and Regulatory	6
NHS Purchasing and Supply Agency	No Specific System	Performance Management	7
Council for the Regulation of Healthcare Professionals covering:	No Specific Systems	Statutory, Regulatory & Professional	7
Health Professions Council			
Nursing and Midwifery Council			
General Medical Council			
General Dental Council			
Royal Pharmaceutical Society			
NHS Estates Agency	No Specific System	Performance Management	8
Police	No Specific System	Investigatory	8
NHS Counter Fraud and Security Agency	No Specific System	Investigatory	9

Noel McCann
Director of Planning & Performance Management

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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Your Ref:
Our Ref:
Date: 7 July 2004

For action:

Chief Executives of HSS Trusts
Chief Executives of HSS Boards
Chief Executives of Special Agencies
General Medical, Community Pharmacy
General Dental & Ophthalmic Practices

For information:

Chief Officers, HSS Councils
Directors of Public Health in HSS Boards
Directors of Social Services in HSS Boards and Trusts
Directors of Dentistry in HSS Boards and Trusts
Directors of Pharmacy in HSS Boards and Trusts
Directors of Nursing in HSS Boards and Trusts
Directors of Primary Care in HSS Boards
Medical Directors in HSS Trusts
Chairs, Local Health and Social Care Groups

Circular HSS (PPM) 06/04

Dear Colleague

REPORTING AND FOLLOW-UP ON SERIOUS ADVERSE INCIDENTS: INTERIM GUIDANCE

Introduction

1. The purpose of this guidance is to provide interim advice for HPSS organisations and Special Agencies on the reporting and management of serious adverse incidents and near misses, pending the issue of more comprehensive guidance on safety. This will be issued once the work currently being undertaken by the Department on the strategic review of the reporting, recording and investigation of adverse incidents and near misses has been concluded.

2. This interim guidance highlights, in particular, the need for the Department to be informed immediately about incidents which are regarded as serious enough for regional action to be taken to ensure improved care or safety for patients, clients or staff. It also draws attention to the need for the Department to be informed where a Trust, Board or Special Agency considers that an event is of such seriousness that it is likely to be of public concern. In addition, the guidance requires Trusts, Boards or Special Agencies to inform the Department where they consider that an incident

requires independent review.

3. The guidance complements existing local and national reporting systems, both mandatory and voluntary, which have been established over the years. These provide for specific incidents relating, for example, to medical devices and equipment, medicines, mental illness, child protection, communicable disease and the safety of staff to be reported to various points in the Department. **These systems should continue to be used in addition to the action required by this interim guidance.** In the context of contractual arrangements for the independent family practitioner services, practices should report serious incidents, in the first instance, to the relevant HSS Board, which will communicate with the Department as appropriate.

Background

4. The consultation paper *Best Practice Best Care*, published by the Department in April 2001, recognised the need for more effective arrangements for monitoring adverse incidents. As a result, a Safety in Health and Social Care Steering Group was established by the Department, with a remit to develop a strategic approach to the reporting, recording and investigation of adverse incidents and near misses and the promotion of good practice to minimise risk.

5. As part of its work, the Steering Group is also undertaking an evaluation of the effectiveness of systems used to identify and manage adverse incidents and near misses, including the Northern Ireland Adverse Incident Centre (NIAIC). NIAIC operates a voluntary system for reporting and investigating adverse incidents in the HPSS and issues alerts and other material on the safety of devices and equipment.

6. It is hoped that the Steering Group will conclude its work later this year, following which comprehensive guidance on safety and the promotion of learning will be brought forward. This may include links, where appropriate, with the National Patient Safety Agency in the NHS.

Defining Serious Adverse Incidents

7. Preliminary feedback from the Steering Group's work highlights a lack of uniformity in incident reporting and management in the HPSS. This also applies to the definition of what constitutes a serious adverse incident.

8. In line with the action required by this Circular, the Department considers that a serious adverse incident should be defined as "*any event or circumstance arising during the course of the business of a HSS organisation/Special Agency or commissioned service that led, or could have led, to serious unintended or unexpected harm, loss or damage*". This may be because:

- it involves a large number of patients;
- there is a question of poor clinical or management judgement;
- a service or piece of equipment has failed;
- a patient has died under unusual circumstances; or
- there is the possibility or perception that any of these might have occurred.

9. Examples of serious adverse incidents include:

- any incident involving serious harm or potentially serious harm to a patient, service user or the public. This could include disease outbreaks, apparent clinical errors or lapses in care;
- any incident which has serious implications for patient or staff safety – involving potential or actual risk to patients or staff;
- any incident involving serious compromises or allegations of serious compromises in the proper delivery of health and social care services.

10. The above list is not exhaustive and Annex A provides a more comprehensive list.

Key Issues for HPSS Organisations

11. HPSS organisations and Special Agencies should be developing a culture of openness. Policies should be in place to raise awareness and to actively encourage the reporting, assessment, management and learning from adverse incidents and near misses. If they have not already done so, all HPSS organisations and Special Agencies should nominate a senior manager at board level who will have overall responsibility for the reporting and management of adverse incidents within the organisation.

12. All HPSS organisations and Special Agencies should have developed, or be developing, centralised systems which facilitate the collection, analysis and reporting of adverse incidents and near misses relating to patients, clients, staff and others. These systems should be capable of supporting an analysis of the type, frequency and severity of the incident or near miss and, where appropriate, should record the action taken.

13. In those situations where a body considers that an independent review is appropriate, it is important that those who will be conducting it are seen to be completely independent. In addition, such reviews should normally be conducted by a multi-professional team, rather than by one individual. It is also important that the Department is made aware of the review at the outset.

Action

14. HPSS organisations and Special Agencies should continue to use established local or national reporting and investigation mechanisms to manage adverse incidents. This will include, where appropriate, notifying other agencies such as the Police Service, the Health and Safety Executive, professional regulatory bodies or the Coroner. Where there is any doubt as to which agencies should be notified, advice should be sought from the Department.

15. The Department will expect urgent local action to be taken to investigate and manage adverse incidents.

16. In addition, where a **serious** adverse incident occurs, it should be reported immediately to the senior manager with responsibility for the reporting and management of adverse incidents within the organisation. If the senior manager considers that the incident is likely to:

- be serious enough to warrant regional action to improve safety or care within the broader HPSS;

- be of public concern; or
- require an independent review,

he/she should provide the Department with a brief report, using the proforma attached at Annex B, within 72 hours of the incident being discovered. The report should be e-mailed to adverse.incidents[redacted] In cases where e-mail cannot be used, the report should be faxed on [redacted]

Action by the Department

17. The Department:

- will collate information on incidents reported to it through this mechanism and provide relevant analysis to the HPSS;
- may also, where appropriate, seek feedback from the relevant organisation on the outcome of the incident to determine whether regional guidance is needed;
- may, in independent reviews, provide guidance in relation to determining specialist input into such reviews.

Enquiries

18. Any enquiries about this Circular from the nominated senior manager should be made, in the first place, to Jonathan Bill, Planning & Performance Management Directorate, on [redacted] or by e-mail at Jonathan.Bill[redacted]

19. This guidance will be reviewed once the Safety in Health and Social Care Steering Group has concluded its work, at which point further, comprehensive, guidance will be issued. In the meantime, the Department will welcome feedback on the issues covered in this guidance. This should be addressed to Jonathan Bill on the e-mail address above, or to Room D2.3, Castle Buildings, Stormont, Belfast, BT4 3SQ.

Yours sincerely

NOEL McCANN
Director of Planning & Performance Management

ANNEX A

SERIOUS ADVERSE INCIDENTS - EXAMPLES

The following are examples of serious adverse incidents. It is not an exhaustive list and is intended as a guide only. Where there are any doubts about an incident it should be reported.

Major Incidents

- Any circumstance which necessitates the activation of an HSS Trust, HSS Board or wider community Emergency Plan

Clinical incidents

- Any clinical incident whose consequences would be regarded as severe
- Serious drug events which might require regional or national guidance, to prevent occurrence or reoccurrence within HPSS/NHS organisations, e.g. maladministration of a spinal medicine, major prescription error causing, or with the potential to cause, serious damage or death of a patient

Court Proceedings

- Any incident which might give rise to serious criminal charges
- Impending court hearing, including Coroners' Inquests, or out of court settlement in cases of large scale litigation
- Legal challenges to the HSS Trust or HSS Board

Incidents involving staff

- Serious complaints about a member of staff or primary care contractor
- Serious error or errors by a member of staff or primary care contractor
- Significant disciplinary matters (e.g. suspensions of staff)
- A serious breach of confidentiality
- Serious verbal and/or physical aggression towards staff

Mortality/morbidity incidents

- Clusters of unexpected or unexplained deaths
- The suicide of any person currently in receipt of health and personal social services on or off HPSS premises, or who has been discharged within the last twelve months.
- Death or injury where foul play is suspected
- Situations when a patient or patients require(s) additional intervention(s) as a result of serious failures in diagnostic processes
- The accidental death of, or serious injury to, a patient, a member of staff, or visitor to HPSS or primary care premises, or involving HPSS or primary care staff or equipment
- Significant harm to children where reported under child protection arrangements
- Vulnerable adult abuse

Premises/equipment incidents

- Serious damage which occurs on HPSS premises or premises on which primary care services are delivered, or to HPSS property or property on which primary care services are delivered, or any incident which results in serious injury to any individual or serious disruption to services (e.g. evacuation of patients due to fire)
- Failure of equipment so serious as to endanger life, whether or not injury results
- Suspicion of malicious activity e.g. tampering with equipment
- Circumstances that lead to the provider no longer being able to provide an element of service

Mental Health or Learning Disability incidents (including substance misuse services)

- The disappearance, absence without leave or absconding of a patient (whether or not detained under the Mental Health Order 1986) where there is serious cause for concern
- Escapes by patients (whether or not detained under the Mental Health Order 1986) from secure accommodation/area
- Homicide, or suspected homicide, by any patient who has received mental health services
- Unexpected death
- All deaths within secure settings
- All deaths of persons who are subject to the Mental Health Order or equivalent legal restriction who has or is receiving mental health service care and treatment
- Any serious criminal acts involving patients, or staff
- An incident that causes serious harm that places life in jeopardy
- Serious injury, resulting in the need for emergency medical treatment via an A&E department, sustained by patient, staff or visitor on HPSS property
- Where a member of staff is suspected of harming patients or serious fraud
- Hostage taking, mass / organised disturbance
- Any omissions/failings of security systems/procedures that jeopardise security
- All incidents reported to or involving the police

ANNEX B

SERIOUS ADVERSE INCIDENT REPORT
1. Organisation:
2. Brief summary (and date) of incident:
3. Why incident considered serious:
4. Action taken:
5. Is any regional action recommended? (if so, full details should be submitted) Y/N -
6. Is an Independent Review being considered? (if so, full details should be submitted) Y/N -
7. Other Organisations informed PSNI Y/N - Coroner Y/N - NIHSE Y/N - HSS Board Y/N - Other (please specify) Y/N -
8. Report submitted by (name and contact details of nominated senior manager or Chief Executive)

Completed proforma should be sent, by email, to:

adverse.incidents[redacted]

If e-mail cannot be used, fax to [redacted]

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

Noel McCann
Director of Planning & Performance Management

Room D4.13, Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

Tel: [redacted]
Fax:
Email: noel.mccann[redacted]

Circular HSS (PPM) 05/05

Your Ref:
Our Ref:

Date: 10 June 2005

For Action (with enclosures):

Chief Executives of HSS Trusts
Chief Executives of HSS Boards
Chief Executives of Special Agencies

For information (without enclosure):

Chief Executive, HPSS Regulation & Improvement Authority
Chief Officers, HSS Councils
Directors of Public Health in HSS Boards
Directors of Social Services/Social Work in HSS Boards and Trusts
Directors of Dentistry in HSS Boards and Trusts
Directors of Pharmacy in HSS Boards and Trusts
Directors of Nursing in HSS Boards and Trusts
Directors of Primary Care in HSS Boards
Medical Directors in HSS Trusts
Chairs, Local Health and Social Care Groups
General Medical, Community Pharmacy, General Dental & Ophthalmic Practices

Dear Colleague

REPORTING OF SERIOUS ADVERSE INCIDENTS WITHIN THE HPSS

Introduction

1. Circular PPM 06/04, issued in July 2004, provided interim advice for HPSS organisations and Special Agencies on the reporting and management of serious adverse incidents and near misses.

2. The purpose of this Circular is to provide an update on safety issues; to underline the need for HPSS organisations to report serious adverse incidents and near

misses to the Department in line with Circular PPM 06/04; and to request details of senior managers who have been assigned overall responsibility for the reporting and management of adverse incidents.

Update on Safety Issues

Safety Group

3. The Department established a Safety in Health and Social Care Steering Group initially to advise on the future role and function of the Northern Ireland Adverse Incident Centre (NIAIC), with particular emphasis on the establishment of NIAIC accountability boundaries. However, the Steering Group considered that there was a need for the Department to take a broader, more systematic approach to safety within the HPSS and to provide greater strategic direction on the recording, reporting and investigation of all adverse incidents and near misses.

4. As part of this work, the Steering Group commissioned Deloitte to carry out a scoping exercise on adverse incidents and near miss reporting in the HPSS and special agencies; and to evaluate the Northern Ireland Adverse Incident Centre.

Key Findings of Deloitte Report

5. The Deloitte report acknowledged that, within HPSS organisations, there is a consistent drive to improve the reporting and management of adverse incidents, based on a common belief and understanding of the benefits it can bring to patient and client safety and care. However, the report also noted inconsistencies in approach, including incident reporting systems, monitoring, collation, analysis and follow-up.

6. The report's key recommendations included the need for:

- a consistent approach to the definition and coding of adverse incidents and near misses;
- more Departmental guidance on risk assessment, reporting structures and links to other organisations;
- the development of improved reporting systems to support the analysis and audit of incidents and the development of mechanisms to improve learning and knowledge;
- links between local reporting arrangements and national, statutory, and confidential reporting mechanisms;
- the development of guidance on local investigations and reviews; and
- improved training and development of staff in the use of risk assessment tools, such as root cause analysis.

Further Work

7. In line with these proposals, a number of projects are now being taken forward by the Department. These include:

   - work to standardise definitions and coding;
   - the development of formal links with the National Patient Safety Agency; and
   - the development of a safety framework for the HPSS.

8. Further information about progress with each of these projects will be issued at a later date.

Reporting Incidents

9. Circular HSS (PPM) 06/04 indicated that the Department, in collating information on serious adverse incidents and near misses, would feed back relevant analysis to the HPSS. In line with this undertaking, a small group has been established in the Department, which reviews all incidents that are notified. It is planned that regular feedback will be issued to the HPSS, including an annual report.

10. As the first step in this process, a briefing session has been arranged for safety managers on 15 June, when the Department will be providing feedback on the operation of the reporting and management arrangements established by Circular PPM 06/04.

11. In the meantime, it is important that notifications required under the interim guidance should continue to be provided to the Department. Safety managers should review the operation of local procedures on a regular basis to ensure that all serious adverse incidents are being reported to the Department.

12. All HPSS organisations are reminded that incidents which are regarded as falling in any of the categories below should be notified to the Department in accordance with the procedures outlined in the guidance:

   - **incidents regarded as serious enough to warrant regional action to improve safety or care within the broader HPSS;**
   - **incidents which are likely to be of public concern;**
   - **incidents which are likely to require an independent review.**

13. All other existing systems should continue to be used. In particular, HPSS organisations should continue to report incidents involving medical devices and equipment to the NIAIC.

Management Arrangements

14. Circular PPM 06/04 indicated that HPSS organisations and Special Agencies should be developing a culture of openness. In that context, it requested all HPSS organisations and Special Agencies to nominate a senior manager at board level who would have overall responsibility for safety and the reporting and management of adverse incidents within the organisation. To assist with future communications on safety issues, the Department has decided to establish a central list of these safety managers.

Action

15. A copy of the Deloitte Report is enclosed for your information; also enclosed is a specific section relating to your Trust, Board or Special Agency as appropriate. Taken together, these should be used to inform the safety agenda within your organisation.

16. Chief Executives of Boards, Trusts and Special Agencies should ensure that copies of the Deloitte Report are available for distribution as appropriate.

17. In line with paragraph 14 above, I should be grateful if you would let Jonathan Bill (jonathan.bill[redacted] have details of your safety manager – their name, position and contact details, **by 30 June 2005**.

Yours sincerely

NOEL McCANN

Department of
Health, Social Services
and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

Best Practice Best Care

The Quality Standards for Health and Social Care

Supporting Implementation of Clinical and Social Care Governance in the HPSS

April 2005

INVESTORS IN PEOPLE

FOREWORD BY THE MINISTER

The people of Northern Ireland are entitled to the highest standards of health and social care. In recent years, considerable progress has been made in improving and modernising services; additional staff have been recruited, new facilities have been developed and new ways of working have been introduced to ensure that services are designed around the needs of those who use them.

This consultation paper is another important milestone in that process of putting service users and carers at the centre of service planning and delivery. A vital part of that approach is the setting of clear standards for all service providers.

The Quality Standards for Health and Social Care sets out the standards that people should expect from Health and Personal Social Services (HPSS) organisations. The standards are being issued in draft form now so that people have an opportunity to comment on them before they are finalised later this year. Once they are finalised, the standards will apply to all HPSS organisations. They will be used by the new Regulation and Improvement Authority to assess the quality of care provided by the HPSS. The new Authority begins work on 1 April 2005 and will become fully operational on a phased basis over the next year.

In developing these standards, our aim is to raise the quality of our health and social services and to improve the health and social well-being of the people of Northern Ireland. The draft standards contained in this document have been developed following discussion with a wide range of interests, including the public, people who use health and social services and their carers, as well as HPSS organisations themselves.

The standards are grouped in five themes:

- safe and effective care;
- timely delivery of quality services;
- promoting, protecting and improving health and social well-being;
- open and effective communication; and
- leadership and accountability of organisations.

Each standard is followed by a range of criteria, which set out how the standard is expected to be met. The document also contains examples of the evidence that HPSS organisations might use to satisfy themselves that the quality of their care meets the required standard. Organisations will need to be able to demonstrate this when they are being assessed by the new Regulation and Improvement Authority, once it becomes fully operational.

At the heart of these standards are key service user and carer values including dignity and respect, independence, rights, choice and safety. The new Authority will be looking to see how HPSS organisations provide quality services and will be reporting their findings both to the Department and to the public.

This paper gives the public, service users and carers, HPSS organisations and staff a chance to have their say in what the standards for health and social services should be. I hope that many people will take the opportunity to make their views known.

ANGELA SMITH MP

Minister for Health, Social Services and Public Safety

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How to respond to consultation

Attached to this document is a booklet to facilitate completion of a response to this consultation. Responses may be forwarded by post or email. They should be returned to;

Miss Suzanne Beaney
General Medical Services
Room D3, Castle Buildings
Stormont Estate
Belfast BT4 3SQ
E-mail: suzanne.beaney[redacted]
Telephone: [redacted]

No later than: 4 July 2005.

Should you require help with completion of the consultation questions, please contact Miss Suzanne Beaney.

This document and associated questionnaire can be made available in large print, Irish, Chinese (Cantonese), and the Department will consider requests for other formats or translation into other minority ethnic languages. It will also be available from the Department's website at www.dhsspsni.gov.uk/publications.

FREEDOM OF INFORMATION ACT 2000 – CONFIDENTIALITY OF CONSULTATIONS

The Department will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. **Before** you submit your response, please read the paragraphs contained in Appendix 2 on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

Section 1: Introduction to the Development of Standards

1.1 Introduction

Almost 95% of the population of Northern Ireland makes contact with health and social services on an annual basis. This contact may be through primary care services, community care services or through hospitals. By contributing to the development of standards for treatment and care, the public will have greater confidence when accessing Health and Personal Social Services (HPSS) organisations. Integral to this, is the development of services appropriate to the needs of the public, delivered safely, effectively and within an acceptable timeframe.

This paper sets out clearly for the public, service users and carers, and those responsible for the planning, delivery, and review of services, the quality standards that the Department considers people should expect from HPSS organisations. It represents a significant step in the process of placing the needs of the service user and carer, and the wider public, at the centre of planning, delivery and review of health and social care services.

1.2 Background to the development of standards

Quality improvement is at the forefront of the development of health and social care services in Northern Ireland. These improvements are centred around five main areas;-

- setting of standards – to improve services and practice;
- improving governance in the HPSS - in other words, the way in which HPSS organisations manage their business;
- improving the regulation of the workforce, and promoting staff development through life-long learning and continuous professional development;
- changing the way HPSS organisations are held to account for the services they provide; and
- establishing a new, independent body to assess the quality of health and social care.

The consultation document "Best Practice – Best Care", published in April 2001, set out the detail of this framework to improve the quality of care. This included links to national standard setting bodies such as the National Institute for Clinical Excellence and the Social Care Institute for Excellence.

1.3 Improving governance in health and social care

From April 2003, a statutory duty of quality has been placed on HPSS Boards, Trusts and Agencies. This means that each organisation has a legal responsibility for satisfying itself that the quality of care it provides meets a required standard. This requirement is just as important as the responsibility to demonstrate financial regularity and propriety. Organisations must ensure that there are visible and rigorous structures, processes, roles and responsibilities in place to deliver, monitor and promote safety and quality improvements in the provision of health and social care. This process is known as *Governance*.

1.4 The setting of standards

In addition to drawing on national and professional standards, a range of local standards is being developed to enhance governance arrangements in the HPSS. These include controls assurance standards, so that by 2006-7, there will be a comprehensive set of specific assurance standards, which the HPSS can use to assess compliance against the required attainment levels. In addition, a number of care standards have been developed to facilitate the inspection and regulation of specific health and social care services provided by the HPSS and the independent sector. These care standards are specified in legislation and will be inspected, regulated and monitored by a new organisation called the Health and Personal Social Services Regulation and Improvement Authority (HPSSRIA).

The development of the *Quality Standards for Health and Social Care*, as outlined in this document, is intended to complement standards already issued or currently in development. Consequently, evidence of compliance with existing or new standards, such as professional standards, charter standards, control assurance or care standards will rightly form part of the evidence of practitioner or organisational commitment to these new quality standards.

1.5 What is a standard?

A standard is a level of quality against which performance can be measured. It can be described as 'essential'- the absolute minimum to ensure safe and effective practice, or 'developmental', - designed to encourage and support a move to better practice. The *Quality Standards for Health and Social Care,* which are contained in this document, are classed as <u>essential</u>.

Given the rapidly changing environment in which the HPSS operates, it is important that standards do not become outdated or serve to stifle innovation. To prevent this, standards need to be regularly reviewed and updated. It will be the Department's responsibility, drawing on the best evidence available, including advice, reports or information from the HPSSRIA, to keep the quality

standards under consideration, with a formal review being completed by the end of 2008.

1.6 Why are standards important?

Raising and maintaining the quality of services provided by the HPSS is a major objective for all involved in the planning, provision, delivery and review of health and social care services. This was a key concern of those who responded to the "Best Practice – Best Care" consultation. Currently, there remains unacceptable variation in the quality of services provided, including timeliness of delivery and ease of access.

In order to improve the quality of these services, change is needed, underpinned and informed by a more cohesive approach to standards development.

Standards:

- give HPSS organisations a measure against which they can assess themselves and demonstrate improvement, thereby raising the quality of their services and reducing unacceptable variations in the quality of services and service provision;
- enable service users and carers to understand what quality of service they are entitled to and provide the opportunity for them to help define and shape the quality of services provided by the HPSS and others;
- provide a focus for members of the public and their elected representatives, to consider whether their money is being spent on efficient and effective services, and delivered to recognised standards;
- help to ensure implementation of the duty HPSS organisations have in respect of human rights and equality of opportunity for the people of Northern Ireland; and
- promote compliance, and underpin the regulation and monitoring of services to determine their quality and safety and to gauge their continuous improvement.

By promoting integration, these *Quality Standards for Health and Social Care* will contribute to the implementation of clinical and social care governance in the HPSS and will be used by HPSS organisations, service users and carers, the wider public and the HPSSRIA to assess the quality of care provision.

1.7 The five quality themes

There are five quality themes on which the draft standards have been developed to improve the health and social well-being of the population of

Northern Ireland. These themes have been identified through pre-consultation with service users, carers and HPSS staff, and through a review of standards developed elsewhere at local, national and international level.

The five quality themes are:

1. Safe and effective care;
2. Timely delivery of quality services;
3. Promoting, protecting and improving health and social well-being;
4. Open and effective communication; and
5. Leadership and accountability of organisations.

1.8 Assessing quality

The new HPSS Regulation and Improvement Authority (HPSSRIA) began work on 1 April 2005. The HPSSRIA was established by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, and has two main functions:

- inspection and regulation of specified health and social care services provided by the HPSS and the independent sector; and
- inspection and review of the services provided by the HPSS in Northern Ireland.

HPSSRIA will have a general duty to encourage improvements in the quality of services commissioned and provided by HPSS and other organisations. It will promote a culture of continuous improvement and best practice through inspection and review of clinical and social care governance arrangements.

Initially, HPSSRIA will take over responsibility for the registration, inspection and regulation of providers of care, for example, residential care, nursing homes and day care facilities. On a phased basis, the HPSSRIA will assume further responsibilities over the coming year(s), including reporting on the quality of care provided by HPSS organisations. Where serious and/or persistent clinical and social care governance problems come to light, it will have a key role to play, in collaboration with other regulatory and inspectoral bodies, in the investigation of such incidents. It will report on its findings to the Department and to the public.

1.9 How will the standards be used to measure quality?

Once the formal consultation process on development of quality standards contained in this document is completed the HPSSRIA, in conjunction with

HPSS organisations, service users and carers, will agree how the standards will be interpreted to assess service quality. It is envisaged that specific tools will be designed to allow the HPSSRIA to measure that quality and assist HPSS organisations in assessing themselves. These tools will not only assess structures and processes, but will also assess clinical and social care outcomes.

Whilst it is for the HPSSRIA to provide guidance on what assessment methods it will use, it is recognised that collecting the evidence to demonstrate that relevant standards have been successfully achieved may be a time consuming process for HPSS organisations. Therefore, information that is currently compiled on existing standards will also be able to be used to contribute to the demonstration of achievement for these standards.

In order to provide the HPSSRIA and HPSS organisations with some examples of how an organisation could demonstrate quality, practical examples of evidence, which might be used, are included in Section 9.

Section 2: Values and Principles Underpinning Service Delivery

2.1 Introduction

Our first premise is that people in receipt of services should be actively involved in all decisions affecting their lives and should fully contribute to any planning for, and evaluation of, services. That belief, which underpins these quality standards, has to be central to all aspects of planning, provision, delivery, review and improvement of the HPSS.

The second is that clinical and social care governance in the HPSS must take account of the organisational structures, functions and the manner of delivery of services currently in place. Clinical and social care governance must also apply to all services provided in community, primary, secondary and tertiary care environments.

Having the right structures and processes in place is only part of the equation. The third and most important premise is that service users and carers be fully valued by HPSS staff.

2.2 Values

The quality of a service provided is dependent on managers and HPSS staff basing their practice on:-

DIGNITY AND RESPECT	The uniqueness and intrinsic value of the individual is acknowledged and each person is treated with respect.
INDEPENDENCE	Service users and staff have as much control as possible over their lives whilst being protected against unreasonable risks.
RIGHTS	In the context of services delivered to them, the individual and human rights of service users are safeguarded.
EQUALITY AND DIVERSITY	Service users and staff are treated equally and their background and culture are valued and respected.
CHOICE	Service users are offered, wherever possible, according to assessed need and available resources, the opportunity to select independently from a range of options based on clear and accurate information.

PRIVACY	Service users have the right to be left alone, undisturbed and free from unnecessary intrusion into their affairs and there is a balance between the consideration of the individual's safety and the safety of others.
FULFILMENT	Service users are enabled and supported to achieve their potential in health and social well-being.
CONFIDENTIALITY	Information about service users and staff is managed appropriately and everyone involved in the service respects confidential matters.
SAFETY	People feel as safe as is possible, in all aspects of their treatment and care and are free from exploitation, neglect and abuse.

2. 3 Overarching principles

The following overarching principles are fundamental to the development of these standards.

USER EXPERIENCE	The views and experiences of service users, carers, staff and local communities are taken into account in the planning, delivery, evaluation and review of services. Service users and carers, where appropriate, are involved in, and informed about, decisions made on every occasion they seek access to or receive services during their journey of care.
SAFETY AND EFFECTIVENESS	Systems are in place to ensure that the safety of service users, carers and staff underpins all aspects of health and social care delivery. In some circumstances, the imperative to protect children and vulnerable adults may take precedence over the specific wish of the service user. Quality systems are in place to enable staff to play a full and active role in providing effective and efficient health and social care services for all who use these services. Staff in the HPSS are fully supported, regularly supervised and adequately trained, both personally and professionally, to provide safe and effective health and social care services.

STRUCTURES AND PROCESSES	Information is used appropriately to optimise benefit in all sectors of health and social care. Structures and processes are in place for the adequate review of service and care delivery.
SERVICE IMPROVEMENT	Policies and procedures are in place to encourage and enable continuous quality improvement.

2.4 Questions for consultation

Section 2 identified the values and principles underpinning the development of the quality standards for health and social care.

Do you agree with the values for service provision? Yes/No? If no, please comment on what you think should be added or removed and briefly state why.

Do you agree with the overarching principles for the development of standards? Yes/No? If no, please comment on what you think should be added or removed and briefly state why.

Section 3: Format of the Standards

3.1 The five quality themes

The five quality themes are applicable to the whole of the HPSS, including those services, which are commissioned or provided by HPSS organisations and family practitioner services. They are underpinned by the duty of quality on HPSS organisations. Where care is commissioned outside Northern Ireland, commissioners must ensure that the quality of care is commensurate with these and other associated standards.

The five quality themes, encompassing the standards, are set out in sections four to eight of this document. These are:-

- Safe and effective care (Section 4);
- Timely delivery of quality services (Section 5);
- Promoting, protecting and improving health and social well-being (Section 6);
- Open and effective communication (Section 7); and
- Leadership and accountability of organisations (Section 8).

3.2 Format of the standards

Each theme has a **title**, which defines the area upon which the standard is focused. Then, a **standard statement** will explain the level of performance to be achieved. The reason why the standard is seen to be important will be covered by the **rationale**. The standard statement will then be expanded into a series of **criteria,** which will provide further detail of areas for consideration by the HPSS organisations and by HPSSRIA.

Questions for consultation can be found at the end of each section.

Information gathered to comply with existing HPSS and other standards can be applied to these standards, if appropriate. Therefore, Section 9 identifies relevant controls assurances and care standards that may also be used as evidence.

Section 4: Theme 1 – Safe and Effective Care

4.1 Standard statement

Safe and effective care is provided by HPSS organisations to those service users who require treatment and care. Services, which have been shown not to be of benefit, should not be provided or commissioned by HPSS organisations.

4.2 Rationale

Services need to be safe, effective and sustainable. Avoiding injury and harm to service users, from the treatment and care that is intended to help them, is an integral part of high quality care. Services must be delivered in a way that minimises risk to staff. Care should be based on the best available evidence of interventions that work and should be delivered by appropriately competent and qualified staff. Systems and processes within organisations should facilitate participation in, and implementation of, evidence-based practice.

This theme has been subdivided into three areas:

- promoting safe practice;
- preventing, detecting, communicating and learning from adverse events; and
- promoting effective care.

4.3 Criteria

4.3.1 Promoting Safe Practice

The organisation:

a) has effective person-centred assessment, care planning and review systems in place, which include risk assessment and risk management processes and appropriate interagency care.

b) acknowledges and promotes the pivotal place that patients, service users and carers have in the prevention and detection of adverse events;

c) has policies and procedures in place to identify and protect children, young people and vulnerable adults from harm and to safeguard their rights in general;

d) promotes effective interagency working in relation to raising awareness of the risk factors associated with abuse, including domestic violence and promotion of effective interagency responses; and

e) has properly maintained systems, policies and procedures in place, which are subject to regular audit and review to ensure:

- efficacy and comparability of outcomes in health and social care;
- compliance with professional and other codes of practice;
- effective and efficient procedures for obtaining valid consent to examination, treatment and/or care;
- accurate, timely and consistent recording of care given or services provided and associated outcomes;
- awareness raising and staff knowledge of reporting arrangements when poor performance and/or unsafe practice in treatment or care comes to light;
- there is choice where food and/or fluid is provided and that procedures are in place to promote the safe handling of food and a healthy diet;
- safe practice in the selection, procurement, prescription, supply, dispensing, storage and administration of medicines across the spectrum of care and support provided;
- risk assessment and risk management in relation to the acquisition and maintenance of medical devices and equipment, and aids and appliances across the spectrum of care and support provided;
- control and reduction in the incidence of healthcare acquired infection and communicable disease;
- appropriate decontamination of reusable medical devices;
- safe and effective disposal of waste, recognising the need to promote the safety of service users and carers, staff and the wider public, and to protect the environment;
- interventional procedures and/or any new methods undertaken by staff are supported by evidence of safety and efficacy;
- implementation of recommendations contained in HPSSRIA reports (when available), service and case management reviews; and
- participation in and implementation of recommendations contained in local or national enquiries e.g. National Confidential Enquiries.

4.3.2 Preventing, detecting, communicating and learning from adverse events

The organisation:

a) has systems and processes in place to prevent, identify, assess and manage and review adverse events across the spectrum of care and support provided;

b) promotes an open and fair culture, rather than one of blame and shame, to encourage reporting and learning from adverse events;

c) has reporting systems in place to collate, analyse and learn from adverse events, share knowledge and prevent reoccurrence of adverse events; and

d) has systems in place that promote ongoing communication with service users and carers when treatment or care goes wrong, and puts in place an individual care plan to minimise injury or harm.

4.3.3 Promoting Effective Care

The organisation:

a) provides relevant, accessible, information to support and enhance service user and carer involvement in self-management of their health and social care needs;

b) promotes a culture of learning to enable staff to enhance and maintain their knowledge and skills;

c) promotes a person-centred approach and actively involves service users and carers in the development, implementation, audit and review of care plans and care pathways;

d) ensures that clinical and social care interventions are carried out under appropriate supervision and leadership, and by appropriately qualified and trained staff, who have access to appropriate support systems;

e) uses recognised clinical and social care standards and outcomes as a means of measuring health and social care quality;

f) promotes the implementation of evidence based practice through use of recognised standards and guidelines;

g) has in place systems to promote active participation of staff in evidence based practice, research and audit; and

h) has systems in place to prioritise, conduct and act upon the findings of clinical and social care audit and to disseminate learning across the organisation and the HPSS, as appropriate.

4.4 Consultation Questions

Section 4, identifies the theme of Safe and Effective Care

1. Is the explanation clear as to why this theme has been considered important? If no, what else should be written and why?

2. Is this a theme, which you would wish to see covered by standards? If no, please state what other major heading(s) should be included and explain your reasons.

3. Do you agree with the standard statement and underpinning criteria? If no, please identify what else should be added or removed from the standard statement and underpinning criteria and briefly explain why.

Section 5: Theme 2 - Timely Delivery of Quality Services

5.1 Standard Statement

To improve the health and social well-being of the local population, each HSS organisation plans, delivers, reviews and strives to continuously improve on the services it provides and/or commissions. Services are flexibly designed to meet the assessed need of service users and carers and are delivered in a timely way, which is sensitive to the individual's needs and preferences.

5.2 Rationale

To meet the needs of local communities and to narrow inequalities in health and social well-being, services should take account of the current and anticipated needs of the local community. Service users, carers, front line staff and the wider public should be meaningfully engaged in all stages of the service planning and decision-making cycle. Assessment of need should be undertaken in partnership with the statutory, voluntary, private and community sectors and be informed by the collation and analysis of information about the current health and social well-being status of the local population, legislative requirements, evidence of best practice and review of current service provision. Service planning should also take account of local and regional priorities and the availability of resources.

This theme has been sub- divided into two main areas:

- service planning processes; and
- service delivery for individuals, carers and relatives.

5.3 Criteria

5.3.1 Service Planning Processes

The organisation:

a) has service planning processes which promote an equitable pattern of service provision or commissioning, having regard to the particular needs of different localities and people;

b) integrates views of service users, carers and local communities, and front line staff into all stages of service planning, development, evaluation and review of health and social care services;

c) promotes service design and provision which incorporates and is informed by:

information about the health and social well-being status of the local population and an assessment of likely future needs;

- evidence of best practice and care, based on research findings, scientific knowledge, and evaluation of experience;
- principles of inclusion, equality and the promotion of good relations;
- risk assessment and an analysis of current service provision and outcomes in relation to meeting assessed needs;
- current and/or pending legislative and regulatory requirements;
- resource availability; and
- opportunities for partnership working across the community, voluntary, private and statutory sectors.

d) has service planning and decision-making processes across all service user groups, which take account of local and/or regional priorities;

e) has standards for the commissioning of services which are readily understood and are available to the public; and

f) ensures that service users have access to its services within locally and/or regionally agreed timescales.

5.3.2 Service delivery for individuals, carers and relatives

The organisation:

a) ensures that all service users, carers and relatives are treated with dignity and respect and that their privacy is promoted;

b) has systems in place to ensure that service users, carers and relatives have the appropriate information to enable them to make informed decisions and choices about their treatment and care, or service provision;

c) ensures that information, where appropriate, is provided in a number of formats, which may include, large print, audio format on tape or compact disc, computer readable format, Braille, etc. and is:

- written in easy to understand, non-technical language;
- laid out simply and clearly;
- reproduced in a clear typeface;
- available on the internet; and
- translated, on request into the preferred language of the reader.

d) incorporates the rights, views and choice of the individual service user into the assessment, planning, delivery and review of his or her treatment and care, and recognises the service user's right to take risks while ensuring

that steps are taken to assist them to identify and manage potential risks to themselves and others;

e) ensures that individual service user information is used for the purpose for which it was collected, and that such information is treated confidentially;

f) promotes multi-disciplinary team work and integrated assessment processes, which minimise the need for service users and carers to repeat basic information; and

g) provides the opportunity for service users and carers to provide comment on service delivery.

5.4 Consultation Questions

Section 5, identifies the theme of Timely Delivery of Quality Services

1. Is the explanation clear as to why this theme has been considered important? If no, what else should be written and why?

2. Is this a theme, which you would wish to see covered by standards? If no, please state what other major heading(s) should be included and explain your reasons.

3. Do you agree with the standard statement and underpinning criteria? If no, please identify what else should be added or removed from the standard statement and underpinning criteria and briefly explain why.

Section 6: Theme 3 - Promoting, Protecting and Improving Health and Social Well- being

6.1 Standard Statement

Each HPSS organisation works in partnership with service users and carers, the wider public and with local and regional organisations to promote, protect and improve health and social well-being, and to tackle inequalities within and between geographic areas, socio-economic and minority groups, taking account of Section 75 of the Northern Ireland Act, 1998.

6.2 Rationale

Individuals are ultimately responsible for their own and their dependents' health and social well-being. However, many of the factors that influence health and social well-being, such as poverty, social exclusion, poor education, unemployment, crime, and poor housing are not solely the responsibility of any one individual or organisation. HPSS organisations, working in partnership with other agencies and community groups, should actively seek to influence and support better decision–making, and establish systems to promote and improve the health and social well-being of the public and reduce inequalities. The goal is to improve the health and social well-being of the population of Northern Ireland, by increasing the length of their lives, improving the quality of life through increasing the number of years spent free from disease, illness, or disability and by providing better opportunities for children and support for families.

6.3 Criteria

The organisation:

a) has structures and processes in place to promote and implement effective partnership arrangements to contribute to improvements in health and social well-being and a reduction in inequalities;

b) is committed to human rights and to Government policies aimed at tackling poverty, social need and social exclusion;

c) actively pursues equality screening and, where appropriate, equality impact assessment in compliance with section 75 of the Northern Ireland Act 1998;

d) actively involves the services users and carers, the wider public, HPSS staff and the community and voluntary sectors, in the planning and development of local solutions to improve health and social well-being and to reduce inequalities;

e) promotes self-management by service users (and carers) and empowers people to take responsibility for their own health, care and social well-being, and to participate as concerned citizens in promoting the health and social well-being of others;

f) collects, collates, develops and uses health and social care information to assess current and future needs of local populations, taking account of health and social well-being inequalities;

g) has effective and efficient emergency planning processes and co-ordinated response action plans in place, as appropriate, to deal with major incidents or emergency situations and their aftermath. The planning processes and action plans are compliant with Departmental guidance;

h) has processes to engage with other organisations to reduce local environmental health hazards, as appropriate;

i) has evidence-based chronic disease management programmes and health promotion programmes and, as appropriate, community development programmes, which take account of local and regional priorities and objectives;

j) has systems to promote a healthier workforce by providing advice, training, support and, as appropriate, services to support staff;

k) has quality assured screening and immunisation programmes in place, as appropriate, and promotes active uptake among service users, carers and the public; and

l) provides opportunities for responsible volunteering, as appropriate.

6.4 Consultation Questions

Section 6, identifies the theme of Promoting, Protecting and Improving Health and Social Well-being.

1. Is the explanation clear as to why this theme has been considered important? If no, what else should be written and why?

2. Is this a theme, which you would wish to see covered by standards? If no, please state what other major heading(s) should be included and explain your reasons.

3. Do you agree with the standard statement and underpinning criteria? If no, please identify what else should be added or removed from the standard statement and underpinning criteria and briefly explain why.

Section 7: Theme 4 - Open and Effective Communication

7.1 Standard statement

HPSS organisations communicate and manage information effectively, to meet the needs of the public, service users and carers, the HPSS organisation and its staff, partner organisations and other agencies.

7.2 Rationale

Good communication and effective use of information are the basis for decision- making by individuals, the public and organisations. They ensure that all relevant facts are collated and used to inform treatment and care, and the assessment, planning, service delivery and resource allocation processes. For information to be useful, it needs to be in an understandable format, accessible to those who need it and readily available. The communication and information management processes within an organisation must take account of the needs of individuals (service users and carers, staff and the public), and any legislative or regulatory requirements including Freedom of Information and Human Rights. Protecting personal information and confidentiality are important to ensure that information is appropriately communicated to those who need to know and effectively used to inform any decisions made. HPSS organisations should be sensitive to the range of information needs required to support individuals, communities and the organisation itself.

7.3 Criteria

The organisation has:

a) an effective information and communication strategy, appropriate to the needs of the public, service users and carers, and the size, functions and complexity of the organisation;

b) up-to-date information and information technology (IT) systems and processes in place to meet its aims and objectives;

c) system(s) and process(es) in place to ensure that urgent communications, safety alerts and notices, standards and good practice guidance are made available in a timely manner to relevant staff and partner organisations; these are monitored to ensure effectiveness;

d) clear communication principles for staff and service users, which include:

- openness and honesty;
- use of appropriate language and methods of communication;

- sensitivity and understanding;
- effective listening; and
- provision of feedback.

e) effective records management policies and procedures covering access and the completion, use, storage, retrieval and safe disposal of records, which it monitors to assure compliance and takes account of Freedom of Information legislation;

f) procedures for protection of service user and carer information which include the timely sharing of information with other professionals, teams and partner organisations as appropriate, to ensure safe and effective provision of care, treatment and services, e.g. in relation to the protection of children or vulnerable adults, and the safe and efficient discharge of individuals from hospital care;

g) effective and efficient procedures for obtaining valid consent to examination, treatment and/or care;

h) an effective complaints and representation procedure and feedback arrangements, which is made available to service users, carers and staff and which is used to inform and improve care, treatment and service delivery;

i) a range of published up-to-date information about services, conditions, treatment, care and support options available, and how to access them both in and out of service hours, which are subject to regular audit and review; and

j) active participation of service users and carers and the wider public in the development and audit of communication and information management systems and processes.

7.4 Consultation Questions

Section 7, identifies the theme of Open and Effective Communication

1. Is the explanation clear as to why this theme has been considered important? If no, what else should be written?

2. Is this a theme, which you would wish to see covered by standards? If no, please state what other major heading(s) should be included and explain your reasons.

3. Do you agree with the standard statement and underpinning criteria? If no, please identify what else should be added or removed from the standard statement and underpinning criteria and briefly explain why.

Section 8: Theme 5 - Leadership and Accountability of Organisations

8.1 Standard statement

Each HPSS organisation is responsible and accountable for assuring the quality of services that it provides to both the public and its staff.

8.2 Rationale

HPSS organisations must provide effective leadership and a clear direction to make the most of its resources (people, skills, time and money), and to deliver high quality services to the public in as safe an environment as is possible. The aim is to ensure a competent, confident workforce and an organisation that is open to learning and is responsive to the needs of service users and carers. The organisation needs to maintain and further enhance public confidence.

8.3 Criteria

The organisation:

a) has a coherent and integrated organisational and governance strategy, appropriate to the needs, size and complexity of the organisation;

b) has structures and processes to support, review and action its governance arrangements including, - corporate, financial, clinical and social care, information, and research governance;

c) actively involves service users and carers in the planning and delivery, evaluation and review of the corporate aims and objectives, and governance arrangements;

d) has processes in place to develop, prioritise, deliver and review the organisation's aims and objectives;

e) ensures financial management achieves economy, effectiveness, efficiency, and probity and accountability in the use of resources;

f) has systems in place to ensure compliance with relevant legislation requirements;

g) ensures effective systems are in place to discharge its responsibilities in relation to delegated statutory functions and in relation to inter-agency working;

h) undertakes systematic risk assessment and risk management of all areas of its work;

i) has sound human resource policies and systems in place to ensure appropriate recruitment, induction, training and development of staff to undertake the roles and responsibilities required by their job, including compliance with:

- Departmental policy and guidance;
- professional and other codes of practice; and
- employment legislation.

j) undertakes robust pre - employment checks including:

- qualifications of staff to ensure they are suitably qualified and are registered with the appropriate professional or occupational body;
- criminal records, and Pre- employment Consultancy Service, as necessary;
- health assessment, as necessary; and
- references.

k) has in place appraisal and supervision systems for staff which support continuous professional development and lifelong learning, facilitate professional and regulatory requirements, and informs the organisation's training, education and workforce development;

l) has a training plan and training programmes, appropriately funded, which, for example, provides training for staff in effective communication principles and information governance arrangements including, the Freedom of Information Act, Data Protection Act, Human Rights and Equality legislation, service user confidentiality and valid consent to examination, treatment and care; and

m) has a workforce strategy in place, as appropriate, that ensures clarity about structure, function, roles and responsibilities and ensures workforce development to meet current and future service needs.

8.4 Consultation Questions

Section 8, identifies the theme of Leadership and Accountability of organisations.

1. Is the explanation clear as to why this theme has been considered important? If no, what else should be written?

2. Is this a theme, which you would wish to see covered by standards? If no, please state what other major heading(s) should be included and explain your reasons.

3. Do you agree with the standard statement and underpinning criteria? If no, please identify what else should be added or removed from the standard statement and underpinning criteria and briefly explain why.

Section 9 – Examples of Organisational Evidence on Quality

9.1 Examples of organisational evidence

The following provides some initial examples of how an organisation might demonstrate that it is meeting the required standards. Not all of these will be relevant to every organisation. Each organisation can vary in size, function and complexity e.g. HSS Boards, HSS Trusts, Central Services Agency and Special Agencies, general dental, pharmacy, medical or optometry practice. It is for HPSSRIA to provide guidance as to how assessment of quality of care will be undertaken across all HPSS sectors.

Organisational evidence should aim to build on evidence already marshalled through, for example, Health and Well-being Investment Plans, Trust Delivery Plans, Primary Care Investment Plans, Health Improvement Plans, Annual Reports, Clinical and Social Care Governance Portfolio Evidence, Controls Assurance and Care Standards, and compliance with new family practitioner contracts for general medical services and community pharmacy practice (when published).

9.2 Theme 1 - *Safe and Effective Care*

The organisation can demonstrate:

a) use of evidence from compliance with other standards, as appropriate;-
   - Care Standards;
   - Occupational Standards;
   - Controls Assurance Standards- (current standards and those with effect from April 2005).

b) a lead individual for service user, carer and staff safety (this could be the same individual as the CSCG lead);

c) nationally and/or regionally agreed standards are incorporated into specific aspects of clinical and social care practice and service provision, and that these are audited;

d) the information it provides is regularly reviewed with service users and carers;

e) a whistle blowing policy is in place, and awareness raising among staff together with effective procedures to manage alleged or identified underperformance;

f) a safety policy, which takes account of the needs of services users and carers, staff, the public and the environment;

g) an effective incident reporting policy and promotion of use amongst staff, and the dissemination of learning;

h) a commitment to the promotion of safety, the training and development of staff, and use of tools, such as significant event analysis and root cause analysis;

i) compliance with Departmental guidance on the decontamination of reusable instruments, and safe practice in relation to medical devices, equipment, aids and appliances;

j) compliance with current medicines legislation particularly in relation to the storage, prescribing, dispensing, recording and disposal of medicines including controlled medicines;

k) proactive systems approaches to enhance the procurement, prescribing, supply, storage and administration of medicines across the primary and secondary care sectors, taking account of the guidance contained in the Use and Control of Medicines (2004);

l) compliance, auditing and review of practice in accordance with Departmental guidance on the safe prescribing, supply and administration of, for example:

- intrathecal chemotherapy;
- blood and blood products;
- intravenous fluid management;
- methotrexate;
- potassium chloride; and
- anticoagulant therapy.

m) policy, surveillance and action plans and review processes towards control of, and reduction in, healthcare acquired infection;

n) a policy on the introduction of interventional procedures and new practice methods including arrangements for audit and review;

o) implementation of recommendations contained in local and national reviews and enquiries – e.g. National Confidential Enquiries;

p) effective processes to ensure access to new and emerging clinically - effective and cost-effective medicines and therapies; and

q) effective policies and procedures which are compliant with Departmental policy and guidance on, for example, the protection of children and the protection of vulnerable adults.

9.3 Theme 2 - *Timely delivery of quality services*

The organisation can demonstrate:

a) use of evidence from compliance with other standards, as appropriate;
   - controls assurance standards (current and those with effect from April 2005); and
   - care standards.

b) service planning processes are linked to corporate, regional and local objectives and priorities;

c) communication of results of service monitoring and evaluation to staff and their use to inform the planning cycle;

d) that it offers effective services within locally and/or regionally agreed timescales benchmarked against similar organisations;

e) progress to compliance with standards in relation to food, fluid and nutrition, e.g. "Essence of Care Standards", and legislative requirements as appropriate;

f) the maintenance and use of a database of service users and carers with particular needs, eg sensory impairment and the database is compliant with the requirements of the Data Protection Act 1998;

g) a range of specialised equipment and aids to daily living and communication are provided in response to assessed need; and

h) independence and choice is promoted through innovative and imaginative use of resources that are available including, for example, the Independent Living Fund, Direct Payments and alternative service development and provision.

9.4 Theme 3 - *Promoting, Protecting and Improving Health and Social Well-being*

The organisation can demonstrate:

a) use of evidence from compliance with other standards, as appropriate;
   - controls assurance standards (current and those with effect from April 2005);
   - care standards.

b) participation in Investing for Health Partnerships and Health Improvement Investment Plans;

c) commitment to tackling poverty, social need and social exclusion;

d) implementation, monitoring and evaluation of appropriate lifestyle strategies, e.g. smoking prevention and cessation, drugs and alcohol, physical activity, food, nutrition and diet and sexual health;

e) monitoring and evaluation of chronic disease management and health promotion programmes resulting in feed back of results to local organisations (where appropriate), which informs future priorities, service development and delivery;

f) promotion, monitoring and quality assurance of screening programmes to agreed national standards, e.g. cervical and breast screening;

g) evidence of commitment to a healthier workforce, e.g. the provision of employee assistance programmes to encourage, for example, smoking cessation, healthier lifestyles, stress reduction and dealing with addiction and the prevention and reduction of hazards and injuries in the work environment;

h) utilisation of community development approaches to the promotion and improvement of health and social well-being;

i) emergency contingency plans, e.g. pandemic influenza, SARS or a major incident requiring the evacuation of people from their homes;

j) arrangements for surveillance and control of communicable disease and healthcare acquired infection; and

k) evidence of use of annual public health and social care reports in the development of priorities, and planning the provision and delivery of services.

9.5 Theme 4 – *Open and Effective Communication*

The organisation can demonstrate:

a) use of evidence from compliance with other standards, as appropriate;-
   - controls assurance standards (current and those applicable from April 2005); and
   - care standards.

b) examples of staff newsletters and other mechanisms used to communicate with staff and other key stakeholders;

c) examples of staff and service user surveys and evidence of change, as appropriate;

d) service standards and Charters of service user and carer rights are displayed as are the outcome of audits and reviews of service performance;

e) compliance with the requirements of the Data Protection and Freedom of Information Acts.

9.6 Theme 5 - *Leadership and Accountability of Organisations*

The organisation can demonstrate:

a) use of evidence from compliance with other standards, as appropriate;-
   - controls assurance standards(current and those applicable from April 2005); and
   - care standards.

b) statement of Internal Control, (HSS Trusts, Boards and relevant agencies);

c) a Clinical and Social Care Governance (CSCG) strategy relevant to work of the organisation, which is kept under regular review, is widely available and disseminated throughout the organisation;

d) publication of an annual report, which includes clinical and social care governance arrangements and continuous improvement;

e) provision of, at least, six-monthly reports to the organisation's executive and non-executive board directors to ensure adequate and effective monitoring and provision of services to children (HSS Trusts);

f) provision of an annual report, to the organisation's board, on:

- established appraisal systems and outcomes; and
- the discharge of delegated statutory functions (HSS Trusts).

g) evidence of monitoring and compliance with family practitioner contracts;

h) evidence of risk assessment and risk management processes in the family practitioner services;

i) evidence that the organisation complies with, for example:

Disability Discrimination Act;

Equality Legislation;

Human rights Act;

Departmental policy and guidance; and

Professional and other codes of practice.

9.7 Questions for Consultation

This section contains first examples of evidence which an organisation might use to demonstrate compliance with the standard statements and underpinning criteria.

Recognising that this is not intended to be an exhaustive list, are there any other major issues, which should be covered in this section? Yes/No?

If yes, please state why, and to which of the five quality themes your suggestion relates to.

APPENDIX 1

GLOSSARY OF TERMS

Adverse event	Any event or circumstance arising during the course of the business of a HPSS organisation/Special Agency or commissioned service that led, or could have led to serious unintended or unexpected harm, loss or damage.
Carer	Carers are people who, without payment, provide help and support to a family member or friend who may not be able to manage at home without this help because of frailty, illness or disability.
Care plan	The outcome of an assessment. A description of what an individual needs and how these needs will be met.
Care Standards	Care Standards are service specific standards currently being developed. They will cover a range of services provided by public, voluntary and private organisations such as nursing homes, residential homes, independent clinics etc.
Clinical and Social Care Governance	A framework within which HPSS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment.
Community care	Health and social services aimed at supporting individuals to remain safely in their own homes for as long as possible.
Community development approach	Consultation with community representatives and groups before taking strategic policy decisions on how to improve health and social well-being in the local community
Controls Assurance Standards	Support effective governance in HPSS bodies. These standards focus on key areas of potential risk and help HPSS organisations demonstrate that they are doing their reasonable best to manage themselves and protect stakeholders from risk.
Direct payments	Money paid by Trusts that allows you to arrange for yourself the social care services that you have been assessed as needing.
Equality impact assessment	Consideration of a policy having regard to its impact on and the need to promote equality of opportunity between: persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation, men and women generally, persons with a disability and persons without and between persons with dependants and persons without.
Evidence based practice	Provision of services which are based on best practice as proven by research findings, scientific knowledge and evaluation of experience.
Family Practitioner Services	The principal primary care services i.e. family doctors, opticians, dentists and pharmacists.
Health Improvement plan	A plan to address identified health and social well-being needs of the local population to meet the strategic aims and objectives of the Investing for Health initiative. (See Investing

	for Health partnership, below).
Health and Well-being Investment Plans	Are annual plans produced by each Health and Social Services Board setting out their plans for commissioning services, addressing 'Priorities for Action' targets, key 'Priorities for Budget' themes and delivering on the 'Investing for Health' strategy.
HPSS Organisation	An organisation which either commissions and purchases health and social services (e.g. one of the 4 Health and Social Services Boards) or which delivers health and social services, e.g. (a hospital trust providing hospital services, a community trust providing health and social services), or a mixed trust providing both hospital and community based services.
Investing for Health partnership	One of the partnerships in each of the Health and Social Services Board areas comprising key statutory, community, social and voluntary interests in the area, with the aim of identifying opportunities for improving the health of people in their area by addressing social, cultural, economic and environmental determinants of health. Authors of Health Improvement Plans.
Person-centred assessment	An assessment, which places the individual at the centre of the process and which responds flexibly and sensitively to his/her needs.
Primary care	The many forms of health and social care and/or treatment accessed through a first point of contact provided outside hospitals e.g. family doctors, pharmacists, nurses, allied health professionals (physiotherapists, psychologists, dieticians etc) social workers, care assistants, dentists, opticians and so on.
Secondary care	Specialist services provided in an acute hospital setting following referral from a primary or community healthcare professional.
Statutory duty	A legal responsibility.
Statutory sector	Government-funded organisations e.g. HSS Boards and Trusts.
Tertiary care	Highly specialised services usually provided in an acute hospital setting by medical and other staff with expertise in a particular medical specialty.
Trust Delivery Plans	Are annual plans set out by HSS Trusts indicating their response to 'Priorities for Action' targets and outlining their plans on a range of other areas such as resource utilisation and governance.

APPENDIX 2

FREEDOM OF INFORMATION ACT 2000 – CONFIDENTIALITY OF CONSULTATIONS

The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely, the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity, should be made public or be treated as confidential. If you do not wish information about your identity to be made public please include an explanation in your response.

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Secretary of State for Constitutional Affairs' Code of Practice on the Freedom of Information Act provides that:

- the Department should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Department's functions and it would not otherwise be provided;

- the Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature; and

- acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see web site at: http://www.informationcommissioner.gov.uk/).

APPENDIX 3

HOW THE STANDARDS WERE DEVELOPED

The standards were developed with the following criteria in mind:

- active involvement of and collaboration with service users, carers and providers at every stage of the process;
- written in straightforward language, avoiding the need for jargon or specialist terminology, where possible;
- evidence-based, taking account of research that demonstrates what is effective and what is not;
- existing relevant standards; and
- the need for achievable, stretching and measurable standards.

These standards, of necessity, are broad based and high-level in order to be relevant and applicable across all health and social care settings. The expectation is that these standards will provide a foundation upon which the any future specific standards will emerge. These standards will be published on paper and electronically (on the internet) and reviewed, by the Department, to ensure that they remain relevant and up to date.

Stage one: A project group was convened to develop the draft standards.

Stage two: Consultation with the Evaluation and Equality Unit (DHSSPS) to ensure consideration of equality as specified in Section 75 of the Northern Ireland Act (1998).

Stage three: A review of the material set out in Appendix 5 was undertaken which includes standards previously developed in Northern Ireland, England, Wales and Scotland and relevant legislation and guidance.

Stage four: In recognition of the fact that these standards could not and should not be developed in isolation from HPSS staff, service users and carers, a pre-consultation exercise was undertaken. This involved sharing the initial development with reference groups and the Department's professional advisory committees. Events in the four HSS Board areas were also held to encompass the views of the different health and social care communities.

Stage five: The standards were revised and issued for public consultation.

Stage six: After public consultation and final revision, the Department will publish the *Quality Standards for Health and Social Care* document. The Department will keep the standards, their application, their impact and the need for further refining under review as the work of HPSSRIA gets fully under way.

APPENDIX 4

TERMS OF REFERENCE and MEMBERSHIP OF GROUPS

STANDARDS FOR QUALITY IN HEALTH AND SOCIAL CARE IN THE HPSS

1. Introduction

Best Practice Best Care, published in April 2001, set out proposals for new arrangements aimed at improving the quality of health and social care services in Northern Ireland. The Best Practice, Best Care document centred on the:

- Setting of standards – improving services and practice;
- Delivering services – ensuring local accountability; and
- Improving the monitoring and regulation of services.

In February 2003, the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 established the Northern Ireland Health and Personal Social Services Regulation and Improvement Authority (HPSSRIA) and set out the legislation to underpin the registration and regulation of establishments and agencies, as defined in the Order, together with arrangements for improving the quality of service provision by the HPSS. Article 34 of the Order outlined the duty of quality placed on HSS Boards and Trusts. Article 35 set out the role of the new HPSSRIA in relation to the monitoring of quality of health and social care. For the HPSS, the Authority will have the following functions:

a. Conduct reviews/inspections and make reports on the statutory bodies and service providers within the remit of the Authority for the purposes of monitoring and improving the quality of Health and Personal Social Services;

b. Report to the Department on the quality of HPSS service provision.

HPSSRIA is currently in development and will become operational on a phased basis from April 2005. The development of generic Quality in Health and Social Care Standards will assist the HPSS by providing a standardised approach to clinical and social care governance and will facilitate the Regulation and Improvement Authority in the monitoring of the quality of service provision provided by the HPSS.

2. Aim

The aim of this project is to produce generic core quality standards, which integrate existing standards on corporate governance with clinical and social care governance including quality, safety, risk management and controls

assurance standards. The principles underpinning the development of these standards will be to ensure that:

- Service users' views and experiences will be taken into account in the planning and delivery of services;
- Systems are in place to promote service user safety as a core principle underpinning all aspects of health and social care; and
- Policies and procedures are in place to promote continuous quality improvement of service provision and to ensure that staff are fully supported in their role of providing effective and efficient health and social care.

3. Objectives

The overall objective is to produce Quality in Health and Social Care Standards, by April 2005. This will provide a useful working document for HPSS organisations and for providers, the public and the HPSSRIA.

The objectives are to:

a) Review current local and national standards for health and social care governance.

b) Review and document the evidence base underpinning existing health and social care governance standards and guidelines.

c) Link development of new quality in health and social care standards to existing standards such as controls assurance standards, care standards and Departmental guidance on corporate governance, risk management and clinical and social care governance.

d) Publish standards, following consultation, which are:

- Relevant to HPSS organisations;
- Clear and measurable;
- User friendly and written in simple language;
- Achievable by HPSS organisations;
- Applicable across the whole of the HPSS; and
- Capable of being reviewed and kept up to date.

EXTERNAL REFERENCE GROUP FOR THE DEVELOPMENT OF STANDARDS FOR QUALITY IN HEALTH AND SOCIAL CARE

The purpose of the External Reference Group is to provide advice and expertise to contribute to the development of Standards for Quality in Health and Social Care within the HPSS.

Chair: Mrs Stella Burnside, Chief Executive Officer, HPSSRIA,

Members:
Mr Colm Donaghy, Chief Executive SHSSB
Ms Patricia Gordon, Chief Executive, South & East Belfast Trust
Mr John Templeton, Chief Executive, Craigavon Area Hospitals Trust
Ms Roberta Wilson, Member of the HPSS Governance Network, Newry & Mourne HSS Trust
Dr Michael McBride, Medical Director, RGH
Professor Dominic Burke, Director of Social Care, WHSSB
Ms Lorna Telford, Ulster Community Hospitals Trust
Mr Eugene Gallagher, Director of Primary Care, WHSSB
Mrs Stella Cunningham, Southern Health & Social Services Council
Ms Sally O'Kane, Non executive Director, Foyle HSS Trust
Mr Alan Finn, Director of Acute Services and Nursing, Down Lisburn Trust
Ms Patricia Beresford, Clinical & Social Care Governance Support Team, Northern Ireland

In Attendance:
Dr Ian Carson, Deputy Chief Medical Officer and Chair of the Clinical and Social Care Governance Sub Group, Best Practice Best Care
Dr Maura Briscoe, Senior Medical Officer, DHSSPS & Project Team Leader
Mrs Maire McMahon, Assistant Chief Inspector, Social Services Inspectorate
Ms Colette O'Kane, Assistant Director of Education, Clinical Governance Support Team, Modernisation Agency
Mr Francis Rice, Nursing Officer, DHSSPS
Mr Mark Timoney, Senior Principal Pharmaceutical Officer, DHSSPS
Project Team Members

Secretariat: Ms Suzanne Beaney, Primary Care Directorate, DHSSPS

PROJECT TEAM FOR THE DEVELOPMENT OF STANDARDS FOR QUALITY IN HEALTH AND SOCIAL CARE

The purpose of the project team is to prepare standards for Quality in Health and Social Care, for public consultation by January 2005. This work will be developed in collaboration with the Clinical & Social Care Governance Sub-Group and the External/Internal Reference Groups.

The Project Team will be assisted in the development of these standards by a member of the Clinical Governance Support Team of the Modernisation Agency.

Chair: Dr Maura Briscoe, SMO, DHSSPS

Members: Ms Colette O'Kane, CGST, Modernisation Agency
Mr Jonathan Bill, QPI Unit, DHSSPS
Ms Elsbeth Rea, Social Services Inspectorate, DHSSPS
Dr Louise Herron, Specialist Registrar in Public Health Medicine, Northern Health & Social Services Board
Mrs Heather Shepherd, Regional Governance & Risk Management Adviser
Mr Pat Newe, Social Services Inspectorate, DHSSPS

Secretariat: Ms Suzanne Beaney, Primary Care Directorate, DHSSPS

INTERNAL REFERENCE GROUP FOR THE DEVELOPMENT OF STANDARDS FOR QUALITY IN HEALTH AND SOCIAL CARE

The Project Team will be supported in the development of Quality in Health and Social Care Standards by an internal reference group. The purpose of the Internal Reference Group is to provide expert advice on specific aspects of standards development.

Membership of Internal Reference Group

Mr Gerard Collins, Standards & Guidelines Unit, DHSSPS
Mrs Jennifer Holmes, Care Standards Project Team Leader, DHSSPS
Ms Elaine Lawson, Assistant Director, Planning & Performance Directorate, DHSSPS
Mr Francis Rice/Ms Nikki Patterson, Nursing Officers, DHSSPS
Mr Mark Timoney, Senior Principal Pharmaceutical Officer, DHSSPS
Mr Donncha O'Carolan, Dental Adviser, DHSSPS
Ms Maggie Riley, Health and Social Services Council (WHSSB), & member of Care Standards Sub-Group
Mrs Maire McMahon, Assistant Chief Inspector, SSI
Mr Brian Godfrey, Assistant Director, Health Estates Agency, DHSSPS

APPENDIX 5

REFERENCE, CIRCULARS AND PUBLICATIONS

1. A guide to pharmaceutical clinical waster (DHSSPS) (2002).

2. A Healthier future- A Twenty Year Vision for Health and Wellbeing in Northern Ireland (DHSSPS) 2004.

3. A Statement of Healthcare Standards – Standards for NHS bodies in Wales, (Welsh Assembly) 2004.

4. A.M.Beaney (ed) (2001) Quality Assurance of Aseptic Preparation Services (3rd Edition) Pharmaceutical Press, London.

5. Approved Social Work in Northern Ireland: From Recommendations to Standards, (DHSSPS), June 2004.

6. Best Practice – Best Care (2001) – A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS (DHSSPS) http://www.dhsspsni.gov.uk/publications/archived/2001/4161finaldoc.asp.

7. Best Practice Best Care - Summary of Responses to the Consultation (DHSSPS), May 2002.

8. Building the Community Pharmacy Partnership (DHSSPS), April 2002.

9. Building the Way Forward in Primary Care (DHSSPS) Dec 2000.

10. Care Standards for Northern Ireland (draft), (DHSSPS) 2004-05, standards available on www.dhsspsni.gov.uk/hss/care_standards/index.asp.

11. Children's Service Planning Guidance, (DHSSPS) July 1998.

12. Circular HSS (F) 2/2004 - Statement on Internal Control – Full Implementation for 2003/04 (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

13. Circular HSS (F) 20/2002 – Clinical Negligence: Prevention of Claims and Claims Handling (DHSSPS).

14. Circular HSS (FAU) 19/2003 – Statement of Internal Control: Transitional Statement 2002/03(DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

15. Circular HSS (MD) 39-02 – (DHSSPS) Safe administration of Intrathecal Chemotherapy.

16. Circular HSS (OS) 1/73 – (DHSSPS) Notification of untoward events in psychiatric and special hospitals.

17. Circular HSS (PDD) 1/1994 – (DHSSPS) Management of Food Services and Food Hygiene in the HPSS.

18. Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

19. Circular HSS (PPM) 13/2002 – Governance in the HPSS – Risk Management (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

20. Circular HSS (PPM) 3/2002 - Corporate Governance: Statement on Internal Control (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

21. Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

22. Circular HSS (PPM) 6/2002 – AS/NZS 4360: 1999 – Risk Management (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

23. Circular HSS (PPM) 6/2004 – Reporting and follow-up on serious adverse incidents: Interim Guidance (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

24. Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services (DHSSPS) http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

25. Circular HSS (PPM) 8/2004 – Governance in the HPSS: Controls assurance standards – update http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

26. Circular HSS (THR) 1/1999 – (DHSSPS) Management of Food Services and Food Hygiene in the HPSS.

27. Circular HSS (THRD) 1/97 – (DHSSPS) Notification of untoward events in psychiatric and specialist hospitals for people with learning disability.

28. Code of Practice on the Recruitment, Assessment, Approval, Training, Management and Support of Foster Carers June, (DHSSPS) June 1999.

29. Controls Assurance Standards (DHSSPS), current standards for Governance
    Financial Management
    Human Resources
    Medicines Management

Medical Devices and Equipment Management
Risk Management
Buildings, Land, Plant and Non-Medical Equipment
Decontamination of Re-Useable Medical Devices
Environmental Management
Fire Safety
Health & Safety Management
Information and Communications Technology
Infection Control
Waste Management

Available on http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

Controls Assurance standards (unpublished), DHSSPS

Records Management
Management of Purchasing and Supply
Emergency Planning
Fleet and Transport

From April 2005, will be available on
http://www.dhsspsni.gov.uk/hss/governance/guidance.asp.

30. Crossing the Quality Chasm: A new Health System for the 21st Century. National Academy of Sciences, 2003 www.nap.edu/catalog/10027.html.

31. Department of Health 2000, *an Organisation with a Memory. Report of an Expert Group on Learning from Adverse Events in the NHS.* The Stationery Office, London.

32. Department of Health 2001 Clinical Governance in Community Pharmacy. Guidelines on good practice for the NHS. Department of Health, London.

33. Department of Health 2001, Building a Safer NHS for Patients. Implementing an Organisation with a Memory, Department of Health, London.

34. Development of Integrated Governance, NHS Confederation, 2004.

35. Doing Less Harm; Improving the Safety and Quality of Care Through Reporting, Analysing and Learning from adverse incidents, Department of Health and NPSA August 2001.

36. Draft Standards for Child Protection, (DHSSPS), September 2003.

37. Draft Standards for Disabled Children in Hospital, DHSSPS, January 2003.

38. Draft Standards: Approved Social Workers, (DHSSPS), November 2004.

39. Drug alerts –issued by the Chief Pharmaceutical Officer on www.dhsspsni.gov.uk/pgroups/pharmaceutical/alerts.asp.

40. Evaluation of HPSS Baseline Assessment and Action Plan – Clinical and Social Care Governance (Deloitte Touche, on behalf of DHSSPS), 2003.

41. From Dependence to Independence – Standards for Social Work Services for Young Disabled Adults, Key Standards and Criteria, (DHSSPS).

42. From Hospital to Home, (DHSSPS) 1997.

43. Good Management, Good Records, (DHSSPS), December 2004.

44. Guidance for reporting accidents with, and defects in, medicinal products (2001), DHSSPS.

45. Guidance Note- Implementing the Equality Good Practice Reviews (DHSSPS) 2004 http://www.dhsspsni.gov.uk/econsultation/Good_practice/GPRs_circ_HSSPS29Jan04.pdf.

46. Guidance on 'Discharge from Hospital and the Continuing Care in the Community of People with a Mental Disorder who could Represent a risk of Serious Physical Harm to Themselves or Others', (DHSSPS), October 2004.

47. Guidance on 'Drug and Substance Misuse in Mental Healthcare Settings', (DHSSPS), October 2004.

48. Guidance on Good Clinical Practice and Clinical Trials (1999), Department of Health, London.

49. Guidance on Handling HPSS Complaints: Hospital, Community Health and Social Services, (DHSSPS) April 2000 **[The HPSS Complaints Procedure is currently under review and will be replaced with effect from 2005].**

50. Guidance on Implementation of the HPSS Complaints Procedure, (DHSSPS), March 1996 **[The HPSS Complaints Procedure is currently under review and will be replaced with effect from 2005].**

51. Guidance on the Management of HIV Infected Health Care Workers and Patient Notification (DHSSPS), July 2002.

52. Guidance to Trusts on reporting defective medicinal products (2001), DHSSPS.

53. Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

54. Healthcare Governance: Working Towards Safe and Effective, Patient – Focused Care (Draft Standards), NHS Quality Improvement Scotland, 2004.

55. HSS (MD) 23/04 influenza and pneumococcal programme for 2004/2005 www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

56. HSS (MD) 10/2004 Good Practice in Consent, Regional forms and Guides www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

57. HSS (MD) 17/04 Reducing the risk of exposure to the agent of CJD through brain biopsies www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

58. HSS (MD) 24/04 Childhood immunisation programme. www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

59. HSS (MD) 08/04 Protecting the blood supply from variant CJD- deferral of donors who have received a blood transfusion www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

60. HSS(MD) 20 /04 and 21/04 (DHSSPS) Decontamination of endoscopes www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

61. HSS (MD) 45/03 Updated National Guidance of the Safe Administration of Intrathecal Chemotherapy.

62. HSS (MD) 36/03 Transmissible Spongiform Encephalopathy agents: safe working and the prevention of infection: publication of revised guidance www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

63. HSS(MD)7/2003 A Reference Guide to Consent for Examination, Treatment or Care; and Good Practice in Consent, Consent for Examination Treatment or Care: A Handbook for the HPSS www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

64. Implementing the Health, Social Services and Public Safety (HSSPS) Good Practice Reviews, (DHSSPS) July 2003.

65. Inspection of Social Care Support Services for Carers of Older People – Consultation on Draft Standards, July 2004.

66. Lessons for CHI Investigations 2000-2003. Commission for Health Improvement.

67. Mental Health Social Work (DHSSPS), April 2003.

68. National Standards – Local Action Health and Social Care Standards and Planning Framework 2005/6-2007/8 (Department of Health), 2004.

69. NIAIC Safety Notice MDEA (NI) 2004/01 Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre.

70. Partnership in Caring – Standards for Services, (DHSSPS) April 2000.

71. Priorities for Action for the Health and Personal Social Services (DHSSPS) 2004-05 http://www.dhsspsni.gov.uk/prior_action/index.asp.

72. Protecting Personal Information in the HPSS (DHSSPS), July 2002.

73. Quality Assurance of Radio Pharmaceuticals: The Radiopharmacy Group and the NHS Pharmaceutical Quality Control Committee. Nuclear Medicine Communications 2001; 22:909-916.

74. Quality Living Standards for Services: Children Living in a Family Placement (DHSSPS), 1995.

75. Quality Living Standards for Services: Children who live away from Home (DHSSPS), 1995.

76. Quality Standards – Assessment and Care Management, (DHSSPS) 1999.

77. Quality Standards – Consumer Involvement in Community Care Services, (DHSSPS) 1999.

78. Role and Responsibilities of Directors for the Care and Protection of Children (Circular CC3/02), (DHSSPS), June 2002.

79. Safety Alerts (NIAIC, Health Estates Agency, Northern Ireland) on www.dhsspsni.gov.uk/safety.asp-2003.

80. Safety Notice SN(NI) 2003/01: Health Estates Agency, Northern Ireland Adverse Incident Centre (NIAIC), Reporting Adverse and Disseminating Warning Notices Relating to Medical Devices, Non-Medical Equipment, Buildings and Plant. www.dhsspsni.gov.uk/safety.asp-2003.

81. SARS information and plans (DHSSPS) www.sarsni.gov.uk, SARS (urgent communications) available on www.dhsspsni.gov.uk/phealth/urgent_letter.asp.

82. Sharing the Learning on Patient and public Involvement from CHI's Work. Commission for Health Improvement www.chi.nhs.uk.

83. Social Work Services for Adults with Sensory Impairment, (DHSSPS) July 2003.

84. Standards for Better Health – Health Care Standards for Services under the NHS- (Consultation Document), Department of Health, 2004.

85. Standards for Social Work Services for Young Disabled Adults, January 2003.

86. Summary of Responses to Standards for Better Health (Department of Health), 2004.

87. Tackling Violence At Home, (DHSSPS), October 2003.

88. The Review of the Public Health Function in Northern Ireland- consultation document (DHSSPS) 2004.

89. Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS.

90. Vincent C, (ed) Clinical Risk. London: BMJ Publishing (2001).

91. Northern Ireland Social Care Council: Codes of Practice for Social Care Workers and Employers of Social Care Workers, September 2002 http://www.niscc.info/.

92. Social Care Institute for Excellence (SCIE): Knowledge Review 7: Improving the use of research in social care practice http://www.scie.org.uk/.

93. SCIE: Practice guide on managing practice.

94. SCIE: Report 5: User participation in the governance and operations of social care regulatory bodies.

95. SCIE: Resource Guide 3: Teaching and learning communication skills in social work education.

96. Public Attitudes Survey (2004), Research Evaluation Services.

RISK MANAGEMENT

Statement of Standard

An independently assured risk management system is in place that conforms to the principles contained in AS/NZS 4360:1999, and which meets HPSS and other requirements in respect of managing risks, hazards, incidents, complaints and claims.

Overview

This standard is principally concerned with ensuring that all HPSS bodies have the basic building blocks in place for managing risk through development and implementation of a comprehensive risk management system.

Risk management should be recognised within an organisation as an integral part of good management practice and should become part of the organisation's culture. It should be integrated into its philosophy, practices and business plans rather than be viewed or practiced as a separate programme. When this is achieved, risk management becomes the business of everyone in the organisation.

The design of a risk management system will be influenced and tailored by the existing structure of the HPSS body, the services provided and the processes and specific practices employed. Employment of a specific risk management approach for all organisations is, therefore, difficult to achieve. However, common principles can be identified and these form the basis for the standard. These common principles in large part originate from the Australian/New Zealand Standard on risk management, which defines a set of generic principles for establishing a risk management system in any organisation. The standard has been licensed for the HPSS and the full standard has been made available to all HPSS bodies, who are encouraged to make good use of the information and guidance contained in AS/NZS 4360:1999.

KEY REFERENCES

Circular DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control

Circular HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control

Circular HSS (PPM) 6/2002 – AS/NZS 4360: 1999 – Risk Management

Standards Australia Risk Management AS/NZS 4360:1999

Internal Control – Guidance for Directors on the Combined Code of Practice on Good Corporate Governance (The 'Turnbull' report).

Social Security (Claims and Payments) Regulations (Northern Ireland) 1977 No.351

The Health Services Advisory Committee (HSAC) publication on management of health and safety in the NHS, published by the Health and Safety Commission

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 No.455

Health Estates (various) Firecode (Northern Ireland)

Safety Notice SN(NI) 2003/01: Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Reporting Adverse and Disseminating Warning Notices Relating to Medical Devices, Non-Medical Equipment, Buildings and Plant.

Circular HSS (PDD) 1/1994 - Management of Food Services and Food Hygiene in the HPSS

Circular HSS (THR) 1/1999 – Management of Food Services and Food Hygiene in the HPSS

Medicines Control Agency (1997) Rules for Pharmaceutical Manufacturers and Distributors

Lord Woolf's Inquiry 'Access to Justice'

Pre-action protocol for the resolution of clinical disputes

Pre-action protocol for personal injury claims

Circular HSS (OS) 1/73 – Notification of untoward events in psychiatric and special hospitals

Circular HSS (THRD) 1/97 - Notification of untoward events in psychiatric and specialist hospitals for people with learning disability

Circular HSS (F) 20/1998 – Clinical Negligence Claims: Claims Handling

Circular HSS (F) 21/1998 – Clinical Negligence Claims: Structured Settlements

Circular HSS (F) 28/1999 – Clinical Negligence Claims: Procedures for Submission of Settlements Over £250,000 for Approval

Circular HSS (F) 19/2000 – Clinical Negligence Central Fund: Accounting Arrangements

Circular HSS (F) 20/2002 – Clinical Negligence: Prevention of Claims and Claims Handling

ALARM /UCL - Clinical incident investigation protocol

Best Practice – Best Care: A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS.

The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 SI 2003/431 (NI 9)

Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.

HPSS Complaints Procedures

HPSS Complaints Procedures Directions (Northern Ireland) Order 1996

Guidance on Implementation of the HPSS Complaints Procedure, March 1996

Guidance on Handling HPSS Complaints: Hospital, Community Health and Social Services, April 2000

NHS Good Practice Guide for Convenors, October 1999

INDEX OF RISK MANAGEMENT CRITERIA

Criterion 1 (*Board accountability*)

Board level responsibility for risk management is clearly defined and there are clear lines of individual accountability for managing risk throughout the organisation, leading to the board.

Criterion 2 (*Organisation-wide risk management processes*)

The organisation's senior management has defined and documented its strategy for managing risks, including objectives for, and its commitment to, risk management. The risk management strategy is relevant to the organisation's strategic context and its goals, objectives and the nature of its business. Management ensures that the strategy is understood, implemented and maintained at all levels of the organisation.

Criterion 3 (*Organisation-wide accountability*)

A committee structure is in place, which supports the risk management accountability arrangements within the organisation and ensures that all significant risks are properly considered and communicated to the board.

Criterion 4 (*Adverse incidents*)

An agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with HPSS guidance.

Criterion 5 (*Complaints and claims*)

An agreed process for reporting, managing, analysing and learning from complaints and claims is in place, in accordance with HPSS guidance.

Criterion 6 (*Risk management process*)

A risk management process, based on the requirements of AS/NZS 4360:1999 and covering all risks, is embedded throughout the organisation at all levels, including the board, with key indicators being used to demonstrate performance. The whole system of risk management is continuously monitored and reviewed by management and the board in order to learn and make improvements to the system.

Criterion 7 (*Capability*)

All employees, including members of the board, clinicians, managers, bank, locum and agency staff, together with, where relevant, contractors and volunteers are provided with appropriate risk management training.

Criterion 8 (*Independent assurance*)

The board receives independent assurance(s) that a risk management system is in place that meets the requirements of this standard.

CRITERION 1

Board level responsibility for risk management is clearly defined and there are clear lines of individual accountability for managing risk throughout the organisation, leading to the board.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.

Guidance

Implementation of risk management programmes at all levels, especially at the corporate level, is a challenge for all managers. Its success will depend largely on the support of the chief executive and senior management team. Critical to this process is the involvement of clinicians – nursing, medical, social services and allied health professionals.

The ultimate goal of any risk management programme is to make the effective management of risk an integral part of everyday management practice. This can only be achieved if there is a comprehensive and cohesive risk management system in place, underpinned by clear accountability arrangements throughout the management organisational structure.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- The Chief Executive has overall responsibility for risk management.
- An Executive Director, who may be the Chief Executive, has been designated as accountable officer for the implementation of risk management.
- Clear lines of accountability for risk management have been established.
- One or more persons are charged with the responsibility for advising on and co-ordinating risk management activities.

Examples of Verification

- Risk management strategy;
- Job descriptions for executive directors and senior managers;
- Job descriptions for specialist risk management advisors;
- Risk management organisational chart;
- Terms of reference for the audit committee;
- Minutes of the audit committee;
- Terms of reference of the board sub-committee(s) responsible for overseeing risk management;
- Minutes of the board sub-committee(s) responsible for overseeing risk management;
- Minutes of the board;

- Copy correspondence or minutes of meetings of the executive directors with responsibility for risk management;
- Audits showing compliance with risk management objectives, financial, organisational and clinical and social care.

CRITERION 2

The organisation's senior management has defined and documented its strategy for managing risks, including objectives for, and its commitment to, risk management. The risk management strategy is relevant to the organisation's strategic context and its goals, objectives and the nature of its business. Management ensures that the strategy is understood, implemented and maintained at all levels of the organisation.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.

Guidance

Management of risk should be integrated into the management philosophy of an organisation. A risk management strategy should be developed, which provides management with a strategic direction.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- There is a board-approved strategy for risk management, which is reviewed annually.
- The risk management strategy includes a list of key objectives for managing risk and is relevant to the organisation's strategic aims and objectives and the nature of its services.
- The strategy takes a holistic approach to the management of risk across the organisation.
- The strategy clearly describes the process for reviewing the organisation's performance with regard to the management of risk.
- The strategy contains guidance on acceptable risk.
- The strategy includes reference to other risk management policies/procedures.
- The contributions of individual directorates/departments and services to the delivery of the overall risk management strategy, reflect their individual risk profile.

Examples of Verification

- Risk management strategy;
- Minutes of the board;
- List of internal and external stakeholders;
- Evidence of the risk management strategy being linked to the strategic/corporate plan;
- Specialist risk management policies and procedures;
- Risk management organisational chart;
- Evidence of strategy distribution to staff and stakeholders;
- Local risk management strategies

CRITERION 3

A committee structure is in place, which supports the risk management accountability arrangements within the organisation and ensures that all significant risks are properly considered and communicated to the board.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.

Guidance

The full benefit of risk management will only be achieved if there is a comprehensive and cohesive system in place, underpinned by an organisation-wide risk management structure.

To ensure that all significant risks are properly considered and communicated to the board, boards of HPSS bodies should ensure they have a sub-committee for overseeing risk management within their organisations.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- There is a board sub-committee(s) responsible for overseeing all aspects of risk management.
- The role and responsibilities of the committee(s) responsible for overseeing risk management activities is/are clearly defined to ensure that any separations of clinical and social care, financial and organisational risks are kept under review.
- The Executive Director designated with responsibility for specific aspects of risk management must be a member of the committee.
- There is at least one Non-Executive Director as a member of the committee.
- The Committee's responsibility includes organisation wide co-ordination and prioritisation of risk management issues.
- The committee(s) responsible for overseeing risk management issues oversee the work of any specialist risk management groups, and these specialist groups report directly to it.
- The role of the Audit Committee in reviewing and providing verification on the systems in place for risk management is clearly defined.

Examples of Verification

- Risk management strategy;
- Terms of reference for committees;
- Risk management organisational chart;
- Minutes of meetings;
- Annual risk management reports;
- Schemes of delegation;
- Annual report;

- Committee objectives;
- Agendas and supporting documentation

CRITERION 4

An agreed process for reporting, managing, analysing and learning from adverse incidents is in place, in accordance with HPSS guidance.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.
- Circular HSS (OS) 1/73 – Notification of untoward events in psychiatric and special hospitals.
- Circular HSS (THRD) 1/97 - Notification of untoward events in psychiatric and specialist hospitals for people with learning disability.
- Circular HSS (F) 20/2002 - Clinical Negligence: Prevention of Claims and Claims Handling.
- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Safety Notice SN(NI) 2003/01: Health Estates, Northern Ireland Adverse Incident Centre (NIAIC), Reporting Adverse and Disseminating Warning Notices Relating to Medical Devices, Non-Medical Equipment, Buildings and Plant
- DHSSPS, 2001 – Guidance for reporting accidents with, and defects in, medicinal products

Guidance

Incident reporting is a fundamental tool of risk management, the aim of which is to collect information about adverse incidents, including near misses and hazards, which help to facilitate wider organisational learning.

Incidents, if not properly managed, may result in loss of public confidence in the organisation, loss of assets and unnecessary proliferation of loss.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- There is a board-approved policy/procedure for recording, reporting, analysing and managing incidents.
- The policy/procedure is based upon a standard definition of incidents.
- The policy/procedure promotes a positive and non-punitive approach towards incident reporting.
- The policy/procedure states that all incidents must be reported promptly and an incident form completed.
- The policy/procedure contains clear guidance to be followed on incident investigation and root cause analysis.
- The policy/procedure states that management actions and preventive measures taken must be recorded.
- For serious adverse incidents that could have an impact upon staff, users or the public the policy/procedure requires them to be advised.

- All incidents are reported on a standard form(s), which may be paper-based or electronic, and which captures a 'minimum dataset' of information in accordance, where relevant, with HPSS guidance.
- All reported incidents are graded according to severity of outcome and potential future risk to users and/or the organisation.
- Based on the grading, reported incidents are subject to an appropriate level of local investigation and causal analysis and, where relevant, an improvement strategy is prepared, implemented and monitored.
- All reported incidents and causal factors are classified and categorised in accordance with a standardised classification scheme.
- Aggregate reviews of local incident data/information are carried out on an ongoing basis and the significant results are communicated to local stakeholders.

Examples of Verification

- Incident reporting policy/procedure;
- Incident report form and guidelines for completion;
- Incident investigation reports;
- Trend analysis reports;
- Minutes of the committees responsible for overseeing risk management;
- Copies of relevant reports to external bodies and stakeholders;
- Induction training programmes;
- Completed incident report forms;
- Relevant correspondence;
- Action plans and follow up reports;
- Major incident policy.

CRITERION 5

An agreed process for reporting, managing, analysing and learning from complaints and claims is in place, in accordance with HPSS guidance.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.
- HPSS (March 1996) Guidance on Implementation of the HPSS Complaints Procedure (revised April 2000)
- Circular HSS (F) 20/2002 - Clinical Negligence: Prevention of Claims and Claims Handling
- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.

Guidance

Competent handling of complaints can assist in improving the quality of care and minimising claims by listening to the voice of service users and using this as an opportunity for the organisation to learn from complainants. Complaints and claims when examined in conjunction with reported incidents, accidents and near misses allow trends to be identified at both a local and strategic level. This leads to prevention of recurrence or more serious incidents and complaints occurring.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- There is a documented complaints procedure, which meets HPSS requirements and is approved by the board.
- There is a designated complaints manager responsible for handling all complaints.
- The arrangements for making complaints are publicised to service users.
- Front line staff receive training and guidance on the complaints procedure to enable them to deal with complaints on the spot.
- The organisation has an effective system for the recording of formal and informal complaints.
- Independent review panels, when they are required, are established in full accordance with the HPSS complaints procedure.
- All reported complaints are graded according to severity as well as potential future risk to users and/or to the organisation.
- One or more persons are charged with the responsibility for the management and co-ordination of claims.
- There is a documented claims management procedure, which meets HPSS requirements and is approved by the Board.
- All reported claims are graded according to severity as well as potential future risk to users and/or to the organisation.

- Information on complaints is reported to and considered by a relevant sub-committee of the Board.

Examples of Verification

- Complaints policy/procedure;
- Claims handling policy/procedure;
- Job descriptions;
- Board reports;
- Risk management committee reports;
- Complaints committee reports
- Training needs analysis;
- Training programmes;
- Training evaluation forms;
- Induction programme;
- Complaints leaflets and posters;
- Complaints files;
- Independent review reports;
- Evidence of claims management training;
- Evidence of claim settlement negotiations.

CRITERION 6

A risk management process, based on the requirements of AS/NZS 4360:1999 and covering all risks, is embedded throughout the organisation at all levels, including the board, with key indicators being used to demonstrate performance. The whole system of risk management is continuously monitored and reviewed by management and the board in order to learn and make improvements to the system.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.

Guidance

The organisation must be aware of its risk profile across its entire range of activities. Specific risk assessments will have been undertaken but in order to prioritise action an organisation-wide review is necessary to ensure that all exposures are duly considered.

"Key risks", sometimes termed "principal risks", are those which have significant potential to impair or affect the operational or financial ability of the organisation to deliver ongoing services, and may be strategic or operational in nature. It is on these "key risks" which the assessment will focus at level one.

At level two, the assessment will focus on whether the remaining risks, almost wholly operational in nature, have been assessed rigorously, thus creating a continuum of risk assessments across the length and breadth of the organisation, encompassing all risks.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- Risks are systematically identified, recorded, assessed and analysed on a continuous basis. A register is maintained for all significant risks at both directorate and corporate (organisation-wide) levels.
- For all risks identified as requiring treatment, actions are determined, appropriately recorded and implemented in order of priority using, where relevant, appropriate decision-making tools (e.g. risk ranking or cost-benefit analysis)
- The board is informed of and, where necessary, consulted on all significant risks and associated risk treatment plans on a continuous basis.
- All relevant stakeholders are kept informed and, where appropriate, consulted on the management of risks faced by the organisation.
- All relevant staff are kept informed of the management of significant risks faced by the organisation.
- Key indicators capable of showing improvements in management of risk and/or providing early warning of risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

- An annual report is produced for the board to demonstrate the risk management system's continuing suitability and effectiveness in satisfying the organisations risk management policy and strategy.

Examples of Verification

- Risk management strategy;
- Risk identification tools;
- Hazard reporting policy and forms;
- Risk assessment tools and forms;
- Completed risk assessments;
- Risk treatment options;
- Evidence of risk treatment;
- Business plans;
- Annual report;
- Risk registers;
- Minutes of committees;
- Job descriptions;
- Training programmes;
- Action plans;
- Evidence of communication with stakeholders;
- Evidence of communication with staff;
- Monitoring and review procedure;
- Performance indicators;
- Evidence of monitoring and review;
- Board minutes;
- Patient surveys;
- Incident, complaints and claims analysis.

CRITERION 7

All employees, including members of the board, clinicians, managers, bank, locum and agency staff, together with, where relevant, contractors and volunteers are provided with appropriate risk management training.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.

Guidance

This contributes to the organisation's risk management culture, which needs to be embedded at all levels throughout the organisation.

An appropriate training programme is an important means of achieving competence and helps to ensure compliance with safe working practices.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- The organisation has assessed and delivered the level of risk management training that is needed throughout.
- Training records are kept, monitored and reviewed and inadequate attendance rectified.
- Induction for all new starters includes risk management training.
- The organisation can demonstrate that risk management training is effective through monitoring and review.
- Employees with responsibility for co-ordinating and advising on aspects of risk management have adequate training and development to fulfil their role.

Examples of Verification

- Training needs assessment;
- Training prospectus;
- Local training needs assessment;
- Training records;
- Reports on attendance levels;
- Induction programme;
- Local induction procedures;
- Training objectives;
- Evidence of review of training objectives;
- Training course evaluations.

CRITERION 8

The board receives independent assurance(s) that a risk management system is in place that meets the requirements of this standard.

Source

- Standards Australia Risk Management AS/NZS 4360: 1999.

Guidance

Reviews by independent bodies will assist organisations in demonstrating performance, and also in highlighting areas that need to be addressed. This will give the organisation assurance that controls are working satisfactorily and that local and national targets are being met.

The following sub-criteria will help in deciding whether the key requirements of the main criterion are being met:

- The role of the internal audit function in reviewing and providing verification on the systems in place for risk management is clearly defined.
- The internal audit function, aided as necessary by relevant technical specialists, carries out periodic audits to provide assurances to the organisation that a suitable risk management system is in place and working properly.
- The organisation has a system in place to ensure that reviews carried out by external agencies are effectively coordinated and any recommendations implemented.
- Reports are presented to the Audit Committee and copied to the overarching committee(s) responsible for risk and any other relevant committee/group.

Examples of Verification

- Internal audit report(s);
- Internal audit statement to Chief Executive;
- Audit Committee minutes;
- Risk Management Committee minutes;
- Clinical and Social Care Governance Committee minutes;
- Reports from HPSSRIA and other review bodies;
- Reports from external audit (NIAO);
- Reports from clinical audit.

MINISTRY OF HEALTH AND SOCIAL SERVICES
HSS4(OS) Branch
Dundonald House Upper Newtownards Road Belfast BT4 3SF
Telex 74578 Telephone [redacted]

Please reply to The Secretary
Your reference

The Chief Administrative Officer of
each Health and Social Services Board

Our reference A1034/73
Circular Ref No HSS4(OS) 1/7
Date 30 October 1973

Dear Sir

NOTIFICATION OF UNTOWARD EVENTS IN PSYCHIATRIC AND SPECIAL CARE HOSPITALS

1. I am writing to draw your attention to a long-standing administrative arrangement whereby the Northern Ireland Hospitals Authority undertook to notify the Ministry of the details of all untoward events involving patients in psychiatric or special care hospitals. Untoward events include:

a) unauthorised absences;

b) accidents; and

c) sudden, unexpected or unnatural deaths.

DEPT. OF HEALTH AND SOCIAL SERVICES
28 MAY 1997
RECEIVED
TRUSTS AND HUMAN RESOURCES DIRECTORATE

2. It is essential that this practice be continued. Each Health and Soci Services Board should therefore arrange for a telephone message to be sent HSS4(OS) Branch, Dundonald House, Upper Newtownards Road, Belfast BT4 3SF, (telephone [redacted]) as soon as possible after the occu of any such untoward event, with the following information:

a) the nature of the occurrence (ie whether an unauthorised absence, a accident or a sudden, unexpected or unnatural death);

b) a brief description of the circumstances of the event;

c) the name of the patient involved and his hospital status;

d) the name of the hospital of which he was an in-patient and if the incident occurred in any place other than that hospital, the locati of the event;

e) the date and time of the occurrence; and

f) whether the patient's relatives, the RUC and the Ministry of Home Affairs, as appropriate, have been informed of the event.

3. To enable the necessary information to be furnished to the Ministry, e Health and Social Services Board should ask the psychiatric and special car hospitals within its area to notify the Board by telephone, in the first pl of the details of an untoward event immediately its occurrence becomes know Immediate notification is particularly important where a death has occurred.

Yours faithfully

L. b. Gillis

P (D) D. (HSS)

(2)

Trusts and Human Resources Directorate

HSS
EXECUTIVE

Chief Executive of each HSS Trust

Chief Executive/General Manager of each
Health and Social Services Board

13 May 1997

HSS (THRD) 1/97

Dear Sir/Madam

NOTIFICATION OF UNTOWARD EVENTS IN PSYCHIATRIC & SPECIALIST HOSPITALS FOR PEOPLE WITH LEARNING DISABILITY

Circular HSS (OS) 1/73 requires Health and Social Services Boards to notify the Department of any untoward events involving patients in psychiatric or special care hospitals.

Since their establishment it has become the practice for Trusts to notify the Department of such events directly. At the same time untoward events whether occurring in hospital or otherwise are reported to HSS Boards and to the Mental Health Commission for Northern Ireland under separate arrangements.

Following a review of its business areas the HSS Executive has decided that, from receipt of this letter, untoward events should be notified to the Trusts and Human Resources Directorate, Room 605, Dundonald House, telephone [redacted] Serious incidents should be notified by phone in the first instance and all incidents should be reported in writing. Trusts should, of course, continue to follow any requirements placed on them by their commissioning Boards and the Mental Health Commission concerning untoward events.

Yours faithfully

John Townson
Deputy Director

cc. Mr Walsh (Mental Health Commission)